

## Performance Report

Sr. No.	Description
1.	<p data-bbox="391 940 1419 989">VDx Reagents - Genrui 3 Part Hematology Analyzers</p> <p data-bbox="867 1058 938 1106">v/s</p> <p data-bbox="342 1184 1471 1232">Reference Reagents - Genrui 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>Genrui- SB22+</b>
<b>Reference Reagents</b>	<b>Genius Reference Reagents</b>
<b>KT03 Diluent</b>	<b>Lot No : 20221103</b> <b>Expiry Date: 02-10-2024</b>
<b>KT03 Lyse Solution</b>	<b>Lot No : 20221102</b> <b>Expiry Date: 01-09-2024</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 Genius Compatible reagents)
5	Coefficient of Variation: Precision (Genius Reference reagents)

Background		
Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102
WBC (10 <sup>9</sup> /L)	0.00	0.00
Lym# (10 <sup>9</sup> /L)	0.00	0.00
Mid# (10 <sup>9</sup> /L)	0.00	0.00
Gran# (10 <sup>9</sup> /L)	0.00	0.00
Lym (%)	0.00	0.00
Mid (%)	0.00	0.00
Gran (%)	0.00	0.00
NLR	0.00	0.00
PLR	0.00	0.00
RBC (10 <sup>12</sup> /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 <sup>9</sup> /L)	0.00	0.00
MPV (fL)	0.00	0.00
PDW-CV (%)	0.00	0.00
PDW-SD (fL)	0.00	0.00
PCT (%)	0.00	0.00
P-LCC (10 <sup>9</sup> /L)	0.00	0.00
P-LCR (%)	0.00	0.00

# Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the developed Vanguard compatible Genius reagents and the Genius 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 = Genius Reference Reagents for Genius-SB22+, 3 Part Hematology Analyzer.  
y = VDX Genius Reagents for Genius – SB22+, 3 Part Hematology Analyzer.

“r” = 0.996

**Sample size: 15**

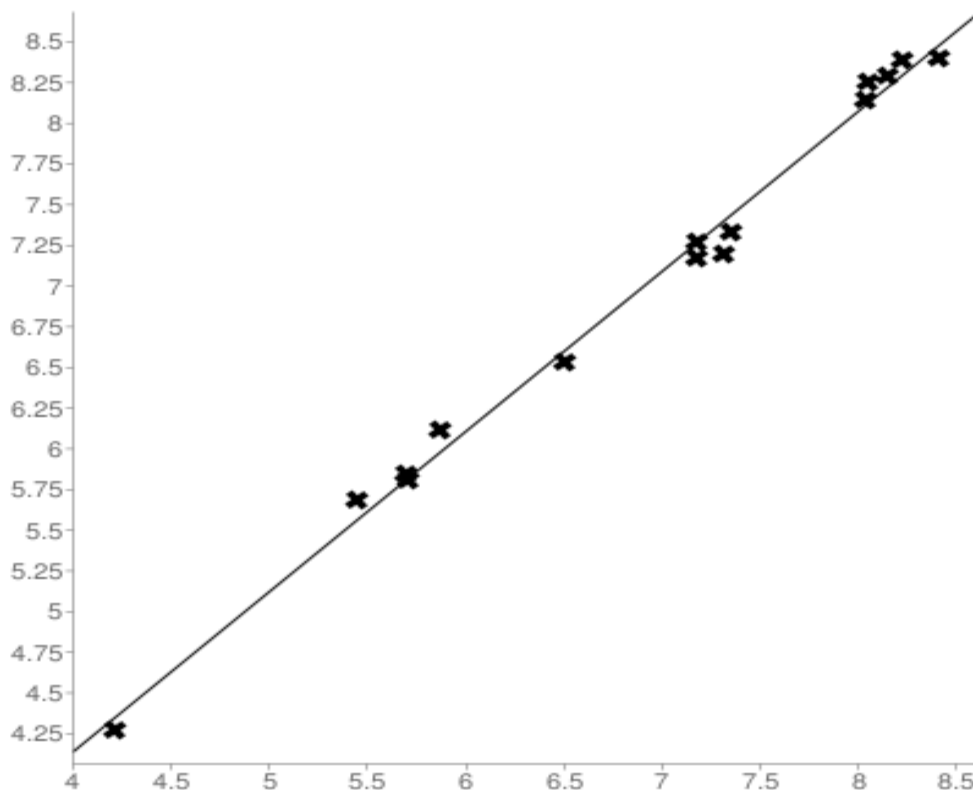
**Mean x ( $\bar{x}$ ): 6.88733333333333**

**Mean y ( $\bar{y}$ ): 6.97933333333333**

**Intercept (a): 0.20174969262643**

**Slope (b): 0.98406499477886**

**Regression line equation:  $y=0.20174969262643+0.98406499477886x$**



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

x = Genius Reference Reagents for Genius-SB22+, 3 Part Hematology Analyzer.  
y = VDX Genius Reagents for Genius – SB22+, 3 Part Hematology Analyzer.

“r” = 0.990

**Sample size: 15**

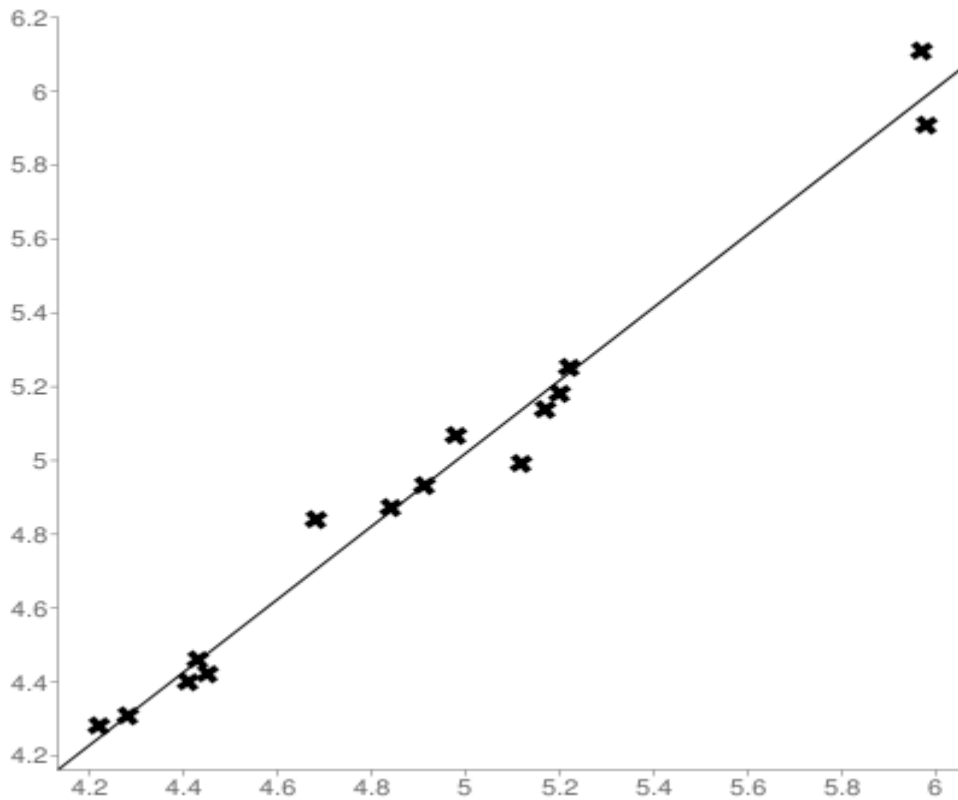
**Mean x ( $\bar{x}$ ): 4.924**

**Mean y ( $\bar{y}$ ): 4.944**

**Intercept (a): 0.079768133117882**

**Slope (b): 0.98786187385908**

**Regression line equation:  $y=0.079768133117882+0.98786187385908x$**





# Coefficient of Correlation (“r”): Hemoglobin

x = Genius Reference Reagents for Genius-SB22+, 3 Part Hematology Analyzer.  
y = VDX Genius Reagents for Genius – SB22+, 3 Part Hematology Analyzer.

“r” = 0.991

**Sample size: 15**

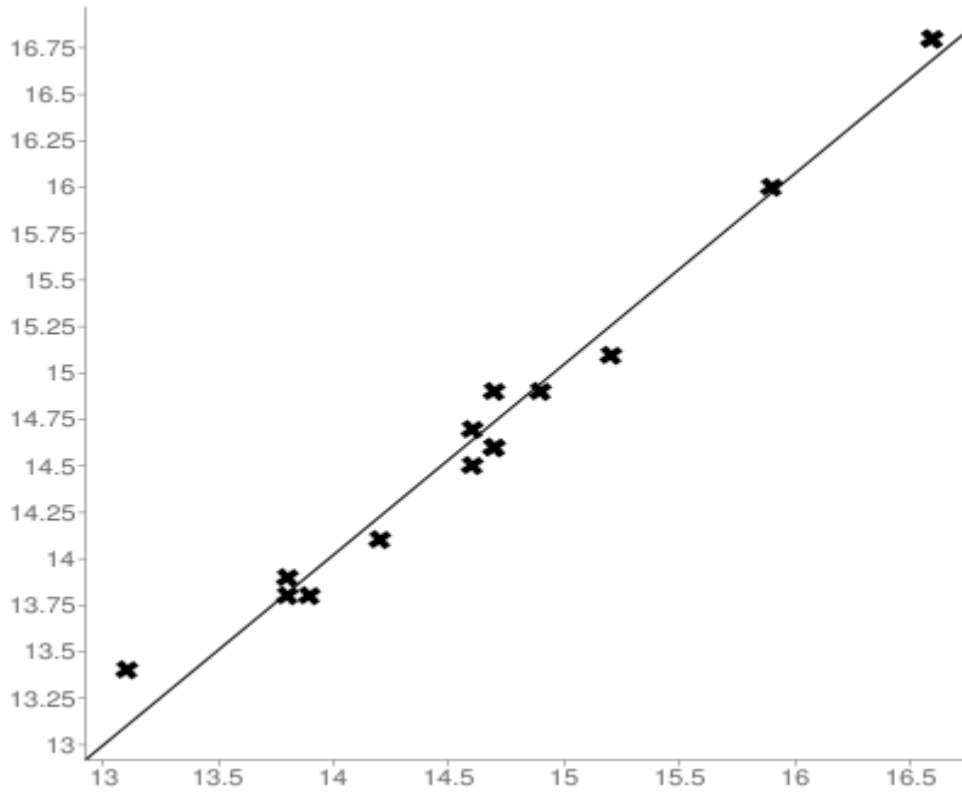
**Mean x (x̄): 14.753333333333**

**Mean y (ȳ): 14.793333333333**

**Intercept (a): -0.33733568298641**

**Slope (b): 1.0255763002476**

**Regression line equation:  $y = 1.0255763002476x - 0.33733568298641$**



# Coefficient of Correlation (“r”): Platelets

x = Genius Reference Reagents for Genius-SB22+, 3 Part Hematology Analyzer.  
y = VDX Genius Reagents for Genius – SB22+, 3 Part Hematology Analyzer.

**“r” = 0.993**

**Sample size: 15**

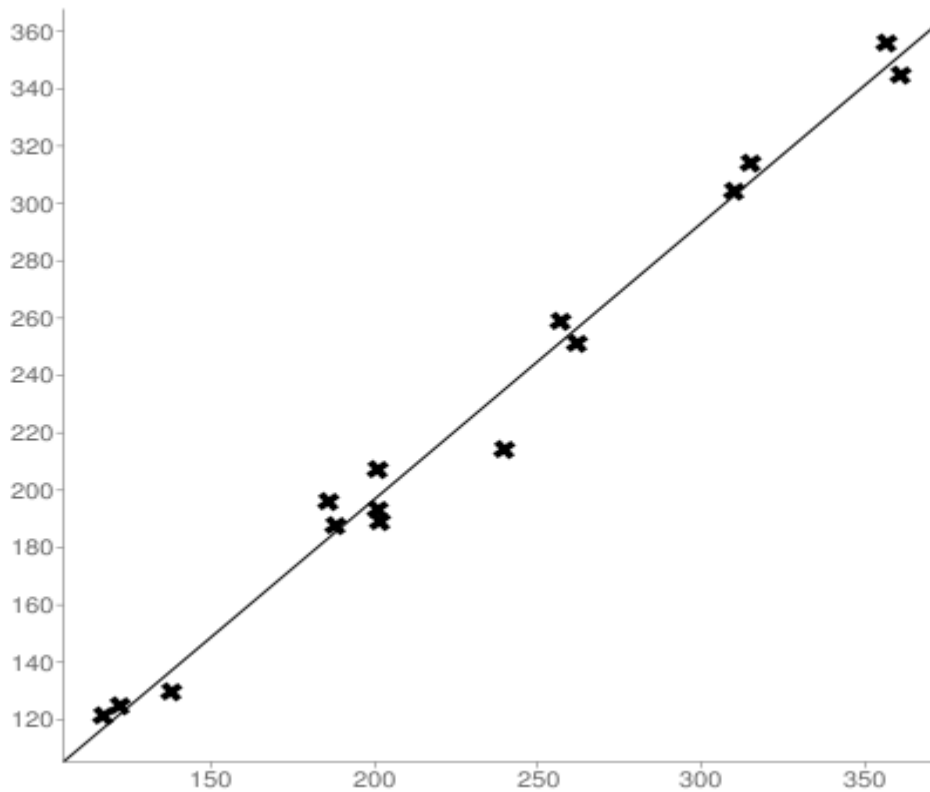
**Mean x ( $\bar{x}$ ): 230.466666666667**

**Mean y ( $\bar{y}$ ): 226.133333333333**

**Intercept (a): 4.5194251474097**

**Slope (b): 0.96158768376883**

**Regression line equation:  $y=4.5194251474097+0.96158768376883x$**



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

x = Genius Reference Reagents for Genius-SB22+, 3 Part Hematology Analyzer.

y = VDX Genius Reagents for Genius – SB22+, 3 Part Hematology Analyzer.

$$“r” = 0.999$$

**Sample size: 15**

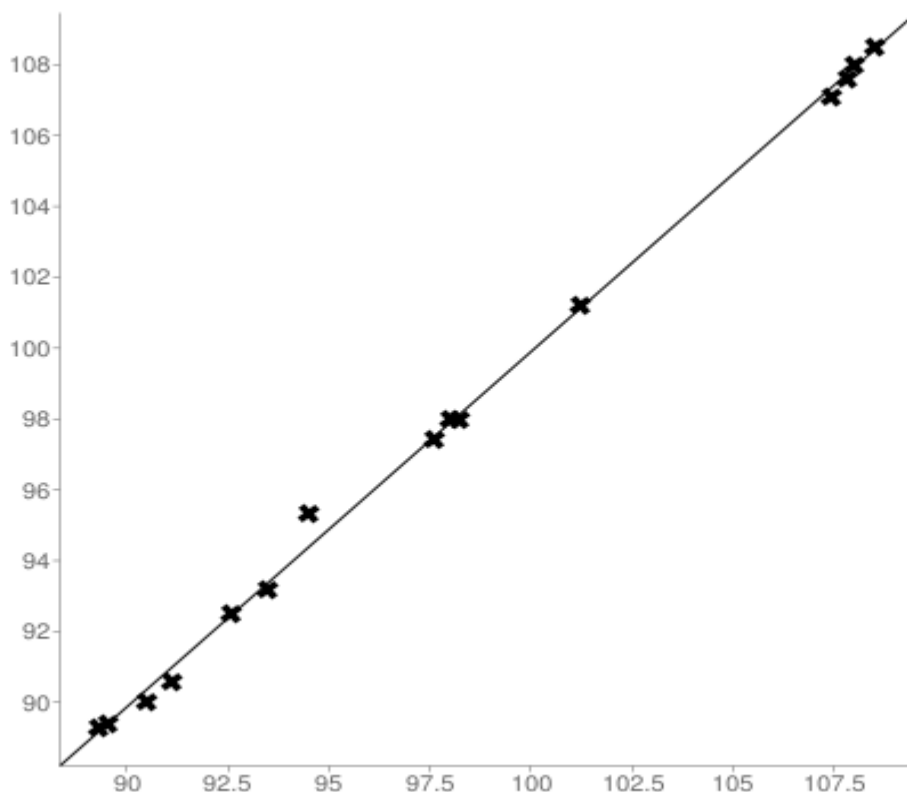
**Mean x (x̄): 97.8466666666667**

**Mean y (ȳ): 97.74**

**Intercept (a): -0.40021683919771**

**Slope (b): 1.003000103964**

**Regression line equation:  $y = 1.003000103964x - 0.40021683919771$**



# 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-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 <sup>9</sup> /L)	1.92	1.95	1.5 - 2.5
Lym# (10 <sup>9</sup> /L)	0.83	0.70	0.6 - 1.2
Mid# (10 <sup>9</sup> /L)	0.12	0.13	0.0 - 0.2
Gran# (10 <sup>9</sup> /L)	0.97	1.12	0.6 - 1.4
Lym (%)	43.30	35.80	32.7 - 54.5
Mid (%)	6.10	6.60	0.4 - 13.0
Gran (%)	50.60	57.60	32.3 - 67.1
NLR	1.17	1.60	
PLR	93.98	112.86	
RBC (10 <sup>12</sup> /L)	2.47	2.47	2.29 - 2.69
HGB (g/dL)	6.70	6.70	6.3 - 7.3
HCT (%)	21.30	21.50	18.9 - 24.9
MCV (fL)	86.30	86.80	81.9 - 93.9
MCH (pg)	27.30	27.20	23.6 - 31.2
MCHC (g/dL)	31.60	31.40	26.4 - 36.0
RDW-CV (%)	16.50	17.20	11.3 - 21.3
RDW-SD (fL)	52.20	54.50	42.4 - 62.4
PLT (10 <sup>9</sup> /L)	78.00	79.00	53 – 103
MPV (fL)	11.60	11.60	8.1 - 14.1
PDW-CV (%)	7.20	7.70	5.2 - 11.2
PDW-SD (fL)	10.40	11.20	
PCT (%)	0.09	0.09	0.036 - 0.136
P-LCC (10 <sup>9</sup> /L)	35.00	36.00	
P-LCR (%)	44.80	46.30	

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

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 <sup>9</sup> /L)	6.87	6.91	5.9 - 7.9
Lym# (10 <sup>9</sup> /L)	1.88	1.91	1.2 - 2.6
Mid# (10 <sup>9</sup> /L)	0.58	0.61	0.1 - 1.1
Gran# (10 <sup>9</sup> /L)	4.41	4.39	3.7 - 5.1
Lym (%)	27.30	27.60	18.0 - 37.4
Mid (%)	8.50	8.80	1.8 - 16.2
Gran (%)	64.20	63.60	50.6 - 76.0
NLR	2.35	2.30	
PLR	122.34	117.80	
RBC (10 <sup>12</sup> /L)	4.53	4.57	4.28 - 4.88
HGB (g/dL)	13.20	13.30	12.7 - 13.9
HCT (%)	42.00	42.40	39.1 - 47.1
MCV (fL)	92.70	92.70	88.1 - 100.1
MCH (pg)	29.00	29.10	25.3 - 32.9
MCHC (g/dL)	31.30	31.40	26.1 - 35.7
RDW-CV (%)	17.50	17.50	12.1 - 22.1
RDW-SD (fL)	59.50	59.40	49.0 - 69.0
PLT (10 <sup>9</sup> /L)	230.00	225.00	184 – 274
MPV (fL)	12.00	11.80	8.3 - 14.3
PDW-CV (%)	7.70	7.50	5.7 - 11.7
PDW-SD (fL)	11.10	10.70	
PCT (%)	0.28	0.27	0.160 - 0.360
P-LCC (10 <sup>9</sup> /L)	110.00	104.00	
P-LCR (%)	47.80	46.20	

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

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-G Lot- HD1G221117 VDx Lyse-G Lot - HLYG220911	All Reagents: Genius as Reference Diluent Lot- 20221103 Lyse Lot- 20221102	Range
WBC (10 <sup>9</sup> /L)	17.80	17.87	15.3 - 20.3
Lym# (10 <sup>9</sup> /L)	3.81	3.86	1.7 - 6.1
Mid# (10 <sup>9</sup> /L)	1.66	1.72	0.4 - 3.0
Gran# (10 <sup>9</sup> /L)	12.33	12.29	8.5 - 15.9
Lym (%)	21.40	21.60	14.4 - 29.8
Mid (%)	9.30	9.60	1.9 - 17.1
Gran (%)	69.30	68.80	58.1 - 78.7
NLR	3.24	3.18	
PLR	125.72	120.47	
RBC (10 <sup>12</sup> /L)	5.68	5.69	5.25 - 6.05
HGB (g/dL)	17.00	17.20	16.7 - 18.3
HCT (%)	56.70	56.60	52.2 - 61.2
MCV (fL)	99.80	99.50	94.4 - 106.4
MCH (pg)	30.00	30.30	27.1 - 34.7
MCHC (g/dL)	30.10	30.40	26.0 - 35.6
RDW-CV (%)	17.20	17.40	12.1 - 22.1
RDW-SD (fL)	62.80	63.40	52.9 - 72.9
PLT (10 <sup>9</sup> /L)	479.00	465.00	401 - 551
MPV (fL)	12.20	12.30	8.7 - 14.7
PDW-CV (%)	7.80	7.60	6.0 - 12.0
PDW-SD (fL)	11.60	11.20	
PCT (%)	0.585	0.570	0.359 - 0.759
P-LCC (10 <sup>9</sup> /L)	244.00	231.00	
P-LCR (%)	50.80	49.70	

**ASSAY VALUES AND EXPECTED RANGES**

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

<b>Instruments:</b>		<i>Genrui KT-6400, KT-63xx, KT-6200 version 2.85 or higher</i>					
		<b>Councill-23 Ultra</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>	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
<b>WBC</b>	10 <sup>9</sup> /L	<b>2,0 ± 0,5</b>	1,5 - 2,5	<b>6,9 ± 1,0</b>	5,9 - 7,9	<b>17,8 ± 2,5</b>	15,3 - 20,3
<b>LYM%</b>	%	<b>43,6 ± 10,9</b>	32,7 - 54,5	<b>27,7 ± 9,7</b>	18,0 - 37,4	<b>22,1 ± 7,7</b>	14,4 - 29,8
<b>MID%</b>	%	<b>6,7 ± 6,3</b>	0,4 - 13,0	<b>9,0 ± 7,2</b>	1,8 - 16,2	<b>9,5 ± 7,6</b>	1,9 - 17,1
<b>NEUT%</b>	%	<b>49,7 ± 17,4</b>	32,3 - 67,1	<b>63,3 ± 12,7</b>	50,6 - 76,0	<b>68,4 ± 10,3</b>	58,1 - 78,7
<b>LYM#</b>	10 <sup>9</sup> /L	<b>0,9 ± 0,3</b>	0,6 - 1,2	<b>1,9 ± 0,7</b>	1,2 - 2,6	<b>3,9 ± 2,2</b>	1,7 - 6,1
<b>MID#</b>	10 <sup>9</sup> /L	<b>0,1 ± 0,1</b>	0,0 - 0,2	<b>0,6 ± 0,5</b>	0,1 - 1,1	<b>1,7 ± 1,3</b>	0,4 - 3,0
<b>NEUT#</b>	10 <sup>9</sup> /L	<b>1,0 ± 0,4</b>	0,6 - 1,4	<b>4,4 ± 0,7</b>	3,7 - 5,1	<b>12,2 ± 3,7</b>	8,5 - 15,9
<b>RBC</b>	10 <sup>12</sup> /L	<b>2,49 ± 0,20</b>	2,29 - 2,69	<b>4,58 ± 0,30</b>	4,28 - 4,88	<b>5,65 ± 0,40</b>	5,25 - 6,05
<b>HGB</b>	g/dL	<b>6,8 ± 0,5</b>	6,3 - 7,3	<b>13,3 ± 0,6</b>	12,7 - 13,9	<b>17,5 ± 0,8</b>	16,7 - 18,3
	g/L	<b>68 ± 5</b>	63 - 73	<b>133 ± 6</b>	127 - 139	<b>175 ± 8</b>	167 - 183
<b>HCT</b>	%	<b>21,9 ± 3,0</b>	18,9 - 24,9	<b>43,1 ± 4,0</b>	39,1 - 47,1	<b>56,7 ± 4,5</b>	52,2 - 61,2
	L/L	<b>0,219 ± 0,030</b>	0,189 - 0,249	<b>0,431 ± 0,040</b>	0,391 - 0,471	<b>0,567 ± 0,045</b>	0,522 - 0,612
<b>MCV</b>	fL	<b>87,9 ± 6,0</b>	81,9 - 93,9	<b>94,1 ± 6,0</b>	88,1 - 100,1	<b>100,4 ± 6,0</b>	94,4 - 106,4
<b>MCH</b>	pg	<b>27,4 ± 3,8</b>	23,6 - 31,2	<b>29,1 ± 3,8</b>	25,3 - 32,9	<b>30,9 ± 3,8</b>	27,1 - 34,7
<b>MCHC</b>	g/dL	<b>31,2 ± 4,8</b>	26,4 - 36,0	<b>30,9 ± 4,8</b>	26,1 - 35,7	<b>30,8 ± 4,8</b>	26,0 - 35,6
	g/L	<b>312 ± 48</b>	264 - 360	<b>309 ± 48</b>	261 - 357	<b>308 ± 48</b>	260 - 356
<b>RDW-SD</b>	fL	<b>52,4 ± 10,0</b>	42,4 - 62,4	<b>59,0 ± 10,0</b>	49,0 - 69,0	<b>62,9 ± 10,0</b>	52,9 - 72,9
<b>RDW-CV</b>	%	<b>16,3 ± 5,0</b>	11,3 - 21,3	<b>17,1 ± 5,0</b>	12,1 - 22,1	<b>17,1 ± 5,0</b>	12,1 - 22,1
<b>Plt</b>	10 <sup>9</sup> /L	<b>78 ± 25</b>	53 - 103	<b>229 ± 45</b>	184 - 274	<b>476 ± 75</b>	401 - 551
<b>MPV</b>	fL	<b>11,1 ± 3,0</b>	8,1 - 14,1	<b>11,3 ± 3,0</b>	8,3 - 14,3	<b>11,7 ± 3,0</b>	8,7 - 14,7
<b>PDW</b>	%	<b>8,2 ± 3,0</b>	5,2 - 11,2	<b>8,7 ± 3,0</b>	5,7 - 11,7	<b>9,0 ± 3,0</b>	6,0 - 12,0
<b>PCT</b>	%	<b>0,086 ± 0,050</b>	0,036 - 0,136	<b>0,260 ± 0,100</b>	0,160 - 0,360	<b>0,559 ± 0,200</b>	0,359 - 0,759


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# Coefficient of Variation:

## Precision (VDx Reagent)

1. Fresh blood sample was collected and tested with the VDx Genius Reagents on Genius-SB22+, 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 Genius compatible reagent on Genius-SB22+, 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 <sup>9</sup> /L)	8.33	8.45	8.49	8.36	8.41	8.33	8.70	8.35	8.27	8.18	<b>8.39</b>	<b>0.14</b>	<b>0.02</b>	<b>1.68</b>
Lym# (10 <sup>9</sup> /L)	2.06	2.10	2.05	2.03	1.93	1.98	2.10	1.99	1.98	2.08	<b>2.03</b>	<b>0.06</b>	<b>0.03</b>	<b>2.85</b>
Mid# (10 <sup>9</sup> /L)	0.87	0.99	0.97	0.91	0.93	0.94	0.96	0.94	0.99	0.90	<b>0.94</b>	<b>0.04</b>	<b>0.04</b>	<b>4.17</b>
Gran# (10 <sup>9</sup> /L)	5.40	5.35	5.47	5.42	5.55	5.41	5.64	5.42	5.30	5.20	<b>5.42</b>	<b>0.12</b>	<b>0.02</b>	<b>2.27</b>
Lym (%)	24.70	24.80	24.20	24.30	22.90	23.80	24.10	23.80	24.00	25.40	<b>24.20</b>	<b>0.68</b>	<b>0.03</b>	<b>2.80</b>
Mid (%)	10.40	11.80	11.40	10.90	11.00	11.30	11.00	11.20	12.00	11.00	<b>11.20</b>	<b>0.46</b>	<b>0.04</b>	<b>4.10</b>
Gran (%)	64.90	63.40	64.40	64.80	66.10	64.90	64.90	65.00	64.00	63.60	<b>64.60</b>	<b>0.79</b>	<b>0.01</b>	<b>1.22</b>
RBC (10 <sup>12</sup> /L)	5.11	5.19	5.22	5.15	5.18	5.16	5.26	5.25	5.11	5.14	<b>5.18</b>	<b>0.05</b>	<b>0.01</b>	<b>1.03</b>
HGB (g/dL)	16.20	16.20	16.30	16.30	16.30	16.30	16.40	16.40	16.10	16.10	<b>16.26</b>	<b>0.11</b>	<b>0.01</b>	<b>0.66</b>
HCT (%)	49.80	50.60	51.10	50.20	50.50	50.50	51.40	51.40	50.00	50.20	<b>50.57</b>	<b>0.56</b>	<b>0.01</b>	<b>1.11</b>
MCV (fL)	97.40	97.60	97.90	97.60	97.50	97.70	97.80	97.90	97.90	97.80	<b>97.71</b>	<b>0.18</b>	<b>0.00</b>	<b>0.18</b>
MCH (pg)	31.60	31.20	31.20	31.60	31.50	31.60	31.20	31.10	31.50	31.30	<b>31.38</b>	<b>0.20</b>	<b>0.01</b>	<b>0.63</b>
MCHC (g/dL)	32.50	32.00	31.90	32.40	32.30	32.30	31.90	31.80	32.20	32.00	<b>32.13</b>	<b>0.24</b>	<b>0.01</b>	<b>0.75</b>
RDW-CV (%)	14.20	14.30	14.30	14.20	14.50	14.20	14.20	14.20	14.40	14.50	<b>14.30</b>	<b>0.12</b>	<b>0.01</b>	<b>0.87</b>
RDW-SD (fL)	50.60	50.90	51.10	50.70	51.80	50.70	50.80	50.90	51.60	51.90	<b>51.10</b>	<b>0.49</b>	<b>0.01</b>	<b>0.95</b>
PLT (10 <sup>9</sup> /L)	217.00	219.00	216.00	218.00	220.00	206.00	211.00	216.00	215.00	207.00	<b>214.50</b>	<b>4.88</b>	<b>0.02</b>	<b>2.28</b>
MPV (fL)	15.00	14.80	15.10	15.00	15.00	14.80	14.90	15.00	14.60	14.90	<b>14.91</b>	<b>0.14</b>	<b>0.01</b>	<b>0.97</b>
PDW-CV (%)	15.00	15.50	14.90	15.00	15.00	14.80	15.20	14.90	14.70	15.30	<b>15.03</b>	<b>0.24</b>	<b>0.02</b>	<b>1.60</b>
PDW-SD (fL)	28.70	29.40	28.50	28.60	28.90	28.10	28.80	28.40	27.60	29.10	<b>28.61</b>	<b>0.51</b>	<b>0.02</b>	<b>1.78</b>
PCT (%)	0.33	0.33	0.33	0.33	0.33	0.31	0.31	0.32	0.32	0.31	<b>0.32</b>	<b>0.01</b>	<b>0.03</b>	<b>2.67</b>
P-LCC (10 <sup>9</sup> /L)	136.00	136.00	139.00	137.00	139.00	129.00	129.00	136.00	131.00	127.00	<b>133.90</b>	<b>4.46</b>	<b>0.03</b>	<b>3.33</b>
P-LCR (%)	62.50	62.00	64.20	62.80	63.00	62.50	61.40	62.90	61.00	61.30	<b>62.36</b>	<b>0.96</b>	<b>0.02</b>	<b>1.54</b>

# Coefficient of Variation:

## Precision (Genius Reference Reagent)

1. Fresh blood sample was collected and tested with the Genius Reference Reagents on Genius SB22+, 3 Part Hematology Analyzer.
2. The sample was tested in 06 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

### Fresh Blood Sample, n = 06

Precision Evaluation report of Genius Reference reagents on Genius-SB22+, 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 <sup>9</sup> /L)	6.57	6.75	6.69	6.63	6.83	6.73					6.70	0.09	0.01	1.37
Lym# (10 <sup>9</sup> /L)	1.78	1.81	1.81	1.92	1.95	1.76					1.84	0.08	0.04	4.23
Mid# (10 <sup>9</sup> /L)	0.88	0.90	0.94	0.82	0.86	0.95					0.89	0.05	0.06	5.51
Gran# (10 <sup>9</sup> /L)	4.01	4.04	3.94	3.89	4.02	4.02					3.99	0.06	0.01	1.47
Lym (%)	25.60	26.80	27.00	29.00	28.60	26.20					27.20	1.34	0.05	4.92
Mid (%)	13.40	13.40	14.10	12.40	12.60	14.10					13.33	0.72	0.05	5.40
Gran (%)	61.00	59.80	58.90	58.60	58.80	59.70					59.47	0.90	0.02	1.51
RBC (10 <sup>12</sup> /L)	5.06	5.11	5.11	5.08	5.17	5.13					5.11	0.04	0.01	0.75
HGB (g/dL)	13.70	13.90	13.80	13.90	14.10	13.90					13.88	0.13	0.01	0.96
HCT (%)	45.80	46.10	46.20	45.80	46.70	46.20					46.13	0.33	0.01	0.72
MCV (fL)	90.50	90.30	90.40	90.20	90.30	90.00					90.28	0.17	0.00	0.19
MCH (pg)	27.10	27.20	26.90	27.30	27.20	27.10					27.13	0.14	0.01	0.50
MCHC (g/dL)	30.00	30.10	29.80	30.30	30.10	30.10					30.07	0.16	0.01	0.54
RDW-CV (%)	15.20	15.30	15.00	15.10	15.10	15.00					15.12	0.12	0.01	0.77
RDW-SD (fL)	50.00	50.20	49.30	49.40	49.30	49.10					49.55	0.44	0.01	0.89
PLT (10 <sup>9</sup> /L)	141.00	140.00	138.00	139.00	151.00	141.00					141.67	4.72	0.03	3.33
MPV (fL)	14.80	15.00	14.70	14.40	15.10	14.90					14.82	0.25	0.02	1.68
PDW-CV (%)	15.70	15.90	15.70	16.60	15.50	15.80					15.87	0.38	0.02	2.41
PDW-SD (fL)	29.60	30.60	29.50	30.60	29.80	30.00					30.02	0.48	0.02	1.61
PCT (%)	0.21	0.21	0.20	0.20	0.21	0.21					0.21	0.00	0.02	2.36
P-LCC (10 <sup>9</sup> /L)	87.00	86.00	82.00	81.00	86.00	86.00					84.67	2.50	0.03	2.96
P-LCR (%)	61.60	61.50	60.00	58.20	63.60	60.90					60.97	1.80	0.03	2.95

## Conclusions

1. The VDX Genius 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Genius Original reagents as Reference.
2. All Measurable parameters showed values of “r” in the range of **0.0.990 to 0.999** displaying the highest degree of correlation between the reagents.
3. The VDX Genius and the Genius Reference 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all parameters.
4. The CV % of Precision with the VDX Genius reagents and the Genius Reference reagents for the parameters are mentioned below.

Parameters	Genius Reference Reagents (CV % of Precision)	VDx Genius Reagents (CV % of Precision)
Measured Parameters	0.19% – 3.33%	0.18% - 2.28%
Calculated Parameters	0.50% - 5.51%	0.63% - 4.17%

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