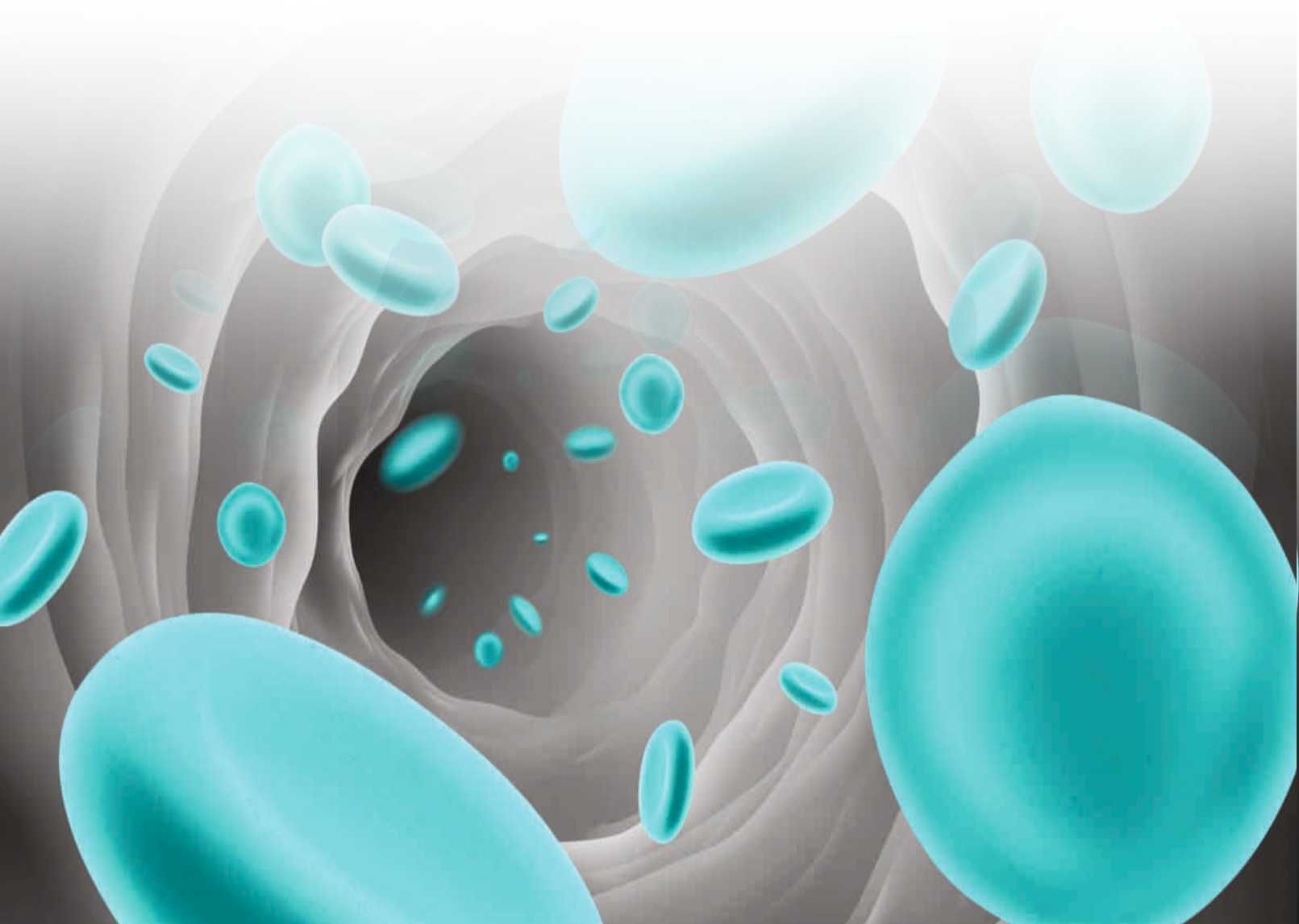




Validation Report - Greece

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 710849
Registergericht / Register Court: Mannheim
UID-Nr. / VAT Reg. No.: DE275261186
Geschäftsführer / Managing Directors: Maxim Dja*

MSC medical GmbH

Wieblinger Weg 17
69123 Heidelberg, Germany

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Α.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

Πασχώνη Φλωρε

Comparative Evaluation

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

v/s

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

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΙΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

VDx : Vanguard Diagnostics (P) Limited

Index

Sr. No.	Subject	Page Nos.
1	Details of the Reagents	4
2	Background Test	5
3	Coefficient of Correlation: Accuracy	6 – 62
4	Performance with 3 rd Party Quality Controls (Low, Normal & High)	63 – 66
5	Coefficient of Variation: Precision (VDx Sysmex Compatible reagents)	67 – 68
6	Coefficient of Variation: Precision (Sysmex Reference reagents)	69 – 70
7	Conclusions	71

Name of the Lab

FLORA PASXONI, GIANNITSA GREECE

Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Sysmex – XP100/ KX-21N
Reference Reagents	Sysmex Reference Reagents
Cellpack	Lot No : D5013 Expiry Date : 07/12/2026
Stromatolyser-WH	Lot No : D4173 Expiry Date: 04/11/2026
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

Background Test		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	0.1	0.1
RBC ($10^6/\mu\text{l}$)	0.0	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 (%)		

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.

ΑΝΘΩΝΗΣ ΝΙΚΟΛΑΪ
ΕΠΙΧΕΙΡΗΣΙΑΚΟΣ ΔΙΕΥΘΥΝΤΗΣ
ΕΡΓΑΣΤΗΡΙΟ ΜΙΚΡΟΒΙΟΛΟΓΙΑΣ
ΚΟΜΗΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΗΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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 (x)
 - 3 Mean y (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 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.996$$

Sample size: 20

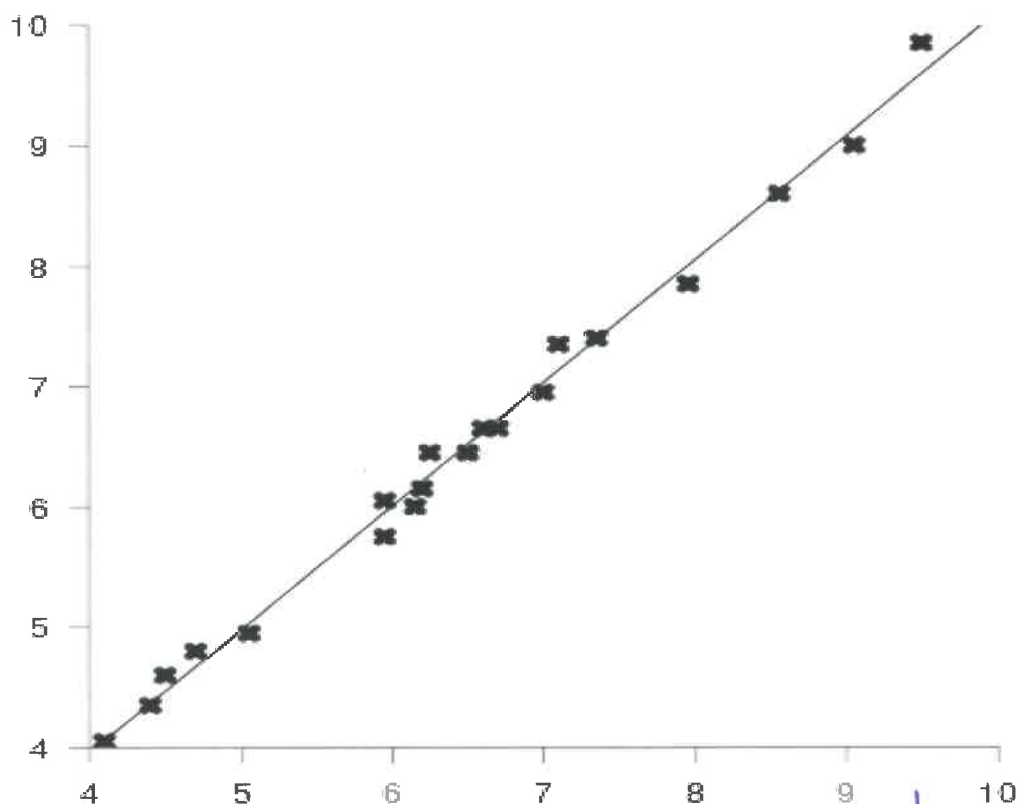
Mean x ($\bar{x}$): 6.4775

Mean y ($\bar{y}$): 6.495

Intercept (a): -0.14794078243381

Slope (b): 1.0255408386621

Regression line equation: $y = 1.0255408386621x - 0.14794078243381$



ΑΝΩΤΑΤΗ ΕΠΙΣΤΗΜΟΝΙΚΗ ΣΧΟΛΗ ΤΕΧΝΟΛΟΓΙΑΣ ΒΙΟΪΑΤΡΙΚΗΣ
ΤΕΧΝΟΛΟΓΙΑΣ ΒΙΟΪΑΤΡΙΚΗΣ
ΤΕΧΝΟΛΟΓΙΑΣ ΒΙΟΪΑΤΡΙΚΗΣ
ΤΕΧΝΟΛΟΓΙΑΣ ΒΙΟΪΑΤΡΙΚΗΣ
ΤΕΧΝΟΛΟΓΙΑΣ ΒΙΟΪΑΤΡΙΚΗΣ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΩΝ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23828 82999 - 8945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Specifications for Approval/Rejection of the Results: WBC

WBC (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 Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE
	4.8	X2	MEAN	Y1	Y2	MEAN		
1	7.5	7.3	7.4	7.3	7.4	7.35	0.68%	OK
2	4	4.1	4.05	4	4.2	4.1	1.22%	OK
3	6.7	6.6	6.65	6.6	6.6	6.6	0.76%	OK
4	6.1	6.2	6.15	6.1	6.3	6.2	0.81%	OK
5	4.8	4.8	4.8	4.8	4.6	4.7	2.13%	OK
6	6.4	6.5	6.45	6.3	6.2	6.25	3.20%	OK
7	9.7	10	9.85	9.6	9.4	9.5	3.68%	OK
8	6	6	6	6.2	6.1	6.15	2.44%	OK
9	7.4	7.3	7.35	7	7.2	7.1	3.52%	OK
10	7.9	7.8	7.85	7.9	8	7.95	1.26%	OK
11	4.6	4.6	4.6	4.6	4.4	4.5	2.22%	OK
12	8.6	8.6	8.6	8.4	8.7	8.55	0.58%	OK
13	8.9	9.1	9	9.1	9	9.05	0.55%	OK
14	5.9	6.2	6.05	5.9	6	5.95	1.68%	OK
15	4.3	4.4	4.35	4.5	4.3	4.4	1.14%	OK
16	6.7	6.6	6.65	6.8	6.6	6.7	0.75%	OK
17	6.9	7	6.95	7	7	7	0.71%	OK
18	5	4.9	4.95	5	5.1	5.05	1.98%	OK
19	6.4	6.5	6.45	6.6	6.4	6.5	0.77%	OK
20	5.7	5.8	5.75	6	5.9	5.95	3.36%	OK
Passing Number	20	Passing Rate		100.0%	Requirement		<±7.5%	
Conclusion		Pass						

Coefficient of Correlation ("r")

0.996374282

Coefficient of Correlation ("r")

0.996374282

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

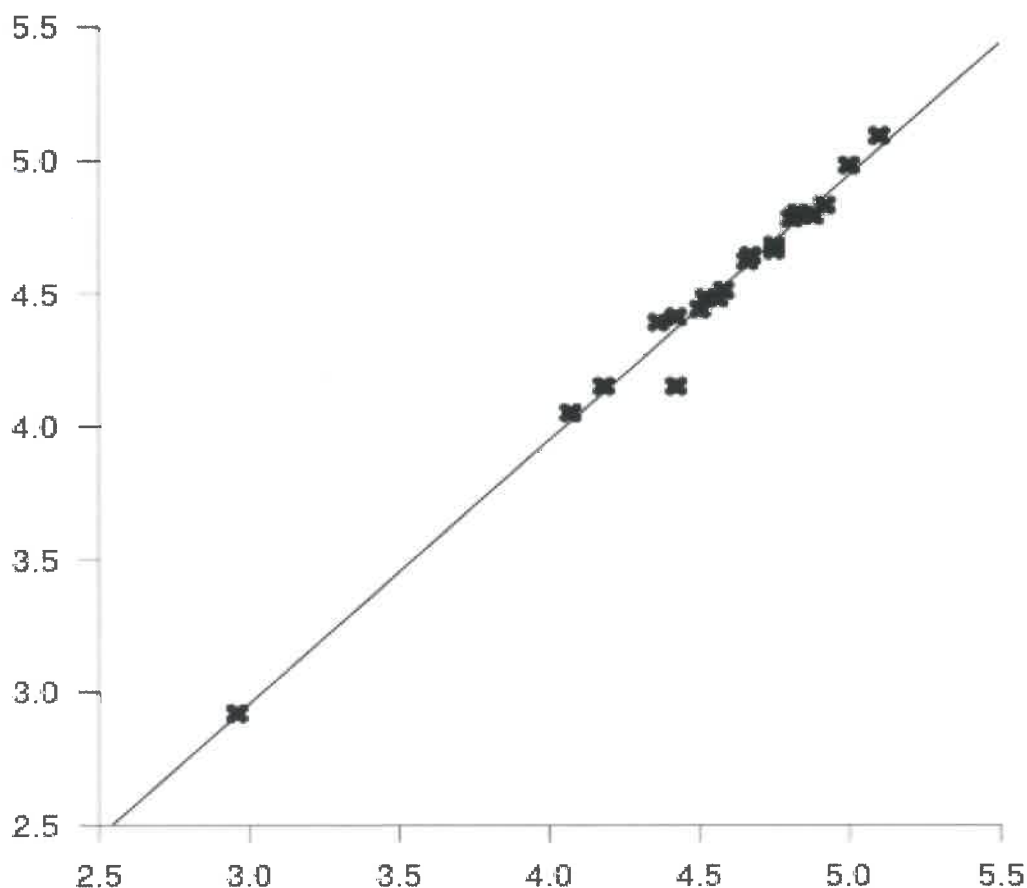
Mean x (x): 4.547

Mean y (y): 4.4925

Intercept (a): -0.030842625641106

Slope (b): 0.9947971466112

Regression line equation: $y = 0.9947971466112x - 0.030842625641106$



ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 68100
Α.Φ.Μ. 801685151 - Α.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 62999 - 6945433450
ΣΥΜΠΡΕΣΤΗΜΕΝΟΣ ΕΟΠΥΥ

VANGUARD
DIAGNOSTICS

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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

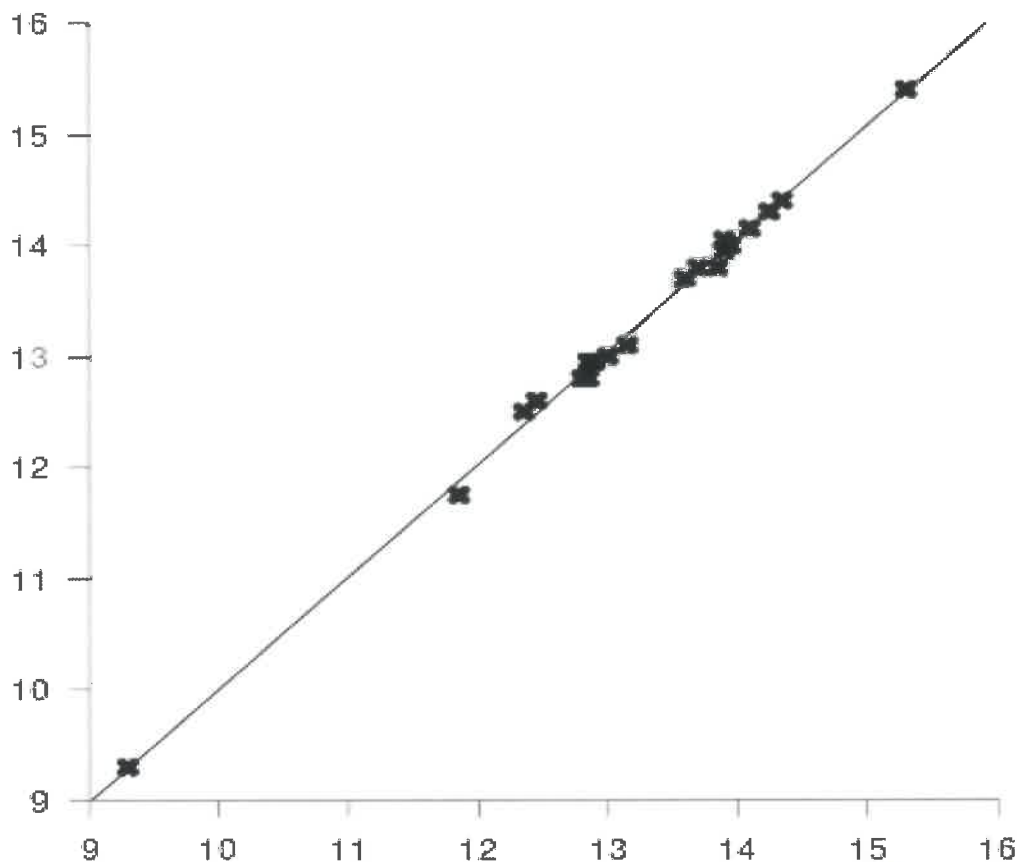
Mean x (x): 13.22

Mean y (y): 13.265

Intercept (a): -0.15970918349551

Slope (b): 1.0154848096441

Regression line equation: $y = 1.0154848096441x - 0.15970918349551$



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
	13.8	X2	MEAN	Y1	Y2	MEAN		
1	13.1	13.1	13.1	13.1	13.2	13.15	0.38%	OK
2	12.8	12.8	12.8	12.8	12.9	12.85	0.39%	OK
3	13.8	13.8	13.8	13.8	13.9	13.85	0.36%	OK
4	12.5	12.5	12.5	12.3	12.4	12.35	1.21%	OK
5	13.8	13.8	13.8	13.7	13.7	13.7	0.73%	OK
6	14.2	14.1	14.15	14	14.2	14.1	0.35%	OK
7	15.4	15.4	15.4	15.3	15.3	15.3	0.65%	OK
8	14.4	14.4	14.4	14.4	14.3	14.35	0.35%	OK
9	13.7	13.7	13.7	13.6	13.6	13.6	0.74%	OK
10	13	12.9	12.95	12.9	12.9	12.9	0.39%	OK
11	14.3	14.3	14.3	14.3	14.2	14.25	0.35%	OK
12	14	14.1	14.05	13.9	13.9	13.9	1.08%	OK
13	12.8	12.8	12.8	12.8	12.8	12.8	0.00%	OK
14	12.6	12.6	12.6	12.4	12.5	12.45	1.20%	OK
15	9.3	9.3	9.3	9.3	9.3	9.3	0.00%	OK
16	13	12.9	12.95	12.9	12.8	12.85	0.78%	OK
17	14	14	14	13.9	14	13.95	0.36%	OK
18	11.8	11.7	11.75	11.9	11.8	11.85	0.84%	OK
19	13.9	14	13.95	13.9	13.9	13.9	0.36%	OK
20	13	13	13	13	13	13	0.00%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.998602996

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

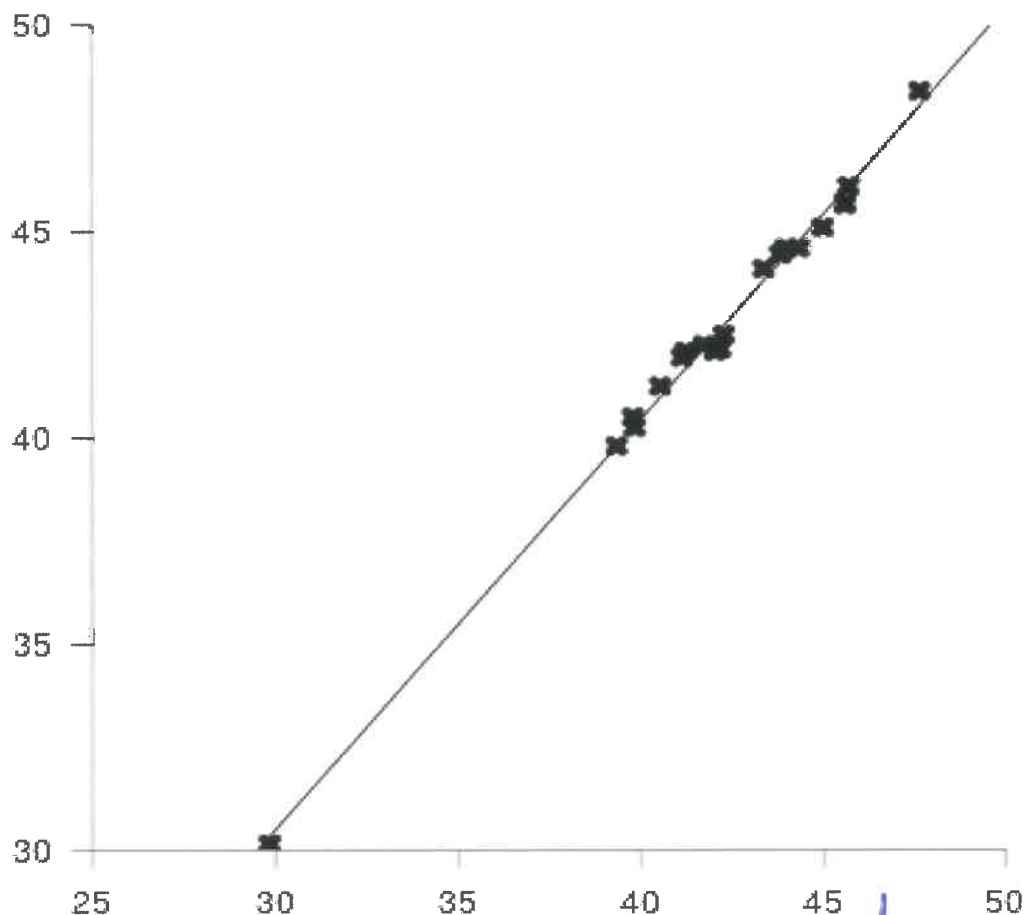
Mean x (x): 42.2625

Mean y (y): 42.685

Intercept (a): 0.65268384117497

Slope (b): 0.99455347314582

Regression line equation: $y = 0.65268384117497 + 0.99455347314582x$



ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΗ - ΠΙΛΛΗΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23829 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΗ - ΠΙΛΛΗΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ: 23829 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

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	
		44.7	X2	MEAN	Y1	Y2			MEAN
1		41.9	42	41.95	41	41.3	41.15	1.94%	OK
2		40.1	40.4	40.25	39.6	40.1	39.85	1.00%	OK
3		44.6	43.6	44.1	43.2	43.6	43.4	1.61%	OK
4		40.4	40.6	40.5	39.5	40.1	39.8	1.76%	OK
5		44.5	44.7	44.6	44.3	44.4	44.35	0.56%	OK
6		46.1	46.1	46.1	45.9	45.5	45.7	0.88%	OK
7		48.3	48.5	48.4	47.9	47.4	47.65	1.57%	OK
8		45.7	45.6	45.65	45.5	45.7	45.6	0.11%	OK
9		42.3	42.2	42.25	41.8	41.7	41.75	1.20%	OK
10		42.2	42	42.1	41.4	41.1	41.25	2.06%	OK
11		44.6	44.6	44.6	44.1	43.9	44	1.36%	OK
12		45.9	45.5	45.7	45.5	45.7	45.6	0.22%	OK
13		42.1	42.1	42.1	42	42.1	42.05	0.12%	OK
14		41.4	41.1	41.25	40.7	40.4	40.55	1.73%	OK
15		30	30.3	30.15	29.8	29.9	29.85	1.01%	OK
16		42.2	42.1	42.15	42.2	42.2	42.2	0.12%	OK
17		45	45.2	45.1	44.5	45.5	45	0.22%	OK
18		40	39.6	39.8	39.2	39.5	39.35	1.14%	OK
19		44.2	44.7	44.45	44.1	43.6	43.85	1.37%	OK
20		42.5	42.5	42.5	42	42.6	42.3	0.47%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3.5%	
Conclusion		Pass							

Coefficient of Correlation ("r")
0.99733421

Coefficient of Correlation ("r")
0.99733421

Coefficient of Correlation ("r"): MCV

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.997$$

Sample size: 20

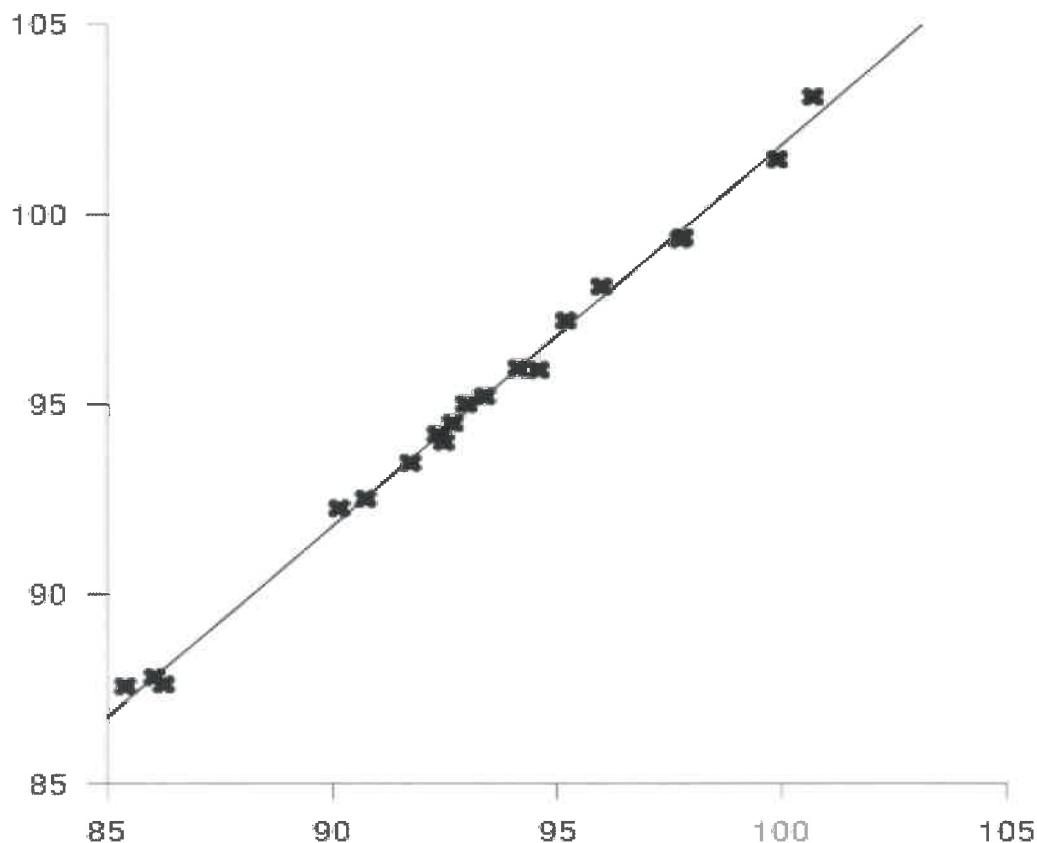
Mean x (x): 93.14

Mean y (y): 94.935

Intercept (a): 1.3081709571747

Slope (b): 1.0052268525105

Regression line equation: $y = 1.3081709571747 + 1.0052268525105x$



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
	95.1	X2	MEAN	Y1	Y2	MEAN		
1	95	95	95	92.8	93.2	93	2.15%	OK
2	99.3	99.5	99.4	98	97.6	97.8	1.64%	OK
3	92.3	92.2	92.25	90.2	90.1	90.15	2.33%	OK
4	87.6	87.5	87.55	85.5	85.3	85.4	2.52%	OK
5	95.3	95.1	95.2	93.5	93.3	93.4	1.93%	OK
6	99.6	99.1	99.35	97.7	97.8	97.75	1.64%	OK
7	97.4	97	97.2	95.4	95	95.2	2.10%	OK
8	94.6	94.4	94.5	92.5	92.9	92.7	1.94%	OK
9	94.2	94.2	94.2	92.5	92.3	92.4	1.95%	OK
10	96.1	95.7	95.9	94.7	94.5	94.6	1.37%	OK
11	87.6	87.6	87.6	86.1	86.4	86.25	1.57%	OK
12	98.1	98.1	98.1	96.4	95.6	96	2.19%	OK
13	87.7	87.9	87.8	86.2	85.9	86.05	2.03%	OK
14	93.5	93.4	93.45	92.1	91.4	91.75	1.85%	OK
15	103.1	103.1	103.1	100.7	100.7	100.7	2.38%	OK
16	94.2	93.8	94	92.5	92.5	92.5	1.62%	OK
17	101.6	101.3	101.45	99.8	100	99.9	1.55%	OK
18	96.2	95.7	95.95	94	94.3	94.15	1.91%	OK
19	92.5	92.5	92.5	90.7	90.8	90.75	1.93%	OK
20	94.2	94.2	94.2	92.5	92.2	92.35	2.00%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±3.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.99796742

Coefficient of Correlation ("r"): MCH

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.985

Sample size: 20

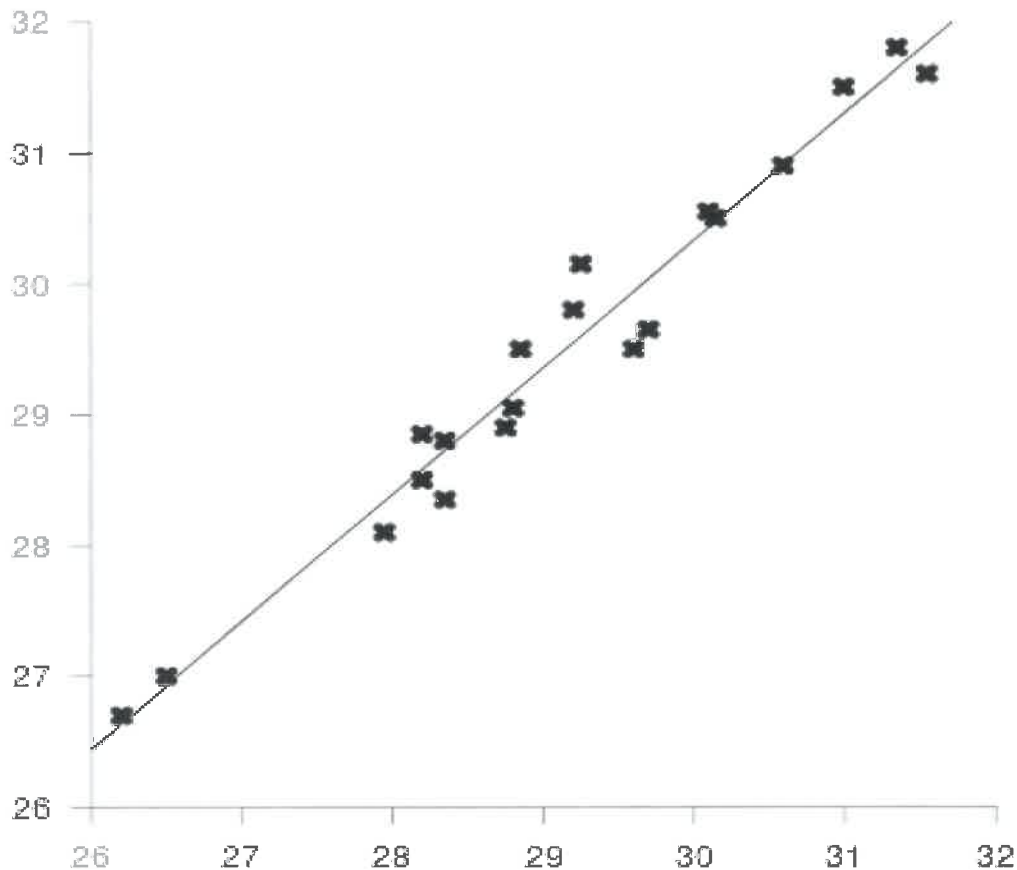
Mean x (x): 29.1325

Mean y (y): 29.485

Intercept (a): 1.2203628575335

Slope (b): 0.97020980494178

Regression line equation: $y = 1.2203628575335 + 0.97020980494178x$



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.							Coefficient of Correlation ("r") 0.985200218
		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							

Coefficient of Correlation ("r"): MCHC

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.929

Sample size: 20

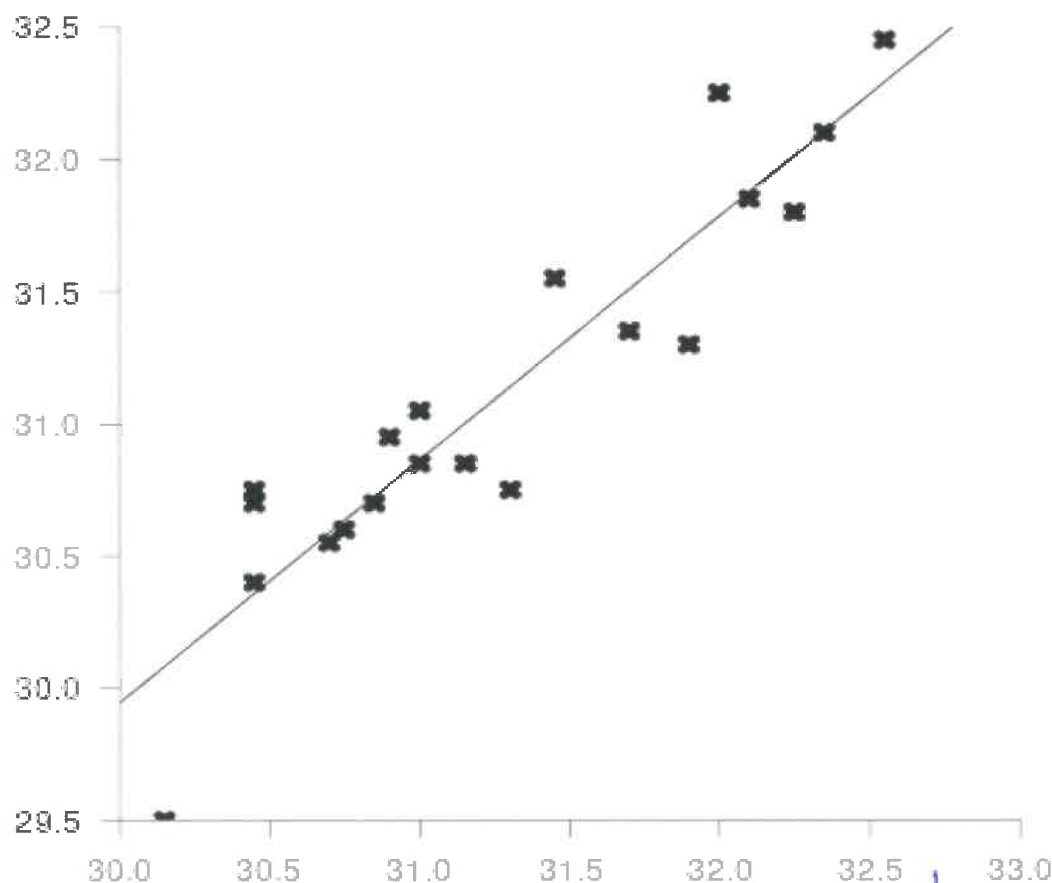
Mean x (x): 31.2725

Mean y (y): 31.115

Intercept (a): 2.3403211003193

Slope (b): 0.92012723318189

Regression line equation: $y=2.3403211003193+0.92012723318189x$



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
	30.9	X2	MEAN	Y1	Y2	MEAN		
1	31.3	31.2	31.25	32	32	32	2.34%	OK
2	31.9	31.7	31.8	32.3	32.2	32.25	1.40%	OK
3	30.9	31.7	31.3	31.9	31.9	31.9	1.88%	OK
4	30.9	30.8	30.85	31.1	30.9	31	0.48%	OK
5	31	30.9	30.95	30.9	30.9	30.9	0.16%	OK
6	30.8	30.6	30.7	30.5	31.2	30.85	0.49%	OK
7	31.9	31.8	31.85	31.9	32.3	32.1	0.78%	OK
8	31.5	31.6	31.55	31.6	31.3	31.45	0.32%	OK
9	32.4	32.5	32.45	32.5	32.6	32.55	0.31%	OK
10	30.8	30.7	30.75	31.2	31.4	31.3	1.76%	OK
11	32.1	32.1	32.1	32.4	32.3	32.35	0.77%	OK
12	30.5	31	30.75	30.5	30.4	30.45	0.99%	OK
13	30.4	30.4	30.4	30.5	30.4	30.45	0.16%	OK
14	30.4	30.7	30.55	30.5	30.9	30.7	0.49%	OK
15	31	30.7	30.85	31.2	31.1	31.15	0.96%	OK
16	30.8	30.6	30.7	30.6	30.3	30.45	0.82%	OK
17	31.1	31	31.05	31.2	30.8	31	0.16%	OK
18	29.5	29.5	29.5	30.4	29.9	30.15	2.16%	OK
19	31.4	31.3	31.35	31.5	31.9	31.7	1.10%	OK
20	30.6	30.6	30.6	31	30.5	30.75	0.49%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.929152768

Coefficient of Correlation ("r"): PLT

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.993

Sample size: 20

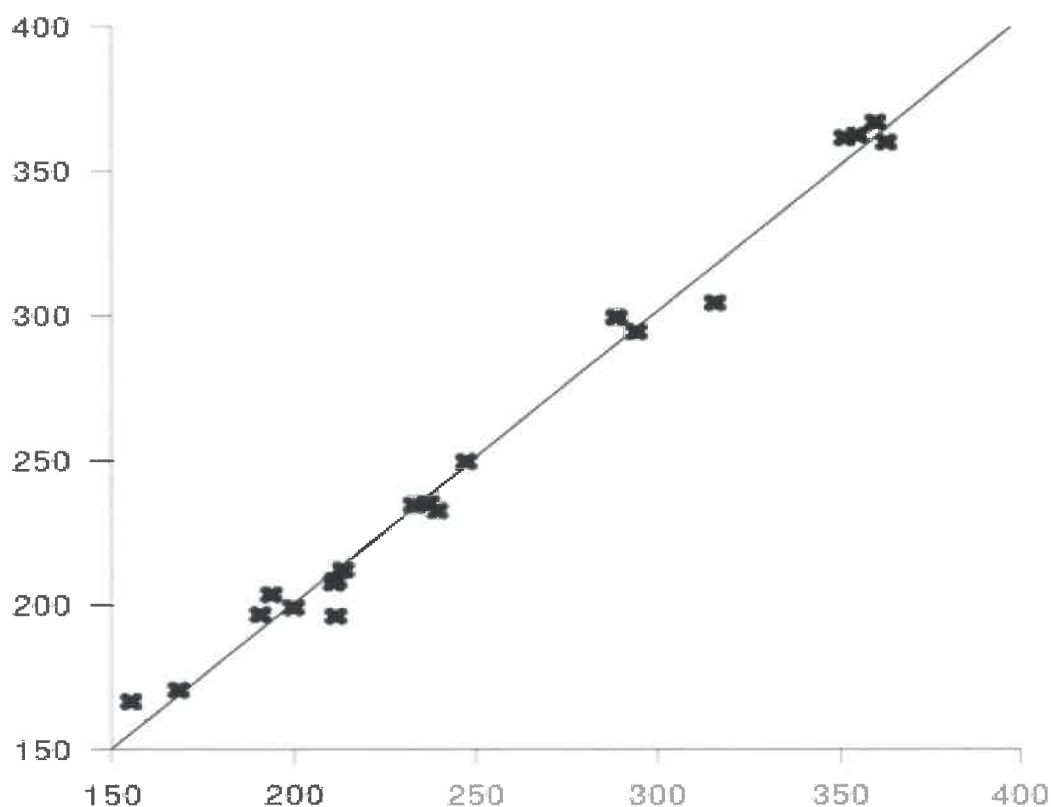
Mean x (x): 252.125

Mean y (y): 253.05

Intercept (a): -1.470960058616

Slope (b): 1.0095030641889

Regression line equation: $y = 1.0095030641889x - 1.470960058616$



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
	186	X2	MEAN	Y1	Y2	MEAN		
1	351	372	361.5	342	361	351.5	2.84%	OK
2	170	171	170.5	164	173	168.5	1.19%	OK
3	252	247	249.5	246	249	247.5	0.81%	OK
4	309	300	304.5	314	318	316	3.64%	OK
5	207	186	196.5	192	190	191	2.88%	OK
6	234	236	235	245	229	237	0.84%	OK
7	189	203	196	212	211	211.5	7.33%	OK
8	356	364	360	370	356	363	0.83%	OK
9	170	163	166.5	159	152	155.5	7.07%	OK
10	300	289	294.5	290	299	294.5	0.00%	OK
11	208	207	207.5	211	211	211	1.66%	OK
12	212	205	208.5	213	210	211.5	1.42%	OK
13	360	365	362.5	350	360	355	2.11%	OK
14	199	199	199	199	201	200	0.50%	OK
15	375	359	367	357	363	360	1.94%	OK
16	210	214	212	221	206	213.5	0.70%	OK
17	294	305	299.5	285	293	289	3.63%	OK
18	205	202	203.5	188	200	194	4.90%	OK
19	223	242	232.5	253	226	239.5	2.92%	OK
20	243	226	234.5	232	234	233	0.64%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±12.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.993856943

Coefficient of Correlation ("r"): LYM%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.990

Sample size: 20

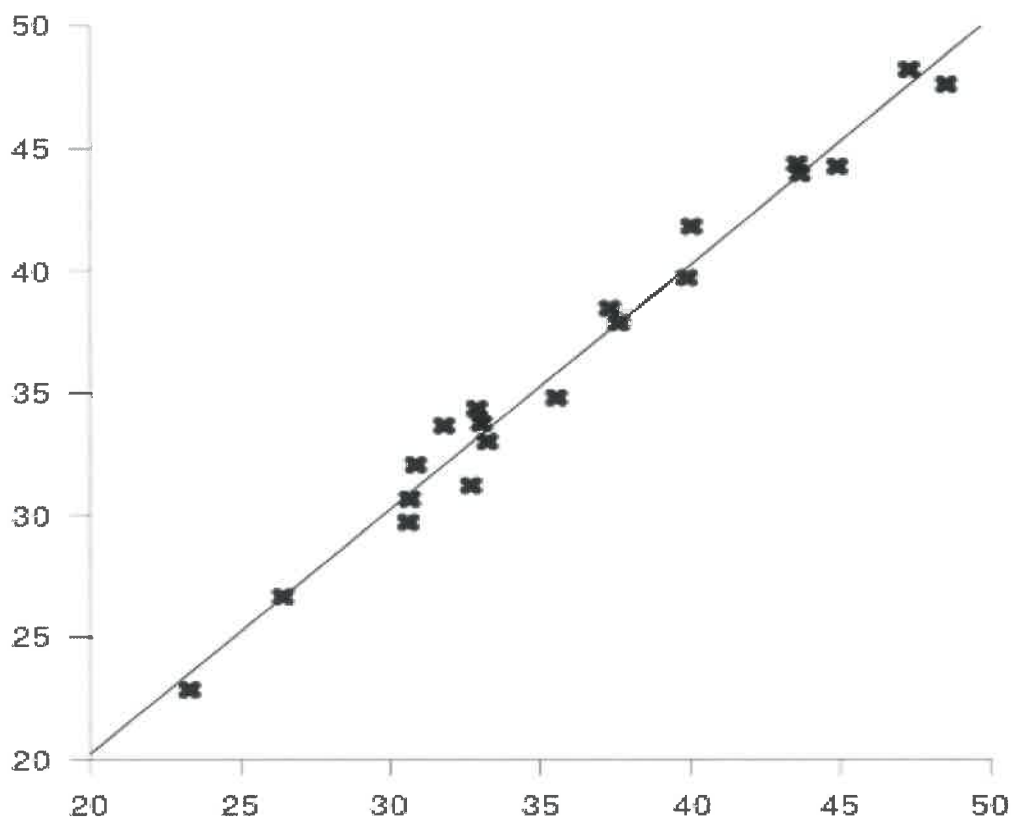
Mean x (x): 36.1875

Mean y (y): 36.44

Intercept (a): 0.17234969720545

Slope (b): 1.0022148615625

Regression line equation: $y=0.17234969720545+1.0022148615625x$



ΔΡΟΣΤΑΤΗΣ ΝΙΚΟΛΑΪΔΗΣ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ
ΚΟΜΗΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΩΝ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82099 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΗΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΩΝ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82099 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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
	33.3	X2	MEAN	Y1	Y2	MEAN		
1	30.7	28.7	29.7	29.9	31.3	30.6	2.94%	OK
2	32.3	31.8	32.05	31.5	30.2	30.85	3.89%	OK
3	39.8	39.6	39.7	39.4	40.3	39.85	0.38%	OK
4	34.7	32.6	33.65	32	31.6	31.8	5.82%	OK
5	36.3	33.3	34.8	36.4	34.7	35.55	2.11%	OK
6	31.7	30.7	31.2	32	33.4	32.7	4.59%	OK
7	34	32	33	33.8	32.7	33.25	0.75%	OK
8	34.9	33.8	34.35	34	31.8	32.9	4.41%	OK
9	34.4	33.1	33.75	32.9	33.2	33.05	2.12%	OK
10	22.9	22.8	22.85	23.1	23.5	23.3	1.93%	OK
11	37.2	39.7	38.45	37	37.6	37.3	3.08%	OK
12	47.7	47.5	47.6	49	48.1	48.55	1.96%	OK
13	38.1	37.6	37.85	37.7	37.5	37.6	0.66%	OK
14	42.9	45	43.95	45.3	42	43.65	0.69%	OK
15	49	47.4	48.2	46.9	47.7	47.3	1.90%	OK
16	44	44.7	44.35	43.1	44	43.55	1.84%	OK
17	27.6	25.7	26.65	26.2	26.6	26.4	0.95%	OK
18	30	31.3	30.65	30.2	31.1	30.65	0.00%	OK
19	43.9	39.7	41.8	39.9	40.1	40	4.50%	OK
20	44.6	43.9	44.25	45.3	44.5	44.9	1.45%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.990963562

Coefficient of Correlation ("r"): NEUT%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.979

Sample size: 20

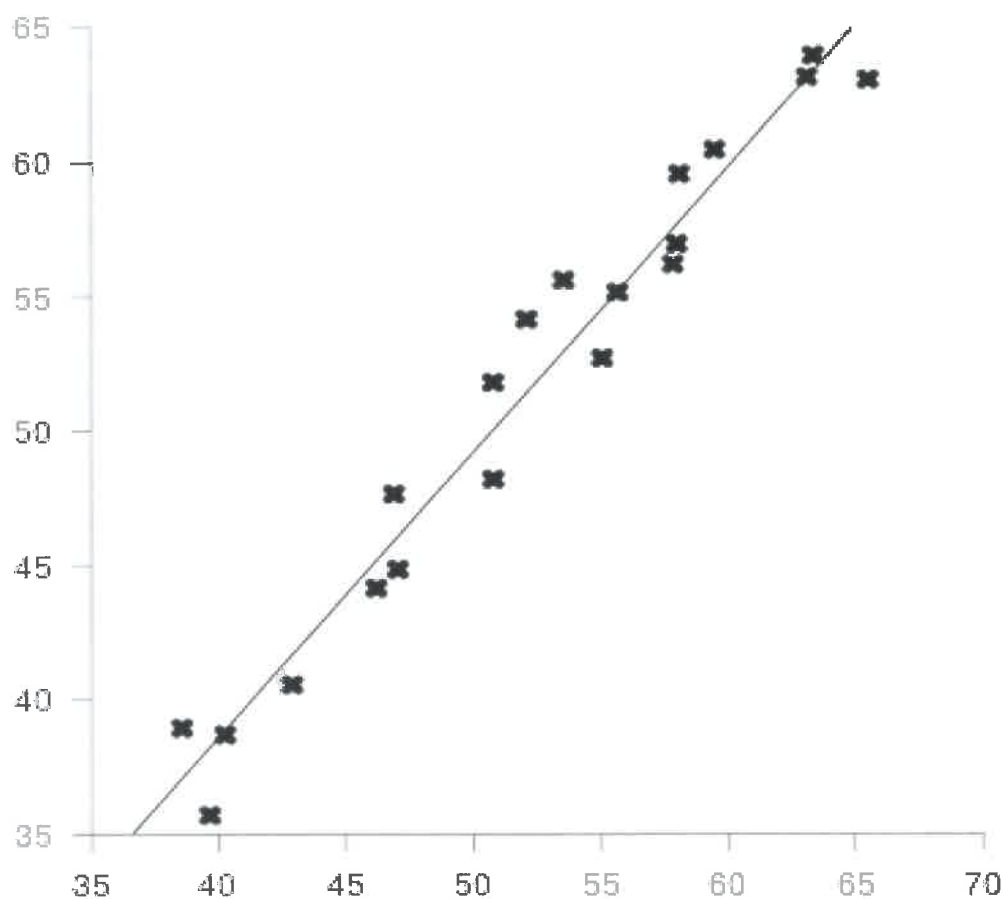
Mean x (x): 52.25

Mean y (y): 51.5725

Intercept (a): -3.7326370309102

Slope (b): 1.0584715221227

Regression line equation: $y = 1.0584715221227x - 3.7326370309102$



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 | 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
	54.5	X2	MEAN	Y1	Y2	MEAN		
1	67	59.3	63.15	63.1	63.9	63.5	0.55%	OK
2	58	54.4	56.2	57.3	58.4	57.85	2.85%	OK
3	47.1	48.2	47.65	48.3	45.5	46.9	1.60%	OK
4	55.5	58.4	56.95	58.3	57.7	58	1.81%	OK
5	53.8	54.5	54.15	51.9	52.3	52.1	3.93%	OK
6	54.5	55.8	55.15	56.1	55.2	55.65	0.90%	OK
7	59.8	61.1	60.45	59	60	59.5	1.60%	OK
8	48.1	48.3	48.2	48.3	53.3	50.8	5.12%	OK
9	58.1	61	59.55	58.4	57.8	58.1	2.50%	OK
10	60.5	65.6	63.05	66.6	64.5	65.55	3.81%	OK
11	51.1	52.5	51.8	51.4	50.2	50.8	1.97%	OK
12	39	38.4	38.7	40.5	40	40.25	3.85%	OK
13	53.4	57.8	55.6	54.3	52.8	53.55	3.83%	OK
14	37.9	33.5	35.7	40.4	38.9	39.65	9.96%	NO
15	44.5	36.6	40.55	44.4	41.4	42.9	5.48%	OK
16	43.8	45.9	44.85	46.7	47.4	47.05	4.68%	OK
17	64.7	63.2	63.95	63.6	63.2	63.4	0.87%	OK
18	55.2	50.2	52.7	54.2	55.9	55.05	4.27%	OK
19	43	45.3	44.15	46.2	46.2	46.2	4.44%	OK
20	39.8	38.1	38.95	37.1	40	38.55	1.04%	OK
Passing Number		19	Passing Rate		95.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.979367058

Coefficient of Correlation ("r"): LYM#

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.995

Sample size: 20

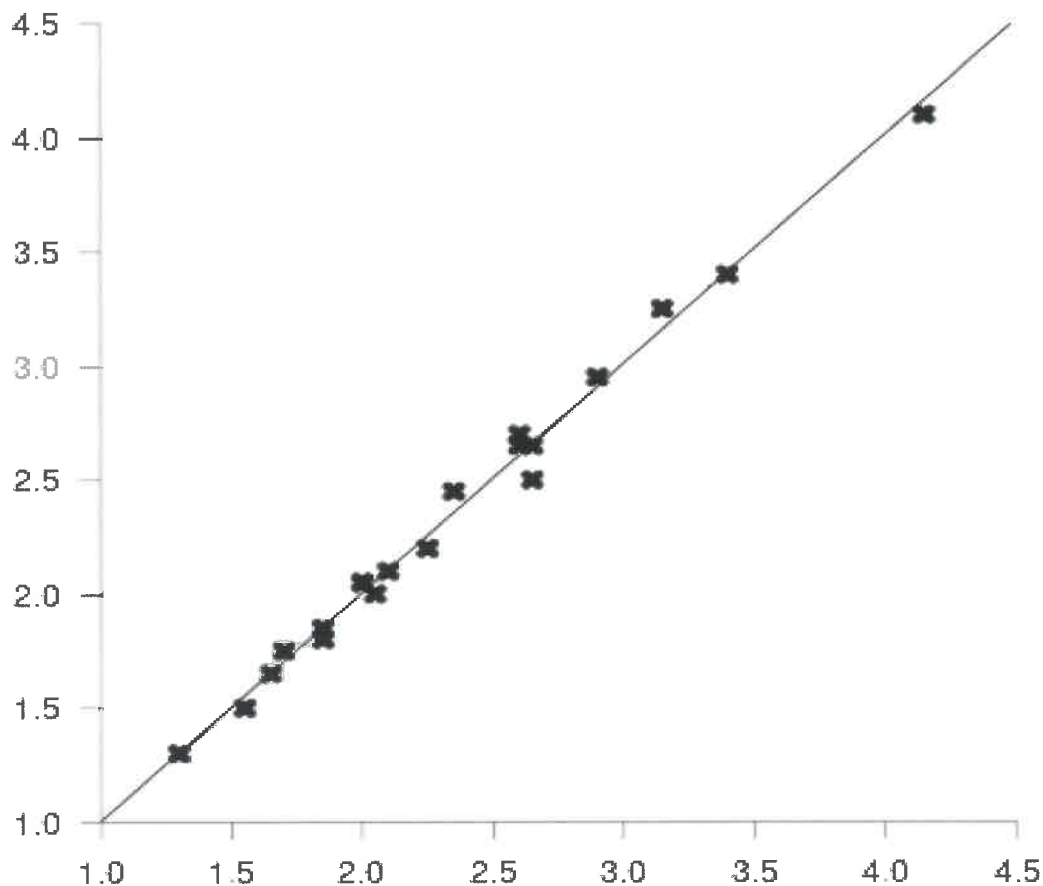
Mean x (x): 2.3375

Mean y (y): 2.345

Intercept (a): -4.7817473798339E-6

Slope (b): 1.0032106018171

Regression line equation: $y = 1.0032106018171x - 4.7817473798339E-6$



Specifications for Approval/Rejection of the Results: LYM#

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

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	II Reagents from Vanguard Diagnostic			III Reagents from Sysmex as Reference			DEVIATION	JUDGE
	1.6	X2	MEAN	Y1	Y2	MEAN		
1	2.3	2.1	2.2	2.2	2.3	2.25	2.22%	OK
2	1.3	1.3	1.3	1.3	1.3	1.3	0.00%	OK
3	2.7	2.6	2.65	2.6	2.7	2.65	0.00%	OK
4	2.1	2	2.05	2	2	2	2.50%	OK
5	1.7	1.6	1.65	1.7	1.6	1.65	0.00%	OK
6	2	2	2	2	2.1	2.05	2.44%	OK
7	3.3	3.2	3.25	3.2	3.1	3.15	3.17%	OK
8	2.1	2	2.05	2.1	1.9	2	2.50%	OK
9	2.5	2.4	2.45	2.3	2.4	2.35	4.26%	OK
10	1.8	1.8	1.8	1.8	1.9	1.85	2.70%	OK
11	1.7	1.8	1.75	1.7	1.7	1.7	2.94%	OK
12	4.1	4.1	4.1	4.1	4.2	4.15	1.20%	OK
13	3.4	3.4	3.4	3.4	3.4	3.4	0.00%	OK
14	2.5	2.8	2.65	2.7	2.5	2.6	1.92%	OK
15	2.1	2.1	2.1	2.1	2.1	2.1	0.00%	OK
16	2.9	3	2.95	2.9	2.9	2.9	1.72%	OK
17	1.9	1.8	1.85	1.8	1.9	1.85	0.00%	OK
18	1.5	1.5	1.5	1.5	1.6	1.55	3.23%	OK
19	2.8	2.6	2.7	2.6	2.6	2.6	3.85%	OK
20	2.5	2.5	2.5	2.7	2.6	2.65	5.66%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.995494594

Coefficient of Correlation ("r"): NEUT#

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.990

Sample size: 20

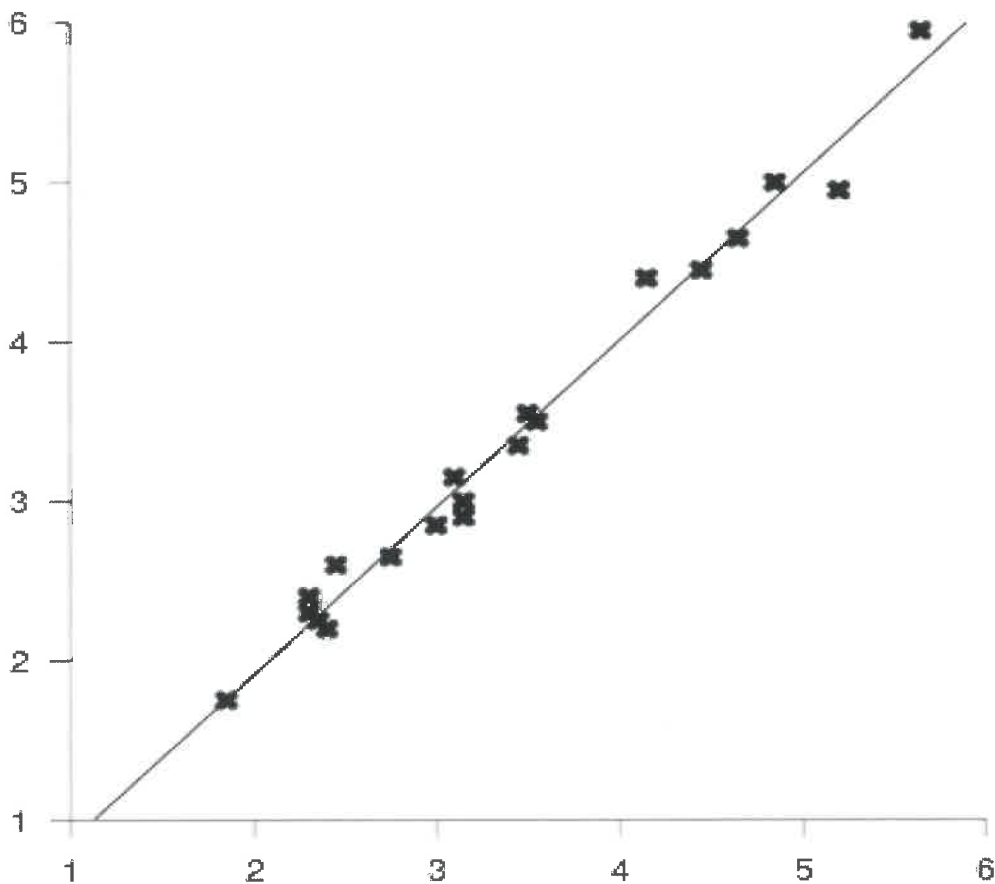
Mean x (x): 3.4125

Mean y (y): 3.3925

Intercept (a): -0.17998934469899

Slope (b): 1.0468833244539

Regression line equation: $y = 1.0468833244539x - 0.17998934469899$



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
	2.6	X2	MEAN	Y1	Y2	MEAN		
1	5	4.3	4.65	4.6	4.7	4.65	0.00%	OK
2	2.3	2.2	2.25	2.3	2.4	2.35	4.26%	OK
3	3.1	3.2	3.15	3.2	3	3.1	1.61%	OK
4	3.4	3.6	3.5	3.5	3.6	3.55	1.41%	OK
5	2.6	2.6	2.6	2.5	2.4	2.45	6.12%	OK
6	3.5	3.6	3.55	3.6	3.4	3.5	1.43%	OK
7	5.8	6.1	5.95	5.7	5.6	5.65	5.31%	OK
8	2.9	2.9	2.9	3	3.3	3.15	7.94%	NO
9	4.3	4.5	4.4	4.1	4.2	4.15	6.02%	OK
10	4.8	5.1	4.95	5.3	5.1	5.2	4.81%	OK
11	2.4	2.4	2.4	2.4	2.2	2.3	4.35%	OK
12	3.4	3.3	3.35	3.4	3.5	3.45	2.90%	OK
13	4.7	5.3	5	5	4.7	4.85	3.09%	OK
14	2.3	2.1	2.2	2.4	2.4	2.4	8.33%	NO
15	1.9	1.6	1.75	2	1.7	1.85	5.41%	OK
16	3	3	3	3.2	3.1	3.15	4.76%	OK
17	4.5	4.4	4.45	4.5	4.4	4.45	0.00%	OK
18	2.8	2.5	2.65	2.7	2.8	2.75	3.64%	OK
19	2.8	2.9	2.85	3.1	2.9	3	5.00%	OK
20	2.3	2.3	2.3	2.2	2.4	2.3	0.00%	OK
Passing Number		18	Passing Rate		90.0%	Requirement		≤±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")
0.990722398

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

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.996$$

Sample size: 20

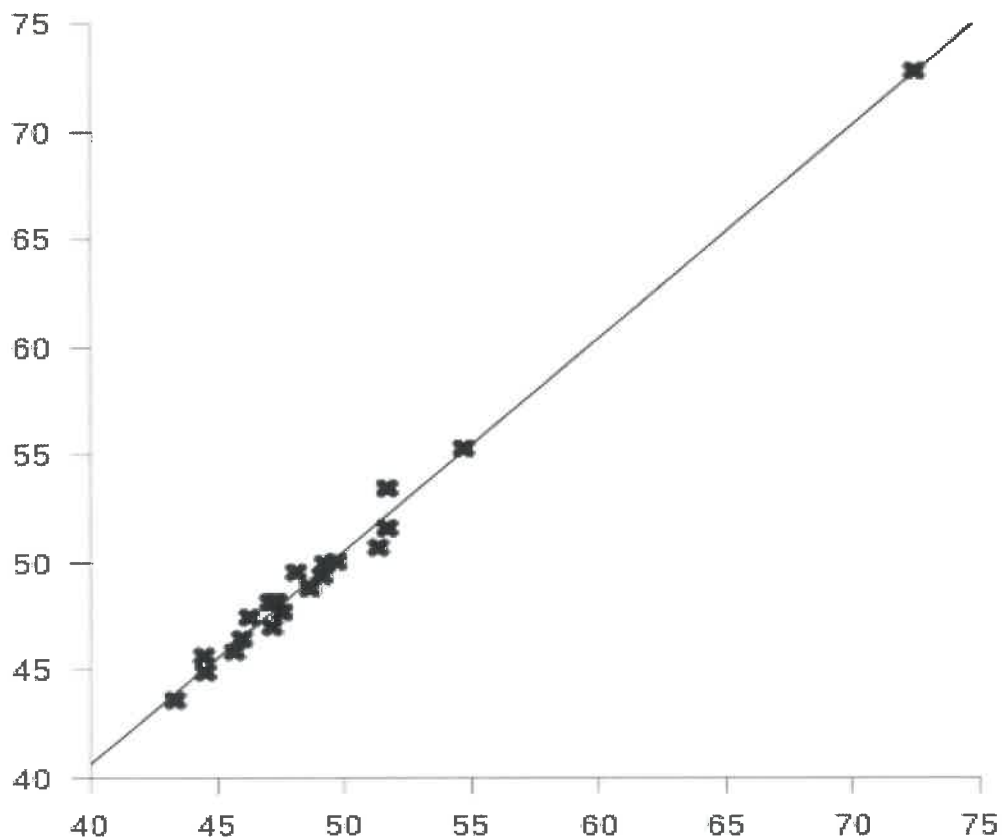
Mean x (x): 49.295

Mean y (y): 49.8275

Intercept (a): 1.0534469165561

Slope (b): 0.98943205362499

Regression line equation: $y = 1.0534469165561 + 0.98943205362499x$



ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΑ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 25620 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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
	48.3	X2	MEAN	Y1	Y2	MEAN		
1	49.7	49.4	49.55	48.2	48	48.1	3.01%	OK
2	47.7	47.7	47.7	48.3	46.8	47.55	0.32%	OK
3	45.9	45.4	45.65	43.7	45.2	44.45	2.70%	OK
4	44.1	43.1	43.6	43.4	43.2	43.3	0.69%	OK
5	49.3	48.3	48.8	48.8	48.5	48.65	0.31%	OK
6	51.4	50	50.7	51	51.7	51.35	1.27%	OK
7	46.4	47.6	47	47.1	47.2	47.15	0.32%	OK
8	46.4	46.5	46.45	46	45.9	45.95	1.09%	OK
9	44.8	45	44.9	44.8	44.2	44.5	0.90%	OK
10	49	47.4	48.2	47.8	46.8	47.3	1.90%	OK
11	47.4	47.5	47.45	46	46.5	46.25	2.59%	OK
12	49.4	50.5	49.95	49	49.5	49.25	1.42%	OK
13	55.3	55.3	55.3	54.4	55	54.7	1.10%	OK
14	48.2	48.1	48.15	47.5	46.6	47.05	2.34%	OK
15	72.2	73.4	72.8	72.9	72	72.45	0.48%	OK
16	49.6	49.2	49.4	50.2	48.1	49.15	0.51%	OK
17	51.8	51.4	51.6	51.6	51.8	51.7	0.19%	OK
18	53.8	53.1	53.45	51.8	51.6	51.7	3.38%	OK
19	45.4	46.3	45.85	46.5	44.8	45.65	0.44%	OK
20	50.1	50	50.05	49	50.4	49.7	0.70%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		≤±7.5%
Conclusion		Pass						

Coefficient of Correlation ("r")

0.996065486

Coefficient of Correlation ("r")
0.996065486

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

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.997$$

Sample size: 20

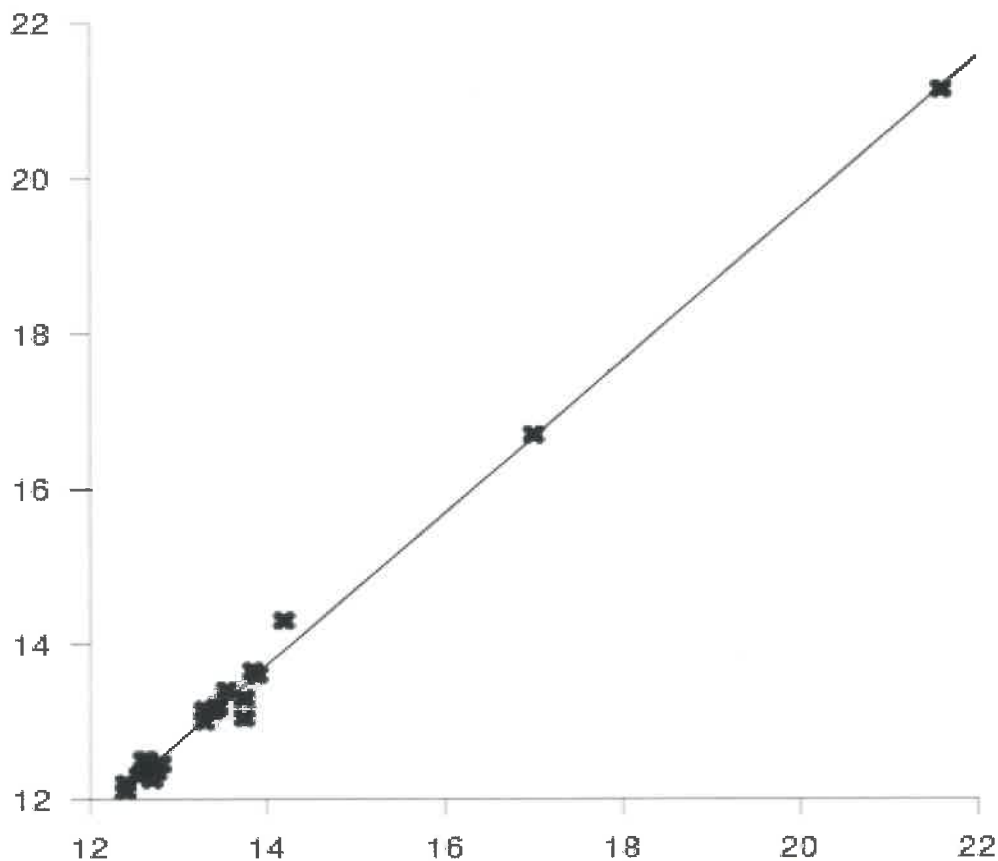
Mean x (x): 13.795

Mean y (y): 13.515

Intercept (a): -0.045767217112564

Slope (b): 0.9830204579277

Regression line equation: $y = 0.9830204579277x - 0.045767217112564$



ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ : 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Specifications for Approval/Rejection of the Results: 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									Coefficient of Correlation ("r") 0.997006528
SAMPLE	All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE	
	13.2	X2	MEAN	Y1	Y2	MEAN			
1	13.4	13.4	13.4	13.6	13.5	13.55	1.11%	OK	
2	12	12.2	12.1	12.5	12.3	12.4	2.42%	OK	
3	12.7	12.3	12.5	12.5	12.7	12.6	0.79%	OK	
4	12.4	12.5	12.45	12.8	12.8	12.8	2.73%	OK	
5	13.2	13.2	13.2	13.5	13.4	13.45	1.86%	OK	
6	13.1	13	13.05	13.7	13.8	13.75	5.09%	OK	
7	12.1	12.4	12.25	12.6	12.8	12.7	3.54%	OK	
8	12.3	12.3	12.3	12.6	12.5	12.55	1.99%	OK	
9	12.1	12.3	12.2	12.4	12.4	12.4	1.61%	OK	
10	12.6	12.4	12.5	12.8	12.5	12.65	1.19%	OK	
11	13.6	13.6	13.6	14	13.8	13.9	2.16%	OK	
12	13	13.3	13.15	13.2	13.4	13.3	1.13%	OK	
13	16.7	16.7	16.7	17	17	17	1.76%	OK	
14	13	13.3	13.15	13.6	13.2	13.4	1.87%	OK	
15	21	21.3	21.15	21.6	21.6	21.6	2.08%	OK	
16	13.5	13.1	13.3	13.9	13.6	13.75	3.27%	OK	
17	13	13	13	13.3	13.3	13.3	2.26%	OK	
18	14.2	14.4	14.3	14.1	14.3	14.2	0.70%	OK	
19	12.3	12.4	12.35	12.8	12.7	12.75	3.14%	OK	
20	13.5	13.8	13.65	13.7	14	13.85	1.44%	OK	
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%	
Conclusion		Pass							

Coefficient of Correlation ("r"): MPV

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.971$$

Sample size: 20

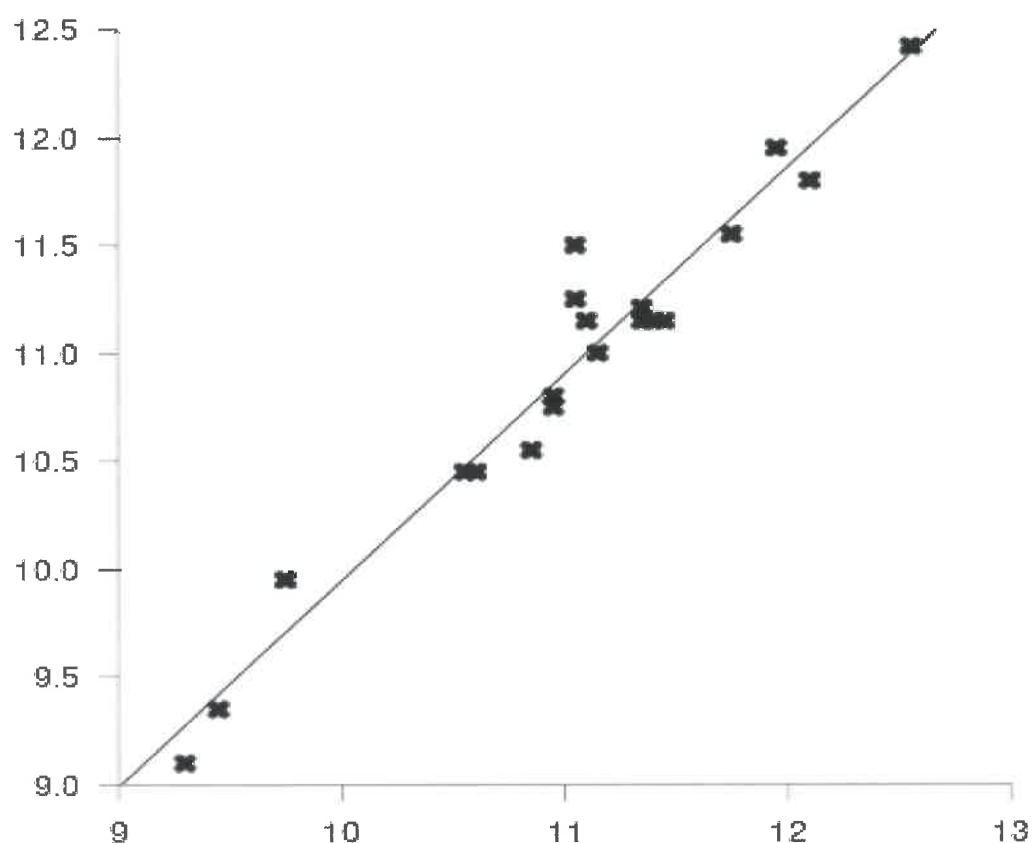
Mean x (x): 11.0325

Mean y (y): 10.934

Intercept (a): 0.36505865541512

Slope (b): 0.95798244682392

Regression line equation: $y = 0.36505865541512 + 0.95798244682392x$



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	
		All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE		
SAMPLE		11	X2	MEAN	Y1	Y2	MEAN			Coefficient of Correlation ("r") 0.971939222	
1		9.8	9.7	9.75	9.9	10	9.95	2.01%	OK		
2		12.2	12.2	12.2	12.6	12.5	12.55	2.79%	OK		
3		10.8	10.5	10.65	11.1	11	11.05	3.62%	OK		
4		10.8	10.8	10.8	10.9	11	10.95	1.37%	OK		
5		11.2	11	11.1	11.4	11.3	11.35	2.20%	OK		
6		11.1	11.2	11.15	11.3	11.5	11.4	2.19%	OK		
7		11.1	11.2	11.15	11.3	11.4	11.35	1.76%	OK		
8		9.1	9.1	9.1	9.3	9.3	9.3	2.15%	OK		
9		11.2	11.1	11.15	11.4	10.8	11.1	0.45%	OK		
10		10.4	10.5	10.45	10.6	10.5	10.55	0.95%	OK		
11		9	9.2	9.1	9.3	9.6	9.45	3.70%	OK		
12		11.1	10.9	11	11.2	11.1	11.15	1.35%	OK		
13		11.1	11.2	11.15	11.5	11.4	11.45	2.62%	OK		
14		11.9	12	11.95	11.6	12.3	11.95	0.00%	OK		
15		11.7	11.3	11.5	11.3	10.8	11.05	4.07%	OK		
16		11.5	11.6	11.55	11.7	11.8	11.75	1.70%	OK		
17		10.5	10.4	10.45	10.7	10.5	10.6	1.42%	OK		
18		11.6	12	11.8	12.1	12.1	12.1	2.48%	OK		
19		10.8	10.7	10.75	10.8	11.1	10.95	1.83%	OK		
20		10.5	10.6	10.55	10.8	10.9	10.85	2.76%	OK		
Passing Number		20	Passing Rate		100.0%	Requirement		<±7.5%			
Conclusion		Pass									

Coefficient of Correlation ("r")
0.971939222

Coefficient of Correlation ("r"): P-LCR%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

"r" = 0.979

Sample size: 20

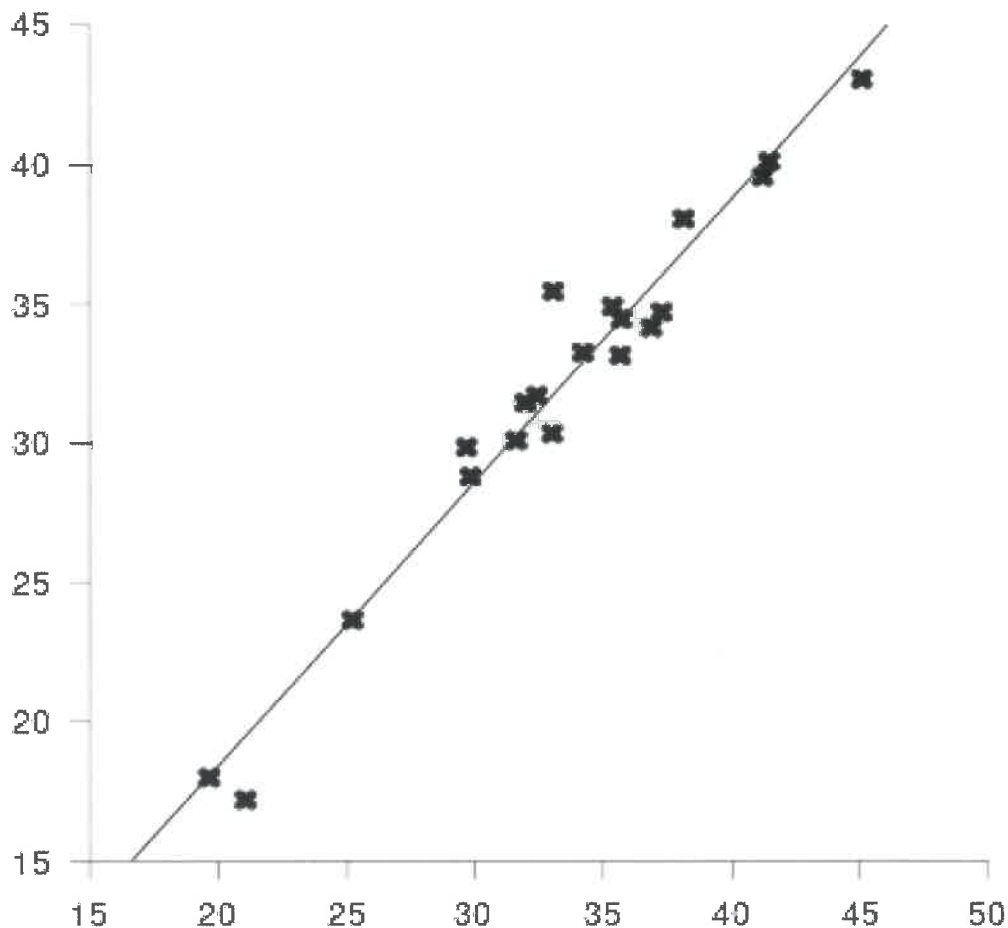
Mean x (x): 33.445

Mean y (y): 32.095

Intercept (a): -1.916687930462

Slope (b): 1.0169438759295

Regression line equation: $y = 1.0169438759295x - 1.916687930462$



Specifications for Approval/Rejection of the Results: P-LCR%

P-LCR (%)		Experimental Scheme : 20 fresh blood samples were used for detection on two different instruments. Calculate the result deviation of the two instruments. 2 times 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	
		All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	JUDGE		
SAMPLE		33.7	X2	MEAN	Y1	Y2	MEAN			Coefficient of Correlation ("r") 0.979709231	
1		24.1	23.2	23.65	24.9	25.5	25.2	6.15%	OK		
2		43.8	42.3	43.05	46.2	44	45.1	4.55%	OK		
3		31.9	28.8	30.35	33.2	32.9	33.05	8.17%	OK		
4		31.8	31.6	31.7	31.9	33	32.45	2.31%	OK		
5		35.2	33.7	34.45	36.2	35.3	35.75	3.64%	OK		
6		33.1	33.2	33.15	35	36.4	35.7	7.14%	OK		
7		34.3	34	34.15	36.5	37.3	36.9	7.45%	OK		
8		18.5	17.5	18	20.4	18.9	19.65	8.40%	OK		
9		34.9	34.9	34.9	36.9	33.9	35.4	1.41%	OK		
10		29.3	30.4	29.85	29.8	29.6	29.7	0.51%	OK		
11		17.9	18.5	18.2	19.6	22.5	21.05	13.54%	OK		
12		34.2	32.3	33.25	34.6	33.9	34.25	2.92%	OK		
13		34.3	35.1	34.7	37.7	36.9	37.3	6.97%	OK		
14		39.3	39.8	39.55	39.1	43.3	41.2	4.00%	OK		
15		36.1	34.8	35.45	34.3	31.9	33.1	7.10%	OK		
16		37.4	38.7	38.05	37.1	39.2	38.15	0.26%	OK		
17		29.9	27.7	28.8	30.8	28.9	29.85	3.52%	OK		
18		39.2	41	40.1	42.3	40.6	41.45	3.26%	OK		
19		31.9	31	31.45	30.7	33.3	32	1.72%	OK		
20		29.7	30.9	30.3	31.6	31.7	31.65	4.27%	OK		
Passing Number		20	Passing Rate		100.0%	Requirement		<±20%			
Conclusion		Pass									

Coefficient of Correlation ("r")
0.979709231

Coefficient of Correlation ("r"): PCT%

x = Sysmex Reference Reagents for 3 Part Hematology Analyzer.

y = VDX Sysmex Reagents for 3 Part Hematology Analyzer.

$$"r" = 0.984$$

Sample size: 20

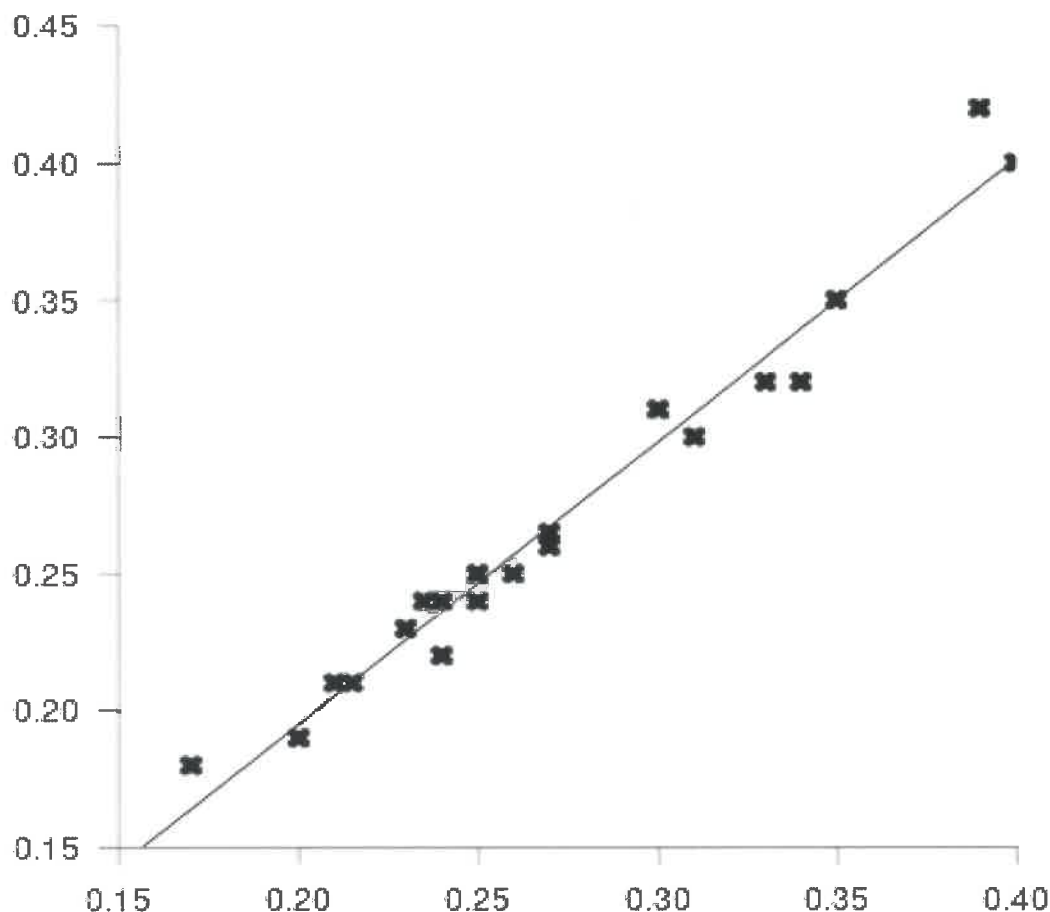
Mean x (x): 0.273

Mean y (y): 0.27025

Intercept (a): -0.011293668122268

Slope (b): 1.0312954876274

Regression line equation: $y = 1.0312954876274x - 0.011293668122268$



Specifications for Approval/Rejection of the Results: PCT%

PCT (%)		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
		All Reagents from Vanguard Diagnostics			All Reagents from Sysmex as Reference			DEVIATION	
SAMPLE		0.2	X2	MEAN	Y1	Y2	MEAN		
1		0.34	0.36	0.35	0.34	0.36	0.35	0.00%	OK
2		0.21	0.21	0.21	0.21	0.22	0.215	2.33%	OK
3		0.27	0.26	0.265	0.27	0.27	0.27	1.85%	OK
4		0.33	0.32	0.325	0.34	0.35	0.345	5.80%	OK
5		0.23	0.2	0.215	0.22	0.21	0.215	0.00%	OK
6		0.26	0.26	0.26	0.28	0.26	0.27	3.70%	OK
7		0.21	0.23	0.22	0.24	0.24	0.24	8.33%	OK
8		0.32	0.33	0.325	0.34	0.33	0.335	2.99%	OK
9		0.19	0.18	0.185	0.18	0.16	0.17	8.82%	OK
10		0.31	0.3	0.305	0.31	0.31	0.31	1.61%	OK
11		0.19	0.19	0.19	0.2	0.2	0.2	5.00%	OK
12		0.24	0.22	0.23	0.24	0.23	0.235	2.13%	OK
13		0.4	0.41	0.405	0.4	0.41	0.405	0.00%	OK
14		0.24	0.24	0.24	0.23	0.25	0.24	0.00%	OK
15		0.44	0.41	0.425	0.4	0.39	0.395	7.59%	OK
16		0.24	0.25	0.245	0.26	0.24	0.25	2.00%	OK
17		0.31	0.32	0.315	0.3	0.31	0.305	3.28%	OK
18		0.24	0.24	0.24	0.23	0.24	0.235	2.13%	OK
19		0.24	0.26	0.25	0.27	0.25	0.26	3.85%	OK
20		0.26	0.24	0.25	0.25	0.25	0.25	0.00%	OK
Passing Number		20	Passing Rate		100.0%	Requirement		<±12.5%	
Conclusion		Pass							

Coefficient of Correlation ("r")
0.98466865

Single Run Sample Comparison

Raw Data for “r”

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Sample-01		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	7.5	7.3
RBC (10 ⁶ /μl)	4.41	4.42
HGB (g/dl)	13.1	13.1
HCT (%)	41.9	41
MCV (fL)	95	92.8
MCH (pg)	29.7	29.6
MCHC (g/dl)	31.3	32
PLT (10 ³ /μl)	351	342
LYM (%)	30.7	29.9
MXD (%)	2.3	7
NEUT (%)	67	63.1
LYM# (10 ³ /μl)	2.3	2.2
MXD# (10 ³ /μl)	0.2	0.5
NEUT# (10 ³ /μl)	5	4.6
RDW-SD (fL)	49.7	48.2
RDW-CV (%)	13.4	13.6
PDW (fL)	12.3	12.4
MPV (fL)	9.8	9.9
P-LCR (%)	24.1	24.9
PCT (%)	0.34	0.34

Sample-02		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4	4
RBC ($10^6/\mu\text{l}$)	4.04	4.04
HGB (g/dl)	12.8	12.8
HCT (%)	40.1	39.6
MCV (fL)	99.3	98
MCH (pg)	31.7	31.7
MCHC (g/dl)	31.9	32.3
PLT ($10^3/\mu\text{l}$)	170	164
LYM (%)	32.3	31.5
MXD (%)	9.7	11.2
NEUT (%)	58	57.3
LYM# ($10^3/\mu\text{l}$)	1.3	1.3
MXD# ($10^3/\mu\text{l}$)	0.4	0.4
NEUT# ($10^3/\mu\text{l}$)	2.3	2.3
RDW-SD (fL)	47.7	48.3
RDW-CV (%)	12	12.5
PDW (fL)	18.6	16.9
MPV (fL)	12.2	12.6
P-LCR (%)	43.8	46.2
PCT (%)	0.2	0.21

Sample-03		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.7	6.6
RBC ($10^6/\mu\text{l}$)	4.83	4.79
HGB (g/dl)	13.8	13.8
HCT (%)	44.6	43.2
MCV (fL)	92.3	90.2
MCH (pg)	28.6	28.8
MCHC (g/dl)	30.9	31.9
PLT ($10^3/\mu\text{l}$)	252	246
LYM (%)	39.8	39.4
MXD (%)	13.1	12.3
NEUT (%)	47.1	48.3
LYM# ($10^3/\mu\text{l}$)	2.7	2.6
MXD# ($10^3/\mu\text{l}$)	0.9	0.8
NEUT# ($10^3/\mu\text{l}$)	3.1	3.2
RDW-SD (fL)	45.9	43.7
RDW-CV (%)	12.7	12.5
PDW (fL)	13.7	13.4
MPV (fL)	10.8	11.1
P-LCR (%)	31.9	33.2
PCT (%)	0.27	0.27

Sample-04		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.1	6.1
RBC ($10^6/\mu\text{l}$)	4.61	4.62
HGB (g/dl)	12.5	12.3
HCT (%)	40.4	39.5
MCV (fL)	87.6	85.5
MCH (pg)	27.1	26.6
MCHC (g/dl)	30.9	31.1
PLT ($10^3/\mu\text{l}$)	309	314
LYM (%)	34.7	32
MXD (%)	9.8	9.7
NEUT (%)	55.5	58.3
LYM# ($10^3/\mu\text{l}$)	2.1	2
MXD# ($10^3/\mu\text{l}$)	0.6	0.6
NEUT# ($10^3/\mu\text{l}$)	3.4	3.5
RDW-SD (fL)	44.1	43.4
RDW-CV (%)	12.4	12.8
PDW (fL)	13.5	14.7
MPV (fL)	10.8	10.9
P-LCR (%)	31.8	31.9
PCT (%)	0.33	0.34

Sample-05		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.8	4.8
RBC ($10^6/\mu\text{l}$)	4.67	4.74
HGB (g/dl)	13.8	13.7
HCT (%)	44.5	44.3
MCV (fL)	95.3	93.5
MCH (pg)	29.6	28.9
MCHC (g/dl)	31	30.9
PLT ($10^3/\mu\text{l}$)	207	192
LYM (%)	36.3	36.4
MXD (%)	9.9	8.7
NEUT (%)	53.8	51.9
LYM# ($10^3/\mu\text{l}$)	2.7	1.7
MXD# ($10^3/\mu\text{l}$)	0.5	0.6
NEUT# ($10^3/\mu\text{l}$)	2.6	2.5
RDW-SD (fL)	49.3	48.8
RDW-CV (%)	13.2	13.5
PDW (fL)	14.8	14.9
MPV (fL)	11.2	11.4
P-LCR (%)	35.2	36.2
PCT (%)	0.23	0.22

Sample-06

Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	6.4	6.3
RBC (10 ⁶ /μl)	4.63	4.7
HGB (g/dl)	14.2	14
HCT (%)	46.1	45.9
MCV (fL)	99.6	97.7
MCH (pg)	30.7	29.8
MCHC (g/dl)	30.8	30.5
PLT (10 ³ /μl)	234	245
LYM (%)	31.7	32
MXD (%)	13.8	11.9
NEUT (%)	54.5	56.1
LYM# (10 ³ /μl)	2	2
MXD# (10 ³ /μl)	0.9	0.7
NEUT# (10 ³ /μl)	3.5	3.6
RDW-SD (fL)	51.4	51
RDW-CV (%)	13.1	13.7
PDW (fL)	13.9	14.4
MPV (fL)	11.1	11.3
P-LCR (%)	33.1	35
PCT (%)	0.26	0.28

Commercial Confidential



ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΗΝΗ 7 - ΤΣΑΛΙ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801669151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82399 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΟΝΗ ΦΛΟΡΑ

Sample-07		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	9.7	9.6
RBC (10 ⁶ /μl)	4.96	5.02
HGB (g/dl)	15.4	15.3
HCT (%)	48.3	47.9
MCV (fL)	97.4	95.4
MCH (pg)	31	30.5
MCHC (g/dl)	31.9	31.9
PLT (10 ³ /μl)	189	212
LYM (%)	34	33.8
MXD (%)	6.2	7.2
NEUT (%)	59.8	59
LYM# (10 ³ /μl)	3.3	3.2
MXD# (10 ³ /μl)	0.6	0.7
NEUT# (10 ³ /μl)	5.8	5.7
RDW-SD (fL)	46.4	47.1
RDW-CV (%)	12.1	12.6
PDW (fL)	14.8	14.5
MPV (fL)	11.1	11.3
P-LCR (%)	34.3	36.5
PCT (%)	0.21	0.24

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΓΕΝΙΚΗ ΔΙΕΥΘΥΝΣΗ
ΔΙΕΥΘΥΝΣΗ ΓΕΝΙΚΗΣ ΙΑΤΡΙΚΗΣ
ΕΛΛΗΝΙΚΟ ΚΕΝΤΡΟ ΕΡΕΥΝΑΣ
ΚΑΙ ΔΙΑΓΝΩΣΤΙΚΗΣ
ΒΙΟΪΑΤΡΙΚΗΣ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙΑ ΠΑΝΝΙΤΣΩΝ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Α.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 62999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ



Sample-08		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6	6.2
RBC ($10^6/\mu\text{l}$)	4.83	4.92
HGB (g/dl)	14.4	14.4
HCT (%)	45.7	45.5
MCV (fL)	94.6	92.5
MCH (pg)	29.8	29.3
MCHC (g/dl)	31.5	31.6
PLT ($10^3/\mu\text{l}$)	356	370
LYM (%)	34.9	34
MXD (%)	17	17.7
NEUT (%)	48.1	48.3
LYM# ($10^3/\mu\text{l}$)	2.1	2.1
MXD# ($10^3/\mu\text{l}$)	1	1.1
NEUT# ($10^3/\mu\text{l}$)	2.9	3
RDW-SD (fL)	46.4	46
RDW-CV (%)	12.3	12.6
PDW (fL)	11.1	11.3
MPV (fL)	9.1	9.3
P-LCR (%)	18.5	20.4
PCT (%)	0.32	0.34

Sample-09		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7.4	7
RBC ($10^6/\mu\text{l}$)	4.49	4.52
HGB (g/dl)	13.7	13.6
HCT (%)	42.3	41.8
MCV (fL)	94.2	92.5
MCH (pg)	30.5	30.1
MCHC (g/dl)	32.4	32.5
PLT ($10^3/\mu\text{l}$)	170	159
LYM (%)	34.4	32.9
MXD (%)	7.5	8.7
NEUT (%)	58.1	58.4
LYM# ($10^3/\mu\text{l}$)	2.5	2.3
MXD# ($10^3/\mu\text{l}$)	0.6	0.6
NEUT# ($10^3/\mu\text{l}$)	4.3	4.1
RDW-SD (fL)	44.8	44.8
RDW-CV (%)	12.1	12.5
PDW (fL)	16	17.5
MPV (fL)	11.2	11.4
P-LCR (%)	34.9	36.9
PCT (%)	0.19	0.18

Sample-10		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	7.9	7.9
RBC ($10^6/\mu\text{l}$)	4.39	44.37
HGB (g/dl)	13	12.9
HCT (%)	42.2	41.4
MCV (fL)	96.1	94.7
MCH (pg)	29.6	29.5
MCHC (g/dl)	30.8	31.2
PLT ($10^3/\mu\text{l}$)	300	290
LYM (%)	22.9	23.1
MXD (%)	16.6	10.3
NEUT (%)	60.5	66.6
LYM# ($10^3/\mu\text{l}$)	1.8	1.8
MXD# ($10^3/\mu\text{l}$)	1.3	0.8
NEUT# ($10^3/\mu\text{l}$)	4.8	5.3
RDW-SD (fL)	49	47.8
RDW-CV (%)	12.6	12.8
PDW (fL)	14.7	13.4
MPV (fL)	10.4	10.6
P-LCR (%)	29.3	29.8
PCT (%)	0.31	0.31

ΕΡΓΑΣΤΗΡΙΟ
 ΜΙΚΡΟΒΙΟΛΟΓΙΑΣ
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΩΝ
 Α.Φ.Μ. 801665151 - Α.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ. 23820 82999 - 6945433450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΓΙΑΣΧΩΝΗ ΦΛΩΡΑ
 ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΩΝ
 Α.Φ.Μ. 801665151 - Α.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ. 23820 82999 - 6945433450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ
 ΓΙΑΣΧΩΝΗ ΦΛΩΡΑ

Sample-11

Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.6	4.6
RBC ($10^6/\mu\text{l}$)	5.09	5.12
HGB (g/dl)	14.3	14.3
HCT (%)	44.6	44.1
MCV (fL)	87.6	86.1
MCH (pg)	28.1	27.9
MCHC (g/dl)	32.1	32.4
PLT ($10^3/\mu\text{l}$)	208	211
LYM (%)	37.2	37
MXD (%)	11.7	11.6
NEUT (%)	51.1	51.4
LYM# ($10^3/\mu\text{l}$)	1.7	1.7
MXD# ($10^3/\mu\text{l}$)	0.5	0.5
NEUT# ($10^3/\mu\text{l}$)	2.4	2.4
RDW-SD (fL)	47.4	46
RDW-CV (%)	13.6	14
PDW (fL)	11.2	11.2
MPV (fL)	9	9.3
P-LCR (%)	17.9	19.6
PCT (%)	0.19	0.2

Sample-12		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	8.6	8.4
RBC (10 ⁶ /μl)	4.68	4.72
HGB (g/dl)	14	13.9
HCT (%)	45.9	45.5
MCV (fL)	98.1	96.4
MCH (pg)	29.9	29.4
MCHC (g/dl)	30.5	30.5
PLT (10 ³ /μl)	212	213
LYM (%)	47.7	49
MXD (%)	13.3	10.5
NEUT (%)	39	40.5
LYM# (10 ³ /μl)	4.1	4.1
MXD# (10 ³ /μl)	1.1	0.9
NEUT# (10 ³ /μl)	3.4	3.4
RDW-SD (fL)	49.4	49
RDW-CV (%)	13	13.2
PDW (fL)	14.9	13
MPV (fL)	11.1	11.2
P-LCR (%)	34.2	34.6
PCT (%)	0.24	0.24

Sample-13		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	8.9	9.1
RBC (10 ⁶ /μl)	4.8	4.87
HGB (g/dl)	12.8	12.8
HCT (%)	42.1	42
MCV (fL)	87.7	86.2
MCH (pg)	26.7	26.3
MCHC (g/dl)	30.4	30.5
PLT (10 ³ /μl)	360	350
LYM (%)	38.1	37.7
MXD (%)	8.5	8
NEUT (%)	53.4	54.3
LYM# (10 ³ /μl)	3.4	3.4
MXD# (10 ³ /μl)	0.8	0.7
NEUT# (10 ³ /μl)	4.7	5
RDW-SD (fL)	55.3	54.4
RDW-CV (%)	16.7	17
PDW (fL)	4.6	15.8
MPV (fL)	11.1	11.5
P-LCR (%)	34.3	37.7
PCT (%)	0.4	0.4

Sample-14		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.9	5.9
RBC ($10^6/\mu\text{l}$)	4.43	4.42
HGB (g/dl)	12.6	12.4
HCT (%)	41.4	40.7
MCV (fL)	93.5	92.2
MCH (pg)	28.4	28.1
MCHC (g/dl)	30.4	30.5
PLT ($10^3/\mu\text{l}$)	199	199
LYM (%)	42.9	45.3
MXD (%)	19.2	14.3
NEUT (%)	37.9	40.4
LYM# ($10^3/\mu\text{l}$)	2.5	2.7
MXD# ($10^3/\mu\text{l}$)	1.1	0.8
NEUT# ($10^3/\mu\text{l}$)	2.3	2.4
RDW-SD (fL)	48.2	47.5
RDW-CV (%)	13	13.6
PDW (fL)	14.9	17.3
MPV (fL)	11.9	11.6
P-LCR (%)	39.3	39.1
PCT (%)	0.24	0.23

ΓΙΑΣΧΩΝΗ ΦΛΩΡΑ
 ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
 Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ.: 23820 82999 - 6945433450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ
ΓΙΑΣΧΩΝΗ ΦΛΩΡΑ

Sample-15		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	4.3	4.5
RBC ($10^6/\mu\text{l}$)	2.91	2.96
HGB (g/dl)	9.3	9.3
HCT (%)	30	29.8
MCV (fL)	103.1	100.7
MCH (pg)	32	31.4
MCHC (g/dl)	31	31.2
PLT ($10^3/\mu\text{l}$)	375	357
LYM (%)	49	46.9
MXD (%)	6.5	8.7
NEUT (%)	44.5	44.4
LYM# ($10^3/\mu\text{l}$)	2.1	2.1
MXD# ($10^3/\mu\text{l}$)	0.3	0.4
NEUT# ($10^3/\mu\text{l}$)	1.9	2
RDW-SD (fL)	72.2	72.9
RDW-CV (%)	21	21.6
PDW (fL)	14.8	16.4
MPV (fL)	11.7	11.3
P-LCR (%)	36.1	34.3
PCT (%)	0.44	0.4

Sample-16		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.7	6.8
RBC ($10^6/\mu\text{l}$)	4.48	4.56
HGB (g/dl)	13	12.9
HCT (%)	42.2	42.2
MCV (fL)	94.2	92.5
MCH (pg)	29	28.3
MCHC (g/dl)	30.8	30.6
PLT ($10^3/\mu\text{l}$)	210	221
LYM (%)	44	43.1
MXD (%)	12.2	10.2
NEUT (%)	43.8	43.7
LYM# ($10^3/\mu\text{l}$)	2.9	2.9
MXD# ($10^3/\mu\text{l}$)	0.8	0.7
NEUT# ($10^3/\mu\text{l}$)	3	3.2
RDW-SD (fL)	49.6	50.2
RDW-CV (%)	13.5	13.9
PDW (fL)	15.1	14.7
MPV (fL)	11.5	11.7
P-LCR (%)	37.4	37.1
PCT (%)	0.24	0.26

Sample-17		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	6.9	7
RBC ($10^6/\mu\text{l}$)	4.43	4.46
HGB (g/dl)	14	13.9
HCT (%)	45	44.5
MCV (fL)	101.6	99.8
MCH (pg)	31.6	31.2
MCHC (g/dl)	31.1	31.2
PLT ($10^3/\mu\text{l}$)	294	285
LYM (%)	27.6	26.2
MXD (%)	7.7	10.2
NEUT (%)	64.7	63.6
LYM# ($10^3/\mu\text{l}$)	1.9	1.8
MXD# ($10^3/\mu\text{l}$)	0.5	0.7
NEUT# ($10^3/\mu\text{l}$)	4.5	4.5
RDW-SD (fL)	51.8	51.6
RDW-CV (%)	13	13.3
PDW (fL)	13.8	13.7
MPV (fL)	10.5	10.7
P-LCR (%)	29.9	30.8
PCT (%)	0.31	0.3

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
 ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑ/ΙΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
 Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ: 25820 87999 - 6945433450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Sample-18		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5	5
RBC ($10^6/\mu\text{l}$)	4.16	4.17
HGB (g/dl)	11.8	11.9
HCT (%)	40	39.2
MCV (fL)	96.2	94
MCH (pg)	28.4	28.5
MCHC (g/dl)	29.5	30.4
PLT ($10^3/\mu\text{l}$)	205	188
LYM (%)	30	30.2
MXD (%)	14.8	15.6
NEUT (%)	55.2	54.2
LYM# ($10^3/\mu\text{l}$)	1.5	1.5
MXD# ($10^3/\mu\text{l}$)	0.7	0.8
NEUT# ($10^3/\mu\text{l}$)	2.8	2.7
RDW-SD (fL)	53.8	51.8
RDW-CV (%)	14.2	14.1
PDW (fL)	17.5	17.3
MPV (fL)	11.6	12.1
P-LCR (%)	39.2	42.3
PCT (%)	0.24	0.23

ΕΡΓΑΣΤΗΡΙΟ ΗΜΕΡΑ 21/05/2023
 ΑΝΤΙΣΤΡΩΦΗ ΕΡΓΑΣΤΗΡΙΑΚΗ ΔΕΙΞΗ
 ΑΝΤΙΣΤΡΩΦΗ ΕΡΓΑΣΤΗΡΙΑΚΗ ΔΕΙΞΗ
 ΑΝΤΙΣΤΡΩΦΗ ΕΡΓΑΣΤΗΡΙΑΚΗ ΔΕΙΞΗ
 ΑΝΤΙΣΤΡΩΦΗ ΕΡΓΑΣΤΗΡΙΑΚΗ ΔΕΙΞΗ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
 ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
 Α.Φ.Μ. 804665151 / Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ.: 23820 82999 - 6945433450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Sample-19		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC (10 ³ /μl)	6.4	6.6
RBC (10 ⁶ /μl)	4.78	4.86
HGB (g/dl)	13.9	13.9
HCT (%)	44.2	44.1
MCV (fL)	92.5	90.7
MCH (pg)	29.1	28.6
MCHC (g/dl)	31.4	31.5
PLT (10 ³ /μl)	223	253
LYM (%)	43.9	39.9
MXD (%)	13.1	13.9
NEUT (%)	43	46.2
LYM# (10 ³ /μl)	2.8	2.6
MXD# (10 ³ /μl)	0.8	0.9
NEUT# (10 ³ /μl)	2.8	3.1
RDW-SD (fL)	45.4	46.5
RDW-CV (%)	12.3	12.8
PDW (fL)	13	13.4
MPV (fL)	10.8	10.8
P-LCR (%)	31.9	30.7
PCT (%)	0.24	0.27

Sample-20		
Parameters	All Reagents from Vanguard Diagnostics	All Reagents from Sysmex as Reference
WBC ($10^3/\mu\text{l}$)	5.7	6
RBC ($10^6/\mu\text{l}$)	4.51	4.54
HGB (g/dl)	13	13
HCT (%)	42.5	42
MCV (fL)	94.2	92.5
MCH (pg)	28.8	28.6
MCHC (g/dl)	30.6	31
PLT ($10^3/\mu\text{l}$)	243	232
LYM (%)	44.6	45.3
MXD (%)	15.6	17.6
NEUT (%)	39.8	37.1
LYM# ($10^3/\mu\text{l}$)	2.5	2.7
MXD# ($10^3/\mu\text{l}$)	0.9	1.1
NEUT# ($10^3/\mu\text{l}$)	2.9	2.2
RDW-SD (fL)	50.1	49
RDW-CV (%)	13.5	13.7
PDW (fL)	13.5	13.5
MPV (fL)	10.5	10.8
P-LCR (%)	29.7	31.6
PCT (%)	0.26	0.25

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΓΕΝΙΚΗ ΔΙΕΥΘΥΝΣΗ
ΔΙΕΥΘΥΝΣΗ ΔΙΑΓΝΩΣΤΙΚΩΝ
ΕΡΓΑΣΤΗΡΙΩΝ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΗ - ΠΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΠΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 81999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ
ΠΑΣΧΩΝΗ ΦΛΩΡΑ

Performance with Hematology 3rd Party Controls

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

Lot No.: 50800822

Expiry: 28/6/2025

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 (%)			

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 /μl)	7.0	7	6.5 - 7.5
RBC (10 ⁶ /μl)	4.4	4.37	4.18 – 4.52
HGB (g/dl)	12.1	11.9	11.4 – 12.4
HCT (%)	33.9	33.9	31.4 – 36.6
MCV (fl)	77.0	77.6	74.2 - 82
MCH (pg)	27.5	27.2	25.9 – 23.9
MCHC (g/dl)	35.7	35.1	32.5 – 37.5
PLT (10 ³ /μl)	215.0	203	183 – 247
LYM (%)	30.9	30.4	26.4 – 35.8
MXD (%)	13.5	13.4	9.4 – 15.8
NEUT (%)	55.6	56.2	52.4 – 60.2
LYM# (10 ³ /μl)	2.2	2.1	1.9 – 2.5
MXD# (10 ³ /μl)	0.9	0.9	0.7 – 1.1
NEUT# (10 ³ /μl)	3.9	4	3.5 – 4.3
RDW-SD (fl)	37.2	38.4	33.2 – 45
RDW-CV (%)	12.5	12.7	10.5 – 14.3
PDW (fl)	8.8	8.8	7.7 – 9.5
MPV (fl)	9.7	9.8	9 – 10.6
P-LCR (%)	17.6	18.7	7 – 28.2

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23826 82999 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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

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	3	4	5	6	7	8	9	10	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{l}$)	3.8	3.7	3.7	3.7	3.8	3.5	3.6	3.5	3.7	3.6	3.66	0.11	0.03	2.94
RBC ($10^6/\mu\text{l}$)	4.82	4.81	4.82	4.86	4.83	4.8	4.82	4.84	4.83	4.88	4.83	0.02	0.00	0.49
HGB (g/dl)	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.4	14.22	0.06	0.00	0.44
HCT (%)	44.4	44.4	44.6	44.9	44.5	44.1	44.3	44.4	44.2	44.6	44.44	0.23	0.01	0.51
MCV (fL)	92.1	92.3	92.5	92.4	92.1	91.9	91.9	91.7	91.5	91.4	91.98	0.37	0.00	0.40
MCH (pg)	29.5	29.5	29.5	29.2	29.4	29.6	29.5	29.3	29.4	29.5	29.44	0.12	0.00	0.40
MCHC (g/dl)	32	32	31.8	31.6	31.9	32.2	32.1	32	32.1	32.3	32.00	0.20	0.01	0.62
PLT ($10^3/\mu\text{l}$)	146	144	139	148	139	137	137	131	142	140	140.30	4.95	0.04	3.52
LYM (%)	39.8	40.7	39.7	39.9	41.6	42	40.6	41.3	40.3	41.4	40.73	0.81	0.02	2.00
MXD (%)	7.8	8.9	8.2	8.4	5.5	6.4	6.5	5.4	10.4	5.1	7.26	1.75	0.24	24.11
NEUT (%)	52.4	50.4	52.1	51.7	52.9	51.6	52.9	53.3	49.3	53.5	52.01	1.33	0.03	2.55
LYM# ($10^3/\mu\text{l}$)	1.5	1.5	1.5	1.5	1.6	1.5	1.5	1.4	1.5	1.5	1.50	0.05	0.03	3.14
MXD# ($10^3/\mu\text{l}$)	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.4	0.2	0.26	0.07	0.27	26.89
NEUT# ($10^3/\mu\text{l}$)	2	1.9	1.9	1.9	2	1.8	1.9	1.9	1.8	1.9	1.90	0.07	0.04	3.51
RDW-SD (fL)	44.7	45.7	45.8	45.7	45.9	44.6	45.1	46.5	45	45.6	45.46	0.59	0.01	1.31
RDW-CV (%)	12.6	12.5	12.6	12.5	12.6	12.3	12.5	12.9	12.5	12.7	12.57	0.16	0.01	1.25
PDW (fL)	14.5	14.1	15.3	14.7	14.9	15.2	13.9	13.9	15	14	14.55	0.55	0.04	3.75
MPV (fL)	10.6	10.4	10.8	10.6	10.5	10.3	10.1	10.8	10.4	10.4	10.49	0.22	0.02	2.08
P-LCR (%)	31.2	30.4	32.7	29.7	31.3	29.8	29	32.1	30.7	29.5	30.64	1.19	0.04	3.89
PCT (%)	0.15	0.15	0.15	0.16	0.15	0.14	0.14	0.14	0.15	0.15	0.15	0.01	0.04	4.27

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 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 /μl)	3.8	3.7	3.7	3.7	3.8	3.5	3.6	3.5	3.7	3.6	3.7	3.65	0.097	2.66%	3.50%	Qualified
RBC (10 ⁶ /μl)	4.82	4.81	4.82	4.86	4.83	4.8	4.82	4.84	4.83	4.88	4.85	4.834	0.024	0.0049916	2.00%	Qualified
HGB (g/dl)	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.4	14.4	14.24	0.084	0.0059219	1.50%	Qualified
HCT (%)	44.4	44.4	44.6	44.9	44.5	44.1	44.3	44.4	44.2	44.6	44.4	44.44	0.227	0.0051093	2.00%	Qualified
MCV (fL)	92.1	92.3	92.5	92.4	92.1	91.9	91.9	91.7	91.5	91.4	91.5	91.92	0.397	0.0043152	2.00%	Qualified
MCH (pg)	29.5	29.5	29.5	29.2	29.4	29.6	29.5	29.3	29.4	29.5	29.7	29.46	0.143	0.0048535	2.00%	Qualified
MCHC (g/dl)	32	32	31.8	31.6	31.9	32.2	32.1	32	32.1	32.3	32.4	32.04	0.237	0.0073859	2.00%	Qualified
PLT (10 ³ /μl)	146	144	139	148	139	137	137	131	142	140	141	139.8	4.541	0.0324833	6.00%	Qualified
LYM (%)	39.8	40.7	39.7	39.9	41.6	42	40.6	41.3	40.3	41.4	40.9	40.84	0.746	0.0182579	15.00%	Qualified
MXD (%)	7.8	8.9	8.2	8.4	5.5	6.4	6.5	5.4	10.4	5.1	7.6	7.24	1.744	0.2409287	30.00%	Qualified
NEUT (%)	52.4	50.4	52.1	51.7	52.9	51.6	52.9	53.3	49.3	53.5	51.5	51.92	1.327	0.0255647	15.00%	Qualified
LYM# (10 ³ /μl)	1.5	1.5	1.5	1.5	1.6	1.5	1.5	1.4	1.5	1.5	1.5	1.5	0.047	0.031427	15.00%	Qualified
MXD# (10 ³ /μl)	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.4	0.2	0.3	0.26	0.070	0.2689253	30.00%	Qualified
NEUT# (10 ³ /μl)	2	1.9	1.9	1.9	2	1.8	1.9	1.9	1.8	1.9	1.9	1.89	0.057	0.0300342	15.00%	Qualified
RDW-SD (fL)	44.7	45.7	45.8	45.7	45.9	44.6	45.1	46.5	45	45.6	45.3	45.52	0.537	0.0117986	4.00%	Qualified
RDW-CV (%)	12.6	12.5	12.6	12.5	12.6	12.3	12.5	12.9	12.5	12.7	12.6	12.57	0.157	0.0124664	4.00%	Qualified
PDW (fL)	14.5	14.1	15.3	14.7	14.9	15.2	13.9	13.9	15	14	15.2	14.62	0.583	0.0398573	12.00%	Qualified
MPV (fL)	10.6	10.4	10.8	10.6	10.5	10.3	10.1	10.8	10.4	10.4	10.6	10.49	0.218	0.0208129	5.00%	Qualified
P-LCR (%)	31.2	30.4	32.7	29.7	31.3	29.8	29	32.1	30.7	29.5	31.8	30.7	1.236	0.0402763	20.00%	Qualified
PCT (%)	0.15	0.15	0.15	0.16	0.15	0.14	0.14	0.14	0.15	0.15	0.15	0.148	0.006	0.0427335	9.00%	Qualified

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
 ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
 ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ - ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
 Α.Φ.Μ. 801665151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
 ΤΗΛ: 23820 42999 - 6945133450
 ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ



ΠΑΣΧΩΝΗ ΦΛΩΡΑ

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	3	4	5	6	7	8	9	10	Mean	SD	CV	CV%
WBC ($10^3/\mu\text{l}$)	3.6	3.8	3.6	3.7	3.7	3.8	3.9	3.9	3.8	3.6	3.74	0.12	0.03	3.14
RBC ($10^6/\mu\text{l}$)	4.87	4.89	4.87	4.93	4.86	4.91	4.91	4.94	4.93	4.89	4.90	0.03	0.01	0.58
HGB (g/dl)	14.5	14.4	14.4	14.4	14.4	14.4	14.4	14.5	14.4	14.5	14.43	0.05	0.00	0.33
HCT (%)	43.7	43.7	43.4	44.1	43.5	43.8	43.8	43.9	44	43.8	43.77	0.21	0.00	0.48
MCV (fL)	89.7	89.4	89.1	89.5	89.5	89.2	89.2	88.9	89.2	89.6	89.33	0.25	0.00	0.28
MCH (pg)	29.8	29.4	29.6	29.2	29.6	29.3	29.3	29.4	29.2	29.7	29.45	0.21	0.01	0.72
MCHC (g/dl)	33.2	33	33.2	32.7	33.1	32.9	32.9	33	32.7	33.1	32.98	0.18	0.01	0.55
PLT ($10^3/\mu\text{l}$)	145	148	144	143	138	144	150	145	143	142	144.20	3.26	0.02	2.26
LYM (%)	38.8	40.4	40.4	37.8	39.1	41.2	36.5	38	38.6	41.6	39.24	1.63	0.04	4.15
MXD (%)	9.3	9	8.5	9.3	9.7	8.4	8.5	8.6	8.5	6.4	8.62	0.90	0.10	10.42
NEUT (%)	51.9	50.6	51.1	52.9	51.2	50.4	55	53.4	52.9	52	52.14	1.43	0.03	2.74
LYM# ($10^3/\mu\text{l}$)	1.4	1.5	1.5	1.4	1.4	1.6	1.4	1.5	1.5	1.5	1.47	0.07	0.05	4.59
MXD# ($10^3/\mu\text{l}$)	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.2	0.30	0.05	0.16	15.71
NEUT# ($10^3/\mu\text{l}$)	1.9	2	1.8	2	1.9	1.9	2.2	2.1	2	1.9	1.97	0.12	0.06	5.89
RDW-SD (fL)	43.7	42.2	43.8	44.8	44.8	43.8	43.8	43.8	44.6	43.3	43.86	0.78	0.02	1.77
RDW-CV (%)	12.9	12.6	12.8	12.9	12.9	12.6	12.7	12.5	12.9	12.7	12.75	0.15	0.01	1.18
PDW (fL)	16.1	17	14.7	16.1	14.9	15.2	15.6	15.8	17	15.1	15.75	0.81	0.05	5.16
MPV (fL)	11.2	11.2	11.4	11.4	11.2	11.2	11.2	10.9	11.5	11	11.22	0.18	0.02	1.62
P-LCR (%)	36.4	36.4	37.3	37.1	36.6	35.9	36.1	34.3	38.2	33.4	36.17	1.41	0.04	3.89
PCT (%)	0.16	0.17	0.16	0.16	0.15	0.16	0.17	0.16	0.16	0.16	0.16	0.01	0.04	3.53

Coefficient of Variation: Precision (Sysmex 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 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 /μl)	3.6	3.8	3.6	3.7	3.7	3.8	3.9	3.9	3.8	3.6	3.8	3.76	0.107	2.86%	3.50%	Qualified
RBC (10 ⁶ /μl)	4.87	4.89	4.87	4.93	4.86	4.91	4.91	4.94	4.93	4.89	4.91	4.904	0.026	0.00536934	2.00%	Qualified
HGB (g/dl)	14.5	14.4	14.4	14.4	14.4	14.4	14.4	14.5	14.4	14.5	14.5	14.43	0.048	0.00334751	1.50%	Qualified
HCT (%)	43.7	43.7	43.4	44.1	43.5	43.8	43.8	43.9	44	43.8	44	43.8	0.221	0.00504814	2.00%	Qualified
MCV (fL)	89.7	89.4	89.1	89.5	89.5	89.2	89.2	88.9	89.2	89.6	89.6	89.32	0.235	0.00262828	2.00%	Qualified
MCH (pg)	29.8	29.4	29.6	29.2	29.6	29.3	29.3	29.4	29.2	29.7	29.5	29.42	0.175	0.00595238	2.00%	Qualified
MCHC (g/dl)	33.2	33	33.2	32.7	33.1	32.9	32.9	33	32.7	33.1	33	32.96	0.165	0.00499559	2.00%	Qualified
PLT (10 ³ /μl)	145	148	144	143	138	144	150	145	143	142	143	144	3.266	0.02268046	6.00%	Qualified
LYM (%)	38.8	40.4	40.4	37.8	39.1	41.2	36.5	38	38.6	41.6	41.6	39.52	1.778	0.04497758	15.00%	Qualified
MXD (%)	9.3	9	8.5	9.3	9.7	8.4	8.5	8.6	8.5	6.4	6.4	8.33	1.100	0.13199824	30.00%	Qualified
NEUT (%)	51.9	50.6	51.1	52.9	51.2	50.4	55	53.4	52.9	52	52	52.15	1.427	0.02736191	15.00%	Qualified
LYM# (10 ³ /μl)	1.4	1.5	1.5	1.4	1.4	1.6	1.4	1.5	1.5	1.5	1.5	1.48	0.063	0.04273348	15.00%	Qualified
MXD# (10 ³ /μl)	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.2	0.2	0.29	0.057	0.19574007	30.00%	Qualified
NEUT# (10 ³ /μl)	1.9	2	1.8	2	1.9	1.9	2.2	2.1	2	1.9	1.9	1.97	0.116	0.05885796	15.00%	Qualified
RDW-SD (fL)	43.7	42.2	43.8	44.8	44.8	43.8	43.8	43.8	44.6	43.3	43.7	43.86	0.776	0.01769987	4.00%	Qualified
RDW-CV (%)	12.9	12.6	12.8	12.9	12.9	12.6	12.7	12.5	12.9	12.7	12.7	12.73	0.142	0.01114011	4.00%	Qualified
PDW (fL)	16.1	17	14.7	16.1	14.9	15.2	15.6	15.8	17	15.1	16.8	15.82	0.874	0.05525101	12.00%	Qualified
MPV (fL)	11.2	11.2	11.4	11.4	11.2	11.2	11.2	10.9	11.5	11	11.4	11.24	0.190	0.01688049	5.00%	Qualified
P-LCR (%)	36.4	36.4	37.3	37.1	36.6	35.9	36.1	34.3	38.2	33.4	37.5	36.28	1.468	0.04046388	20.00%	Qualified
PCT (%)	0.16	0.17	0.16	0.16	0.15	0.16	0.17	0.16	0.16	0.16	0.16	0.161	0.006	0.03525753	9.00%	Qualified

Conclusions

1. The VDX 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 **0.971 to 99** displaying **the highest** degree of correlation between the reagents.
3. The VDX 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 VDX Sysmex reagents and the Sysmex Reference reagents was found to be as under:

Parameters	Sysmex Reference Reagents (CV % - Precision)	VDx Sysmex Reagents (CV % - Precision)
Measured Parameters	0.28% - 15.71%	0.40% - 26.89%
Calculated Parameters	0.55% - 5.16%	0.40% - 4.27%

5. Values obtained with 3rd Party controls (Normal) from **Sysmex** were found to be **within** specified ranges for VDX Sysmex 3 Part Hematology Reagents and Sysmex Reference reagents
6. The VDX 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.

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΠΑΙΔΕΙΑΣ, ΕΡΕΥΝΑΣ ΚΑΙ ΘΡΗΣΚΕΥΜΑΤΩΝ
ΙΝΣΤΙΤΟΥΤΟ ΤΕΧΝΟΛΟΓΙΑΣ ΥΠΟΛΟΓΙΣΤΩΝ ΚΑΙ ΕΚΔΟΣΕΩΝ
ΔΙΟΙΚΗΤΙΚΗ ΥΠΗΡΕΣΙΑ ΤΟΥ ΙΝΣΤΙΤΟΥΤΟΥ
ΛΟΓΙΣΤΗΡΙΟ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ
ΜΙΚΡΟΒΙΟΛΟΓΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΓΙΑΝΝΙΤΣΩΝ Ε.Ε.
ΚΟΜΝΗΝΩΝ 7 - ΤΣΑΛΙ / ΓΙΑΝΝΙΤΣΑ Τ.Κ. 58100
Α.Φ.Μ. 801685151 - Δ.Ο.Υ. ΓΙΑΝΝΙΤΣΩΝ
ΤΗΛ.: 23820 82980 - 6945433450
ΣΥΜΒΕΒΛΗΜΕΝΟΣ ΕΟΠΥΥ

ΠΑΣΧΩΝΗ ΦΛΩΡΑ

