

Performance Report

Sr. No.	Description
1.	<p data-bbox="370 940 1438 989">VDx Reagents - Mindray 3 Part Hematology Analyzers</p> <p data-bbox="867 1058 938 1106">v/s</p> <p data-bbox="323 1184 1487 1232">Reference Reagents - Mindray 3 Part Hematology Analyzer</p>

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Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Mindray - BC3200
Reference Reagents	Reference Mindray Reagents
M-30D Diluent	Lot No : 2022091601 Expiry Date: 15-09-2024
M-30 CF Lyse	Lot No : 2022021601 Expiry Date: 15-02-2024

Details of Tests Conducted

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

Background Test

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

Coefficient of Correlation Studies

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

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

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

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

Where n is the total number of samples, 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 Reagents for Mindray- BC3200, 3 Part Hematology Analyzer.

“r” = 0.995

Sample size: 8

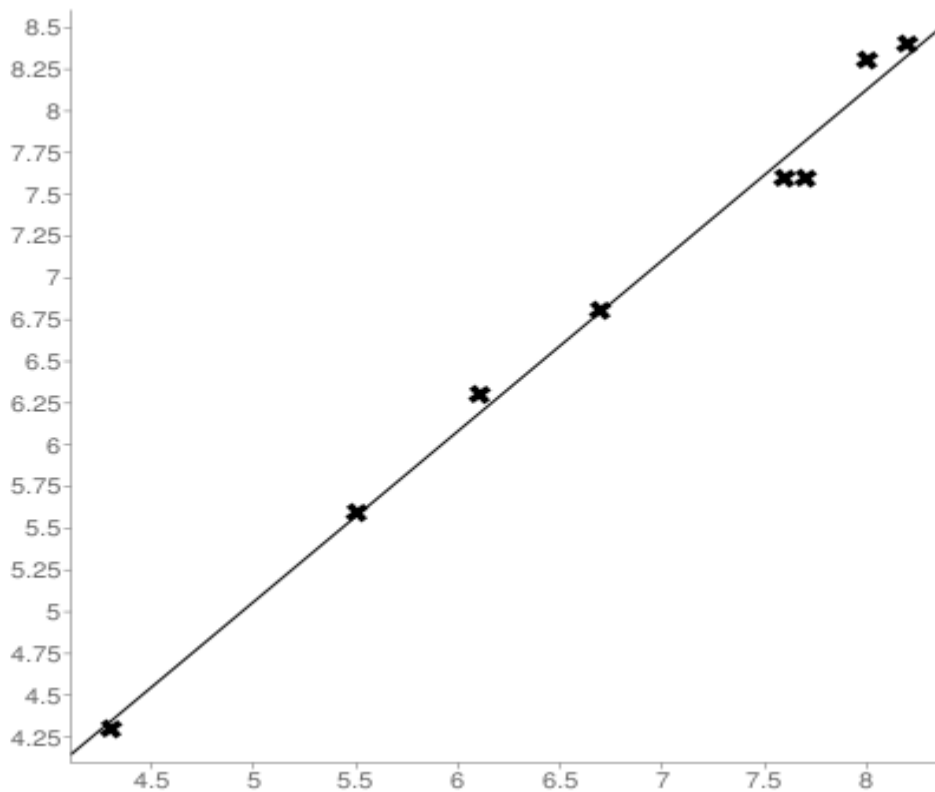
Mean x (x̄): 6.7625

Mean y (ȳ): 6.8625

Intercept (a): -0.052781700084669

Slope (b): 1.0225924879977

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



Coefficient of Correlation (“r”): RBC

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

“r” = 0.995

Sample size: 8

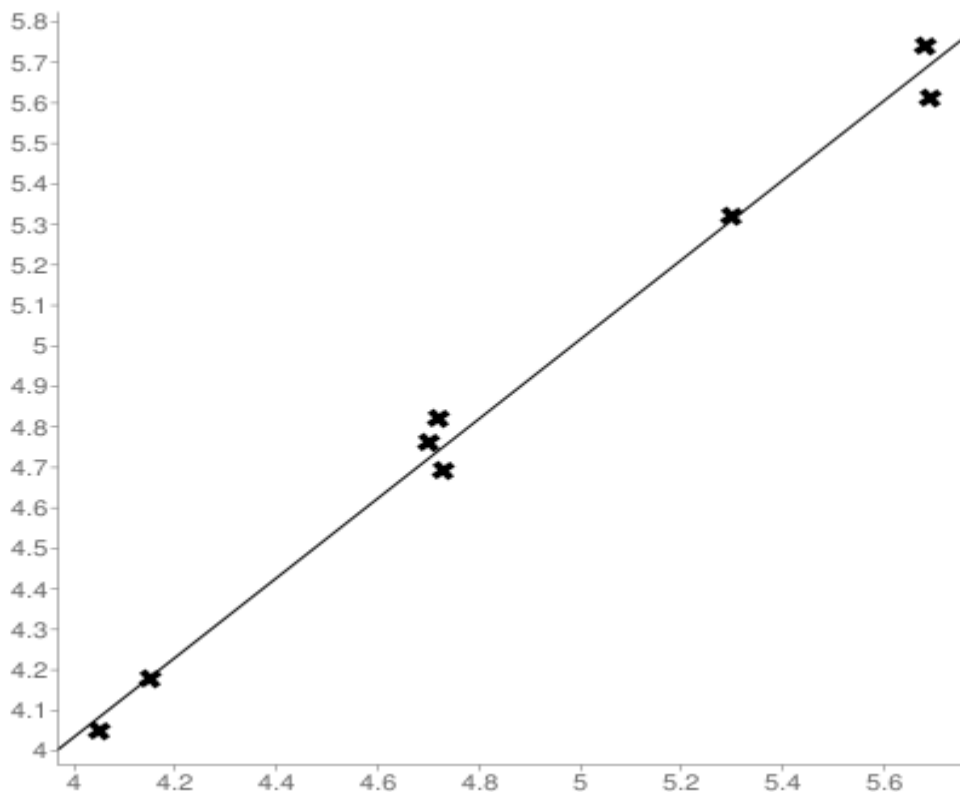
Mean x (x̄): 4.8775

Mean y (ȳ): 4.89625

Intercept (a): 0.10791521758717

Slope (b): 0.98171907379043

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



Coefficient of Correlation (“r”): Hemoglobin

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

$$“r” = 0.997$$

Sample size: 8

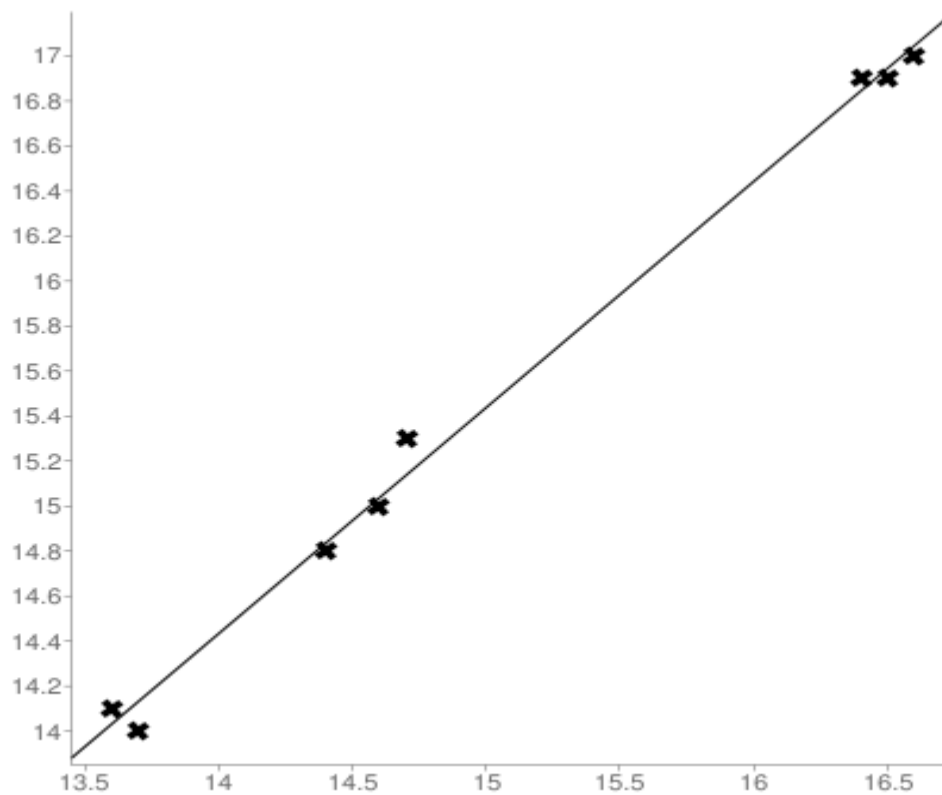
Mean x (\bar{x}): 15.0625

Mean y (\bar{y}): 15.5

Intercept (a): 0.36731446755378

Slope (b): 1.0046596204114

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



Coefficient of Correlation (“r”): Platelets

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

$$“r” = 0.998$$

Sample size: 8

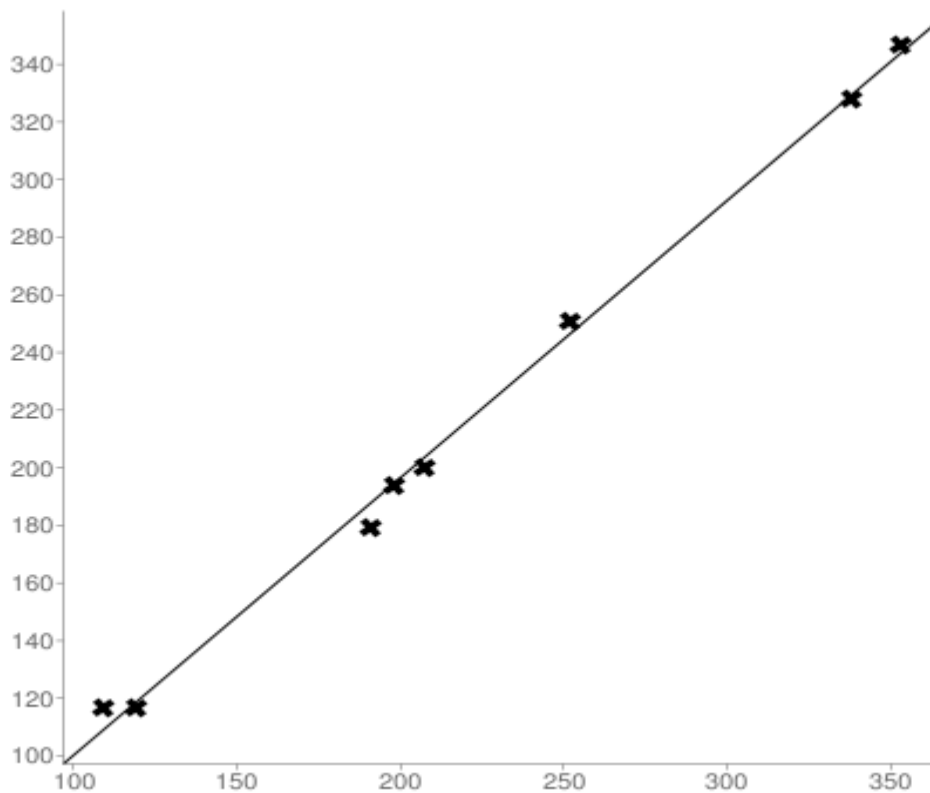
Mean x (\bar{x}): 220.875

Mean y (\bar{y}): 216.625

Intercept (a): 4.0912693771722

Slope (b): 0.96223533954874

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



Coefficient of Correlation (“r”): MCV

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

$$“r” = 0.995$$

Sample size: 8

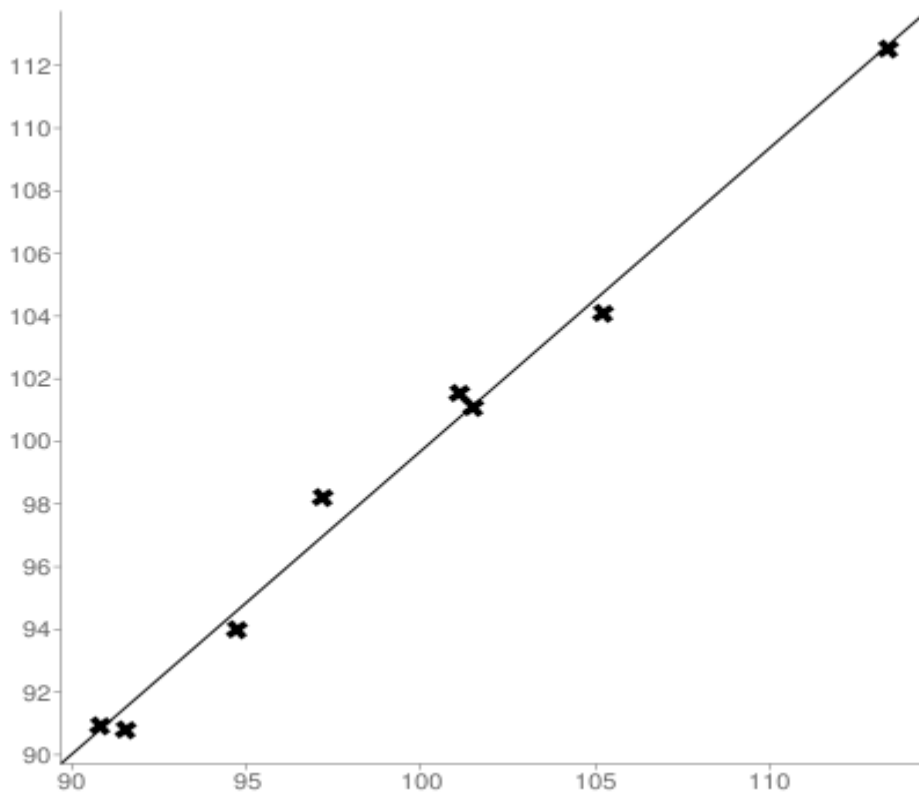
Mean x (\bar{x}): 99.425

Mean y (\bar{y}): 99.1375

Intercept (a): 3.0220295576336

Slope (b): 0.96671330593278

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

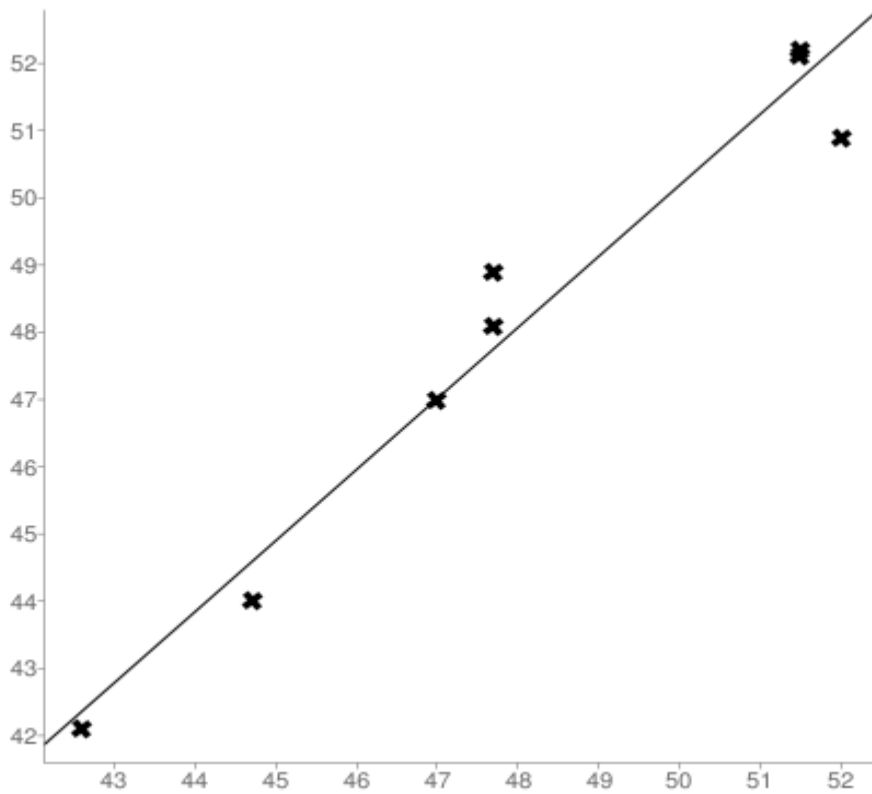


Coefficient of Correlation (“r”): HCT

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

$$“r” = 0.978$$

Sample size: 8
Mean x (\bar{x}): 48.0875
Mean y (\bar{y}): 48.1625
Intercept (a): -2.649725262112
Slope (b): 1.0566618198516
Regression line equation: $y=1.0566618198516x-2.649725262112$



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

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

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

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

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

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901

05-03-2023

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

DIAGON Ltd.

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


Coefficient of Variation:

Precision (VDx Reagent)

1. Fresh blood sample was collected and tested with the VDx Mindray Reagents on Mindray- BC3200, 3 Part Hematology Analyzer.
2. The sample was tested in 10 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 10

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

Coefficient of Variation:

Precision (Mindray Reference Reagent)

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

Fresh Blood Sample, n = 07

Precision Evaluation report of Mindray Reference reagents on Mindray-BC3200, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	1st	11nd Repeat	111rd Repeat	1Vth Repeat	Vth Repeat	V1th Repeat	V11th Repeat	V111th Repeat	1Xth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10 ³ /μL)	7.2	7.2	7.3	7.2	7.2	7.0	7.0				7.16	0.11	0.02	1.58
Lymph # (10 ³ /μL)	2.0	2.0	2.0	2.0	2.0	1.9	1.9				1.97	0.05	0.02	2.48
Mid# (10 ³ /μL)	0.5	0.5	0.5	0.5	0.5	0.6	0.6				0.53	0.05	0.09	9.23
Gran# (10 ³ /μL)	4.7	4.7	4.8	4.7	4.7	4.5	4.5				4.66	0.11	0.02	2.43
Lymph (%)	27.9	27.4	27.9	27.3	27.1	27.7	27.5				27.54	0.30	0.01	1.11
Mid (%)	7.1	7.6	6.7	7.2	7.1	8.3	8.0				7.43	0.56	0.08	7.60
Gran (%)	65.0	65.0	65.4	65.5	65.8	64.0	64.5				65.03	0.62	0.01	0.95
HGB (g/dL)	15.5	15.4	15.8	15.4	15.8	15.4	15.3				15.51	0.20	0.01	1.31
RBC (10 ³ /μL)	4.24	4.26	4.28	4.9	4.33	4.16	4.14				4.33	0.26	0.06	6.00
HCT (%)	48.6	48.9	49.1	47.7	49.3	47.4	47.4				48.34	0.82	0.02	1.70
MCV (fL)	114.7	114.9	114.9	114.0	114.0	114.0	114.7				114.46	0.44	0.00	0.38
MCH (pg)	36.5	36.1	36.9	36.7	36.4	37.4	36.9				36.70	0.42	0.01	1.15
MCHC (g/dL)	31.8	31.4	32.1	32.2	32.0	32.4	32.2				32.01	0.33	0.01	1.03
RDW-CV (%)	14.8	15.1	15.1	15.1	14.8	15.1	14.8				14.97	0.16	0.01	1.07
RDW-SD (fL)	61.3	63.1	63.1	59.5	61.1	62.1	63.1				61.90	1.36	0.02	2.20
PLT (10 ³ /μL)	207	219	209	214	221	212	202				212.00	6.68	0.03	3.15
MPV (fL)	9.6	9.7	9.6	9.8	9.6	9.7	9.7				9.67	0.08	0.01	0.78
PDW	16.0	16.0	15.8	15.9	15.8	15.8	15.9				15.89	0.09	0.01	0.57
PCT (%)	0.198	0.212	0.2	0.209	0.212	0.205	0.195				0.20	0.01	0.03	3.38

Conclusions

1. The V Dx Mindray 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 **0.978 to 0.998** displaying the highest degree of correlation between the reagents.
3. The V Dx Mindray and the Mindray Reference 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all the parameters.
4. The CV % of Precision with the V Dx Mindray reagents and the Mindray Reference reagents for the parameters are mentioned below.

Parameters	Sysmex Reference Reagents (CV % of Precision)	V Dx Sysmex Reagents (CV % of Precision)
Measured Parameters	0.38% – 6.00%	0.24% - 3.62%
Calculated Parameters	0.57% - 9.28%	0.96% - 6.98%

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