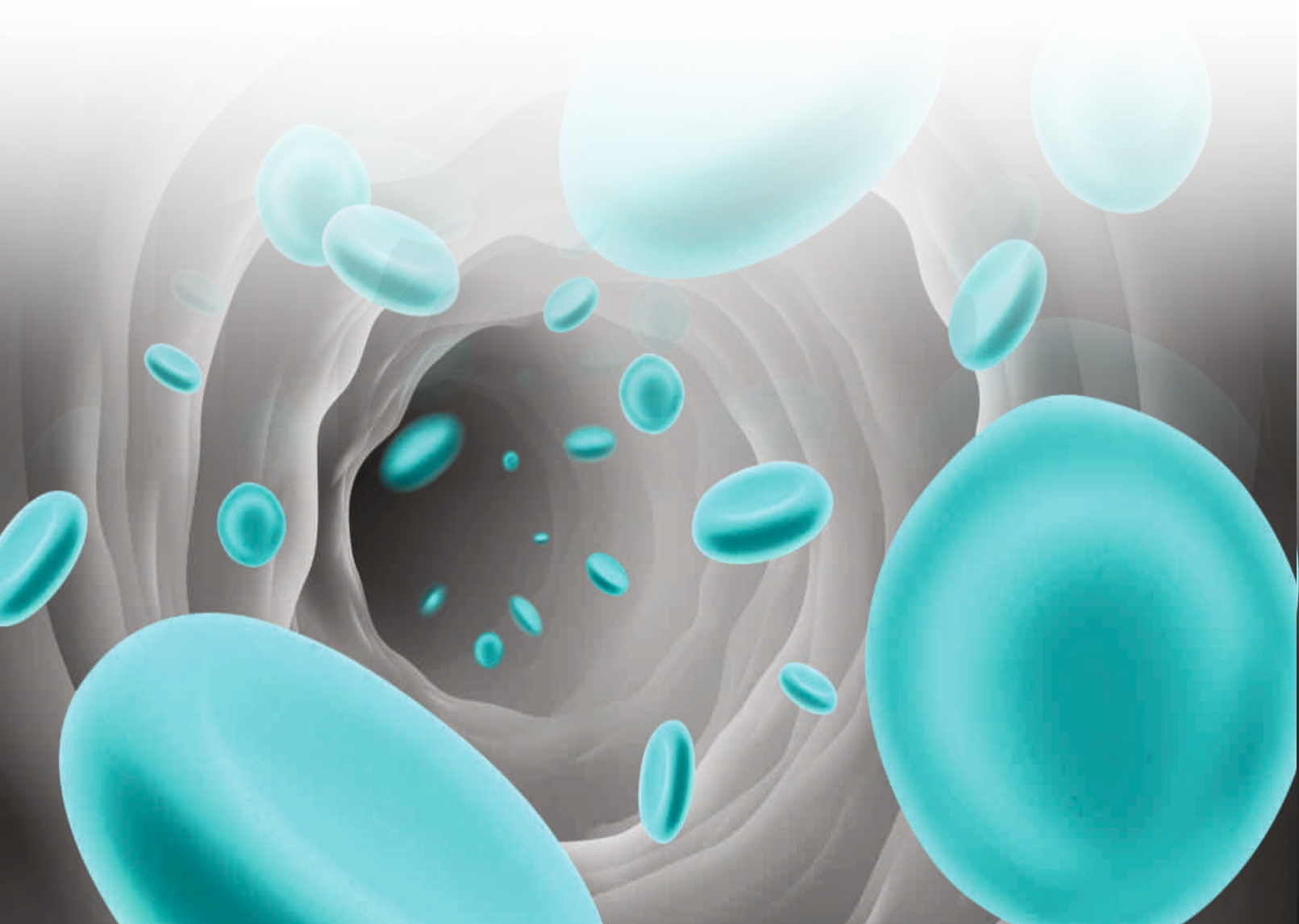




Validation Report - Greece

Sysmex- 3 Part & 5 Part Reagents

Evaluation of Hematology Reagents

Technical Report

Reagents for 3 Part Sysmex Hematology Analyzers

In collaboration with



Sitz der Gesellschaft / Office: Wieblinger Weg 17, 69123 Heidelberg
Handelsregister-Nr. / Commercial Register No.: HRB 710843
Registergericht / Register Court: Mannheim
UID-Nr. / VAT Reg. No.: DE275261186
Geschäftsführer / Managing Directors: Madim Dija

MSC medical GmbH

Wieblinger Weg 17
69123 Heidelberg, Germany

ΒΟΛΙΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΛΙΑ Ε ΠΑΝΑΓΙΩΤΑ
ΥΠΟΧΡΕΩΤΗΤΗΣ ΜΟ, ΜΣ, Ε
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Α.Μ.Κ.Α. 02427101729

Comparative Evaluation

**VDx Compatible Reagents for the Sysmex 3 Part
Hematology Analyzer**

v/s

**Reference Reagents for the Sysmex 3 Part
Hematology Analyzer**

VDx : Vanguard Diagnostics (P) Limited

ΒΟΛΙΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΛΙΑ Ε. ΠΑΝΑΓΙΩΤΗ
ΙΑΤΡΟΙ ΕΙΔΙΚΑΙΟΛΟΓΟΣ ΜΕ ΜΣ'C
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Name of the Lab

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Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Sysmex – KX-21N (SN B1805)
Reference Reagents	Sysmex Reference Reagents
Cellpack	Lot No : D4808 Expiry Date : 30/11/2025
Stromatolyser-WH	Lot No : D4167 Expiry Date: 1/8/2026
VDx Reagents 1) Diluent Pack 5P1-S (20L) 2) Lyse-S	Lot No : HD5P1S250301 Expiry Date : 28/2/27 Lot No : HVLS250101 Expiry Date : 30/12/26

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

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Background Test		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	0	0
RBC ($10^6/\mu\text{l}$)	0.1	0
HGB (g/dl)	0	0
HCT (%)		
MCV (fL)		
MCH (pg)	0	
MCHC (g/dl)		
PLT ($10^3/\mu\text{l}$)	0	0
LYM (%)		
MXD (%)		
NEUT (%)		
LYM# ($10^3/\mu\text{l}$)		
MXD# ($10^3/\mu\text{l}$)		
NEUT# ($10^3/\mu\text{l}$)		
RDW-SD (fL)		
RDW-CV (%)		
PDW (fL)		
MPV (fL)		
P-LCR (%)		
PCT (%)		

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Accuracy Study

(Coefficient of Correlation)

Objective: to determine the correlation between the results obtained with Vanguard's compatible reagents for Sysmex 3 Part Analyzer and Reference reagents for Sysmex 3 Part Analyzer.

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
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Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the developed Vanguard compatible 3 Part Sysmex reagents and the 3 Part 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, 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 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.996$$

Sample size: 20

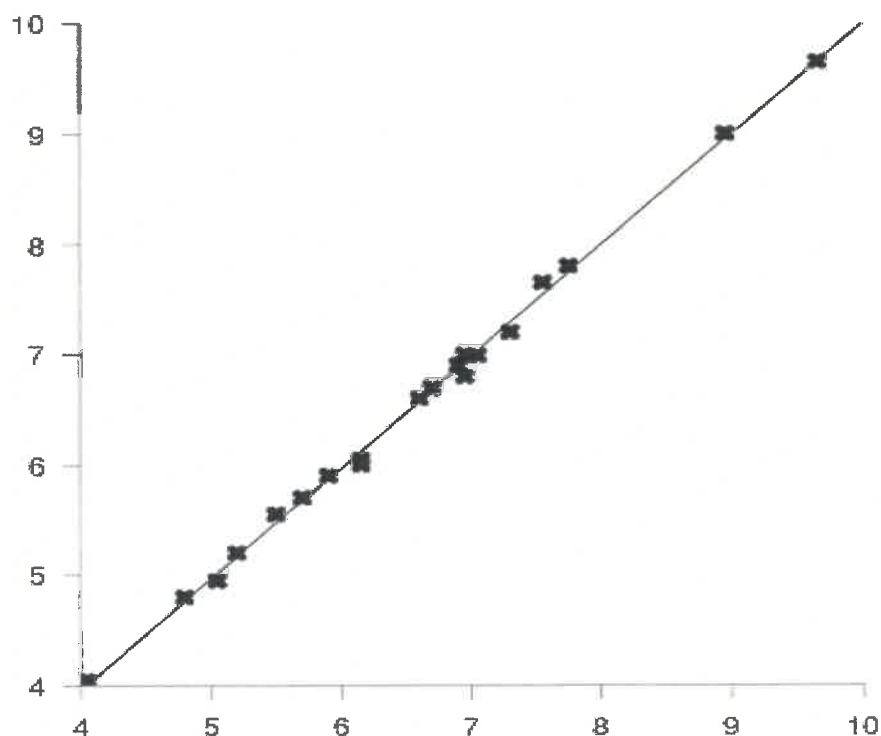
Mean x (x̄): 6.5425

Mean y (ȳ): 6.5245

Intercept (a): -0.079576250931953

Slope (b): 1.0094117311321

Regression line equation: $y = 1.0094117311321x - 0.079576250931953$



ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
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Specifications for Approval/Rejection of the Results: WBC

WBC ($10^3/\mu\text{L}$)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	6.6	X2	MEAN	Y1	Y2	MEAN		
1	5.3	5.2	5.3	5.3	5.1	5.2	0.96%	OK
2	6.8	7	6.9	6.8	7	6.9	0.00%	OK
3	4.1	4	4.05	4	4.1	4.05	0.00%	OK
4	7	6.9	6.95	7.1	7	7.05	1.42%	OK
5	6.5	6.6	6.55	6.7	6.7	6.7	2.24%	OK
6	4.9	4.9	4.9	4.9	4.7	4.8	2.08%	OK
7	5.9	5.9	5.9	5.8	6	5.9	0.00%	OK
8	7.1	6.9	7	6.9	7	6.95	0.72%	OK
9	6.9	7	6.95	7.3	7.3	7.3	4.79%	NO
10	5.7	5.7	5.7	5.6	5.8	5.7	0.00%	OK
11	6	6.1	6.05	6.1	6.2	6.15	1.63%	OK
12	6.2	5.8	6	6.1	6.2	6.15	2.44%	OK
13	6.6	6.6	6.6	6.7	6.5	6.6	0.00%	OK
14	9.6	9.7	9.65	9.7	9.6	9.65	0.00%	OK
15	5.5	5.6	5.55	5.4	5.6	5.5	0.91%	OK
16	9	9	9	8.9	9	8.95	0.56%	OK
17	7.7	7.6	7.65	7.6	7.5	7.55	1.32%	OK
18	6.9	6.7	6.8	6.9	7	6.95	2.16%	OK
19	4.9	5	4.95	5.1	5	5.05	1.98%	OK
20	7.7	7.9	7.8	7.7	7.8	7.75	0.65%	OK
Passing Number		19	Passing Rate		95.0%	Requirement		<±3,5%
Conclusion		Pass						

Coefficient of Correlation ("r") .

0.996629354

Coefficient of Correlation ("r"): RBC

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.997$$

Sample size: 20

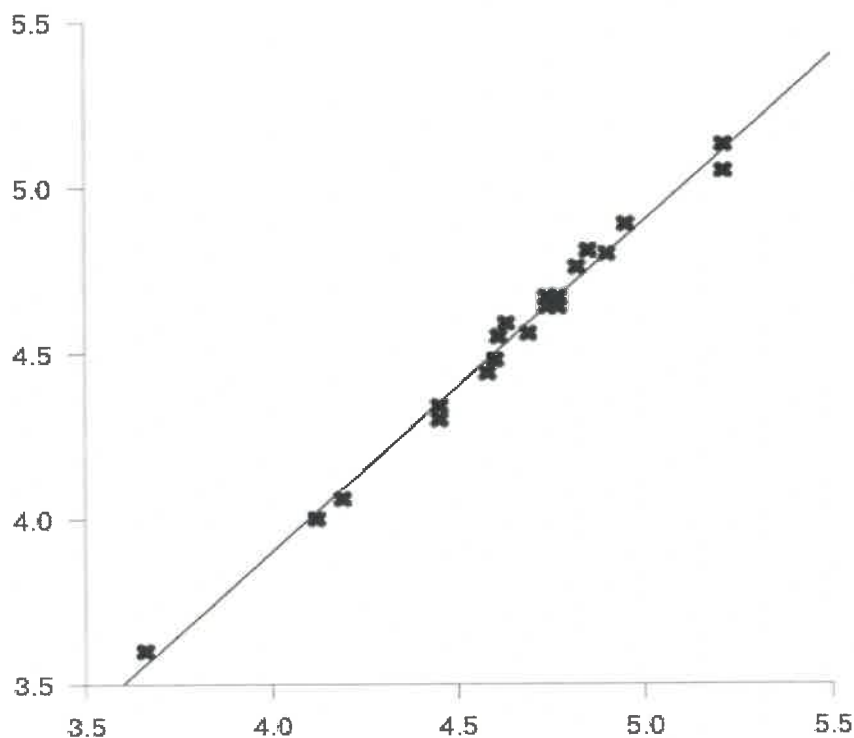
Mean x ($\bar{x}$): 4.647

Mean y ($\bar{y}$): 4.549

Intercept (a): -0.10598135139354

Slope (b): 1.0017175277369

Regression line equation: $y = 1.0017175277369x - 0.10598135139354$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
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Specifications for Approval/Rejection of the Results: RBC

RBC ($10^6/\mu\text{l}$)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	4.67	4.65	4.66	4.74	4.73	4.735	1.58%	OK
2	5.05	5.09	5.07	5.21	5.17	5.19	2.31%	OK
3	4.56	4.58	4.57	4.69	4.69	4.69	2.56%	OK
4	4.3	4.37	4.335	4.45	4.42	4.435	2.25%	OK
5	4.76	4.78	4.77	4.82	4.8	4.81	0.83%	OK
6	4.44	4.49	4.465	4.58	4.51	4.545	1.76%	OK
7	4.67	4.69	4.68	4.77	4.7	4.735	1.16%	OK
8	4.34	4.45	4.395	4.45	4.48	4.465	1.57%	OK
9	3.6	3.6	3.6	3.66	3.66	3.66	1.64%	OK
10	4.59	4.58	4.585	4.63	4.72	4.675	1.93%	OK
11	4.8	4.82	4.81	4.9	4.86	4.88	1.43%	OK
12	4.06	4.11	4.085	4.19	4.2	4.195	2.62%	OK
13	4.48	4.43	4.455	4.6	4.52	4.56	2.30%	OK
14	4.64	4.56	4.6	4.74	4.72	4.73	2.75%	OK
15	5.13	5.12	5.125	5.21	5.29	5.25	2.38%	OK
16	4.64	4.69	4.665	4.77	4.75	4.76	2.00%	OK
17	4.89	4.83	4.86	4.95	4.93	4.94	1.62%	OK
18	4.55	4.48	4.515	4.61	4.65	4.63	2.48%	OK
19	4	4.01	4.005	4.12	4.1	4.11	2.55%	OK
20	4.81	4.72	4.765	4.85	4.82	4.835	1.45%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.9975474

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
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Coefficient of Correlation ("r"): HGB

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.998

Sample size: 20

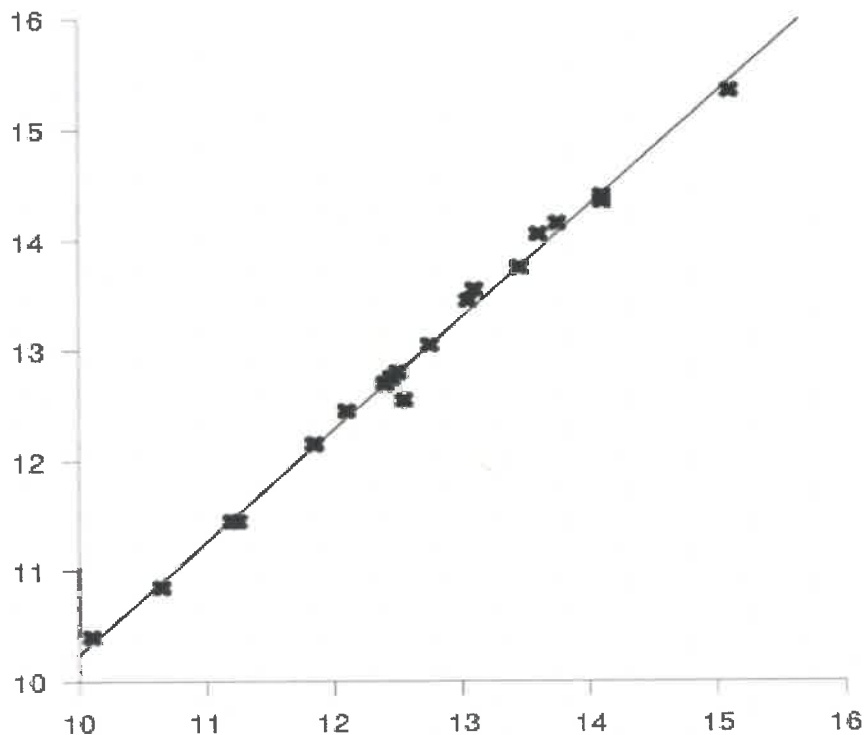
Mean x (x̄): 6.5425

Mean y (ȳ): 6.5245

Intercept (a): -0.079576250931953

Slope (b): 1.0094117311321

Regression line equation: $y = 1.0094117311321x - 0.079576250931953$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

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Specifications for Approval/Rejection of the Results: HGB

HGB (g/dl)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	12.5	X2	MEAN	Y1	Y2	MEAN		
1	14.2	14.1	14.15	13.7	13.8	13.75	2.91%	OK
	15.3	15.4	15.35	15.1	15.1	15.1	1.66%	OK
3	14.1	14	14.05	13.6	13.6	13.6	3.31%	OK
4	12.7	12.7	12.7	12.4	12.4	12.4	2.42%	OK
5	12.6	12.5	12.55	12.2	12.3	12.25	2.45%	OK
6	12.1	12.2	12.15	11.8	11.9	11.85	2.53%	OK
7	13.4	13.5	13.45	13.1	13	13.05	3.07%	OK
8	13.8	13.7	13.75	13.5	13.4	13.45	2.23%	OK
9	11.5	11.4	11.45	11.2	11.2	11.2	2.23%	OK
10	12.2	12.1	12.15	11.8	11.9	11.85	2.53%	OK
11	14.3	14.4	14.35	14.1	14.1	14.1	1.77%	OK
12	10.4	10.4	10.4	10.1	10.1	10.1	2.97%	OK
13	13.6	13.5	13.55	13	13.2	13.1	3.44%	OK
14	11.4	11.5	11.45	11.3	11.2	11.25	1.78%	OK
15	10.8	10.9	10.85	10.7	10.6	10.65	1.88%	OK
16	12.4	12.5	12.45	12.1	12.1	12.1	2.89%	OK
17	14.4	14.4	14.4	14.1	14.1	14.1	2.13%	OK
18	13	13.1	13.05	12.7	12.8	12.75	2.35%	OK
19	12.8	12.8	12.8	12.5	12.5	12.5	2.40%	OK
20	12.7	12.8	12.75	12.5	12.4	12.45	2.41%	OK
Passing Number	20	Passing Rate		100.0%	Requirement		<=13.5%	
Conclusion		Pass						

Coefficient of Correlation ("r")

0.998677997

Coefficient of Correlation ("r")
0.998677997

ΒΟΙΛΑ ΠΑΥΛΙΩΤΑ
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Coefficient of Correlation ("r"): HCT

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.997$$

Sample size: 20

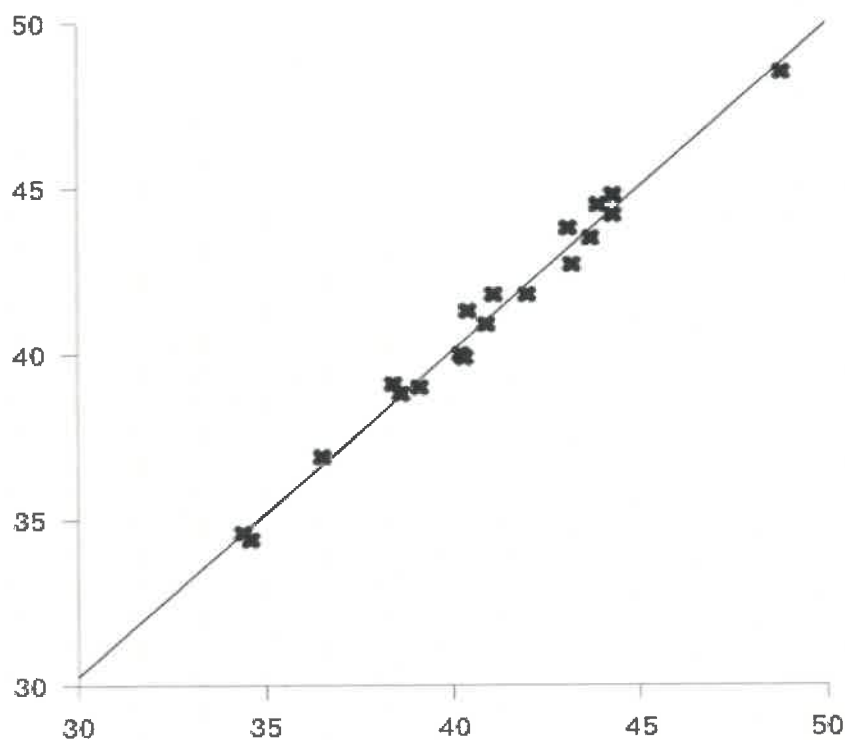
Mean x (x̄): 40.875

Mean y (ȳ): 41.02

Intercept (a): 0.66882543306168

Slope (b): 0.98646069103871

Regression line equation: $y=0.66882543306168+0.98646069103871x$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

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Specifications for Approval/Rejection of the Results: HCT

HCT (%)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	41.4	X2	MEAN	Y1	Y2	MEAN		
1	44.8	44.5	44.65	44.3	44.3	44.3	0.79%	OK
2	48.5	48.8	48.65	48.8	48.4	48.6	0.10%	OK
3	42.7	43	42.85	43.2	43.2	43.2	0.81%	OK
4	40	40.5	40.25	40.2	39.9	40.05	0.50%	OK
5	40.9	41.4	41.15	40.9	40.6	40.75	0.98%	OK
6	39	39.3	39.15	39.1	38.8	38.95	0.51%	OK
7	44.2	44.3	44.25	44.3	43.5	43.9	0.80%	OK
8	41.8	42.9	42.35	42	42.2	42.1	0.58%	OK
9	34.6	34.4	34.5	34.5	34.4	34.45	0.15%	OK
10	39.1	38.8	38.95	38.4	39.2	38.8	0.39%	OK
11	44.5	44.4	44.45	43.9	44.2	44.05	0.91%	OK
12	34.4	34.6	34.5	34.6	34.7	34.65	0.43%	OK
13	43.5	43	43.25	43.7	42.7	43.2	0.12%	OK
14	38.8	38.1	38.45	38.6	38.5	38.55	0.26%	OK
15	36.9	36.7	36.8	36.5	37.1	36.8	0.00%	OK
16	39.9	40.4	40.15	40.3	40	40.15	0.00%	OK
17	43.8	43.4	43.6	43.1	43	43.05	1.28%	OK
18	41.8	41.2	41.5	41.1	41.6	41.35	0.36%	OK
19	39.9	39.8	39.85	40.3	40.1	40.2	0.87%	OK
20	41.3	40.5	40.9	40.4	40.3	40.35	1.36%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.997357543

Coefficient of Correlation ("r")
0.997357543

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729

Coefficient of Correlation ("r"): MCV

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.998$$

Sample size: 20

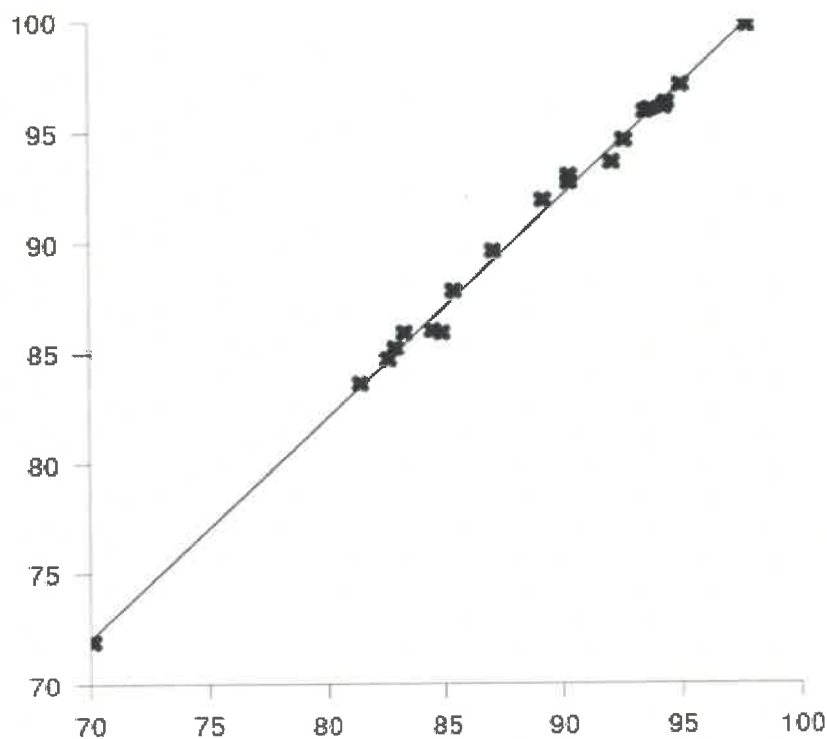
Mean x ($\bar{x}$): 88.27

Mean y ($\bar{y}$): 90.38

Intercept (a): 1.6546721114616

Slope (b): 1.0051583537843

Regression line equation: $y = 1.6546721114616 + 1.0051583537843x$



ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΥΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
Α.Φ.Μ. 0752000066 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
127101729

Specifications for Approval/Rejection of the Results: MCV

MCV (fL)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	95.9	95.7	95.8	93.5	93.7	93.6	2.35%	OK
2	96	95.9	95.95	93.7	93.6	93.65	2.46%	OK
3	93.6	93.9	93.75	92.1	92.1	92.1	1.79%	OK
4	93	92.7	92.85	90.3	90.3	90.3	2.82%	OK
5	85.9	86.6	86.25	84.9	84.6	84.75	1.77%	OK
6	87.8	87.5	87.65	85.4	86	85.7	2.28%	OK
7	94.6	94.5	94.55	92.9	92.6	92.75	1.94%	OK
8	96.3	96.4	96.35	94.4	94.2	94.3	2.17%	OK
9	96.1	95.6	95.85	94.3	94	94.15	1.81%	OK
10	85.2	84.7	84.95	82.9	83.1	83	2.35%	OK
11	92.7	92.1	92.4	90.3	90.2	90.25	2.38%	OK
12	84.7	84.2	84.45	82.6	82.6	82.6	2.24%	OK
13	97.1	97.1	97.1	95	94.5	94.75	2.48%	OK
14	83.6	83.6	83.6	81.4	81.6	81.5	2.58%	OK
15	71.9	71.7	71.8	70.1	70.1	70.1	2.43%	OK
16	86	86.1	86.05	84.5	84.2	84.35	2.02%	OK
17	89.6	89.8	89.7	87.1	87.2	87.15	2.93%	OK
18	91.9	92	91.95	89.2	89.5	89.35	2.91%	OK
19	99.8	99.3	99.55	97.8	97.8	97.8	1.79%	OK
20	85.9	85.8	85.85	83.3	83.6	83.45	2.88%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.998679174

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38175 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200364 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Coefficient of Correlation ("r"): MCH

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.996

Sample size: 20

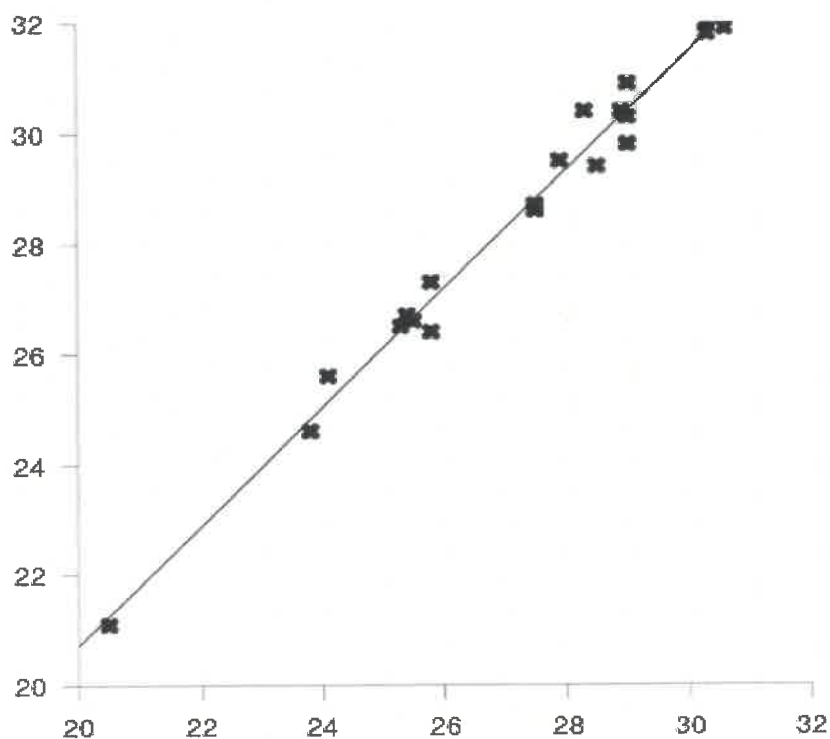
Mean x (x̄): 27.38

Mean y (ȳ): 28.425

Intercept (a): -0.83366500829128

Slope (b): 1.0776672194582

Regression line equation: $y = 1.0776672194582x - 0.83366500829128$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 36475 - Α.Μ.Τ. 93091

Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

ΚΑΔ 92127101729



Specifications for Approval/Rejection of the Results: MCH

MCH (pg)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	30.4	30.3	30.35	28.9	29.2	29.05	4.48%	OK
2	30.3	30.3	30.3	29	29.2	29.1	4.12%	OK
3	30.9	30.6	30.75	29	29	29	6.03%	OK
4	29.5	29.1	29.3	27.9	28.1	28	4.64%	OK
5	26.5	26.2	26.35	25.3	25.6	25.45	3.54%	OK
6	27.3	27.2	27.25	25.8	26.4	26.1	4.41%	OK
7	28.7	28.8	28.75	27.5	27.7	27.6	4.17%	OK
8	31.8	30.8	31.3	30.3	29.9	30.1	3.99%	OK
9	31.9	31.7	31.8	30.6	30.6	30.6	3.92%	OK
10	26.6	26.4	26.5	25.5	25.2	25.35	4.54%	OK
11	29.8	29.9	29.85	29	28.8	28.9	3.29%	OK
12	25.6	25.3	25.45	24.1	24	24.05	5.82%	OK
13	30.4	30.5	30.45	28.3	29.2	28.75	5.91%	OK
14	24.6	25.2	24.9	23.8	23.7	23.75	4.84%	OK
15	21.1	21.3	21.2	20.5	20	20.25	4.69%	OK
16	26.7	26.7	26.7	25.4	25.5	25.45	4.91%	OK
17	29.4	29.8	29.6	28.5	28.6	28.55	3.68%	OK
18	28.6	29.2	28.9	27.5	27.5	27.5	5.09%	OK
19	32	31.9	31.95	30.3	30.5	30.4	5.10%	OK
20	26.4	27.1	26.75	25.8	25.7	25.75	3.88%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.996842208

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

ΑΦ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729

Coefficient of Correlation ("r"): MCHC

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.967$$

Sample size: 20

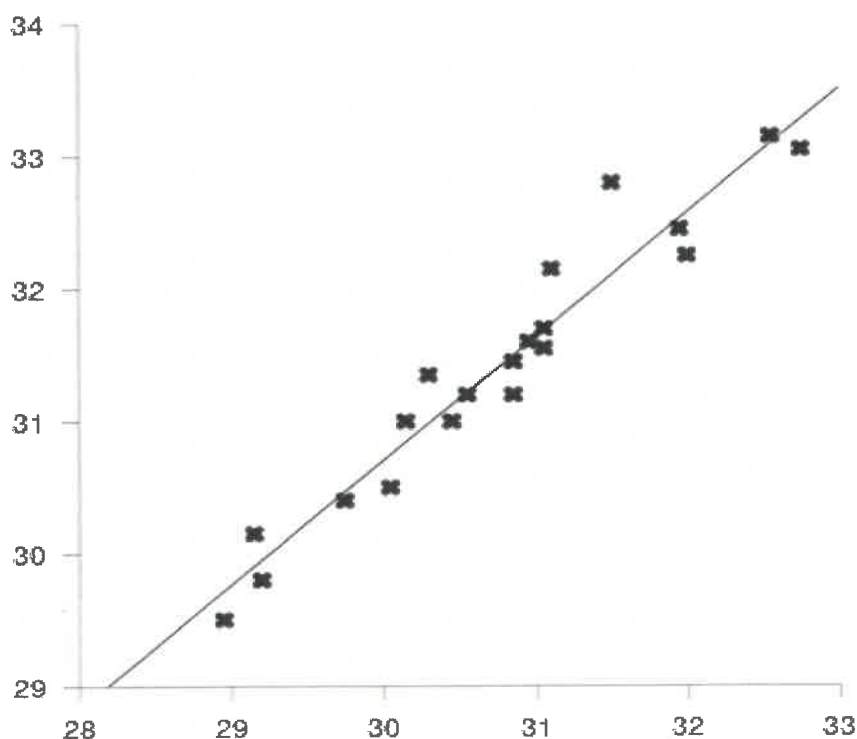
Mean x (x): 30.7575

Mean y (y): 31.4125

Intercept (a): 2.5898872461669

Slope (b): 0.93709218089354

Regression line equation: $y = 2.5898872461669 + 0.93709218089354x$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

ΑΦΜ. 075200356 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

ΥΠΟΛΟΓΙΣΤΕΡΑ 127101729



Specifications for Approval/Rejection of the Results: MCHC

MCHC (g/dl)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	31.7	31.7	31.7	30.9	31.2	31.05	2.09%	OK
2	31.5	31.6	31.55	30.9	31.2	31.05	1.61%	OK
3	33	32.6	32.8	31.5	31.5	31.5	4.13%	OK
4	31.8	31.4	31.6	30.8	31.1	30.95	2.10%	OK
5	30.8	30.2	30.5	29.8	30.3	30.05	1.50%	OK
6	31	31	31	30.2	30.7	30.45	1.81%	OK
7	30.3	30.5	30.4	29.6	29.9	29.75	2.18%	OK
8	33	31.9	32.45	32.1	31.8	31.95	1.56%	OK
9	33.2	33.1	33.15	32.5	32.6	32.55	1.84%	OK
10	31.2	31.2	31.2	30.7	30.4	30.55	2.13%	OK
11	32.1	32.4	32.25	32.1	31.9	32	0.78%	OK
12	30.2	30.1	30.15	29.2	29.1	29.15	3.43%	OK
13	31.3	31.4	31.35	29.7	30.9	30.3	3.47%	OK
14	29.4	30.2	29.8	29.3	29.1	29.2	2.05%	OK
15	29.3	29.7	29.5	29.3	28.6	28.95	1.90%	OK
16	31.1	30.9	31	30	30.3	30.15	2.82%	OK
17	32.9	33.2	33.05	32.7	32.8	32.75	0.92%	OK
18	31.1	31.8	31.45	30.9	30.8	30.85	1.94%	OK
19	32.1	32.2	32.15	31	31.2	31.1	3.38%	OK
20	30.8	31.6	31.2	30.9	30.8	30.85	1.13%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.96708826

Coefficient of Correlation ("r"): PLT

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.997$$

Sample size: 20

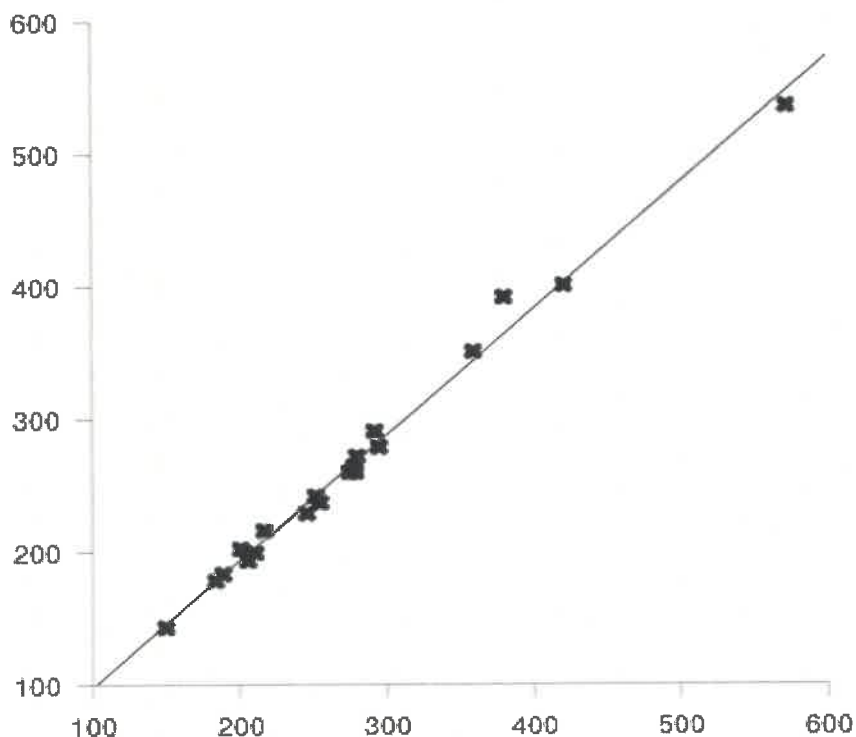
Mean x ($\bar{x}$): 277.15

Mean y ($\bar{y}$): 266.4

Intercept (a): 2.7077410182974

Slope (b): 0.95144239214037

Regression line equation: $y = 2.7077410182974 + 0.95144239214037x$



ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΥΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ 210211475 - Α.Μ.Τ. 93691
Α.Φ.Μ. 075200369 - Α.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729

Commercial Confidential



Specifications for Approval/Rejection of the Results: PLT

PLT ($10^3/\mu\text{l}$)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostic			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	177	X2	MEAN	Y1	Y2	MEAN		
1	260	268	264	275	269	272	2.94%	OK
2	229	234	231.5	246	257	251.5	7.95%	OK
3	143	147	145	150	135	142.5	1.75%	OK
4	242	254	248	252	252	252	1.59%	OK
5	178	177	177.5	184	184	184	3.53%	OK
6	392	394	393	380	389	384.5	2.21%	OK
7	183	178	180.5	189	177	183	1.37%	OK
8	193	201	197	206	214	210	6.19%	OK
9	260	268	264	279	282	280.5	5.88%	OK
10	264	260	262	278	279	278.5	5.92%	OK
11	199	204	201.5	211	213	212	4.95%	OK
12	401	414	407.5	421	438	429.5	5.12%	OK
13	237	242	239.5	255	250	252.5	5.15%	OK
14	351	346	348.5	359	365	362	3.73%	OK
15	291	286	288.5	292	322	307	6.03%	OK
16	586	577	581.5	573	606	589.5	1.36%	OK
17	272	268	270	280	267	273.5	1.28%	OK
18	279	284	281.5	295	291	293	3.92%	OK
19	202	206	204	201	221	211	3.32%	OK
20	216	212	214	217	226	221.5	3.39%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		≤12.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.997204308

Coefficient of Correlation ("r"): LYM%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.970

Sample size: 20

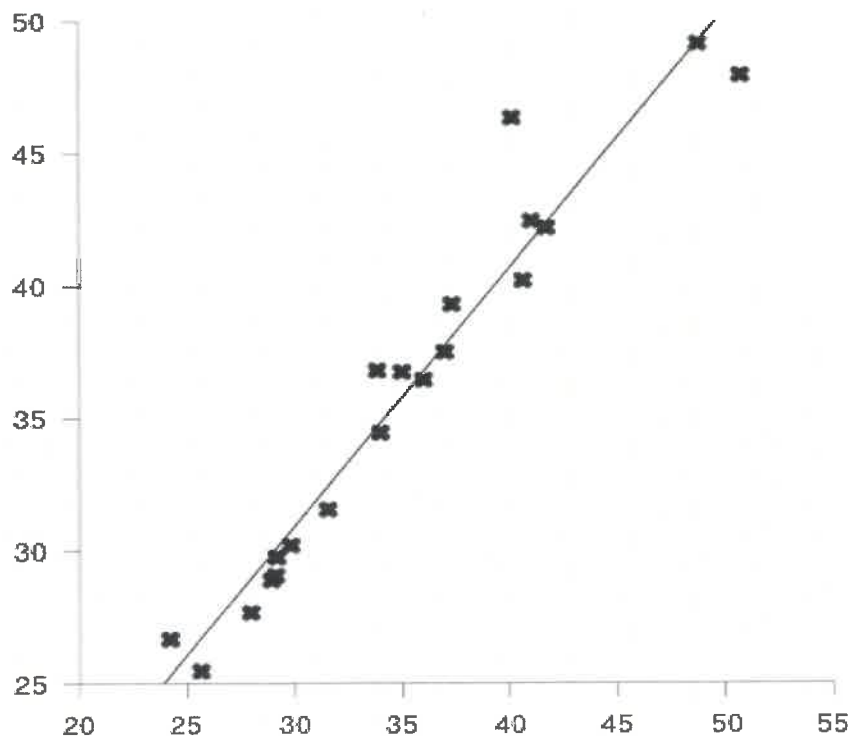
Mean x (x̄): 35.1315

Mean y (ȳ): 35.9365

Intercept (a): 1.7251717215655

Slope (b): 0.97380778726882

Regression line equation: $y = 1.7251717215655 + 0.97380778726882x$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ: 26220 88475 - Α.Μ.Τ. 93691
Α.Φ.Μ. 075200850 / Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Commercial Confidential



Specifications for Approval/Rejection of the Results: LYM%

LYM (%)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	46.9	49	47.95	51.1	50.4	50.75	5.52%	OK
2	39.9	40.5	40.2	40.6	40.7	40.65	1.11%	OK
3	31.2	31.2	31.2	29.2	30.4	29.8	4.70%	OK
4	30.7	28.8	29.75	29.3	29	29.15	2.06%	OK
5	30.4	27.37	28.885	28.3	29.5	28.9	0.05%	OK
6	32.9	36	34.45	33.5	34.5	34	1.32%	OK
7	36.7	38.3	37.5	36.6	37.4	37	1.35%	OK
8	29.1	29	29.05	28.3	29.9	29.1	0.17%	OK
9	26.4	24.9	25.65	24.1	24.3	24.2	5.99%	OK
10	48.6	49.7	49.15	48.7	48.9	48.8	0.72%	OK
11	37.1	35.8	36.45	36.6	35.4	36	1.25%	OK
12	24.5	26.4	25.45	24.9	26.4	25.65	0.78%	OK
13	35.3	33.8	34.55	30.7	32.4	31.55	9.51%	NO
14	36.1	35.5	35.8	33.5	34.2	33.85	5.76%	OK
15	43	39.6	41.3	37	37.7	37.35	10.58%	NO
16	39.4	43	41.2	43.6	39.9	41.75	1.32%	OK
17	34.7	36.8	35.75	36.2	33.8	35	2.14%	OK
18	42.8	49.9	46.35	41	39.3	40.15	15.44%	NO
19	42.1	42.8	42.45	40.8	41.3	41.05	3.41%	OK
20	29.3	26	27.65	27	28.9	27.95	1.07%	OK
Passing Number		17	Passing Rate		85.0%	Requirement		<=7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.97061346

Coefficient of Correlation ("r"): NEUT%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.970$$

Sample size: 20

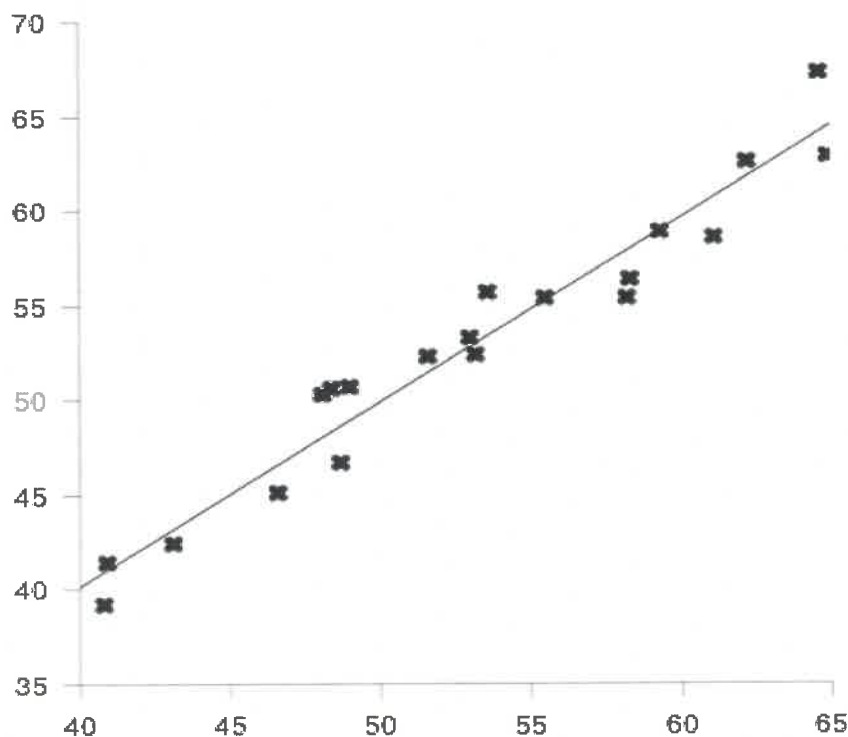
Mean x ($\bar{x}$): 53.055

Mean y ($\bar{y}$): 52.88

Intercept (a): 1.1079497867857

Slope (b): 0.97581849426471

Regression line equation: $y = 1.1079497867857 + 0.97581849426471x$



ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΙΛΑ Ε. ΓΙΑΝΝΑΚΟΠΟΥΛΟΥ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS C
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 2623 41475 - Α.Μ.Τ. 93691
Α.Ο.Μ. 075200066 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729



Specifications for Approval/Rejection of the Results: NEUT%

NEUT (%)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	59.7	X2	MEAN	Y1	Y2	MEAN		
1	39.2	38.4	38.8	40.8	41	40.9	5.13%	OK
2	45.1	49	47.05	46.6	45.9	46.25	1.73%	OK
3	56.4	56.4	56.4	58.3	57.5	57.9	2.59%	OK
4	62.6	63.9	63.25	62.2	62.1	62.15	1.77%	OK
5	58.9	59.7	59.3	59.3	56.7	58	2.24%	OK
6	52.4	51.9	52.15	53.2	52.3	52.75	1.14%	OK
7	50.3	49.6	49.95	48.1	48.8	48.45	3.10%	OK
8	58.6	62.4	60.5	61.1	59.6	60.35	0.25%	OK
9	55.4	56.9	56.15	58.2	55.4	56.8	1.14%	OK
10	41.4	42.4	41.9	40.9	40.3	40.6	3.20%	OK
11	50.7	51.3	51	49	52.5	50.75	0.49%	OK
12	67.2	63.9	65.55	63.6	64.3	63.95	2.50%	OK
13	53.3	52.6	52.95	53	55.6	54.3	2.49%	OK
14	55.7	56.3	56	51.6	51.7	51.65	8.42%	NO
15	52.3	52.7	52.5	51.6	50.6	51.1	2.74%	OK
16	42.4	44.5	43.45	43.1	43	43.05	0.93%	OK
17	55.4	53.4	54.4	55.5	56.1	55.8	2.51%	OK
18	50.6	47.2	48.9	48.4	49.9	49.15	0.51%	OK
19	46.7	46.4	46.55	48.7	47.9	48.3	3.62%	OK
20	60.9	62.7	61.8	64.9	62.8	63.85	3.21%	OK
Passing Number		19	Passing Rate		95.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.970712979

Coefficient of Correlation ("r"): LYM#

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.988

Sample size: 20

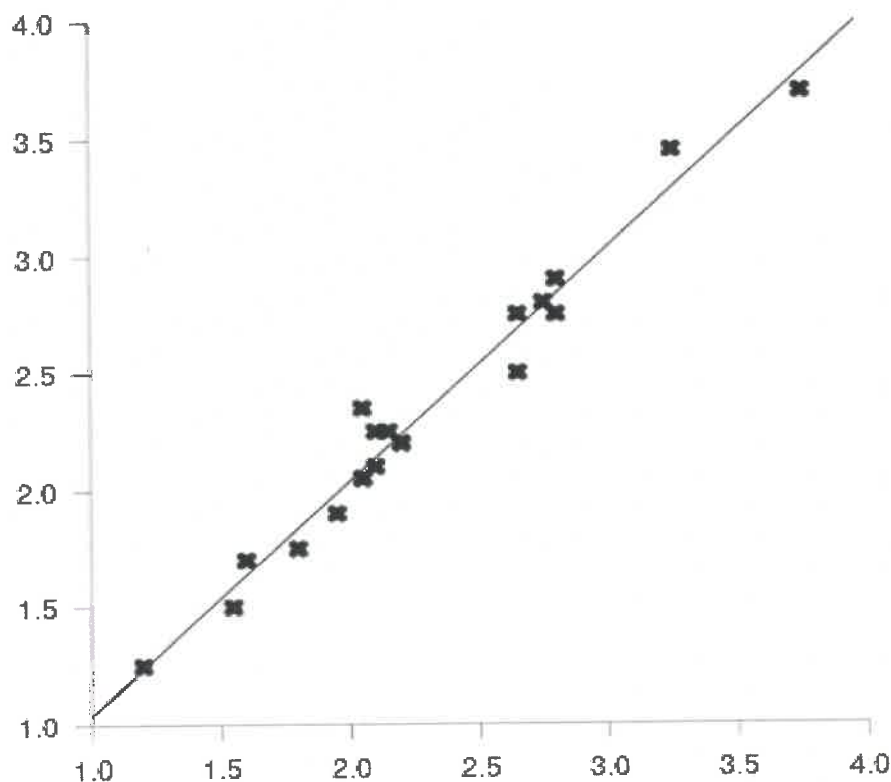
Mean x (x̄): 2.2825

Mean y (ȳ): 2.32

Intercept (a): 0.038949048629636

Slope (b): 0.99936514846456

Regression line equation: $y = 0.038949048629636 + 0.99936514846456x$



ΒΟΓΙΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΓΙΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 28220 38475 - Α.Μ.Τ. 93691
ΛΟΓΙΣΤΗΡΙΑ Ο.Υ ΑΜΑΛΙΑΔΑΣ
Αρ. Πρωτ. 02127101729

Commercial Confidential



Specifications for Approval/Rejection of the Results: LYM#

LYM# (10³/μl)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostic			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	1.8	X2	MEAN	Y1	Y2	MEAN		
1	2.5	2.5	2.5	2.7	2.6	2.65	5.66%	OK
2	2.7	2.8	2.75	2.8	2.8	2.8	1.79%	OK
3	1.3	1.2	1.25	1.2	1.2	1.2	4.17%	OK
4	2.1	2	2.05	2.1	2	2.05	0.00%	OK
5	2	1.8	1.9	1.9	2	1.95	2.56%	OK
6	1.6	1.8	1.7	1.6	1.6	1.6	6.25%	OK
7	2.2	2.3	2.25	2.1	2.2	2.15	4.65%	OK
8	2.1	2	2.05	2	2.1	2.05	0.00%	OK
9	1.8	1.7	1.75	1.8	1.8	1.8	2.78%	OK
10	2.8	2.8	2.8	2.7	2.8	2.75	1.82%	OK
11	2.2	2.2	2.2	2.2	2.2	2.2	0.00%	OK
12	1.5	1.5	1.5	1.5	1.6	1.55	3.23%	OK
13	2.3	2.2	2.25	2.1	2.1	2.1	7.14%	OK
14	3.5	3.4	3.45	3.2	3.3	3.25	6.15%	OK
15	2.4	2.3	2.35	2	2.1	2.05	14.63%	NO
16	3.5	3.9	3.7	3.9	3.6	3.75	1.33%	OK
17	2.7	2.8	2.75	2.8	2.5	2.65	3.77%	OK
18	3	2.8	2.9	2.8	2.8	2.8	3.57%	OK
19	2.1	2.1	2.1	2.1	2.1	2.1	0.00%	OK
20	2.3	2.1	2.2	2.1	2.3	2.2	0.00%	OK
Passing Number	19		Passing Rate	95.0%		Requirement	<=7.5%	
Conclusion	Pass							

Coefficient of Correlation ("r")

0.988619699

Coefficient of Correlation ("r")
0.988619699

Coefficient of Correlation ("r"): NEUT#

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.989$$

Sample size: 20

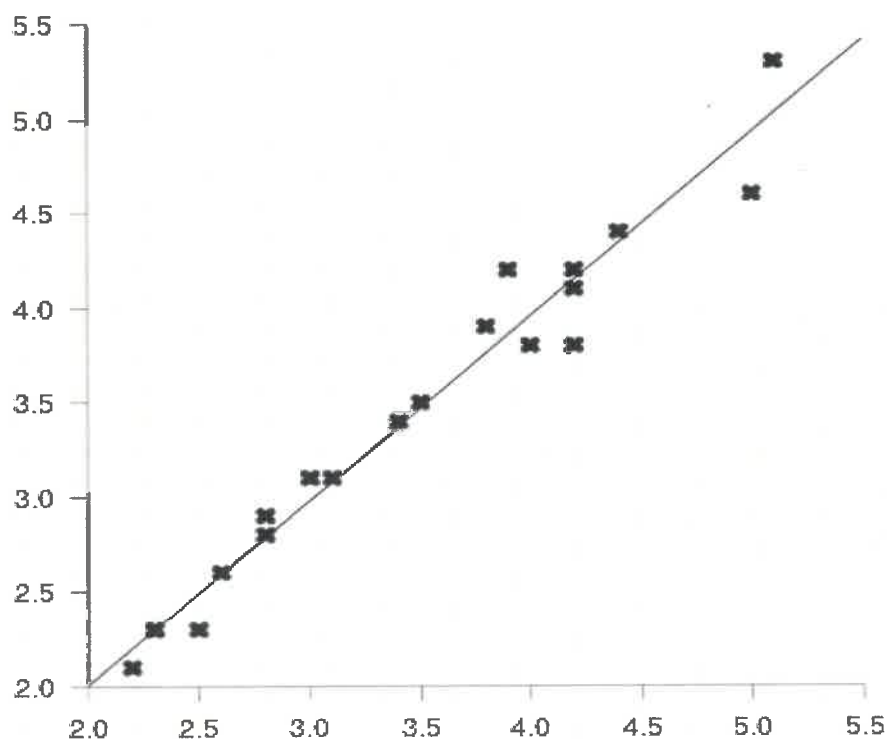
Mean x (x̄): 3.465

Mean y (ȳ): 3.435

Intercept (a): 0.058287445831029

Slope (b): 0.97452021765338

Regression line equation: $y = 0.058287445831029 + 0.97452021765338x$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 33475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200336 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 92127101729



Specifications for Approval/Rejection of the Results: NEUT#

NEUT# ($10^3/\mu\text{l}$)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	X1	X2	MEAN	Y1	Y2	MEAN		
1	2.1	2	2.05	2.2	2.1	2.15	4.65%	OK
2	3.1	3.5	3.3	3.1	3.3	3.2	3.12%	OK
3	2.3	2.3	2.3	2.3	2.4	2.35	2.13%	OK
4	4.4	4.4	4.4	4.4	4.4	4.4	0.00%	OK
5	3.8	4	3.9	4	3.8	3.9	0.00%	OK
6	2.6	2.5	2.55	2.6	2.5	2.55	0.00%	OK
7	2.9	2.9	2.9	2.8	3	2.9	0.00%	OK
8	4.1	4.3	4.2	4.2	4.2	4.2	0.00%	OK
9	3.8	4	3.9	4.2	4	4.1	4.88%	OK
10	2.3	2.4	2.35	2.3	2.4	2.35	0.00%	OK
11	3.1	3.1	3.1	3	3.2	3.1	0.00%	OK
12	4.2	3.7	3.95	3.9	4	3.95	0.00%	OK
13	3.5	3.4	3.45	3.5	3.6	3.55	2.82%	OK
14	5.3	5.5	5.4	5.1	4.9	5	8.00%	NO
15	2.8	2.9	2.85	2.8	2.8	2.8	1.79%	OK
16	3.9	4	3.95	3.8	3.9	3.85	2.60%	OK
17	4.2	4.1	4.15	4.2	4.2	4.2	1.19%	OK
18	3.4	3.2	3.3	3.4	3.4	3.4	2.94%	OK
19	2.3	2.4	2.35	2.5	2.4	2.45	4.08%	OK
20	4.6	4.9	4.75	5	4.9	4.95	4.04%	OK
Passing Number		19	Passing Rate		95.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.989807018

Coefficient of Correlation ("r"): RDW-SD

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.986$$

Sample size: 20

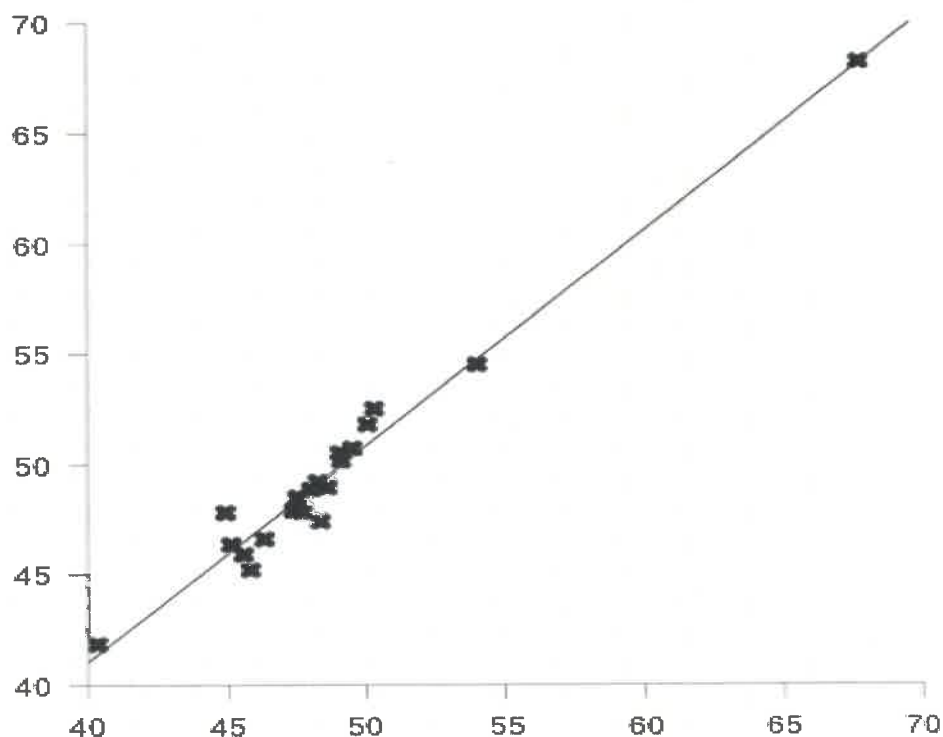
Mean x (x̄): 48.6725

Mean y (ȳ): 49.535

Intercept (a): 1.8487544229816

Slope (b): 0.97973692695091

Regression line equation: $y = 1.8487544229816 + 0.97973692695091x$



ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ: 26220 34475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075280086 Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Α.Κ. 12127101729



Specifications for Approval/Rejection of the Results: RDW-SD

RDW-SD (fL)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	50.7	X2	MEAN	Y1	Y2	MEAN		
1	50.1	50.2	50.15	48.2	50	49.1	2.14%	OK
2	52.4	51.2	51.8	50.4	49.7	50.05	3.50%	OK
3	48.3	49.6	48.95	48	49.2	48.6	0.72%	OK
4	48.2	47.4	47.8	44.9	44.9	44.9	6.46%	OK
5	50.3	50.7	50.5	48.7	49.4	49.05	2.96%	OK
6	48.3	47.5	47.9	47.8	46.9	47.35	1.16%	OK
7	50	51.4	50.7	48.1	50.9	49.5	2.42%	OK
8	46.8	48	47.4	48	48.7	48.35	1.96%	OK
9	56.4	52.6	54.5	55.1	52.9	54	0.93%	OK
10	44.6	45.8	45.2	44.7	46.9	45.8	1.31%	OK
11	49	49.4	49.2	48.6	47.9	48.25	1.97%	OK
12	69.5	66.9	68.2	67.3	68.1	67.7	0.74%	OK
13	48.9	48.8	48.85	48.7	47.3	48	1.77%	OK
14	48.5	48.5	48.5	47.3	47.7	47.5	2.11%	OK
15	41.9	41.8	41.85	40	40.7	40.35	3.72%	OK
16	46	45.8	45.9	46.4	44.7	45.55	0.77%	OK
17	46.9	45.8	46.35	45.4	44.8	45.1	2.77%	OK
18	48.4	47.3	47.85	47.7	47.7	47.7	0.31%	OK
19	52.6	52.4	52.5	48.7	51.9	50.3	4.37%	OK
20	46	47.2	46.6	46.1	46.5	46.3	0.65%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.986362263

Coefficient of Correlation ("r")
0.986362263

Coefficient of Correlation ("r"): RDW-CV

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.999$$

Sample size: 20

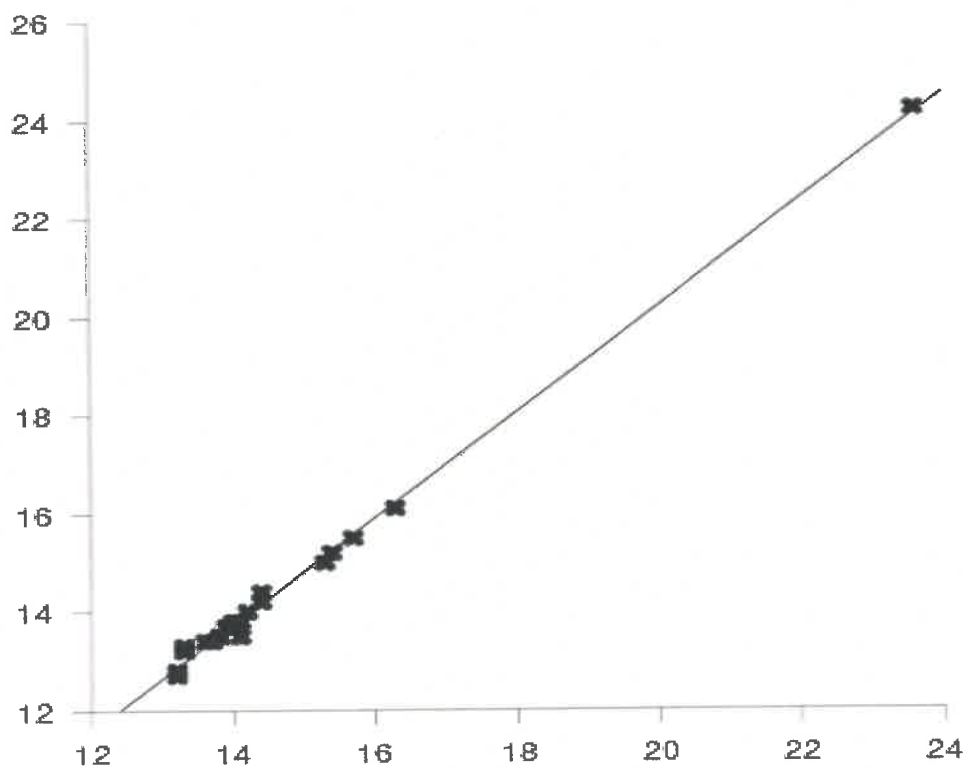
Mean x (x̄): 14.675

Mean y (ȳ): 14.47

Intercept (a): -1.3883165077823

Slope (b): 1.0806348557262

Regression line equation: $y = 1.0806348557262x - 1.3883165077823$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΪΑΤΡΟΛΟΓΟΣ ΜΕ.ΜΕ

25ης ΜΑΡΤΙΟΥ ΣΥΜΑΛΙΑΔΑ

Τηλ.: 26220 34478 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200386 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729

Commercial Confidential



Specifications for Approval/Rejection of the Results: RDW CV

RDW-CV (%)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	15.1	X2	MEAN	Y1	Y2	MEAN		
1	13.3	13.6	13.45	13.3	13.7	13.5	0.37%	OK
2	13.7	13.7	13.7	13.9	13.7	13.8	0.72%	OK
3	13.4	13.65	13.525	13.7	14	13.85	2.35%	OK
4	13.2	13.2	13.2	13.3	13.3	13.3	0.75%	OK
5	15.2	15.1	15.15	15.4	15.4	15.4	1.62%	OK
6	14.4	14.2	14.3	14.4	14.5	14.45	1.04%	OK
7	13.8	14.1	13.95	14.1	14.2	14.15	1.41%	OK
8	12.7	12.9	12.8	13.2	13.3	13.25	3.40%	OK
9	16	15.5	15.75	16.3	15.8	16.05	1.87%	OK
10	14	14.2	14.1	14.2	14.6	14.4	2.08%	OK
11	13.8	13.8	13.8	14	13.9	13.95	1.08%	OK
12	24.2	23.6	23.9	23.6	24.4	24	0.42%	OK
13	12.8	12.8	12.8	13.2	12.8	13	1.54%	OK
14	15	15.4	15.2	15.3	15.5	15.4	1.30%	OK
15	15.5	15.5	15.5	15.7	15.7	15.7	1.27%	OK
16	13.5	13.6	13.55	14.1	13.7	13.9	2.52%	OK
17	13.4	13.4	13.4	13.6	13.6	13.6	1.47%	OK
18	13.5	13.3	13.4	13.8	14	13.9	3.60%	OK
19	13.7	13.8	13.75	14	14	14	1.79%	OK
20	14.2	14.4	14.3	14.4	14.6	14.5	1.38%	OK
Passing Number	20		Passing Rate	100.0%		Requirement	<±7.5%	
Conclusion	Pass							

Coefficient of Correlation ("r")

0.999039014

Coefficient of Correlation ("r")
0.999039014

Coefficient of Correlation ("r"): PDW

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.953

Sample size: 20

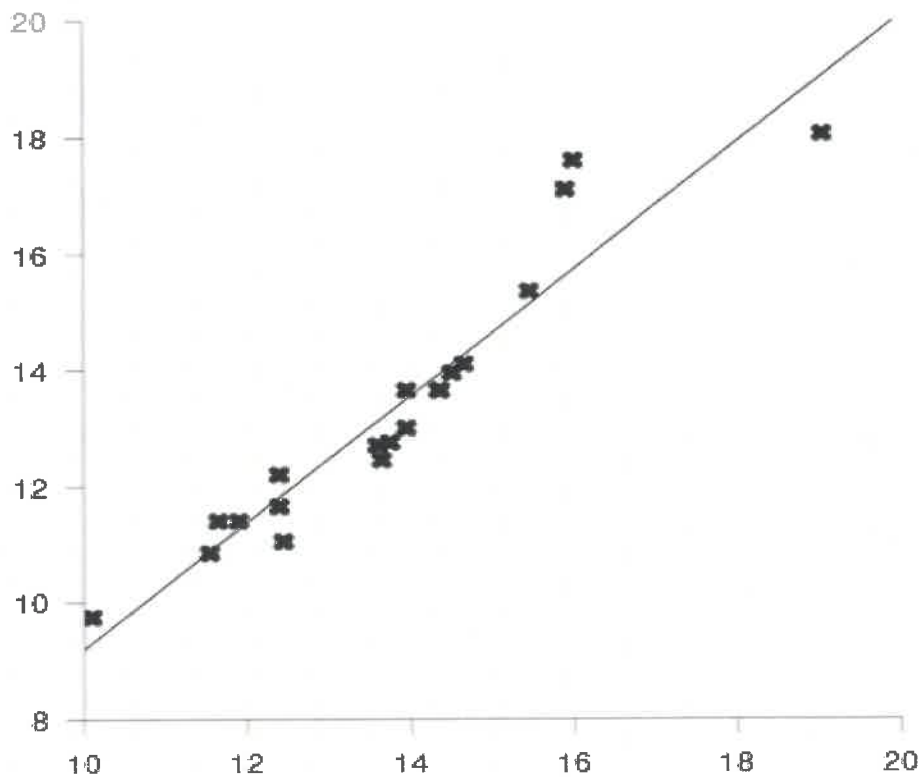
Mean x (x̄): 13.78

Mean y (ȳ): 13.315

Intercept (a): -1.6940767302038

Slope (b): 1.0891927960961

Regression line equation: $y = 1.0891927960961x - 1.6940767302038$



ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 26220 38475 · Α.Μ.Τ. 93691
Α.Ο.Μ. 075200366 · Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729



Specifications for Approval/Rejection of the Results: PDW

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.								
2 times I measure each sample								
Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements								
PDW (fL)								
Coefficient of Correlation ("r") 0.953055408								
SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	18.5	X2	MEAN	Y1	Y2	MEAN		
1	13	11.9	12.45	13.4	13.9	13.65	8.79%	OK
2	14.2	11.8	13	13.4	14.5	13.95	6.81%	OK
3	18.8	15.4	17.1	15.9	15.9	15.9	7.55%	OK
4	15.5	15.2	15.35	15.2	15.7	15.45	0.65%	OK
5	17.6	18.5	18.05	19.9	18.2	19.05	5.25%	OK
6	11.5	11.3	11.4	11.4	11.9	11.65	2.15%	OK
7	17.5	17.7	17.6	15.5	16.5	16	10.00%	OK
8	12	12.4	12.2	12.4	12.4	12.4	1.61%	OK
9	13.8	14.4	14.1	14.5	14.8	14.65	3.75%	OK
10	13.9	14	13.95	15	14	14.5	3.79%	OK
11	13.5	13.8	13.65	13.9	14	13.95	2.15%	OK
12	11	11.1	11.05	13.1	11.8	12.45	11.24%	OK
13	11.5	11.8	11.65	12.3	12.5	12.4	6.05%	OK
14	13.8	13.5	13.65	14	14.7	14.35	4.88%	OK
15	11.6	11.2	11.4	12.1	11.7	11.9	4.20%	OK
16	9.7	9.8	9.75	10.1	10.1	10.1	3.47%	OK
17	10.7	11	10.85	11.3	11.8	11.55	6.06%	OK
18	13.1	12.4	12.75	13.8	13.7	13.75	7.27%	OK
19	12.2	13.2	12.7	14	13.2	13.6	6.62%	OK
20	13.6	13.7	13.65	14	14.7	14.35	4.88%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±12%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.953055408

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c



25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729

Coefficient of Correlation ("r"): MPV

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.985

Sample size: 20

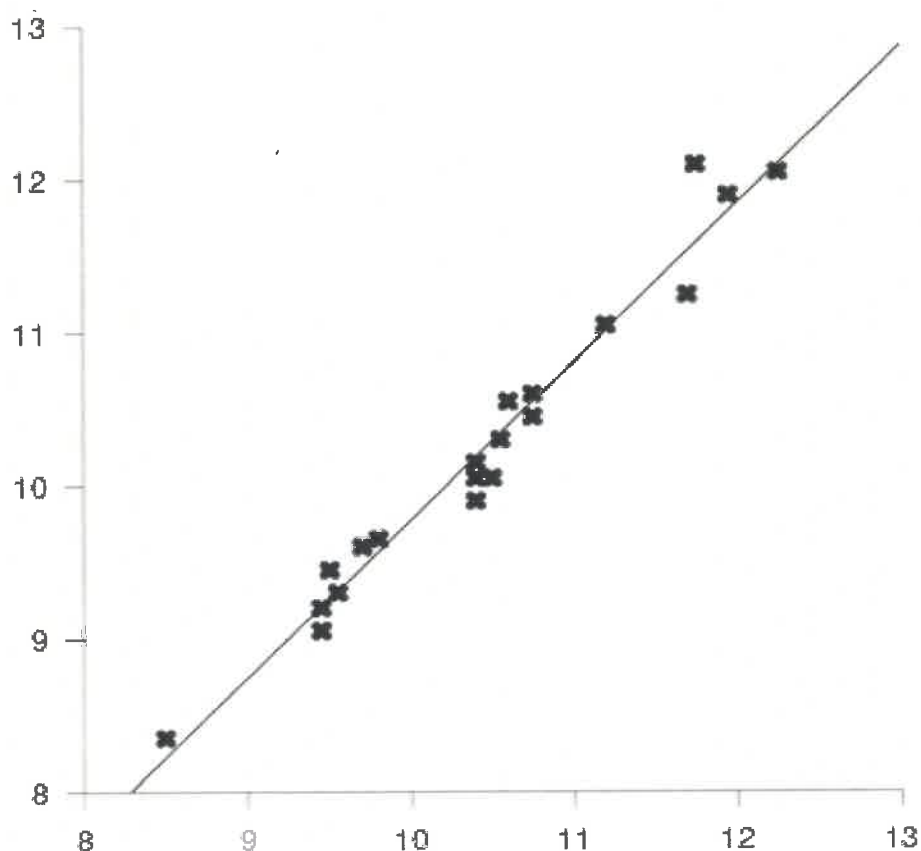
Mean x ($\bar{x}$): 10.4575

Mean y ($\bar{y}$): 10.25

Intercept (a): -0.57217930671076

Slope (b): 1.0348725131925

Regression line equation: $y = 1.0348725131925x - 0.57217930671076$



ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

Commercial-Only-Product 075200365 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729



Specifications for Approval/Rejection of the Results: MPV

MPV (fL)

Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments.

2 times I measure each sample

Judgment Standard : The deviation requirements are in the table below. A sample pass rate of 80% is considered to meet the requirements

SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	12	X2	MEAN	Y1	Y2	MEAN		
1	9.9	9.9	9.9	10.4	10.4	10.4	4.81%	OK
2	10.4	10.2	10.3	10.6	10.5	10.55	2.37%	OK
3	12.2	12	12.1	12.1	11.4	11.75	2.98%	OK
4	11.2	11.3	11.25	11.6	11.8	11.7	3.85%	OK
5	12.1	12	12.05	12.6	11.9	12.25	1.63%	OK
6	9.5	9.4	9.45	9.5	9.5	9.5	0.53%	OK
7	12.1	11.7	11.9	11.9	12	11.95	0.42%	OK
8	9.7	9.5	9.6	9.7	9.7	9.7	1.03%	OK
9	11	11.1	11.05	11.3	11.1	11.2	1.34%	OK
10	10.5	10.7	10.6	10.9	10.6	10.75	1.40%	OK
11	10.7	10.4	10.55	10.7	10.5	10.6	0.47%	OK
12	9	9.1	9.05	9.5	9.4	9.45	4.23%	OK
13	9.6	9.7	9.65	9.7	9.9	9.8	1.53%	OK
14	10.4	10.5	10.45	10.8	10.7	10.75	2.79%	OK
15	9.3	9.3	9.3	9.6	9.5	9.55	2.62%	OK
16	8.4	8.3	8.35	8.5	8.5	8.5	1.76%	OK
17	9.1	9.3	9.2	9.4	9.5	9.45	2.65%	OK
18	10	10.1	10.05	10.5	10.5	10.5	4.29%	OK
19	10.1	10.2	10.15	10.4	10.4	10.4	2.40%	OK
20	10.3	10.3	10.3	10.2	10.7	10.45	1.44%	OK
Passing Number	20		Passing Rate	100.0%		Requirement	<±7.5%	
Conclusion	Pass							

Coefficient of Correlation ("r")

0.985980085

Coefficient of Correlation ("r")
0.985980085

ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΙΛΑ Ε ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729



Single Run Sample Comparison

Raw Data for “r”

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
Α.Μ.Κ.Α. 02127101729

Sample-01		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.3	5.3
RBC ($10^6/\mu\text{l}$)	4.67	4.74
HGB (g/dl)	14.2	13.7
HCT (%)	44.8	44.3
MCV (fL)	95.9	93.5
MCH (pg)	30.4	28.9
MCHC (g/dl)	31.7	30.9
PLT ($10^3/\mu\text{l}$)	260	275
LYM (%)	46.9	51.1
MXD (%)	13.9	8.1
NEUT (%)	39.2	40.8
LYM# ($10^3/\mu\text{l}$)	2.5	2.7
MXD# ($10^3/\mu\text{l}$)	0.7	0.4
NEUT# ($10^3/\mu\text{l}$)	2.1	2.2
RDW-SD (fL)	50.1	48.2
RDW-CV (%)	13.3	13.3

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS, C
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200386 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α 02127101729



Sample-02		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.8	6.8
RBC ($10^6/\mu\text{l}$)	5.05	5.21
HGB (g/dl)	15.3	15.1
HCT (%)	48.5	48.8
MCV (fL)	96	93.7
MCH (pg)	30.3	29.0
MCHC (g/dl)	31.5	30.9
PLT ($10^3/\mu\text{l}$)	229	246
LYM (%)	39.9	40.6
MXD (%)	15	12.8
NEUT (%)	45.1	46.6
LYM# ($10^3/\mu\text{l}$)	2.7	2.6
MXD# ($10^3/\mu\text{l}$)	1	0.9
NEUT# ($10^3/\mu\text{l}$)	3.1	3.1
RDW-SD (fL)	52.4	50.4
RDW-CV (%)	13.7	13.9

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ: 26220 38475 - Α.Μ.Τ. 93691.
 Α.Φ.Μ. 075200368 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Α. 02127101729



Sample-03		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.1	4
RBC ($10^6/\mu\text{l}$)	4.56	4.69
HGB (g/dl)	14.1	13.6
HCT (%)	42.7	43.2
MCV (fL)	93.6	92.1
MCH (pg)	30.9	29
MCHC (g/dl)	33	31.5
PLT ($10^3/\mu\text{l}$)	143	150
LYM (%)	31.2	29.2
MXD (%)	12.4	12.5
NEUT (%)	56.4	58.3
LYM# ($10^3/\mu\text{l}$)	1.3	1.2
MXD# ($10^3/\mu\text{l}$)	0.5	0.5
NEUT# ($10^3/\mu\text{l}$)	2.3	2.3
RDW-SD (fL)	48.3	48
RDW-CV (%)	13.4	13.7

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΗ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ: 26220 88475 - Α.Μ.Τ. 93691
 Α.Ο.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-04		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7	7.1
RBC ($10^6/\mu\text{l}$)	4.3	4.45
HGB (g/dl)	12.7	12.4
HCT (%)	40	40.2
MCV (fL)	93	90.3
MCH (pg)	29.5	27.9
MCHC (g/dl)	31.8	30.8
PLT ($10^3/\mu\text{l}$)	242	252
LYM (%)	30.7	29.3
MXD (%)	6.7	8.5
NEUT (%)	62.6	62.2
LYM# ($10^3/\mu\text{l}$)	2.1	2.1
MXD# ($10^3/\mu\text{l}$)	0.5	0.6
NEUT# ($10^3/\mu\text{l}$)	4.4	4.4
RDW-SD (fL)	48.2	44.9
RDW-CV (%)	13.2	13.3

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MSc
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 30475 - Α.Μ.Τ. 93691
 Α.Ο.Μ. 07520386 Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-05		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.5	6.7
RBC ($10^6/\mu\text{l}$)	4.76	4.82
HGB (g/dl)	12.6	12.2
HCT (%)	40.9	40.9
MCV (fL)	85.9	84.9
MCH (pg)	26.5	25.3
MCHC (g/dl)	30.8	29.8
PLT ($10^3/\mu\text{l}$)	178	184
LYM (%)	30.4	28.3
MXD (%)	10.7	12.4
NEUT (%)	58.9	59.3
LYM# ($10^3/\mu\text{l}$)	2	1.9
MXD# ($10^3/\mu\text{l}$)	0.7	0.8
NEUT# ($10^3/\mu\text{l}$)	3.8	4
RDW-SD (fL)	50.3	48.7
RDW-CV (%)	15.2	15.4

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ M.D.M.S.
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ: 26220 38475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 078200386 - Α.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-06		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.9	4.9
RBC ($10^6/\mu\text{l}$)	4.44	4.58
HGB (g/dl)	12.1	11.8
HCT (%)	39	39.1
MCV (fL)	87.8	85.4
MCH (pg)	27.3	25.8
MCHC (g/dl)	31	30.2
PLT ($10^3/\mu\text{l}$)	392	380
LYM (%)	32.9	33.5
MXD (%)	14.7	13.3
NEUT (%)	52.4	53.2
LYM# ($10^3/\mu\text{l}$)	1.6	1.6
MXD# ($10^3/\mu\text{l}$)	0.7	0.7
NEUT# ($10^3/\mu\text{l}$)	2.6	2.6
RDW-SD (fL)	48.3	47.8
RDW-CV (%)	14.4	14.4

ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38475 - Α.Μ.Τ. 9369,
 Α.Φ.Μ. 075200365 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Τ. 02027101729



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Sample-07		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.9	5.8
RBC ($10^6/\mu\text{l}$)	4.67	4.77
HGB (g/dl)	13.4	13.1
HCT (%)	44.2	44.3
MCV (fL)	94.6	92.6
MCH (pg)	28.7	27.5
MCHC (g/dl)	30.3	29.6
PLT ($10^3/\mu\text{l}$)	183	189
LYM (%)	36.7	36.6
MXD (%)	13	15.3
NEUT (%)	50.3	48.1
LYM# ($10^3/\mu\text{l}$)	2.2	2.1
MXD# ($10^3/\mu\text{l}$)	0.8	0.9
NEUT# ($10^3/\mu\text{l}$)	2.9	2.8
RDW-SD (fL)	50	48.1
RDW-CV (%)	13.8	14.1

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220.35475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200386 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729

Sample-08		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7.1	6.9
RBC ($10^6/\mu\text{l}$)	4.34	4.45
HGB (g/dl)	13.8	13.5
HCT (%)	41.8	42
MCV (fL)	96.3	94.4
MCH (pg)	31.8	30.3
MCHC (g/dl)	33	32.1
PLT ($10^3/\mu\text{l}$)	193	206
LYM (%)	29.1	28.3
MXD (%)	12.3	10.6
NEUT (%)	58.6	61.1
LYM# ($10^3/\mu\text{l}$)	2.1	2
MXD# ($10^3/\mu\text{l}$)	0.9	0.7
NEUT# ($10^3/\mu\text{l}$)	4.1	4.2
RDW-SD (fL)	46.8	48
RDW-CV (%)	12.7	13.2

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200366 Λ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729



Sample-09		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.9	7.3
RBC ($10^6/\mu\text{l}$)	3.6	3.66
HGB (g/dl)	11.5	11.2
HCT (%)	34.6	34.4
MCV (fL)	96.1	94
MCH (pg)	31.9	30.6
MCHC (g/dl)	33.2	32.6
PLT ($10^3/\mu\text{l}$)	260	279
LYM (%)	26.4	24.1
MXD (%)	18.2	17.7
NEUT (%)	55.4	58.2
LYM# ($10^3/\mu\text{l}$)	1.8	1.8
MXD# ($10^3/\mu\text{l}$)	1.3	1.3
NEUT# ($10^3/\mu\text{l}$)	3.8	4.2
RDW-SD (fL)	56.4	55.1
RDW-CV (%)	16	16.3

ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200363 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729

Sample-10		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.7	5.6
RBC ($10^6/\mu\text{l}$)	4.59	4.63
HGB (g/dl)	12.2	11.8
HCT (%)	39.1	38.4
MCV (fL)	85.2	82.9
MCH (pg)	26.6	25.5
MCHC (g/dl)	31.2	30.7
PLT ($10^3/\mu\text{l}$)	264	278
LYM (%)	48.6	48.7
MXD (%)	10	10.4
NEUT (%)	41.4	40.9
LYM# ($10^3/\mu\text{l}$)	2.8	2.7
MXD# ($10^3/\mu\text{l}$)	0.6	0.6
NEUT# ($10^3/\mu\text{l}$)	2.3	2.3
RDW-SD (fL)	44.6	44.7
RDW-CV (%)	14	14.2

Sample-11		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.0	6.1
RBC ($10^6/\mu\text{l}$)	4.8	4.90
HGB (g/dl)	14.3	14.1
HCT (%)	44.5	43.9
MCV (fL)	92.7	90.3
MCH (pg)	29.8	29.0
MCHC (g/dl)	32.1	32.1
PLT ($10^3/\mu\text{l}$)	199	211
LYM (%)	37.1	36.6
MXD (%)	12.2	14.4
NEUT (%)	50.7	49.0
LYM# ($10^3/\mu\text{l}$)	2.2	2.2
MXD# ($10^3/\mu\text{l}$)	0.5	0.9
NEUT# ($10^3/\mu\text{l}$)	3.1	3.0
RDW-SD (fL)	49	48.6
RDW-CV (%)	13.8	14.0

Sample-12		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.2	6.26.1
RBC ($10^6/\mu\text{l}$)	4.06	4.19
HGB (g/dl)	10.4	10.1
HCT (%)	34.4	34.6
MCV (fL)	84.7	82.6
MCH (pg)	25.6	24.0
MCHC (g/dl)	30.2	29.1
PLT ($10^3/\mu\text{l}$)	401	421
LYM (%)	24.5	24.9
MXD (%)	8.3	11.5
NEUT (%)	67.3	63.6
LYM# ($10^3/\mu\text{l}$)	1.5	1.5
MXD# ($10^3/\mu\text{l}$)	0.5	0.6
NEUT# ($10^3/\mu\text{l}$)	4.2	3.9
RDW-SD (fL)	69.5	67.3
RDW-CV (%)	24.2	23.6

ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΥΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 33475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-13		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.6	6.7
RBC ($10^6/\mu\text{l}$)	4.48	4.60
HGB (g/dl)	13.6	13
HCT (%)	43.5	43.7
MCV (fL)	97.1	95
MCH (pg)	30.4	28.3
MCHC (g/dl)	31.3	29.7
PLT ($10^3/\mu\text{l}$)	237	255
LYM (%)	35.3	30.7
MXD (%)	11.4	16.3
NEUT (%)	53.3	53
LYM# ($10^3/\mu\text{l}$)	2.3	2.1
MXD# ($10^3/\mu\text{l}$)	0.8	1.1
NEUT# ($10^3/\mu\text{l}$)	3.5	3.5
RDW-SD (fL)	48.9	48.7
RDW-CV (%)	12.8	13.2

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ: 2622038475 - Α.Μ.Τ. 93691
 Α.Φ.Μ. 075200386 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729

Sample-14		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	9.6	9.7
RBC ($10^6/\mu\text{l}$)	4.64	4.74
HGB (g/dl)	11.4	11.3
HCT (%)	38.8	38.6
MCV (fL)	83.6	81.4
MCH (pg)	24.6	23.8
MCHC (g/dl)	29.4	29.3
PLT ($10^3/\mu\text{l}$)	351	359
LYM (%)	36.1	33.5
MXD (%)	8.2	14.9
NEUT (%)	55.7	51.6
LYM# ($10^3/\mu\text{l}$)	3.5	3.2
MXD# ($10^3/\mu\text{l}$)	0.8	1.4
NEUT# ($10^3/\mu\text{l}$)	5.3	5.1
RDW-SD (fL)	48.5	47.3
RDW-CV (%)	15	15.3

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ.: 26220 38475 - Α.Μ.Τ. 9351
 Α.Φ.Μ. 075200366 - Δ.Ο.Υ. ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-15		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.5	5.4
RBC ($10^6/\mu\text{l}$)	5.13	5.21
HGB (g/dl)	10.8	10.7
HCT (%)	36.9	36.5
MCV (fL)	71.9	70.1
MCH (pg)	21.1	20.5
MCHC (g/dl)	29.3	29.3
PLT ($10^3/\mu\text{l}$)	291	292
LYM (%)	43	37
MXD (%)	4.7	11.4
NEUT (%)	52.3	51.6
LYM# ($10^3/\mu\text{l}$)	2.4	2
MXD# ($10^3/\mu\text{l}$)	0.3	0.6
NEUT# ($10^3/\mu\text{l}$)	2.8	2.8
RDW-SD (fL)	41.9	40
RDW-CV (%)	15.5	15.7

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729



Sample-16		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	9	8.9
RBC ($10^6/\mu\text{l}$)	4.64	4.77
HGB (g/dl)	12.4	12.1
HCT (%)	39.9	40.3
MCV (fL)	86	84.5
MCH (pg)	26.7	25.4
MCHC (g/dl)	31.1	30
PLT ($10^3/\mu\text{l}$)	536	573
LYM (%)	39.4	43.6
MXD (%)	18.2	13.3
NEUT (%)	42.4	43.1
LYM# ($10^3/\mu\text{l}$)	3.5	3.9
MXD# ($10^3/\mu\text{l}$)	1.6	1.2
NEUT# ($10^3/\mu\text{l}$)	3.9	3.8
RDW-SD (fL)	46	46.4
RDW-CV (%)	13.5	14.1

ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΥΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS'c
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 Α.Μ.Κ.Α. 02127101729



Sample-17		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7.7	7.6
RBC ($10^6/\mu\text{l}$)	4.89	4.95
HGB (g/dl)	14.4	14.1
HCT (%)	43.8	43.1
MCV (fL)	89.6	87.1
MCH (pg)	29.4	28.5
MCHC (g/dl)	32.9	32.7
PLT ($10^3/\mu\text{l}$)	272	280
LYM (%)	34.7	36.2
MXD (%)	9.9	8.3
NEUT (%)	55.4	55.5
LYM# ($10^3/\mu\text{l}$)	2.7	2.8
MXD# ($10^3/\mu\text{l}$)	0.8	0.6
NEUT# ($10^3/\mu\text{l}$)	4.2	4.2
RDW-SD (fL)	46.9	45.4
RDW-CV (%)	13.4	13.6

ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
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 Α.Μ.Κ. 02127101729

Sample-18		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.9	6.9
RBC ($10^6/\mu\text{l}$)	4.55	4.61
HGB (g/dl)	13	12.1
HCT (%)	41.8	41.1
MCV (fL)	91.9	89.2
MCH (pg)	28.6	27.5
MCHC (g/dl)	31.1	30.9
PLT ($10^3/\mu\text{l}$)	279	295
LYM (%)	42.8	41
MXD (%)	6.6	10.6
NEUT (%)	50.6	48.4
LYM# ($10^3/\mu\text{l}$)	3	2.8
MXD# ($10^3/\mu\text{l}$)	0.5	0.7
NEUT# ($10^3/\mu\text{l}$)	3.4	3.4
RDW-SD (fL)	48.4	47.7
RDW-CV (%)	13.5	13.8

ΒΟΛΙΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΛΙΑ Ε. ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΪΜΜΟΛΟΓΟΣ MD, MS^c
 25ης ΜΑΡΤΙΟΥ 2, ΑΜΑΛΙΑΔΑ
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 Α.Μ.ΚΑ. 02127101729



Sample-19		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.9	5.1
RBC ($10^6/\mu\text{l}$)	4	4.12
HGB (g/dl)	12.8	12.5
HCT (%)	39.9	40.3
MCV (fL)	99.8	97.8
MCH (pg)	32	30.3
MCHC (g/dl)	32.1	31
PLT ($10^3/\mu\text{l}$)	202	201
LYM (%)	42.1	40.8
MXD (%)	11.2	10.5
NEUT (%)	46.7	48.7
LYM# ($10^3/\mu\text{l}$)	2.1	2.1
MXD# ($10^3/\mu\text{l}$)	0.5	0.5
NEUT# ($10^3/\mu\text{l}$)	2.3	2.5
RDW-SD (fL)	52.6	48.7
RDW-CV (%)	13.7	14

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
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 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
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 Α.Φ.Μ. 075200386 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101729



Sample-20		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7.7	7.7
RBC ($10^6/\mu\text{l}$)	4.81	4.85
HGB (g/dl)	12.7	12.5
HCT (%)	41.3	40.4
MCV (fL)	85.9	83.3
MCH (pg)	26.4	25.8
MCHC (g/dl)	30.8	30.9
PLT ($10^3/\mu\text{l}$)	216	217
LYM (%)	29.3	27
MXD (%)	9.8	8.1
NEUT (%)	60.9	64.9
LYM# ($10^3/\mu\text{l}$)	2.3	2.1
MXD# ($10^3/\mu\text{l}$)	0.8	0.6
NEUT# ($10^3/\mu\text{l}$)	4.6	5
RDW-SD (fL)	46	46.1
RDW-CV (%)	14.2	14.4

ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ
 25
 Τηλ.
 Α.Φ.Μ. 07

ΒΟΥΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
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 Τηλ.: 210 9475 - Α.Μ.Τ. 9369
 Α.Φ.Μ. 07



Performance with Hematology 3rd Party Controls

Product: EIGHTCHECK-3WP-N (SYSMEX)
Normal Control

Lot No.: 50800822

Expiry: 28/6/2025

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
ΥΠΟΥΡΓΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
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Α.Φ.Μ. 075200368 - Α.Μ.Α.Α.Δ.Α.Σ
Α.Μ.Η. 0212100129

Low Control, Lot No. , Expiry:			
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference	Range
WBC ($10^3/\mu\text{l}$)			
RBC ($10^6/\mu\text{l}$)			
HGB (g/dl)			
HCT (%)			
MCV (fL)			
MCH (pg)			
MCHC (g/dl)			
PLT ($10^3/\mu\text{l}$)			
LYM (%)			
MXD (%)			
NEUT (%)			
LYM# ($10^3/\mu\text{l}$)			
MXD# ($10^3/\mu\text{l}$)			
NEUT# ($10^3/\mu\text{l}$)			
RDW-SD (fL)			
RDW-CV (%)			
PDW (fL)			
MPV (fL)			
P-LCR (%)			

ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ
 ΒΟΥΛΑ Ε ΠΑΝΑΓΙΩΤΑ
 ΚΥΤΟΣΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
 25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ
 Τηλ: 26220 38475 - Α.Μ.Τ. 93891
 ΑΔΜ. 07526356 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ. 72127101729

EIGHTCHECK-3WP-N (SYSMEX)			
Normal Control, Lot No. 50800822, Expiry: 28/6/2025			
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference	Range
WBC ($10^3/\mu\text{l}$)	6.9	6.8	6.5 - 7.5
RBC ($10^6/\mu\text{l}$)	4.31	4.43	4.18 - 4.52
HGB (g/dl)	11.8	11.6	11.4 - 12.4
HCT (%)	33.1	34.1	31.4 - 36.6
MCV (fL)	76.8	77	74.2 - 82
MCH (pg)	27.4	26.2	25.9 - 23.9
MCHC (g/dl)	35.6	34.0	32.5 - 37.5
PLT ($10^3/\mu\text{l}$)	217	226	183 - 247
LYM (%)	31.8	30	26.4 - 35.8
MXD (%)	11	13.6	9.4 - 15.8
NEUT (%)	57.2	56.4	52.4 - 60.2
LYM# ($10^3/\mu\text{l}$)	2.2	2	1.9 - 2.5
MXD# ($10^3/\mu\text{l}$)	0.8	0.9	0.7 - 1.1
NEUT# ($10^3/\mu\text{l}$)	3.9	3.9	3.5 - 4.3
RDW-SD (fL)	38.7	39.7	33.2 - 45
RDW-CV (%)	13.1	13.2	10.5 - 14.3
PDW (fL)	9	8.8	7.7 - 9.5
MPV (fL)	9.9	9.8	9 - 10.6
P-LCR (%)	19.4	18.6	7 - 28.2

ΒΟΪΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΪΛΑ Ε. ΠΑΝΑΓΙΩΤΑ

ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD, MS^c

25ης ΜΑΡΤΙΟΥ 2 ΑΜΑΛΙΑΔΑ

Τηλ.: 26220 38475 - Α.Μ.Τ. 93691

Α.Φ.Μ. 075200366 - Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ

Α.Μ.Κ.Α. 02127101729



Other High Control, Lot No. , Expiry:			
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference	Range
WBC ($10^3/\mu\text{l}$)			
RBC ($10^6/\mu\text{l}$)			
HGB (g/dl)			
HCT (%)			
MCV (fL)			
MCH (pg)			
MCHC (g/dl)			
PLT ($10^3/\mu\text{l}$)			
LYM (%)			
MXD (%)			
NEUT (%)			
LYM# ($10^3/\mu\text{l}$)			
MXD# ($10^3/\mu\text{l}$)			
NEUT# ($10^3/\mu\text{l}$)			
RDW-SD (fL)			
RDW-CV (%)			
PDW (fL)			
MPV (fL)			
P-LCR (%)			

ΒΟΥΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΥΛΑ Ε ΠΑΝΑΓΙΩΤΑ
 ΙΑΤΡΟΣ ΒΙΟΠΑΘΟΛΟΓΟΣ MD,MS^c
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 Τηλ.: 26220 38475 - Α.Μ.Τ. 93691
 ΑΦ.Μ. 075200356 Δ.Ο.Υ ΑΜΑΛΙΑΔΑΣ
 Α.Μ.Κ.Α. 02127101/29



Coefficient of Variation: Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Sysmex Reagents on **KX-21N**, 3 Part Hematology Analyzer.
2. The sample was tested in 10 replicates to study Precision.

Fresh Blood Sample, n = 10

Parameters	1	2	2	4	5	6	7	8	9	10	Mean	SD	CV	CV%
WBC (10 ³ /μl)	6.1	6.2	6.1	6	6.1	6.1	6.3	6.2	6.3	6.2	6.16	0.10	0.02	1.57
RBC (10 ⁶ /μl)	5.29	5.29	5.28	5.31	5.37	5.3	5.29	5.3	5.26	5.26	5.30	0.03	0.01	0.59
HGB (g/dl)	16.1	16.2	16.2	16.2	16.2	16.2	16.3	16.2	16.2	16.3	16.21	0.06	0.00	0.35
HCT (%)	47.3	47	47	47.3	47.7	47.3	47	47.3	46.8	46.8	47.15	0.28	0.01	0.59
MCV (fL)	89.4	88.8	89	89.1	88.8	89.2	88.8	89.2	89	89	89.03	0.20	0.00	0.22
MCH (pg)	30.4	30.6	30.7	30.5	30.2	30.6	30.8	30.6	30.8	31	30.62	0.23	0.01	0.74
MCHC (g/dl)	34	34.5	34.5	34.2	34	34.2	34.7	34.2	34.6	34.8	34.37	0.29	0.01	0.83
PLT (10 ³ /μl)	236	222	225	244	232	229	235	245	240	245	235.30	8.30	0.04	3.53
LYM (%)	39.7	38.3	38.9	39.6	42.6	40.8	39.6	40.9	38.9	37.5	39.68	1.46	0.04	3.68
MXD (%)	6.7	6.6	5.9	6.5	6.1	3.5	5.3	5.2	5.5	7.2	5.85	1.05	0.18	17.99
NEUT (%)	53.6	55.1	55.2	53.9	51.3	55.7	55.1	53.9	55.6	55.3	54.47	1.34	0.02	2.47
LYM# (10 ³ /μl)	2.4	2.4	2.4	2.4	2.6	2.5	2.5	2.5	2.5	2.3	2.45	0.08	0.03	3.47
MXD# (10 ³ /μl)	0.4	0.4	0.4	0.4	0.4	0.2	0.3	0.3	0.3	0.4	0.35	0.07	0.20	20.20
NEUT# (10 ³ /μl)	3.3	3.4	3.3	3.2	3.1	3.4	3.5	3.4	3.5	3.5	3.36	0.13	0.04	4.02
RDW-SD (fL)	42.2	43.6	42.2	41	41	42.7	41.2	42	42	41.2	41.91	0.84	0.02	2.00
RDW-CV (%)	12.4	12.7	12.5	12.5	12.5	12.8	12.5	12.8	12.7	12.4	12.58	0.15	0.01	1.23
PDW (fL)	12.4	12.4	13.2	13.2	12.2	11.9	12.9	13.3	12.5	12	12.60	0.52	0.04	4.10
MPV (fL)	9.8	9.9	9.9	10	10.1	9.9	9.9	10	9.8	9.8	9.91	0.10	0.01	1.00
P-LCR (%)	24.3	24.7	26.4	25.4	26	25.1	25.2	26.7	25.3	24.5	25.24	0.75	0.03	2.97

ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ

ΒΟΙΛΑ Ε. ΠΑΝΑΓΙΩΤΑ
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Coefficient of Variation: Precision (VDx Reagents)

1. Fresh blood sample was collected and tested with the VDx Sysmex Reagents on **KX-21N**, 3 Part Hematology Analyzer.
2. The sample was tested in 11 replicates, and then calculate the CV of 2nd to 11th results

Parameters	1	2	3	4	5	6	7	8	9	10	11	MEAN	SD	CV	Criterion CVs	Conclusion
WBC ($10^3/\mu\text{l}$)	6.1	6.1	6.2	6.1	6	6.1	6.1	6.3	6.2	6.3	6.2	6.16	0.097	1.57%	3.50%	Qualified
RBC ($10^6/\mu\text{l}$)	5.27	5.29	5.29	5.28	5.31	5.37	5.3	5.29	5.3	5.26	5.26	5.295	0.031	0.0058549	2.00%	Qualified
HGB (g/dl)	16.2	16.1	16.2	16.2	16.2	16.2	16.2	16.3	16.2	16.2	16.3	16.21	0.057	0.0035018	1.50%	Qualified
HCT (%)	47.2	47.3	47	47	47.3	47.7	47.3	47	47.3	46.8	46.8	47.15	0.280	0.005936	2.00%	Qualified
MCV (fl)	89.6	89.4	88.8	89	89.1	88.8	89.2	88.8	89.2	89	89	89.03	0.200	0.0022496	2.00%	Qualified
MCH (pg)	30.7	30.4	30.6	30.7	30.5	30.2	30.6	30.8	30.6	30.8	31	30.62	0.225	0.0073512	2.00%	Qualified
MCHC (g/dl)	34.3	34	34.5	34.5	34.2	34	34.2	34.7	34.2	34.6	34.8	34.37	0.287	0.0083485	2.00%	Qualified
PLT ($10^3/\mu\text{l}$)	241	236	222	225	244	232	229	235	245	240	245	235.3	8.301	0.0352767	6.00%	Qualified
LYM (%)	39	39.7	38.3	38.9	39.6	42.6	40.8	39.6	40.9	38.9	37.5	39.68	1.459	0.0367671	15.00%	Qualified
MXD (%)	6.9	6.7	6.6	5.9	6.5	6.1	3.5	5.3	5.2	5.5	7.2	5.85	1.052	0.1798712	30.00%	Qualified
NEUT (%)	54.1	53.6	55.1	55.2	53.9	51.3	55.7	55.1	53.9	55.6	55.3	54.47	1.344	0.0246771	15.00%	Qualified
LYM# ($10^3/\mu\text{l}$)	2.4	2.4	2.4	2.4	2.4	2.6	2.5	2.5	2.5	2.5	2.3	2.45	0.085	0.0346872	15.00%	Qualified
MXD# ($10^3/\mu\text{l}$)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.2	0.3	0.3	0.4	0.36	0.070	0.1942239	30.00%	Qualified
NEUT# ($10^3/\mu\text{l}$)	3.3	3.3	3.4	3.3	3.2	3.1	3.4	3.5	3.4	3.5	3.5	3.36	0.135	0.0401755	15.00%	Qualified
RDW-SD (fl)	41.8	42.2	43.6	42.2	41	41	42.7	41.2	42	42	41.2	41.91	0.839	0.0200091	4.00%	Qualified
RDW-CV (%)	12.7	12.4	12.7	12.5	12.5	12.5	12.8	12.5	12.8	12.7	12.4	12.58	0.155	0.0123147	4.00%	Qualified
PDW (fl)	13.1	12.4	12.4	13.2	13.2	12.2	11.9	12.9	13.3	12.5	12	12.6	0.516	0.040984	12.00%	Qualified
MPV (fl)	9.7	9.8	9.9	9.9	10	10.1	9.9	9.9	10	9.8	9.8	9.91	0.099	0.0100346	5.00%	Qualified
P-LCR (%)	24.5	24.3	24.7	26.4	25.4	26	25.1	25.2	26.7	25.3	24.5	25.36	0.795	0.0313369	20.00%	Qualified

ΒΟΙΛΑ ΠΑΝΑΓΙΩΤΑ
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Coefficient of Variation: Precision (Sysmex Reagents)

1. Fresh blood sample was collected and tested with the Sysmex Reagents on **KX-21N**, 3 Part Hematology Analyzer.
2. The sample was tested in 10 replicates to study Precision.

Fresh Blood Sample, n = 10

Parameters	1	2	2	4	5	6	7	8	9	10	Mean	SD	CV	CV%
WBC (10 ³ /μl)	6	5.9	6	6.1	5.9	6.2	5.9	6	6.1	5.9	6.00	0.11	0.02	1.76
RBC (10 ⁶ /μl)	5.4	5.35	5.41	5.37	5.32	5.39	5.37	5.36	5.31	5.39	5.37	0.03	0.01	0.62
HGB (g/dl)	15.8	15.7	15.7	15.7	15.7	15.7	15.6	15.7	15.7	15.8	15.71	0.06	0.00	0.36
HCT (%)	47.6	47.3	47.7	47.2	46.8	47.5	47.1	47.3	46.7	47.3	47.25	0.32	0.01	0.68
MCV (fL)	88.1	88.4	88.2	87.9	88	88.1	87.7	88.2	87.9	87.8	88.03	0.21	0.00	0.24
MCH (pg)	29.3	29.3	29	29.2	29.5	29.1	29.1	29.3	29.6	29.3	29.27	0.18	0.01	0.62
MCHC (g/dl)	33.2	33.2	32.9	33.3	33.5	33.1	33.1	33.2	33.6	33.4	33.25	0.21	0.01	0.62
PLT (10 ³ /μl)	251	250	266	253	230	246	237	242	259	247	248.10	10.38	0.04	4.18
LYM (%)	39.1	37.9	38	38	37.1	36.6	34.9	37.8	38	38	37.54	1.13	0.03	3.01
MXD (%)	6.8	7.7	6	5	6.3	7.6	7.2	6.7	6.6	7.1	6.70	0.80	0.12	11.96
NEUT (%)	54.1	54.4	56	57	56.6	55.8	57.9	55.5	55.4	54.9	55.76	1.17	0.02	2.11
LYM# (10 ³ /μl)	2.3	2.2	2.3	2.3	2.2	2.3	2.1	2.3	2.3	2.2	2.25	0.07	0.03	3.14
MXD# (10 ³ /μl)	0.4	0.5	0.4	0.3	0.4	0.5	0.4	0.4	0.4	0.4	0.41	0.06	0.14	13.85
NEUT# (10 ³ /μl)	3.3	3.2	3.3	3.5	3.3	3.4	3.4	3.3	3.4	3.3	3.34	0.08	0.03	2.52
RDW-SD (fL)	41.3	42	40.7	42.5	40.8	42.1	41.7	42	42.3	41.9	41.73	0.61	0.01	1.46
RDW-CV (%)	12.8	12.9	12.8	12.8	12.5	13	12.5	12.9	12.9	12.8	12.79	0.17	0.01	1.30
PDW (fL)	13.5	12.5	13	13.3	12.3	13.4	13	13.4	13.2	13.8	13.14	0.46	0.03	3.48
MPV (fL)	10	10	9.9	9.9	9.8	9.8	10.2	10	9.9	10.1	9.96	0.13	0.01	1.27
P-LCR (%)	26.5	25.8	24.7	25.3	24.2	25.3	26.4	26.5	26.6	26	25.84	0.80	0.03	3.08

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Coefficient of Variation: Precision (Sysmex Reagents)

1. Fresh blood sample was collected and tested with the VDX Sysmex Reagents on **KX-21N**, 3 Part Hematology Analyzer.
2. The sample was tested in 11 replicates, and then calculate the CV of 2nd to 11th results

Parameters	1	2	3	4	5	6	7	8	9	10	11	MEAN	SD	CV	Criterion CVs	Conclusion
WBC ($10^3/\mu\text{l}$)	5.7	6	5.9	6	6.1	5.9	6.2	5.9	6	6.1	5.9	6	0.105	1.76%	3.50%	Qualified
RBC ($10^6/\mu\text{l}$)	5.67	5.4	5.35	5.41	5.37	5.32	5.39	5.37	5.36	5.31	5.39	5.367	0.033	0.00615151	2.00%	Qualified
HGB (g/dl)	16.7	15.8	15.7	15.7	15.7	15.7	15.7	15.6	15.7	15.7	15.8	15.71	0.057	0.00361328	1.50%	Qualified
HCT (%)	49.7	47.6	47.3	47.7	47.2	46.8	47.5	47.1	47.3	46.7	47.3	47.25	0.321	0.00678497	2.00%	Qualified
MCV (fL)	87.7	88.1	88.4	88.2	87.9	88.0	88.1	87.7	88.2	87.9	87.8	88.033	0.224	0.00254002	2.00%	Qualified
MCH (pg)	29.5	29.3	29.3	29	29.2	29.5	29.1	29.1	29.3	29.6	29.3	29.27	0.183	0.00624797	2.00%	Qualified
MCHC (g/dL)	33.6	33.2	33.2	33.9	33.3	33.5	33.1	33.1	33.2	33.6	33.4	33.35	0.255	0.00764471	2.00%	Qualified
PLT ($10^3/\mu\text{l}$)	234	251	250	266	253	230	246	237	242	259	247	248.1	10.376	0.04182072	6.00%	Qualified
LYM (%)	37.2	39.1	37.9	38	38	37.1	36.6	37.9	37.8	38	38	37.84	0.648	0.01713575	15.00%	Qualified
MXD (%)	6.7	6.8	7.7	6	5	6.3	7.6	7.2	6.7	6.6	7.1	6.7	0.801	0.1196101	30.00%	Qualified
NEUT (%)	56.1	54.1	54.4	56	57	56.6	55.8	57.9	55.5	55.4	54.9	55.76	1.175	0.02107108	15.00%	Qualified
LYM# ($10^3/\mu\text{l}$)	2.1	2.3	2.2	2.3	2.3	2.2	2.3	2.1	2.3	2.3	2.2	2.25	0.071	0.03142697	15.00%	Qualified
MXD# ($10^3/\mu\text{l}$)	0.4	0.4	0.5	0.4	0.3	0.4	0.5	0.4	0.4	0.4	0.4	0.41	0.057	0.1384503	30.00%	Qualified
NEUT# ($10^3/\mu\text{l}$)	3.2	3.3	3.2	3.3	3.5	3.3	3.4	3.4	3.3	3.4	3.3	3.34	0.084	0.02524773	15.00%	Qualified
RDW-SD (fL)	42.2	41.3	42	40.7	42.5	40.8	42.1	41.7	42	42.3	41.9	44.73	9.704	0.21695028	4.00%	Not qualified
RDW-CV (%)	12.8	12.8	12.9	12.8	12.8	12.5	13	12.5	12.9	12.9	12.8	12.79	0.166	0.01300493	4.00%	Qualified
PDW (fL)	13.1	13.5	12.5	13	13.3	12.3	13.4	13	13.4	13.2	13.8	13.14	0.458	0.0348196	12.00%	Qualified
MPV (fL)	10	10	10	9.9	9.9	9.8	9.8	10.2	10	9.9	10.1	9.96	0.126	0.01269991	5.00%	Qualified
P-LCR (%)	25.5	26.5	25.8	24.7	25.3	24.3	25.3	26.4	26.5	26.6	26	25.74	0.813	0.03157255	20.00%	Qualified

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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 Measurable parameters showed values of "r" in the range of **0.967 to 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 % (Precision) with the V Dx Sysmex reagents and the Sysmex Reference reagents was found to be as under:

Parameters	Sysmex Reference Reagents (CV % - Precision)	V Dx Sysmex Reagents (CV % - Precision)
Measured Parameters	0.24% - 13.85%	0.22% - 20.20%
Calculated Parameters	0.62% - 3.48%	0.74% - 4.10%

5. Values obtained with 3rd Party controls (Normal) from **Sysmex** were found to be **within** specified ranges 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 parameters identified for the evaluation.

