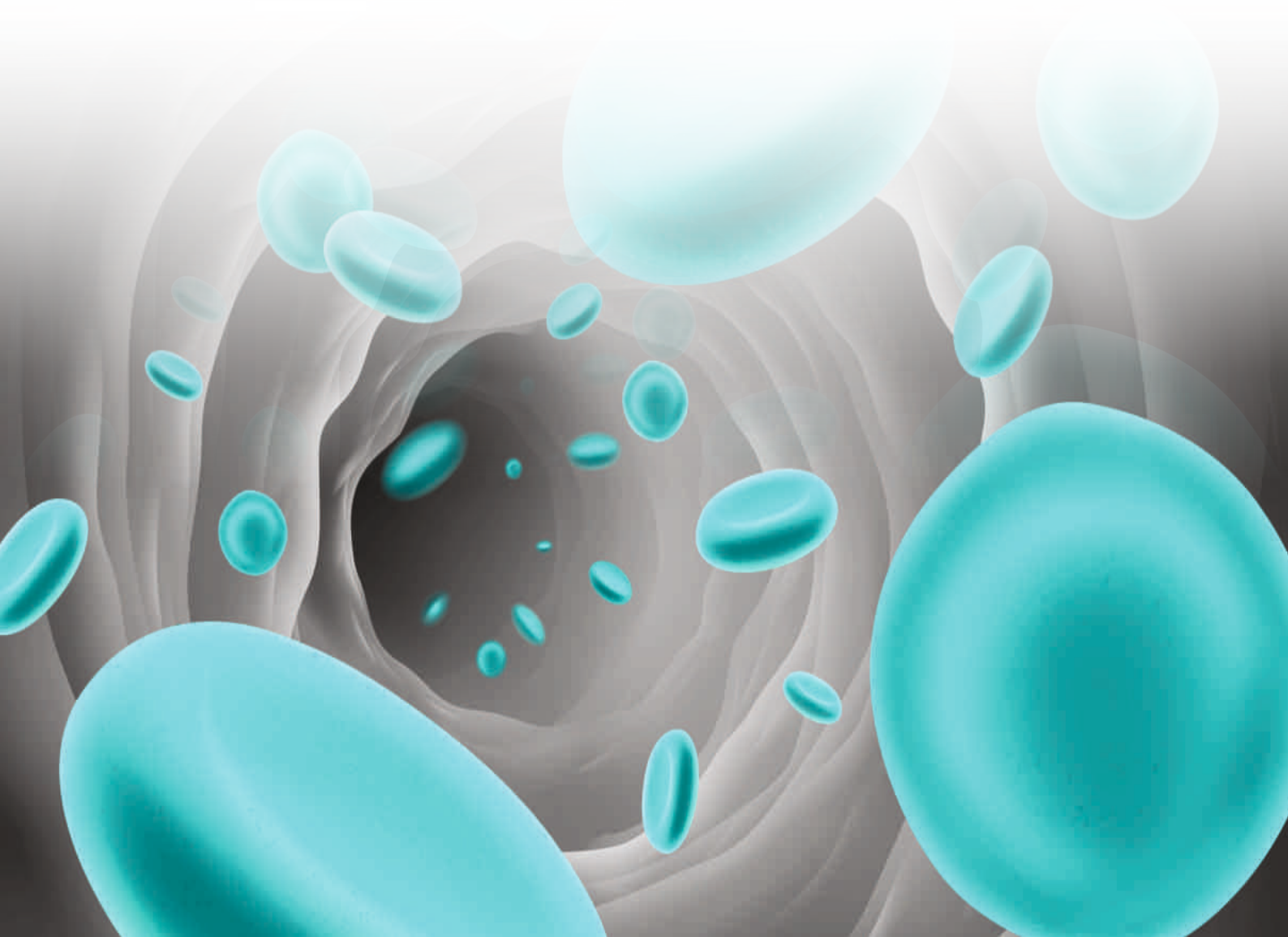




Evaluation Report

Hematology Compatible Reagents

Compatible Hematology Reagents

Technical Report

Reagents for 3 Part Hematology Analyzers

Developed By



**Vanguard Diagnostics (P) Limited,
C-123, Phase-1, Okhla Industrial Area,
New Delhi -110020, INDIA**

Index

Sr. No.	Subject	Page Nos.
1	Comparative Evaluation Report of Sysmex 3 Part Reagents (Vanguard Reagents v/s Reference Reagents)	4 – 40
2	Comparative Evaluation Report of Mindray 3 Part Reagents (Vanguard Reagents v/s Reference Reagents)	41 – 69
3	Comparative Evaluation Report of Genrui / Genius 3 Part Reagents (Vanguard Reagents v/s Reference Reagents)	70 – 104
4	Comparative Evaluation Report of Nihon Kohden 3 Part Reagents (Vanguard Reagents v/s Reference Reagents)	105 – 134
5	Comparative Evaluation Report of Horiba 3 Part Reagents (Vanguard Reagents v/s Reference Reagents)	135 - 171

6	Comparative Evaluation Report of Dirui 3 Part Reagents (Vanguard Reagents v/s Sysmex Reference Reagents)	172 – 201
7	Comparative Evaluation Report of Urit 3 Part Reagents (Vanguard Reagents v/s Mindray Reference Reagents)	202 – 230
8	Comparative Evaluation Report of Prokan 3 Part Reagents (Vanguard Reagents v/s Mindray Reference Reagents)	231 – 259
9	Comparative Evaluation report of Rayto 3 Part Reagents (VDx Reagents v/s Reference Mindray Reagents)	260 – 289
10	Comparative Evaluation report of Dymind 3 Part Reagents (VDx Reagents v/s Reference Mindray Reagents)	290 – 319

Note: *VDx is an acronym for Vanguard Diagnostics*

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	6 - 7
2	Background Test	8
3	Coefficient of Correlation: Accuracy	9 – 32
4	Quality Control (Low, Normal & High)	33 - 37
5	Coefficient of Variation: Precision (VDx Sysmex Compatible Reagents)	38
6	Coefficient of Variation: Precision (Sysmex Reference Reagents)	39
7	Conclusions	40

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Sysmex - XP100
Reference Reagents	Sysmex Reference Reagents
Cellpack	Lot No : X2177 Expiry Date : 06-04-2024
Stromatolyser-WH	Lot No : X2030 Expiry Date : 13-04-2023

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Sysmex Compatible Reagents)
5	Coefficient of Variation: Precision (Sysmex Reference Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	0.0	0.0
RBC (10 ⁶ /μl)	0.0	0.0
HGB (g/dl)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dl)	0.0	0.0
PLT (10 ³ /μl)	0.0	0.0
LYM (%)	0.0	0.0
MXD (%)	0.0	0.0
NEUT (%)	0.0	0.0
LYM# (10 ³ /μl)	0.0	0.0
MXD# (10 ³ /μl)	0.0	0.0
NEUT# (10 ³ /μl)	0.0	0.0
RDW-SD (fL)	0.0	0.0
RDW-CV (%)	0.0	0.0
PDW (fL)	0.0	0.0
MPV (fL)	0.0	0.0
P-LCR (%)	0.0	0.0
PCT (%)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Sysmex reagents and the Sysmex Reference Reagents.
- II. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

Coefficient of Correlation (“r”): WBC

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

“r” = 0.983

Sample size: 16

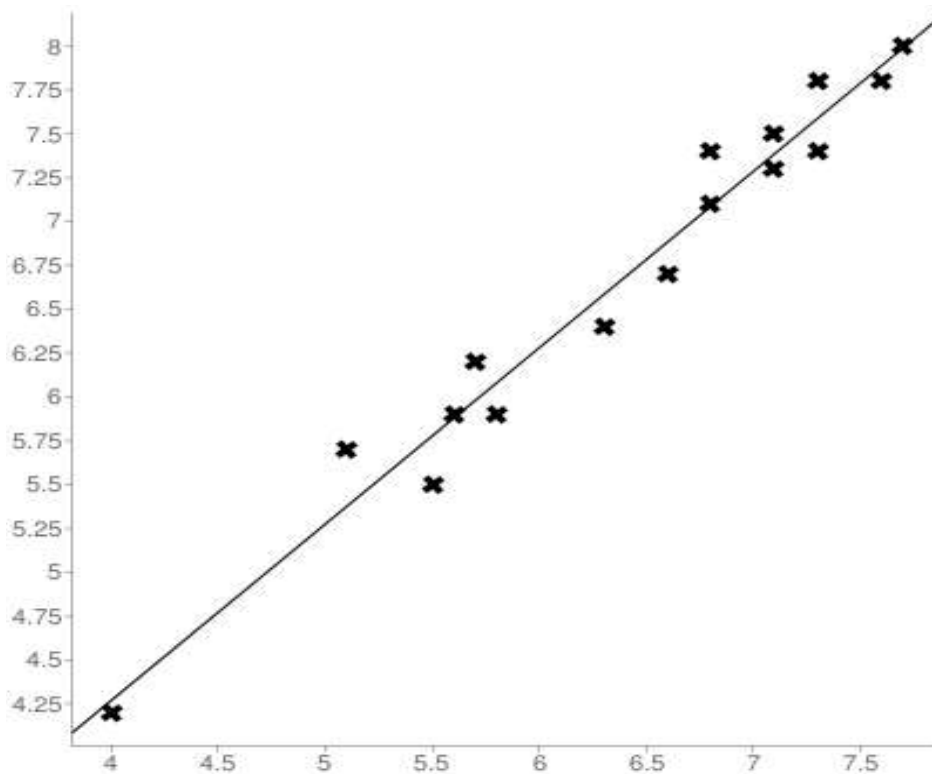
Mean x ($\bar{x}$): 6.39375

Mean y ($\bar{y}$): 6.675

Intercept (a): 0.24973382231161

Slope (b): 1.0049292164518

Regression line equation: $y = 0.24973382231161 + 1.0049292164518x$



Coefficient of Correlation (“r”): RBC

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

$$“r” = 0.995$$

Sample size: 16

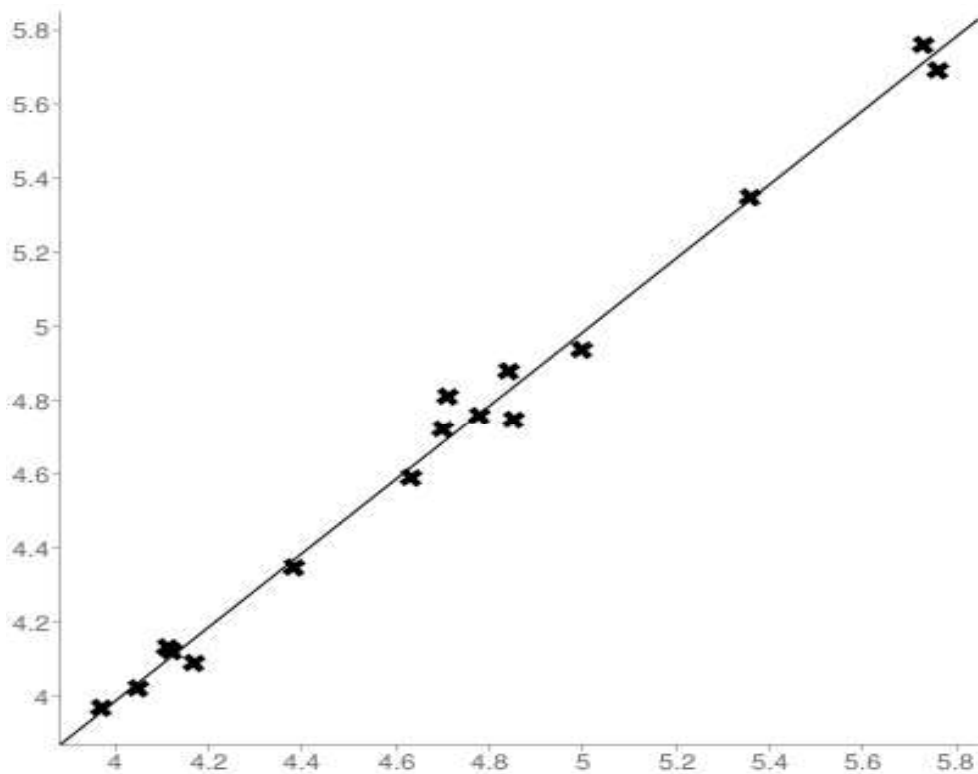
Mean x (x̄): 4.6975

Mean y (ȳ): 4.683125

Intercept (a): 0.0013023063907616

Slope (b): 0.99666262769755

Regression line equation: $y = 0.0013023063907616 + 0.99666262769755x$



Coefficient of Correlation (“r”): Hemoglobin

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 16

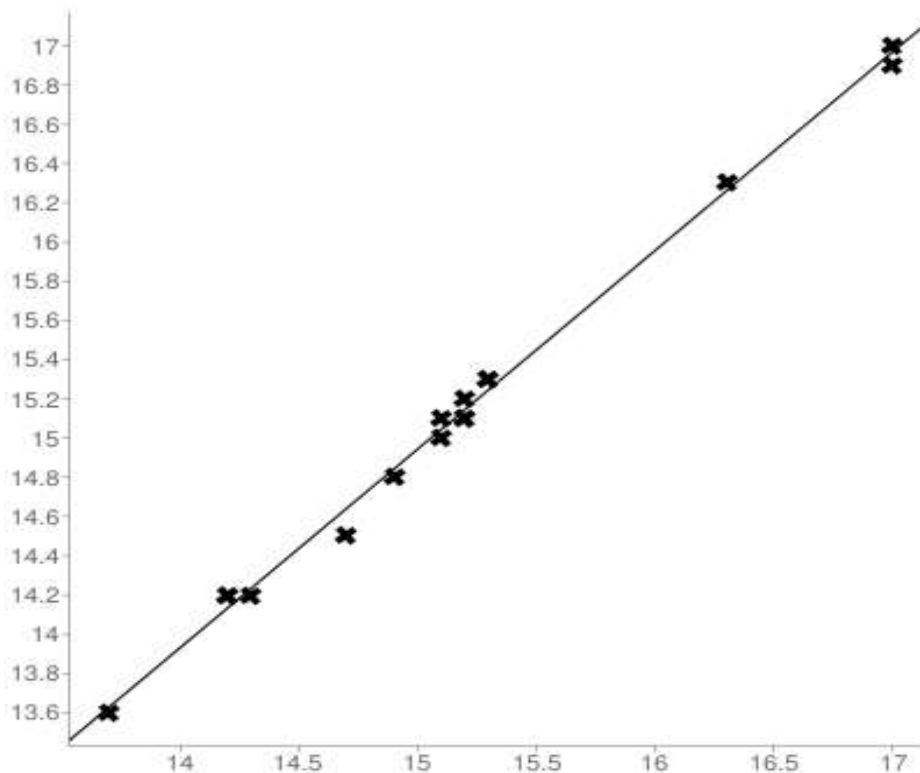
Mean x (x̄): 15.16875

Mean y (ȳ): 15.1125

Intercept (a): -0.25504932564509

Slope (b): 1.0131058475909

Regression line equation: $y = 1.0131058475909x - 0.25504932564509$



Coefficient of Correlation (“r”): Platelets

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 16

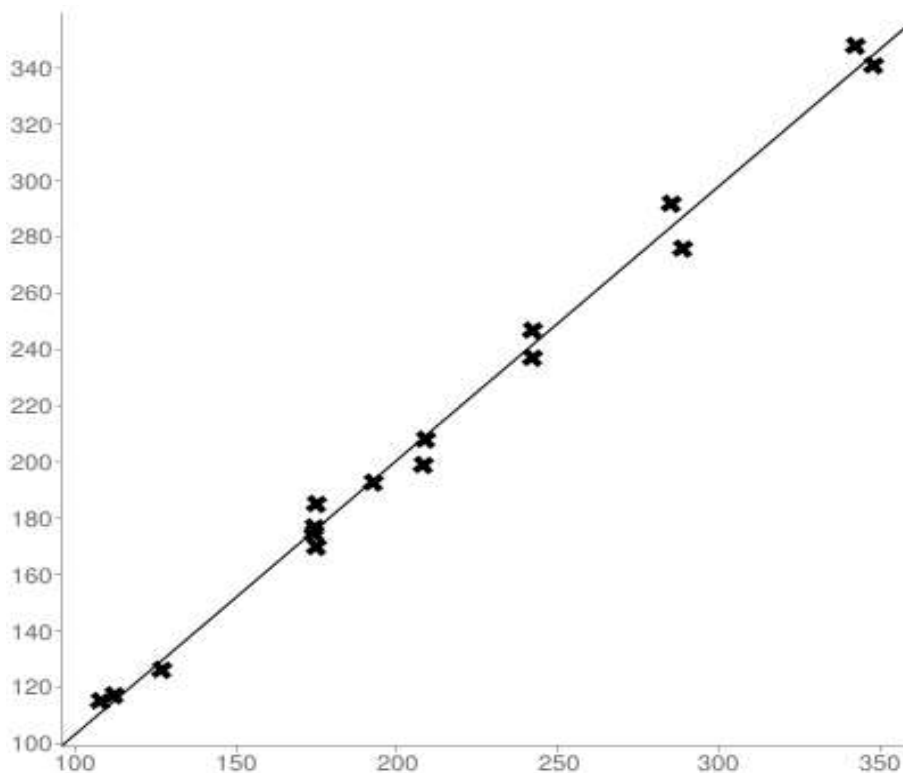
Mean x ($\bar{x}$): 212.6875

Mean y ($\bar{y}$): 212.875

Intercept (a): 5.6144519167176

Slope (b): 0.9744839169358

Regression line equation: $y = 5.6144519167176 + 0.9744839169358x$



Coefficient of Correlation (“r”): MCV

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.
y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

$$“r” = 0.998$$

Sample size: 16

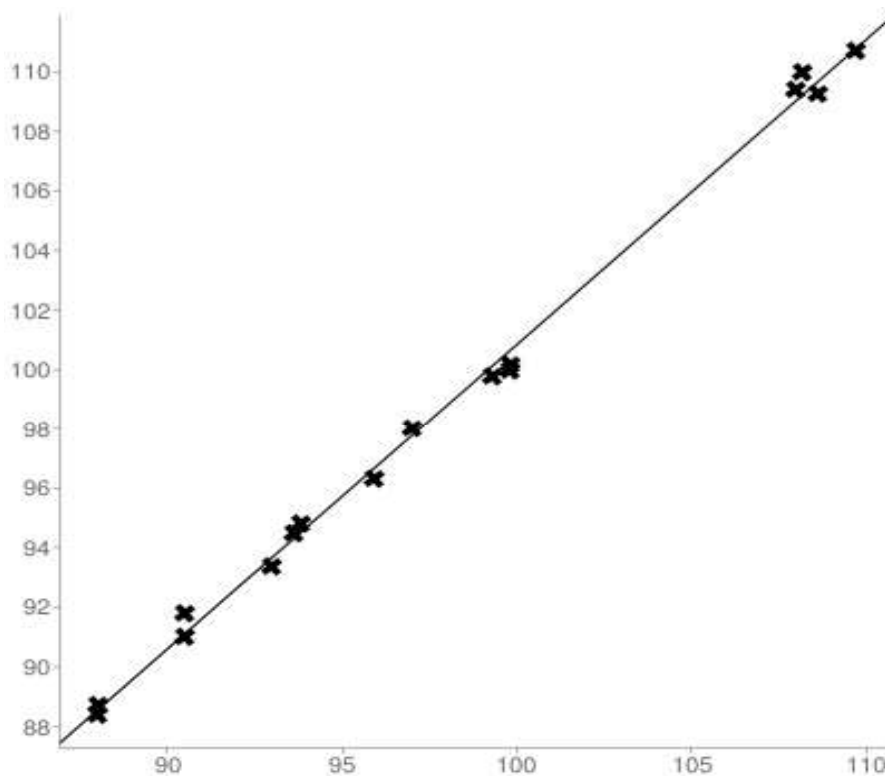
Mean x (x): 97.73125

Mean y (y): 98.51875

Intercept (a): -1.5500363374495

Slope (b): 1.0239180030691

Regression line equation: $y = 1.0239180030691x - 1.5500363374495$



Coefficient of Correlation (“r”): HCT

x = Sysmex Reference Reagents for XP100, 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for XP100, 3 Part Hematology Analyzer.

$$“r” = 0.999$$

Sample size: 16

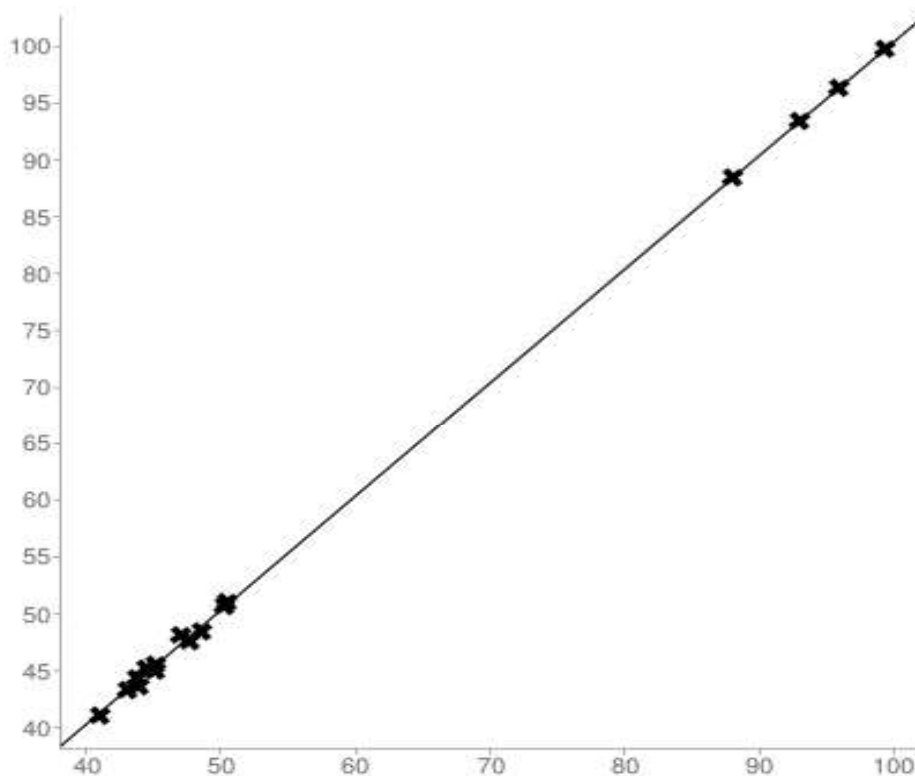
Mean x (x̄): 57.9125

Mean y (ȳ): 58.2625

Intercept (a): 0.20773813970541

Slope (b): 1.0024564966164

Regression line equation: $y = 0.20773813970541 + 1.0024564966164x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.4	7.3
RBC (10 ⁶ /μl)	4.76	4.78
HGB (g/dl)	15.1	15.1
HCT (%)	47.6	47.7
MCV (fL)	100.0	99.8
MCH (pg)	31.7	31.6
MCHC (g/dl)	31.7	31.7
PLT (10 ³ /μl)	117	112
LYM (%)	19.7	18.6
MXD (%)	13.9	17.7
NEUT (%)	66.4	63.7
LYM# (10 ³ /μl)	1.5	1.4
MXD# (10 ³ /μl)	1.0	1.3
NEUT# (10 ³ /μl)	4.9	4.6
RDW-SD (fL)	51.2	50.1
RDW-CV (%)	12.9	13.2
PDW (fL)	*	*
MPV (fL)	*	*
P-LCR (%)	*	*
PCT (%)	*	*

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.8	7.3
RBC (10 ⁶ /μl)	4.81	4.71
HGB (g/dl)	15.3	15.3
HCT (%)	48.2	47.0
MCV (fL)	100.2	99.8
MCH (pg)	31.8	32.5
MCHC (g/dl)	31.7	32.6
PLT (10 ³ /μl)	115	108
LYM (%)	20.5	18.3
MXD (%)	11.2	15.7
NEUT (%)	68.3	66.0
LYM# (10 ³ /μl)	1.6	1.3
MXD# (10 ³ /μl)	0.9	1.1
NEUT# (10 ³ /μl)	5.3	4.9
RDW-SD (fL)	50.9	51.9
RDW-CV (%)	13.0	13.2
PDW (fL)	*	*
MPV (fL)	*	*
P-LCR (%)	*	*
PCT (%)	*	*

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: ysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.3	7.1
RBC (10 ⁶ /μl)	5.76	5.73
HGB (g/dl)	16.9	17.0
HCT (%)	51.1	50.4
MCV (fL)	88.7	88.0
MCH (pg)	29.3	29.7
MCHC (g/dl)	33.1	33.7
PLT (10 ³ /μl)	348	342
LYM (%)	19.6	17.4
MXD (%)	7.0	8.0
NEUT (%)	73.4	74.6
LYM# (10 ³ /μl)	1.4	1.2
MXD# (10 ³ /μl)	0.5	0.6
NEUT# (10 ³ /μl)	5.4	5.3
RDW-SD (fL)	42.9	43.9
RDW-CV (%)	12.5	12.7
PDW (fL)	15.0	16.8
MPV (fL)	11.4	12.2
P-LCR (%)	36.4	43.7
PCT (%)	0.40	0.42

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	6.7	6.6
RBC (10 ⁶ /μl)	4.02	4.05
HGB (g/dl)	14.2	14.3
HCT (%)	40.1	40.2
MCV (fL)	99.8	99.3
MCH (pg)	35.3	35.3
MCHC (g/dl)	35.4	35.6
PLT (10 ³ /μl)	237	242
LYM (%)	33.3	35.3
MXD (%)	8.4	7.5
NEUT (%)	58.3	57.2
LYM# (10 ³ /μl)	2.2	2.3
MXD# (10 ³ /μl)	0.6	0.5
NEUT# (10 ³ /μl)	3.9	3.8
RDW-SD (fL)	51.6	51.0
RDW-CV (%)	13.5	13.8
PDW (fL)	15.2	14.7
MPV (fL)	10.8	11.0
P-LCR (%)	32.7	35
PCT (%)	0.26	0.27

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	4.2	4.0
RBC (10 ⁶ /μl)	4.72	4.70
HGB (g/dl)	14.2	14.2
HCT (%)	44.1	43.7
MCV (fL)	93.4	93.0
MCH (pg)	30.1	30.2
MCHC (g/dl)	32.2	32.5
PLT (10 ³ /μl)	193	193
LYM (%)	31.1	31.5
MXD (%)	9.6	8.3
NEUT (%)	59.3	60.2
LYM# (10 ³ /μl)	1.3	1.3
MXD# (10 ³ /μl)	0.4	0.3
NEUT# (10 ³ /μl)	2.5	2.4
RDW-SD (fL)	45.9	48.5
RDW-CV (%)	12.7	13.3
PDW (fL)	22.2	24.7
MPV (fL)	13.5	14.6
P-LCR (%)	53	60.4
PCT (%)	0.26	0.28

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.1	6.8
RBC (10 ⁶ /μl)	5.69	5.76
HGB (g/dl)	17.0	17.0
HCT (%)	50.3	50.7
MCV (fL)	88.4	88.0
MCH (pg)	29.9	29.5
MCHC (g/dl)	33.8	33.5
PLT (10 ³ /μl)	341	348
LYM (%)	17.7	18.0
MXD (%)	6.3	6.1
NEUT (%)	76.0	75.9
LYM# (10 ³ /μl)	1.3	1.2
MXD# (10 ³ /μl)	0.4	0.4
NEUT# (10 ³ /μl)	5.4	5.2
RDW-SD (fL)	43.3	44.9
RDW-CV (%)	12.6	12.9
PDW (fL)	14.7	15.3
MPV (fL)	11.2	11.7
P-LCR (%)	34.9	38.5
PCT (%)	0.38	0.41

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	5.5	5.5
RBC (10 ⁶ /μl)	4.59	4.63
HGB (g/dl)	14.5	14.7
HCT (%)	44.2	44.4
MCV (fL)	96.3	95.9
MCH (pg)	31.6	31.7
MCHC (g/dl)	32.8	33.1
PLT (10 ³ /μl)	292	285
LYM (%)	30.2	29.2
MXD (%)	8.3	8.5
NEUT (%)	61.5	62.3
LYM# (10 ³ /μl)	1.7	1.6
MXD# (10 ³ /μl)	0.5	0.5
NEUT# (10 ³ /μl)	3.3	3.4
RDW-SD (fL)	48.5	48.1
RDW-CV (%)	12.8	13.0
PDW (fL)	13.8	15.0
MPV (fL)	10.9	11.5
P-LCR (%)	31.9	38.1
PCT (%)	0.32	0.33

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	6.4	6.3
RBC (10 ⁶ /μl)	4.88	4.84
HGB (g/dl)	14.8	14.9
HCT (%)	44.4	43.8
MCV (fL)	91.0	90.5
MCH (pg)	30.3	30.8
MCHC (g/dl)	33.3	34.0
PLT (10 ³ /μl)	185	175
LYM (%)	22.2	22.1
MXD (%)	9.5	13.6
NEUT (%)	68.3	64.3
LYM# (10 ³ /μl)	1.4	1.4
MXD# (10 ³ /μl)	0.6	0.9
NEUT# (10 ³ /μl)	4.4	4.0
RDW-SD (fL)	48.5	49.8
RDW-CV (%)	14.1	14.9
PDW (fL)	20.1	19.8
MPV (fL)	13.4	13.9
P-LCR (%)	51.2	55.7
PCT (%)	0.25	0.24

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.5	7.1
RBC (10 ⁶ /μl)	4.75	4.85
HGB (g/dl)	14.2	14.2
HCT (%)	43.6	43.9
MCV (fL)	91.8	90.5
MCH (pg)	29.9	29.3
MCHC (g/dl)	32.6	32.3
PLT (10 ³ /μl)	126	127
LYM (%)	31.9	33.5
MXD (%)	15.7	8.3
NEUT (%)	52.4	58.2
LYM# (10 ³ /μl)	2.4	2.4
MXD# (10 ³ /μl)	1.2	0.6
NEUT# (10 ³ /μl)	3.9	4.1
RDW-SD (fL)	47.5	49.3
RDW-CV (%)	13.2	13.9
PDW (fL)	20.9	*
MPV (fL)	13.2	*
P-LCR (%)	49.1	*
PCT (%)	0.17	*

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	5.9	5.6
RBC (10 ⁶ /μl)	4.35	4.38
HGB (g/dl)	13.6	13.7
HCT (%)	41.1	41.0
MCV (fL)	94.5	93.6
MCH (pg)	31.3	31.3
MCHC (g/dl)	33.1	33.4
PLT (10 ³ /μl)	170	175
LYM (%)	30.0	30.0
MXD (%)	14.0	14.4
NEUT (%)	56.0	55.6
LYM# (10 ³ /μl)	1.8	1.7
MXD# (10 ³ /μl)	0.8	0.8
NEUT# (10 ³ /μl)	3.3	3.1
RDW-SD (fL)	45.7	47.0
RDW-CV (%)	12.2	12.8
PDW (fL)	19.1	21.6
MPV (fL)	12.2	14.0
P-LCR (%)	44.2	54.7
PCT (%)	0.21	0.25

Sample - 11		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.4	6.8
RBC (10 ⁶ /μl)	3.97	3.97
HGB (g/dl)	15.1	15.2
HCT (%)	43.4	43.1
MCV (fL)	109.3	108.6
MCH (pg)	38.0	38.3
MCHC (g/dl)	34.8	35.3
PLT (10 ³ /μl)	199	208
LYM (%)	25.7	24.0
MXD (%)	10.5	12.2
NEUT (%)	63.8	63.8
LYM# (10 ³ /μl)	1.9	1.6
MXD# (10 ³ /μl)	0.8	0.8
NEUT# (10 ³ /μl)	4.7	4.4
RDW-SD (fL)	60.7	59.3
RDW-CV (%)	14.6	14.9
PDW (fL)	16.5	18.5
MPV (fL)	11.3	12.3
P-LCR (%)	36.4	44.3
PCT (%)	0.23	0.26

Sample - 12		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	6.2	5.7
RBC (10 ⁶ /μl)	4.12	4.12
HGB (g/dl)	15.1	15.2
HCT (%)	45.6	45.2
MCV (fL)	110.7	109.7
MCH (pg)	36.7	36.9
MCHC (g/dl)	33.1	33.6
PLT (10 ³ /μl)	177	174
LYM (%)	35.2	40.1
MXD (%)	11.4	9.9
NEUT (%)	53.4	50.0
LYM# (10 ³ /μl)	2.2	2.3
MXD# (10 ³ /μl)	0.7	0.6
NEUT# (10 ³ /μl)	3.3	2.8
RDW-SD (fL)	59.2	59.2
RDW-CV (%)	13.8	14.3
PDW (fL)	18.7	22.8
MPV (fL)	12.6	13.7
P-LCR (%)	46.2	52
PCT (%)	0.22	0.24

Sample - 13		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	7.8	7.6
RBC (10 ⁶ /μl)	4.13	4.11
HGB (g/dl)	15.3	15.3
HCT (%)	45.2	44.4
MCV (fL)	109.4	108.0
MCH (pg)	37.0	37.2
MCHC (g/dl)	33.8	34.5
PLT (10 ³ /μl)	276	289
LYM (%)	35.5	40.0
MXD (%)	14.1	13.9
NEUT (%)	50.4	46.1
LYM# (10 ³ /μl)	2.8	3.0
MXD# (10 ³ /μl)	1.1	1.1
NEUT# (10 ³ /μl)	3.9	3.5
RDW-SD (fL)	53.1	53.5
RDW-CV (%)	12.3	12.9
PDW (fL)	14.9	16.3
MPV (fL)	10.9	11.6
P-LCR (%)	32.5	38.1
PCT (%)	0.30	0.34

Sample - 14		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	8.0	7.7
RBC (10 ⁶ /μl)	4.94	5.00
HGB (g/dl)	16.3	16.3
HCT (%)	48.4	48.5
MCV (fL)	98.0	97.0
MCH (pg)	33.0	32.6
MCHC (g/dl)	33.7	33.6
PLT (10 ³ /μl)	247	242
LYM (%)	34.0	34.2
MXD (%)	9.5	10.3
NEUT (%)	56.5	55.5
LYM# (10 ³ /μl)	2.7	2.6
MXD# (10 ³ /μl)	0.8	0.8
NEUT# (10 ³ /μl)	4.5	4.3
RDW-SD (fL)	48.9	47.6
RDW-CV (%)	12.8	13.2
PDW (fL)	19.4	21.5
MPV (fL)	13.0	14.3
P-LCR (%)	49.9	58.7
PCT (%)	0.32	0.35

Sample - 15		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	5.9	5.8
RBC (10 ⁶ /μl)	4.09	4.17
HGB (g/dl)	15.0	15.1
HCT (%)	45.0	45.1
MCV (fL)	110.0	108.2
MCH (pg)	36.7	36.2
MCHC (g/dl)	33.3	33.5
PLT (10 ³ /μl)	175	174
LYM (%)	40.0	39.0
MXD (%)	14.8	12.3
NEUT (%)	45.2	48.7
LYM# (10 ³ /μl)	2.4	2.3
MXD# (10 ³ /μl)	0.9	0.7
NEUT# (10 ³ /μl)	2.6	2.8
RDW-SD (fL)	57.7	58.5
RDW-CV (%)	14.0	14.5
PDW (fL)	20.5	21.7
MPV (fL)	12.8	13.8
P-LCR (%)	47.3	54.2
PCT (%)	0.22	0.24

Sample - 16		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-S Lot : HVDS221018 VDx Lyse-S Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack Lot : X2177 Stromatolyser Lot : X2030
WBC (10 ³ /μl)	5.7	5.1
RBC (10 ⁶ /μl)	5.35	5.36
HGB (g/dl)	17.2	17.2
HCT (%)	50.7	50.3
MCV (fL)	94.8	93.8
MCH (pg)	32.1	32.1
MCHC (g/dl)	33.9	34.2
PLT (10 ³ /μl)	208	209
LYM (%)	39.0	39.2
MXD (%)	12.5	13.4
NEUT (%)	48.5	47.4
LYM# (10 ³ /μl)	2.2	2.0
MXD# (10 ³ /μl)	0.7	0.7
NEUT# (10 ³ /μl)	2.8	2.4
RDW-SD (fL)	48.4	49.3
RDW-CV (%)	13.9	14.0
PDW (fL)	17.4	18.7
MPV (fL)	12.2	13.1
P-LCR (%)	43.1	51.1
PCT (%)	0.25	0.27

Performance with Hematology 3rd Party Controls

Diagon D Check D Plus

Low, Normal & High Controls

Lot No : 2V0901

Expiry : 05.03.2023

Diagon D Check D Plus			
(Low Control, Lot No: 2V0901, Expiry Date : 05.03.2023)			
Parameters	All Reagents : Vanguard Diagnostics VDx Diluent-S, Lot : HVDS221018 VDx Lyse-S, Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack, Lot:X2177 Stromatolyser, Lot : X2030	Range
WBC (10 ³ /μl)	3.2	3.1	2.4 - 3.4
RBC (10 ⁶ /μl)	2.44	2.47	2.28 - 2.68
HGB (g/dl)	7.2	7.1	6.6 - 7.6
HCT (%)	18.6	18.9	15.0 - 21.0
MCV (fL)	76.2	76.5	66.7 - 78.7
MCH (pg)	29.5	28.7	25.2 - 32.2
MCHC (g/dl)	38.7	37.6	35.0 - 44.0
PLT (10 ³ /μl)	70	74	42 - 92
LYM (%)	29.1	29.3	15.2 - 35.4
MXD (%)	13.6	11.6	0.0 - 28.0
NEUT (%)	57.3	59.1	45.5 - 75.9
LYM# (10 ³ /μl)	0.9	0.9	0.4 - 1.0
MXD# (10 ³ /μl)	0.4	0.4	0.0 - 0.8
NEUT# (10 ³ /μl)	1.9	1.8	1.3 - 2.3
RDW-SD (fL)	34.0	34.4	26.3 - 42.3
RDW-CV (%)	12.0	12.7	6.4 - 16.4
PDW (fL)	7.4	7.9	1.2 - 13.2
MPV (fL)	10.4	10.3	4.7 - 14.7
P-LCR (%)	22.4	22.9	
PCT (%)	0.07	0.08	0.00 - 0.12

Diagon D Check D Plus			
(Normal Control, Lot No: 2V0901, Expiry Date: 05.03.2023)			
Parameters	All Reagents : Vanguard Diagnostics VDx Diluent-S, Lot : HVDS221018 VDx Lyse-S, Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack, Lot:X2177 Stromatolyser, Lot : X2030	Range
WBC (10 ³ /μl)	8.2	8.3	6.8 - 8.8
RBC (10 ⁶ /μl)	4.26	4.23	4.18 - 4.78
HGB (g/dl)	13.6	13.6	13.0 - 14.2
HCT (%)	34.9	34.7	31.2 - 40.2
MCV (fL)	81.9	82.0	73.7 - 85.7
MCH (pg)	31.9	32.2	26.6 - 34.2
MCHC (g/dl)	39.0	39.2	33.3 - 42.9
PLT (10 ³ /μl)	220	228	175 - 265
LYM (%)	28.2	28.9	22.6 - 37.6
MXD (%)	13.7	13.9	6.5 - 19.5
NEUT (%)	58.1	57.2	48.4 - 65.4
LYM# (10 ³ /μl)	2.3	2.4	1.8 - 3.0
MXD# (10 ³ /μl)	1.1	1.2	0.5 - 1.5
NEUT# (10 ³ /μl)	4.8	4.7	3.7 - 5.1
RDW-SD (fL)	34.1	36.1	27.4 - 45.4
RDW-CV (%)	11.3	11.9	5.8 - 15.8
PDW (fL)	7.7	8.1	4.2 - 10.2
MPV (fL)	11.1	10.7	6.5 - 12.5
P-LCR (%)	28.3	25.0	
PCT (%)	0.24	0.24	0.006 - 0.36

Diagon D Check D Plus

(High Control, Lot No: 2V0901, Expiry Date : 05.03.2023)

Parameters	All Reagents : Vanguard Diagnostics VDx Diluent-S, Lot : HVDS221018 VDx Lyse-S, Lot : HLYS221114	All Reagents: Sysmex as Reference Cellpack, Lot:X2177 Stromatolyser, Lot : X2030	Range
WBC (10 ³ /μl)	17.4	17.3	14.3 - 19.3
RBC (10 ⁶ /μl)	5.23	5.18	5.11 - 5.91
HGB (g/dl)	17.6	17.7	16.9 - 18.5
HCT (%)	45.1	44.7	41.6 - 50.6
MCV (fL)	86.2	86.3	77.8 - 89.8
MCH (pg)	33.7	34.2	28.3 - 35.9
MCHC (g/dl)	39.0	39.6	33.5 - 43.1
PLT (10 ³ /μl)	510	514	434 - 564
LYM (%)	31.3	31.4	28.9 - 39.1
MXD (%)	17.6	15.9	7.4 - 22.0
NEUT (%)	51.1	52.7	41.1 - 61.6
LYM# (10 ³ /μl)	5.4	5.4	4.8 - 6.6
MXD# (10 ³ /μl)	3.1	2.8	1.3 - 3.8
NEUT# (10 ³ /μl)	8.9	9.1	6.9 - 10.3
RDW-SD (fL)	36.1	37.7	28.6 - 48.6
RDW-CV (%)	10.5	11.3	6.3 - 16.3
PDW (fL)	8.1	8.2	4.3 - 10.3
MPV (fL)	11.3	11.1	6.6 - 12.6
P-LCR (%)	32.7	30.4	
PCT (%)	0.58	0.57	0.18 - 0.78

**D-Check D Plus****CONTROL****ASSAY VALUES AND EXPECTED RANGES**

Vizsgálati értékek és várható tartományok

LOT: 2V0901 **05-03-2023**

Instruments:		Sysmex XP series					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 2V0901		LOT: 2V0901		LOT: 2V0901	
		Mean $\pm$ Limit	Range Variation	Mean $\pm$ Limit	Range Variation	Mean $\pm$ Limit	Range Variation
WBC	$10^3/\mu\text{L}$	$2,9 \pm 0,5$	2,4 - 3,4	$8,1 \pm 1,0$	7,1 - 9,1	$17,1 \pm 2,8$	14,3 - 19,9
RBC	$10^6/\mu\text{L}$	$2,48 \pm 0,20$	2,28 - 2,68	$4,32 \pm 0,30$	4,02 - 4,62	$5,35 \pm 0,40$	4,95 - 5,75
Hgb	g/dL	$7,1 \pm 0,5$	6,6 - 7,6	$13,5 \pm 0,7$	12,8 - 14,2	$17,6 \pm 0,9$	16,7 - 18,5
	g/L	71 ± 5	66 - 76	135 ± 7	128 - 142	176 ± 9	167 - 185
Hct	%	$18,0 \pm 3,0$	15,0 - 21,0	$33,7 \pm 4,5$	29,2 - 38,2	$43,9 \pm 4,5$	39,4 - 48,4
	L/L	$0,180 \pm 0,030$	0,150 - 0,210	$0,337 \pm 0,045$	0,292 - 0,382	$0,439 \pm 0,045$	0,394 - 0,484
MCV	fL	$72,7 \pm 6,0$	66,7 - 78,7	$78,1 \pm 6,0$	72,1 - 84,1	$82,1 \pm 6,0$	76,1 - 88,1
MCH	pg	$28,7 \pm 3,5$	25,2 - 32,2	$31,4 \pm 3,5$	27,9 - 34,9	$32,9 \pm 3,5$	29,4 - 36,4
MCHC	g/dL	$39,5 \pm 4,5$	35,0 - 44,0	$40,1 \pm 4,5$	35,6 - 44,6	$40,0 \pm 4,5$	35,5 - 44,5
	g/L	395 ± 45	350 - 440	401 ± 45	356 - 446	400 ± 45	355 - 445
RDW-SD	fL	$30,3 \pm 12,0$	26,3 - 42,3	$34,6 \pm 12,0$	26,9 - 44,9	$35,7 \pm 12,0$	27,8 - 47,8
RDW-CV	%	$11,9 \pm 8,0$	6,4 - 16,4	$11,8 \pm 8,0$	5,8 - 15,8	$11,7 \pm 8,0$	6,1 - 16,1
Pit	$10^3/\mu\text{L}$	67 ± 25	42 - 92	226 ± 45	181 - 271	498 ± 80	418 - 578
MPV	fL	$9,7 \pm 5,0$	4,7 - 14,7	$9,9 \pm 5,0$	4,9 - 14,9	$10,1 \pm 5,0$	5,1 - 15,1
PCT	%	$0,06 \pm 0,06$	0,00 - 0,12	$0,22 \pm 0,15$	0,07 - 0,37	$0,51 \pm 0,30$	0,21 - 0,81
PDW	fL	$7,2 \pm 6,0$	1,2 - 13,2	$7,2 \pm 6,0$	1,2 - 13,2	$7,6 \pm 6,0$	1,6 - 13,6
P-LCR	%	$14,5 \pm 14,0$	0,5 - 28,5	$15,3 \pm 15,0$	0,3 - 30,3	$18,2 \pm 15,0$	3,2 - 33,2
LYMPH#	$10^3/\mu\text{L}$	$0,7 \pm 0,3$	0,4 - 1,0	$2,3 \pm 0,8$	1,5 - 3,1	$5,6 \pm 1,4$	4,2 - 7,0
MXD#	$10^3/\mu\text{L}$	$0,4 \pm 0,4$	0,0 - 0,8	$1,1 \pm 1,1$	0,0 - 2,2	$2,6 \pm 1,3$	1,3 - 3,9
NEUT#	$10^3/\mu\text{L}$	$1,8 \pm 0,5$	1,3 - 2,3	$4,7 \pm 1,7$	3,0 - 6,4	$8,9 \pm 2,2$	6,7 - 11,1
LYMPH%	%	$25,3 \pm 10,1$	15,2 - 35,4	$28,6 \pm 10,0$	18,6 - 38,6	$32,6 \pm 8,1$	24,5 - 40,7
MXD%	%	$14,0 \pm 14,0$	0,0 - 28,0	$13,4 \pm 13,4$	0,0 - 26,8	$15,1 \pm 7,6$	7,5 - 22,7
NEUT%	%	$60,7 \pm 15,2$	45,5 - 75,9	$58,0 \pm 20,3$	37,7 - 78,3	$52,3 \pm 13,1$	39,2 - 65,4

Occasionally leukocyte cell population are incorrectly identified. If this occurs, rerun the sample.

A leukocita sejtpopulációk időnként helytelenül kerülnek meghatározásra. Ha ez történik mérje újra a mintát!



DIAGON Ltd
48-52., Baross Str.
Budapest, Hungary
H-1047



Coefficient of Variation: Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Sysmex Reagents on XP100, 3 Part Hematology Analyzer.
2. The sample was tested in 06 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 06

Precision Evaluation report of VDx Sysmex Compatible reagent on Sysmex - XP100, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{l}$)	7	7	7.2	6.8	6.8	6.9					6.95	0.15	0.02	2.18
RBC ($10^6/\mu\text{l}$)	4.13	4.13	4.13	4.09	4.1	4.07					4.11	0.03	0.01	0.62
HGB (g/dl)	15.4	15.4	15.4	15.3	15.3	15.4					15.37	0.05	0.00	0.34
HCT (%)	44.3	44.7	44.6	44.3	44.4	44.2					44.42	0.19	0.00	0.44
MCV (fL)	107.3	108.2	108	108.3	108.3	108.6					108.12	0.44	0.00	0.41
MCH (pg)	37.3	37.3	37.3	37.4	37.3	37.8					37.40	0.20	0.01	0.53
MCHC (g/dl)	34.8	34.5	34.5	34.5	34.5	34.8					34.60	0.15	0.00	0.45
PLT ($10^3/\mu\text{l}$)	266	261	259	270	274	274					267.33	6.44	0.02	2.41
LYM (%)	37.9	36.3	37.9	37.4	37.5	38.0					37.50	0.64	0.02	1.69
MXD (%)	10.5	10.7	11.8	10.8	12.3	11.3					11.23	0.70	0.06	6.26
NEUT (%)	51.6	53	50.3	51.8	50.2	50.7					51.27	1.08	0.02	2.10
LYM# ($10^3/\mu\text{l}$)	2.7	2.5	2.7	2.5	2.6	2.6					2.60	0.09	0.03	3.44
MXD# ($10^3/\mu\text{l}$)	0.7	0.7	0.8	0.7	0.80	0.8					0.75	0.05	0.07	7.30
NEUT# ($10^3/\mu\text{l}$)	3.6	3.8	3.7	3.6	3.4	3.5					3.60	0.14	0.04	3.93
RDW-SD (fL)	52.4	51.9	52.3	51.7	53	52.8					52.35	0.50	0.01	0.96
RDW-CV (%)	12.5	12.6	12.7	12.3	12.5	12.5					12.52	0.13	0.01	1.06
PDW (fL)	15.4	16.4	15.4	15.6	14.4	16.2					15.57	0.71	0.05	4.55
MPV (fL)	11.2	11.4	11.2	11.3	11.2	11.6					11.32	0.16	0.01	1.42
P-LCR (%)	35.4	36.9	34.4	35.9	34.8	37.2					35.77	1.12	0.03	3.14
PCT (%)	0.30	0.30	0.29	0.30	0.31	0.32					0.30	0.01	0.03	3.40

Coefficient of Variation:

Precision (Sysmex Reference Reagents)

1. Fresh blood sample was collected and tested with the Sysmex Reference Reagents on XP100, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 07

Precision Evaluation report of Sysmex Reference reagent on XP100, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{l}$)	7.2	7.3	7.2	7.2	7.1	7.1	7.1				7.17	0.08	0.01	1.05
RBC ($10^6/\mu\text{l}$)	4.23	4.22	4.24	4.19	4.23	4.2	4.15				4.21	0.03	0.01	0.74
HGB (g/dl)	15.8	15.9	15.9	15.6	15.6	15.6	15.5				15.70	0.16	0.01	1.04
HCT (%)	45.2	45.1	45.2	44.8	45.1	44.9	44.2				44.93	0.35	0.01	0.79
MCV (fL)	106.9	106.9	106.6	106.9	106.6	106.9	106.5				106.76	0.18	0.00	0.17
MCH (pg)	37.4	37.7	37.5	37.2	36.9	37.1	37.3				37.30	0.26	0.01	0.71
MCHC (g/dl)	35.0	35.3	35.2	34.8	34.6	34.7	35.1				34.96	0.26	0.01	0.75
PLT ($10^3/\mu\text{l}$)	241	245	233	254	258	275	268				253.43	14.95	0.06	5.90
LYM (%)	36.0	37.4	36.8	35.6	36.1	38.5	36.1				36.64	1.01	0.03	2.76
MXD (%)	14.9	14.6	15.5	16.1	15.7	14.5	15.8				15.30	0.63	0.04	4.12
NEUT (%)	49.1	48.0	47.7	48.3	48.2	47	48.1				48.06	0.63	0.01	1.32
LYM# ($10^3/\mu\text{l}$)	2.6	2.7	2.6	2.6	2.6	2.7	2.6				2.63	0.05	0.02	1.86
MXD# ($10^3/\mu\text{l}$)	1.1	1.1	1.1	1.2	1.1	1.0	1.1				1.10	0.06	0.05	5.25
NEUT# ($10^3/\mu\text{l}$)	3.5	3.5	3.5	3.4	3.4	3.4	3.4				3.44	0.05	0.02	1.55
RDW-SD (fL)	52.8	51.6	51.8	51.9	52.4	52.0	51.2				51.96	0.52	0.01	1.01
RDW-CV (%)	12.9	12.6	12.8	13.1	12.8	12.9	12.8				12.84	0.15	0.01	1.18
PDW (fL)	15.8	14.9	16.7	16.0	17.1	16.2	17.2				16.27	0.81	0.05	4.96
MPV (fL)	11.8	11.6	11.8	11.8	11.9	11.6	11.8				11.76	0.11	0.01	0.96
P-LCR (%)	39.6	37.8	39.7	39.1	40.6	37.2	40.0				39.14	1.22	0.03	3.12
PCT (%)	0.28	0.28	0.27	0.30	0.31	0.32	0.32				0.30	0.02	0.07	6.93

Conclusions

1. The V Dx Sysmex 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Sysmex original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.983 to 0.999** displaying the highest degree of correlation between the reagents.
3. The V Dx Sysmex and the Sysmex Reference 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all the parameters.
4. The CV % with the V Dx Sysmex Reagents and the Sysmex Reference Reagents were found to be as under:

Parameters	Sysmex Reference Reagents (CV % - Precision)	V Dx Sysmex Reagents (CV % - Precision)
Measured Parameters	0.17% – 5.90%	0.34% - 2.41%
Calculated Parameters	0.71% - 6.93%	0.45% - 7.30%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges both for V Dx Sysmex 3 Part Hematology Reagents and Sysmex Reference reagents
6. **The V Dx Sysmex 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Sysmex Reference Reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	43 - 44
2	Background Test	45
3	Coefficient of Correlation: Accuracy	46 – 61
4	Quality Control (Low, Normal & High)	62 - 66
5	Coefficient of Variation: Precision (VDx Mindray Compatible Reagents)	67
6	Coefficient of Variation: Precision (Mindray Reference Reagents)	68
7	Conclusions	69

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Mindray BC 3200
Reference Reagents	Reference Mindray Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date : 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date : 15-02-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Mindray Compatible Reagents)
5	Coefficient of Variation: Precision (Mindray Reference Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M Lot : HDIM2211146 VDx Lyse-M Lot : HVLM210708 VDx Rinse-M Lot : HRIM221025	All Reagents: Mindray as Reference M-30D Diluent Lot:2022091601 M-30CF Lyse Lot : 2022021601
WBC (10 ³ /μL)	0.0	0.0
Lymph # (10 ³ /μL)	0.0	0.0
Mid# (10 ³ /μL)	0.0	0.0
Gran# (10 ³ /μL)	0.0	0.0
Lymph (%)	0.0	0.0
Mid (%)	0.0	0.0
Gran (%)	0.0	0.0
HGB (g/dL)	0.0	0.0
RBC (10 ³ /μL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
RDW-CV (%)	0.0	0.0
RDW-SD (fL)	0.0	0.0
PLT (10 ³ /μL)	0.0	0.0
MPV (fL)	0.0	0.0
PDW	0.0	0.0
PCT (%)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Mindray Reagents and the Reference Mindray Reagents.
- II. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

Coefficient of Correlation (“r”): WBC

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.
y = VDX Reagents for Mindray- BC 3200, 3 Part Hematology Analyzer.

$$“r” = 0.995$$

Sample size: 8

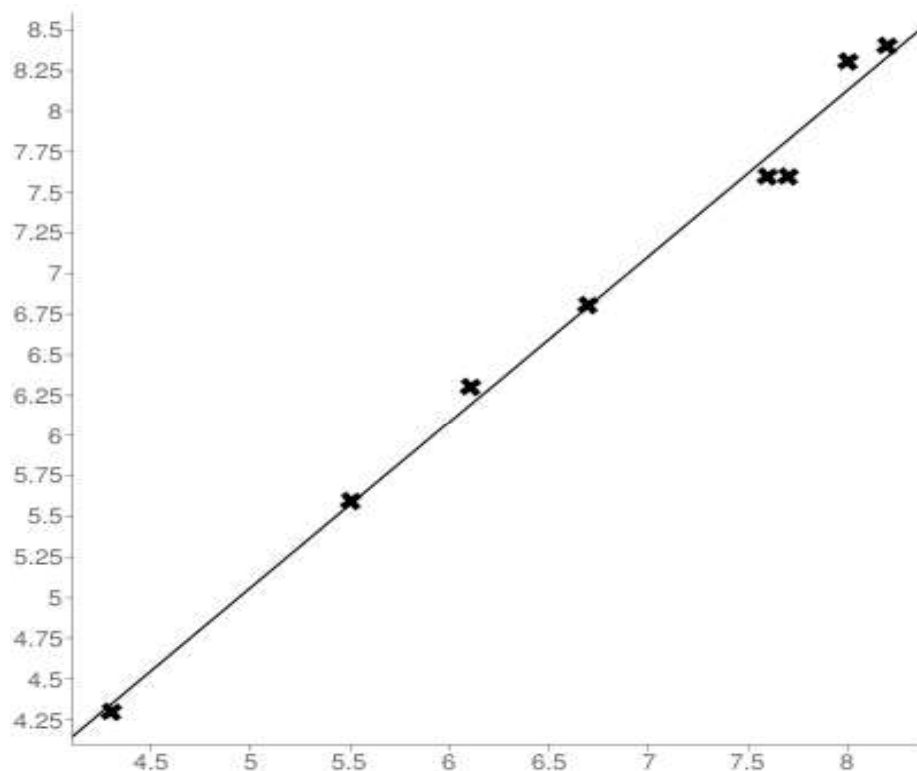
Mean x ($\bar{x}$): 6.7625

Mean y ($\bar{y}$): 6.8625

Intercept (a): -0.052781700084669

Slope (b): 1.0225924879977

Regression line equation: $y = 1.0225924879977x - 0.052781700084669$



Coefficient of Correlation (“r”): RBC

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

y = VDX Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

$$“r” = 0.995$$

Sample size: 8

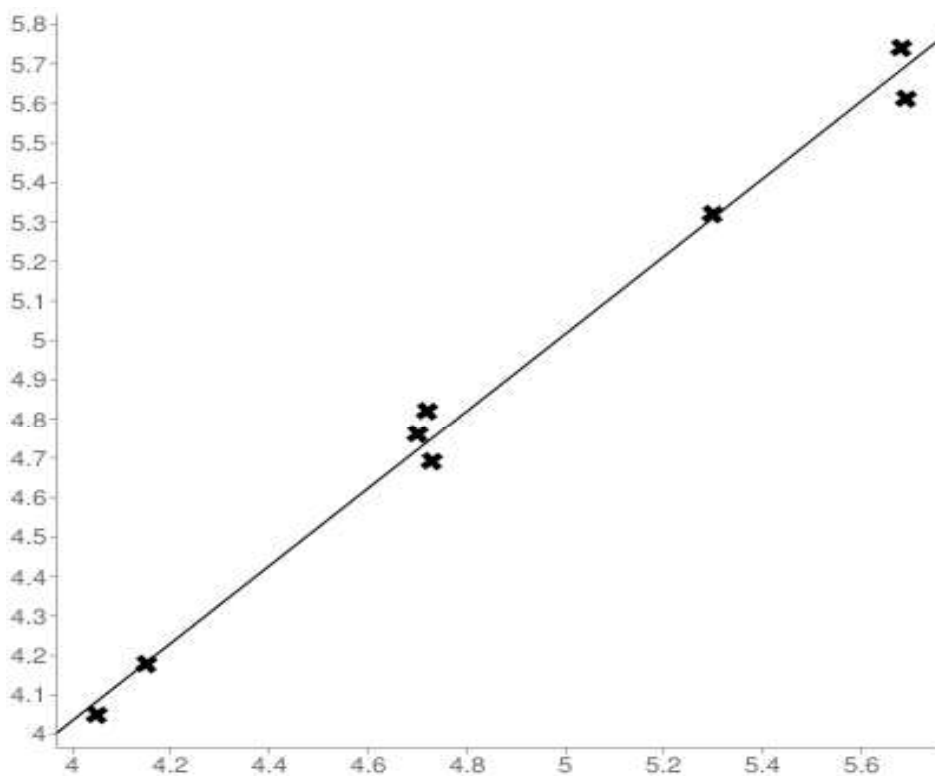
Mean x (x̄): 4.8775

Mean y (ȳ): 4.89625

Intercept (a): 0.10791521758717

Slope (b): 0.98171907379043

Regression line equation: $y = 0.10791521758717 + 0.98171907379043x$



Coefficient of Correlation (“r”): Hemoglobin

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

y = VDX Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 8

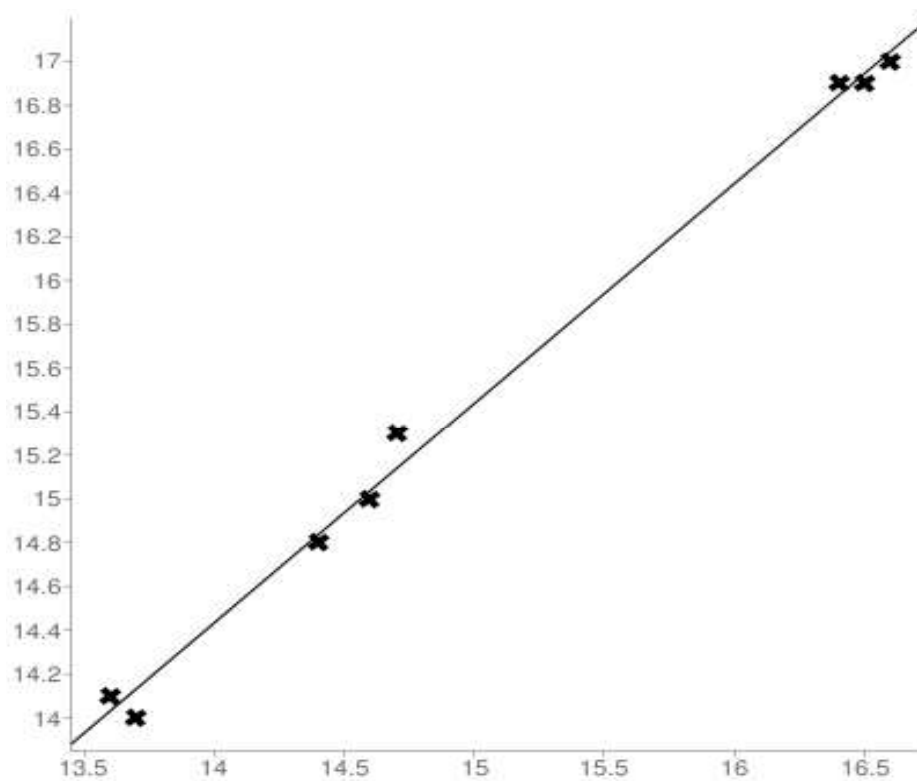
Mean x (x̄): 15.0625

Mean y (ȳ): 15.5

Intercept (a): 0.36731446755378

Slope (b): 1.0046596204114

Regression line equation: $y = 0.36731446755378 + 1.0046596204114x$



Coefficient of Correlation (“r”): Platelets

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

y = VDX Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

$$“r” = 0.998$$

Sample size: 8

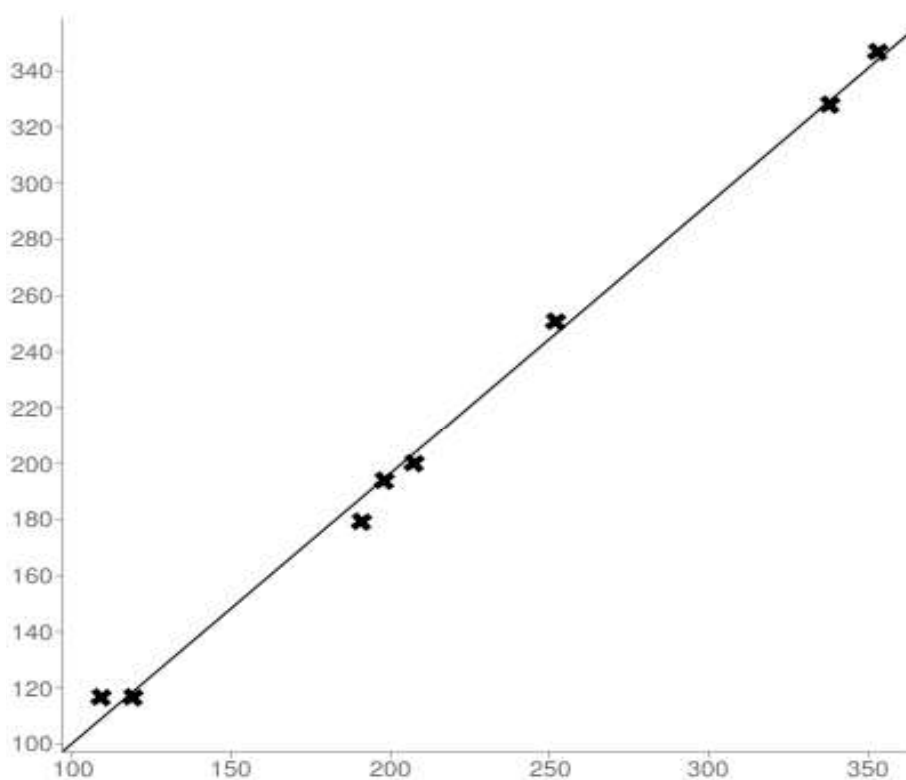
Mean x ($\bar{x}$): 220.875

Mean y ($\bar{y}$): 216.625

Intercept (a): 4.0912693771722

Slope (b): 0.96223533954874

Regression line equation: $y = 4.0912693771722 + 0.96223533954874x$



Coefficient of Correlation (“r”): MCV

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

y = VDX Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

$$“r” = 0.995$$

Sample size: 8

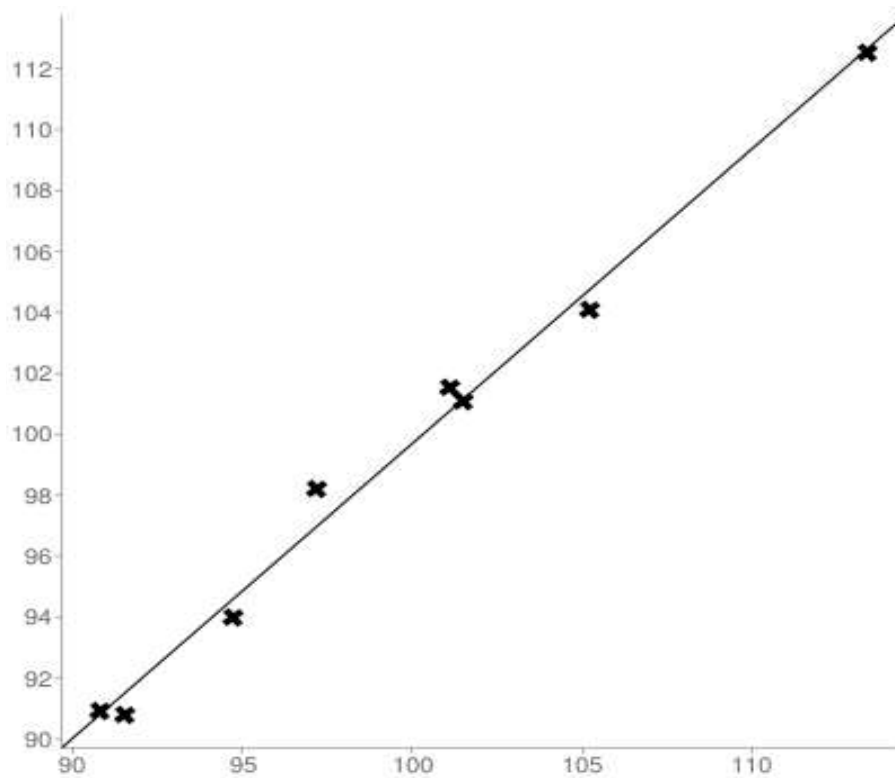
Mean x (x): 99.425

Mean y (y): 99.1375

Intercept (a): 3.0220295576336

Slope (b): 0.96671330593278

Regression line equation: $y=3.0220295576336+0.96671330593278x$



Coefficient of Correlation (“r”): HCT

x = Mindray Reference Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.
y = VDX Reagents for Mindray BC 3200, 3 Part Hematology Analyzer.

“r” = 0.978

Sample size: 8

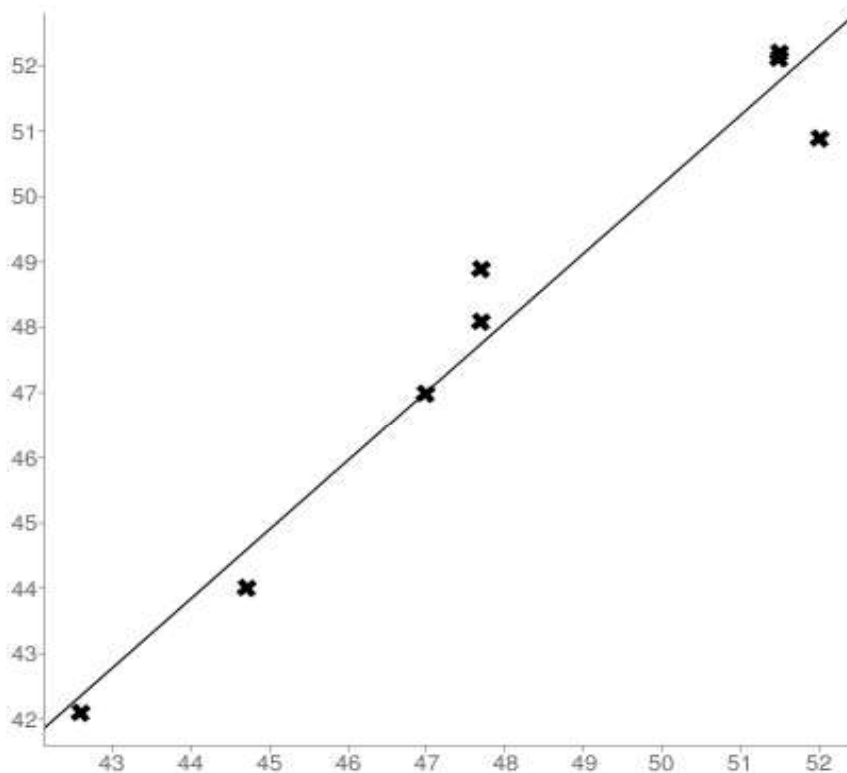
Mean x (x̄): 48.0875

Mean y (ȳ): 48.1625

Intercept (a): -2.649725262112

Slope (b): 1.0566618198516

Regression line equation: $y = 1.0566618198516x - 2.649725262112$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	8.3	8.0
Lymph # (10 ³ /μL)	2.1	1.8
Mid# (10 ³ /μL)	0.8	0.7
Gran# (10 ³ /μL)	5.4	5.5
Lymph (%)	24.8	22.1
Mid (%)	9.7	8.6
Gran (%)	65.5	69.3
HGB (g/dL)	15.0	14.6
RBC (10 ³ /μL)	4.76	4.7
HCT (%)	48.1	47.7
MCV (fL)	101.1	101.5
MCH (pg)	31.5	31.0
MCHC (g/dL)	31.1	30.6
RDW-CV (%)	13.8	13.4
RDW-SD (fL)	53.3	51.6
PLT (10 ³ /μL)	117	119.0
MPV (fL)	10.9	11.7
PDW	15.6	15.8
PCT (%)	0.127	0.139

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	8.4	8.2
Lymph # (10 ³ /μL)	2.1	1.7
Mid# (10 ³ /μL)	0.7	0.5
Gran# (10 ³ /μL)	5.6	6.0
Lymph (%)	25.5	21.2
Mid (%)	7.9	5.6
Gran (%)	66.6	73.2
HGB (g/dL)	15.3	14.7
RBC (10 ³ /μL)	4.82	4.72
HCT (%)	48.9	47.7
MCV (fL)	101.5	101.1
MCH (pg)	31.7	31.1
MCHC (g/dL)	31.2	30.8
RDW-CV (%)	13.4	13.8
RDW-SD (fL)	49.9	50.8
PLT (10 ³ /μL)	117	109
MPV (fL)	11.1	10.9
PDW	15.4	15.9
PCT (%)	0.129	0.118

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	7.6	7.6
Lymph # (10 ³ /μL)	1.3	1.5
Mid# (10 ³ /μL)	0.5	0.5
Gran# (10 ³ /μL)	5.8	5.6
Lymph (%)	17.4	20.0
Mid (%)	7.1	6.4
Gran (%)	75.5	73.6
HGB (g/dL)	16.9	16.4
RBC (10 ³ /μL)	5.74	5.68
HCT (%)	52.1	51.5
MCV (fL)	90.9	90.8
MCH (pg)	29.4	28.8
MCHC (g/dL)	32.4	31.8
RDW-CV (%)	12.2	12.3
RDW-SD (fL)	42.0	41.1
PLT (10 ³ /μL)	347	353
MPV (fL)	9.5	9.6
PDW	15.7	15.8
PCT (%)	0.329	0.338

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	6.8	6.7
Lymph # (10 ³ /μL)	2.3	2.4
Mid# (10 ³ /μL)	0.5	0.5
Gran# (10 ³ /μL)	4.0	3.8
Lymph (%)	34.3	35.7
Mid (%)	7.1	7.9
Gran (%)	58.6	56.4
HGB (g/dL)	14.1	13.6
RBC (10 ³ /μL)	4.05	4.05
HCT (%)	42.1	42.6
MCV (fL)	104.1	105.2
MCH (pg)	34.8	33.5
MCHC (g/dL)	33.4	31.9
RDW-CV (%)	13.8	14.0
RDW-SD (fL)	50.8	52.5
PLT (10 ³ /μL)	251	252
MPV (fL)	9.1	8.9
PDW	15.6	15.8
PCT (%)	0.228	0.224

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	4.3	4.3
Lymph # (10 ³ /μL)	1.5	1.4
Mid# (10 ³ /μL)	0.3	0.4
Gran# (10 ³ /μL)	2.5	2.5
Lymph (%)	35.6	31.7
Mid (%)	6.8	11.0
Gran (%)	57.6	57.3
HGB (g/dL)	14.0	13.7
RBC (10 ³ /μL)	4.69	4.73
HCT (%)	44.0	44.7
MCV (fL)	94.0	94.7
MCH (pg)	29.8	28.9
MCHC (g/dL)	31.8	30.6
RDW-CV (%)	13.6	13.2
RDW-SD (fL)	46.3	44.6
PLT (10 ³ /μL)	194	198
MPV (fL)	11.2	11.1
PDW	15.7	15.8
PCT (%)	0.217	0.219

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	7.6	7.7
Lymph # (10 ³ /μL)	1.4	1.5
Mid# (10 ³ /μL)	0.4	0.6
Gran# (10 ³ /μL)	5.8	5.6
Lymph (%)	18.7	19.1
Mid (%)	5.7	7.8
Gran (%)	75.6	73.1
HGB (g/dL)	16.9	16.5
RBC (10 ³ /μL)	5.61	5.69
HCT (%)	50.9	52.0
MCV (fL)	90.8	91.5
MCH (pg)	30.1	28.9
MCHC (g/dL)	33.2	31.7
RDW-CV (%)	12.6	12.1
RDW-SD (fL)	40.2	41.1
PLT (10 ³ /μL)	328	338
MPV (fL)	9.6	9.5
PDW	15.5	15.6
PCT (%)	0.314	0.321

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	6.3	6.1
Lymph # (10 ³ /μL)	2.8	2.4
Mid# (10 ³ /μL)	0.4	0.5
Gran# (10 ³ /μL)	3.1	3.2
Lymph (%)	44.2	40.0
Mid (%)	7.1	9.0
Gran (%)	48.7	51.0
HGB (g/dL)	14.8	14.4
RBC (10 ³ /μL)	4.18	4.15
HCT (%)	47.0	47.0
MCV (fL)	112.5	113.4
MCH (pg)	35.4	34.6
MCHC (g/dL)	31.4	30.6
RDW-CV (%)	14.8	14.8
RDW-SD (fL)	60.4	56.8
PLT (10 ³ /μL)	179	191
MPV (fL)	10.6	10.8
PDW	15.7	16.0
PCT (%)	0.189	0.206

Sample - 08

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601
WBC (10 ³ /μL)	5.6	5.5
Lymph # (10 ³ /μL)	2.4	2.0
Mid# (10 ³ /μL)	0.5	0.8
Gran# (10 ³ /μL)	2.7	2.7
Lymph (%)	42.7	36.8
Mid (%)	9.7	13.8
Gran (%)	47.6	49.4
HGB (g/dL)	17.0	16.6
RBC (10 ³ /μL)	5.32	5.30
HCT (%)	52.2	51.5
MCV (fL)	98.2	97.2
MCH (pg)	31.9	31.3
MCHC (g/dL)	32.5	32.2
RDW-CV (%)	14.0	14.0
RDW-SD (fL)	48.1	47.3
PLT (10 ³ /μL)	200	207
MPV (fL)	10.4	10.4
PDW	15.4	15.4
PCT (%)	0.208	0.215

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D

(Low Control, Lot- 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601	Range
WBC ($10^3/\mu\text{L}$)	2.5	2.6	2.3 - 3.3
Lymph # ($10^3/\mu\text{L}$)	1.2	1.3	1.0 - 1.8
Gran# ($10^3/\mu\text{L}$)	1.1	1.2	0.7 - 1.7
Lymph (%)	48.9	48.4	38.0 - 63.2
Gran (%)	43.9	44.8	28.3 - 58.9
HGB (g/dL)	6.9	6.7	5.6 - 7.6
RBC ($10^3/\mu\text{L}$)	2.41	2.41	2.30 - 2.70
HCT (%)	20.1	20.5	17.1 - 23.1
MCV (fL)	83.6	85.2	74.4 - 86.4
MCH (pg)	28.6	27.8	24.4 - 32.0
MCHC (g/dL)	34.3	32.6	30.2 - 39.8
PLT ($10^3/\mu\text{L}$)	81	82	52 – 102

Diagon D Check D			
(Normal Control, Lot- 1V0901, Expiry Date: 05.03.2023)			
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601	Range
WBC ($10^3/\mu\text{L}$)	8.4	8.0	7.4 - 9.4
Lymph # ($10^3/\mu\text{L}$)	2.7	2.7	1.7 - 3.5
Gran# ($10^3/\mu\text{L}$)	5.2	4.8	4.5 - 6.1
Lymph (%)	32.0	33.6	30.4 - 42.4
Gran (%)	61.9	60.4	44.0 - 81.8
HGB (g/dL)	14.1	13.3	13.0 - 14.2
RBC ($10^3/\mu\text{L}$)	4.50	4.36	4.21 - 4.81
HCT (%)	40.2	39.7	34.6 - 42.6
MCV (fL)	89.4	91.2	79.7 - 91.7
MCH (pg)	31.3	30.5	26.3 - 33.9
MCHC (g/dL)	35.0	33.5	30.4 - 40.0
PLT ($10^3/\mu\text{L}$)	221	221	184 – 274

Diagon D Check D

(High Control, Lot- 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-M, Lot- HDIM2211146 VDx Lyse-M, Lot- HVLM210708 VDx Rinse-M, Lot- HRIM221025	All Reagents: Mindray as Reference M-30D Diluent, Lot-2022091601 M-30CF Lyse, Lot-2022021601	Range
WBC (10 ³ /μL)	19.5	19.6	17.8 - 22.8
Lymph # (10 ³ /μL)	4.9	5.0	2.3 - 7.7
Gran# (10 ³ /μL)	13.5	13.5	9.9 - 18.5
Lymph (%)	24.9	25.3	15.9 - 33.1
Gran (%)	69.0	68.8	49.1 - 91.1
HGB (g/dL)	17.5	17.1	16.7 - 18.3
RBC (10 ³ /μL)	5.44	5.38	5.10 - 5.90
HCT (%)	52.3	52.5	45.8 - 54.8
MCV (fL)	96.2	97.6	85.4 - 97.4
MCH (pg)	32.1	31.7	28.0 - 35.6
MCHC (g/dL)	33.4	32.5	30.0 - 39.6
PLT (10 ³ /μL)	475	472	423 - 553

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901

05-03-2023

Instruments:		Diagon D-Cell 60, D-Cell 60CS; Mindray BC-3200, BC-3000Plus, BC-2900, BC-2800, BC-1800					
		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,8 ± 0,5	2,3 - 3,3	8,4 ± 1,0	7,4 - 9,4	20,3 ± 2,5	17,8 - 22,8
RBC	10 ¹² /L	2,50 ± 0,20	2,30 - 2,70	4,51 ± 0,30	4,21 - 4,81	5,50 ± 0,40	5,10 - 5,90
Hgb	g/dL	7,1 ± 0,5	6,6 - 7,6	13,6 ± 0,6	13,0 - 14,2	17,5 ± 0,8	16,7 - 18,3
	g/L	71 ± 5	66 - 76	136 ± 6	130 - 142	175 ± 8	167 - 183
Hct	%	20,1 ± 3,0	17,1 - 23,1	38,6 ± 4,0	34,6 - 42,6	50,3 ± 4,5	45,8 - 54,8
	L/L	0,201 ± 0,030	0,171 - 0,231	0,386 ± 0,040	0,346 - 0,426	0,503 ± 0,045	0,458 - 0,548
MCV	fL	80,4 ± 6,0	74,4 - 86,4	85,7 ± 6,0	79,7 - 91,7	91,4 ± 6,0	85,4 - 97,4
MCH	pg	28,2 ± 3,8	24,4 - 32,0	30,1 ± 3,8	26,3 - 33,9	31,8 ± 3,8	28,0 - 35,6
MCHC	g/dL	35,0 ± 4,8	30,2 - 39,8	35,2 ± 4,8	30,4 - 40,0	34,8 ± 4,8	30,0 - 39,6
	g/L	350 ± 48	302 - 398	352 ± 48	304 - 400	348 ± 48	300 - 396
RDW-SD	fL	42,2 ± 8,0	34,2 - 50,2	43,9 ± 9,0	34,9 - 52,9	46,3 ± 10,0	36,3 - 56,3
RDW-CV	%	14,8 ± 5,0	9,8 - 19,8	14,6 ± 5,0	9,6 - 19,6	14,5 ± 5,0	9,5 - 19,5
Plt	10 ⁹ /L	77 ± 25	52 - 102	229 ± 45	184 - 274	488 ± 65	423 - 553
MPV	fL	9,4 ± 3,0	6,4 - 12,4	9,4 ± 3,0	6,4 - 12,4	9,5 ± 3,0	6,5 - 12,5
PDW	%	13,3 ± 3,0	10,3 - 16,3	13,3 ± 3,0	10,3 - 16,3	13,3 ± 3,0	10,3 - 16,3
PCT	%	0,072 ± 0,050	0,022 - 0,122	0,216 ± 0,100	0,116 - 0,316	0,465 ± 0,200	0,265 - 0,665
LYMPH#	10 ⁹ /L	1,4 ± 0,4	1,0 - 1,8	2,6 ± 0,9	1,7 - 3,5	5,0 ± 2,7	2,3 - 7,7
MID#	10 ⁹ /L	0,2 ± 0,2	0,0 - 0,4	0,5 ± 0,4	0,1 - 0,9	1,1 ± 0,8	0,3 - 1,9
GRAN#	10 ⁹ /L	1,2 ± 0,5	0,7 - 1,7	5,3 ± 0,8	4,5 - 6,1	14,2 ± 4,3	9,9 - 18,5
LYMPH%	%	50,6 ± 12,6	38,0 - 63,2	31,4 ± 11,0	20,4 - 42,4	24,5 ± 8,6	15,9 - 33,1
MID%	%	5,8 ± 4,4	1,4 - 10,2	5,7 ± 4,5	1,2 - 10,2	5,4 ± 4,3	1,1 - 9,7
GRAN%	%	43,6 ± 15,3	28,3 - 58,9	62,9 ± 18,9	44,0 - 81,8	70,1 ± 21,0	49,1 - 91,1

DIAGON Ltd.

48-52., Baross Str.

Budapest, Hungary

H-1047



Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Mindray Reagents on Mindray BC 3200, 3 Part Hematology Analyzer.
2. The sample was tested in 10 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 10

Precision Evaluation report of VDx Mindray compatible reagent on Mindray BC3200, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIRD Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	6.3	6.4	6.4	6.5	6.2	6.2	6.3	6.4	6.2	6.2	6.31	0.11	0.02	1.74
Lymph # ($10^3/\mu\text{L}$)	2.2	2.3	2.2	2.4	2.2	2.4	2.2	2.3	2.3	2.2	2.27	0.08	0.04	3.63
Mid# ($10^3/\mu\text{L}$)	0.7	0.8	0.8	0.7	0.7	0.7	0.8	0.8	0.7	0.7	0.74	0.05	0.07	6.98
Gran# ($10^3/\mu\text{L}$)	3.4	3.3	3.4	3.4	3.3	3.1	3.3	3.3	3.2	3.3	3.30	0.09	0.03	2.86
Lymph (%)	35.4	36.3	34.0	36.8	35.9	38.2	35.3	35.8	36.8	36.2	36.07	1.11	0.03	3.08
Mid (%)	10.8	12.5	12.5	11.6	12.0	11.2	12.0	12.2	12.3	10.7	11.78	0.67	0.06	5.71
Gran (%)	53.8	51.2	53.5	51.6	52.1	50.6	52.7	52.0	50.9	52.1	52.05	1.05	0.02	2.02
HGB (g/dL)	13.1	13.3	13.2	13.5	13.2	13.3	13.3	13.3	13.4	13.1	13.27	0.13	0.01	0.94
RBC ($10^3/\mu\text{L}$)	4.43	4.39	4.36	4.44	4.45	4.50	4.47	4.42	4.43	4.42	4.43	0.04	0.01	0.88
HCT (%)	42.1	41.8	41.4	42.0	42.4	42.9	42.5	42.1	42.1	42.2	42.15	0.40	0.01	0.96
MCV (fL)	95.1	95.2	95.1	94.7	95.4	95.5	95.1	95.4	95.1	95.1	95.17	0.23	0.00	0.24
MCH (pg)	29.5	30.2	30.2	30.4	29.6	29.5	29.7	30.0	30.2	29.7	29.90	0.34	0.01	1.13
MCHC (g/dL)	31.1	31.8	31.8	32.1	31.1	31.0	31.2	31.5	31.8	31.2	31.46	0.39	0.01	1.24
RDW-CV (%)	12.6	12.9	12.9	12.9	12.6	12.9	12.9	12.9	12.9	12.9	12.84	0.13	0.01	0.99
RDW-SD (fL)	45.4	43.8	45.4	44.6	45.4	44.6	42.8	45.4	45.4	45.4	44.82	0.90	0.02	2.00
PLT ($10^3/\mu\text{L}$)	179	186	176	177	177	184	179	162	179	175	177.40	6.42	0.04	3.62
MPV (fL)	10.4	10.4	10.6	10.3	10.6	10.2	10.4	10.3	10.4	10.3	10.39	0.13	0.01	1.24
PDW	15.4	15.9	15.7	15.6	15.7	15.9	15.9	15.6	15.9	15.9	15.75	0.18	0.01	1.13
PCT (%)	0.186	0.193	0.186	0.182	0.187	0.187	0.186	0.166	0.186	0.180	0.18	0.01	0.04	3.88

Coefficient of Variation:

Precision (Mindray Reference Reagents)

1. Fresh blood sample was collected and tested with the Mindray Reference Reagents on Mindray-BC3200, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 07

Precision Evaluation report of Mindray Reference reagents on Mindray-BC3200, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	7.2	7.2	7.3	7.2	7.2	7.0	7.0				7.16	0.11	0.02	1.58
Lymph # ($10^3/\mu\text{L}$)	2.0	2.0	2.0	2.0	2.0	1.9	1.9				1.97	0.05	0.02	2.48
Mid# ($10^3/\mu\text{L}$)	0.5	0.5	0.5	0.5	0.5	0.6	0.6				0.53	0.05	0.09	9.23
Gran# ($10^3/\mu\text{L}$)	4.7	4.7	4.8	4.7	4.7	4.5	4.5				4.66	0.11	0.02	2.43
Lymph (%)	27.9	27.4	27.9	27.3	27.1	27.7	27.5				27.54	0.30	0.01	1.11
Mid (%)	7.1	7.6	6.7	7.2	7.1	8.3	8.0				7.43	0.56	0.08	7.60
Gran (%)	65.0	65.0	65.4	65.5	65.8	64.0	64.5				65.03	0.62	0.01	0.95
HGB (g/dL)	15.5	15.4	15.8	15.4	15.8	15.4	15.3				15.51	0.20	0.01	1.31
RBC ($10^3/\mu\text{L}$)	4.24	4.26	4.28	4.9	4.33	4.16	4.14				4.33	0.26	0.06	6.00
HCT (%)	48.6	48.9	49.1	47.7	49.3	47.4	47.4				48.34	0.82	0.02	1.70
MCV (fL)	114.7	114.9	114.9	114.0	114.0	114.0	114.7				114.46	0.44	0.00	0.38
MCH (pg)	36.5	36.1	36.9	36.7	36.4	37.4	36.9				36.70	0.42	0.01	1.15
MCHC (g/dL)	31.8	31.4	32.1	32.2	32.0	32.4	32.2				32.01	0.33	0.01	1.03
RDW-CV (%)	14.8	15.1	15.1	15.1	14.8	15.1	14.8				14.97	0.16	0.01	1.07
RDW-SD (fL)	61.3	63.1	63.1	59.5	61.1	62.1	63.1				61.90	1.36	0.02	2.20
PLT ($10^3/\mu\text{L}$)	207	219	209	214	221	212	202				212.00	6.68	0.03	3.15
MPV (fL)	9.6	9.7	9.6	9.8	9.6	9.7	9.7				9.67	0.08	0.01	0.78
PDW	16.0	16.0	15.8	15.9	15.8	15.8	15.9				15.89	0.09	0.01	0.57
PCT (%)	0.198	0.212	0.2	0.209	0.212	0.205	0.195				0.20	0.01	0.03	3.38

Conclusions

1. The VDX Mindray 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.978 to 0.998** displaying the highest degree of correlation between the reagents.
3. The VDX Mindray and the Mindray Reference 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all the parameters.
4. The CV % with the VDX Mindray Reagents and the Mindray Reference Reagents were found to be as under:

Parameters	Mindray Reference Reagents (CV % - Precision)	VDx Mindray Reagents (CV % - Precision)
Measured Parameters	0.38% – 6.00%	0.24% - 3.62%
Calculated Parameters	0.57% - 9.28%	0.96% - 6.98%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges both for VDX Mindray 3 Part Hematology Reagents and Mindray Reference reagents
6. **The VDX Mindray 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Mindray Reference Reagents for all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	72 - 73
2	Background Test	74
3	Coefficient of Correlation: Accuracy	75 – 96
4	Quality Control (Low, Normal & High)	97 - 101
5	Coefficient of Variation: Precision (VDx Genius Compatible Reagents)	102
6	Coefficient of Variation: Precision (Genius Reference Reagents)	103
7	Conclusions	104

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Genrui - SB22+
Reference Reagents	Genius Reference Reagents
KT03 Diluent	Lot No : 20221103 Expiry Date : 02-10-2024
KT03 Lyse Solution	Lot No : 20221102 Expiry Date : 01-09-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Genius Compatible Reagents)
5	Coefficient of Variation: Precision (Genius Reference Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent - G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	0.00	0.00
Lym# (10 ⁹ /L)	0.00	0.00
Mid# (10 ⁹ /L)	0.00	0.00
Gran# (10 ⁹ /L)	0.00	0.00
Lym (%)	0.00	0.00
Mid (%)	0.00	0.00
Gran (%)	0.00	0.00
NLR	0.00	0.00
PLR	0.00	0.00
RBC (10 ¹² /L)	0.00	0.00
HGB (g/dL)	0.00	0.00
HCT (%)	0.00	0.00
MCV (fL)	0.00	0.00
MCH (pg)	0.00	0.00
MCHC (g/dL)	0.00	0.00
RDW-CV (%)	0.00	0.00
RDW-SD (fL)	0.00	0.00
PLT (10 ⁹ /L)	0.00	0.00
MPV (fL)	0.00	0.00
PDW-CV (%)	0.00	0.00
PDW-SD (fL)	0.00	0.00
PCT (%)	0.00	0.00
P-LCC (10 ⁹ /L)	0.00	0.00
P-LCR (%)	0.00	0.00

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Genius Reagents and the Genius Reference Reagents.
- II. The Coefficient of Correlation (“r”) was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of “r”
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When “r” is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Genius Reference Reagents for Genius SB22+, 3 Part Hematology Analyzer.

y = VDX Genius Reagents for Genius SB22+, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 15

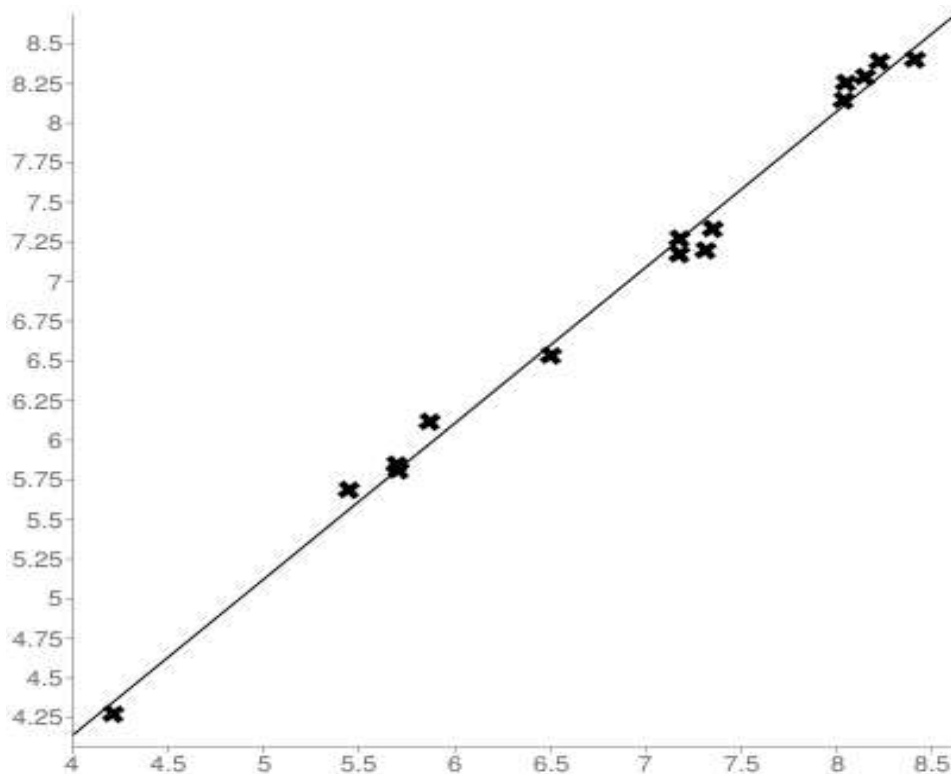
Mean x (x): 6.88733333333333

Mean y (y): 6.97933333333333

Intercept (a): 0.20174969262643

Slope (b): 0.98406499477886

Regression line equation: $y=0.20174969262643+0.98406499477886x$



Coefficient of Correlation (“r”): RBC

x = Genius Reference Reagents for Genius SB22+, 3 Part Hematology Analyzer.

y = VDX Genius Reagents for Genius SB22+, 3 Part Hematology Analyzer.

$$“r” = 0.990$$

Sample size: 15

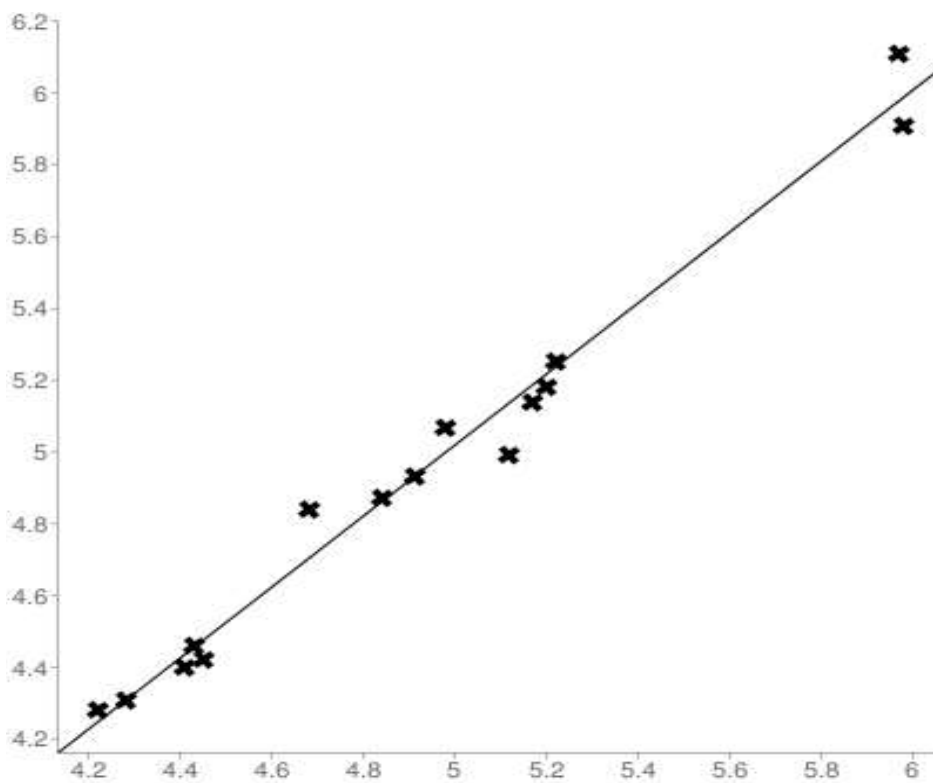
Mean x (x̄): 4.924

Mean y (ȳ): 4.944

Intercept (a): 0.079768133117882

Slope (b): 0.98786187385908

Regression line equation: $y = 0.079768133117882 + 0.98786187385908x$



Coefficient of Correlation (“r”): Hemoglobin

x = Genius Reference Reagents for Genius SB22+, 3 Part Hematology Analyzer.

y = VDX Genius Reagents for Genius SB22+, 3 Part Hematology Analyzer.

“r” = 0.991

Sample size: 15

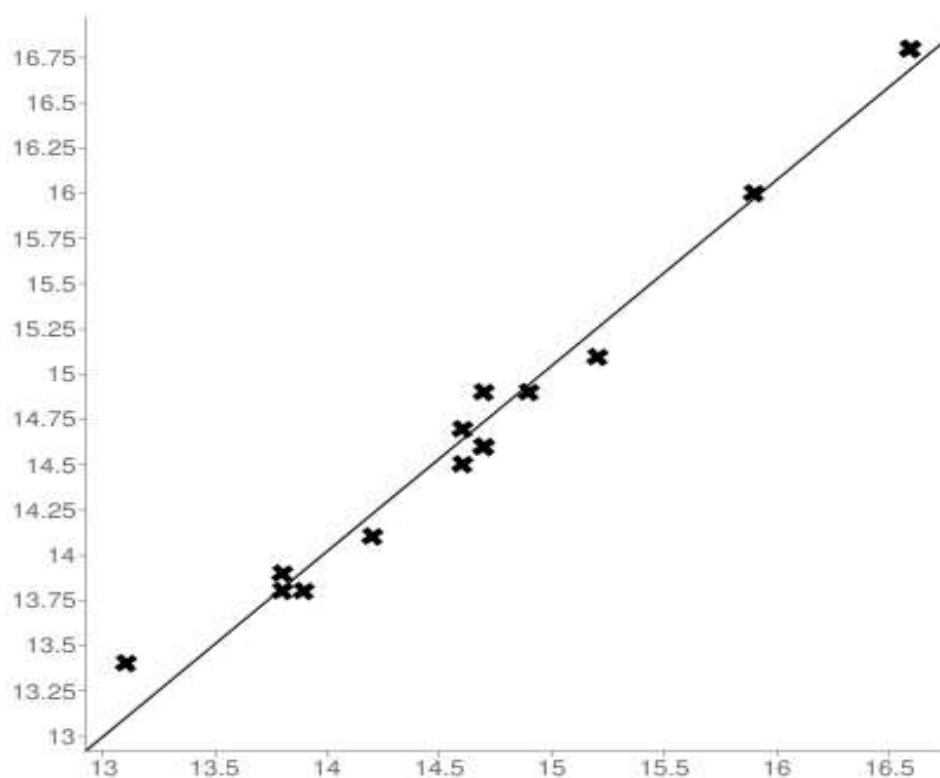
Mean x (x̄): 14.753333333333

Mean y (ȳ): 14.793333333333

Intercept (a): -0.33733568298641

Slope (b): 1.0255763002476

Regression line equation: $y = 1.0255763002476x - 0.33733568298641$



Coefficient of Correlation (“r”): Platelets

x = Genius Reference Reagents for Genius SB22+, 3 Part Hematology Analyzer.
y = VDX Genius Reagents for Genius SB22+, 3 Part Hematology Analyzer.

$$“r” = 0.993$$

Sample size: 15

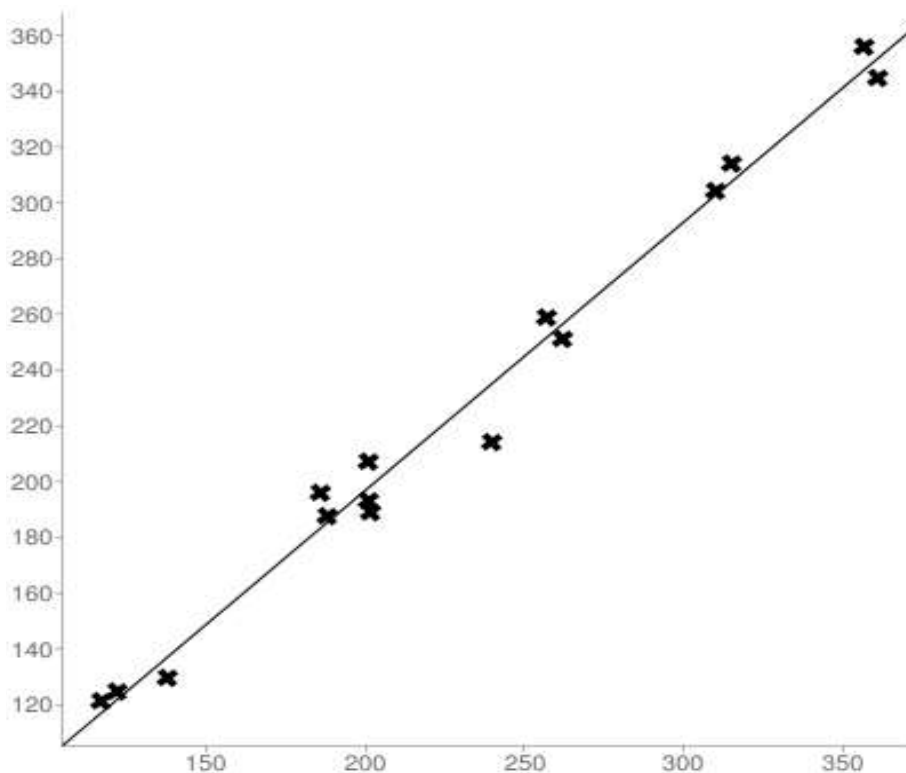
Mean x (x̄): 230.46666666667

Mean y (ȳ): 226.13333333333

Intercept (a): 4.5194251474097

Slope (b): 0.96158768376883

Regression line equation: $y = 4.5194251474097 + 0.96158768376883x$



Coefficient of Correlation (“r”): MCV

x = Genius Reference Reagents for Genius SB22+, 3 Part Hematology Analyzer.
y = VDX Genius Reagents for Genius SB22+, 3 Part Hematology Analyzer.

$$“r” = 0.999$$

Sample size: 15

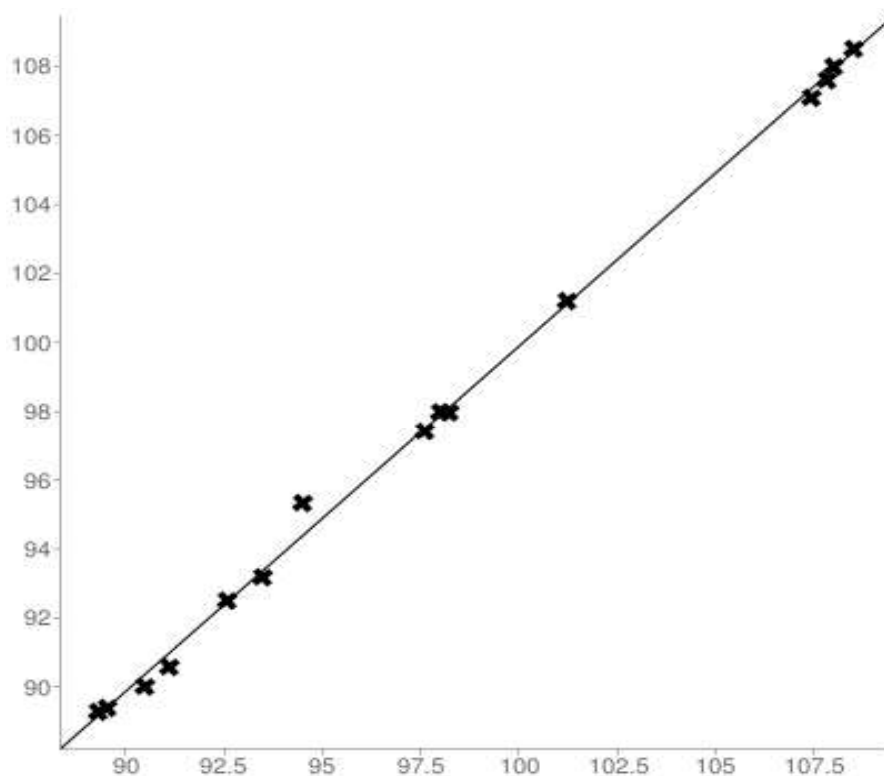
Mean x ($\bar{x}$): 97.846666666667

Mean y ($\bar{y}$): 97.74

Intercept (a): -0.40021683919771

Slope (b): 1.003000103964

Regression line equation: $y = 1.003000103964x - 0.40021683919771$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	8.39	8.22
Lym# (10 ⁹ /L)	1.27	1.27
Mid# (10 ⁹ /L)	0.73	0.86
Gran# (10 ⁹ /L)	6.39	6.09
Lym (%)	15.10	15.40
Mid (%)	8.70	10.50
Gran (%)	76.20	74.10
NLR	5.03	4.80
PLR	98.43	96.06
RBC (10 ¹² /L)	5.07	4.98
HGB (g/dL)	15.10	14.70
HCT (%)	49.70	48.80
MCV (fL)	98.00	98.20
MCH (pg)	29.70	29.60
MCHC (g/dL)	30.30	30.20
RDW-CV (%)	14.30	14.30
RDW-SD (fL)	51.50	51.50
PLT (10 ⁹ /L)	125.00	122.00
MPV (fL)	15.60	15.50
PDW-CV (%)	15.00	15.60
PDW-SD (fL)	30.00	30.70
PCT (%)	0.20	0.19
P-LCC (10 ⁹ /L)	80.00	78.00
P-LCR (%)	64.20	63.50

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	8.40	8.41
Lym# (10 ⁹ /L)	1.15	1.24
Mid# (10 ⁹ /L)	0.43	1.03
Gran# (10 ⁹ /L)	6.82	6.14
Lym (%)	13.70	14.80
Mid (%)	5.10	12.30
Gran (%)	81.20	72.90
NLR	5.93	4.95
PLR	105.22	94.35
RBC (10 ¹² /L)	4.99	5.12
HGB (g/dL)	15.10	15.20
HCT (%)	48.90	50.20
MCV (fL)	98.00	98.00
MCH (pg)	30.20	29.60
MCHC (g/dL)	30.80	30.20
RDW-CV (%)	14.10	14.30
RDW-SD (fL)	50.70	51.60
PLT (10 ⁹ /L)	121.00	117.00
MPV (fL)	15.10	15.40
PDW-CV (%)	15.70	15.20
PDW-SD (fL)	30.40	29.80
PCT (%)	0.18	0.18
P-LCC (10 ⁹ /L)	75.00	74.00
P-LCR (%)	61.70	63.50

Sample - 3		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	8.29	8.15
Lym# (10 ⁹ /L)	1.17	1.16
Mid# (10 ⁹ /L)	0.70	0.92
Gran# (10 ⁹ /L)	6.42	6.07
Lym (%)	14.10	14.20
Mid (%)	8.40	11.30
Gran (%)	77.50	74.50
NLR	5.49	5.23
PLR	294.87	311.21
RBC (10 ¹² /L)	5.91	5.98
HGB (g/dL)	16.80	16.60
HCT (%)	52.80	53.40
MCV (fL)	89.30	89.30
MCH (pg)	28.30	27.80
MCHC (g/dL)	31.70	31.10
RDW-CV (%)	14.00	14.20
RDW-SD (fL)	45.40	45.40
PLT (10 ⁹ /L)	345.00	361.00
MPV (fL)	12.30	12.70
PDW-CV (%)	14.20	14.90
PDW-SD (fL)	19.60	21.40
PCT (%)	0.43	0.46
P-LCC (10 ⁹ /L)	157.00	169.00
P-LCR (%)	45.50	46.90

Sample - 4		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	6.53	6.50
Lym# (10 ⁹ /L)	1.68	1.62
Mid# (10 ⁹ /L)	0.53	0.55
Gran# (10 ⁹ /L)	4.32	4.33
Lym (%)	25.70	24.90
Mid (%)	8.10	8.50
Gran (%)	66.20	66.60
NLR	2.57	2.67
PLR	154.17	158.64
RBC (10 ¹² /L)	4.31	4.28
HGB (g/dL)	13.90	13.80
HCT (%)	43.60	43.30
MCV (fL)	101.20	101.20
MCH (pg)	32.20	32.30
MCHC (g/dL)	31.80	32.00
RDW-CV (%)	14.60	14.60
RDW-SD (fL)	54.50	54.60
PLT (10 ⁹ /L)	259.00	257.00
MPV (fL)	11.50	11.70
PDW-CV (%)	14.90	14.80
PDW-SD (fL)	19.10	19.50
PCT (%)	0.30	0.30
P-LCC (10 ⁹ /L)	104.00	110.00
P-LCR (%)	40.00	42.80

Sample - 5		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot : HD1G221117 VDx Lyse-G Lot : HLYG220911	All Reagents: Genius as Reference Diluent Lot : 20221103 Lyse Lot : 20221102
WBC (10 ⁹ /L)	4.27	4.21
Lym# (10 ⁹ /L)	0.92	1.16
Mid# (10 ⁹ /L)	0.54	0.51
Gran# (10 ⁹ /L)	2.81	2.54
Lym (%)	21.60	27.50
Mid (%)	12.60	12.00
Gran (%)	65.80	60.50
NLR	3.05	2.19
PLR	225.00	173.28
RBC (10 ¹² /L)	4.93	4.91
HGB (g/dL)	13.80	13.80
HCT (%)	45.60	45.50
MCV (fL)	92.50	92.60
MCH (pg)	28.10	28.10
MCHC (g/dL)	30.30	30.40
RDW-CV (%)	14.20	14.20
RDW-SD (fL)	48.00	47.90
PLT (10 ⁹ /L)	207.00	201.00
MPV (fL)	15.10	15.30
PDW-CV (%)	15.30	15.60
PDW-SD (fL)	29.40	30.20
PCT (%)	0.31	0.31
P-LCC (10 ⁹ /L)	130.00	127.00
P-LCR (%)	62.90	63.10

Sample - 6		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	8.25	8.05
Lym# (10 ⁹ /L)	1.17	1.18
Mid# (10 ⁹ /L)	0.68	0.78
Gran# (10 ⁹ /L)	6.40	6.09
Lym (%)	14.20	14.70
Mid (%)	8.20	9.70
Gran (%)	77.60	75.60
NLR	5.47	5.16
PLR	304.27	302.54
RBC (10 ¹² /L)	6.11	5.97
HGB (g/dL)	16.80	16.60
HCT (%)	54.60	53.40
MCV (fL)	89.40	89.50
MCH (pg)	27.60	27.80
MCHC (g/dL)	30.80	31.10
RDW-CV (%)	14.40	13.80
RDW-SD (fL)	46.30	44.40
PLT (10 ⁹ /L)	356.00	357.00
MPV (fL)	12.40	12.60
PDW-CV (%)	14.90	14.80
PDW-SD (fL)	21.30	21.60
PCT (%)	0.44	0.45
P-LCC (10 ⁹ /L)	164.00	171.00
P-LCR (%)	46.10	47.90

Sample - 7		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	5.81	5.71
Lym# (10 ⁹ /L)	1.17	1.22
Mid# (10 ⁹ /L)	0.64	0.58
Gran# (10 ⁹ /L)	4.00	3.91
Lym (%)	20.20	21.40
Mid (%)	11.00	10.20
Gran (%)	68.80	68.40
NLR	3.42	3.20
PLR	268.38	258.20
RBC (10 ¹² /L)	4.87	4.84
HGB (g/dL)	14.10	14.20
HCT (%)	45.90	45.70
MCV (fL)	94.30	94.50
MCH (pg)	28.90	29.40
MCHC (g/dL)	30.70	31.10
RDW-CV (%)	13.80	13.60
RDW-SD (fL)	47.60	47.00
PLT (10 ⁹ /L)	314.00	315.00
MPV (fL)	11.90	12.30
PDW-CV (%)	13.90	14.10
PDW-SD (fL)	19.00	20.00
PCT (%)	0.37	0.39
P-LCC (10 ⁹ /L)	137.00	147.00
P-LCR (%)	43.50	46.80

Sample - 8		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	7.27	7.17
Lym# (10 ⁹ /L)	1.38	1.63
Mid# (10 ⁹ /L)	0.81	0.69
Gran# (10 ⁹ /L)	5.08	4.85
Lym (%)	19.00	22.80
Mid (%)	11.20	9.60
Gran (%)	69.80	67.60
NLR	3.68	2.98
PLR	139.86	123.31
RBC (10 ¹² /L)	5.18	5.20
HGB (g/dL)	14.70	14.60
HCT (%)	47.00	47.40
MCV (fL)	90.60	91.10
MCH (pg)	28.40	28.10
MCHC (g/dL)	31.40	30.90
RDW-CV (%)	15.10	14.90
RDW-SD (fL)	49.70	49.40
PLT (10 ⁹ /L)	193.00	201.00
MPV (fL)	14.60	14.40
PDW-CV (%)	14.40	15.00
PDW-SD (fL)	26.70	27.60
PCT (%)	0.28	0.29
P-LCC (10 ⁹ /L)	116.00	121.00
P-LCR (%)	60.10	60.10

Sample - 9		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	7.17	7.18
Lym# (10 ⁹ /L)	1.71	1.76
Mid# (10 ⁹ /L)	0.75	0.72
Gran# (10 ⁹ /L)	4.71	4.70
Lym (%)	23.90	24.50
Mid (%)	10.40	10.00
Gran (%)	65.70	65.50
NLR	2.75	2.67
PLR	76.02	78.41
RBC (10 ¹² /L)	5.14	5.17
HGB (g/dL)	13.80	13.90
HCT (%)	46.30	46.80
MCV (fL)	90.00	90.50
MCH (pg)	26.90	26.80
MCHC (g/dL)	29.90	29.70
RDW-CV (%)	15.00	15.20
RDW-SD (fL)	49.00	50.10
PLT (10 ⁹ /L)	130.00	138.00
MPV (fL)	15.90	15.60
PDW-CV (%)	15.10	15.40
PDW-SD (fL)	30.50	30.60
PCT (%)	0.21	0.22
P-LCC (10 ⁹ /L)	86.00	89.00
P-LCR (%)	66.10	64.50

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	5.84	5.69
Lym# (10 ⁹ /L)	1.26	1.32
Mid# (10 ⁹ /L)	0.68	0.73
Gran# (10 ⁹ /L)	3.90	3.64
Lym (%)	21.50	23.20
Mid (%)	11.60	12.80
Gran (%)	66.90	64.00
NLR	3.10	2.76
PLR	155.56	140.91
RBC (10 ¹² /L)	4.84	4.68
HGB (g/dL)	13.70	13.10
HCT (%)	45.10	43.80
MCV (fL)	93.20	93.50
MCH (pg)	28.40	28.10
MCHC (g/dL)	30.40	30.00
RDW-CV (%)	13.70	13.40
RDW-SD (fL)	46.80	45.80
PLT (10 ⁹ /L)	196.00	186.00
MPV (fL)	14.70	14.50
PDW-CV (%)	15.10	15.40
PDW-SD (fL)	28.40	28.40
PCT (%)	0.29	0.27
P-LCC (10 ⁹ /L)	116.00	114.00
P-LCR (%)	59.50	61.40

Sample - 11		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	7.20	7.31
Lym# (10 ⁹ /L)	1.18	1.22
Mid# (10 ⁹ /L)	0.68	0.90
Gran# (10 ⁹ /L)	5.34	5.19
Lym (%)	16.40	16.70
Mid (%)	9.50	12.30
Gran (%)	74.10	71.00
NLR	4.53	4.25
PLR	181.36	196.72
RBC (10 ¹² /L)	4.28	4.22
HGB (g/dL)	14.60	14.70
HCT (%)	46.50	45.80
MCV (fL)	108.50	108.50
MCH (pg)	34.20	34.80
MCHC (g/dL)	31.50	32.10
RDW-CV (%)	15.10	15.20
RDW-SD (fL)	60.80	61.30
PLT (10 ⁹ /L)	214.00	240.00
MPV (fL)	12.90	13.00
PDW-CV (%)	15.70	15.80
PDW-SD (fL)	24.40	24.60
PCT (%)	0.28	0.31
P-LCC (10 ⁹ /L)	108.00	123.00
P-LCR (%)	50.30	51.00

Sample - 12		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	5.69	5.45
Lym# (10 ⁹ /L)	1.49	1.50
Mid# (10 ⁹ /L)	0.46	0.63
Gran# (10 ⁹ /L)	3.74	3.32
Lym (%)	26.20	27.50
Mid (%)	8.10	11.60
Gran (%)	65.70	60.90
NLR	2.51	2.21
PLR	126.85	134.67
RBC (10 ¹² /L)	4.42	4.45
HGB (g/dL)	14.90	14.70
HCT (%)	47.70	48.00
MCV (fL)	108.00	108.00
MCH (pg)	33.80	33.00
MCHC (g/dL)	31.20	30.60
RDW-CV (%)	14.80	14.60
RDW-SD (fL)	59.50	58.60
PLT (10 ⁹ /L)	189.00	202.00
MPV (fL)	14.20	13.90
PDW-CV (%)	16.20	16.30
PDW-SD (fL)	29.30	29.00
PCT (%)	0.27	0.28
P-LCC (10 ⁹ /L)	107.00	113.00
P-LCR (%)	56.50	56.20

Sample - 13		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	7.33	7.35
Lym# (10 ⁹ /L)	2.10	2.48
Mid# (10 ⁹ /L)	0.86	0.79
Gran# (10 ⁹ /L)	4.37	4.08
Lym (%)	28.60	33.80
Mid (%)	11.70	10.80
Gran (%)	59.70	55.40
NLR	2.08	1.65
PLR	144.76	125.00
RBC (10 ¹² /L)	4.40	4.41
HGB (g/dL)	14.90	14.90
HCT (%)	47.30	47.60
MCV (fL)	107.60	107.80
MCH (pg)	33.90	33.80
MCHC (g/dL)	31.50	31.40
RDW-CV (%)	13.50	13.20
RDW-SD (fL)	54.00	52.90
PLT (10 ⁹ /L)	304.00	310.00
MPV (fL)	12.00	12.20
PDW-CV (%)	14.60	15.40
PDW-SD (fL)	19.50	21.70
PCT (%)	0.37	0.38
P-LCC (10 ⁹ /L)	130.00	140.00
P-LCR (%)	42.80	45.20

Sample - 14		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	8.14	8.04
Lym# (10 ⁹ /L)	1.98	2.39
Mid# (10 ⁹ /L)	0.79	0.89
Gran# (10 ⁹ /L)	5.37	4.76
Lym (%)	24.30	29.70
Mid (%)	9.70	11.10
Gran (%)	66.00	59.20
NLR	2.71	1.99
PLR	126.77	109.62
RBC (10 ¹² /L)	5.25	5.22
HGB (g/dL)	16.00	15.90
HCT (%)	51.10	51.00
MCV (fL)	97.40	97.60
MCH (pg)	30.60	30.40
MCHC (g/dL)	31.40	31.10
RDW-CV (%)	14.20	14.10
RDW-SD (fL)	50.70	50.30
PLT (10 ⁹ /L)	251.00	262.00
MPV (fL)	14.90	15.10
PDW-CV (%)	14.70	14.60
PDW-SD (fL)	28.00	28.40
PCT (%)	0.37	0.40
P-LCC (10 ⁹ /L)	156.00	168.00
P-LCR (%)	62.40	64.20

Sample - 15		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot - HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot - 20221103 Lyse Lot - 20221102
WBC (10 ⁹ /L)	6.11	5.87
Lym# (10 ⁹ /L)	1.81	1.95
Mid# (10 ⁹ /L)	0.68	0.57
Gran# (10 ⁹ /L)	3.62	3.35
Lym (%)	29.60	33.20
Mid (%)	11.10	9.70
Gran (%)	59.30	57.10
NLR	2.00	1.72
PLR	103.87	96.41
RBC (10 ¹² /L)	4.46	4.43
HGB (g/dL)	14.50	14.60
HCT (%)	47.70	47.60
MCV (fL)	107.10	107.40
MCH (pg)	32.50	33.00
MCHC (g/dL)	30.40	30.70
RDW-CV (%)	15.00	14.80
RDW-SD (fL)	59.80	58.80
PLT (10 ⁹ /L)	188.00	188.00
MPV (fL)	14.00	14.20
PDW-CV (%)	15.90	16.30
PDW-SD (fL)	28.50	29.50
PCT (%)	0.26	0.27
P-LCC (10 ⁹ /L)	106.00	108.00
P-LCR (%)	56.30	57.50

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D

(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 ⁹ /L)	1.92	1.95	1.5 - 2.5
Lym# (10 ⁹ /L)	0.83	0.70	0.6 - 1.2
Mid# (10 ⁹ /L)	0.12	0.13	0.0 - 0.2
Gran# (10 ⁹ /L)	0.97	1.12	0.6 - 1.4
Lym (%)	43.30	35.80	32.7 - 54.5
Mid (%)	6.10	6.60	0.4 - 13.0
Gran (%)	50.60	57.60	32.3 - 67.1
NLR	1.17	1.60	
PLR	93.98	112.86	
RBC (10 ¹² /L)	2.47	2.47	2.29 - 2.69
HGB (g/dL)	6.70	6.70	6.3 - 7.3
HCT (%)	21.30	21.50	18.9 - 24.9
MCV (fL)	86.30	86.80	81.9 - 93.9
MCH (pg)	27.30	27.20	23.6 - 31.2
MCHC (g/dL)	31.60	31.40	26.4 - 36.0
RDW-CV (%)	16.50	17.20	11.3 - 21.3
RDW-SD (fL)	52.20	54.50	42.4 - 62.4
PLT (10 ⁹ /L)	78.00	79.00	53 – 103
MPV (fL)	11.60	11.60	8.1 - 14.1
PDW-CV (%)	7.20	7.70	5.2 - 11.2
PDW-SD (fL)	10.40	11.20	
PCT (%)	0.09	0.09	0.036 - 0.136
P-LCC (10 ⁹ /L)	35.00	36.00	
P-LCR (%)	44.80	46.30	

Diagon D Check D

(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 ⁹ /L)	6.87	6.91	5.9 - 7.9
Lym# (10 ⁹ /L)	1.88	1.91	1.2 - 2.6
Mid# (10 ⁹ /L)	0.58	0.61	0.1 - 1.1
Gran# (10 ⁹ /L)	4.41	4.39	3.7 - 5.1
Lym (%)	27.30	27.60	18.0 - 37.4
Mid (%)	8.50	8.80	1.8 - 16.2
Gran (%)	64.20	63.60	50.6 - 76.0
NLR	2.35	2.30	
PLR	122.34	117.80	
RBC (10 ¹² /L)	4.53	4.57	4.28 - 4.88
HGB (g/dL)	13.20	13.30	12.7 - 13.9
HCT (%)	42.00	42.40	39.1 - 47.1
MCV (fL)	92.70	92.70	88.1 - 100.1
MCH (pg)	29.00	29.10	25.3 - 32.9
MCHC (g/dL)	31.30	31.40	26.1 - 35.7
RDW-CV (%)	17.50	17.50	12.1 - 22.1
RDW-SD (fL)	59.50	59.40	49.0 - 69.0
PLT (10 ⁹ /L)	230.00	225.00	184 - 274
MPV (fL)	12.00	11.80	8.3 - 14.3
PDW-CV (%)	7.70	7.50	5.7 - 11.7
PDW-SD (fL)	11.10	10.70	
PCT (%)	0.28	0.27	0.160 - 0.360
P-LCC (10 ⁹ /L)	110.00	104.00	
P-LCR (%)	47.80	46.20	

Diagon D Check D

(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 ⁹ /L)	17.80	17.87	15.3 - 20.3
Lym# (10 ⁹ /L)	3.81	3.86	1.7 - 6.1
Mid# (10 ⁹ /L)	1.66	1.72	0.4 - 3.0
Gran# (10 ⁹ /L)	12.33	12.29	8.5 - 15.9
Lym (%)	21.40	21.60	14.4 - 29.8
Mid (%)	9.30	9.60	1.9 - 17.1
Gran (%)	69.30	68.80	58.1 - 78.7
NLR	3.24	3.18	
PLR	125.72	120.47	
RBC (10 ¹² /L)	5.68	5.69	5.25 - 6.05
HGB (g/dL)	17.00	17.20	16.7 - 18.3
HCT (%)	56.70	56.60	52.2 - 61.2
MCV (fL)	99.80	99.50	94.4 - 106.4
MCH (pg)	30.00	30.30	27.1 - 34.7
MCHC (g/dL)	30.10	30.40	26.0 - 35.6
RDW-CV (%)	17.20	17.40	12.1 - 22.1
RDW-SD (fL)	62.80	63.40	52.9 - 72.9
PLT (10 ⁹ /L)	479.00	465.00	401 - 551
MPV (fL)	12.20	12.30	8.7 - 14.7
PDW-CV (%)	7.80	7.60	6.0 - 12.0
PDW-SD (fL)	11.60	11.20	
PCT (%)	0.585	0.570	0.359 - 0.759
P-LCC (10 ⁹ /L)	244.00	231.00	
P-LCR (%)	50.80	49.70	

ASSAY VALUES AND EXPECTED RANGES

LOT: 1V0901
05-03-2023

Instruments:		Genrui KT-6400, KT-63xx, KT-6200 version 2.85 or higher					
		Council-23 Ultra					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,0 ± 0,5	1,5 - 2,5	6,9 ± 1,0	5,9 - 7,9	17,8 ± 2,5	15,3 - 20,3
LYM%	%	43,6 ± 10,9	32,7 - 54,5	27,7 ± 9,7	18,0 - 37,4	22,1 ± 7,7	14,4 - 29,8
MID%	%	6,7 ± 6,3	0,4 - 13,0	9,0 ± 7,2	1,8 - 16,2	9,5 ± 7,6	1,9 - 17,1
NEUT%	%	49,7 ± 17,4	32,3 - 67,1	63,3 ± 12,7	50,6 - 76,0	68,4 ± 10,3	58,1 - 78,7
LYM#	10 ⁹ /L	0,9 ± 0,3	0,6 - 1,2	1,9 ± 0,7	1,2 - 2,6	3,9 ± 2,2	1,7 - 6,1
MID#	10 ⁹ /L	0,1 ± 0,1	0,0 - 0,2	0,6 ± 0,5	0,1 - 1,1	1,7 ± 1,3	0,4 - 3,0
NEUT#	10 ⁹ /L	1,0 ± 0,4	0,6 - 1,4	4,4 ± 0,7	3,7 - 5,1	12,2 ± 3,7	8,5 - 15,9
RBC	10 ¹² /L	2,49 ± 0,20	2,29 - 2,69	4,58 ± 0,30	4,28 - 4,88	5,65 ± 0,40	5,25 - 6,05
HGB	g/dL	6,8 ± 0,5	6,3 - 7,3	13,3 ± 0,6	12,7 - 13,9	17,5 ± 0,8	16,7 - 18,3
	g/L	68 ± 5	63 - 73	133 ± 6	127 - 139	175 ± 8	167 - 183
HCT	%	21,9 ± 3,0	18,9 - 24,9	43,1 ± 4,0	39,1 - 47,1	56,7 ± 4,5	52,2 - 61,2
	L/L	0,219 ± 0,030	0,189 - 0,249	0,431 ± 0,040	0,391 - 0,471	0,567 ± 0,045	0,522 - 0,612
MCV	fL	87,9 ± 6,0	81,9 - 93,9	94,1 ± 6,0	88,1 - 100,1	100,4 ± 6,0	94,4 - 106,4
MCH	pg	27,4 ± 3,8	23,6 - 31,2	29,1 ± 3,8	25,3 - 32,9	30,9 ± 3,8	27,1 - 34,7
MCHC	g/dL	31,2 ± 4,8	26,4 - 36,0	30,9 ± 4,8	26,1 - 35,7	30,8 ± 4,8	26,0 - 35,6
	g/L	312 ± 48	264 - 360	309 ± 48	261 - 357	308 ± 48	260 - 356
RDW-SD	fL	52,4 ± 10,0	42,4 - 62,4	59,0 ± 10,0	49,0 - 69,0	62,9 ± 10,0	52,9 - 72,9
RDW-CV	%	16,3 ± 5,0	11,3 - 21,3	17,1 ± 5,0	12,1 - 22,1	17,1 ± 5,0	12,1 - 22,1
Pit	10 ⁹ /L	78 ± 25	53 - 103	229 ± 45	184 - 274	476 ± 75	401 - 551
MPV	fL	11,1 ± 3,0	8,1 - 14,1	11,3 ± 3,0	8,3 - 14,3	11,7 ± 3,0	8,7 - 14,7
PDW	%	8,2 ± 3,0	5,2 - 11,2	8,7 ± 3,0	5,7 - 11,7	9,0 ± 3,0	6,0 - 12,0
PCT	%	0,086 ± 0,050	0,036 - 0,136	0,260 ± 0,100	0,160 - 0,360	0,559 ± 0,200	0,359 - 0,759


 DIAGON Ltd.
 48-52., Baross Str.
 Budapest, Hungary
 H-1047


Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Genius Reagents on Genius-SB22+, 3 Part Hematology Analyzer.
2. The sample was tested in 10 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 10

Precision Evaluation report of VDx Genius compatible reagent on Genius-SB22+, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^9/L$)	8.33	8.45	8.49	8.36	8.41	8.33	8.70	8.35	8.27	8.18	8.39	0.14	0.02	1.68
Lym# ($10^9/L$)	2.06	2.10	2.05	2.03	1.93	1.98	2.10	1.99	1.98	2.08	2.03	0.06	0.03	2.85
Mid# ($10^9/L$)	0.87	0.99	0.97	0.91	0.93	0.94	0.96	0.94	0.99	0.90	0.94	0.04	0.04	4.17
Gran# ($10^9/L$)	5.40	5.35	5.47	5.42	5.55	5.41	5.64	5.42	5.30	5.20	5.42	0.12	0.02	2.27
Lym (%)	24.70	24.80	24.20	24.30	22.90	23.80	24.10	23.80	24.00	25.40	24.20	0.68	0.03	2.80
Mid (%)	10.40	11.80	11.40	10.90	11.00	11.30	11.00	11.20	12.00	11.00	11.20	0.46	0.04	4.10
Gran (%)	64.90	63.40	64.40	64.80	66.10	64.90	64.90	65.00	64.00	63.60	64.60	0.79	0.01	1.22
RBC ($10^{12}/L$)	5.11	5.19	5.22	5.15	5.18	5.16	5.26	5.25	5.11	5.14	5.18	0.05	0.01	1.03
HGB (g/dL)	16.20	16.20	16.30	16.30	16.30	16.30	16.40	16.40	16.10	16.10	16.26	0.11	0.01	0.66
HCT (%)	49.80	50.60	51.10	50.20	50.50	50.50	51.40	51.40	50.00	50.20	50.57	0.56	0.01	1.11
MCV (fL)	97.40	97.60	97.90	97.60	97.50	97.70	97.80	97.90	97.90	97.80	97.71	0.18	0.00	0.18
MCH (pg)	31.60	31.20	31.20	31.60	31.50	31.60	31.20	31.10	31.50	31.30	31.38	0.20	0.01	0.63
MCHC (g/dL)	32.50	32.00	31.90	32.40	32.30	32.30	31.90	31.80	32.20	32.00	32.13	0.24	0.01	0.75
RDW-CV (%)	14.20	14.30	14.30	14.20	14.50	14.20	14.20	14.20	14.40	14.50	14.30	0.12	0.01	0.87
RDW-SD (fL)	50.60	50.90	51.10	50.70	51.80	50.70	50.80	50.90	51.60	51.90	51.10	0.49	0.01	0.95
PLT ($10^9/L$)	217.00	219.00	216.00	218.00	220.00	206.00	211.00	216.00	215.00	207.00	214.50	4.88	0.02	2.28
MPV (fL)	15.00	14.80	15.10	15.00	15.00	14.80	14.90	15.00	14.60	14.90	14.91	0.14	0.01	0.97
PDW-CV (%)	15.00	15.50	14.90	15.00	15.00	14.80	15.20	14.90	14.70	15.30	15.03	0.24	0.02	1.60
PDW-SD (fL)	28.70	29.40	28.50	28.60	28.90	28.10	28.80	28.40	27.60	29.10	28.61	0.51	0.02	1.78
PCT (%)	0.33	0.33	0.33	0.33	0.33	0.31	0.31	0.32	0.32	0.31	0.32	0.01	0.03	2.67
P-LCC ($10^9/L$)	136.00	136.00	139.00	137.00	139.00	129.00	129.00	136.00	131.00	127.00	133.90	4.46	0.03	3.33
P-LCR (%)	62.50	62.00	64.20	62.80	63.00	62.50	61.40	62.90	61.00	61.30	62.36	0.96	0.02	1.54

Coefficient of Variation:

Precision (Genius Reference Reagents)

1. Fresh blood sample was collected and tested with the Genius Reference Reagents on Genius SB22+, 3 Part Hematology Analyzer.
2. The sample was tested in 06 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 06

Precision Evaluation report of Genius Reference reagents on Genius-SB22+, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^9/L$)	6.57	6.75	6.69	6.63	6.83	6.73					6.70	0.09	0.01	1.37
Lym# ($10^9/L$)	1.78	1.81	1.81	1.92	1.95	1.76					1.84	0.08	0.04	4.23
Mid# ($10^9/L$)	0.88	0.90	0.94	0.82	0.86	0.95					0.89	0.05	0.06	5.51
Gran# ($10^9/L$)	4.01	4.04	3.94	3.89	4.02	4.02					3.99	0.06	0.01	1.47
Lym (%)	25.60	26.80	27.00	29.00	28.60	26.20					27.20	1.34	0.05	4.92
Mid (%)	13.40	13.40	14.10	12.40	12.60	14.10					13.33	0.72	0.05	5.40
Gran (%)	61.00	59.80	58.90	58.60	58.80	59.70					59.47	0.90	0.02	1.51
RBC ($10^{12}/L$)	5.06	5.11	5.11	5.08	5.17	5.13					5.11	0.04	0.01	0.75
HGB (g/dL)	13.70	13.90	13.80	13.90	14.10	13.90					13.88	0.13	0.01	0.96
HCT (%)	45.80	46.10	46.20	45.80	46.70	46.20					46.13	0.33	0.01	0.72
MCV (fL)	90.50	90.30	90.40	90.20	90.30	90.00					90.28	0.17	0.00	0.19
MCH (pg)	27.10	27.20	26.90	27.30	27.20	27.10					27.13	0.14	0.01	0.50
MCHC (g/dL)	30.00	30.10	29.80	30.30	30.10	30.10					30.07	0.16	0.01	0.54
RDW-CV (%)	15.20	15.30	15.00	15.10	15.10	15.00					15.12	0.12	0.01	0.77
RDW-SD (fL)	50.00	50.20	49.30	49.40	49.30	49.10					49.55	0.44	0.01	0.89
PLT ($10^9/L$)	141.00	140.00	138.00	139.00	151.00	141.00					141.67	4.72	0.03	3.33
MPV (fL)	14.80	15.00	14.70	14.40	15.10	14.90					14.82	0.25	0.02	1.68
PDW-CV (%)	15.70	15.90	15.70	16.60	15.50	15.80					15.87	0.38	0.02	2.41
PDW-SD (fL)	29.60	30.60	29.50	30.60	29.80	30.00					30.02	0.48	0.02	1.61
PCT (%)	0.21	0.21	0.20	0.20	0.21	0.21					0.21	0.00	0.02	2.36
P-LCC ($10^9/L$)	87.00	86.00	82.00	81.00	86.00	86.00					84.67	2.50	0.03	2.96
P-LCR (%)	61.60	61.50	60.00	58.20	63.60	60.90					60.97	1.80	0.03	2.95

Conclusions

1. The VDX Genius 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Genius original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.0.990 to 0.999** displaying the highest degree of correlation between the reagents.
3. The VDX Genius and the Genius Reference 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all the parameters.
4. The CV % with the VDX Genius reagents and the Genius Reference reagents were found to be as under:

Parameters	Genius Reference Reagents (CV % - Precision)	VDx Genius Reagents (CV % - Precision)
Measured Parameters	0.19% – 3.33%	0.18% - 2.28%
Calculated Parameters	0.50% - 5.51%	0.63% - 4.17%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges both for VDX Genius 3 Part Hematology Reagents and Genius Reference reagents
6. **The VDX Genius 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Genius Reference reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	107 – 108
2	Background Test	109
3	Coefficient of Correlation: Accuracy	110 – 126
4	Quality Control (Low, Normal & High)	127 - 131
5	Coefficient of Variation: Precision (VDx Nihon Kohden Compatible Reagents)	132
6	Coefficient of Variation: Precision (Nihon Kohden Reference Reagents)	133
7	Conclusions	134

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Nihon Kohden - Celltac α
Reference Reagents	Nihon Kohden Reference Reagents
Diluent	Lot No : 225422 Expiry Date : 02-2024
Hemolynac-3N	Lot No : 225354 Expiry Date : 01-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Nihon Kohden Compatible Reagents)
5	Coefficient of Variation: Precision (Nihon Kohden Reference Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac-3N Lot - 225354
WBC ($10^3/\mu\text{L}$)	0.0	0.0
RBC ($10^6/\mu\text{L}$)	0.0	0.0
HGB (g/dL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
PLT ($10^3/\mu\text{L}$)	0.0	0.0
Lym #	0.0	0.0
Mon#	0.0	0.0
Gran#	0.0	0.0
Lym%	0.0	0.0
Mon%	0.0	0.0
Gran%	0.0	0.0
RDW (%)	0.0	0.0
PCT (%)	0.0	0.0
MPV (fL)	0.0	0.0
PDW (%)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Nihon Kohden Reagents and the Reference Nihon Kohden Reagents.
- II. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

Sample size: 9

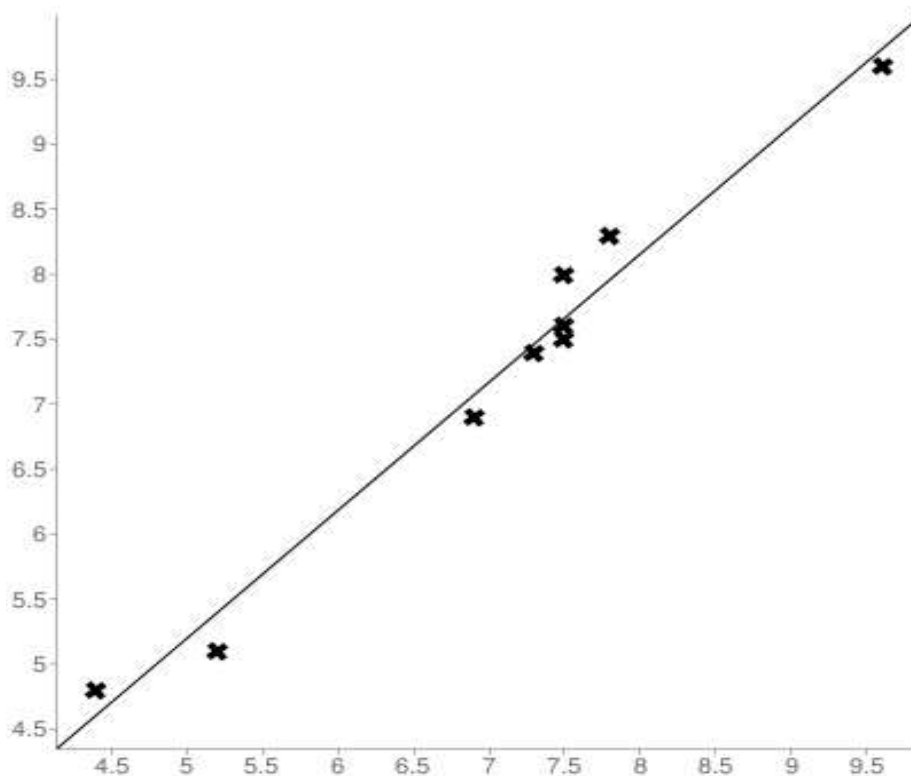
Mean x ($\bar{x}$): 7.0777777777778

Mean y ($\bar{y}$): 7.2444444444444

Intercept (a): 0.26261602344897

Slope (b): 0.98644357596482

Regression line equation: $y = 0.26261602344897 + 0.98644357596482x$



Coefficient of Correlation (“r”): RBC

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.

y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.993$$

Sample size: 9

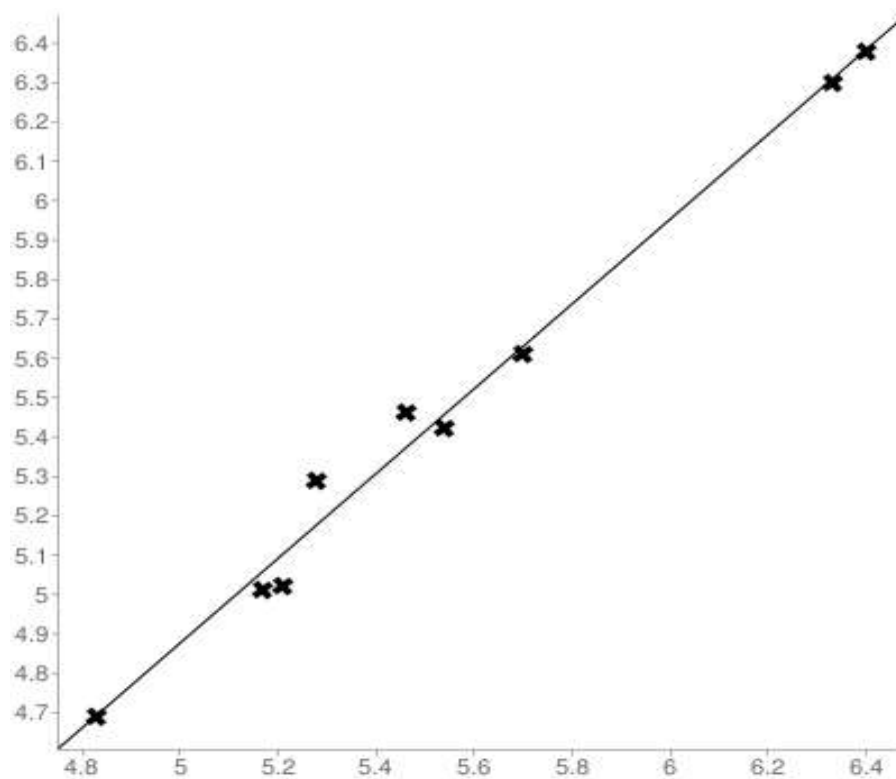
Mean x (x̄): 5.54666666666667

Mean y (ȳ): 5.46444444444444

Intercept (a): -0.50417128625391

Slope (b): 1.0760725476019

Regression line equation: $y = 1.0760725476019x - 0.50417128625391$



Coefficient of Correlation (“r”): Hemoglobin

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.

y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 9

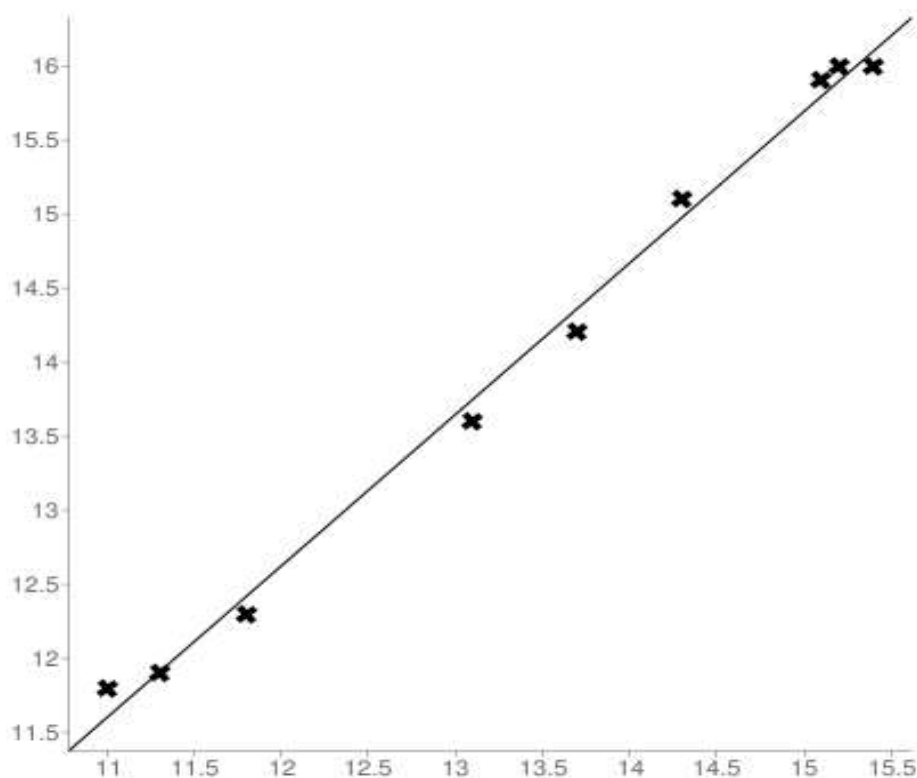
Mean x (x̄): 13.433333333333

Mean y (ȳ): 14.088888888889

Intercept (a): 0.34939876957523

Slope (b): 1.0227908277405

Regression line equation: $y = 0.34939876957523 + 1.0227908277405x$



Coefficient of Correlation (“r”): Platelets

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.993$$

Sample size: 9

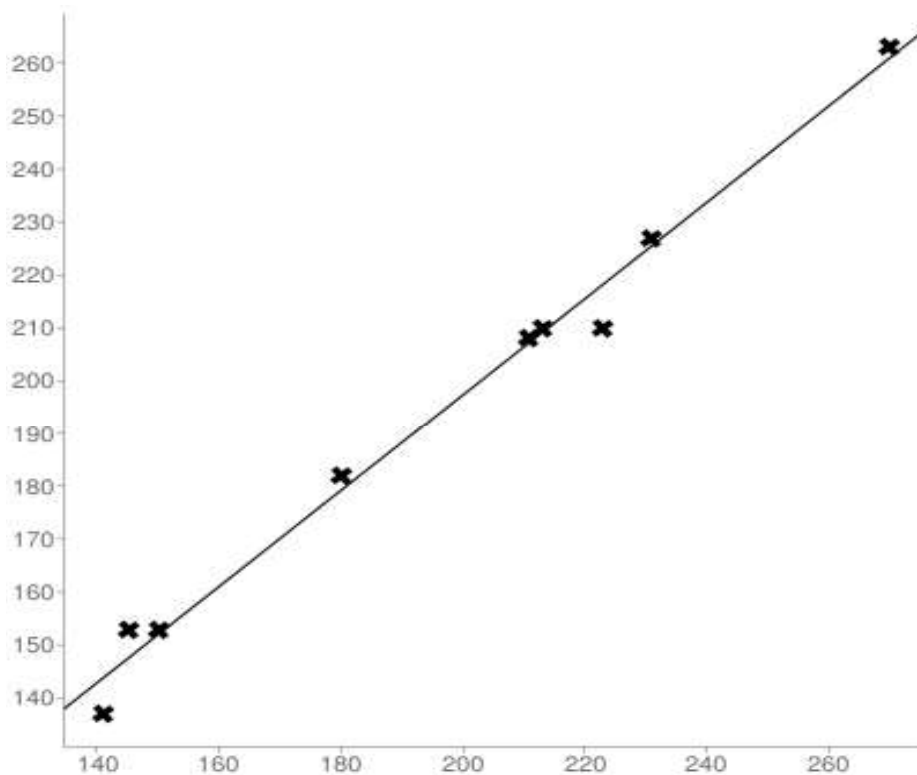
Mean x (x̄): 196

Mean y (ȳ): 193.66666666667

Intercept (a): 15.653619370217

Slope (b): 0.90822983314515

Regression line equation: $y = 15.653619370217 + 0.90822983314515x$



Coefficient of Correlation (“r”): MCV

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.998$$

Sample size: 9

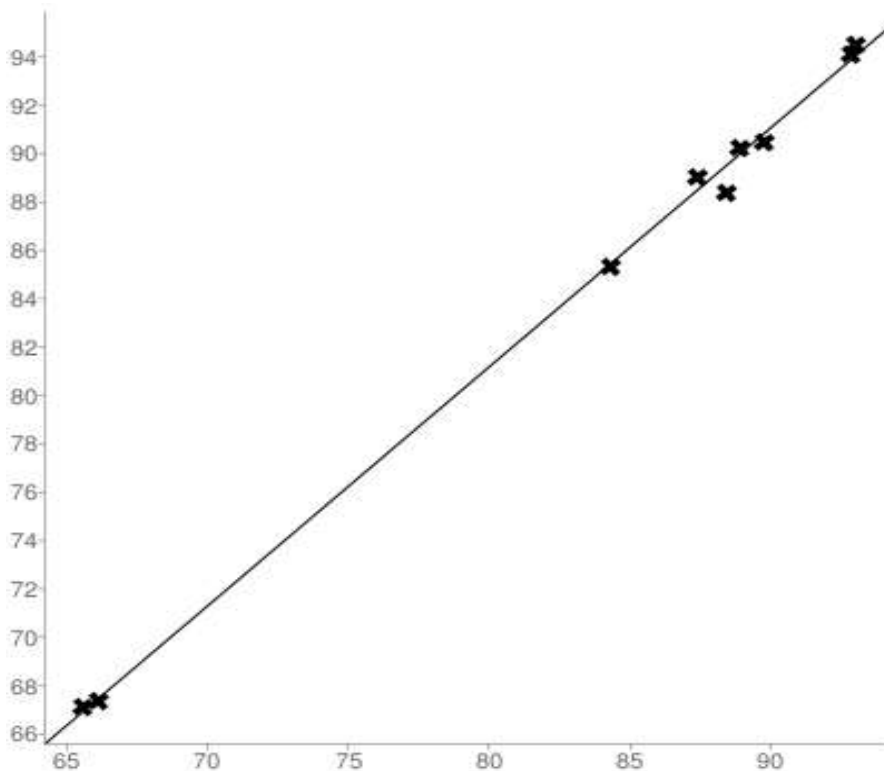
Mean x (x̄): 84.044444444444

Mean y (ȳ): 85.166666666667

Intercept (a): 2.1377009693544

Slope (b): 0.98791736022714

Regression line equation: $y = 2.1377009693544 + 0.98791736022714x$



Coefficient of Correlation (“r”): HCT

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.

y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

Sample size: 9

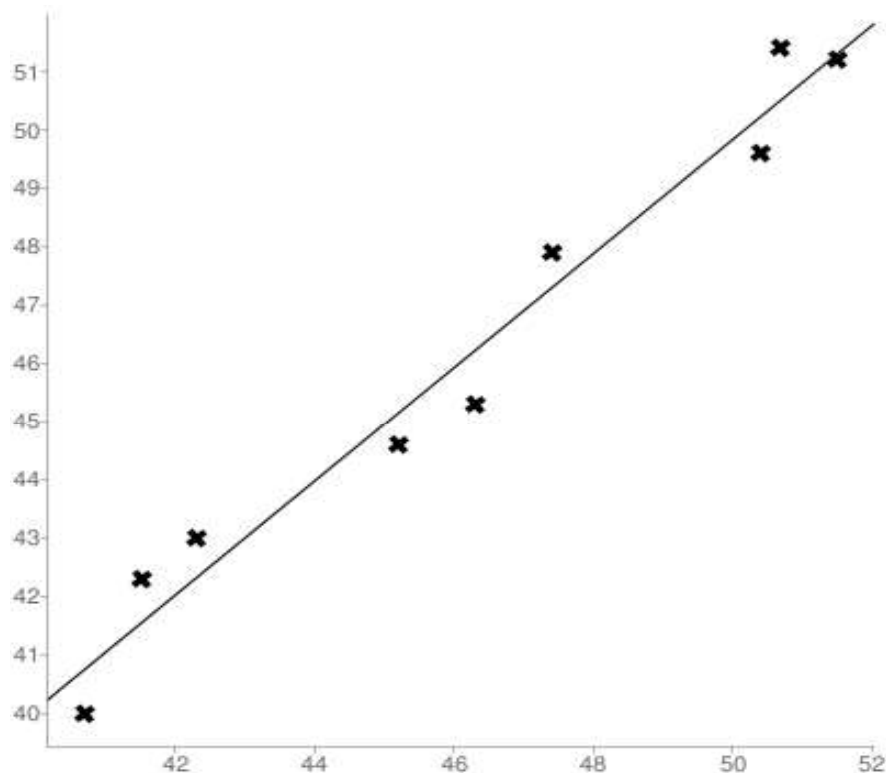
Mean x (x̄): 46.222222222222

Mean y (ȳ): 46.144444444444

Intercept (a): 1.052301884325

Slope (b): 0.97555116115643

Regression line equation: $y = 1.052301884325 + 0.97555116115643x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	8.0	7.5
RBC (10 ⁶ /μL)	5.46	5.46
HGB (g/dL)	15.9	15.1
HCT (%)	51.4	50.7
MCV (fL)	94.1	92.9
MCH (pg)	29.1	27.7
MCHC (g/dL)	30.9	29.8
PLT (10 ³ /μL)	137	141
Lym #	2.9	2.8
Mon#	0.3	0.4
Gran#	4.8	4.3
Lym%	36.0	36.9
Mon%	3.8	5.2
Gran%	60.2	57.9
RDW (%)	15.3	15.5
PCT (%)	0.25	0.22
MPV (fL)	18.3	15.7
PDW (%)	15.4	16.3

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac-3N Lot - 225354
WBC (10 ³ /μL)	8.3	7.8
RBC (10 ⁶ /μL)	5.42	5.54
HGB (g/dL)	16.0	15.4
HCT (%)	51.2	51.5
MCV (fL)	94.5	93.0
MCH (pg)	29.5	27.8
MCHC (g/dL)	31.3	29.9
PLT (10 ³ /μL)	153	150
Lym #	1.7	3.0
Mon#	0.4	0.4
Gran#	6.2	4.4
Lym%	20.0	38.1
Mon%	5.2	5.7
Gran%	74.8	56.2
RDW (%)	15.3	15.4
PCT (%)	0.26	0.26
MPV (fL)	17.2	17.5
PDW (%)	15.2	16.6

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	9.6	9.6
RBC (10 ⁶ /μL)	4.69	4.83
HGB (g/dL)	12.3	11.8
HCT (%)	40.0	40.7
MCV (fL)	85.3	84.3
MCH (pg)	26.2	24.4
MCHC (g/dL)	30.8	29.0
PLT (10 ³ /μL)	263	270
Lym #	4.2	3.9
Mon#	0.5	0.6
Gran#	4.9	5.1
Lym%	43.9	41.0
Mon%	4.7	6.0
Gran%	51.4	53.0
RDW (%)	15.8	15.4
PCT (%)	0.44	0.42
MPV (fL)	16.7	15.5
PDW (%)	17.0	16.8

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	5.1	5.2
RBC (10 ⁶ /μL)	5.02	5.21
HGB (g/dL)	14.2	13.7
HCT (%)	45.3	46.3
MCV (fL)	90.2	88.9
MCH (pg)	28.3	26.3
MCHC (g/dL)	31.3	29.6
PLT (10 ³ /μL)	182	180
Lym #	1.4	1.5
Mon#	0.2	0.3
Gran#	3.5	3.4
Lym%	26.9	29.3
Mon%	4.7	5.7
Gran%	68.4	65.0
RDW (%)	16.6	16.1
PCT (%)	0.33	0.30
MPV (fL)	17.9	16.5
PDW (%)	16.2	16.4

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac-3N Lot - 225354
WBC (10 ³ /μL)	4.8	4.4
RBC (10 ⁶ /μL)	5.01	5.17
HGB (g/dL)	13.6	13.1
HCT (%)	44.6	45.2
MCV (fL)	89.0	87.4
MCH (pg)	27.1	25.3
MCHC (g/dL)	30.5	29.0
PLT (10 ³ /μL)	153	145
Lym #	1.6	1.5
Mon#	0.2	0.3
Gran#	3.0	2.6
Lym%	33.4	34.9
Mon%	5.1	5.9
Gran%	61.5	59.2
RDW (%)	16.1	15.7
PCT (%)	0.30	0.27
MPV (fL)	19.4	18.8
PDW (%)	15.7	16.3

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	7.5	7.5
RBC (10 ⁶ /μL)	6.30	6.33
HGB (g/dL)	11.8	11.0
HCT (%)	42.3	41.5
MCV (fL)	67.1	65.6
MCH (pg)	18.7	17.4
MCHC (g/dL)	27.9	26.5
PLT (10 ³ /μL)	210	213
Lym #	2.6	2.6
Mon#	0.4	0.4
Gran#	4.5	4.5
Lym%	34.3	35.0
Mon%	4.7	5.6
Gran%	61.0	59.4
RDW (%)	18.6	18.6
PCT (%)	0.33	0.29
MPV (fL)	15.5	13.8
PDW (%)	13.7	13.7

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	7.6	7.5
RBC (10 ⁶ /μL)	6.38	6.40
HGB (g/dL)	11.9	11.3
HCT (%)	43.0	42.3
MCV (fL)	67.4	66.1
MCH (pg)	18.7	17.7
MCHC (g/dL)	27.7	26.7
PLT (10 ³ /μL)	210	223
Lym #	2.7	2.6
Mon#	0.4	0.4
Gran#	4.5	4.5
Lym%	36.1	34.8
Mon%	5.6	5.2
Gran%	58.3	60.0
RDW (%)	18.8	18.8
PCT (%)	0.33	0.31
MPV (fL)	15.5	14.0
PDW (%)	14.1	13.7

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	6.9	6.9
RBC (10 ⁶ /μL)	5.29	5.28
HGB (g/dL)	15.1	14.3
HCT (%)	47.9	47.4
MCV (fL)	90.5	89.8
MCH (pg)	28.5	27.1
MCHC (g/dL)	31.5	30.2
PLT (10 ³ /μL)	227	231
Lym #	3.3	3.1
Mon#	0.2	0.4
Gran#	3.4	3.4
Lym%	48.2	44.5
Mon%	3.5	5.0
Gran%	48.3	50.5
RDW (%)	14.3	14.3
PCT (%)	0.29	0.30
MPV (fL)	12.6	12.8
PDW (%)	17.2	17.2

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot - HVDNK221011 VDx Lyse-NK Lot - HVLNK221002 VDx Cleaner-NK Lot - HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot - 225422 Hemolynac - 3N Lot-225354
WBC (10 ³ /μL)	7.4	7.3
RBC (10 ⁶ /μL)	5.61	5.70
HGB (g/dL)	16.0	15.2
HCT (%)	49.6	50.4
MCV (fL)	88.4	88.4
MCH (pg)	28.5	26.7
MCHC (g/dL)	32.3	30.2
PLT (10 ³ /μL)	208	211
Lym #	3.6	3.7
Mon#	0.3	0.4
Gran#	3.5	3.2
Lym%	49.0	50.6
Mon%	4.3	5.2
Gran%	46.7	44.2
RDW (%)	15.1	14.7
PCT (%)	0.28	0.29
MPV (fL)	13.7	13.6
PDW (%)	17.4	17.4

Performance with Hematology 3rd Part Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D

(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	2.5	2.4	1.8 - 2.8
RBC (10 ⁶ /μL)	2.53	2.51	2.32 - 2.72
HGB (g/dL)	6.9	6.4	6.5 - 7.5
HCT (%)	21.5	20.5	18.6 - 24.6
MCV (fL)	85.0	81.7	79.7 - 91.7
MCH (pg)	27.3	25.5	24.1 - 31.7
MCHC (g/dL)	32.1	31.2	27.7 - 37.3
PLT (10 ³ /μL)	70	70	51 - 101
Lym #	1.6	1.5	NA
Mon#	0.2	0.2	NA
Gran#	0.7	0.7	NA
Lym%	63.8	62.6	NA
Mon%	8.3	7.3	NA
Gran%	27.9	30.1	NA
RDW (%)	18.1	18.6	11.9 - 21.9
PCT (%)	0.08	0.07	NA
MPV (fL)	10.8	10.6	4.4 - 10.4
PDW (%)	13.5	14.3	11.7 - 17.7

Diagon D Check D

(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	7.2	7.1	6.0 - 8.0
RBC (10 ⁶ /μL)	4.56	4.47	4.26 - 4.86
HGB (g/dL)	13.6	12.7	12.8 - 14.0
HCT (%)	40.7	38.5	36.6 - 45.6
MCV (fL)	89.3	86.1	82.9 - 96.9
MCH (pg)	29.8	28.4	25.5 - 33.1
MCHC (g/dL)	33.4	33.0	27.7 - 37.3
PLT (10 ³ /μL)	226	214	196 - 286
Lym #	3.2	3.0	NA
Mon#	0.3	0.3	NA
Gran#	3.7	3.8	NA
Lym%	43.8	42.7	NA
Mon%	4.5	4.7	NA
Gran%	51.7	52.6	NA
RDW (%)	17.2	17.6	11.4 - 21.4
PCT (%)	0.24	0.21	NA
MPV (fL)	10.4	10.0	4.6 - 10.6
PDW (%)	12.5	12.9	10.3 - 16.3

Diagon D Check D

(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	17.7	17.7	14.4 - 19.4
RBC (10 ⁶ /μL)	5.59	5.54	5.13 - 5.93
HGB (g/dL)	17.5	16.8	16.4 - 18.0
HCT (%)	53.0	51.0	47.6 - 56.6
MCV (fL)	94.8	92.1	87.2 - 101.2
MCH (pg)	31.3	30.3	27.3 - 34.9
MCHC (g/dL)	33.0	32.9	28.2 - 37.8
PLT (10 ³ /μL)	488	483	447 – 617
Lym #	6.0	6.3	NA
Mon#	0.7	0.7	NA
Gran#	11.0	10.7	NA
Lym%	34.0	17.4	NA
Mon%	4.0	0.5	NA
Gran%	62.0	57.9	NA
RDW (%)	17.2	15.5	11.1 - 21.1
PCT (%)	0.55	0.22	NA
MPV (fL)	11.3	15.7	4.7 - 10.7
PDW (%)	11.2	16.3	10.3 - 16.3



D-Check D

CONTROL

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901



05-03-2023

Instruments:		NIHON KOHDEN MEK-7222 (1)					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean $\pm$ Limit	Range Variation	Mean $\pm$ Limit	Range Variation	Mean $\pm$ Limit	Range Variation
WBC	$10^9/L$	$2,3 \pm 0,5$	1,8 - 2,8	$7,0 \pm 1,0$	6,0 - 8,0	$16,9 \pm 2,5$	14,4 - 19,4
RBC	$10^{12}/L$	$2,52 \pm 0,20$	2,32 - 2,72	$4,56 \pm 0,30$	4,26 - 4,86	$5,53 \pm 0,40$	5,13 - 5,93
Hgb	g/dL	$7,0 \pm 0,5$	6,5 - 7,5	$13,4 \pm 0,6$	12,8 - 14,0	$17,2 \pm 0,8$	16,4 - 18,0
	g/L	70 ± 5	65 - 75	134 ± 6	128 - 140	172 ± 8	164 - 180
Hct	%	$21,6 \pm 3,0$	18,6 - 24,6	$41,1 \pm 4,5$	36,6 - 45,6	$52,1 \pm 4,5$	47,6 - 56,6
	L/L	$0,216 \pm 0,030$	0,186 - 0,246	$0,411 \pm 0,045$	0,366 - 0,456	$0,521 \pm 0,045$	0,476 - 0,566
MCV	fL	$85,7 \pm 6,0$	79,7 - 91,7	$89,9 \pm 7,0$	82,9 - 96,9	$94,2 \pm 7,0$	87,2 - 101,2
MCH	pg	$27,9 \pm 3,8$	24,1 - 31,7	$29,3 \pm 3,8$	25,5 - 33,1	$31,1 \pm 3,8$	27,3 - 34,9
MCHC	g/dL	$32,5 \pm 4,8$	27,7 - 37,3	$32,5 \pm 4,8$	27,7 - 37,3	$33,0 \pm 4,8$	28,2 - 37,8
	g/L	325 ± 48	277 - 373	325 ± 48	277 - 373	330 ± 48	282 - 378
RDW-CV	%	$16,9 \pm 5,0$	11,9 - 21,9	$16,4 \pm 5,0$	11,4 - 21,4	$16,1 \pm 5,0$	11,1 - 21,1
Plt	$10^9/L$	76 ± 25	51 - 101	241 ± 45	196 - 286	532 ± 85	447 - 617
MPV	fL	$7,4 \pm 3,0$	4,4 - 10,4	$7,6 \pm 3,0$	4,6 - 10,6	$7,7 \pm 3,0$	4,7 - 10,7
PDW	%	$14,7 \pm 3,0$	11,7 - 17,7	$13,3 \pm 3,0$	10,3 - 16,3	$13,3 \pm 3,0$	10,3 - 16,3

(1) Assay Values were obtained on analyzer using DIAGON reagents.

(1) DIAGON reagensek használata során kapott értékek.



DIAGON Ltd.
48-52., Baross Str.
Budapest, Hungary
H-1047



Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Nihon Kohden Reagents on Celltac alpha, 3 Part Hematology Analyzer.
2. The sample was tested in 06 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 06

Precision Evaluation report of VDx Nihon Kohden compatible reagent on Celltac alpha, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	4.8	4.6	4.8	4.5	4.6	4.5					4.63	0.14	0.03	2.95
RBC ($10^6/\mu\text{L}$)	5.07	5	5.03	4.98	5.02	5.03					5.02	0.03	0.01	0.61
HGB (g/dL)	13.6	13.5	13.6	13.4	13.5	13.5					13.52	0.08	0.01	0.56
HCT (%)	45	44.5	44.5	44.4	44.7	44.7					44.63	0.22	0.00	0.48
MCV (fL)	88.8	89	88.5	89.2	89	88.9					88.90	0.24	0.00	0.27
MCH (pg)	26.8	27	27	26.90	26.90	26.80					26.90	0.09	0.00	0.33
MCHC (g/dL)	30.2	30.3	30.6	30.20	30.20	30.20					30.28	0.16	0.01	0.53
PLT ($10^3/\mu\text{L}$)	146	143	138	141	142	149					143.17	3.87	0.03	2.70
Lym #	1.8	1.9	1.8	1.8	1.9	1.7					1.82	0.08	0.04	4.14
Mon#	0.3	0.3	0.3	0.3	0.3	0.3					0.30	0.00	0.00	0.00
Gran#	2.5	2.4	2.7	2.4	2.4	2.5					2.48	0.12	0.05	4.71
Lym%	40.2	40.6	37.3	41.0	40.4	37.7					39.53	1.60	0.04	4.05
Mon%	6.5	6.0	6.3	6.5	6.4	6.5					6.37	0.20	0.03	3.09
Gran%	53.3	53.4	56.4	51.9	53.2	55.8					54.00	1.73	0.03	3.20
RDW (%)	15.7	15.6	15.6	15.7	15.9	15.2					15.62	0.23	0.01	1.48
PCT (%)	0.28	0.28	0.27	0.26	0.27	0.28					0.27	0.01	0.03	2.99
MPV (fL)	19.30	19.7	19.8	19.6	18.7	19					19.35	0.43	0.02	2.23
PDW (%)	16.00	16.20	16.00	16.20	16.00	16.00					16.07	0.10	0.01	0.64

Coefficient of Variation:

Precision (Nihon Kohden Reference Reagents)

1. Fresh blood sample was collected and tested with the Nihon Kohden Reference Reagents on Celltac alpha, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh, Blood Sample No- 1, n = 07

Precision Evaluation report of Reference Nihon Kohden reagent on Celltac alpha, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	4.5	4.6	4.6	4.6	4.6	4.7	4.6				4.60	0.06	0.01	1.26
RBC ($10^6/\mu\text{L}$)	5.05	5.08	5.1	5.04	5.05	5.08	5.1				5.07	0.02	0.00	0.49
HGB (g/dL)	12.8	12.8	12.8	12.9	12.8	13.0	12.9				12.86	0.08	0.01	0.61
HCT (%)	43.8	44.2	44.4	44	44	44.4	44.6				44.20	0.28	0.01	0.64
MCV (fL)	86.7	87	87.1	87.3	87.1	87.4	87.5				87.16	0.27	0.00	0.31
MCH (pg)	25.3	25.2	25.1	25.6	25.3	25.6	25.3				25.34	0.19	0.01	0.75
MCHC (g/dL)	29.2	29	28.8	29.3	29.1	29.3	28.9				29.09	0.20	0.01	0.67
PLT ($10^3/\mu\text{L}$)	162	153	161	165	170	168	168				163.86	5.81	0.04	3.55
Lym #	1.7	1.7	1.6	1.7	1.7	1.7	1.8				1.70	0.06	0.03	3.40
Mon#	0.3	0.3	0.3	0.3	0.3	0.3	0.3				0.30	0.00	0.00	0.00
Gran#	2.5	2.6	2.7	2.6	2.6	2.7	2.4				2.59	0.11	0.04	4.13
Lym%	37.9	37.3	35.6	37.2	37.4	36.7	38.3				37.20	0.87	0.02	2.34
Mon%	6.3	6.6	6.5	7.0	7.0	6.6	6.6				6.66	0.26	0.04	3.86
Gran%	55.8	56.1	57.9	55.8	55.6	56.7	54.8				56.10	0.98	0.02	1.74
RDW (%)	15.8	15.8	15.8	15.5	15.2	15.7	15.1				15.56	0.30	0.02	1.92
PCT (%)	0.32	0.29	0.29	0.32	0.32	0.30	0.30				0.31	0.01	0.05	4.57
MPV (fL)	19.5	18.6	18.0	19.3	18.8	17.7	17.8				18.53	0.72	0.04	3.89
PDW (%)	16.5	15.9	16.3	16.0	16.0	16.7	16.7				16.30	0.34	0.02	2.10

Conclusions

1. The VDX Nihon Kohden 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Nihon Kohden original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.987 to 0.998** displaying the highest degree of correlation between the reagents.
3. The VDX Nihon Kohden and the Nihon Kohden Reference 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
4. The CV % of Precision with the VDX Nihon Kohden reagents and the Nihon Kohden Reference reagents for the parameters are mentioned below.

Parameters	Nihon Kohden Reference Reagents (CV % of Precision)	VDX Nihon Kohden Reagents (CV % of Precision)
Measured Parameters	0.31% – 3.55%	0.27% - 2.95%
Calculated Parameters	0.00% - 4.57%	0.33% - 4.71%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges with VDX Nihon Kohden 3 Part Hematology Reagents for all the parameters and Nihon Kohden Reference reagents for all the parameters except Hemoglobin for the Low and Normal Controls.
6. **The VDX Nihon Kohden 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Nihon Kohden reference reagents in all parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	137 - 138
2	Background Test	139
3	Coefficient of Correlation: Accuracy	140 – 163
4	Quality Control (Low, Normal & High)	164 - 168
5	Coefficient of Variation: Precision (VDx Horiba Compatible Reagents)	169
6	Coefficient of Variation: Precision (Horiba Reference Reagents)	170
7	Conclusions	171

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Horiba - ABX Micros ES60
Reference Reagents	Reference Horiba Reagents
Minidil LMG	Lot No : 220407F17 Expiry Date : 07-10-2023
Minilysebio	Lot No : 220412B47 Expiry Date : 12-04-2023
ABX Miniclean	Lot No : 220518T17 Expiry Date. : 18-05-2023

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Horiba Compatible Reagents)
5	Coefficient of Variation: Precision (Horiba Reference Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent -A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	0.0	0.0
Lym (%)	0.0	0.0
Mon (%)	0.0	0.0
Gran (%)	0.0	0.0
Lym# (10 ³ /mm ³)	0.0	0.0
Mon# (10 ³ /mm ³)	0.0	0.0
Gran# (10 ³ /mm ³)	0.0	0.0
RBC (10 ⁶ /mm ³)	0.0	0.0
HGB (g/dl)	0.0	0.0
HCT (%)	0.0	0.0
MCV (μm ³)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dl)	0.0	0.0
RDW (%)	0.0	0.0
PLT (10 ³ /mm ³)	0.0	0.0
MPV (μm ³)	0.0	0.0
PCT (%)	0.0	0.0
PDW (%)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Horiba Reagents and the Reference Horiba Reagents.
- II. The Coefficient of Correlation (“r”) was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of “r”
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When “r” is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Horiba Reference Reagents for ABX Micros ES 60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES 60, 3 Part Hematology Analyzer.

$$“r” = 0.989$$

Sample size: 16

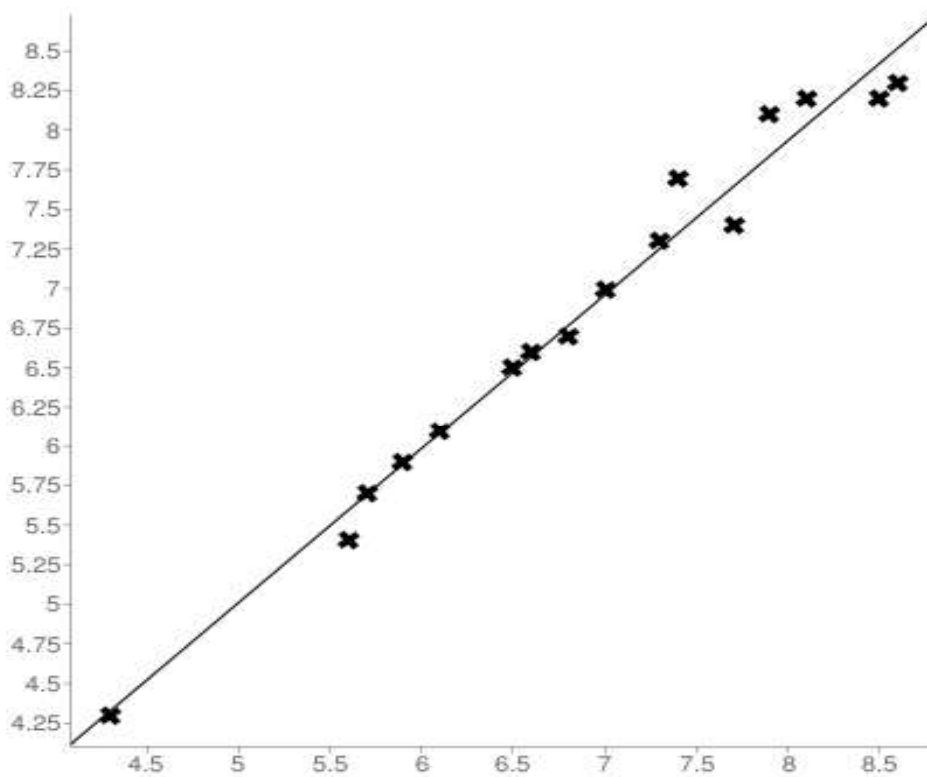
Mean x (x̄): 6.875

Mean y (ȳ): 6.8375

Intercept (a): 0.12998070429337

Slope (b): 0.9756391702846

Regression line equation: $y = 0.12998070429337 + 0.9756391702846x$



Coefficient of Correlation (“r”): RBC

x = Horiba Reference Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

$$“r” = 0.989$$

Sample size: 16

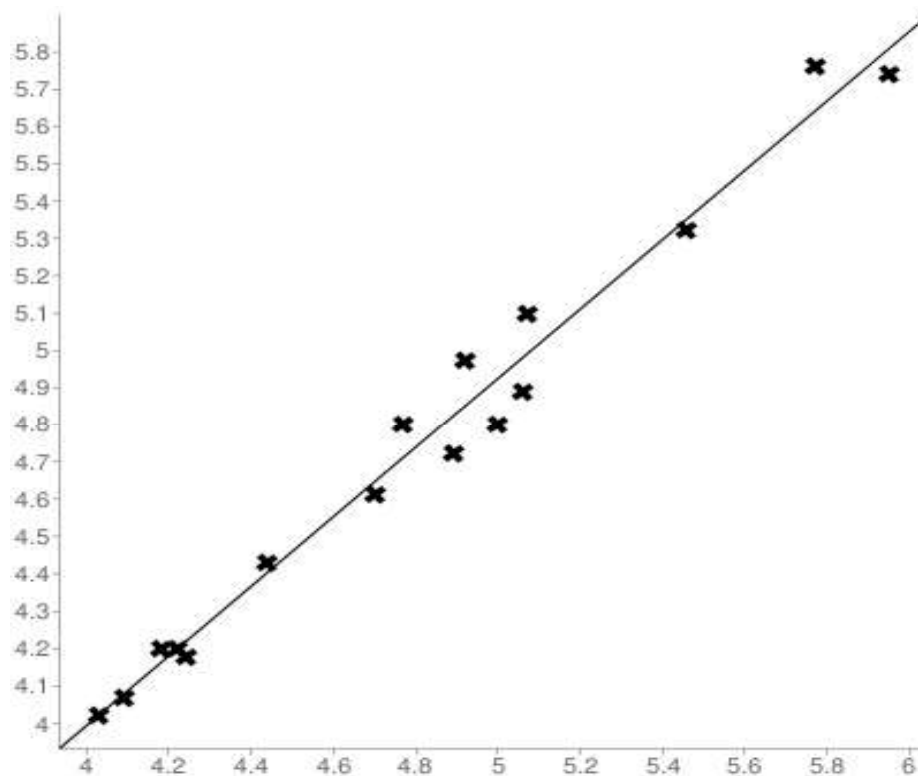
Mean x (x̄): 4.799375

Mean y (ȳ): 4.738125

Intercept (a): 0.27567091032748

Slope (b): 0.92979900292695

Regression line equation: $y = 0.27567091032748 + 0.92979900292695x$



Coefficient of Correlation (“r”): Hemoglobin

x = Horiba Reference Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

$$“r” = 0.970$$

Sample size: 16

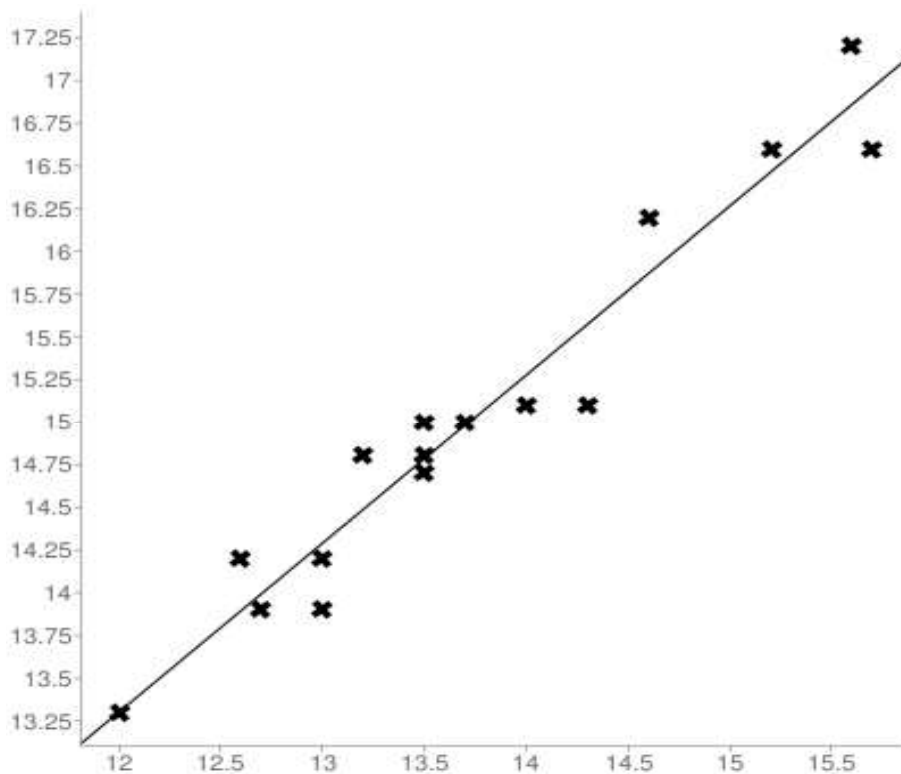
Mean x ($\bar{x}$): 13.75625

Mean y ($\bar{y}$): 15.0375

Intercept (a): 1.44074417609

Slope (b): 0.98840569369632

Regression line equation: $y = 1.44074417609 + 0.98840569369632x$



Coefficient of Correlation (“r”): Platelets

x = Horiba Reference Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

$$“r” = 0.979$$

Sample size: 16

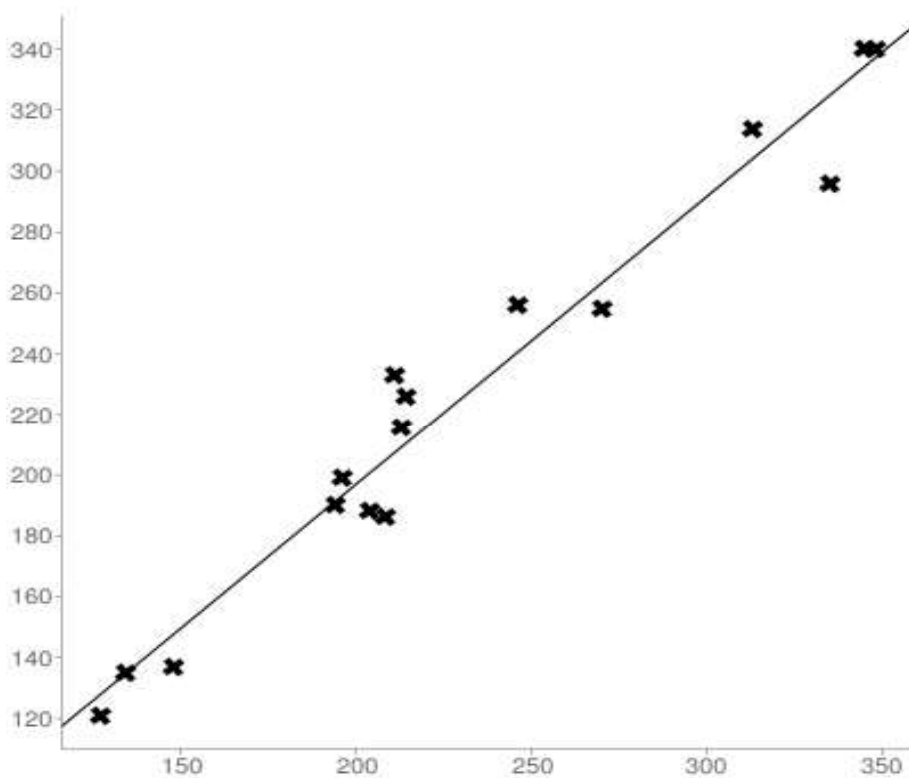
Mean x (x̄): 231.625

Mean y (ȳ): 227

Intercept (a): 7.6949017721113

Slope (b): 0.94681100152353

Regression line equation: $y = 7.6949017721113 + 0.94681100152353x$



Coefficient of Correlation (“r”): MCV

x = Horiba Reference Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 16

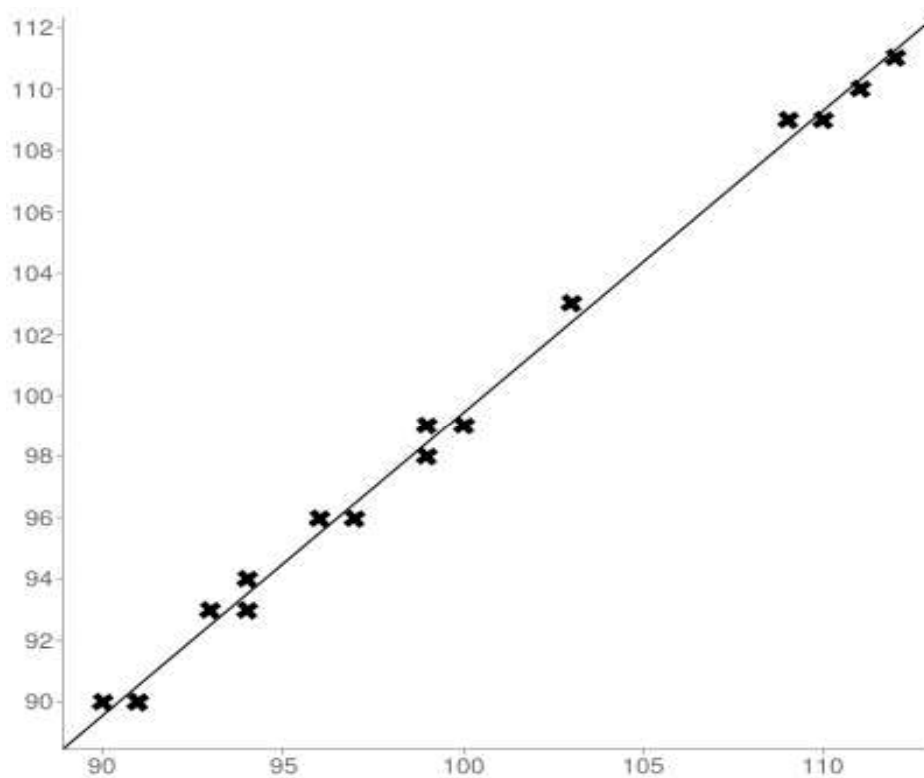
Mean x (x): 99.3125

Mean y (y): 98.75

Intercept (a): 0.73328959836724

Slope (b): 0.98695240177856

Regression line equation: $y=0.73328959836724+0.98695240177856x$



Coefficient of Correlation (“r”): HCT

x = Horiba Reference Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

y = VDX Reagents for ABX Micros ES60, 3 Part Hematology Analyzer.

$$“r” = 0.971$$

Sample size: 16

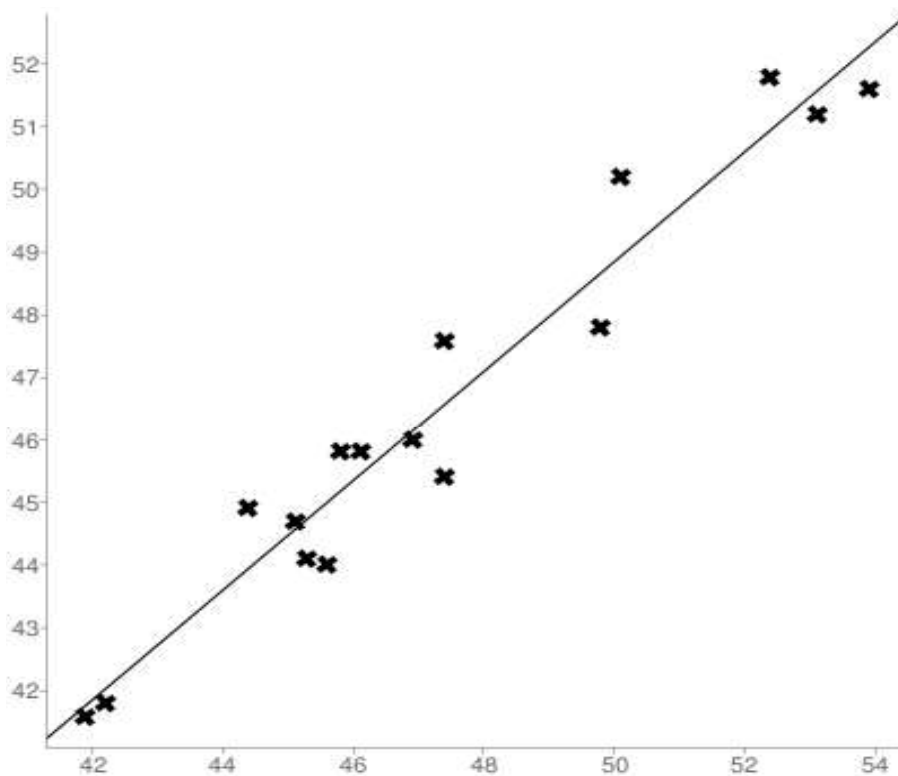
Mean x (x̄): 47.3375

Mean y (ȳ): 46.51875

Intercept (a): 5.1421859689746

Slope (b): 0.87407581792502

Regression line equation: $y = 5.1421859689746 + 0.87407581792502x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	8.2	8.5
Lym (%)	25.4	26.0
Mon (%)	6.4	5.7
Gran (%)	68.2	68.3
Lym# (10 ³ /mm ³)	2.00	2.20
Mon# (10 ³ /mm ³)	0.50	0.40
Gran# (10 ³ /mm ³)	5.70	5.90
RBC (10 ⁶ /mm ³)	4.80	4.77
HGB (g/dl)	15.1	14.0
HCT (%)	47.6	47.4
MCV (μm ³)	99	99
MCH (pg)	31.4	29.2
MCHC (g/dl)	31.6	29.4
RDW (%)	14.3	14.2
PLT (10 ³ /mm ³)	121	127
MPV (μm ³)	12.6	11.9
PCT (%)	0.153	0.151
PDW (%)	18.5	18.9

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	8.3	8.6
Lym (%)	24.7	26.1
Mon (%)	7.0	6.2
Gran (%)	68.3	67.7
Lym# (10 ³ /mm ³)	2.00	2.20
Mon# (10 ³ /mm ³)	0.50	0.50
Gran# (10 ³ /mm ³)	5.80	5.90
RBC (10 ⁶ /mm ³)	4.80	5.00
HGB (g/dl)	15.1	14.3
HCT (%)	47.8	49.8
MCV (μm ³)	99	100
MCH (pg)	31.4	28.7
MCHC (g/dl)	31.6	28.8
RDW (%)	13.9	13.9
PLT (10 ³ /mm ³)	137	148
MPV (μm ³)	11.3	11.7
PCT (%)	0.120	0.174
PDW (%)	20.6	18.6

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	7.4	7.7
Lym (%)	17.8	18.8
Mon (%)	6.0	5.5
Gran (%)	76.2	75.7
Lym# ($10^3/\text{mm}^3$)	1.30	1.40
Mon# ($10^3/\text{mm}^3$)	0.40	0.40
Gran# ($10^3/\text{mm}^3$)	5.70	5.90
RBC ($10^6/\text{mm}^3$)	5.74	5.95
HGB (g/dl)	16.6	15.7
HCT (%)	51.6	53.9
MCV (μm^3)	90	91
MCH (pg)	29.0	26.4
MCHC (g/dl)	32.2	29.1
RDW (%)	12.9	13.2
PLT ($10^3/\text{mm}^3$)	340	345
MPV (μm^3)	10.0	9.8
PCT (%)	0.342	0.339
PDW (%)	15.7	14.1

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	6.6	6.6
Lym (%)	33.3	34.5
Mon (%)	7.4	5.8
Gran (%)	59.3	59.7
Lym# ($10^3/\text{mm}^3$)	2.10	2.20
Mon# ($10^3/\text{mm}^3$)	0.40	0.30
Gran# ($10^3/\text{mm}^3$)	4.10	4.10
RBC ($10^6/\text{mm}^3$)	4.07	4.09
HGB (g/dl)	13.9	12.7
HCT (%)	41.8	42.2
MCV (μm^3)	103	103
MCH (pg)	34.1	31.2
MCHC (g/dl)	33.2	30.2
RDW (%)	13.8	14.1
PLT ($10^3/\text{mm}^3$)	256	246
MPV (μm^3)	9.6	9.2
PCT (%)	0.246	0.226
PDW (%)	15.2	15.0

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	4.3	4.3
Lym (%)	31.8	35.5
Mon (%)	8.0	6.9
Gran (%)	60.2	57.6
Lym# ($10^3/\text{mm}^3$)	1.30	1.50
Mon# ($10^3/\text{mm}^3$)	0.30	0.20
Gran# ($10^3/\text{mm}^3$)	2.70	2.60
RBC ($10^6/\text{mm}^3$)	4.72	4.89
HGB (g/dl)	13.9	13.0
HCT (%)	44.0	45.6
MCV (μm^3)	93	93
MCH (pg)	29.5	26.7
MCHC (g/dl)	31.7	28.5
RDW (%)	12.8	13.9
PLT ($10^3/\text{mm}^3$)	226	214
MPV (μm^3)	11.6	11.9
PCT (%)	0.263	0.255
PDW (%)	20.3	19.2

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	7.3	7.3
Lym (%)	17.6	19.8
Mon (%)	6.8	5.1
Gran (%)	75.6	75.1
Lym# (10 ³ /mm ³)	1.20	1.40
Mon# (10 ³ /mm ³)	0.40	0.30
Gran# (10 ³ /mm ³)	5.70	5.60
RBC (10 ⁶ /mm ³)	5.76	5.77
HGB (g/dl)	16.6	15.2
HCT (%)	51.8	52.4
MCV (μm ³)	90	91
MCH (pg)	28.9	26.4
MCHC (g/dl)	32.1	29.1
RDW (%)	13.1	13.0
PLT (10 ³ /mm ³)	340	348
MPV (μm ³)	10.2	9.9
PCT (%)	0.347	0.345
PDW (%)	16.6	16.6

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	5.7	5.7
Lym (%)	29.7	31.2
Mon (%)	8.1	6.8
Gran (%)	62.2	62.0
Lym# ($10^3/\text{mm}^3$)	1.60	1.70
Mon# ($10^3/\text{mm}^3$)	0.40	0.30
Gran# ($10^3/\text{mm}^3$)	3.70	3.70
RBC ($10^6/\text{mm}^3$)	4.61	4.70
HGB (g/dl)	14.2	13.0
HCT (%)	44.1	45.3
MCV (μm^3)	96	96
MCH (pg)	30.7	27.7
MCHC (g/dl)	32.1	28.7
RDW (%)	13.3	13.6
PLT ($10^3/\text{mm}^3$)	314	313
MPV (μm^3)	9.8	9.6
PCT (%)	0.309	0.299
PDW (%)	14.7	14.5

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A, Lot - HVDA221015 VDx Lyse-A, Lot - HVLA220804 VDx Cleaner-A, Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG, Lot - 220407F17 Minilysebio, Lot - 220412B47 ABX Miniclean, Lot - 220518T17
WBC (10 ³ /mm ³)	6.7	6.8
Lym (%)	21.4	23.9
Mon (%)	8.9	7.1
Gran (%)	69.7	69.0
Lym# (10 ³ /mm ³)	1.40	1.60
Mon# (10 ³ /mm ³)	0.60	0.40
Gran# (10 ³ /mm ³)	4.70	4.80
RBC (10 ⁶ /mm ³)	4.89	5.06
HGB (g/dl)	14.7	13.5
HCT (%)	45.4	47.4
MCV (μm ³)	93	94
MCH (pg)	30.1	26.7
MCHC (g/dl)	32.5	28.5
RDW (%)	14.1	14.6
PLT (10 ³ /mm ³)	199	196
MPV (μm ³)	11.5	11.4
PCT (%)	0.229	0.223
PDW (%)	16.3	18.2

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	7.7	7.4
Lym (%)	35.1	36.0
Mon (%)	9.0	6.1
Gran (%)	55.9	57.9
Lym# ($10^3/\text{mm}^3$)	2.70	2.60
Mon# ($10^3/\text{mm}^3$)	0.60	0.40
Gran# ($10^3/\text{mm}^3$)	4.40	4.40
RBC ($10^6/\text{mm}^3$)	4.97	4.92
HGB (g/dl)	14.2	12.6
HCT (%)	44.9	44.4
MCV (μm^3)	90	90
MCH (pg)	28.6	25.7
MCHC (g/dl)	31.7	28.4
RDW (%)	14.3	14.4
PLT ($10^3/\text{mm}^3$)	135	134
MPV (μm^3)	12.4	11.8
PCT (%)	0.168	0.158
PDW (%)	19.5	20.5

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	5.9	5.9
Lym (%)	31.6	33.6
Mon (%)	8.0	6.6
Gran (%)	60.4	59.8
Lym# ($10^3/\text{mm}^3$)	1.80	1.90
Mon# ($10^3/\text{mm}^3$)	0.40	0.30
Gran# ($10^3/\text{mm}^3$)	3.70	3.70
RBC ($10^6/\text{mm}^3$)	4.43	4.44
HGB (g/dl)	13.3	12.0
HCT (%)	41.6	41.9
MCV (μm^3)	94	94
MCH (pg)	30.0	27.1
MCHC (g/dl)	32.0	28.6
RDW (%)	13.4	13.6
PLT ($10^3/\text{mm}^3$)	190	194
MPV (μm^3)	11.5	11.5
PCT (%)	0.218	0.222
PDW (%)	17.4	18.4

Sample - 11		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	7.0	7.0
Lym (%)	25.3	26.4
Mon (%)	5.1	3.9
Gran (%)	69.6	69.7
Lym# ($10^3/\text{mm}^3$)	1.70	18.00
Mon# ($10^3/\text{mm}^3$)	0.30	0.20
Gran# ($10^3/\text{mm}^3$)	5.00	5.00
RBC ($10^6/\text{mm}^3$)	4.02	4.03
HGB (g/dl)	14.8	13.5
HCT (%)	44.7	45.1
MCV (μm^3)	111	112
MCH (pg)	36.8	33.4
MCHC (g/dl)	33.0	29.9
RDW (%)	15.2	15.3
PLT ($10^3/\text{mm}^3$)	216	213
MPV (μm^3)	10.5	10.4
PCT (%)	0.226	0.221
PDW (%)	17.6	18.0

Sample - 12		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	6.1	6.1
Lym (%)	40.0	41.2
Mon (%)	5.1	4.1
Gran (%)	54.9	54.7
Lym# ($10^3/\text{mm}^3$)	2.40	2.50
Mon# ($10^3/\text{mm}^3$)	0.30	0.20
Gran# ($10^3/\text{mm}^3$)	3.40	3.40
RBC ($10^6/\text{mm}^3$)	4.18	4.24
HGB (g/dl)	15.0	13.5
HCT (%)	46.0	46.9
MCV (μm^3)	110	111
MCH (pg)	36.0	32.0
MCHC (g/dl)	32.7	28.8
RDW (%)	14.6	15.2
PLT ($10^3/\text{mm}^3$)	186	208
MPV (μm^3)	11.0	11.0
PCT (%)	0.205	0.228
PDW (%)	18.2	18.1

Sample - 13		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	8.1	7.9
Lym (%)	39.5	40.9
Mon (%)	6.9	6.4
Gran (%)	53.6	52.7
Lym# ($10^3/\text{mm}^3$)	3.10	3.20
Mon# ($10^3/\text{mm}^3$)	0.50	0.50
Gran# ($10^3/\text{mm}^3$)	4.50	4.20
RBC ($10^6/\text{mm}^3$)	4.20	4.22
HGB (g/dl)	15.0	13.7
HCT (%)	45.8	46.1
MCV (μm^3)	109	109
MCH (pg)	35.8	32.4
MCHC (g/dl)	32.8	29.7
RDW (%)	13.2	13.1
PLT ($10^3/\text{mm}^3$)	296	335
MPV (μm^3)	9.9	9.7
PCT (%)	0.294	0.325
PDW (%)	15.4	15.4

Sample - 14		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	8.2	8.1
Lym (%)	34.3	36.5
Mon (%)	6.5	5.8
Gran (%)	59.2	57.7
Lym# (10 ³ /mm ³)	2.80	2.90
Mon# (10 ³ /mm ³)	0.50	0.40
Gran# (10 ³ /mm ³)	4.90	4.80
RBC (10 ⁶ /mm ³)	5.10	5.07
HGB (g/dl)	16.2	14.6
HCT (%)	50.2	50.1
MCV (μm ³)	98	99
MCH (pg)	31.8	28.7
MCHC (g/dl)	32.3	29.1
RDW (%)	13.3	13.9
PLT (10 ³ /mm ³)	255	270
MPV (μm ³)	12.1	11.7
PCT (%)	0.308	0.316
PDW (%)	18.2	17.8

Sample - 15		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC (10 ³ /mm ³)	6.5	6.5
Lym (%)	38.5	42.9
Mon (%)	7.6	6.1
Gran (%)	53.9	51.0
Lym# (10 ³ /mm ³)	2.40	2.70
Mon# (10 ³ /mm ³)	0.40	0.30
Gran# (10 ³ /mm ³)	3.70	3.50
RBC (10 ⁶ /mm ³)	4.20	4.18
HGB (g/dl)	14.8	13.2
HCT (%)	45.8	45.8
MCV (μm ³)	109	110
MCH (pg)	35.2	31.7
MCHC (g/dl)	32.3	28.9
RDW (%)	14.3	14.6
PLT (10 ³ /mm ³)	188	204
MPV (μm ³)	11.5	10.7
PCT (%)	0.216	0.218
PDW (%)	18.4	17.4

Sample - 16		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot - HVDA221015 VDx Lyse-A Lot - HVLA220804 VDx Cleaner-A Lot - HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot - 220407F17 Minilysebio Lot - 220412B47 ABX Miniclean Lot - 220518T17
WBC ($10^3/\text{mm}^3$)	5.4	5.6
Lym (%)	40.2	41.8
Mon (%)	7.1	7.2
Gran (%)	52.7	51.0
Lym# ($10^3/\text{mm}^3$)	2.10	2.30
Mon# ($10^3/\text{mm}^3$)	0.30	0.40
Gran# ($10^3/\text{mm}^3$)	3.00	2.90
RBC ($10^6/\text{mm}^3$)	5.32	5.46
HGB (g/dl)	17.2	15.6
HCT (%)	51.2	53.1
MCV (μm^3)	96	97
MCH (pg)	32.3	28.5
MCHC (g/dl)	33.6	29.3
RDW (%)	14.0	15.0
PLT ($10^3/\text{mm}^3$)	233	211
MPV (μm^3)	10.9	10.7
PCT (%)	0.253	0.227
PDW (%)	16.0	14.7

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D

(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot- HVDA221015 VDx Lyse-A Lot- HVLA220804 VDx Cleaner-A Lot- HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot- 220407F17 Minilysebio Lot- 220412B47 ABX Miniclean Lot- 220518T17	Range
WBC ($10^3/\text{mm}^3$)	2.5	2.5	1.9 - 2.9
Lym (%)	45.5	47.6	40.1 - 74.5
Mon (%)	11.3	11.6	1.3 - 11.7
Gran (%)	43.2	40.8	23.5 - 48.9
Lym# ($10^3/\text{mm}^3$)	1.10	1.20	0.7 - 1.9
Mon# ($10^3/\text{mm}^3$)	0.20	0.20	0.0 - 0.2
Gran# ($10^3/\text{mm}^3$)	1.20	1.10	0.6 - 1.4
RBC ($10^6/\text{mm}^3$)	2.39	2.33	2.18 - 2.58
HGB (g/dl)	6.9	6.3	6.4 - 7.4
HCT (%)	19.1	18.3	15.3 - 21.3
MCV (μm^3)	80	78	71.0 - 83.0
MCH (pg)	28.8	27.2	25.1 - 32.7
MCHC (g/dl)	36.1	34.7	32.8 - 42.4
RDW (%)	12.9	12.6	10.8 - 20.8
PLT ($10^3/\text{mm}^3$)	86	87	53 - 103
MPV (μm^3)	10.0	9.6	4.9 - 10.9
PCT (%)	0.086	0.084	0.007 - 0.107
PDW (%)	9.0	8.3	6.9 - 12.9

Diagon D Check D			
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)			
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot- HVDA221015 VDx Lyse-A Lot- HVLA220804 VDx Cleaner-A Lot- HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot- 220407F17 Minilysebio Lot-220412B47 ABX Miniclean Lot- 220518T17	Range
WBC (10 ³ /mm ³)	7.7	7.6	6.0 - 8.0
Lym (%)	32.0	33.3	24.6 - 45.6
Mon (%)	5.9	5.8	2.0 - 17.4
Gran (%)	62.1	60.9	41.4 - 69.0
Lym# (10 ³ /mm ³)	2.40	2.50	1.7 - 3.1
Mon# (10 ³ /mm ³)	0.40	0.40	0.2 - 1.0
Gran# (10 ³ /mm ³)	4.90	4.70	2.8 - 5.2
RBC (10 ⁶ /mm ³)	4.36	4.29	4.04 - 4.64
HGB (g/dl)	13.3	12.4	12.7 - 13.9
HCT (%)	37.2	35.8	31.4 - 40.4
MCV (μm ³)	85	83	76.5 - 88.5
MCH (pg)	30.5	28.9	26.7 - 34.3
MCHC (g/dl)	35.8	34.7	32.2 - 41.8
RDW (%)	12.2	12.1	10.7 - 20.7
PLT (10 ³ /mm ³)	238	251	189 - 279
MPV (μm ³)	9.7	9.4	4.9 - 10.9
PCT (%)	0.231	0.235	0.077 - 0.277
PDW (%)	9.2	9.0	6.9 - 12.9

Diagon D Check D			
(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)			
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-A Lot- HVDA221015 VDx Lyse-A Lot- HVLA220804 VDx Cleaner-A Lot- HVRA220807	All Reagents: Horiba as Reference Minidil LMG Lot- 220407F17 Minilysebio Lot- 220412B47 ABX Miniclean Lot- 220518T17	Range
WBC ($10^3/\text{mm}^3$)	18.9	18.9	14.8 - 19.8
Lym (%)	26.9	26.8	18.8 - 35.0
Mon (%)	4.6	4.3	2.2 - 19.6
Gran (%)	68.5	68.9	46.7 - 77.7
Lym# ($10^3/\text{mm}^3$)	5.00	5.00	3.2 - 6.0
Mon# ($10^3/\text{mm}^3$)	0.80	0.80	0.7 - 2.9
Gran# ($10^3/\text{mm}^3$)	13.10	13.10	8.2 - 13.6
RBC ($10^6/\text{mm}^3$)	5.33	5.39	4.92 - 5.72
HGB (g/dl)	17.3	16.5	16.2 - 17.8
HCT (%)	49.0	48.5	42.5 - 51.5
MCV (μm^3)	92	90	82.4 - 94.4
MCH (pg)	32.5	30.6	28.2 - 35.8
MCHC (g/dl)	35.4	34.1	31.4 - 41.0
RDW (%)	12.2	11.7	10.1 - 20.1
PLT ($10^3/\text{mm}^3$)	523	508	401 - 571
MPV (μm^3)	9.8	9.7	4.9 - 10.9
PCT (%)	0.512	0.491	0.170 - 0.570
PDW (%)	9.2	9.0	7.1 - 13.1

ASSAY VALUES AND EXPECTED RANGES
LOT: 1V0901

Vizsgálati értékek és várható tartományok


05-03-2023

Instruments:		ABX MICROS 60, ABX MICROS ES 60 SIEMENS ADVIA 60					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,4 ± 0,5	1,9 - 2,9	7,0 ± 1,0	6,0 - 8,0	17,3 ± 2,5	14,8 - 19,8
RBC	10 ¹² /L	2,38 ± 0,20	2,18 - 2,58	4,34 ± 0,30	4,04 - 4,64	5,32 ± 0,40	4,92 - 5,72
Hgb	g/dL	6,9 ± 0,5	6,4 - 7,4	13,3 ± 0,6	12,7 - 13,9	17,0 ± 0,8	16,2 - 17,8
	g/L	69 ± 5	64 - 74	133 ± 6	127 - 139	170 ± 8	162 - 178
Hct	%	18,3 ± 3,0	15,3 - 21,3	35,9 ± 4,5	31,4 - 40,4	47,0 ± 4,5	42,5 - 51,5
	L/L	0,183 ± 0,030	0,153 - 0,213	0,359 ± 0,045	0,314 - 0,404	0,470 ± 0,045	0,425 - 0,515
MCV	fL	77,0 ± 6,0	71,0 - 83,0	82,5 ± 6,0	76,5 - 88,5	88,4 ± 6,0	82,4 - 94,4
MCH	pg	28,9 ± 3,8	25,1 - 32,7	30,5 ± 3,8	26,7 - 34,3	32,0 ± 3,8	28,2 - 35,8
MCHC	g/dL	37,6 ± 4,8	32,8 - 42,4	37,0 ± 4,8	32,2 - 41,8	36,2 ± 4,8	31,4 - 41,0
	g/L	376 ± 48	328 - 424	370 ± 48	322 - 418	362 ± 48	314 - 410
RDW-CV	%	15,8 ± 5,0	10,8 - 20,8	15,7 ± 5,0	10,7 - 20,7	15,1 ± 5,0	10,1 - 20,1
Plt	10 ⁹ /L	78 ± 25	53 - 103	234 ± 45	189 - 279	486 ± 85	401 - 571
MPV	fL	7,9 ± 3,0	4,9 - 10,9	7,9 ± 3,0	4,9 - 10,9	7,9 ± 3,0	4,9 - 10,9
PDW		9,9 ± 3,0	6,9 - 12,9	9,9 ± 3,0	6,9 - 12,9	10,1 ± 3,0	7,1 - 13,1
PCT	%	0,057 ± 0,050	0,007 - 0,107	0,177 ± 0,100	0,077 - 0,277	0,370 ± 0,200	0,170 - 0,570
PCT	mL/L	0,57 ± 0,50	0,07 - 1,07	1,77 ± 1,00	0,77 - 2,77	3,70 ± 2,00	1,70 - 5,70
LYMPH#	10 ⁹ /L	1,3 ± 0,6	0,7 - 1,9	2,4 ± 0,7	1,7 - 3,1	4,6 ± 1,4	3,2 - 6,0
MID#	10 ⁹ /L	0,1 ± 0,1	0,0 - 0,2	0,6 ± 0,4	0,2 - 1,0	1,8 ± 1,1	0,7 - 2,9
GRAN#	10 ⁹ /L	1,0 ± 0,4	0,6 - 1,4	4,0 ± 1,2	2,8 - 5,2	10,9 ± 2,7	8,2 - 13,6
LYMPH%	%	57,3 ± 17,2	40,1 - 74,5	35,1 ± 10,5	24,6 - 45,6	26,9 ± 8,1	18,8 - 35,0
MID%	%	6,5 ± 5,2	1,3 - 11,7	9,7 ± 7,7	2,0 - 17,4	10,9 ± 8,7	2,2 - 19,6
GRAN%	%	36,2 ± 12,7	23,5 - 48,9	55,2 ± 13,8	41,4 - 69,0	62,2 ± 15,5	46,7 - 77,7

DIAGON Ltd.

48-52., Baross Str.

Budapest, Hungary

H-1047


IVD


Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Horiba Reagents on ABX Micros ES60, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 07

Precision Evaluation report of VDx Horiba compatible reagent on Horiba Micros ES60, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IInd Repeat	IIIRD Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\text{mm}^3$)	5.4	5.3	5.2	5.3	5.5	5.5	5.6				5.40	0.14	0.03	2.62
Lym (%)	39.8	40.2	40.1	39.6	39.1	40.9	40.8				40.07	0.64	0.02	1.60
Mon (%)	9.3	9.1	8.9	9.5	9.3	9.3	9.3				9.24	0.19	0.02	2.06
Gran (%)	50.9	50.7	51	50.9	51.6	49.8	49.9				50.69	0.64	0.01	1.26
Lym# ($10^3/\text{mm}^3$)	2.1	2.1	2.1	2.1	2.1	2.2	2.2				2.13	0.05	0.02	2.29
Mon# ($10^3/\text{mm}^3$)	0.5	0.5	0.5	0.50	0.50	0.50	0.50				0.50	0.00	0.00	0.00
Gran# ($10^3/\text{mm}^3$)	2.8	2.8	2.7	2.70	2.90	2.80	2.90				2.80	0.08	0.03	2.92
RBC ($10^6/\text{mm}^3$)	5.55	5.29	5.39	5.4	5.39	5.46	5.5				5.43	0.09	0.02	1.57
HGB (g/dl)	17.4	16.5	16.8	16.9	17	17	17.1				16.96	0.28	0.02	1.63
HCT (%)	53.6	50.8	52.1	51.9	51.9	52.6	53.1				52.29	0.92	0.02	1.75
MCV (μm^3)	97	96	97	96	96	96	96				96.29	0.49	0.01	0.51
MCH (pg)	31.3	31.3	31.2	31.3	31.5	31.2	31.1				31.27	0.13	0.00	0.40
MCHC (g/dl)	32.4	32.6	32.3	32.6	32.7	32.4	32.3				32.47	0.16	0.00	0.49
RDW (%)	14.1	14.1	13.7	14.3	14	14.2	14.3				14.10	0.21	0.01	1.48
PLT ($10^3/\text{mm}^3$)	221	214	217	225	216	229	235				222.43	7.66	0.03	3.44
MPV (μm^3)	10.70	10.70	10.80	10.70	10.60	10.50	10.80				10.69	0.11	0.01	1.00
PCT (%)	0.235	0.23	0.223	0.239	0.219	0.24	0.253				0.23	0.01	0.05	4.88
PDW (%)	15.80	15.60	16.30	16.50	17.20	17.10	16.70				16.46	0.61	0.04	3.69

Coefficient of Variation:

Precision (Horiba Reference Reagents)

1. Fresh blood sample was collected and tested with the Horiba Reference Reagents on ABX Micros ES60, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh, Blood Sample, n = 07

Precision Evaluation report of Horiba Reference reagent on Horiba Micros ES60, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\text{mm}^3$)	5.5	5.8	5.6	5.7	5.7	5.6	5.7				5.66	0.10	0.02	1.73
Lym (%)	44.2	45.5	45.4	44.9	45	45.4	48				45.49	1.20	0.03	2.63
Mon (%)	7.4	7.4	8.2	7.7	7.7	7.9	7.4				7.67	0.30	0.04	3.96
Gran (%)	48.4	47.1	46.4	47.4	47.3	46.7	44.6				46.84	1.17	0.03	2.50
Lym# ($10^3/\text{mm}^3$)	2.4	2.6	2.5	2.5	2.5	2.5	2.7				2.53	0.10	0.04	3.76
Mon# ($10^3/\text{mm}^3$)	0.4	0.40	0.40	0.40	0.40	0.40	0.40				0.40	0.00	0.00	0.00
Gran# ($10^3/\text{mm}^3$)	2.7	2.80	2.70	2.80	2.80	2.70	2.60				2.73	0.08	0.03	2.77
RBC ($10^6/\text{mm}^3$)	5.4	5.53	5.53	5.45	5.41	5.45	5.51				5.47	0.05	0.01	1.00
HGB (g/dl)	15.3	15.7	15.4	15.6	15.4	15.5	15.7				15.51	0.16	0.01	1.01
HCT (%)	52.1	53.8	53.4	52.6	52.6	53.3	53.2				53.00	0.59	0.01	1.11
MCV (μm^3)	96	97	96	96	97	98	97				96.71	0.76	0.01	0.78
MCH (pg)	28.4	28.3	27.9	28.5	28.5	28.4	28.5				28.36	0.21	0.01	0.76
MCHC (g/dl)	29.4	29.1	28.9	29.6	29.2	29.1	29.5				29.26	0.25	0.01	0.86
RDW (%)	14.4	14.6	14.3	14.3	14.6	14.7	14.3				14.46	0.17	0.01	1.19
PLT ($10^3/\text{mm}^3$)	208	205	193	195	188	205	216				201.43	9.78	0.05	4.85
MPV (μm^3)	10.30	10.10	10.30	10.40	10.10	10.20	10.00				10.20	0.14	0.01	1.39
PCT (%)	0.214	0.207	0.198	0.203	0.191	0.210	0.216				0.21	0.01	0.04	4.34
PDW (%)	15.30	15.40	15.70	16.00	14.50	13.80	16.20				15.27	0.85	0.06	5.58

Conclusions

1. The VDX Horiba 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Horiba original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.970 to 0.997** displaying the highest degree of correlation between the reagents.
3. The VDX Horiba and the Horiba Reference 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
4. The CV % with the VDX Horiba reagents and the Horiba Reference reagents were found to be as under:

Parameters	Horiba Reference Reagents (CV % - Precision)	VDx Horiba Reagents (CV % - Precision)
Measured Parameters	0.78% – 4.85%	0.51% - 3.44%
Calculated Parameters	0.00% - 5.58%	0.00% - 4.88%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges with VDX Horiba 3 Part Hematology Reagents for all the parameters and Horiba Reference reagents for all the parameters except Hemoglobin for the Low and Normal Controls.
6. **The VDX Horiba 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Horiba reference reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents	174 - 175
2	Background Test	176
3	Coefficient of Correlation: Accuracy	177 – 194
4	Quality Control (Low, Normal & High)	195 - 199
5	Coefficient of Variation: Precision (VDx Dirui Compatible Reagents)	200
6	Conclusions	201

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Dirui – BC 3600
Reference Reagents	Original Sysmex Reagents
Cellpack	Lot No : X2177 Expiry Date: 06-04-2024
Stromatolyser-WH	Lot No : X2030 Expiry Date: 13-04-2023

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Dirui Compatible Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC ($10^3/\mu\text{L}$)	0.0	0.0
RBC ($10^6/\mu\text{L}$)	0.0	0.0
HGB (g/dL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
PLT ($10^3/\mu\text{L}$)	0.0	0.0
LYM# ($10^3/\mu\text{L}$)	0.0	0.0
MXD# ($10^3/\mu\text{L}$)	0.0	0.0
NEUT# ($10^3/\mu\text{L}$)	0.0	0.0
LYM (%)	0.0	0.0
MXD (%)	0.0	0.0
NEUT (%)	0.0	0.0
RDW-CV (%)	0.0	0.0
RDW-SD (fL)	0.0	0.0
PDW (fL)	0.0	0.0
MPV (fL)	0.0	0.0
P-LCR (%)	0.0	0.0
PCT (%)	0.0	0.0
P-LCC ($10^3/\mu\text{L}$)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Dirui Reagents and the Reference Sysmex Reagents.
- II. The Coefficient of Correlation (“r”) was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of “r”
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When “r” is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.

y = VDX Dirui Reagents for Dirui- BC 3600, 3 Part Hematology Analyzer.

$$“r” = 0.998$$

Sample size: 10

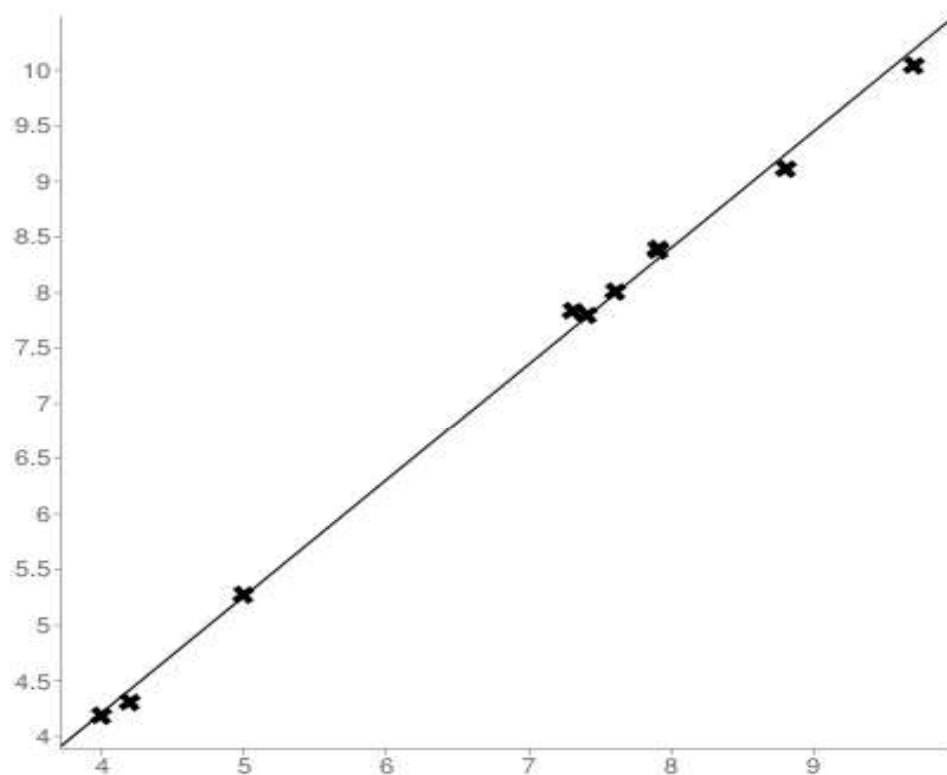
Mean x (x̄): 6.98

Mean y (ȳ): 7.333

Intercept (a): 0.017753899273692

Slope (b): 1.0480295273247

Regression line equation: $y = 0.017753899273692 + 1.0480295273247x$



Coefficient of Correlation (“r”): RBC

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.
y = VDX Dirui Reagents for Dirui- BC3600, 3 Part Hematology Analyzer.

$$“r” = 0.995$$

Sample size: 10

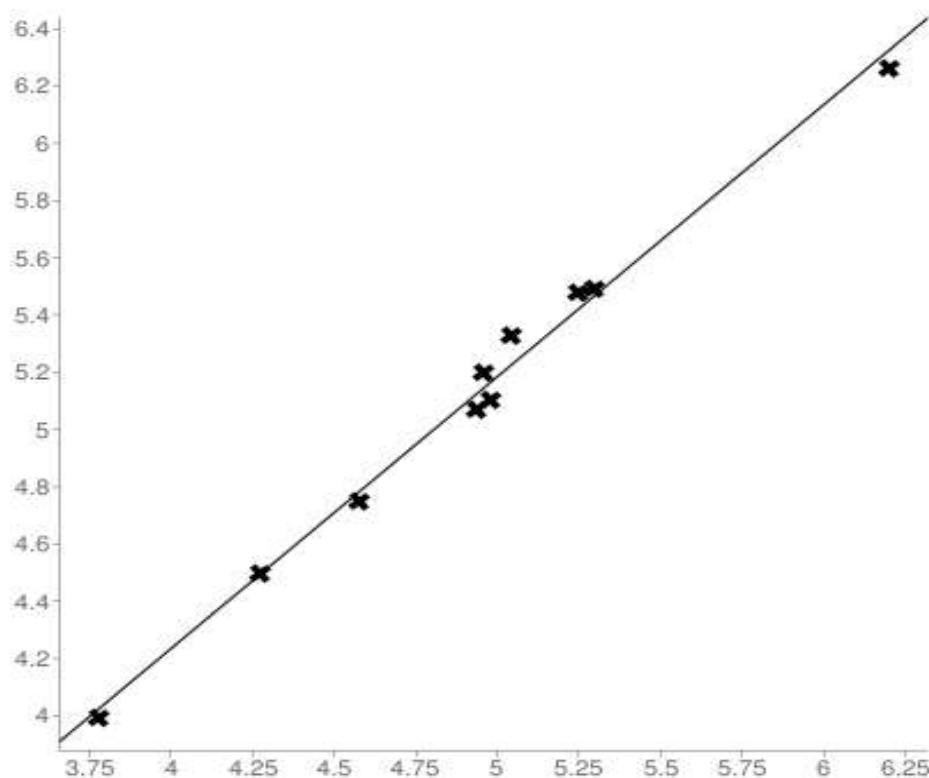
Mean x ($\bar{x}$): 4.93

Mean y ($\bar{y}$): 5.117

Intercept (a): 0.43202694482971

Slope (b): 0.95029879415219

Regression line equation: $y = 0.43202694482971 + 0.95029879415219x$



Coefficient of Correlation (“r”): Hemoglobin

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.

y = VDX Dirui Reagents for Dirui- BC3600, 3 Part Hematology Analyzer.

$$“r” = 0.998$$

Sample size: 10

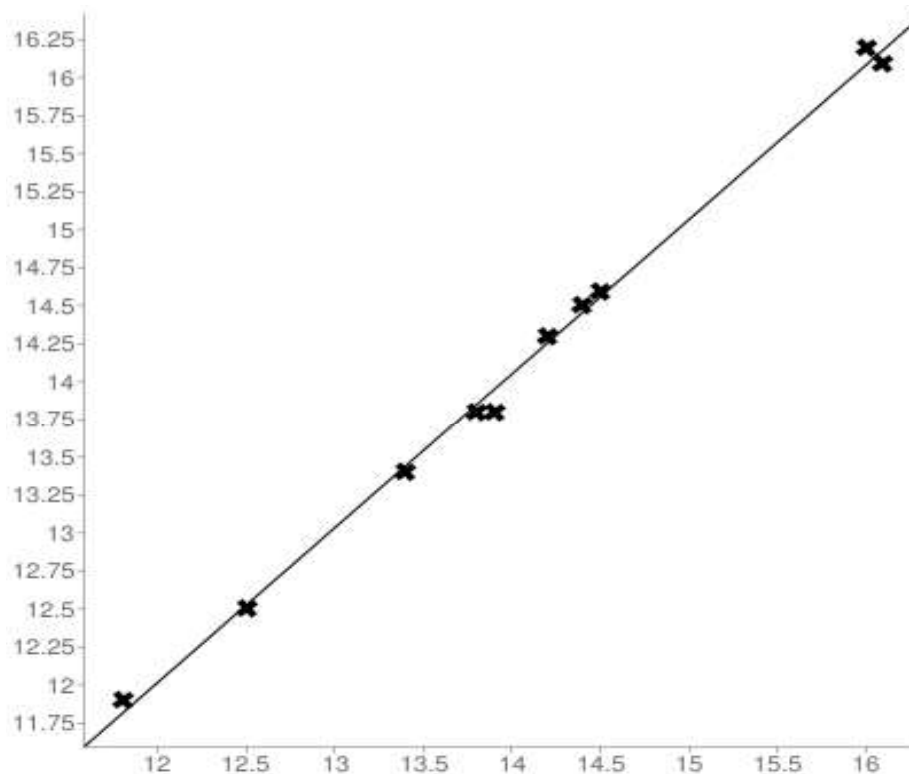
Mean x ($\bar{x}$): 14.06

Mean y ($\bar{y}$): 14.11

Intercept (a): -0.18255329576063

Slope (b): 1.0165400637099

Regression line equation: $y = 1.0165400637099x - 0.18255329576063$



Coefficient of Correlation (“r”): Platelets

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.

y = VDX Dirui Reagents for Dirui- BC3600, 3 Part Hematology Analyzer.

$$“r” = 0.989$$

Sample size: 10

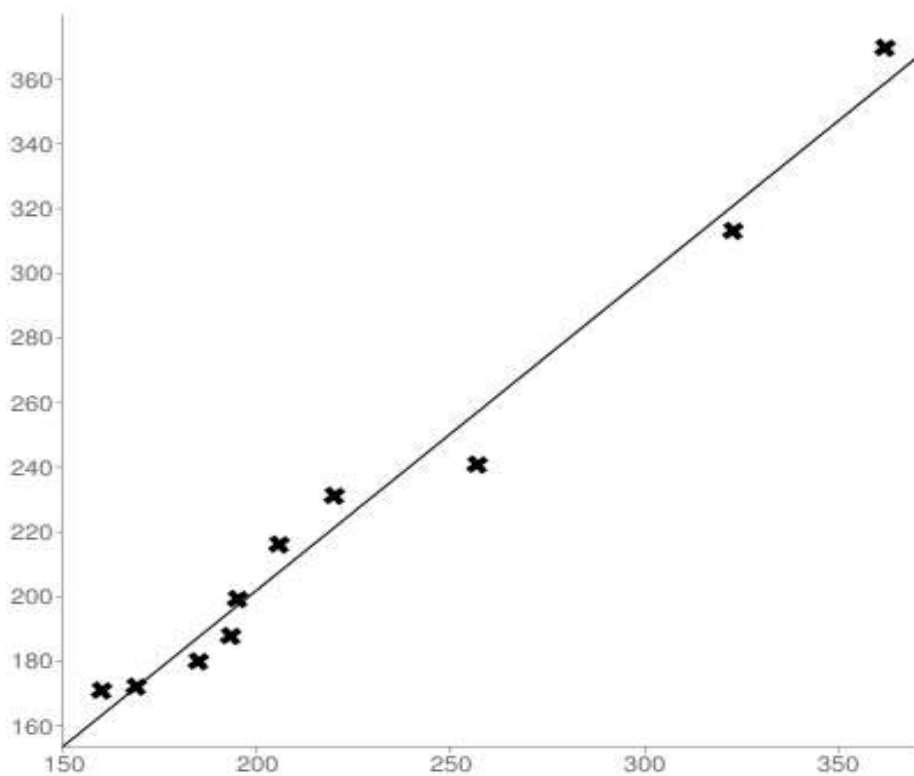
Mean x ($\bar{x}$): 227

Mean y ($\bar{y}$): 228.1

Intercept (a): 8.3969872993994

Slope (b): 0.96785468150044

Regression line equation: $y = 8.3969872993994 + 0.96785468150044x$



Coefficient of Correlation (“r”): MCV

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.
y = VDX Dirui Reagents for Dirui- BC3600, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 10

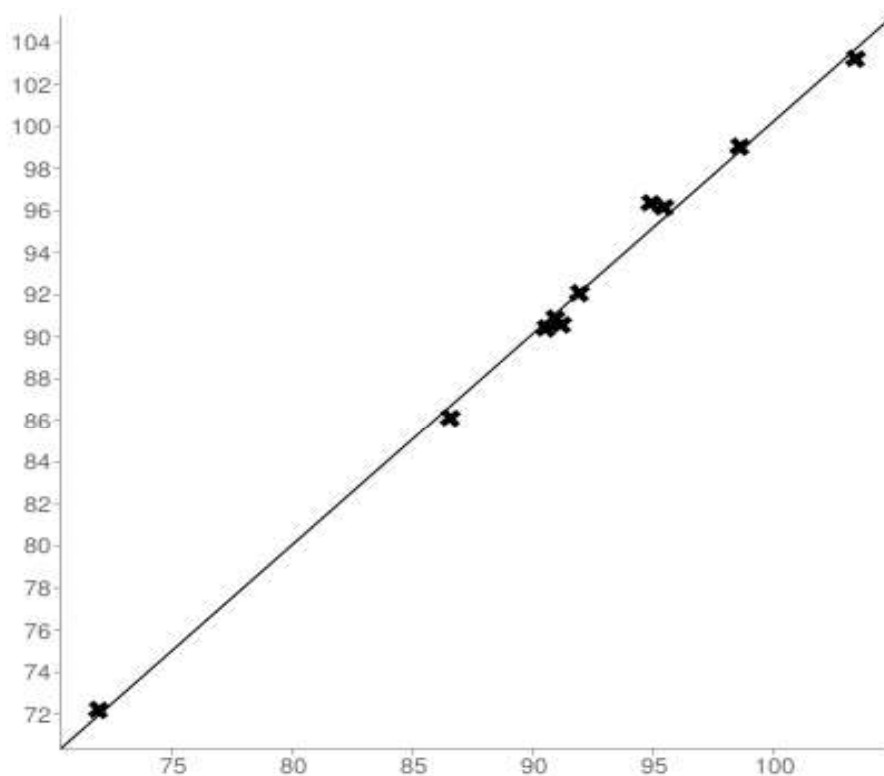
Mean x ($\bar{x}$): 91.52

Mean y ($\bar{y}$): 91.7

Intercept (a): -0.51546105509277

Slope (b): 1.0075990062838

Regression line equation: $y = 1.0075990062838x - 0.51546105509277$



Coefficient of Correlation (“r”): HCT

x = Sysmex Reference Reagents for Sysmex XP100, 3 Part Hematology Analyzer.

y = VDX Dirui Reagents for Dirui- BC3600, 3 Part Hematology Analyzer.

“r” = 0.982

Sample size: 10

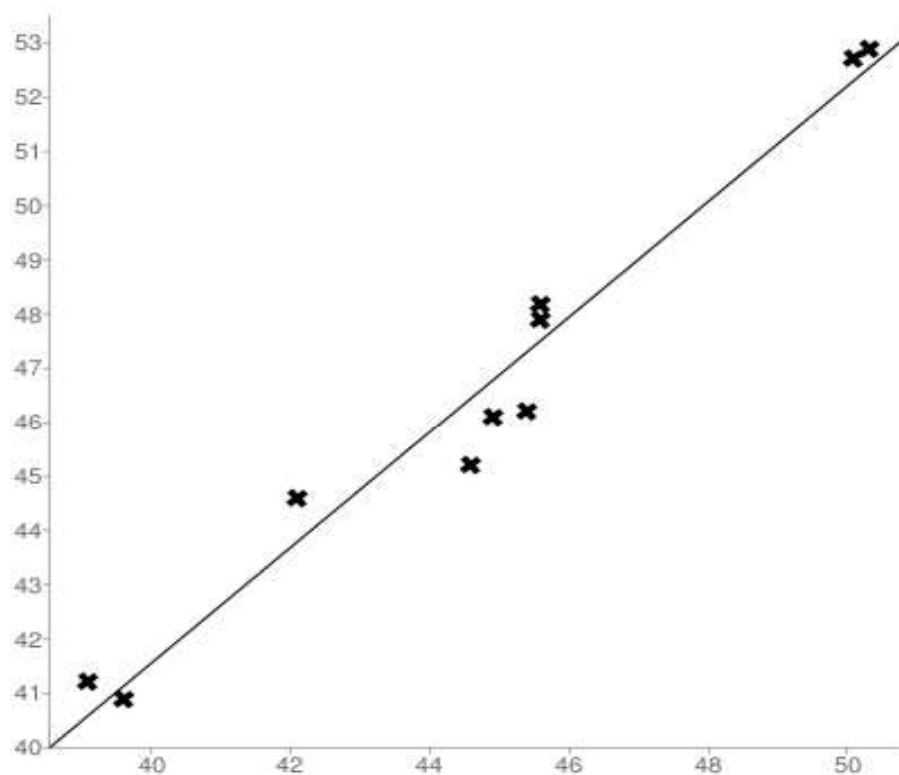
Mean x (x̄): 44.73

Mean y (ȳ): 46.59

Intercept (a): -1.0685925189863

Slope (b): 1.0654726697739

Regression line equation: $y = 1.0654726697739x - 1.0685925189863$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	7.8	7.4
RBC (10 ⁶ /μL)	5.48	5.25
HGB (g/dL)	16.2	16.0
HCT (%)	52.7	50.1
MCV (fL)	96.2	95.4
MCH (pg)	29.6	30.5
MCHC (g/dL)	30.7	31.9
PLT (10 ³ /μL)	180	185
LYM# (10 ³ /μL)	2.5	2.3
MXD# (10 ³ /μL)	0.97	0.8
NEUT# (10 ³ /μL)	4.3	4.3
LYM (%)	32.1	31.7
MXD (%)	12.5	11.0
NEUT (%)	55.4	57.3
RDW-CV (%)	15.5	13.0
RDW-SD (fL)	44.5	NA
PDW (fL)	19.4	25.3
MPV (fL)	13.8	13.5
P-LCR (%)	34.7	53.2
PCT (%)	0.248	NA
P-LCC (10 ³ /μL)	62	NA

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	7.83	7.3
RBC (10 ⁶ /μL)	5.49	5.30
HGB (g/dL)	16.1	16.1
HCT (%)	52.9	50.3
MCV (fL)	96.3	94.9
MCH (pg)	29.3	30.4
MCHC (g/dL)	30.4	32.0
PLT (10 ³ /μL)	172	169
LYM# (10 ³ /μL)	2.5	2.3
MXD# (10 ³ /μL)	1.11	1.0
NEUT# (10 ³ /μL)	4.2	4.0
LYM (%)	32.1	31.1
MXD (%)	14.1	14.0
NEUT (%)	53.8	54.9
RDW-CV (%)	15.5	12.7
RDW-SD (fL)	44.5	NA
PDW (fL)	19.4	24.4
MPV (fL)	14.3	13.7
P-LCR (%)	35.6	53.4
PCT (%)	0.246	NA
P-LCC (10 ³ /μL)	61	NA

Sample - 03

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	10.04	9.7
RBC (10 ⁶ /μL)	4.75	4.58
HGB (g/dL)	12.5	12.5
HCT (%)	40.9	39.6
MCV (fL)	86.1	86.5
MCH (pg)	26.3	27.3
MCHC (g/dL)	30.6	31.6
PLT (10 ³ /μL)	313	323
LYM# (10 ³ /μL)	3.6	3.6
MXD# (10 ³ /μL)	1.03	0.9
NEUT# (10 ³ /μL)	5.5	5.2
LYM (%)	35.5	37.6
MXD (%)	10.3	8.9
NEUT (%)	54.2	53.5
RDW-CV (%)	13.7	13.1
RDW-SD (fL)	41.0	NA
PDW (fL)	18.5	20.2
MPV (fL)	12.9	12.3
P-LCR (%)	32.9	43.5
PCT (%)	0.404	NA
P-LCC (10 ³ /μL)	103	NA

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	5.28	5.0
RBC (10 ⁶ /μL)	5.20	4.96
HGB (g/dL)	14.6	14.5
HCT (%)	47.9	45.6
MCV (fL)	92.1	91.9
MCH (pg)	28.1	29.2
MCHC (g/dL)	30.5	31.8
PLT (10 ³ /μL)	231	220
LYM# (10 ³ /μL)	1.3	1.2
MXD# (10 ³ /μL)	0.75	0.5
NEUT# (10 ³ /μL)	3.3	3.3
LYM (%)	24.1	24.4
MXD (%)	14.3	10.8
NEUT (%)	61.6	64.8
RDW-CV (%)	15.1	14.7
RDW-SD (fL)	44.5	NA
PDW (fL)	19.0	19.8
MPV (fL)	13.7	13.2
P-LCR (%)	35.1	50.9
PCT (%)	0.316	NA
P-LCC (10 ³ /μL)	81	NA

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	4.18	4.0
RBC (10 ⁶ /μL)	5.07	4.94
HGB (g/dL)	13.8	13.8
HCT (%)	46.1	44.9
MCV (fL)	90.9	90.9
MCH (pg)	27.2	27.9
MCHC (g/dL)	29.9	30.7
PLT (10 ³ /μL)	171	160
LYM# (10 ³ /μL)	1.2	1.2
MXD# (10 ³ /μL)	0.73	0.7
NEUT# (10 ³ /μL)	2.2	2.1
LYM (%)	29.5	30.2
MXD (%)	17.4	16.7
NEUT (%)	53.1	53.1
RDW-CV (%)	15.8	14.1
RDW-SD (fL)	44.5	NA
PDW (fL)	20.0	0.0
MPV (fL)	14.6	0.0
P-LCR (%)	36.4	0.0
PCT (%)	0.250	NA
P-LCC (10 ³ /μL)	62	NA

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC ($10^3/\mu\text{L}$)	8.38	7.9
RBC ($10^6/\mu\text{L}$)	5.33	5.04
HGB (g/dL)	14.5	14.4
HCT (%)	48.2	45.6
MCV (fL)	90.4	90.5
MCH (pg)	27.2	28.6
MCHC (g/dL)	30.1	31.6
PLT ($10^3/\mu\text{L}$)	199	195
LYM# ($10^3/\mu\text{L}$)	1.8	1.8
MXD# ($10^3/\mu\text{L}$)	0.96	0.9
NEUT# ($10^3/\mu\text{L}$)	5.6	5.2
LYM (%)	21.8	22.7
MXD (%)	11.4	11.2
NEUT (%)	66.8	66.1
RDW-CV (%)	15.3	13.1
RDW-SD (fL)	41.9	NA
PDW (fL)	19.1	0.0
MPV (fL)	14.9	0.0
P-LCR (%)	37.1	0.0
PCT (%)	0.297	NA
P-LCC ($10^3/\mu\text{L}$)	74	NA

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	8.01	7.6
RBC (10 ⁶ /μL)	6.26	6.20
HGB (g/dL)	11.9	11.8
HCT (%)	45.2	44.6
MCV (fL)	72.2	71.9
MCH (pg)	19.0	19.0
MCHC (g/dL)	26.3	26.5
PLT (10 ³ /μL)	221	257
LYM# (10 ³ /μL)	2.4	2.1
MXD# (10 ³ /μL)	0.77	0.5
NEUT# (10 ³ /μL)	4.9	5.0
LYM (%)	29.7	27.6
MXD (%)	9.6	6.3
NEUT (%)	60.7	66.1
RDW-CV (%)	17.1	16.4
RDW-SD (fL)	37.6	NA
PDW (fL)	13.4	0.0
MPV (fL)	11.9	0.0
P-LCR (%)	32.0	0.0
PCT (%)	0.263	NA
P-LCC (10 ³ /μL)	71	NA

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	4.30	4.2
RBC (10 ⁶ /μL)	4.50	4.27
HGB (g/dL)	13.8	13.9
HCT (%)	44.6	42.1
MCV (fL)	99.0	98.6
MCH (pg)	30.7	32.6
MCHC (g/dL)	30.9	33.0
PLT (10 ³ /μL)	216	206
LYM# (10 ³ /μL)	1.9	1.9
MXD# (10 ³ /μL)	0.43	0.4
NEUT# (10 ³ /μL)	2.0	1.9
LYM (%)	43.4	44.9
MXD (%)	10.1	8.7
NEUT (%)	46.5	46.4
RDW-CV (%)	13.5	12.2
RDW-SD (fL)	45.3	NA
PDW (fL)	15.8	13.5
MPV (fL)	10.6	10.3
P-LCR (%)	26.6	28.1
PCT (%)	0.229	NA
P-LCC (10 ³ /μL)	57	NA

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	9.11	8.8
RBC (10 ⁶ /μL)	3.99	3.78
HGB (g/dL)	13.4	13.4
HCT (%)	41.2	39.1
MCV (fL)	103.2	103.4
MCH (pg)	33.6	35.4
MCHC (g/dL)	32.5	34.3
PLT (10 ³ /μL)	370	362
LYM# (10 ³ /μL)	2.9	2.9
MXD# (10 ³ /μL)	1.09	0.7
NEUT# (10 ³ /μL)	5.1	5.2
LYM (%)	31.8	32.6
MXD (%)	11.9	7.8
NEUT (%)	56.3	59.6
RDW-CV (%)	16.5	15.6
RDW-SD (fL)	52.2	NA
PDW (fL)	15.0	13.1
MPV (fL)	10.3	10.1
P-LCR (%)	25.8	26.5
PCT (%)	0.381	NA
P-LCC (10 ³ /μL)	95	NA

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent Lot - HDITS221106 VDx Lyse Lot - HLITS221102	All Reagents: Sysmex as Reference Cellpack Lot - X2177 Stromatolyser Lot - X2030
WBC (10 ³ /μL)	8.40	7.9
RBC (10 ⁶ /μL)	5.10	4.98
HGB (g/dL)	14.3	14.2
HCT (%)	46.2	45.4
MCV (fL)	90.6	91.2
MCH (pg)	28.0	28.5
MCHC (g/dL)	31.0	31.3
PLT (10 ³ /μL)	188	193
LYM# (10 ³ /μL)	1.9	1.7
MXD# (10 ³ /μL)	0.93	0.8
NEUT# (10 ³ /μL)	5.6	5.4
LYM (%)	22.3	21.9
MXD (%)	11.0	10.4
NEUT (%)	66.7	67.7
RDW-CV (%)	14.2	13.1
RDW-SD (fL)	42.8	NA
PDW (fL)	19.1	0.0
MPV (fL)	14.6	0.0
P-LCR (%)	36.4	0.0
PCT (%)	0.274	NA
P-LCC (10 ³ /μL)	68	NA

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D

(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent, Lot - HDITS221106 VDx Lyse, Lot - HLITS221102	Range
WBC (10 ³ /μL)	2.13	1.35 - 2.35
RBC (10 ⁶ /μL)	2.41	2.15 - 2.55
HGB (g/dL)	6.9	6.3 - 7.3
HCT (%)	19.4	15.6 - 21.6
MCV (fL)	80.7	73.1 - 85.1
MCH (pg)	28.6	25.1 - 32.7
MCHC (g/dL)	35.6	31.7 - 41.3
PLT (10 ³ /μL)	81	55 - 105
LYM# (10 ³ /μL)	1.36	0.62 - 1.64
MXD# (10 ³ /μL)	0.17	0.08 - 0.20
NEUT# (10 ³ /μL)	0.6	0.49 - 0.67
LYM (%)	63.8	39.7 - 82.5
MXD (%)	7.8	4.5 - 10.5
NEUT (%)	28.4	26.7 - 36.1
RDW-CV (%)	13.9	8.3 - 18.3
RDW-SD (fL)	34.2	24.6 - 40.6
PDW (fL)	16.6	13.0 - 19.0
MPV (fL)	11.5	8.1 - 14.1
P-LCR (%)	28.8	6.8 - 46.8
PCT (%)	0.093	0.04 - 0.14
P-LCC (10 ³ /μL)	23	

Diagon D Check D		
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent, Lot- HDITS221106 VDx Lyse, Lot- HLITS221102	Range
WBC ($10^3/\mu\text{L}$)	6.0	4.71 - 6.71
RBC ($10^6/\mu\text{L}$)	4.36	4.06 - 4.66
HGB (g/dL)	13.6	12.7 - 13.9
HCT (%)	37.6	32.6 - 41.6
MCV (fL)	86.3	79.2 - 91.2
MCH (pg)	31.2	26.8 - 34.4
MCHC (g/dL)	36.2	31.1 - 40.7
PLT ($10^3/\mu\text{L}$)	230	181 - 271
LYM# ($10^3/\mu\text{L}$)	2.42	1.69 - 2.83
MXD# ($10^3/\mu\text{L}$)	0.59	0.32 - 0.94
NEUT# ($10^3/\mu\text{L}$)	2.99	2.4 - 3.24
LYM (%)	40.3	29.7 - 49.5
MXD (%)	9.9	5.5 - 16.5
NEUT (%)	49.8	42.0 - 56.8
RDW-CV (%)	13.7	8.4 - 18.4
RDW-SD (fL)	35.1	25.2 - 43.2
PDW (fL)	12.2	9.4 - 15.4
MPV (fL)	11.2	7.7 - 13.7
P-LCR (%)	30.1	7.2 - 47.2
PCT (%)	0.258	0.09 - 0.39
P-LCC ($10^3/\mu\text{L}$)	69	

Diagon D Check D

(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent, Lot- HDITS221106 VDx Lyse, Lot- HLITS221102	Range
WBC ($10^3/\mu\text{L}$)	14.48	10.97 - 15.97
RBC ($10^6/\mu\text{L}$)	5.36	4.96 - 5.76
HGB (g/dL)	17.6	16.6 - 18.2
HCT (%)	49.5	44.2 - 53.2
MCV (fL)	92.3	84.9 - 96.9
MCH (pg)	32.8	28.7 - 36.3
MCHC (g/dL)	35.6	31.0 - 40.6
PLT ($10^3/\mu\text{L}$)	461	411 - 541
LYM# ($10^3/\mu\text{L}$)	4.49	3.31 - 4.57
MXD# ($10^3/\mu\text{L}$)	1.84	0.82 - 2.46
NEUT# ($10^3/\mu\text{L}$)	8.15	6.35 - 9.53
LYM (%)	31	24.6 - 33.2
MXD (%)	12.7	6.1 - 18.3
NEUT (%)	56.3	47.1 - 70.7
RDW-CV (%)	13.2	8.0 - 18.0
RDW-SD (fL)	37.6	26.0 - 46.0
PDW (fL)	11	7.7 - 13.7
MPV (fL)	11.6	7.9 - 13.9
P-LCR (%)	33.3	9.8 - 49.8
PCT (%)	0.535	0.22 - 0.82
P-LCC ($10^3/\mu\text{L}$)	154	

ASSAY VALUES AND EXPECTED RANGES

05-03-2023

Instruments:		iCount3 TS					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	1,85 ± 0,50	1,35 - 2,35	5,71 ± 1,00	4,71 - 6,71	13,47 ± 2,50	10,97 - 15,97
RBC	10 ¹² /L	2,35 ± 0,20	2,15 - 2,55	4,36 ± 0,30	4,06 - 4,66	5,36 ± 0,40	4,96 - 5,76
Hgb	g/dL	6,8 ± 0,5	6,3 - 7,3	13,3 ± 0,6	12,7 - 13,9	17,4 ± 0,8	16,6 - 18,2
	g/L	68 ± 5	63 - 73	133 ± 6	127 - 139	174 ± 8	166 - 182
Hct	%	18,6 ± 3,0	15,6 - 21,6	37,1 ± 4,5	32,6 - 41,6	48,7 ± 4,5	44,2 - 53,2
	L/L	0,186 ± 0,030	0,156 - 0,216	0,371 ± 0,045	0,326 - 0,416	0,487 ± 0,045	0,442 - 0,532
MCV	fL	79,1 ± 6,0	73,1 - 85,1	85,2 ± 6,0	79,2 - 91,2	90,9 ± 6,0	84,9 - 96,9
MCH	pg	28,9 ± 3,8	25,1 - 32,7	30,6 ± 3,8	26,8 - 34,4	32,5 ± 3,8	28,7 - 36,3
MCHC	g/dL	36,5 ± 4,8	31,7 - 41,3	35,9 ± 4,8	31,1 - 40,7	35,8 ± 4,8	31,0 - 40,6
	g/L	365 ± 48	317 - 413	359 ± 48	311 - 407	358 ± 48	310 - 406
RDW-SD	fL	32,6 ± 8,0	24,6 - 40,6	34,2 ± 9,0	25,2 - 43,2	36,0 ± 10,0	26,0 - 46,0
RDW-CV	%	13,3 ± 5,0	8,3 - 18,3	13,4 ± 5,0	8,4 - 18,4	13,0 ± 5,0	8,0 - 18,0
Plt	10 ⁹ /L	80 ± 25	55 - 105	226 ± 45	181 - 271	476 ± 65	411 - 541
MPV	fL	11,1 ± 3,0	8,1 - 14,1	10,7 ± 3,0	7,7 - 13,7	10,9 ± 3,0	7,9 - 13,9
PCT	%	0,09 ± 0,05	0,04 - 0,14	0,24 ± 0,15	0,09 - 0,39	0,52 ± 0,30	0,22 - 0,82
PDW	fL	16,0 ± 3,0	13,0 - 19,0	12,4 ± 3,0	9,4 - 15,4	10,7 ± 3,0	7,7 - 13,7
P-LCR		26,8 ± 20,0	6,8 - 46,8	27,2 ± 20,0	7,2 - 47,2	29,8 ± 20,0	9,8 - 49,8
LYM#	10 ⁹ /L	1,13 ± 0,51	0,62 - 1,64	2,26 ± 0,57	1,69 - 2,83	3,89 ± 0,58	3,31 - 4,47
MXD#	10 ⁹ /L	0,14 ± 0,06	0,08 - 0,20	0,63 ± 0,31	0,32 - 0,94	1,64 ± 0,82	0,82 - 2,46
NEUT#	10 ⁹ /L	0,58 ± 0,09	0,49 - 0,67	2,82 ± 0,42	2,40 - 3,24	7,94 ± 1,59	6,35 - 9,53
LYM%	%	61,1 ± 21,4	39,7 - 82,5	39,6 ± 9,9	29,7 - 49,5	28,9 ± 4,3	24,6 - 33,2
MXD%	%	7,5 ± 3,0	4,5 - 10,5	11,0 ± 5,5	5,5 - 16,5	12,2 ± 6,1	6,1 - 18,3
NEUT%	%	31,4 ± 4,7	26,7 - 36,1	49,4 ± 7,4	42,0 - 56,8	58,9 ± 11,8	47,1 - 70,7



DIAGON Ltd
 48-52., Baross Str.
 Budapest, Hungary
 H-1047


IVD


Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Dirui Reagents on Dirui – BC 3600, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 07

Precision Evaluation report of VDx Dirui Compatible reagent on Dirui-BC3600, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIInd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	6.87	6.71	6.5	6.7	6.61	6.75	6.8				6.71	0.12	0.02	1.82
RBC ($10^6/\mu\text{L}$)	6.42	6.55	6.52	6.35	6.48	6.58	6.57				6.50	0.09	0.01	1.31
HGB (g/dL)	11.7	11.9	11.6	11.7	11.6	11.7	11.8				11.71	0.11	0.01	0.91
HCT (%)	43.3	44	43.7	42.4	43.1	43.8	43.7				43.43	0.55	0.01	1.26
MCV (fL)	67.4	67.2	67	66.8	66.5	66.6	66.5				66.86	0.36	0.01	0.53
MCH (pg)	18.2	18.2	17.8	18.4	17.9	17.8	18				18.04	0.23	0.01	1.27
MCHC (g/dL)	27.0	27.0	26.5	27.6	26.9	26.7	27.0				26.96	0.34	0.01	1.26
PLT ($10^3/\mu\text{L}$)	254	264	249	249	251	247	253				252.43	5.65	0.02	2.24
LYM# ($10^3/\mu\text{L}$)	2.49	2.57	2.40	2.48	2.43	2.49	2.57				2.49	0.06	0.03	2.57
MXD# ($10^3/\mu\text{L}$)	0.64	0.57	0.63	0.62	0.64	0.61	0.61				0.62	0.02	0.04	3.94
NEUT# ($10^3/\mu\text{L}$)	3.68	3.57	3.47	3.6	3.54	3.65	3.55				3.58	0.07	0.02	1.98
LYM (%)	36.2	38.3	37	37	36.7	36.9	37.8				37.13	0.70	0.02	1.89
MXD (%)	10.1	9.0	9.6	9.3	9.6	9.1	10.0				9.53	0.42	0.04	4.44
NEUT (%)	53.7	53.2	53.4	53.7	53.7	54	52.2				53.41	0.59	0.01	1.11
RDW-CV (%)	17	16.4	16.4	16.4	18	18	18				17.17	0.80	0.05	4.68
RDW-SD (fL)	35.1	35.9	35.9	35.1	35.1	35.1	35.1				35.33	0.39	0.01	1.10
PDW (fL)	13.8	13.6	14.3	13.8	13.5	14.3	13.4				13.81	0.36	0.03	2.62
MPV (fL)	10.8	10.9	11.0	10.8	10.9	11.1	10.8				10.90	0.12	0.01	1.06
P-LCR (%)	28.3	28.7	29.0	28.3	29.2	29.0	28.4				28.70	0.37	0.01	1.30
PCT (%)	0.274	0.288	0.274	0.269	0.274	0.274	0.273				0.28	0.01	0.02	2.16
P-LCC ($10^3/\mu\text{L}$)	72	76	72	70	73	72	72				72.43	1.81	0.03	2.50

Conclusions

1. The VDX Dirui 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Sysmex original Reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.982 to 0.998** displaying the highest degree of correlation between the reagents.
3. The VDX Dirui 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
4. The CV % of with the VDX Dirui Reagents were found to be as under:

Parameters	VDX Dirui Reagents (CV % - Precision)
Measured Parameters	0.53% - 2.24%
Calculated Parameters	1.06% - 4.68%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges for VDX Dirui 3 Part Hematology Reagents.
6. **The VDX Dirui 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Sysmex Reference Reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	204 – 205
2	Background Test	206
3	Coefficient of Correlation: Accuracy	207 – 222
4	Quality Control (Low, Normal & High)	223 - 227
5	Coefficient of Variation: Precision (VDx Urit Compatible Reagents)	228 - 229
6	Conclusions	230

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Urit – 2900 Plus
Reference Reagents	Mindray Reference Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date : 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date : 15-02-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Urit Compatible Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	0.00	0.00
Lym (%)	0.00	0.00
MID (%)	0.00	0.00
Gran (%)	0.00	0.00
Lym# (10 ⁹ /L)	0.00	0.00
MID# (10 ⁹ /L)	0.00	0.00
Gran# (10 ⁹ /L)	0.00	0.00
RBC (10 ¹² /L)	0.00	0.00
HGB (g/dL)	0.00	0.00
HCT (%)	0.00	0.00
MCV (fL)	0.00	0.00
MCH (pg)	0.00	0.00
MCHC (g/dL)	0.00	0.00
RDW-CV (%)	0.00	0.00
RDW-SD (fL)	0.00	0.00
PLT (10 ⁹ /L)	0.00	0.00
MPV (fL)	0.00	0.00
PDW (fL)	0.00	0.00
PCT (%)	0.00	0.00
P-LCR (%)	0.00	
P-LCC (10 ⁹ /L)	0.00	

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Urit Reagents and the Mindray Reference Reagents.
- II. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

Coefficient of Correlation (“r”): WBC

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 8

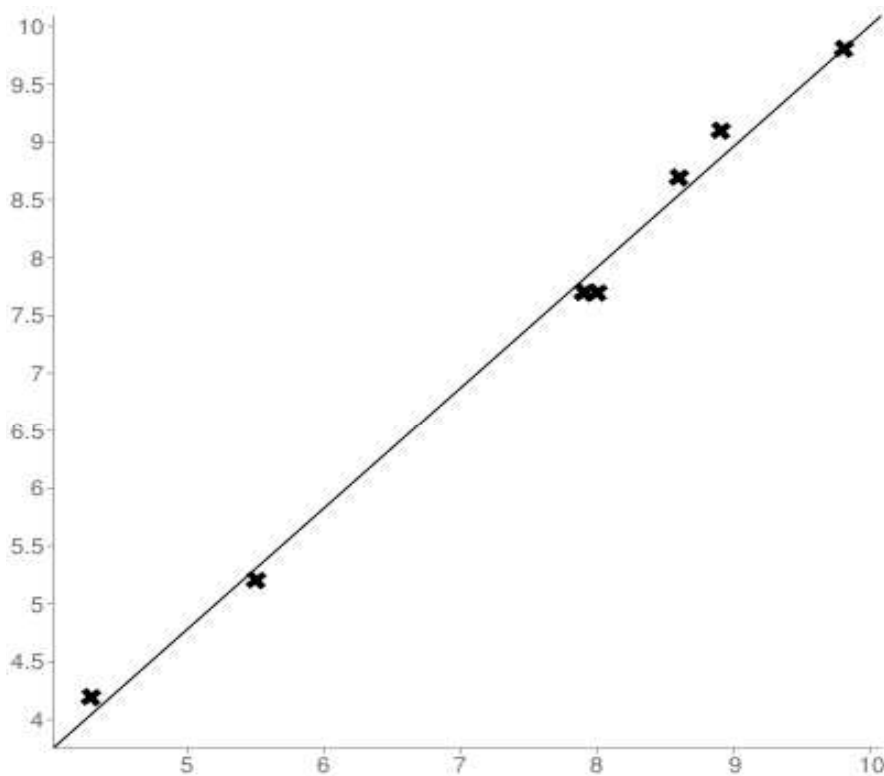
Mean x ($\bar{x}$): 7.6125

Mean y ($\bar{y}$): 7.5125

Intercept (a): -0.4581386565956

Slope (b): 1.0470461289452

Regression line equation: $y = 1.0470461289452x - 0.4581386565956$



Coefficient of Correlation (“r”): RBC

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 8

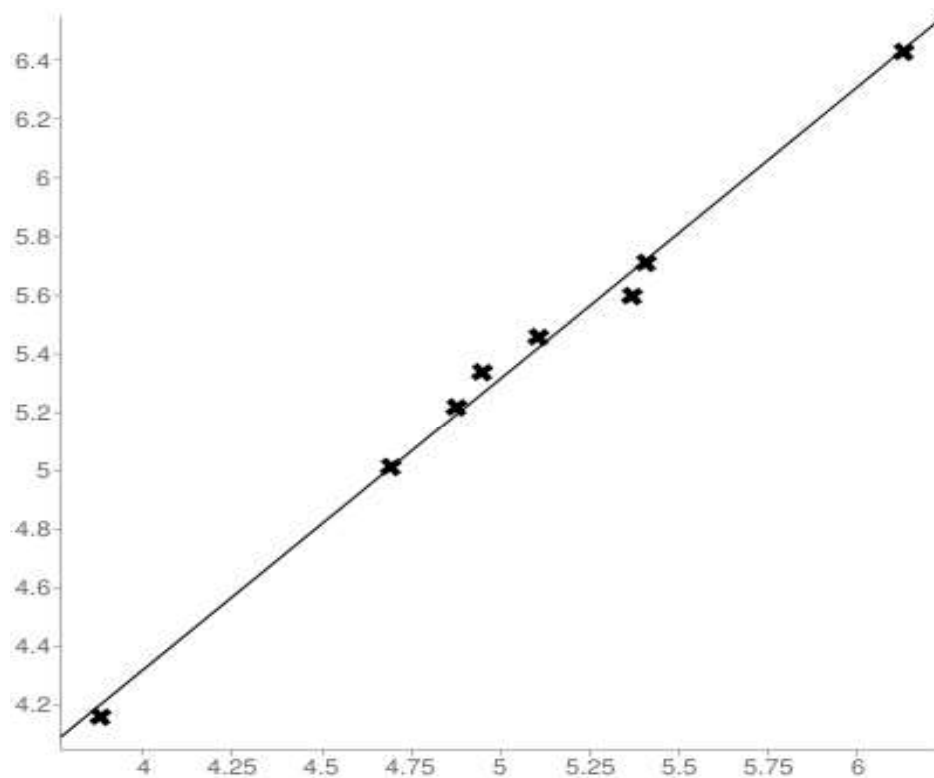
Mean x ($\bar{x}$): 5.0525

Mean y ($\bar{y}$): 5.36625

Intercept (a): 0.34688213380503

Slope (b): 0.99344242774764

Regression line equation: $y = 0.34688213380503 + 0.99344242774764x$



Coefficient of Correlation (“r”): Hemoglobin

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

“r” = 0.965

Sample size: 8

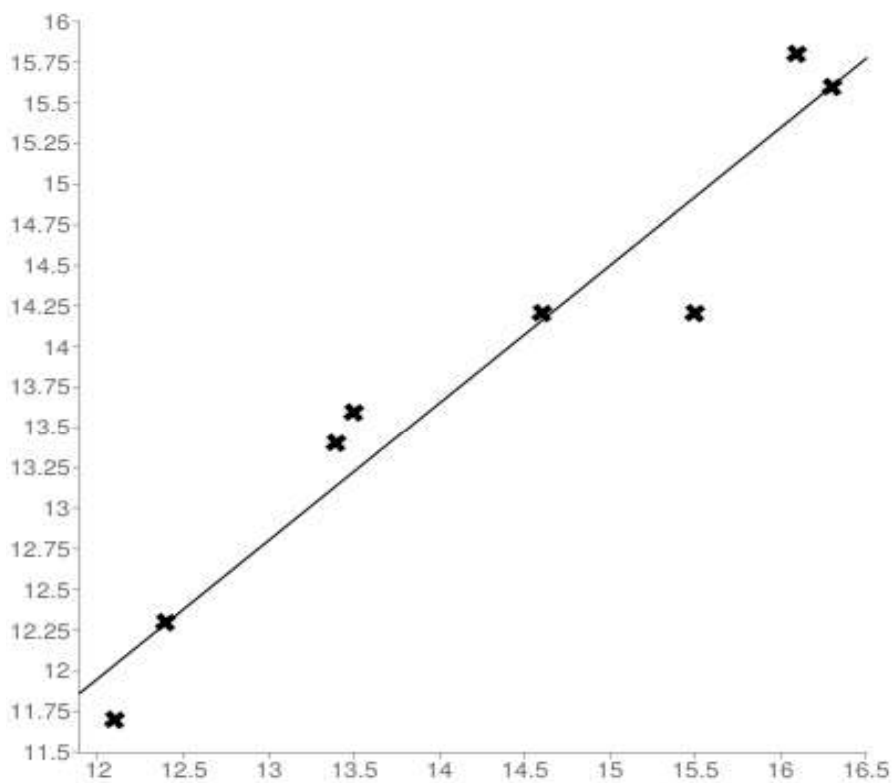
Mean x ($\bar{x}$): 14.2375

Mean y ($\bar{y}$): 13.85

Intercept (a): 1.7694654952723

Slope (b): 0.8485011065656

Regression line equation: $y = 1.7694654952723 + 0.8485011065656x$



Coefficient of Correlation (“r”): Platelets

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.986$$

Sample size: 8

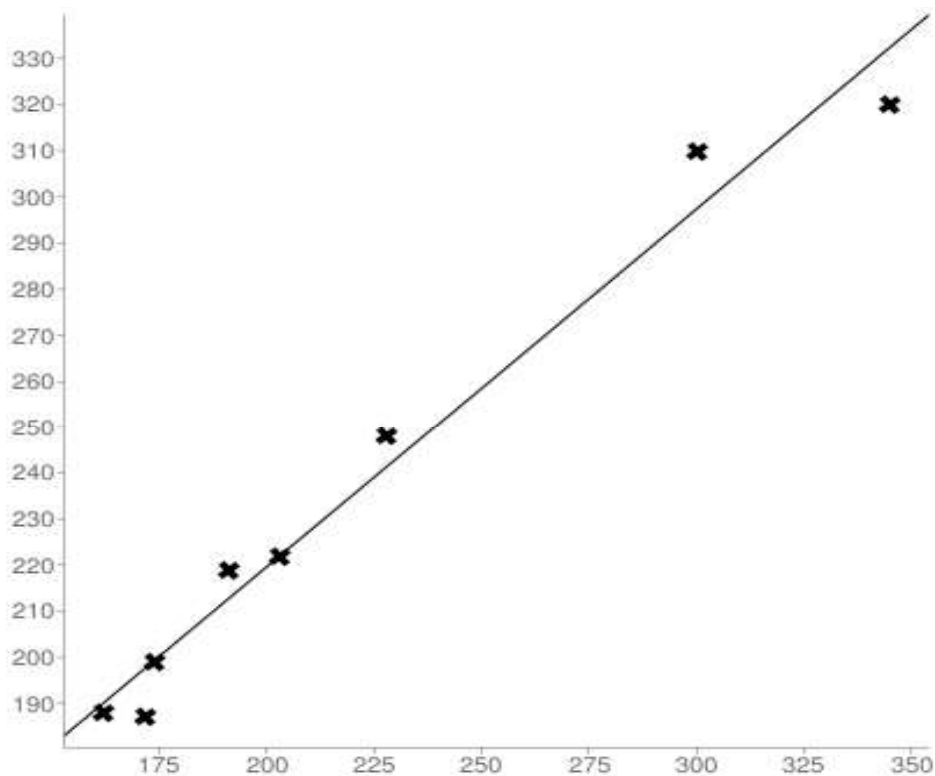
Mean x ($\bar{x}$): 221.875

Mean y ($\bar{y}$): 236.625

Intercept (a): 64.16976662537

Slope (b): 0.77726302366031

Regression line equation: $y = 64.16976662537 + 0.77726302366031x$



Coefficient of Correlation (“r”): MCV

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 8

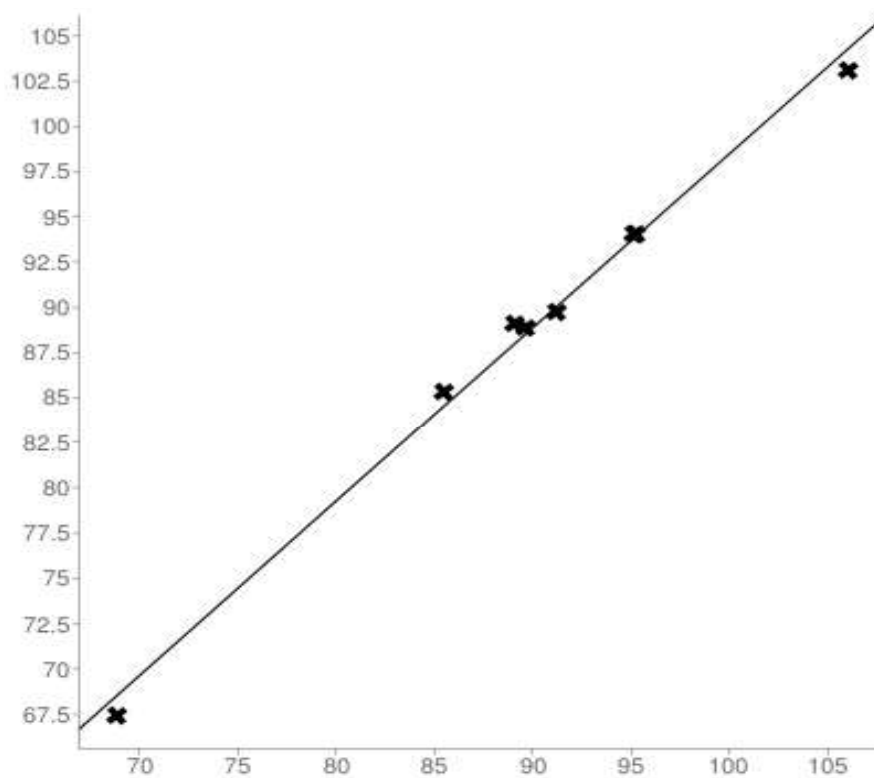
Mean x (x̄): 90.1

Mean y (ȳ): 88.95

Intercept (a): 2.3927692151168

Slope (b): 0.96067958695764

Regression line equation: $y = 2.3927692151168 + 0.96067958695764x$



Coefficient of Correlation (“r”): HCT

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.

y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.986$$

Sample size: 8

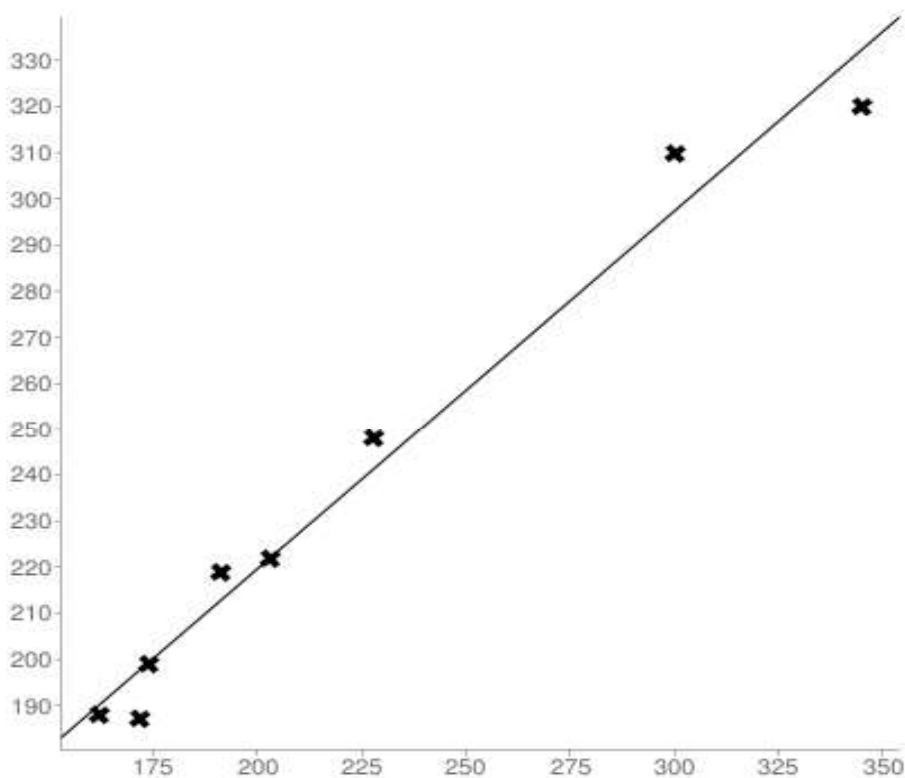
Mean x (x̄): 221.875

Mean y (ȳ): 236.625

Intercept (a): 64.16976662537

Slope (b): 0.77726302366031

Regression line equation: $y = 64.16976662537 + 0.77726302366031x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot-2022091601 M-30CF Lyse Lot-2022021601
WBC (10 ⁹ /L)	7.70	7.90
Lym (%)	29.00	30.40
MID (%)	6.20	9.80
Gran (%)	64.80	59.80
Lym# (10 ⁹ /L)	2.30	2.40
MID# (10 ⁹ /L)	0.50	0.80
Gran# (10 ⁹ /L)	5.00	4.70
RBC (10 ¹² /L)	5.71	5.41
HGB (g/dL)	15.80	16.10
HCT (%)	53.60	51.50
MCV (fL)	94.00	95.20
MCH (pg)	27.60	29.70
MCHC (g/dL)	29.40	31.20
RDW-CV (%)	13.00	12.60
RDW-SD (fL)	45.70	43.80
PLT (10 ⁹ /L)	187.00	172.00
MPV (fL)	11.80	10.90
PDW (fL)	20.70	15.90
PCT (%)	0.22	0.19
P-LCR (%)	41.90	NA
P-LCC (10 ⁹ /L)	77.00	NA

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	7.70	7.90
Lym (%)	30.80	33.80
MID (%)	6.10	8.30
Gran (%)	63.10	57.90
Lym# (10 ⁹ /L)	2.40	2.70
MID# (10 ⁹ /L)	0.50	0.60
Gran# (10 ⁹ /L)	4.80	4.60
RBC (10 ¹² /L)	5.60	5.37
HGB (g/dL)	15.60	16.30
HCT (%)	53.10	51.10
MCV (fL)	94.10	95.30
MCH (pg)	27.60	30.30
MCHC (g/dL)	29.30	31.80
RDW-CV (%)	13.00	12.90
RDW-SD (fL)	45.70	43.80
PLT (10 ⁹ /L)	199.00	174.00
MPV (fL)	12.70	11.20
PDW (fL)	20.70	15.40
PCT (%)	0.25	0.19
P-LCR (%)	44.60	
P-LCC (10 ⁹ /L)	88.00	

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot-2022021601
WBC (10 ⁹ /L)	9.80	9.80
Lym (%)	33.80	35.00
MID (%)	7.00	7.90
Gran (%)	59.20	57.10
Lym# (10 ⁹ /L)	3.30	3.40
MID# (10 ⁹ /L)	0.70	0.80
Gran# (10 ⁹ /L)	5.80	5.60
RBC (10 ¹² /L)	5.01	4.69
HGB (g/dL)	12.30	12.40
HCT (%)	42.70	40.00
MCV (fL)	85.30	85.50
MCH (pg)	24.50	26.40
MCHC (g/dL)	28.80	31.00
RDW-CV (%)	13.60	13.50
RDW-SD (fL)	42.60	41.10
PLT (10 ⁹ /L)	310.00	300.00
MPV (fL)	10.80	10.30
PDW (fL)	18.20	15.60
PCT (%)	0.33	0.31
P-LCR (%)	35.90	
P-LCC (10 ⁹ /L)	111.00	

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot -2022021601
WBC (10 ⁹ /L)	5.20	5.50
Lym (%)	25.60	28.60
MID (%)	7.10	8.90
Gran (%)	67.30	62.50
Lym# (10 ⁹ /L)	1.30	1.60
MID# (10 ⁹ /L)	0.40	0.50
Gran# (10 ⁹ /L)	3.50	3.40
RBC (10 ¹² /L)	5.34	4.95
HGB (g/dL)	14.20	14.50
HCT (%)	47.80	45.10
MCV (fL)	89.70	91.20
MCH (pg)	26.50	29.00
MCHC (g/dL)	29.70	32.10
RDW-CV (%)	14.40	13.90
RDW-SD (fL)	45.70	44.60
PLT (10 ⁹ /L)	222.00	203.00
MPV (fL)	10.90	11.00
PDW (fL)	21.00	15.30
PCT (%)	0.24	0.22
P-LCR (%)	37.20	
P-LCC (10 ⁹ /L)	78.00	

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	4.20	4.30
Lym (%)	31.60	35.20
MID (%)	7.00	7.80
Gran (%)	61.40	57.00
Lym# (10 ⁹ /L)	1.30	1.50
MID# (10 ⁹ /L)	0.30	0.30
Gran# (10 ⁹ /L)	2.60	2.50
RBC (10 ¹² /L)	5.22	4.88
HGB (g/dL)	13.60	13.50
HCT (%)	46.40	43.70
MCV (fL)	88.90	89.60
MCH (pg)	26.00	27.60
MCHC (g/dL)	29.30	30.80
RDW-CV (%)	13.80	13.60
RDW-SD (fL)	44.10	42.80
PLT (10 ⁹ /L)	188.00	162.00
MPV (fL)	13.20	11.40
PDW (fL)	18.20	15.80
PCT (%)	0.24	0.18
P-LCR (%)	47.60	
P-LCC (10 ⁹ /L)	89.00	

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	9.10	8.90
Lym (%)	31.00	29.80
MID (%)	4.80	8.70
Gran (%)	64.20	61.50
Lym# (10 ⁹ /L)	2.80	2.70
MID# (10 ⁹ /L)	0.40	0.70
Gran# (10 ⁹ /L)	5.90	5.50
RBC (10 ¹² /L)	4.16	3.88
HGB (g/dL)	13.40	13.40
HCT (%)	42.80	41.10
MCV (fL)	103.10	106.10
MCH (pg)	32.20	34.50
MCHC (g/dL)	31.30	32.60
RDW-CV (%)	13.10	13.80
RDW-SD (fL)	48.70	51.60
PLT (10 ⁹ /L)	320.00	345.00
MPV (fL)	9.40	8.40
PDW (fL)	13.00	15.30
PCT (%)	0.30	0.29
P-LCR (%)	23.90	
P-LCC (10 ⁹ /L)	76.00	

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	8.70	8.60
Lym (%)	21.20	25.30
MID (%)	5.30	5.00
Gran (%)	73.50	69.70
Lym# (10 ⁹ /L)	1.90	2.20
MID# (10 ⁹ /L)	0.50	0.40
Gran# (10 ⁹ /L)	6.40	6.00
RBC (10 ¹² /L)	5.46	5.11
HGB (g/dL)	14.20	14.60
HCT (%)	48.60	45.50
MCV (fL)	89.10	89.10
MCH (pg)	26.00	28.50
MCHC (g/dL)	29.20	32.00
RDW-CV (%)	14.40	13.00
RDW-SD (fL)	45.70	41.10
PLT (10 ⁹ /L)	219.00	191.00
MPV (fL)	11.90	11.40
PDW (fL)	21.30	15.40
PCT (%)	0.26	0.22
P-LCR (%)	44.00	
P-LCC (10 ⁹ /L)	88.00	

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ⁹ /L)	7.70	8.00
Lym (%)	26.80	30.80
MID (%)	6.60	7.70
Gran (%)	66.60	61.50
Lym# (10 ⁹ /L)	2.10	2.50
MID# (10 ⁹ /L)	0.50	0.60
Gran# (10 ⁹ /L)	5.10	4.90
RBC (10 ¹² /L)	6.43	6.13
HGB (g/dL)	11.70	12.13
HCT (%)	43.30	42.10
MCV (fL)	67.40	68.80
MCH (pg)	18.10	19.90
MCHC (g/dL)	27.00	28.90
RDW-CV (%)	16.40	16.70
RDW-SD (fL)	38.00	41.10
PLT (10 ⁹ /L)	248.00	228.00
MPV (fL)	11.00	9.60
PDW (fL)	*	14.90
PCT (%)	0.27	0.22
P-LCR (%)	41.80	
P-LCC (10 ⁹ /L)	112.00	

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D		
(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	Range
WBC (10 ⁹ /L)	2.2	1.8 - 2.8
Lym (%)	55.9	42.1 - 63.1
MID (%)	3.6	0.0 - 10.4
Gran (%)	40.5	29.5 - 54.9
Lym# (10 ⁹ /L)	1.2	0.9 - 1.5
MID# (10 ⁹ /L)	0.1	0.0 - .2
Gran# (10 ⁹ /L)	0.9	0.7 - 1.3
RBC (10 ¹² /L)	2.46	2.23 - 2.63
HGB (g/dL)	6.9	6.4 - 7.4
HCT (%)	21.9	17.5 - 23.5
MCV (fL)	89.3	78.5 - 90.5
MCH (pg)	28.0	24.6 - 32.2
MCHC (g/dL)	31.5	28.8 - 38.4
RDW-CV (%)	15.8	10.9 - 20.9
RDW-SD (fL)	.48.7	40.0 - 56.0
PLT (10 ⁹ /L)	89	51 - 101
MPV (fL)	11.1	6.5 - 14.5
PDW (fL)	9.6	
PCT (%)	0.09	
P-LCR (%)	20.0	
P-LCC (10 ⁹ /L)	17	

Diagon D Check D		
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	Range
WBC ($10^9/L$)	7.6	6.5 - 8.5
Lym (%)	31.0	22.2 - 40.8
MID (%)	5.9	0.0 - 11.4
Gran (%)	63.1	53.5 - 72.3
Lym# ($10^9/L$)	2.4	1.7 - 3.1
MID# ($10^9/L$)	0.5	0.0 - 0.8
Gran# ($10^9/L$)	4.7	4.0 - 5.4
RBC ($10^{12}/L$)	4.5	4.17 - 4.77
HGB (g/dL)	13.6	12.9 - 14.1
HCT (%)	42.0	35.0 - 44.0
MCV (fL)	93.5	82.5 - 94.5
MCH (pg)	30.2	26.4 - 34.0
MCHC (g/dL)	32.3	29.3 - 38.9
RDW-CV (%)	15.1	11.2 - 21.2
RDW-SD (fL)	51.8	41.6 - 59.6
PLT ($10^9/L$)	232	179 - 269
MPV (fL)	9.5	6.0 - 12.0
PDW (fL)	11.7	
PCT (%)	0.22	
P-LCR (%)	20.7	
P-LCC ($10^9/L$)	48	

Diagon D Check D		
(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-U Lot - HVDU221017 VDx Detergent-U Lot - HVDTU220908 VDx Lytic-U Lot - HVLU221006	Range
WBC (10 ⁹ /L)	18.6	16.2 - 21.2
Lym (%)	22.2	10.9 - 17.7
MID (%)	6.2	0.0 - 10.6
Gran (%)	71.6	65.5 - 80.1
Lym# (10 ⁹ /L)	4.1	2.0 - 6.2
MID# (10 ⁹ /L)	1.2	0.1 - 1.9
Gran# (10 ⁹ /L)	13.3	9.5 - 17.7
RBC (10 ¹² /L)	5.45	5.08 - 5.88
HGB (g/dL)	17.3	16.7 - 18.3
HCT (%)	54.3	47.2 - 56.2
MCV (fL)	99.7	88.4 - 100.4
MCH (pg)	31.7	28.2 - 35.8
MCHC (g/dL)	31.8	29.1 - 38.7
RDW-CV (%)	15.4	11.1 - 21.1
RDW-SD (fL)	54.8	43.5 - 63.5
PLT (10 ⁹ /L)	464	377 - 507
MPV (fL)	8.9	5.6 - 6.2
PDW (fL)	13.3	
PCT (%)	0.41	
P-LCR (%)	19.6	
P-LCC (10 ⁹ /L)	90	

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok


LOT: 1V0901
05-03-2023

Instruments:		Urit-2900Plus					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,3 ± 0,5	1,8 - 2,8	7,5 ± 1,0	6,5 - 8,5	18,7 ± 2,5	16,2 - 21,2
RBC	10 ¹² /L	2,43 ± 0,20	2,23 - 2,63	4,47 ± 0,30	4,17 - 4,77	5,48 ± 0,40	5,08 - 5,88
Hgb	g/dL	6,9 ± 0,5	6,4 - 7,4	13,5 ± 0,6	12,9 - 14,1	17,5 ± 0,8	16,7 - 18,3
	g/L	69 ± 5	64 - 74	135 ± 6	129 - 141	175 ± 8	167 - 183
Hct	%	20,5 ± 3,0	17,5 - 23,5	39,5 ± 4,5	35,0 - 44,0	51,7 ± 4,5	47,2 - 56,2
	L/L	0,205 ± 0,030	0,175 - 0,235	0,395 ± 0,045	0,350 - 0,440	0,517 ± 0,045	0,472 - 0,562
MCV	fL	84,5 ± 6,0	78,5 - 90,5	88,5 ± 6,0	82,5 - 94,5	94,4 ± 6,0	88,4 - 100,4
MCH	pg	28,4 ± 3,8	24,6 - 32,2	30,2 ± 3,8	26,4 - 34,0	32,0 ± 3,8	28,2 - 35,8
MCHC	g/dL	33,6 ± 4,8	28,8 - 38,4	34,1 ± 4,8	29,3 - 38,9	33,9 ± 4,8	29,1 - 38,7
	g/L	336 ± 48	288 - 384	341 ± 48	293 - 389	339 ± 48	291 - 387
RDW-CV	%	15,9 ± 5,0	10,9 - 20,9	16,2 ± 5,0	11,2 - 21,2	16,1 ± 5,0	11,1 - 21,1
RDW-SD	fL	48,0 ± 8,0	40,0 - 56,0	50,6 ± 9,0	41,6 - 59,6	53,5 ± 10,0	43,5 - 63,5
Plt	10 ⁹ /L	76 ± 25	51 - 101	224 ± 45	179 - 269	442 ± 65	377 - 507
MPV	fL	10,5 ± 4,0	6,5 - 14,5	9,0 ± 3,0	6,0 - 12,0	8,6 ± 3,0	5,6 - 11,6
LYM#	10 ⁹ /L	1,2 ± 0,3	0,9 - 1,5	2,4 ± 0,7	1,7 - 3,1	4,1 ± 2,1	2,0 - 6,2
MID#	10 ⁹ /L	0,1 ± 0,1	0,0 - 0,2	0,4 ± 0,4	0,0 - 0,8	1,0 ± 0,9	0,1 - 1,9
GRAN#	10 ⁹ /L	1,0 ± 0,3	0,7 - 1,3	4,7 ± 0,7	4,0 - 5,4	13,6 ± 4,1	9,5 - 17,7
LYM%	%	52,6 ± 10,5	42,1 - 63,1	31,4 ± 9,4	22,0 - 40,8	21,9 ± 11,0	10,9 - 32,9
MID%	%	5,2 ± 5,2	0,0 - 10,4	5,7 ± 5,7	0,0 - 11,4	5,3 ± 5,3	0,0 - 10,6
GRAN%	%	42,2 ± 12,7	29,5 - 54,9	62,9 ± 9,4	53,5 - 72,3	72,8 ± 7,3	65,5 - 80,1


 DIAGON Ltd.
 48-52., Baross Str.
 Budapest, Hungary
 H-1047

IVD


Coefficient of Variation: Precision (VDx Reagents)

1. Two fresh blood samples were collected and tested with the VDx Urit Reagents on Urit-2900 Plus, 3 Part Hematology Analyzer.
2. The samples were tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample-01, n = 07

Precision Evaluation report of Urit compatible reagent on Urit-2900Plus, 3 Part Hematology Analyzer														
Fresh Blood Sample-1														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10 ⁹ /L)	5.7	5.6	5.6	5.6	5.7	5.6	5.7				5.64	0.05	0.01	0.95
Lym (%)	29.9	30.7	27.7	28.5	28.1	27.6	28.5				28.71	1.16	0.04	4.04
MID (%)	5.8	6.3	6.3	6.5	6.6	5.8	6.5				6.26	0.33	0.05	5.29
Gran (%)	64.3	63	66	65	65.3	66.6	65				65.03	1.16	0.02	1.79
Lym# (10 ⁹ /L)	1.7	1.8	1.6	1.6	1.6	1.6	1.7				1.66	0.08	0.05	4.75
MID# (10 ⁹ /L)	0.3	0.4	0.4	0.4	0.4	0.3	0.4				0.37	0.05	0.13	13.14
Gran# (10 ⁹ /L)	3.7	3.5	3.7	3.6	3.8	3.8	3.7				3.69	0.11	0.03	2.90
RBC (10 ¹² /L)	5.39	5.04	5.06	5.11	5.07	5.05	5.05				5.11	0.13	0.02	2.46
HGB (g/dL)	14.5	14.4	14.5	14.4	14.4	14.4	14.4				14.43	0.05	0.00	0.34
HCT (%)	51.0	47.7	47.8	48.3	47.9	47.7	47.7				48.30	1.21	0.03	2.50
MCV (fL)	94.8	94.7	94.6	94.6	94.6	94.6	94.6				94.64	0.08	0.00	0.08
MCH (pg)	26.9	28.5	28.6	28.1	28.4	28.5	28.5				28.21	0.60	0.02	2.13
MCHC (g/dL)	28.4	30.1	30.3	29.8	30	30.1	30.1				29.83	0.65	0.02	2.17
RDW-CV (%)	12.3	12.3	12.3	12.3	12.3	12.9	12.3				12.39	0.23	0.02	1.83
RDW-SD (fL)	42.6	42.6	42.6	42.6	42.6	44.1	42.6				42.81	0.57	0.01	1.32
PLT (10 ⁹ /L)	330	306	307	314	314	311	308				312.86	8.21	0.03	2.63
MPV (fL)	10.7	10.6	10.1	10.6	10.5	10.5	10.4				10.49	0.20	0.02	1.86
PDW (fL)	13.6	15.8	15.1	15.5	16.7	15.8	15.1				15.37	0.95	0.06	6.19
PCT (%)	0.35	0.32	0.31	0.33	0.32	0.32	0.32				0.32	0.01	0.04	3.92
P-LCR (%)	32.1	32.6	29.8	32.2	33	32	31.3				31.86	1.05	0.03	3.29
P-LCC (10 ⁹ /L)	101	99	92	101	103	99	99				99.14	3.48	0.04	3.51

Fresh Blood Sample-02, n = 08

Precision Evaluation report of Urit compatible reagent on Urit-2900Plus, 3 Part Hematology Analyzer														
Fresh Blood Sample-2														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^9/L$)	6.6	6.8	6.8	6.8	6.6	6.7	6.6	6.6			6.69	0.10	0.01	1.48
Lym (%)	34.7	33	34.1	34.7	33.5	34.3	34.1	32.7			33.89	0.75	0.02	2.21
MID (%)	7.4	7.5	6.8	6.7	7.7	7.4	6.9	7.3			7.21	0.36	0.05	5.05
Gran (%)	57.9	59.5	59.1	58.6	58.8	58.3	59	60			58.90	0.66	0.01	1.13
Lym# ($10^9/L$)	2.3	2.2	2.3	2.4	2.2	2.3	2.3	2.2			2.28	0.07	0.03	3.11
MID# ($10^9/L$)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5			0.50	0.00	0.00	0.00
Gran# ($10^9/L$)	3.9	4	3.9	3.9	3.9	4	3.8	4			3.93	0.07	0.02	1.80
RBC ($10^{12}/L$)	4.43	4.43	4.44	4.45	4.47	4.43	4.45	4.47			4.45	0.02	0.00	0.38
HGB (g/dL)	13.9	14.2	14.1	14.1	13.9	14	13.9	13.9			14.00	0.12	0.01	0.85
HCT (%)	45.6	45.8	45.8	45.9	46	45.6	45.7	45.9			45.79	0.15	0.00	0.32
MCV (fL)	103	103.4	103.3	103.2	103.1	103.1	102.9	102.9			103.11	0.18	0.00	0.18
MCH (pg)	31.3	32	31.7	31.6	31	31.6	31.2	31			31.43	0.36	0.01	1.14
MCHC (g/dL)	30.4	31	30.7	30.7	30.2	30.7	30.4	30.2			30.54	0.28	0.01	0.93
RDW-CV (%)	13.7	13	13	13.1	14.2	13.7	12.5	13.1			13.29	0.54	0.04	4.05
RDW-SD (fL)	48.7	48.7	48.7	50.2	51.8	48.7	48.7	50.2			49.46	1.16	0.02	2.35
PLT ($10^9/L$)	256	261	263	263	263	258	257	257			259.75	3.06	0.01	1.18
MPV (fL)	10.7	10.8	10.7	11	10.8	10.7	10.8	10.4			10.74	0.17	0.02	1.57
PDW (fL)	16.6	18.2	16.4	16.7	17.3	17.9	18.9	15.8			17.23	1.04	0.06	6.05
PCT (%)	0.27	0.28	0.28	0.28	0.28	0.27	0.27	0.26			0.27	0.01	0.03	2.72
P-LCR (%)	31.6	35	35.6	35.2	34.3	33.1	33.6	31.9			33.79	1.51	0.04	4.46
P-LCC ($10^9/L$)	80	88	93	92	92	85	86	81			87.13	5.03	0.06	5.77

Conclusions

1. The VDX Urit 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray original reagents as Reference.
2. All measured parameters showed values of “r” in the range of **0.965 to 0.997** displaying the highest degree of correlation between the reagents.
3. The VDX Urit 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
4. The CV % with the VDX Urit Reagents were found to be as under:

Parameters	VDx Urit Reagents (CV % - Precision)
Measured Parameters	0.08% - 2.63%
Calculated Parameters	1.32% - 13.14%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges for VDX Urit 3 Part Hematology Reagents.
6. **The VDX Urit 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Mindray reference reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	233 - 234
2	Background Test	235
3	Coefficient of Correlation: Accuracy	236 – 252
4	Quality Control (Low, Normal & High)	253 - 257
5	Coefficient of Variation: Precision (VDx Prokan Compatible Reagents)	258
6	Conclusions	259

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Prokan – Orion 60
Reference Reagents	Mindray Reference Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date. : 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date. : 15-02-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Prokan Compatible Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot- HVDP220304 VDx Cleaner-P Lot- HVCP220908 VDx Lyse-P Lot- HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot-2022091601 M-30CF Lyse Lot-2022021601
WBC (10 ³ /μL)	0.0	0.0
Lym (%)	0.0	0.0
MID (%)	0.0	0.0
Gran (%)	0.0	0.0
Lym# (10 ³ /μL)	0.0	0.0
MID# (10 ³ /μL)	0.0	0.0
Gran# (10 ³ /μL)	0.0	0.0
RBC (10 ³ /μL)	0.0	0.0
HGB (g/dL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
RDW-SD (fL)	0.0	0.0
RDW-CV (%)	0.0	0.0
PLT (10 ³ /μL)	0.0	0.0
MPV (fL)	0.0	0.0
PDW (%)	0.0	0.0
PCT (%)	0.0	0.0
P-LCR (%)	0.0	

Coefficient of Correlation Studies

- IV. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Prokan Reagents and the Mindray Reference Reagents.
- V. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- VI. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

Coefficient of Correlation (“r”): WBC

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Prokan Reagents for Prokan-Orion 60, 3 Part Hematology Analyzer.

$$“r” = 0.991$$

Sample size: 10

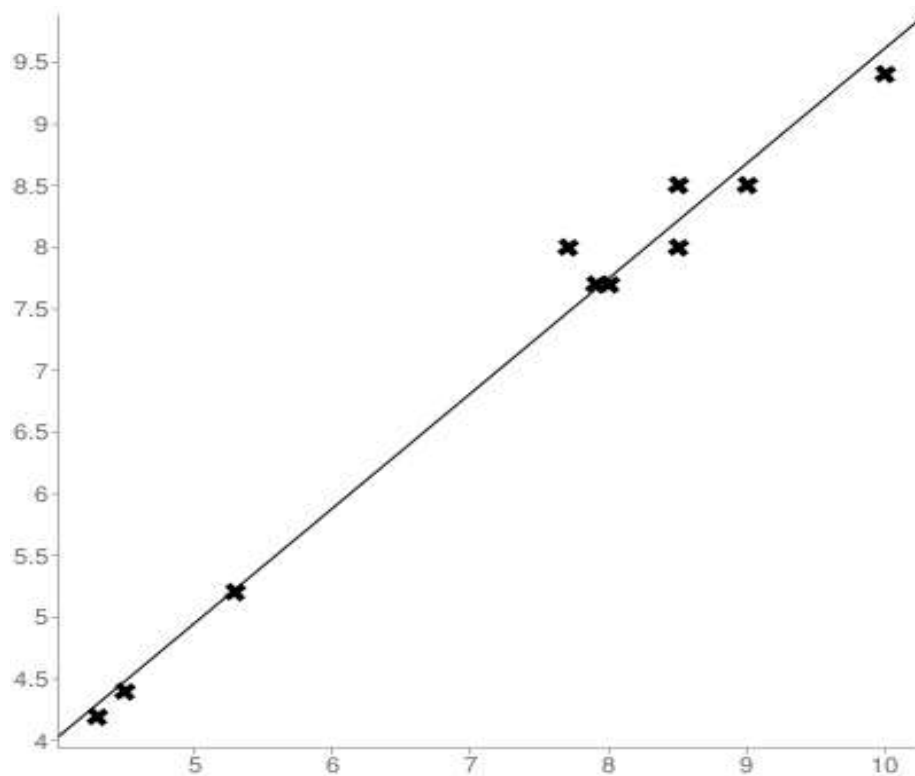
Mean x (x̄): 7.37

Mean y (ȳ): 7.16

Intercept (a): 0.28745015920369

Slope (b): 0.93250337052867

Regression line equation: $y = 0.28745015920369 + 0.93250337052867x$



Coefficient of Correlation (“r”): RBC

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Prokan Reagents for Prokan-Orion 60, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

Sample size: 10

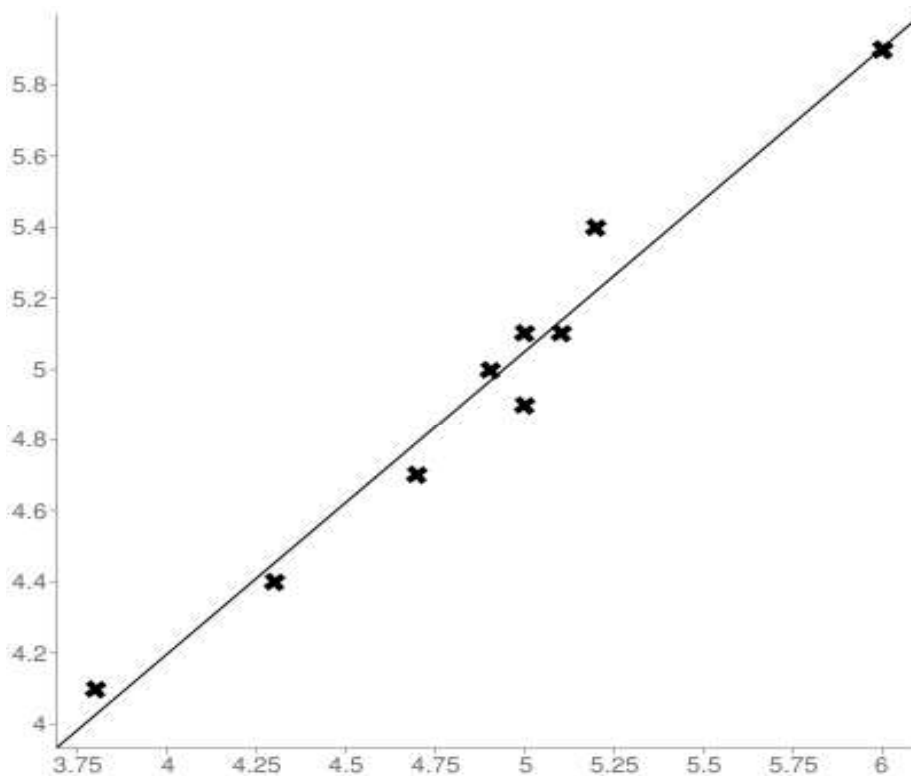
Mean x ($\bar{x}$): 5

Mean y ($\bar{y}$): 5.05

Intercept (a): 0.78529411764707

Slope (b): 0.85294117647059

Regression line equation: $y = 0.78529411764707 + 0.85294117647059x$



Coefficient of Correlation (“r”): Hemoglobin

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Prokan Reagents for Prokan-Orion 60, 3 Part Hematology Analyzer.

“r” = 0.992

Sample size: 10

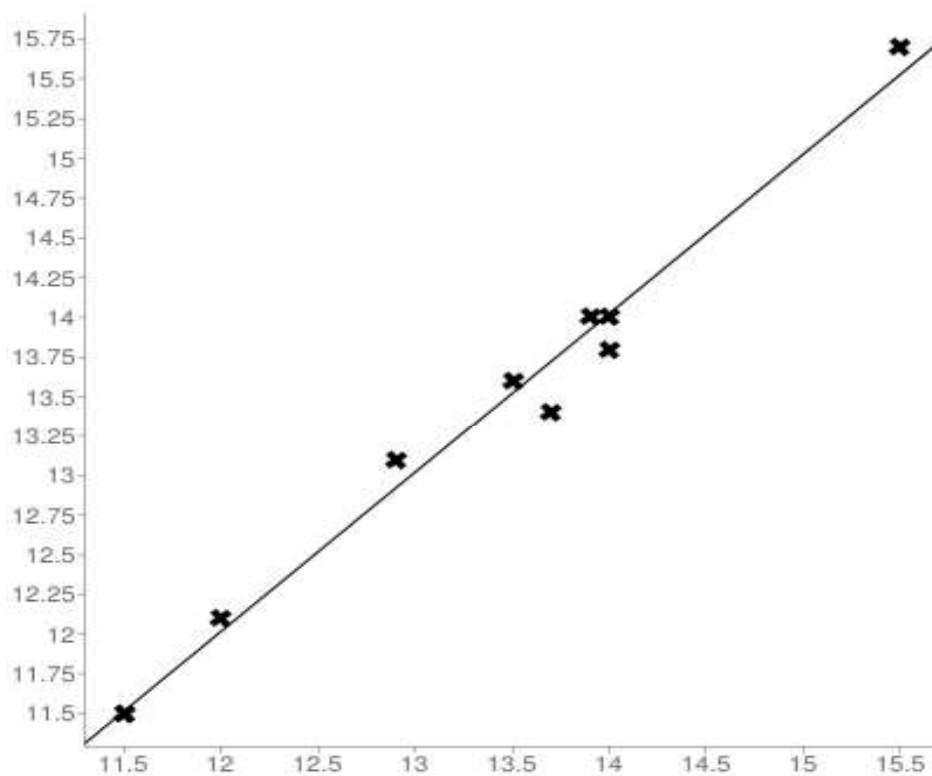
Mean x (x̄): 13.25

Mean y (ȳ): 13.27

Intercept (a): -0.034136874361339

Slope (b): 1.0040858018386

Regression line equation: $y = 1.0040858018386x - 0.034136874361339$



Coefficient of Correlation (“r”): Platelets

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.

y = VDX Prokan Reagents for Prokan-Orion 60, 3 Part Hematology Analyzer.

$$“r” = 0.994$$

Sample size: 10

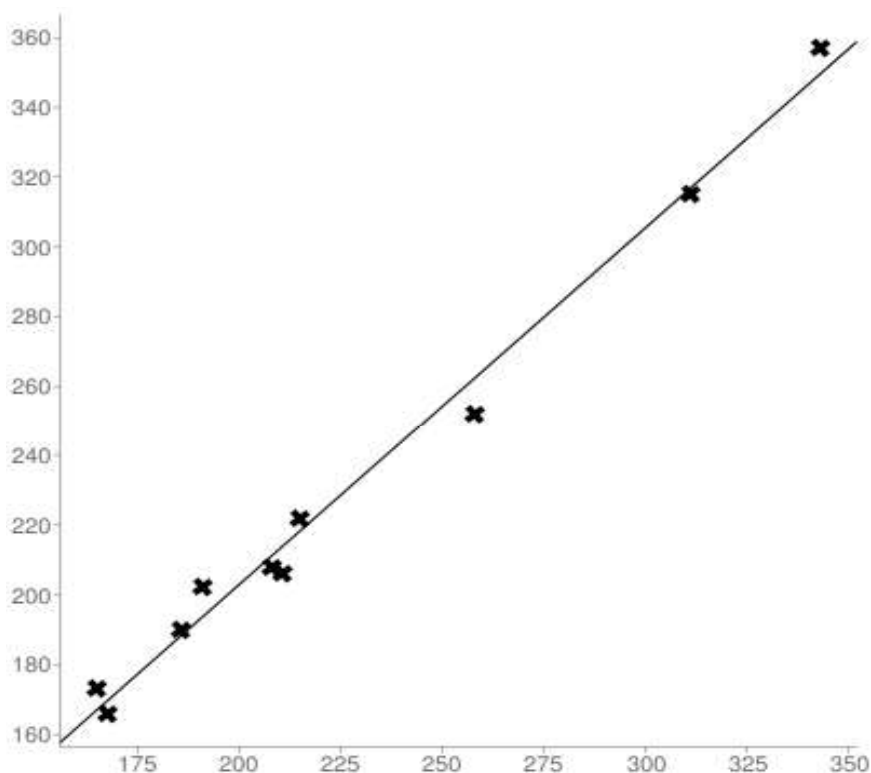
Mean x (x̄): 225.6

Mean y (ȳ): 229.1

Intercept (a): -2.6124109680038

Slope (b): 1.0270940202482

Regression line equation: $y = 1.0270940202482x - 2.6124109680038$



Coefficient of Correlation (“r”): MCV

x = Mindray Reference Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Prokan Reagents for Prokan-Orion 60, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 10

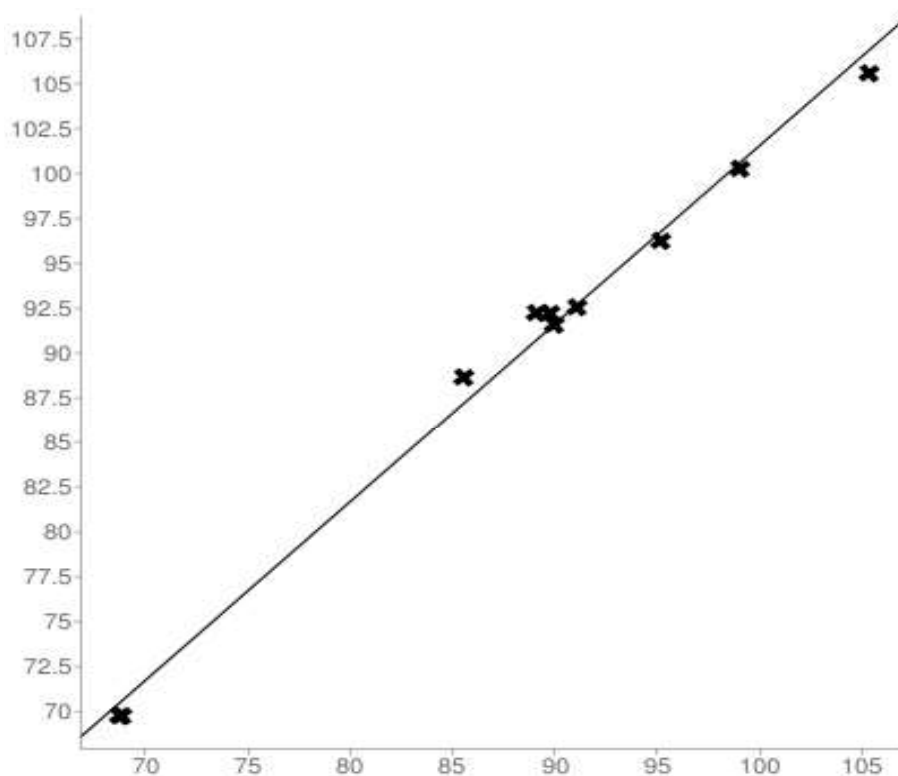
Mean x (x̄): 88.28

Mean y (ȳ): 89.89

Intercept (a): 2.1055650130758

Slope (b): 0.99438644072184

Regression line equation: $y = 2.1055650130758 + 0.99438644072184x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	8.0	7.7
Lym (%)	30.8	30.4
MID (%)	6.8	4.8
Gran (%)	62.4	64.8
Lym# (10 ³ /μL)	2.5	2.3
MID# (10 ³ /μL)	0.6	0.4
Gran# (10 ³ /μL)	4.9	5.0
RBC (10 ³ /μL)	5.4	5.2
HGB (g/dL)	15.7	15.5
HCT (%)	52.0	49.6
MCV (fL)	96.3	95.2
MCH (pg)	29.0	29.6
MCHC (g/dL)	30.1	31.2
RDW-SD (fL)	42.7	44.6
RDW-CV (%)	12.8	13.2
PLT (10 ³ /μL)	173.0	165.0
MPV (fL)	11.4	10.6
PDW (%)	15.4	15.7
PCT (%)	0.2	0.2
P-LCR (%)	29.1	

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	9.4	10.0
Lym (%)	33.7	32.9
MID (%)	8.1	8.0
Gran (%)	58.2	59.1
Lym# (10 ³ /μL)	3.2	3.3
MID# (10 ³ /μL)	0.8	0.8
Gran# (10 ³ /μL)	5.4	5.9
RBC (10 ³ /μL)	4.7	4.7
HGB (g/dL)	12.1	12.0
HCT (%)	41.5	39.8
MCV (fL)	88.6	85.6
MCH (pg)	25.7	25.7
MCHC (g/dL)	29.1	30.1
RDW-SD (fL)	36.3	40.2
RDW-CV (%)	11.9	13.0
PLT (10 ³ /μL)	315.0	311.0
MPV (fL)	11.2	10.3
PDW (%)	15.1	15.7
PCT (%)	0.4	0.3
P-LCR (%)	27.7	

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot -2022021601
WBC (10 ³ /μL)	5.2	5.3
Lym (%)	25.2	26.9
MID (%)	8.5	7.7
Gran (%)	66.3	65.4
Lym# (10 ³ /μL)	1.3	1.4
MID# (10 ³ /μL)	0.4	0.4
Gran# (10 ³ /μL)	3.5	3.5
RBC (10 ³ /μL)	5.0	4.9
HGB (g/dL)	14.0	14.0
HCT (%)	45.9	44.8
MCV (fL)	92.6	91.1
MCH (pg)	28.2	28.4
MCHC (g/dL)	30.5	31.2
RDW-SD (fL)	40.6	47.3
RDW-CV (%)	12.7	14.5
PLT (10 ³ /μL)	208.0	208.0
MPV (fL)	11.7	10.4
PDW (%)	15.6	15.6
PCT (%)	0.2	0.2
P-LCR (%)	31.7	

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot- HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	4.4	4.5
Lym (%)	30.2	29.3
MID (%)	4.6	6.5
Gran (%)	65.2	64.2
Lym# (10 ³ /μL)	1.3	1.3
MID# (10 ³ /μL)	0.2	0.3
Gran# (10 ³ /μL)	2.9	2.9
RBC (10 ³ /μL)	4.9	5.0
HGB (g/dL)	13.1	13.7
HCT (%)	45.1	45.0
MCV (fL)	91.6	90.0
MCH (pg)	26.5	27.3
MCHC (g/dL)	29.0	30.4
RDW-SD (fL)	40.6	43.8
RDW-CV (%)	12.8	13.6
PLT (10 ³ /μL)	166.0	168.0
MPV (fL)	11.6	11.4
PDW (%)	14.3	15.8
PCT (%)	0.2	0.2
P-LCR (%)	31.9	

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot- HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	8.0	8.5
Lym (%)	21.9	20.7
MID (%)	5.7	6.1
Gran (%)	72.4	73.2
Lym# (10 ³ /μL)	1.8	1.8
MID# (10 ³ /μL)	0.5	0.5
Gran# (10 ³ /μL)	5.7	6.2
RBC (10 ³ /μL)	5.1	5.1
HGB (g/dL)	13.8	14.0
HCT (%)	46.6	44.9
MCV (fL)	92.2	89.1
MCH (pg)	27.2	27.7
MCHC (g/dL)	29.6	31.1
RDW-SD (fL)	38.5	43.8
RDW-CV (%)	12.1	13.6
PLT (10 ³ /μL)	190.0	186.0
MPV (fL)	12.2	11.6
PDW (%)	15.4	15.1
PCT (%)	0.2	0.2
P-LCR (%)	35.7	

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot- HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	7.7	8.0
Lym (%)	27.9	27.4
MID (%)	7.9	7.8
Gran (%)	64.2	64.8
Lym# (10 ³ /μL)	2.2	2.2
MID# (10 ³ /μL)	0.6	0.6
Gran# (10 ³ /μL)	4.9	5.2
RBC (10 ³ /μL)	5.9	6.0
HGB (g/dL)	11.5	11.5
HCT (%)	40.9	41.0
MCV (fL)	69.8	68.7
MCH (pg)	19.6	19.2
MCHC (g/dL)	28.1	28.0
RDW-SD (fL)	36.3	38.5
RDW-CV (%)	14.4	16.7
PLT (10 ³ /μL)	222.0	215.0
MPV (fL)	9.3	9.7
PDW (%)	9.5	14.9
PCT (%)	0.2	0.2
P-LCR (%)	10.3	

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	4.2	4.3
Lym (%)	38.9	41.5
MID (%)	7.9	6.0
Gran (%)	53.2	52.5
Lym# (10 ³ /μL)	1.6	1.8
MID# (10 ³ /μL)	0.3	0.2
Gran# (10 ³ /μL)	2.3	2.3
RBC (10 ³ /μL)	4.4	4.3
HGB (g/dL)	13.6	13.5
HCT (%)	43.9	42.3
MCV (fL)	100.3	99.0
MCH (pg)	31.0	31.5
MCHC (g/dL)	30.9	31.5
RDW-SD (fL)	40.6	43.8
RDW-CV (%)	11.7	12.2
PLT (10 ³ /μL)	206.0	211.0
MPV (fL)	10.5	8.7
PDW (%)	13.6	15.5
PCT (%)	0.2	0.2
P-LCR (%)	21.0	

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	8.5	9.0
Lym (%)	29.2	27.9
MID (%)	5.3	6.3
Gran (%)	65.5	65.8
Lym# (10 ³ /μL)	2.5	2.5
MID# (10 ³ /μL)	0.5	0.6
Gran# (10 ³ /μL)	5.5	5.9
RBC (10 ³ /μL)	4.1	3.8
HGB (g/dL)	13.3	12.9
HCT (%)	42.7	39.9
MCV (fL)	105.6	105.4
MCH (pg)	32.8	34.0
MCHC (g/dL)	31.1	32.3
RDW-SD (fL)	42.7	51.6
RDW-CV (%)	11.7	14.2
PLT (10 ³ /μL)	357.0	343.0
MPV (fL)	10.2	8.2
PDW (%)	13.3	15.4
PCT (%)	0.4	0.3
P-LCR (%)	18.2	

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot- HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	8.5	8.5
Lym (%)	21.3	21.1
MID (%)	3.5	7.0
Gran (%)	75.2	71.9
Lym# (10 ³ /μL)	1.8	1.8
MID# (10 ³ /μL)	0.3	0.6
Gran# (10 ³ /μL)	6.4	6.1
RBC (10 ³ /μL)	5.1	5.0
HGB (g/dL)	14.0	13.9
HCT (%)	46.8	44.6
MCV (fL)	92.2	89.8
MCH (pg)	27.5	27.9
MCHC (g/dL)	29.9	31.1
RDW-SD (fL)	40.6	42.8
RDW-CV (%)	12.7	13.2
PLT (10 ³ /μL)	202.0	191.0
MPV (fL)	12.2	11.6
PDW (%)	15.4	15.4
PCT (%)	0.2	0.2
P-LCR (%)	36.0	

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot - HVDP220304 VDx Cleaner-P Lot - HVCP220908 VDx Lyse-P Lot - HVLP220808	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot - 2022021601
WBC (10 ³ /μL)	7.7	7.9
Lym (%)	28.3	27.0
MID (%)	8.7	5.1
Gran (%)	63.0	67.9
Lym# (10 ³ /μL)	2.2	2.1
MID# (10 ³ /μL)	0.7	0.4
Gran# (10 ³ /μL)	4.8	5.4
RBC (10 ³ /μL)	5.9	6.0
HGB (g/dL)	11.5	11.5
HCT (%)	40.7	41.1
MCV (fL)	69.7	68.9
MCH (pg)	19.6	19.2
MCHC (g/dL)	28.2	27.9
RDW-SD (fL)	36.3	40.2
RDW-CV (%)	14.5	16.7
PLT (10 ³ /μL)	252.0	258.0
MPV (fL)	9.9	10.6
PDW (%)	10.2	15.4
PCT (%)	0.2	0.3
P-LCR (%)	18.1	

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D		
(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot- HVDP220304 VDx Cleaner-P Lot- HVCP220908 VDx Lyse-P Lot- HVLP220808	Range
WBC ($10^3/\mu\text{L}$)	2.3	1.8 - 2.8
Lym (%)	46.7	34.8 - 58.0
MID (%)	7.3	0.0 - 14.2
Gran (%)	46.0	30.2 - 62.8
Lym# ($10^3/\mu\text{L}$)	1.10	0.8 - 1.4
MID# ($10^3/\mu\text{L}$)	0.20	0.0 - 0.4
Gran# ($10^3/\mu\text{L}$)	1.00	0.6 - 1.4
RBC ($10^3/\mu\text{L}$)	2.54	2.35 - 2.75
HGB (g/dL)	6.8	6.5 - 7.5
HCT (%)	23.0	20.8 - 26.8
MCV (fL)	90.90	87.4 - 99.4
MCH (pg)	26.7	23.4 - 31.0
MCHC (g/dL)	29.5	24.4 - 34.0
RDW-SD (fL)	55.6	51.3 - 57.3
RDW-CV (%)	17.7	11.9 - 21.9
PLT ($10^3/\mu\text{L}$)	67	38 - 88
MPV (fL)	9.9	7.1 - 13.1
PDW (%)	10.7	6.2 - 18.2
PCT (%)	0.06	0.02 - 0.10
P-LCR (%)	11.9	

Diagon D Check D		
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot- HVDP220304 VDx Cleaner-P Lot- HVCP220908 VDx Lyse-P Lot- HVLP220808	Range
WBC ($10^3/\mu\text{L}$)	7.1	6.3 - 8.3
Lym (%)	27.2	17.8 - 37.0
MID (%)	9.2	0.0 - 17.2
Gran (%)	63.6	48.0 - 80.0
Lym# ($10^3/\mu\text{L}$)	1.90	1.3 - 2.7
MID# ($10^3/\mu\text{L}$)	0.70	0.0 - 1.2
Gran# ($10^3/\mu\text{L}$)	4.50	3.5 - 5.9
RBC ($10^3/\mu\text{L}$)	4.79	4.32 - 4.92
HGB (g/dL)	13.9	13.0 - 14.2
HCT (%)	45.6	41.2 - 49.2
MCV (fL)	95.2	91.8 - 103.8
MCH (pg)	29.0	25.7 - 33.3
MCHC (g/dL)	30.4	25.4 - 35.0
RDW-SD (fL)	55.6	53.4 - 59.4
RDW-CV (%)	16.9	11.8 - 21.8
PLT ($10^3/\mu\text{L}$)	219	171 - 261
MPV (fL)	10.5	7.3 - 13.6
PDW (%)	10.7	6.8 - 18.8
PCT (%)	0.22	0.17 - 0.29
P-LCR (%)	15.2	

Diagon D Check D		
(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-P Lot- HVDP220304 VDx Cleaner-P Lot- HVCP220908 VDx Lyse-P Lot- HVLP220808	Range
WBC (10 ³ /μL)	17.0	15.1 - 20.1
Lym (%)	20.0	10.9 - 28.7
MID (%)	10.6	0.0 - 15.4
Gran (%)	69.4	54.4 - 90.6
Lym# (10 ³ /μL)	3.4	1.6 - 5.4
MID# (10 ³ /μL)	1.8	0.0 - 2.8
Gran# (10 ³ /μL)	11.8	8.9 - 16.5
RBC (10 ³ /μL)	5.84	5.34 - 6.14
HGB (g/dL)	18.0	17.2 - 18.8
HCT (%)	58.6	55.0 - 64.0
MCV (fL)	100.5	97.7 - 109.7
MCH (pg)	30.8	27.6 - 35.2
MCHC (g/dL)	30.7	25.5 - 35.1
RDW-SD (fL)	55.6	53.3 - 59.3
RDW-CV (%)	16.0	10.8 - 20.8
PLT (10 ³ /μL)	485	446 - 576
MPV (fL)	10.7	7.9 - 13.9
PDW (%)	11.5	7.4 - 19.4
PCT (%)	0.51	0.46 - 0.66
P-LCR (%)	15.4	

ASSAY VALUES AND EXPECTED RANGES

LOT: 1V0901
05-03-2023

Instruments:		Prokan ORION 60					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,3 ± 0,5	1,8 - 2,8	7,3 ± 1,0	6,3 - 8,3	17,6 ± 2,5	15,1 - 20,1
RBC	10 ¹² /L	2,55 ± 0,20	2,35 - 2,75	4,62 ± 0,30	4,32 - 4,92	5,74 ± 0,40	5,34 - 6,14
Hgb	g/dL	7,0 ± 0,5	6,5 - 7,5	13,6 ± 0,6	13,0 - 14,2	18,0 ± 0,8	17,2 - 18,8
	g/L	70 ± 5	65 - 75	136 ± 6	130 - 142	180 ± 8	172 - 188
Hct	%	23,8 ± 3,0	20,8 - 26,8	45,2 ± 4,0	41,2 - 49,2	59,5 ± 4,5	55,0 - 64,0
	L/L	0,238 ± 0,030	0,208 - 0,268	0,452 ± 0,040	0,412 - 0,492	0,595 ± 0,045	0,550 - 0,640
MCV	fL	93,4 ± 6,0	87,4 - 99,4	97,8 ± 6,0	91,8 - 103,8	103,7 ± 6,0	97,7 - 109,7
MCH	pg	27,2 ± 3,8	23,4 - 31,0	29,5 ± 3,8	25,7 - 33,3	31,4 ± 3,8	27,6 - 35,2
MCHC	g/dL	29,2 ± 4,8	24,4 - 34,0	30,2 ± 4,8	25,4 - 35,0	30,3 ± 4,8	25,5 - 35,1
	g/L	292 ± 48	244 - 340	302 ± 48	254 - 350	303 ± 48	255 - 351
RDW-SD	fL	54,3 ± 3,0	51,3 - 57,3	56,4 ± 3,0	53,4 - 59,4	56,3 ± 3,0	53,3 - 59,3
RDW-CV	%	16,9 ± 5,0	11,9 - 21,9	16,8 ± 5,0	11,8 - 21,8	15,8 ± 5,0	10,8 - 20,8
Plt	10 ⁹ /L	63 ± 25	38 - 88	216 ± 45	171 - 261	511 ± 65	446 - 576
MPV	fL	10,1 ± 3,0	7,1 - 13,1	10,6 ± 3,0	7,6 - 13,6	10,9 ± 3,0	7,9 - 13,9
PDW	%	12,2 ± 6,0	6,2 - 18,2	12,8 ± 6,0	6,8 - 18,8	13,4 ± 6,0	7,4 - 19,4
PCT	%	0,06 ± 0,04	0,02 - 0,10	0,23 ± 0,06	0,17 - 0,29	0,56 ± 0,10	0,46 - 0,66
LYMPH#	10 ⁹ /L	1,1 ± 0,3	0,8 - 1,4	2,0 ± 0,7	1,3 - 2,7	3,5 ± 1,9	1,6 - 5,4
MID#	10 ⁹ /L	0,2 ± 0,2	0,0 - 0,4	0,6 ± 0,6	0,0 - 1,2	1,4 ± 1,4	0,0 - 2,8
GRAN#	10 ⁹ /L	1,0 ± 0,4	0,6 - 1,4	4,7 ± 1,2	3,5 - 5,9	12,7 ± 3,8	8,9 - 16,5
LYMPH%	%	46,4 ± 11,6	34,8 - 58,0	27,4 ± 9,6	17,8 - 37,0	19,8 ± 8,9	10,9 - 28,7
MID%	%	7,1 ± 7,1	0,0 - 14,2	8,6 ± 8,6	0,0 - 17,2	7,7 ± 7,7	0,0 - 15,4
GRAN%	%	46,5 ± 16,3	30,2 - 62,8	64,0 ± 16,0	48,0 - 80,0	72,5 ± 18,1	54,4 - 90,6


 DIAGON Ltd.
 48-52., Baross Str.
 Budapest, Hungary
 H-1047


Coefficient of Variation:

Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Prokan Reagents on Prokan Orion 60, 3 Part Hematology Analyzer.
2. The sample was tested in 09 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 09

Precision Evaluation report of VDx Prokan compatible reagent on Prokan-Orion60, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{L}$)	7.4	7.6	7.4	7.3	7.3	7.3	7.5	7.4	7.3		7.39	0.11	0.01	1.43
Lym (%)	36.2	36.4	36.3	35.8	36.7	37.1	37.5	36.8	36.8		36.62	0.51	0.01	1.39
MID (%)	5.9	6.5	5.0	6.2	4.7	4.8	4.3	6.7	4.1		5.36	0.98	0.18	18.30
Gran (%)	57.9	57.1	58.7	58	58.6	58.1	58.2	56.5	59.1		58.02	0.80	0.01	1.39
Lym# ($10^3/\mu\text{L}$)	2.7	2.8	2.7	2.6	2.7	2.7	2.8	2.7	2.7		2.71	0.06	0.02	2.22
MID# ($10^3/\mu\text{L}$)	0.4	0.5	0.4	0.5	0.3	0.4	0.3	0.5	0.3		0.40	0.09	0.22	21.65
Gran# ($10^3/\mu\text{L}$)	4.3	4.3	4.3	4.2	4.3	4.2	4.4	4.2	4.3		4.28	0.07	0.02	1.56
RBC ($10^3/\mu\text{L}$)	5.54	5.74	5.55	5.42	5.42	5.49	5.49	5.42	5.46		5.50	0.10	0.02	1.85
HGB (g/dL)	15.7	16.1	15.6	15.5	15.4	15.7	15.5	15.5	15.5		15.61	0.21	0.01	1.34
HCT (%)	51.7	52.9	51.1	50	49.8	50.4	50.5	49.7	50.2		50.70	1.04	0.02	2.05
MCV (fL)	92.2	92.2	92.2	92.4	92	91.9	92	91.8	92.1		92.09	0.18	0.00	0.20
MCH (pg)	28.3	28	28.1	28.5	28.4	28.5	28.2	28.5	28.3		28.31	0.18	0.01	0.65
MCHC (g/dL)	30.7	30.4	30.5	31	30.9	31.1	30.6	31.1	30.8		30.79	0.26	0.01	0.84
RDW-SD (fL)	40.6	38.5	40.6	40.6	40.6	38.5	40.6	38.5	40.6		39.90	1.05	0.03	2.63
RDW-CV (%)	12.7	12.1	12.7	12.6	12.8	12.1	12.8	12.1	12.8		12.52	0.32	0.03	2.58
PLT ($10^3/\mu\text{L}$)	222	206	222	217	219	211	219	211	222		216.56	5.85	0.03	2.70
MPV (fL)	11.0	10.4	10.8	10.9	10.9	11	10.9	11	11.1		10.89	0.20	0.02	1.86
PDW (%)	15.6	13.8	15.4	15.4	15.1	15.4	15.4	15.4	15.4		15.21	0.54	0.04	3.58
PCT (%)	0.24	0.21	0.23	0.23	0.23	0.23	0.23	0.23	0.24		0.23	0.01	0.04	3.77
P-LCR (%)	27.7	24.2	26.1	27	25.9	27	26.1	27.1	27.1		26.47	1.04	0.04	3.92

Conclusions

4. The VDX Prokan 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray original Reagents as Reference.
5. All measured parameters showed values of “r” in the range of **0.950 to 0.996** displaying the highest degree of correlation between the reagents.
6. The VDX Prokan 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
7. The CV % with the VDX Prokan Reagents were found to be as under:

Parameters	VDX Prokan Reagents (CV % - Precision)
Measured Parameters	0.20% - 2.70%
Calculated Parameters	0.65% - 21.65%

8. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges for VDX Prokan 3 Part Hematology Reagents.
9. **The VDX Prokan 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Mindray Reference Reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	262 - 263
2	Background Test	264
3	Coefficient of Correlation: Accuracy	265 – 281
4	Quality Control (Low, Normal & High)	282 - 286
5	Coefficient of Variation: Precision (VDx Rayto Compatible Reagents)	287 - 288
6	Conclusions	289

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Rayto – Councell 23 Plus
Reference Reagents	Mindray Reference Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date : 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date : 15-02-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Rayto Compatible Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot-2022091601 M-30CF Lyse Lot-2022021601
WBC (10 ³ /μL)	0.0	0.0
Lym (%)	0.0	0.0
MID (%)	0.0	0.0
Gran (%)	0.0	0.0
Lym# (10 ³ /μL)	0.0	0.0
MID# (10 ³ /μL)	0.0	0.0
Gran# (10 ³ /μL)	0.0	0.0
RBC (10 ³ /μL)	0.0	0.0
HGB (g/dL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
RDW-SD (fL)	0.0	0.0
RDW-CV (%)	0.0	0.0
PLT (10 ³ /μL)	0.0	0.0
MPV (fL)	0.0	0.0
PDW (%)	0.0	0.0
PCT (%)	0.0	0.0
P-LCR (%)	0.0	

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Rayto Reagents and the Mindray Reference Reagents.
- II. The Coefficient of Correlation ("r") was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

Coefficient of Correlation (“r”): WBC

x = Reference Mindray Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.

y = VDX Rayto Reagents for Rayto - Councell 23 Plus, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 10

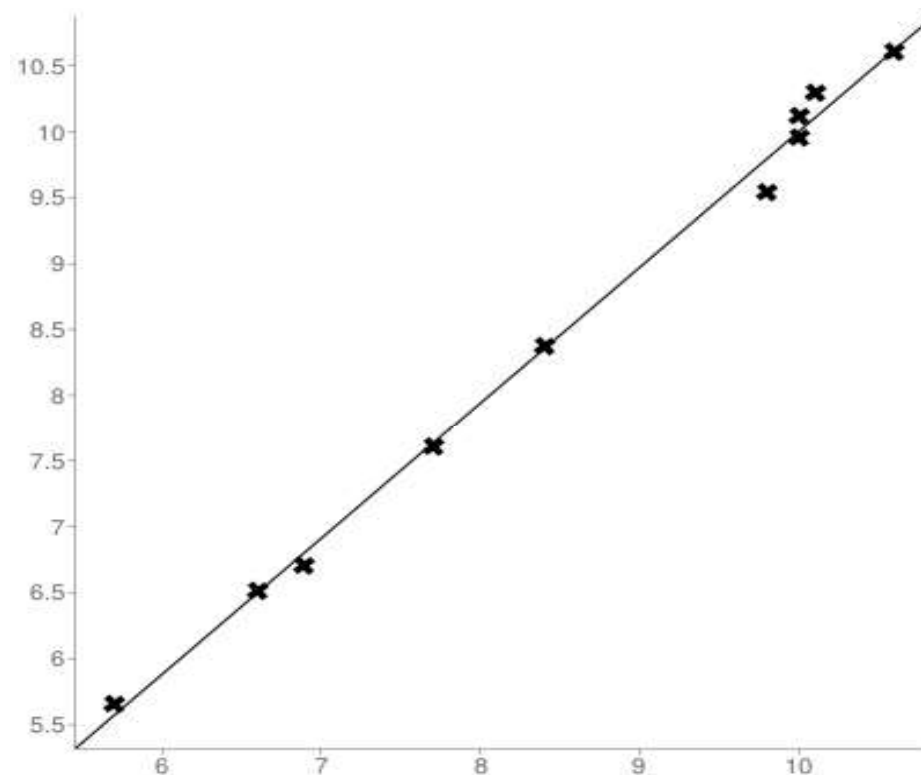
Mean x (x): 8.58

Mean y (y): 8.538

Intercept (a): -0.30586683960226

Slope (b): 1.0307537109094

Regression line equation: $y=1.0307537109094x-0.30586683960226$



Coefficient of Correlation (“r”): RBC

x = Reference Mindray Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.

y = VDX Rayto Reagents for Rayto - Councell 23 Plus, 3 Part Hematology Analyzer.

$$“r” = 0.967$$

Sample size: 10

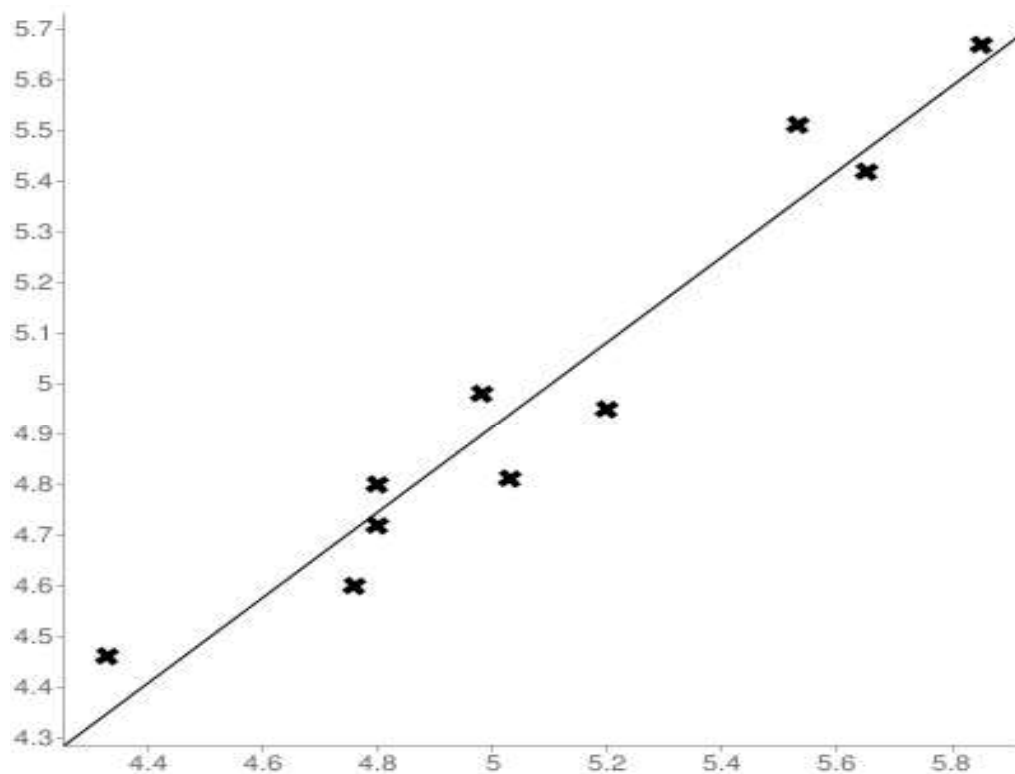
Mean x (x̄): 5.093

Mean y (ȳ): 4.992

Intercept (a): 0.69761210038572

Slope (b): 0.84319416839079

Regression line equation: $y = 0.69761210038572 + 0.84319416839079x$



Coefficient of Correlation (“r”): Hemoglobin

x = Reference Mindray Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.

y = VDX Rayto Reagents for Rayto - Councell 23 Plus, 3 Part Hematology Analyzer.

$$“r” = 0.954$$

Sample size: 10

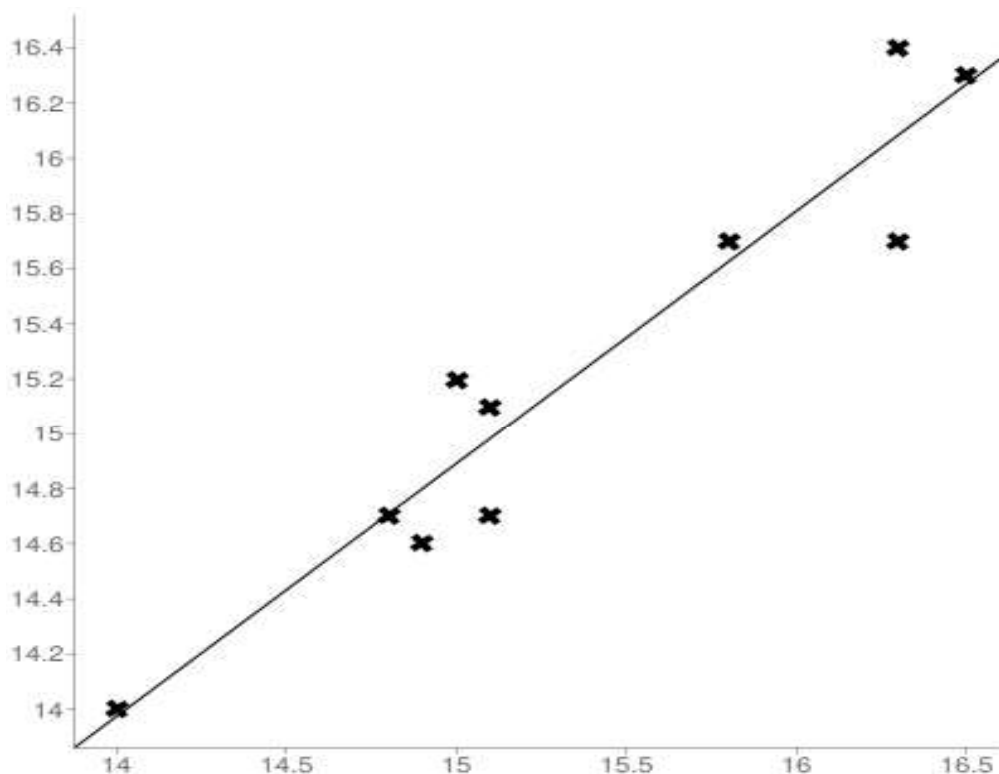
Mean x (x̄): 15.38

Mean y (ȳ): 15.24

Intercept (a): 1.1329715061066

Slope (b): 0.91723202170958

Regression line equation: $y = 1.1329715061066 + 0.91723202170958x$



Coefficient of Correlation (“r”): Platelets

x = Reference Mindray Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.

y = VDX Rayto Reagents for Rayto - Councell 23 Plus, 3 Part Hematology Analyzer.

$$“r” = 0.989$$

Sample size: 10

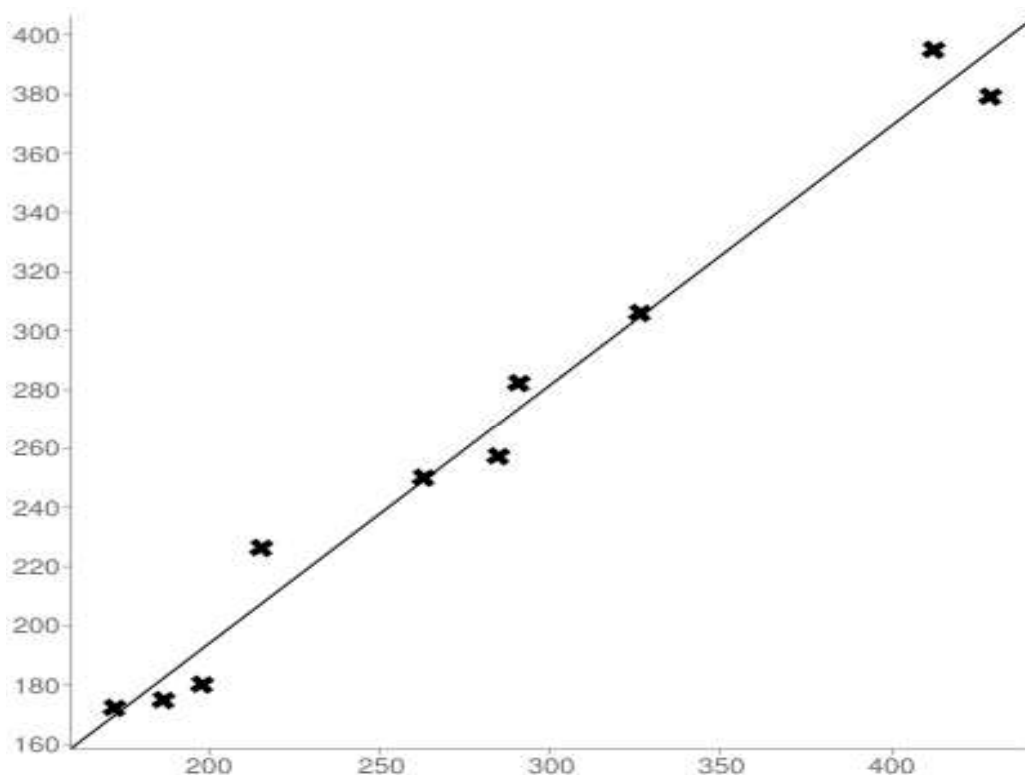
Mean x ($\bar{x}$): 277.7

Mean y ($\bar{y}$): 262.2

Intercept (a): 19.201129232413

Slope (b): 0.87504094622826

Regression line equation: $y = 19.201129232413 + 0.87504094622826x$



Coefficient of Correlation (“r”): MCV

x = Reference Mindray Reagents for Mindray-BC 3200, 3 Part Hematology Analyzer.
y = VDX Rayto Reagents for Rayto - Councell 23 Plus, 3 Part Hematology Analyzer.

$$“r” = 0.980$$

Sample size: 10

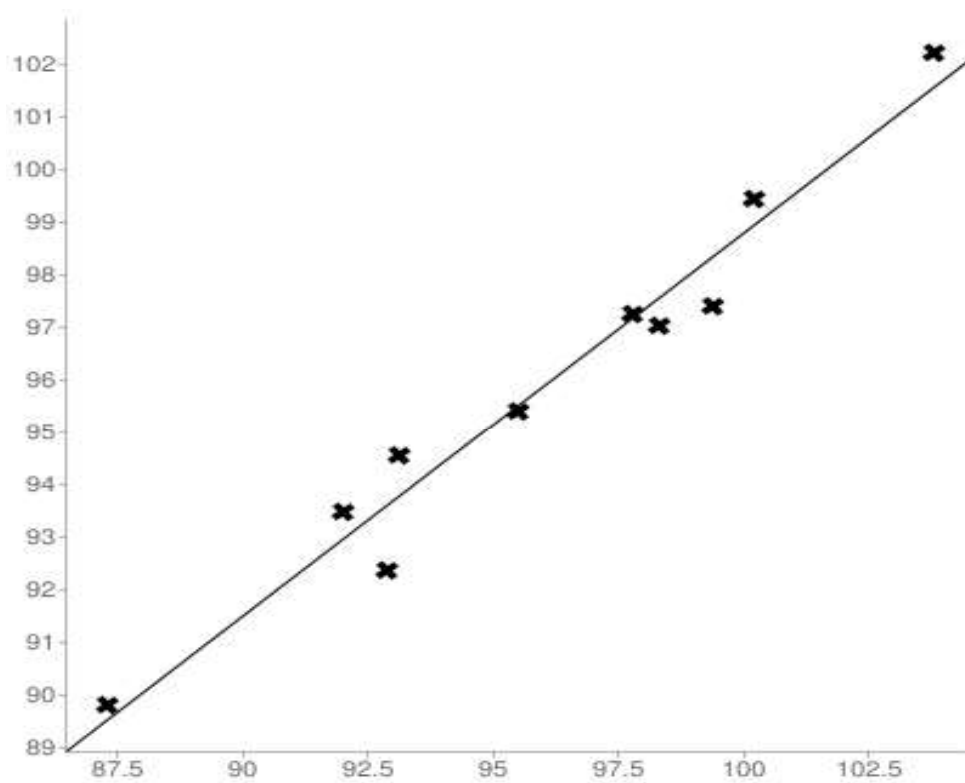
Mean x (x̄): 96.03

Mean y (ȳ): 95.89

Intercept (a): 25.808515257469

Slope (b): 0.72978740750319

Regression line equation: $y = 25.808515257469 + 0.72978740750319x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.55	9.80
Lymph # (10 ⁹ /L)	3.01	2.60
Mid # (10 ⁹ /L)	0.67	0.60
Gran # (10 ⁹ /L)	5.87	6.60
Lymph (%)	31.47	26.60
Mid (%)	7.02	6.60
Gran (%)	61.51	66.80
RBC (10¹²/L)	5.42	5.65
HGB (g/dL)	15.70	16.30
MCHC (g/dL)	31.36	31.10
MCH (pg)	28.96	28.80
MCV (fl)	92.35	92.90
RDW-CV (%)	12.55	14.20
RDW-SD (fL)	41.30	46.30
HCT (%)	50.06	52.40
PLT (10⁹/L)	172.00	172.00
MPV (fL)	9.38	11.60
PDW (%)	8.65	15.60
PCT (%)	0.16	0.20
PLCR (%)	86.44	

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.96	10.00
Lymph # (10 ⁹ /L)	3.02	2.60
Mid # (10 ⁹ /L)	0.45	1.00
Gran # (10 ⁹ /L)	6.49	6.40
Lymph (%)	30.36	26.00
Mid (%)	4.48	9.70
Gran (%)	65.16	64.30
RBC (10¹²/L)	4.60	4.76
HGB (g/dL)	14.60	14.90
MCHC (g/dL)	32.57	31.50
MCH (pg)	31.72	31.30
MCV (fl)	97.39	99.40
RDW-CV (%)	11.60	14.60
RDW-SD (fL)	40.27	48.90
HCT (%)	44.83	47.30
PLT (10⁹/L)	175.00	186.00
MPV (fL)	8.43	9.90
PDW (%)	10.56	16.00
PCT (%)	0.15	0.18
PLCR (%)	78.21	

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	8.38	8.40
Lymph # (10 ⁹ /L)	3.16	2.60
Mid # (10 ⁹ /L)	0.40	0.70
Gran # (10 ⁹ /L)	4.82	5.10
Lymph (%)	37.70	31.30
Mid (%)	4.78	8.90
Gran (%)	52.52	59.80
RBC (10¹²/L)	4.95	5.20
HGB (g/dL)	15.10	15.10
MCHC (g/dL)	32.24	31.10
MCH (pg)	30.48	29.00
MCV (fl)	94.55	93.10
RDW-CV (%)	12.30	12.80
RDW-SD (fL)	41.02	42.80
HCT (%)	46.83	48.40
PLT (10⁹/L)	257.00	285.00
MPV (fL)	7.33	8.10
PDW (%)	13.66	15.20
PCT (%)	0.19	0.23
PLCR (%)	70.70	

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	6.51	6.60
Lymph # (10 ⁹ /L)	2.05	1.80
Mid # (10 ⁹ /L)	0.27	0.50
Gran # (10 ⁹ /L)	4.19	4.30
Lymph (%)	31.56	27.00
Mid (%)	4.22	8.60
Gran (%)	64.22	64.40
RBC (10¹²/L)	4.80	4.80
HGB (g/dL)	14.70	14.80
MCHC (g/dL)	31.55	31.40
MCH (pg)	30.61	30.80
MCV (fl)	97.03	98.30
RDW-CV (%)	11.84	14.20
RDW-SD (fL)	40.51	51.60
HCT (%)	46.60	47.10
PLT (10⁹/L)	395.00	412.00
MPV (fL)	7.00	7.80
PDW (%)	14.84	15.40
PCT (%)	0.28	0.32
PLCR (%)	65.15	

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	10.60	10.60
Lymph # (10 ⁹ /L)	3.50	2.90
Mid # (10 ⁹ /L)	1.57	1.40
Gran # (10 ⁹ /L)	5.53	6.30
Lymph (%)	33.04	27.10
Mid (%)	14.75	13.30
Gran (%)	52.21	59.60
RBC (10¹²/L)	5.51	5.53
HGB (g/dL)	16.30	16.50
MCHC (g/dL)	31.63	32.40
MCH (pg)	29.56	29.80
MCV (fl)	93.47	92.00
RDW-CV (%)	12.52	12.10
RDW-SD (fL)	41.27	42.00
HCT (%)	51.54	50.80
PLT (10⁹/L)	282.00	291.00
MPV (fL)	7.73	8.80
PDW (%)	12.41	15.70
PCT (%)	0.22	0.26
PLCR (%)	70.77	

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	6.70	6.90
Lymph # (10 ⁹ /L)	2.11	1.90
Mid # (10 ⁹ /L)	0.31	0.60
Gran # (10 ⁹ /L)	4.28	4.40
Lymph (%)	31.44	27.50
Mid (%)	4.59	8.60
Gran (%)	63.97	63.90
RBC (10¹²/L)	4.81	5.03
HGB (g/dL)	14.70	15.10
MCHC (g/dL)	31.41	30.70
MCH (pg)	30.54	30.00
MCV (fl)	97.25	97.80
RDW-CV (%)	11.80	13.60
RDW-SD (fL)	40.47	49.90
HCT (%)	46.80	49.10
PLT (10⁹/L)	379.00	429.00
MPV (fL)	7.03	7.80
PDW (%)	14.75	15.40
PCT (%)	0.27	0.33
PLCR (%)	65.24	

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot -2022021601
WBC (10⁹/L)	5.65	5.70
Lymph # (10 ⁹ /L)	2.47	2.00
Mid # (10 ⁹ /L)	0.47	0.70
Gran # (10 ⁹ /L)	2.71	3.00
Lymph (%)	43.53	34.50
Mid (%)	8.25	12.10
Gran (%)	48.22	53.40
RBC (10¹²/L)	5.67	5.85
HGB (g/dL)	16.40	16.30
MCHC (g/dL)	32.19	31.90
MCH (pg)	28.90	27.80
MCV (fl)	89.81	87.30
RDW-CV (%)	13.33	12.20
RDW-SD (fL)	42.23	38.50
HCT (%)	50.95	51.00
PLT (10⁹/L)	226.00	215.00
MPV (fL)	7.73	8.70
PDW (%)	12.40	15.50
PCT (%)	0.17	0.19
PLCR (%)	71.64	

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	7.61	7.70
Lymph # (10 ⁹ /L)	3.47	3.10
Mid # (10 ⁹ /L)	0.29	0.60
Gran # (10 ⁹ /L)	3.85	4.00
Lymph (%)	45.53	40.40
Mid (%)	3.86	8.10
Gran (%)	50.61	51.50
RBC (10¹²/L)	4.72	4.80
HGB (g/dL)	15.70	15.80
MCHC (g/dL)	32.54	31.70
MCH (pg)	33.26	32.90
MCV (fl)	102.23	103.80
RDW-CV (%)	11.03	13.80
RDW-SD (fL)	39.76	52.50
HCT (%)	48.25	49.80
PLT (10⁹/L)	306.00	326.00
MPV (fL)	7.27	8.10
PDW (%)	13.87	15.50
PCT (%)	0.22	0.26
PLCR (%)	66.33	

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot -2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	10.30	10.10
Lymph # (10 ⁹ /L)	4.08	3.50
Mid # (10 ⁹ /L)	0.52	0.90
Gran # (10 ⁹ /L)	5.70	5.70
Lymph (%)	39.62	34.20
Mid (%)	5.02	8.90
Gran (%)	55.36	56.90
RBC (10¹²/L)	4.98	4.98
HGB (g/dL)	15.20	15.00
MCHC (g/dL)	31.97	31.50
MCH (pg)	30.50	30.10
MCV (fl)	95.39	95.50
RDW-CV (%)	12.14	13.30
RDW-SD (fL)	40.84	45.40
HCT (%)	47.54	47.50
PLT (10⁹/L)	180.00	198.00
MPV (fL)	8.86	11.10
PDW (%)	9.60	15.80
PCT (%)	0.16	0.22
PLCR (%)	83.16	

Sample - 10		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	All Reagents: Mindray as Reference M-30D Diluent Lot-2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	10.12	10.00
Lymph # (10 ⁹ /L)	3.20	2.70
Mid # (10 ⁹ /L)	0.44	0.90
Gran # (10 ⁹ /L)	6.48	6.40
Lymph (%)	31.61	27.00
Mid (%)	4.32	9.10
Gran (%)	64.07	63.90
RBC (10¹²/L)	4.46	4.33
HGB (g/dL)	14.00	14.00
MCHC (g/dL)	31.54	32.30
MCH (pg)	31.36	32.30
MCV (fL)	99.43	100.20
RDW-CV (%)	11.44	13.40
RDW-SD (fL)	40.12	48.90
HCT (%)	44.39	43.30
PLT (10⁹/L)	250.00	263.00
MPV (fL)	7.75	8.80
PDW (%)	12.34	15.80
PCT (%)	0.19	0.23
PLCR (%)	70.50	

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D		
(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	Range
WBC (10⁹/L)	2.5	1.8 - 2.8
Lymph # (10 ⁹ /L)	1.19	0.8 - 1.6
Mid # (10 ⁹ /L)	0.16	0.0 - 0.2
Gran # (10 ⁹ /L)	1.15	0.6 - 1.4
Lymph (%)	47.26	38.8 - 64.6
Mid (%)	6.32	1.1 - 8.3
Gran (%)	46.42	32.7 - 54.5
RBC (10¹²/L)	2.61	2.25 - 2.65
HGB (g/dL)	7.0	6.3 - 7.3
MCHC (g/dL)	32.34	30.6 - 40.2
MCH (pg)	26.84	24.2 - 31.8
MCV (fL)	83.0	73.0 - 85.0
RDW-CV (%)	13.9	9.4 - 19.4
RDW-SD (fL)	42.93	
HCT (%)	21.65	16.3 - 22.3
PLT (10⁹/L)	85.0	61 - 111
MPV (fL)	7.69	4.46 - 10.46
PDW (%)	12.52	
PCT (%)	0.070	0.011 - 0.111
PLCR (%)	89.13	

Diagon D Check D		
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	Range
WBC (10⁹/L)	7.34	6.2 - 8.2
Lymph # (10 ⁹ /L)	2.08	1.5 - 3.1
Mid # (10 ⁹ /L)	0.37	0.1 - 0.5
Gran # (10 ⁹ /L)	4.89	3.9 - 5.3
Lymph (%)	28.30	20.6 - 42.8
Mid (%)	4.99	0.8 - 6.4
Gran (%)	66.71	51.8 - 77.6
RBC (10¹²/L)	4.65	4.15 - 4.75
HGB (g/dL)	13.6	12.6 - 13.8
MCHC (g/dL)	33.18	30.9 - 40.5
MCH (pg)	29.22	26.0 - 33.6
MCV (fL)	88.06	77.5 - 89.5
RDW-CV (%)	12.65	9.5 - 19.5
RDW-SD (fL)	41.42	
HCT (%)	40.98	33.2 - 41.2
PLT (10⁹/L)	215.0	195 - 285
MPV (fL)	7.7	4.63 - 10.63
PDW (%)	12.51	
PCT (%)	0.170	0.075 - 0.275
PLCR (%)	89.56	

Diagon D Check D
(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics Diluent-R Lot- HVDR220902 Lyse-R Lot- HVCR211004 Cleaner-R Lot- HVDTR220904	Range
WBC (10⁹/L)	17.3	14.7 - 19.7
Lymph # (10 ⁹ /L)	3.82	1.8 - 6.2
Mid # (10 ⁹ /L)	0.58	0.1 - 1.1
Gran # (10 ⁹ /L)	12.9	8.8 - 16.5
Lymph (%)	22.09	15.0 - 31.2
Mid (%)	3.37	0.7 - 6.5
Gran (%)	74.54	62.3 - 84.3
RBC (10¹²/L)	5.61	5.02 - 5.82
HGB (g/dL)	17.2	16.4 - 18.0
MCHC (g/dL)	33.1	31.1 - 40.7
MCH (pg)	30.64	27.8 - 35.4
MCV (fL)	92.58	82.2 - 94.2
RDW-CV (%)	11.74	9.5 - 19.5
RDW-SD (fL)	40.41	
HCT (%)	51.96	43.3 - 52.3
PLT (10⁹/L)	493.0	399 - 549
MPV (fL)	7.61	4.84 - 10.84
PDW (%)	12.76	
PCT (%)	0.380	0.162 - 0.562
PLCR (%)	91.23	



D-Check D

CONTROL

ASSAY VALUES AND EXPECTED RANGES



LOT: 1V0901

05-03-2023

Instruments:		Rayto RT-7600s, Linear STEL 3					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,3 ± 0,5	1,8 - 2,8	7,2 ± 1,0	6,2 - 8,2	17,2 ± 2,5	14,7 - 19,7
RBC	10 ¹² /L	2,45 ± 0,20	2,25 - 2,65	4,45 ± 0,30	4,15 - 4,75	5,42 ± 0,40	5,02 - 5,82
Hgb	g/dL	6,8 ± 0,5	6,3 - 7,3	13,2 ± 0,6	12,6 - 13,8	17,2 ± 0,8	16,4 - 18,0
	g/L	68 ± 5	63 - 73	132 ± 6	126 - 138	172 ± 8	164 - 180
Hct	%	19,3 ± 3,0	16,3 - 22,3	37,2 ± 4,0	33,2 - 41,2	47,8 ± 4,5	43,3 - 52,3
	L/L	0,193 ± 0,030	0,163 - 0,223	0,372 ± 0,040	0,332 - 0,412	0,478 ± 0,045	0,433 - 0,523
MCV	fL	79,0 ± 6,0	73,0 - 85,0	83,5 ± 6,0	77,5 - 89,5	88,2 ± 6,0	82,2 - 94,2
MCH	pg	28,0 ± 3,8	24,2 - 31,8	29,8 ± 3,8	26,0 - 33,6	31,6 ± 3,8	27,8 - 35,4
MCHC	g/dL	35,4 ± 4,8	30,6 - 40,2	35,7 ± 4,8	30,9 - 40,5	35,9 ± 4,8	31,1 - 40,7
	g/L	354 ± 48	306 - 402	357 ± 48	309 - 405	359 ± 48	311 - 407
RDW-CV	%	14,4 ± 5,0	9,4 - 19,4	14,5 ± 5,0	9,5 - 19,5	14,5 ± 5,0	9,5 - 19,5
Plt	10 ⁹ /L	86 ± 25	61 - 111	240 ± 45	195 - 285	474 ± 75	399 - 549
MPV	fL	7,46 ± 3,00	4,46 - 10,46	7,63 ± 3,00	4,63 - 10,63	7,84 ± 3,00	4,84 - 10,84
PDW	%	8,94 ± 3,00	5,94 - 11,94	8,17 ± 3,00	5,17 - 11,17	8,25 ± 3,00	5,25 - 11,25
PCT	%	0,061 ± 0,050	0,011 - 0,111	0,175 ± 0,100	0,075 - 0,275	0,362 ± 0,200	0,162 - 0,562
LYMPH#	10 ⁹ /L	1,2 ± 0,4	0,8 - 1,6	2,3 ± 0,8	1,5 - 3,1	4,0 ± 2,2	1,8 - 6,2
MID#	10 ⁹ /L	0,1 ± 0,1	0,0 - 0,2	0,3 ± 0,2	0,1 - 0,5	0,6 ± 0,5	0,1 - 1,1
GRAN#	10 ⁹ /L	1,0 ± 0,4	0,6 - 1,4	4,6 ± 0,7	3,9 - 5,3	12,6 ± 3,8	8,8 - 16,4
LYMPH%	%	51,7 ± 12,9	38,8 - 64,6	31,7 ± 11,1	20,6 - 42,8	23,1 ± 8,1	15,0 - 31,2
MID%	%	4,7 ± 3,6	1,1 - 8,3	3,6 ± 2,8	0,8 - 6,4	3,6 ± 2,9	0,7 - 6,5
GRAN%	%	43,6 ± 10,9	32,7 - 54,5	64,7 ± 12,9	51,8 - 77,6	73,3 ± 11,0	62,3 - 84,3

DIAGON Ltd.

48-52., Baross Str.

Budapest, Hungary

H-1047



Coefficient of Variation:

Precision (VDx Reagents)

1. Two fresh blood samples were collected and tested with the VDx Rayto Reagents on Rayto- Councell 23 Plus, 3 Part Hematology Analyzer.
2. The samples were tested in 09 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample - 01, n = 09

Precision Evaluation report of VDx Rayto compatible reagent on Rayto-Councell 23 Plus, 3 Part Hematology Analyzer														
Fresh Blood Sample-01														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10⁹/L)	8.37	8.53	8.34	8.51	8.54	8.49	8.29	8.25	8.44		8.42	0.11	0.01	1.29
Lymph # (10 ⁹ /L)	3.5	3.58	3.43	3.59	3.54	3.5	3.44	3.52	3.63		3.53	0.07	0.02	1.90
Mid # (10 ⁹ /L)	0.45	0.47	0.44	0.52	0.50	0.45	0.45	0.48	0.47		0.47	0.03	0.06	5.63
Gran # (10 ⁹ /L)	4.42	4.48	4.47	4.4	4.5	4.54	4.4	4.25	4.34		4.42	0.09	0.02	2.01
Lymph (%)	41.69	41.93	41.03	42.13	41.39	41.15	41.44	42.61	42.96		41.81	0.66	0.02	1.57
Mid (%)	5.41	5.55	5.32	6.09	5.83	5.29	5.44	5.82	5.61		5.60	0.27	0.05	4.81
Gran (%)	52.9	52.52	53.65	51.78	52.78	53.56	53.12	51.57	51.43		52.59	0.83	0.02	1.58
RBC (10¹²/L)	4.81	4.73	4.75	4.79	4.79	4.8	4.76	4.7	4.76		4.77	0.04	0.01	0.75
HGB (g/dL)	15.8	15.7	15.7	15.7	15.8	15.6	15.5	15.7	15.5		15.67	0.11	0.01	0.71
MCHC (g/dL)	33.46	33.62	33.55	33.2	33.4	32.93	33.05	33.79	32.99		33.33	0.30	0.01	0.91
MCH (pg)	32.84	33.18	33.05	32.79	33.02	32.5	32.58	33.41	32.58		32.88	0.31	0.01	0.93
MCV (fl)	98.14	98.7	98.51	98.76	98.86	98.69	98.57	98.88	98.74		98.65	0.23	0.00	0.23
RDW-CV (%)	10.87	10.79	10.82	10.78	10.77	10.79	10.81	10.77	10.79		10.80	0.03	0.00	0.29
RDW-SD (fl)	39.65	39.6	39.62	39.6	39.59	39.6	39.61	39.59	39.6		39.61	0.02	0.00	0.05
HCT (%)	47.22	46.7	46.79	47.29	47.31	47.37	46.9	46.47	46.98		47.00	0.31	0.01	0.67
PLT (10⁹/L)	175.00	177.00	167.00	175.00	160.00	172.00	185.00	180.00	171.00		173.56	7.28	0.04	4.20
MPV (fL)	8.23	8.48	8.28	8.39	8.12	8.54	8.32	8.31	8.45		8.35	0.13	0.02	1.58
PDW (%)	11.03	10.43	10.91	10.64	11.33	10.29	10.82	10.83	10.50		10.75	0.32	0.03	3.01
PCT (%)	0.14	0.15	0.14	0.15	0.15	0.15	0.15	0.15	0.14		0.15	0.00	0.03	3.41
PLCR (%)	77.71	79.01	76.09	79.27	75.86	81.10	79.00	78.97	78.49		78.39	1.63	0.02	2.09

Fresh Blood Sample - 02, n = 09

Precision Evaluation report of VDX Rayto compatible reagent on Rayto-Council 23 Plus, 3 Part Hematology Analyzer														
Fresh Blood Sample-02														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10 ⁹ /L)	6.87	6.91	6.71	6.92	6.66	6.72	6.66	6.81	6.72		6.78	0.10	0.02	1.53
Lymph # (10 ⁹ /L)	2.98	2.89	2.87	2.94	2.86	2.8	2.81	2.9	2.87		2.88	0.06	0.02	1.98
Mid # (10 ⁹ /L)	0.57	0.61	0.59	0.65	0.64	0.60	0.63	0.68	0.64		0.62	0.03	0.05	5.44
Gran # (10 ⁹ /L)	3.32	3.41	3.25	3.33	3.16	3.32	3.22	3.23	3.21		3.27	0.08	0.02	2.38
Lymph (%)	43.32	41.76	42.68	42.38	42.86	41.56	42.01	42.5	42.52		42.40	0.55	0.01	1.30
Mid (%)	8.21	8.86	8.74	9.29	9.50	8.84	9.37	9.93	9.43		9.13	0.51	0.06	5.62
Gran (%)	48.47	49.38	48.58	48.33	47.64	49.60	48.62	47.57	48.05		48.47	0.69	0.01	1.43
RBC (10 ¹² /L)	4.33	4.33	4.35	4.41	4.35	4.41	4.49	4.45	4.44		4.40	0.06	0.01	1.32
HGB (g/dL)	14	14.1	14.1	14.2	14	14.1	14.1	14.1	14.2		14.10	0.07	0.01	0.50
MCHC (g/dL)	33.38	33.62	33.59	33.34	33.26	33.03	32.47	32.73	33.06		33.16	0.38	0.01	1.16
MCH (pg)	32.34	32.53	32.45	32.17	32.15	31.95	31.41	31.67	31.99		32.07	0.36	0.01	1.14
MCV (fl)	96.89	96.76	96.61	96.49	96.67	96.72	96.72	96.77	96.78		96.71	0.11	0.00	0.12
RDW-CV (%)	11.04	11.06	11.08	11.1	11.07	11.06	11.06	11.06	11.05		11.06	0.02	0.00	0.16
RDW-SD (fL)	39.77	39.79	39.8	39.82	39.8	39.79	39.79	39.79	39.78		39.79	0.01	0.00	0.04
HCT (%)	41.94	41.94	41.98	42.59	42.09	42.68	43.42	43.08	42.95		42.52	0.56	0.01	1.31
PLT (10 ⁹ /L)	239.00	236.00	239.00	249.00	245.00	245.00	234.00	251.00	227.00		240.56	7.68	0.03	3.19
MPV (fL)	7.8	8	7.68	7.98	7.94	7.94	7.92	7.89	8.01		7.91	0.11	0.01	1.34
PDW (%)	12.21	11.63	12.55	11.69	11.79	11.80	11.85	11.94	11.61		11.90	0.31	0.03	2.57
PCT (%)	0.19	0.19	0.18	0.2	0.19	0.19	0.19	0.2	0.18		0.19	0.01	0.04	3.72
PLCR (%)	74.45	78.88	74.24	77.09	75.85	75.38	75.78	73.88	77.86		75.93	1.71	0.02	2.25

Conclusions

4. The VDX Rayto 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray original Reagents as Reference.
5. All measured parameters showed values of “r” in the range of 0.967 to 0.997 displaying the highest degree of correlation between the reagents.
6. The VDX Rayto 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
7. The CV % with the VDX Rayto Reagents were found to be as under:

Parameters	VDX Rayto Reagents (CV % - Precision)
Measured Parameters	0.23% - 4.20%
Calculated Parameters	0.05% - 5.63%

8. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges for VDX Rayto 3 Part Hematology Reagents.
9. **The VDX Rayto 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Mindray Reference Reagents in all the parameters identified for the evaluation.**

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents & Tests Conducted	292 - 293
2	Background Test	294
2	Coefficient of Correlation: Accuracy	295 – 311
3	Quality Control (Low, Normal & High)	312 - 316
4	Coefficient of Variation: Precision (VDx Dymind Compatible Reagents)	317 - 318
5	Conclusions	319

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Dymind – DH36
Reference Reagents	Mindray Reference Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date : 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date : 15-02-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Dymind Compatible Reagents)

Background Test		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-C Lot - HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	0.00	0.00
Lymph (%)	0.00	0.0
Mid (%)	0.00	0.0
Gran (%)	0.00	0.0
Lymph # (10 ⁹ /L)	0.00	0.0
Mid # (10 ⁹ /L)	0.00	0.0
Gran # (10 ⁹ /L)	0.00	0.0
RBC (10¹²/L)	0.00	0.00
HGB (g/dL)	0.0	0.0
HCT (%)	0.00	0.0
MCV (fL)	0.00	0.0
MCH (pg)	0.00	0.0
MCHC (g/dL)	0.00	0.0
RDW-CV (%)	0.00	0.0
RDW-SD (fL)	0.00	0.0
PLT (10⁹/L)	0.0	0.0
MPV (fL)	0.00	0.0
PDW (%)	0.00	0.0
PCT (%)	0.00	0.0
PLCR (%)	0.00	
PLCC (10 ⁹ /L)	0.00	

Coefficient of Correlation Studies

- IV. The objective was to determine the correlation between the results obtained with the Vanguard Compatible Dymind Reagents and the Mindray Reference Reagents.
- V. The Coefficient of Correlation (“r”) was calculated for each major parameter of the Complete Blood Count.
- VI. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of “r”
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When “r” is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Reference Mindray Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Dymind Reagents for Dymind-DH36, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 10

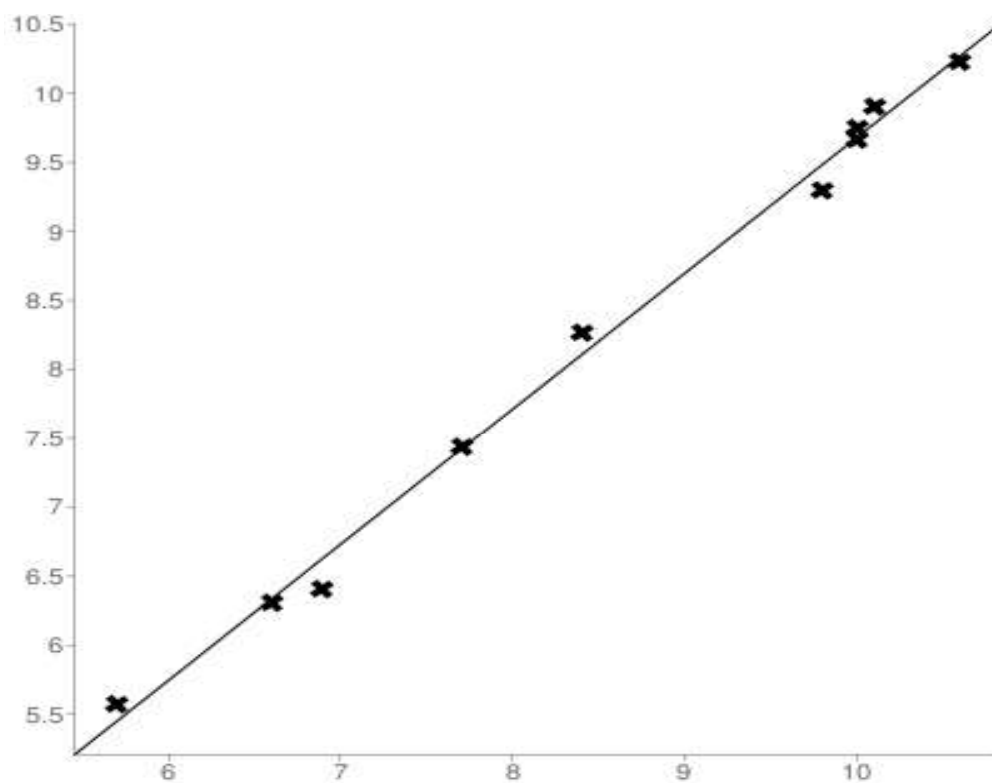
Mean x (x̄): 8.58

Mean y (ȳ): 8.282

Intercept (a): -0.159018590575

Slope (b): 0.98380170053322

Regression line equation: $y = 0.98380170053322x - 0.159018590575$



Coefficient of Correlation (“r”): RBC

x = Reference Mindray Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Dymind Reagents for Dymind-DH36, 3 Part Hematology Analyzer.

$$“r” = 0.969$$

Sample size: 10

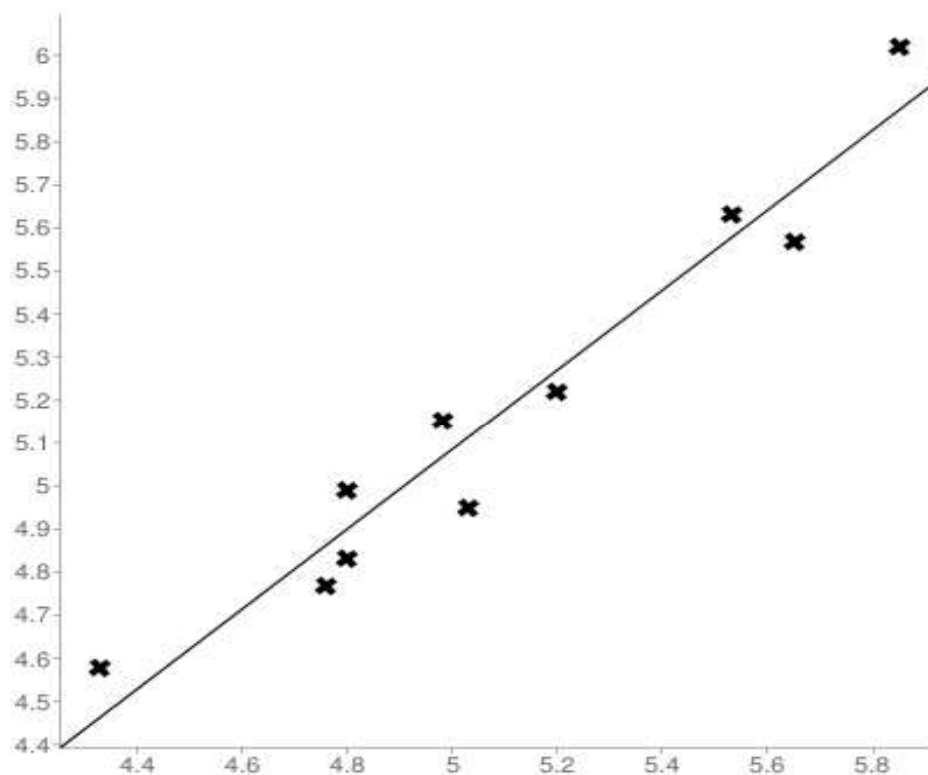
Mean x ($\bar{x}$): 5.093

Mean y ($\bar{y}$): 5.171

Intercept (a): 0.44754611861439

Slope (b): 0.927440385114

Regression line equation: $y = 0.44754611861439 + 0.927440385114x$



Coefficient of Correlation (“r”): Hemoglobin

x = Reference Mindray Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Dymind Reagents for Dymind-DH36, 3 Part Hematology Analyzer.

$$“r” = 0.940$$

Sample size: 10

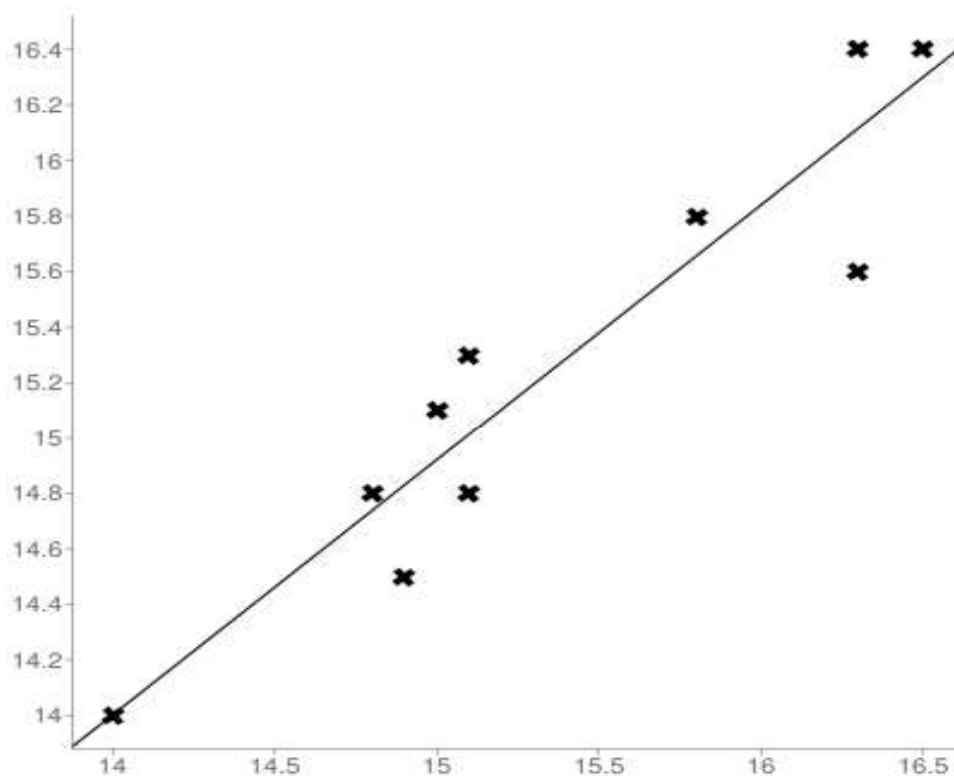
Mean x (x̄): 15.38

Mean y (ȳ): 15.27

Intercept (a): 1.1473202170963

Slope (b): 0.91824966078698

Regression line equation: $y = 1.1473202170963 + 0.91824966078698x$



Coefficient of Correlation (“r”): Platelets

x = Reference Mindray Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.

y = VDX Dymind Reagents for Dymind-DH36, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 10

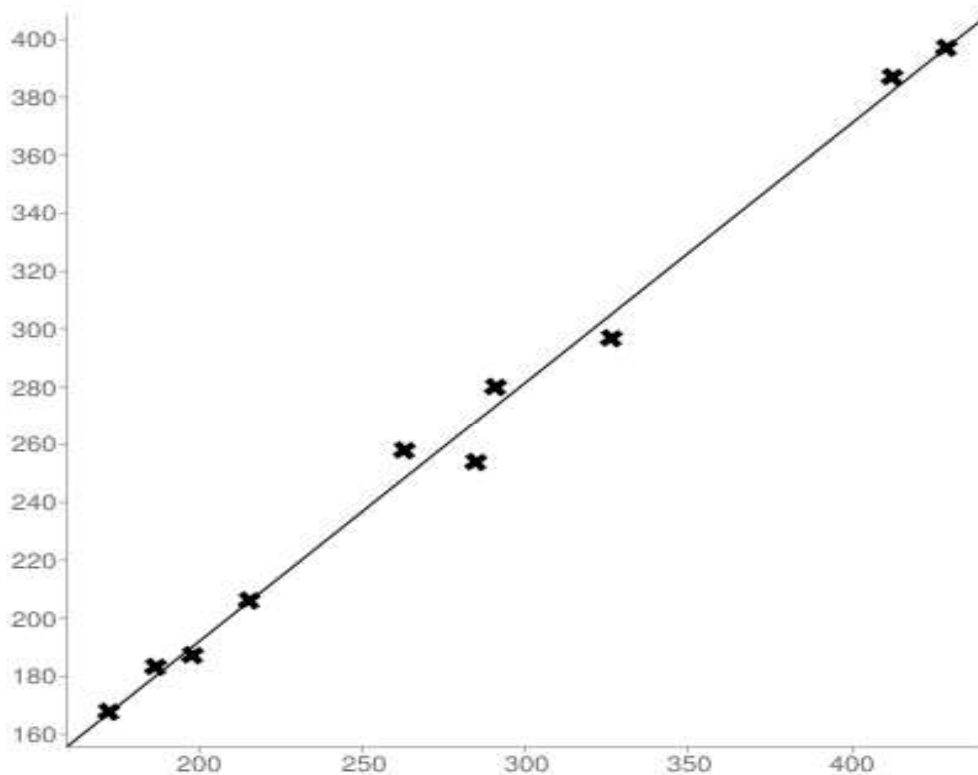
Mean x (x̄): 277.7

Mean y (ȳ): 261.7

Intercept (a): 13.290342398817

Slope (b): 0.8945252344299

Regression line equation: $y = 13.290342398817 + 0.8945252344299x$



Coefficient of Correlation (“r”): MCV

x = Reference Mindray Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Dymind Reagents for Dymind-DH36, 3 Part Hematology Analyzer.

$$“r” = 0.994$$

Sample size: 10

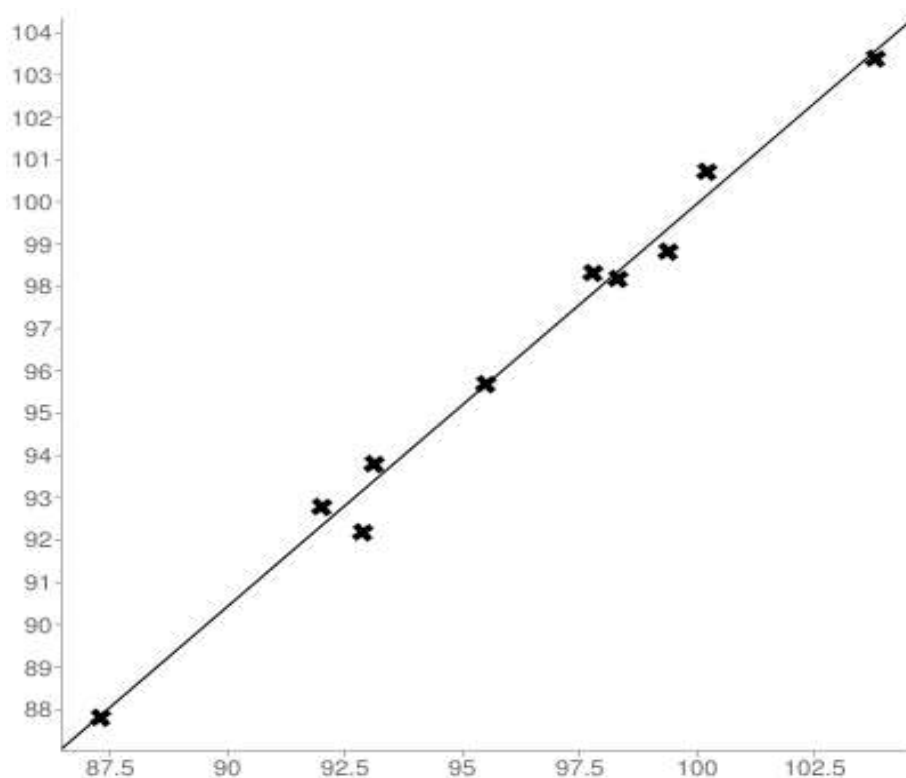
Mean x ($\bar{x}$): 96.03

Mean y ($\bar{y}$): 96.17

Intercept (a): 4.7185808623569

Slope (b): 0.95232134892891

Regression line equation: $y = 4.7185808623569 + 0.95232134892891x$



Raw Data for “r”

Sample - 01		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot- HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.30	9.80
Lymph (%)	29.50	26.6
Mid (%)	65.10	66.8
Gran (%)	5.40	6.60
Lymph # (10 ⁹ /L)	2.74	2.60
Mid # (10 ⁹ /L)	6.06	6.60
Gran # (10 ⁹ /L)	0.50	0.60
RBC (10¹²/L)	5.57	5.65
HGB (g/dL)	15.6	16.3
HCT (%)	51.40	52.4
MCV (fL)	92.20	92.9
MCH (pg)	28.00	28.8
MCHC (g/dL)	30.40	31.1
RDW-CV (%)	13.7	14.2
RDW-SD (fL)	51.30	46.3
PLT (10⁹/L)	168.0	172.0
MPV (fL)	12.90	11.6
PDW (%)	16.40	15.6
PCT (%)	0.216	0.199
PLCR (%)	51.00	
PLCC (10 ⁹ /L)	86.00	

Sample - 02		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot- HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.66	10.00
Lymph (%)	25.60	26.0
Mid (%)	65.60	64.3
Gran (%)	8.80	9.70
Lymph # (10 ⁹ /L)	2.47	2.60
Mid # (10 ⁹ /L)	6.34	6.40
Gran # (10 ⁹ /L)	0.85	1.00
RBC (10¹²/L)	4.77	4.76
HGB (g/dL)	14.5	14.9
HCT (%)	47.10	47.3
MCV (fL)	98.80	99.4
MCH (pg)	30.40	31.3
MCHC (g/dL)	30.80	31.5
RDW-CV (%)	13.4	14.6
RDW-SD (fL)	54.00	48.9
PLT (10⁹/L)	183.0	186.0
MPV (fL)	11.20	9.9
PDW (%)	16.30	16.0
PCT (%)	0.205	0.184
PLCR (%)	39.20	
PLCC (10 ⁹ /L)	72.00	

Sample - 03		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot- HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	8.27	8.40
Lymph (%)	33.80	31.3
Mid (%)	58.60	59.8
Gran (%)	7.60	8.90
Lymph # (10 ⁹ /L)	2.80	2.60
Mid # (10 ⁹ /L)	4.84	5.10
Gran # (10 ⁹ /L)	0.63	0.70
RBC (10¹²/L)	5.22	5.20
HGB (g/dL)	15.3	15.1
HCT (%)	48.90	48.4
MCV (fL)	93.80	93.1
MCH (pg)	29.30	29.0
MCHC (g/dL)	31.20	31.1
RDW-CV (%)	12.9	12.8
RDW-SD (fL)	49.00	42.8
PLT (10⁹/L)	254.0	285.0
MPV (fL)	9.40	8.1
PDW (%)	15.90	15.2
PCT (%)	0.239	0.230
PLCR (%)	25.60	
PLCC (10 ⁹ /L)	65.00	

Sample - 04		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot- HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot- 2022021601
WBC (10⁹/L)	6.31	6.60
Lymph (%)	25.80	27.0
Mid (%)	64.50	64.4
Gran (%)	9.70	8.60
Lymph # (10 ⁹ /L)	1.63	1.80
Mid # (10 ⁹ /L)	4.07	4.30
Gran # (10 ⁹ /L)	0.61	0.50
RBC (10¹²/L)	4.99	4.80
HGB (g/dL)	14.8	14.8
HCT (%)	49.00	47.1
MCV (fL)	98.20	98.3
MCH (pg)	29.70	30.8
MCHC (g/dL)	30.30	31.4
RDW-CV (%)	13.6	14.2
RDW-SD (fL)	54.30	51.6
PLT (10⁹/L)	387.0	412.0
MPV (fL)	8.90	7.8
PDW (%)	15.90	15.4
PCT (%)	0.345	0.321
PLCR (%)	21.40	
PLCC (10 ⁹ /L)	83.00	

Sample - 05		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	10.23	10.60
Lymph (%)	29.30	27.1
Mid (%)	56.70	59.6
Gran (%)	14.00	13.30
Lymph # (10 ⁹ /L)	3.00	2.90
Mid # (10 ⁹ /L)	5.80	6.30
Gran # (10 ⁹ /L)	1.43	1.40
RBC (10¹²/L)	5.63	5.53
HGB (g/dL)	16.4	16.5
HCT (%)	52.30	50.8
MCV (fL)	92.80	92.0
MCH (pg)	29.10	29.8
MCHC (g/dL)	31.40	32.4
RDW-CV (%)	12.9	12.1
RDW-SD (fL)	48.30	42.0
PLT (10⁹/L)	280.0	291.0
MPV (fL)	9.60	8.8
PDW (%)	15.90	15.7
PCT (%)	0.270	0.256
PLCR (%)	28.60	
PLCC (10 ⁹ /L)	80.00	

Sample - 06		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	6.40	6.90
Lymph (%)	27.00	27.5
Mid (%)	64.90	63.9
Gran (%)	8.10	8.60
Lymph # (10 ⁹ /L)	1.73	1.90
Mid # (10 ⁹ /L)	4.15	4.40
Gran # (10 ⁹ /L)	0.52	0.60
RBC (10¹²/L)	4.95	5.03
HGB (g/dL)	14.8	15.1
HCT (%)	48.60	49.1
MCV (fL)	98.30	97.8
MCH (pg)	29.90	30.0
MCHC (g/dL)	30.40	30.7
RDW-CV (%)	13.5	13.6
RDW-SD (fL)	54.20	49.9
PLT (10⁹/L)	397.0	429.0
MPV (fL)	8.90	7.8
PDW (%)	15.80	15.4
PCT (%)	0.353	0.334
PLCR (%)	21.70	
PLCC (10 ⁹ /L)	86.00	

Sample - 07		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot- HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	5.57	5.70
Lymph (%)	37.20	34.5
Mid (%)	52.90	53.4
Gran (%)	9.90	12.10
Lymph # (10 ⁹ /L)	2.07	2.00
Mid # (10 ⁹ /L)	2.95	3.00
Gran # (10 ⁹ /L)	0.55	0.70
RBC (10¹²/L)	6.02	5.85
HGB (g/dL)	16.4	16.3
HCT (%)	52.80	51.0
MCV (fL)	87.80	87.3
MCH (pg)	27.30	27.8
MCHC (g/dL)	31.10	31.9
RDW-CV (%)	12.9	12.2
RDW-SD (fL)	45.60	38.5
PLT (10⁹/L)	206.0	215.0
MPV (fL)	9.60	8.7
PDW (%)	16.10	15.5
PCT (%)	0.197	0.187
PLCR (%)	26.10	
PLCC (10 ⁹ /L)	54.00	

Sample - 08		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	7.43	7.70
Lymph (%)	42.40	40.4
Mid (%)	50.80	51.5
Gran (%)	6.80	8.10
Lymph # (10 ⁹ /L)	3.15	3.10
Mid # (10 ⁹ /L)	3.77	4.00
Gran # (10 ⁹ /L)	0.51	0.60
RBC (10¹²/L)	4.83	4.80
HGB (g/dL)	15.8	15.8
HCT (%)	49.90	49.8
MCV (fL)	103.40	103.8
MCH (pg)	32.70	32.9
MCHC (g/dL)	31.60	31.7
RDW-CV (%)	13.3	13.8
RDW-SD (fL)	56.10	52.5
PLT (10⁹/L)	297.0	326.0
MPV (fL)	9.20	8.1
PDW (%)	16.00	15.5
PCT (%)	0.274	0.264
PLCR (%)	23.60	
PLCC (10 ⁹ /L)	70.00	

Sample - 09		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.90	10.10
Lymph (%)	35.30	34.2
Mid (%)	57.50	56.9
Gran (%)	7.20	8.90
Lymph # (10 ⁹ /L)	3.49	3.50
Mid # (10 ⁹ /L)	5.70	5.70
Gran # (10 ⁹ /L)	0.71	0.90
RBC (10¹²/L)	5.15	4.98
HGB (g/dL)	15.1	15.0
HCT (%)	49.30	47.5
MCV (fL)	95.70	95.5
MCH (pg)	29.30	30.1
MCHC (g/dL)	30.60	31.5
RDW-CV (%)	13.0	13.3
RDW-SD (fL)	50.70	45.4
PLT (10⁹/L)	187.0	198.0
MPV (fL)	12.40	11.1
PDW (%)	16.40	15.8
PCT (%)	0.232	0.219
PLCR (%)	49.70	
PLCC (10 ⁹ /L)	93.00	

Sample - 10		
	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot- HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	All Reagents: Mindray as Reference M-30D Diluent Lot - 2022091601 M-30CF Lyse Lot - 2022021601
WBC (10⁹/L)	9.75	10.00
Lymph (%)	29.10	27.0
Mid (%)	64.60	63.9
Gran (%)	6.30	9.10
Lymph # (10 ⁹ /L)	2.84	2.70
Mid # (10 ⁹ /L)	6.30	6.40
Gran # (10 ⁹ /L)	0.61	0.90
RBC (10¹²/L)	4.58	4.33
HGB (g/dL)	14.0	14.0
HCT (%)	46.10	43.3
MCV (fL)	100.70	100.2
MCH (pg)	30.70	32.3
MCHC (g/dL)	30.50	32.3
RDW-CV (%)	13.2	13.4
RDW-SD (fL)	54.30	48.9
PLT (10⁹/L)	258.0	263.0
MPV (fL)	9.60	8.8
PDW (%)	16.70	15.8
PCT (%)	0.248	0.231
PLCR (%)	28.50	
PLCC (10 ⁹ /L)	74.00	

Performance with Hematology 3rd Party Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D		
(Low Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot - HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	Range
WBC (10⁹/L)	2.17	1.78 - 2.78
Lymph (%)	52.80	41.2 - 61.8
Mid (%)	39.30	27.6 - 57.4
Gran (%)	7.90	0.9 - 11.1
Lymph # (10 ⁹ /L)	1.15	0.94 - 1.4
Mid # (10 ⁹ /L)	0.85	0.63 - 1.31
Gran # (10 ⁹ /L)	0.17	0.02 - 0.26
RBC (10¹²/L)	2.55	2.39 - 2.79
HGB (g/dL)	6.9	6.4 - 7.6
HCT (%)	21.20	18.6 - 24.6
MCV (fL)	83.20	77.3 - 89.3
MCH (pg)	27.20	23.0 - 30.6
MCHC (g/dL)	32.70	27.4 - 37.0
RDW-CV (%)	13.90	10.9 - 20.9
RDW-SD (fL)	47.20	37.5 - 57.5
PLT (10⁹/L)	80.0	49 - 99
MPV (fL)	9.8	6.6 - 12.6
PDW (%)	14.30	10.8 - 16.8
PCT (%)	0.079	0.021 - 0.121
PLCR (%)	24.40	
PLCC (10 ⁹ /L)	20	

Diagon D Check D		
(Normal Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot - HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	Range
WBC (10⁹/L)	7.41	6.14 - 8.14
Lymph (%)	31.00	25.1 - 41.9
Mid (%)	64.00	53.2 - 72.0
Gran (%)	5.00	0.5 - 7.3
Lymph # (10 ⁹ /L)	2.30	1.79 - 2.99
Mid # (10 ⁹ /L)	4.74	3.8 - 5.14
Gran # (10 ⁹ /L)	0.37	0.04 - 0.52
RBC (10¹²/L)	4.71	4.38 - 4.98
HGB (g/dL)	13.5	12.7 - 14.1
HCT (%)	42.00	37.6 - 45.6
MCV (fL)	89.20	82.9 - 94.9
MCH (pg)	28.60	24.8 - 32.4
MCHC (g/dL)	32.10	27.3 - 36.9
RDW-CV (%)	13.80	11.0 - 21.0
RDW-SD (fL)	50.20	40.9 - 60.9
PLT (10⁹/L)	206.0	180 - 270
MPV (fL)	10.0	6.7 - 12.7
PDW (%)	13.70	11.3 - 17.3
PCT (%)	0.207	0.118 - 0.318
PLCR (%)	26.50	
PLCC (10 ⁹ /L)	55	

Diagon D Check D		
(High Control, Lot - 1V0901, Expiry Date: 05.03.2023)		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-CD Lot - HVDCD221009 VDx Lyse-CD Lot - HVLCD221006	Range
WBC (10⁹/L)	18.2	15.14 - 20.14
Lymph (%)	26.60	12.2 - 42.0
Mid (%)	68.50	59.4 - 80.4
Gran (%)	4.9	0.4 - 5.6
Lymph # (10 ⁹ /L)	4.85	2.15 - 7.41
Mid # (10 ⁹ /L)	12.49	10.49 - 14.19
Gran # (10 ⁹ /L)	0.89	0.07 - 0.98
RBC (10¹²/L)	5.69	5.36 - 6.16
HGB (g/dL)	17.4	16.6 - 18.2
HCT (%)	54.7	50.2 - 59.2
MCV (fL)	96.00	89.1 - 101.1
MCH (pg)	30.50	26.5 - 34.1
MCHC (g/dL)	31.80	27.0 - 36.6
RDW-CV (%)	13.70	11.2 - 21.2
RDW-SD (fL)	53.60	44.6 - 64.6
PLT (10⁹/L)	444.0	397 - 527
MPV (fL)	10.40	6.7 - 12.7
PDW (%)	13.60	11.5 - 17.5
PCT (%)	0.462	0.248 - 0.648
PLCR (%)	30.40	
PLCC (10 ⁹ /L)	135	



D-Check D

CONTROL

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901



05-03-2023

Instruments:		DYMIND DH-31, DH-33, DH-36, DH-36VET ,BIOTA Vabio360					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,28 ± 0,50	1,78 - 2,78	7,14 ± 1,00	6,14 - 8,14	17,64 ± 2,50	15,14 - 20,14
LYMPH%	%	51,5 ± 10,3	41,2 - 61,8	33,5 ± 8,4	25,1 - 41,9	27,1 ± 14,9	12,2 - 42,0
GRAN%	%	42,5 ± 14,9	27,6 - 57,4	62,6 ± 9,4	53,2 - 72,0	69,9 ± 10,5	59,4 - 80,4
MID%	%	6,0 ± 5,1	0,9 - 11,1	3,9 ± 3,4	0,5 - 7,3	3,0 ± 2,6	0,4 - 5,6
LYMPH#	10 ⁹ /L	1,17 ± 0,23	0,94 - 1,40	2,39 ± 0,60	1,79 - 2,99	4,78 ± 2,63	2,15 - 7,41
GRAN#	10 ⁹ /L	0,97 ± 0,34	0,63 - 1,31	4,47 ± 0,67	3,80 - 5,14	12,34 ± 1,85	10,49 - 14,19
MID#	10 ⁹ /L	0,14 ± 0,12	0,02 - 0,26	0,28 ± 0,24	0,04 - 0,52	0,52 ± 0,45	0,07 - 0,98
RBC	10 ¹² /L	2,59 ± 0,20	2,39 - 2,79	4,68 ± 0,30	4,38 - 4,98	5,76 ± 0,40	5,36 - 6,16
HGB	g/dL	7,0 ± 0,6	6,4 - 7,6	13,4 ± 0,7	12,7 - 14,1	17,4 ± 0,8	16,6 - 18,2
	g/L	70 ± 6	64 - 76	134 ± 7	127 - 141	174 ± 8	166 - 182
HCT	%	21,6 ± 3,0	18,6 - 24,6	41,6 ± 4,0	37,6 - 45,6	54,7 ± 4,5	50,2 - 59,2
	L/L	0,216 ± 0,030	0,186 - 0,246	0,416 ± 0,040	0,376 - 0,456	0,547 ± 0,045	0,502 - 0,592
MCV	fL	83,3 ± 6,0	77,3 - 89,3	88,9 ± 6,0	82,9 - 94,9	95,1 ± 6,0	89,1 - 101,1
MCH	pg	26,8 ± 3,8	23,0 - 30,6	28,6 ± 3,8	24,8 - 32,4	30,3 ± 3,8	26,5 - 34,1
MCHC	g/dL	32,2 ± 4,8	27,4 - 37,0	32,1 ± 4,8	27,3 - 36,9	31,8 ± 4,8	27,0 - 36,6
	g/L	322 ± 48	274 - 370	321 ± 48	273 - 369	318 ± 48	270 - 366
RDW-CV	%	15,9 ± 5,0	10,9 - 20,9	16,0 ± 5,0	11,0 - 21,0	16,2 ± 5,0	11,2 - 21,2
RDW-SD	fL	47,5 ± 10,0	37,5 - 57,5	50,9 ± 10,0	40,9 - 60,9	54,6 ± 10,0	44,6 - 64,6
Pit	10 ⁹ /L	74 ± 25	49 - 99	225 ± 45	180 - 270	462 ± 65	397 - 527
MPV	fL	9,6 ± 3,0	6,6 - 12,6	9,7 ± 3,0	6,7 - 12,7	9,7 ± 3,0	6,7 - 12,7
PDW	%	13,8 ± 3,0	10,8 - 16,8	14,3 ± 3,0	11,3 - 17,3	14,5 ± 3,0	11,5 - 17,5
PCT	%	0,071 ± 0,050	0,021 - 0,121	0,218 ± 0,100	0,118 - 0,318	0,448 ± 0,200	0,248 - 0,648

DIAGON Ltd.

48-52., Baross Str.
Budapest, Hungary
H-1047



Coefficient of Variation:

Precision (VDx Reagents)

1. Two fresh blood samples were collected and tested with the VDx Dymind Reagents on Dymind- DH36, 3 Part Hematology Analyzer.
2. The samples were tested in 09 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample - 01, n = 09

Precision Evaluation report of VDx Dymind compatible reagent on Dymind DH36, 3 Part Hematology Analyzer														
Fresh Blood Sample-01														
Parameters	Ist	IInd Repeat	IIInd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC ($10^9/L$)	8.14	7.93	7.96	8.15	8.31	8.32	8.13	8.21	8.13		8.14	0.13	0.02	1.64
Lymph (%)	40.1	40.4	40.4	41.1	40	40.3	41.2	41.2	40.9		40.62	0.48	0.01	1.18
Mid (%)	51.10	50.70	51.20	49.60	49.90	49.40	49.50	49.70	49.10		50.02	0.78	0.02	1.55
Gran (%)	8.8	8.9	8.4	9.3	10.1	10.3	9.3	9.1	10		9.36	0.65	0.07	6.93
Lymph # ($10^9/L$)	3.26	3.2	3.22	3.35	3.32	3.35	3.35	3.38	3.33		3.31	0.06	0.02	1.94
Mid # ($10^9/L$)	4.16	4.02	4.07	4.04	4.15	4.11	4.02	4.08	3.99		4.07	0.06	0.01	1.47
Gran # ($10^9/L$)	0.72	0.71	0.67	0.76	0.84	0.86	0.76	0.75	0.81		0.76	0.06	0.08	8.15
RBC ($10^{12}/L$)	4.59	4.62	4.62	4.6	4.63	4.66	4.63	4.6	4.63		4.62	0.02	0.00	0.46
HGB (g/dL)	15.3	15.2	15.3	15.3	15.5	15.3	15.4	15.3	15.5		15.34	0.10	0.01	0.66
HCT (%)	48.2	48.4	48.3	48.4	48.3	48.9	48.7	48.1	48.6		48.43	0.25	0.01	0.53
MCV (fL)	105.1	104.7	104.7	105.2	104.4	104.9	105.1	104.7	105.1		104.88	0.27	0.00	0.26
MCH (pg)	33.3	32.9	33.3	33.3	33.4	32.9	33.2	33.3	33.4		33.22	0.19	0.01	0.58
MCHC (g/dL)	31.7	31.5	31.8	31.7	32	31.4	31.6	31.8	31.8		31.70	0.18	0.01	0.57
RDW-CV (%)	14	13.8	13.9	14.2	13.9	14.3	14.1	14	14.1		14.03	0.16	0.01	1.13
RDW-SD (fL)	60.1	59	59.5	61	59.4	61.2	60.6	59.9	60.3		60.11	0.74	0.01	1.23
PLT ($10^9/L$)	177	166	173	173	174	169	165	172	180		172.11	4.86	0.03	2.82
MPV (fL)	10.8	11	11.1	10.8	10.7	10.9	10.6	10.9	10.8		10.84	0.15	0.01	1.39
PDW (%)	16.30	16.30	16.40	16.50	16.20	16.20	16.40	16.20	16.40		16.32	0.11	0.01	0.67
PCT (%)	0.191	0.181	0.192	0.186	0.185	0.184	0.176	0.187	0.198		0.19	0.01	0.03	3.45
PLCR (%)	37.00	38.90	40.00	38.00	36.40	36.90	36.80	37.70	37.20		37.66	1.16	0.03	3.07
PLCC ($10^9/L$)	66.00	64.00	69.00	66.00	63.00	62.00	61.00	65.00	67.00		64.78	2.54	0.04	3.92

Fresh Blood Sample- 02, n = 08

Precision Evaluation report of VDx Dymind compatible reagent on Dymind DH36, 3 Part Hematology Analyzer														
Fresh Blood Sample-02														
Parameters	Ist	IIInd Repeat	IIIInd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10⁹/L)	6.53	6.78	6.57	6.62	6.57	6.69	6.72	6.69			6.65	0.09	0.01	1.31
Lymph (%)	52.6	50.8	52.1	52.4	51.8	51.3	53.3	51.8			52.01	0.78	0.01	1.49
Mid (%)	39.30	41.00	40.30	41.00	41.50	41.60	38.90	41.00			40.58	1.00	0.02	2.46
Gran (%)	8.1	8.2	7.6	6.6	6.7	7.1	7.8	7.2			7.41	0.61	0.08	8.20
Lymph # (10 ⁹ /L)	3.43	3.44	3.42	3.47	3.4	3.43	3.58	3.47			3.46	0.06	0.02	1.62
Mid # (10 ⁹ /L)	2.57	2.78	2.65	2.71	2.73	2.79	2.62	2.72			2.70	0.08	0.03	2.86
Gran # (10 ⁹ /L)	0.53	0.56	0.50	0.44	0.44	0.47	0.52	0.48			0.49	0.04	0.09	8.73
RBC (10¹²/L)	4.28	4.18	4.3	4.29	4.25	4.26	4.25	4.23			4.26	0.04	0.01	0.90
HGB (g/dL)	13.7	13.7	13.7	13.7	13.7	13.8	13.8	13.7			13.73	0.05	0.00	0.34
HCT (%)	43.6	42.4	43.8	43.7	43.3	43.4	43.2	43			43.30	0.45	0.01	1.04
MCV (fL)	101.8	101.3	101.9	101.8	101.8	101.9	101.7	101.6			101.73	0.20	0.00	0.19
MCH (pg)	31.9	32.8	31.9	31.9	32.3	32.3	32.5	32.3			32.24	0.32	0.01	1.01
MCHC (g/dL)	31.3	32.3	31.3	31.3	31.7	31.7	31.9	31.8			31.66	0.35	0.01	1.12
RDW-CV (%)	13.5	13.2	13.3	13.3	13.4	13.4	13.3	13.3			13.34	0.09	0.01	0.69
RDW-SD (fL)	56.2	54.6	55.4	55.5	55.8	55.7	55.1	55			55.41	0.51	0.01	0.91
PLT (10⁹/L)	238	225	235	237	232	225	234	233			232.38	4.96	0.02	2.13
MPV (fL)	10.2	10.4	10.5	10.5	10.5	10.3	10.4	10.4			10.40	0.11	0.01	1.03
PDW (%)	16.30	16.60	16.30	16.30	16.20	16.20	16.20	16.10			16.28	0.15	0.01	0.91
PCT (%)	0.243	0.234	0.247	0.249	0.244	0.233	0.243	0.242			0.24	0.01	0.02	2.34
PLCR (%)	33.30	34.70	36.00	34.40	35.30	33.20	34.40	33.70			34.38	0.97	0.03	2.82
PLCC (10 ⁹ /L)	79.00	78.00	84.00	82.00	82.00	75.00	81.00	79.00			80.00	2.83	0.04	3.54

Conclusions

4. The VDX Dymind 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray original reagents as Reference.
5. All measured parameters showed values of “r” in the range of **0.940 to 0.997** displaying the highest degree of correlation between the reagents.
6. The VDX Dymind 3 Part Hematology Reagents showed an excellent Coefficient of Variation (CV %) for all parameters.
7. The CV % with the VDX Dymind reagents were found to be as under:

Parameters	VDx Dymind Reagents (CV % - Precision)
Measured Parameters	0.26% - 2.82%
Calculated Parameters	0.53% - 8.15%

8. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges for VDX Dymind 3 Part Hematology Reagents.
9. **The VDX Dymind 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Mindray Reference Reagents in all the parameters identified for the evaluation.**

***** End of Report *****