

## Performance Report

Sr. No.	Description
1.	<p data-bbox="386 940 1422 989">VDx Reagents - Prokan 3 Part Hematology Analyzers</p> <p data-bbox="867 1058 938 1106">v/s</p> <p data-bbox="324 1184 1487 1232">Reference Reagents - Mindray 3 Part Hematology Analyzer</p>

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# Details of Reagents

<b>Type of Reagents</b>	<b>3 Part Hematology Reagents</b>
<b>Instrument Model</b>	<b>Prokan – Orion60</b>
<b>Reference Reagents</b>	<b>Mindray Reference Reagents</b>
<b>M-30D Diluent</b>	<b>Lot No : 2022091601</b> <b>Expiry Date: 15-09-2024</b>
<b>M-30 CF Lyse</b>	<b>Lot No : 2022021601</b> <b>Expiry Date: 15-02-2024</b>

## Details of Tests Conducted

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

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

## Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the developed Vanguard compatible Prokan 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 Prokan Reagents for Prokan-Orion60, 3 Part Hematology Analyzer.

$$“r” = 0.991$$

**Sample size: 10**

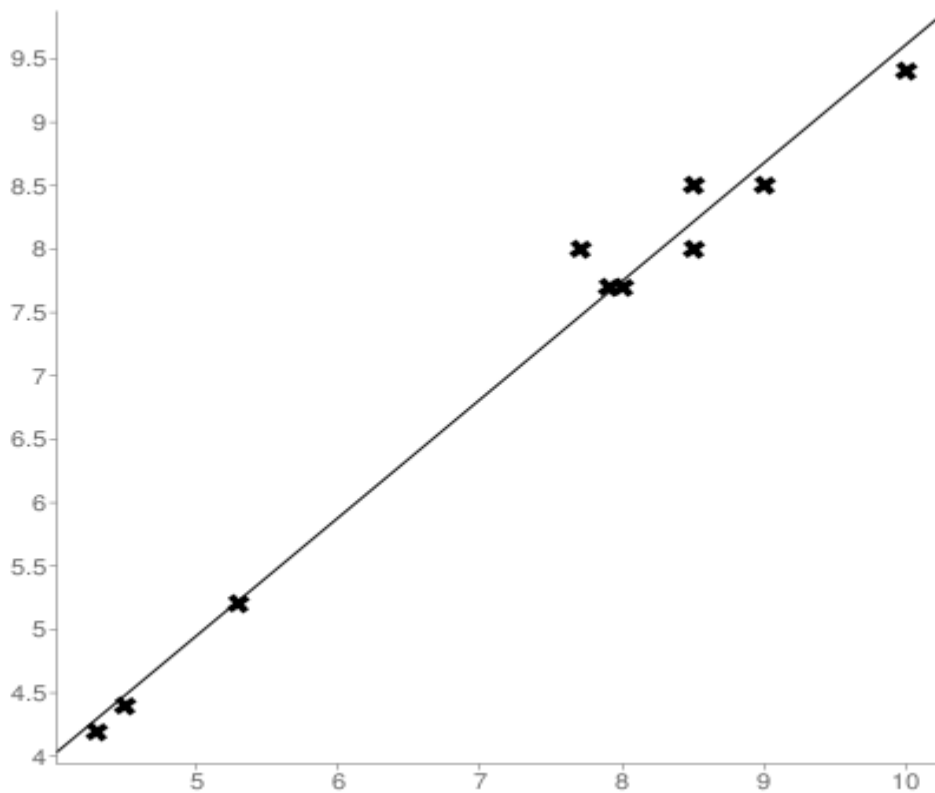
**Mean x ( $\bar{x}$ ): 7.37**

**Mean y ( $\bar{y}$ ): 7.16**

**Intercept (a): 0.28745015920369**

**Slope (b): 0.93250337052867**

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



## Coefficient of Correlation (“r”): RBC

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.  
y = VDX Prokan Reagents for Prokan-Orion60, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

**Sample size: 10**

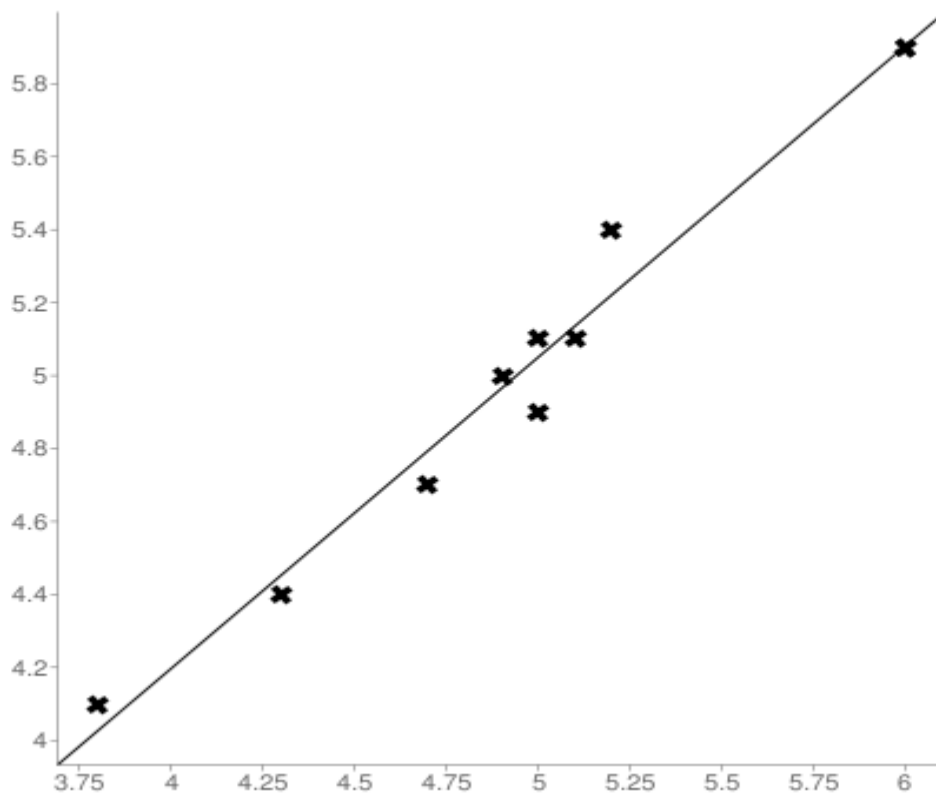
**Mean x ( $\bar{x}$ ): 5**

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

**Intercept (a): 0.78529411764707**

**Slope (b): 0.85294117647059**

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





# Coefficient of Correlation (“r”): Hemoglobin

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.  
y = VDX Prokan Reagents for Prokan-Orion60, 3 Part Hematology Analyzer.

**“r” = 0.992**

**Sample size: 10**

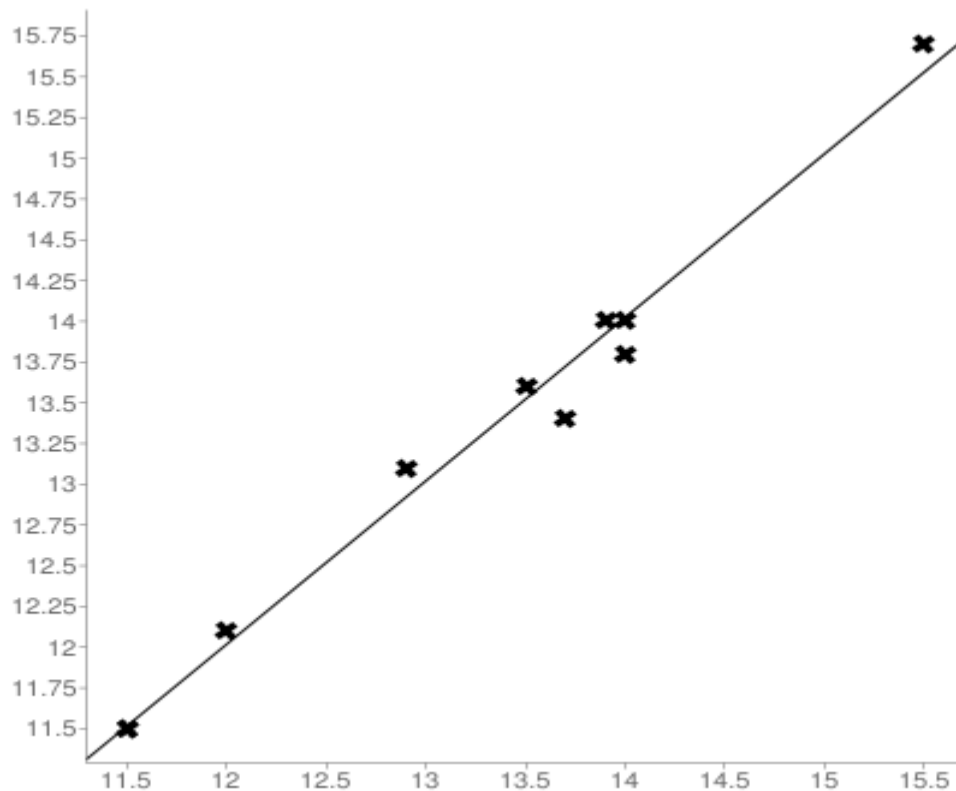
**Mean x (x̄): 13.25**

**Mean y (ȳ): 13.27**

**Intercept (a): -0.034136874361339**

**Slope (b): 1.0040858018386**

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



# Coefficient of Correlation (“r”): Platelets

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.  
y = VDX Prokan Reagents for Prokan-Orion60, 3 Part Hematology Analyzer.

$$“r” = 0.994$$

**Sample size: 10**

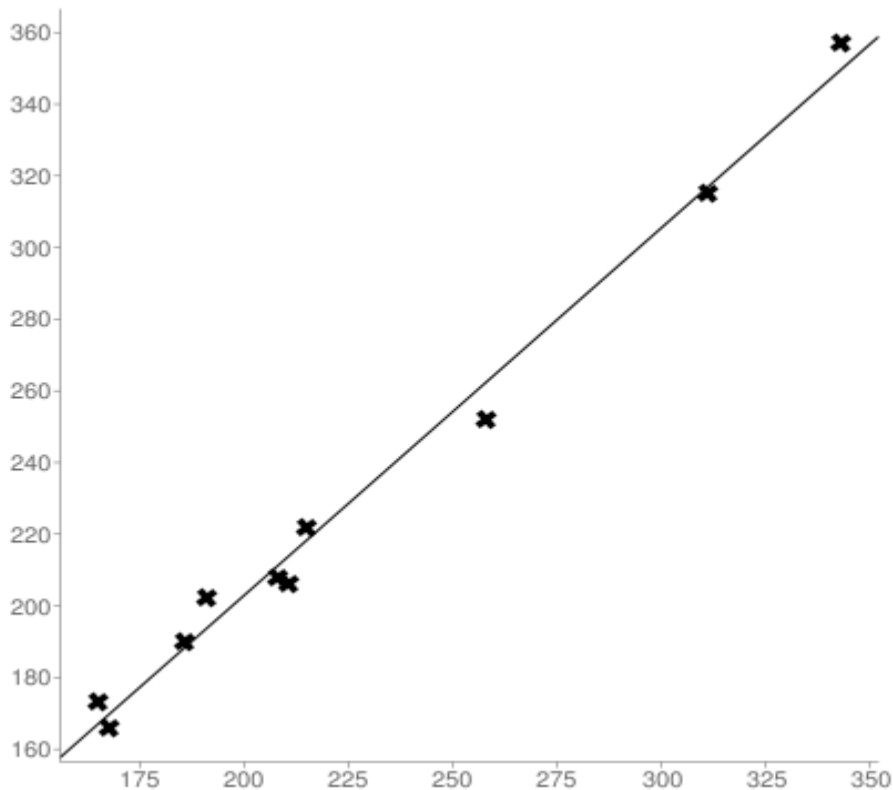
**Mean x ( $\bar{x}$ ): 225.6**

**Mean y ( $\bar{y}$ ): 229.1**

**Intercept (a): -2.6124109680038**

**Slope (b): 1.0270940202482**

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



# Coefficient of Correlation (“r”): MCV

x = Mindray Reference Reagents for Mindray-BC3200, 3 Part Hematology Analyzer.  
y = VDX Prokan Reagents for Prokan-Orion60, 3 Part Hematology Analyzer.

**“r” = 0.996**

**Sample size: 10**

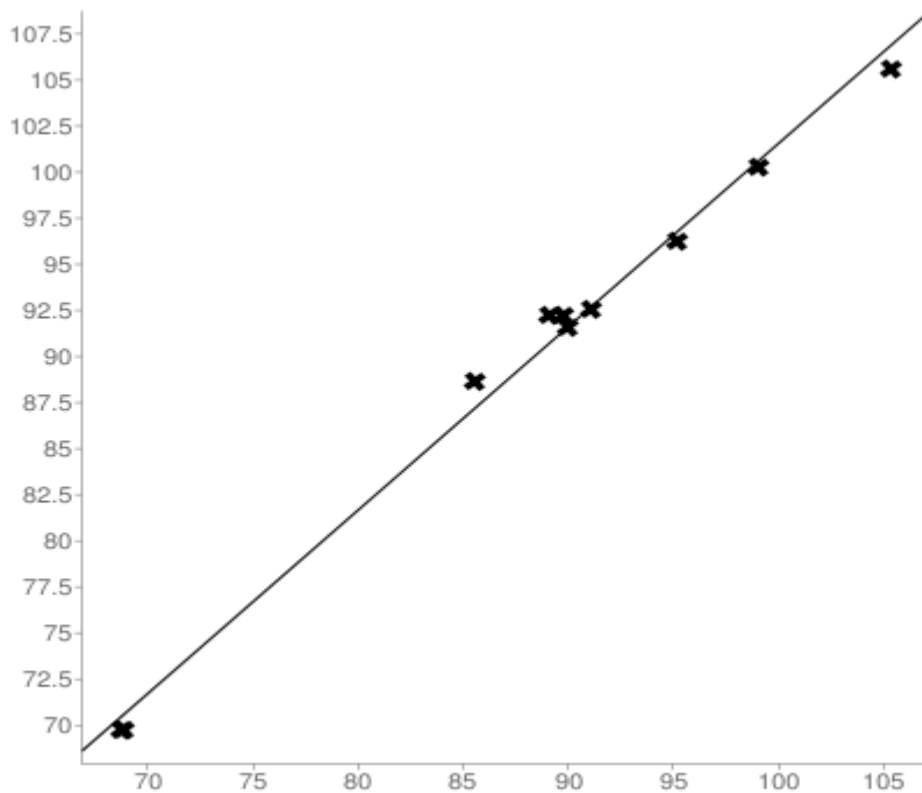
**Mean x ( $\bar{x}$ ): 88.28**

**Mean y ( $\bar{y}$ ): 89.89**

**Intercept (a): 2.1055650130758**

**Slope (b): 0.99438644072184**

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



## **Performance with Hematology 3<sup>rd</sup> 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-P Lot- HVDP220304 VDx Cleaner-P Lot- HVCP220908 VDx Lyse-P Lot- HVLP220808	Range
WBC (10 <sup>3</sup> /μL)	2.3	1.8 - 2.8
Lym (%)	46.7	34.8 - 58.0
MID (%)	7.3	0.0 - 14.2
Gran (%)	46.0	30.2 - 62.8
Lym# (10 <sup>3</sup> /μL)	1.10	0.8 - 1.4
MID# (10 <sup>3</sup> /μL)	0.20	0.0 - 0.4
Gran# (10 <sup>3</sup> /μL)	1.00	0.6 - 1.4
RBC (10 <sup>3</sup> /μL)	2.54	2.35 - 2.75
HGB (g/dL)	6.8	6.5 - 7.5
HCT (%)	23.0	20.8 - 26.8
MCV (fL)	90.90	87.4 - 99.4
MCH (pg)	26.7	23.4 - 31.0
MCHC (g/dL)	29.5	24.4 - 34.0
RDW-SD (fL)	55.6	51.3 - 57.3
RDW-CV (%)	17.7	11.9 - 21.9
PLT (10 <sup>3</sup> /μL)	67	38 - 88
MPV (fL)	9.9	7.1 - 13.1
PDW (%)	10.7	6.2 - 18.2
PCT (%)	0.06	0.02 - 0.10
P-LCR (%)	11.9	

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

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

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

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

**CONTROL**
**ASSAY VALUES AND EXPECTED RANGES**

**LOT: 1V0901**  
**05-03-2023**

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


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# Coefficient of Variation:

## Precision (VDx Reagent)

1. Fresh blood sample was collected and tested with the VDx Prokan Reagents on Prokan Orion60, 3 Part Hematology Analyzer.
2. The sample was tested in 09 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

**Fresh Blood Sample, n = 09**

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

## Conclusions

4. The VDX Prokan 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Mindray Original reagents as Reference.
5. All Measurable parameters showed values of “r” in the range of 0.950 to 0.996 displaying the highest degree of correlation between the reagents.
6. The VDX Prokan 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all parameters.
7. The CV % of Precision with the VDX Prokan reagents for the parameters are mentioned below.

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

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