

Performance Report

Sr. No.	Description
1.	<p data-bbox="418 1003 1390 1050">VDx Reagents - Urit 3 Part Hematology Analyzers</p> <p data-bbox="867 1121 938 1167">v/s</p> <p data-bbox="324 1251 1487 1297">Reference Reagents - Mindray 3 Part Hematology Analyzer</p>

Index

Sr. No.	Subject	Page Nos.
1	Details of Reagents	3 – 5
2	Coefficient of Correlation: Accuracy	6 – 12
3	Quality Control (Low, Normal & High)	13 - 17
4	Coefficient of Variation: Precision (VDx Urit Compatible reagents)	18 - 19
5	Conclusions	20

Details of Reagents

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

Details of Tests Conducted

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

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

Coefficient of Correlation Studies

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

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

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

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

Where n is the total number of samples, 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 = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.
y = VDX Urit Reagents for Urit-2900Plus, 3 Part Hematology Analyzer.

$$“r” = 0.996$$

Sample size: 8

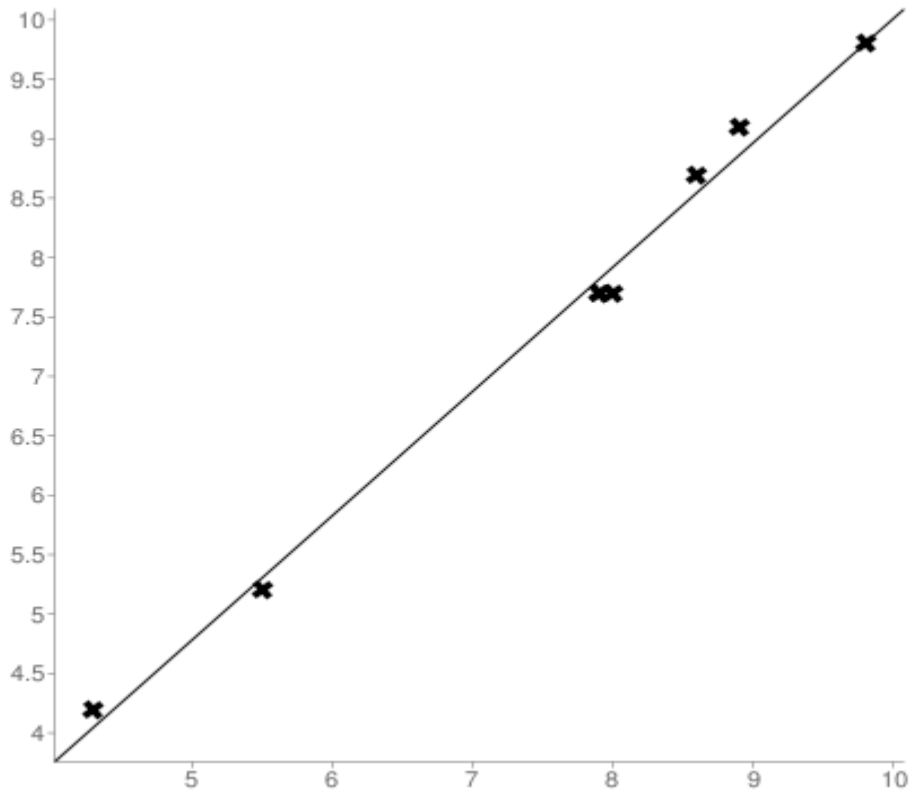
Mean x (\bar{x}): 7.6125

Mean y (\bar{y}): 7.5125

Intercept (a): -0.4581386565956

Slope (b): 1.0470461289452

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



Coefficient of Correlation (“r”): RBC

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

$$“r” = 0.997$$

Sample size: 8

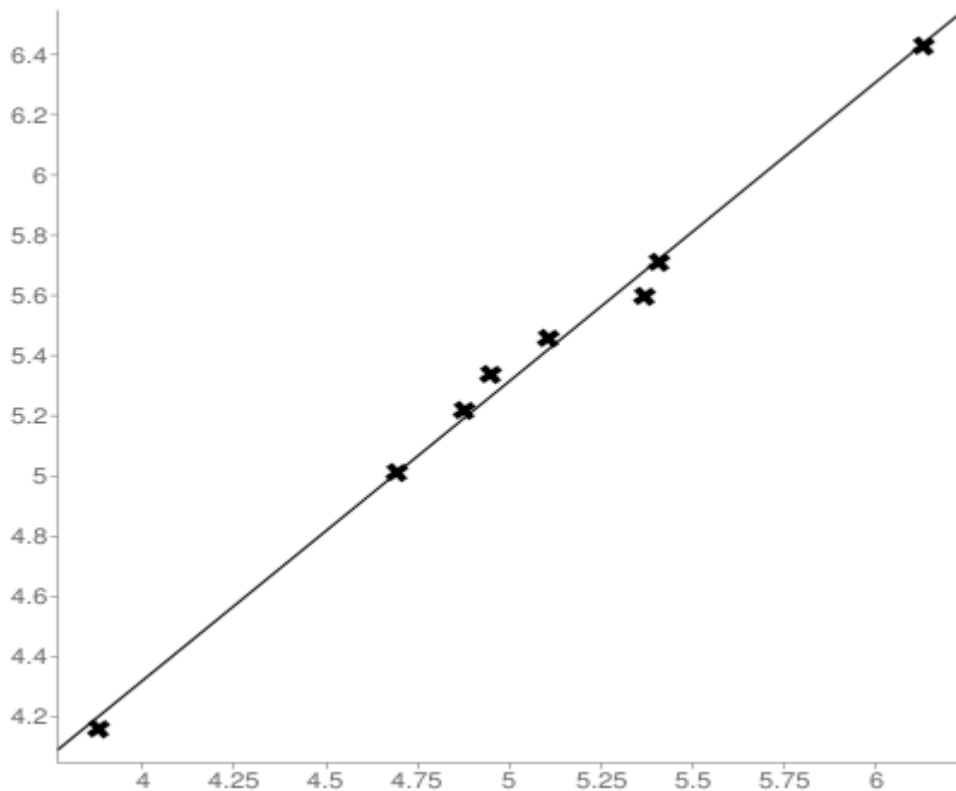
Mean x (\bar{x}): 5.0525

Mean y (\bar{y}): 5.36625

Intercept (a): 0.34688213380503

Slope (b): 0.99344242774764

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



Coefficient of Correlation (“r”): Hemoglobin

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

“r” = 0.965

Sample size: 8

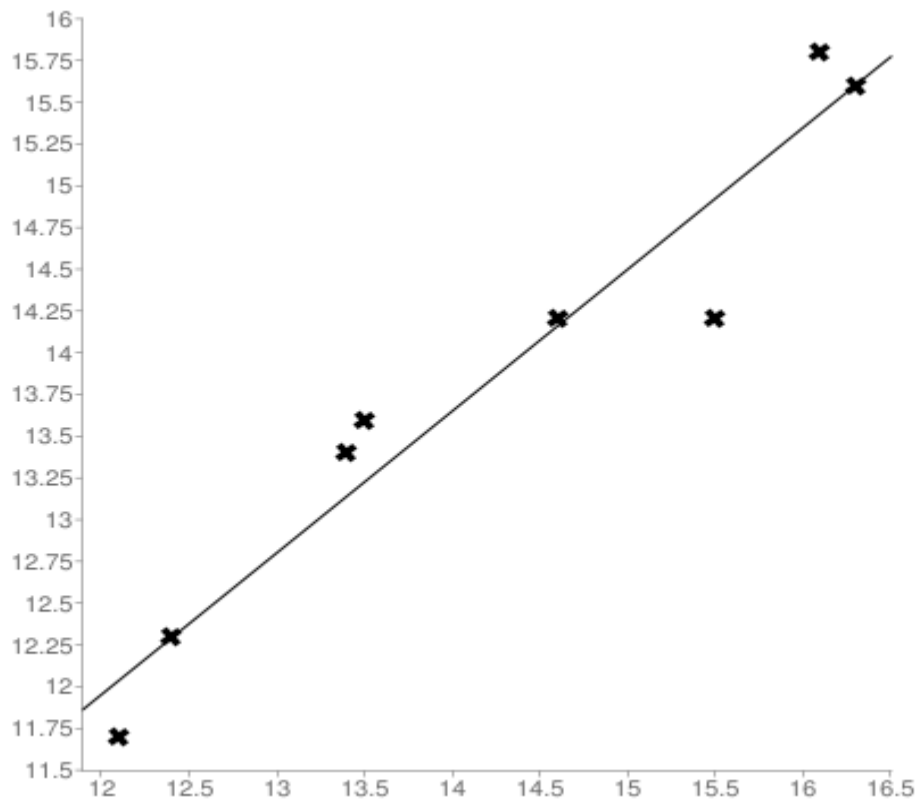
Mean x (\bar{x}): 14.2375

Mean y (\bar{y}): 13.85

Intercept (a): 1.7694654952723

Slope (b): 0.8485011065656

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

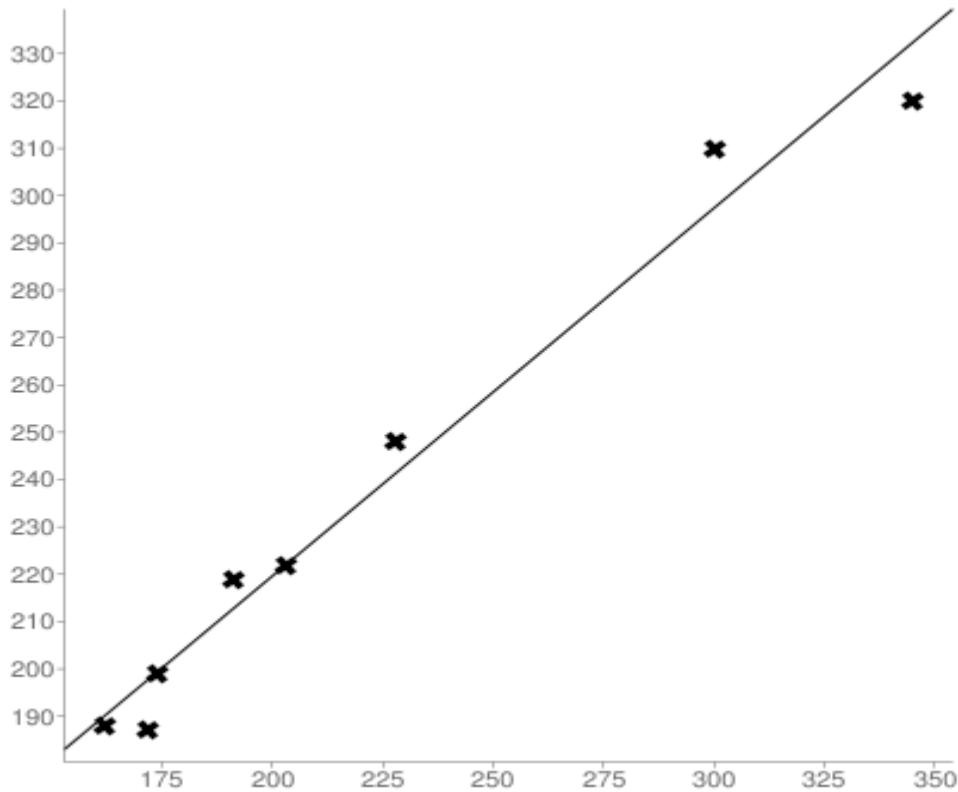


Coefficient of Correlation (“r”): Platelets

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

“r” = 0.986

Sample size: 8
Mean x (\bar{x}): 221.875
Mean y (\bar{y}): 236.625
Intercept (a): 64.16976662537
Slope (b): 0.77726302366031
Regression line equation: $y=64.16976662537+0.77726302366031x$



Coefficient of Correlation (“r”): MCV

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

$$“r” = 0.996$$

Sample size: 8

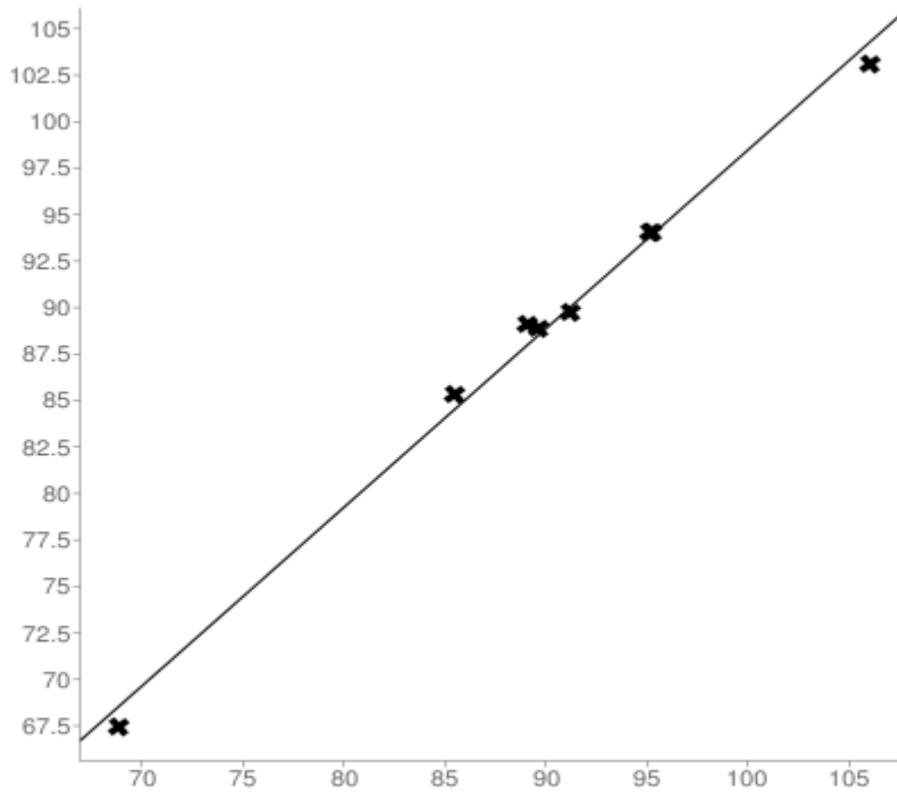
Mean x (\bar{x}): 90.1

Mean y (\bar{y}): 88.95

Intercept (a): 2.3927692151168

Slope (b): 0.96067958695764

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



Coefficient of Correlation (“r”): HCT

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

$$“r” = 0.986$$

Sample size: 8

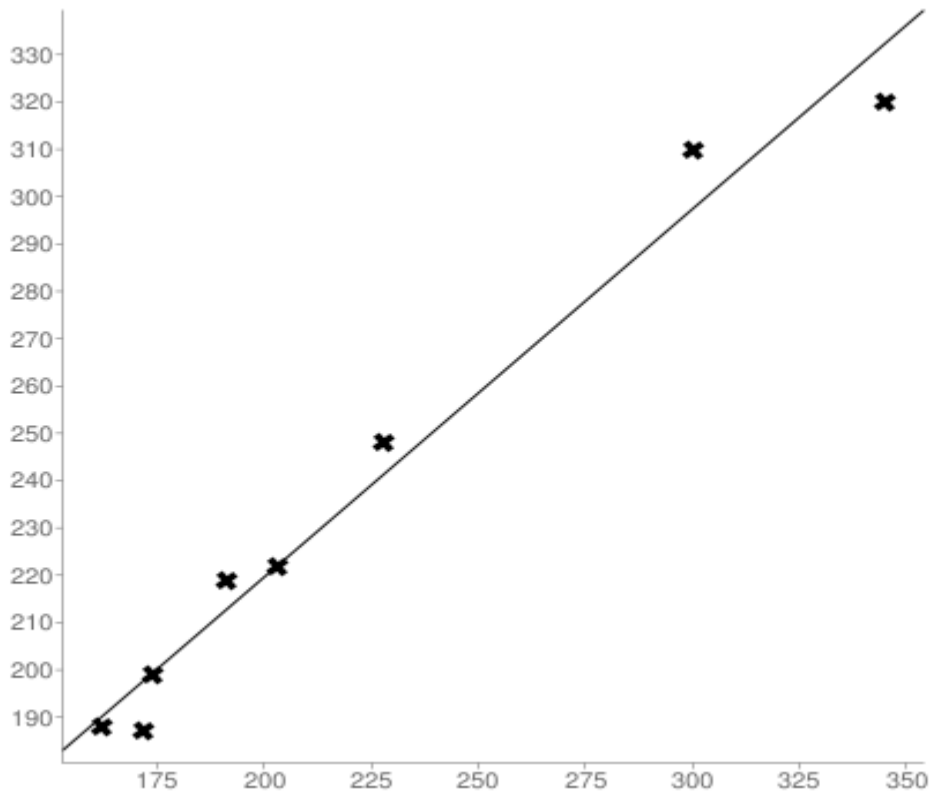
Mean x (\bar{x}): 221.875

Mean y (\bar{y}): 236.625

Intercept (a): 64.16976662537

Slope (b): 0.77726302366031

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



Performance with Hematology 3rd Part Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D
(Low Control, Lot - 1V0901, Exp.- 05.03.2023)

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

Diagon D Check D
(Normal Control, Lot - 1V0901, Exp.- 05.03.2023)

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

Diagon D Check D
(High Control, Lot - 1V0901, Exp.- 05.03.2023)

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


ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901

05-03-2023

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


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


Coefficient of Variation:

Precision (VDx Reagent)

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

Fresh Blood Sample-01, n = 07

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

Fresh Blood Sample-02, n = 08

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

Conclusions

1. The VDX Urit 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray Original reagents as Reference.
2. All Measurable parameters showed values of “r” in the range of **0.965 to 0.997** displaying the highest degree of correlation between the reagents.
3. The VDX Urit 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all parameters.
4. The CV % of Precision with the VDX Urit reagents for the parameters are mentioned below.

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

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