InSight V3 PLUS Veterinary Haematology Analyser

Performance Evaluation Report

Contents

1. Testing Information

Date: 01/04/2021 – 28/04/2021

Environment
Temperature: 25-28°C
Relative Humidity: 50-60%

2. Results Summary

2.1 Blank

2.2.1 Dog

Parameter	Requirement	Result	
		V3-1#	Conclusion
WBC	≤0.20×10^9 /L	0×10^9 /L	Passed
RBC	≤0.02×10^12 /L	0×10^12 /L	Passed
HGB	≤1g /L	0g /L	Passed
PLT	≤10.0×10^9/L	1×10^9/L	Passed

2.1.2 Cat

Parameter	Requirement	Result	
		V3-1#	Conclusion
WBC	≤0.20×10^9 /L	0×10^9 /L	Passed
RBC	≤0.02×10^12 /L	0×10^12 /L	Passed
HGB	≤1g /L	0g /L	Passed
PLT	≤10.0×10^9/L	0×10^9/L	Passed

2.1.3 Rabbit

Parameter	Requirement	Result	
		V3-1#	Conclusion
WBC	≤0.20×10^9 /L	0×10^9 /L	Passed
RBC	≤0.02×10^12 /L	0×10^12 /L	Passed
HGB	≤1g /L	0g /L	Passed
PLT	≤10.0×10^9/L	0×10^9/L	Passed

2.1.4 Goat

Parameter	Requirement	Result	
		V3-1#	Conclusion
WBC	≤0.20×10^9 /L	0×10^9 /L	Passed
RBC	≤0.02×10^12 /L	0×10^12 /L	Passed
HGB	≤1g /L	0g /L	Passed

2.2 Precision

2.2.1 Dog

Parameter	CV Requirement	Result	
		V3-1#	Conclusion
WBC	≤3%	0.72%	Passed
RBC	≤2%	0.65%	Passed
HGB	≤2%	0.79%	Passed
PLT	≤6% (100×10^9/L ~149×10^9/L) ≤5% (150×10^9/L ~500×10^9/L)	2.67%	Passed
HCT	≤2%	0.80%	Passed
MCV	≤1%	0.37%	Passed

2.2.2 Cat

Parameter	CV Requirement	Result	
		V3-1#	Conclusion
WBC	≤3%	1.06%	Passed
RBC	≤2%	0.45%	Passed
HGB	≤2%	0.53%	Passed
PLT	≤6% (100×10^9/L ~149×10^9/L) ≤5% (150×10^9/L ~500×10^9/L)	2.51%	Passed
HCT	≤2%	0.74%	Passed
MCV	≤1%	0.41%	Passed

2.2.3 Rabbit

Parameter	CV Requirement	Result	
		V3-1#	Conclusion
WBC	≤3%	1.10%	Passed
RBC	≤2%	0.53%	Passed
HGB	≤2%	0.78%	Passed
PLT	≤6% (100×10^9/L ~149×10^9/L) ≤5% (150×10^9/L ~500×10^9/L)	2.10%	Passed
HCT	≤2%	0.56%	Passed
MCV	≤1%	0.29%	Passed

2.2.4 Goat

Parameter	CV Requirement	Result	
		V3-1#	Conclusion
WBC	≤3%	1.29%	Passed
RBC	≤2%	0.13%	Passed
HGB	≤2%	1.64%	Passed
HCT	≤2%	0.99%	Passed
MCV	≤1%	0.91%	Passed

2.3 Linearity

Test carried out in Dog mode. The results are as follows:

Parameter	Requirement	Result	
		V3-1#	Conclusion
WBC	≤±0.5×10^9/L(WBC≤10×10^9/L) ≤±6%(WBC>10×10^9/L)	0.00*10^9/L -2.97%~3.03%	Passed
RBC	≤±0.05×10^12/L(RBC≤1×10^12/L) ≤±6%(RBC>1×10^12/L)	0.00 -1.33%~1.69%	Passed
HGB	≤±3g/L(HGB≤70g/L) ≤±3%(HGB>70g/L)	0.01 -0.66%~1.25%	Passed
PLT	≤±15×10^9/L(PLT≤100×10^9/L) ≤±12%(PLT>100×10^9/L)	0.00 1.26%~1.51%	Passed

2.4 Carryover

The test results are as follows:

Parameter	Carryover Requirement	Result	
		V3-1#	Conclusion
WBC	≤0.5%	0.08%	Passed
RBC	≤0.5%	0.00%	Passed
HGB	≤0.6%	0.40%	Passed
PLT	≤1.0%	0.80%	Passed

3. Raw Data

3.1 Blank

3.1.1 Test Method

In Dog, Cat, Rabbit and Goat whole blood mode, test the diluent as a sample 3 times consecutively on the analyser. Take the maximum value of the 3 test results as the blank test value.

The results should meet the requirements in the following table:

Parameter	Measures Value Range
WBC	≤0.20×10^9 /L
RBC	≤0.02×10^{12} /L
HGB	≤1g /L
PLT	≤10.0×10^9/L

Note: There is no PLT result in Goat mode.

3.1.2 Test Data

Dog	WBC (×10∧9)	RBC (×10∧12)	HGB (g/L)	PLT (×10∧9)
1	0	0	0	0
2	0	0	0	0
3	0	0	0	1
Maximum	0	0	0	1
Standard ≤	**0.2**	**0.02**	**1**	**10**
Conclusion	**Passed**	**Passed**	**Passed**	**Passed**

Cat	WBC (×10∧9)	RBC (×10∧12)	HGB (g/L)	PLT (×10∧9)
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
Maximum	0	0	0	0
Standard ≤	**0.2**	**0.02**	**1**	**10**
Conclusion	**Passed**	**Passed**	**Passed**	**Passed**

Rabbit	WBC (×10∧9)	RBC (×10∧12)	HGB (g/L)	PLT (×10∧9)
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
Maximum	0	0	0	0
Standard ≤	**0.2**	**0.02**	**1**	**10**
Conclusion	**Passed**	**Passed**	**Passed**	**Passed**

Goat	WBC (×10∧9)	RBC (×10∧12)	HGB (g/L)
1	0	0	0
2	0	0	0
3	0	0	0
Maximum	0	0	0
Standard ≤	**0.2**	**0.02**	**1**
Conclusion	**Passed**	**Passed**	**Passed**

3.2 Precision

3.2.1 Test Method

In Dog, Cat, Rabbit and Goat whole blood mode, test the whole blood samples of Dog, Cat, Rabbit and Goat 10 times repeatedly. Calculate the standard deviation (S) using formula (1) and calculate the variable coefficient (CV, %) using formula (2). The results should meet the requirements in the following table:

Parameter	Precision Range	Acceptable Limits (CV)
WBC	3.5×10^9/L ~15.0×10^9/L	≤3.0%
RBC	3.00×10^12/L ~6.00×10^12/L	≤2.0%
HGB	100 g/L ~180 g/L	≤2.0%
PLT	100×10^9/L ~149×10^9/L	≤6.0%
	150×10^9/L ~500×10^9/L	≤5.0%
HCT / MCV	35%~50% (HCT) / 70fL ~120Fl (MCV)	≤2.0% ≤1.0%

$$S = \sqrt{\frac{\sum_{i=1}^{n}(X_i - \overline{X})^2}{n-1}} \quad \textbf{(1)}$$

$$CV = \frac{S}{\overline{X}} \times 100\% \quad \textbf{(2)}$$

S - Standard deviation

CV - Coefficient of Variation

$\overline{X}$ - Mean value

X_i - Test value of the first test

n - Test times

3.2.2 Test Data

Dog	WBC (10^9/L)	RBC (10^12/L)	HGB (g/L)	PLT (10^9/L)	HCT (%)	MCV (fL)
1	13.68	6.01	120	234	36	59.9
2	13.55	6.03	120	252	36.2	60.1
3	13.53	6.06	122	247	36.5	60.3
4	13.82	6.01	121	244	36.2	60.3
5	13.75	6.06	121	248	36.4	60.1
6	13.7	5.96	119	251	35.8	60.1
7	13.55	5.96	120	245	35.9	60.3
8	13.69	6.04	119	248	36.1	59.8
9	13.75	5.97	121	236	35.6	59.7
10	13.72	6.04	120	236	36.4	60.3
AVG	13.674	6.014	120.3	244.1	36.11	60.09
SD	0.09913	0.03893	0.94868	6.52261	0.28848	0.22336
CV	0.72%	0.65%	0.79%	2.67%	0.80%	0.37%

CV Requirement ≤	**3.00%**	**2.00%**	**2.00%**	**5.00%**	**2.00%**	**1.00%**
Result	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Cat	WBC (10^9/L)	RBC (10^12/L)	HGB (g/L)	PLT (10^9/L)	HCT (%)	MCV (fL)
1	12.22	6.83	96	146	30.7	44.9
2	12.4	6.85	96	140	30.5	44.5
3	12.41	6.88	96	149	30.7	44.6
4	12.25	6.84	96	145	30.6	44.8
5	12.35	6.80	97	148	30.2	44.5
6	11.99	6.79	97	139	30.3	44.6
7	12.15	6.83	97	142	30.5	44.6
8	12.39	6.87	97	149	30.8	44.8
9	12.28	6.88	97	144	30.9	44.9
10	12.25	6.85	97	142	30.8	45
AVG	12.269	6.842	96.6	144.4	30.6	44.72
SD	0.1306	0.0308	0.5164	3.6271	0.2261	0.1814
CV	1.06%	0.45%	0.53%	2.51%	0.74%	0.41%
CV Requirement ≤	**3.00%**	**2.00%**	**2.00%**	**5.00%**	**2.00%**	**1.00%**
Result	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Rabbit	WBC (10^9/L)	RBC (10^12/L)	HGB (g/L)	PLT (10^9/L)	HCT (%)	MCV (fL)
1	11.21	5.77	128	282	39.4	68.2
2	11.41	5.77	128	288	39.6	68.6
3	11.11	5.77	128	293	39.5	68.5
4	11.15	5.73	129	288	39.3	68.5
5	11.08	5.79	128	297	39.7	68.5
6	11.34	5.72	127	289	39.1	68.3
7	11.19	5.73	127	301	39	68.1
8	11.05	5.81	127	281	39.6	68.2

9	11.36	5.8	127	290	39.4	68
10	11.22	5.77	130	291	39.4	68.3
AVG	11.212	5.766	127.9	290	39.4	68.32
SD	0.1229	0.0306	0.9944	6.0919	0.2211	0.1989
CV	1.10%	0.53%	0.78%	2.10%	0.56%	0.29%
CV Requirement ≤	**3.00%**	**2.00%**	**2.00%**	**5.00%**	**2.00%**	**1.00%**
Result	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Goat	WBC (10^9/L)	RBC (10^12/L)	HGB (g/L)	HCT (%)	MCV (fL)
1	10.81	16.8	76	35.4	21.1
2	10.94	16.81	78	35.6	21.2
3	10.72	16.81	78	35.3	21
4	10.61	16.75	76	35	20.9
5	10.62	16.82	75	36.2	21.5
6	10.62	16.78	76	35.1	20.9
7	10.98	16.82	76	35.3	21
8	10.65	16.79	75	35.1	20.9
9	10.69	16.79	78	35.6	21.2
10	10.62	16.81	75	35.6	21.2
AVG	10.726	16.798	76.3	35.42	21.09
SD	0.1381	0.0215	1.2517	0.3521	0.1912
CV	1.29%	0.13%	1.64%	0.99%	0.91%
CV Requirement≤	**3.00%**	**2.00%**	**2.00%**	**2.00%**	**1.00%**
Result	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

3.3 Linearity

3.3.1 Test Method

The linearity is tested in Dog mode only.

Dilute the high level control material to be 5 concentrations. The high concentration is close to the upper limit of the linear range and the low concentration is close to the lower limit of the linear

range. In Custom 3 whole blood mode, each control material at different concentrations is tested 3 times, and the mean value is calculated. Take the dilution ratio as independent variable (X).

The measured mean value of each sample as the dependent variable (Y) to calculate correlation index by formula (3). The regression equation is calculated using the following linear regression method, then the theoretical values of each concentration point are obtained from the regression equation to calculate the absolute or relative deviation between the measured mean and the theoretical value.

$$r = \frac{\sum(X-\overline{X})(Y-\overline{Y})}{\sqrt{\sum(X-\overline{X})^2(Y-\overline{Y})^2}} \qquad \textbf{(3)}$$

r - Correlation index

$\overline{X}$ —— X - Mean value

$\overline{Y}$ —— Y - Mean value

3.3.2 Linear Regression Method

Set the linear regression straight line as $y=ax+b$, the test value corresponding to dilution ratio X_i as Y_i so the deviation ratio of linear regression theory value can be expressed as $\frac{Z_i-Y_i}{Y_i}=\frac{X_i*a+b-Y_i}{Y_i}$.

In this regression method, it is expected that the squared sum of deviation rates between all the tested values Y_i and the theoretical values of linear regression Z_i is the minimum.

Then, calculate the linearity regression using the equation $y=ax+b$.

3.3.3 Test Data

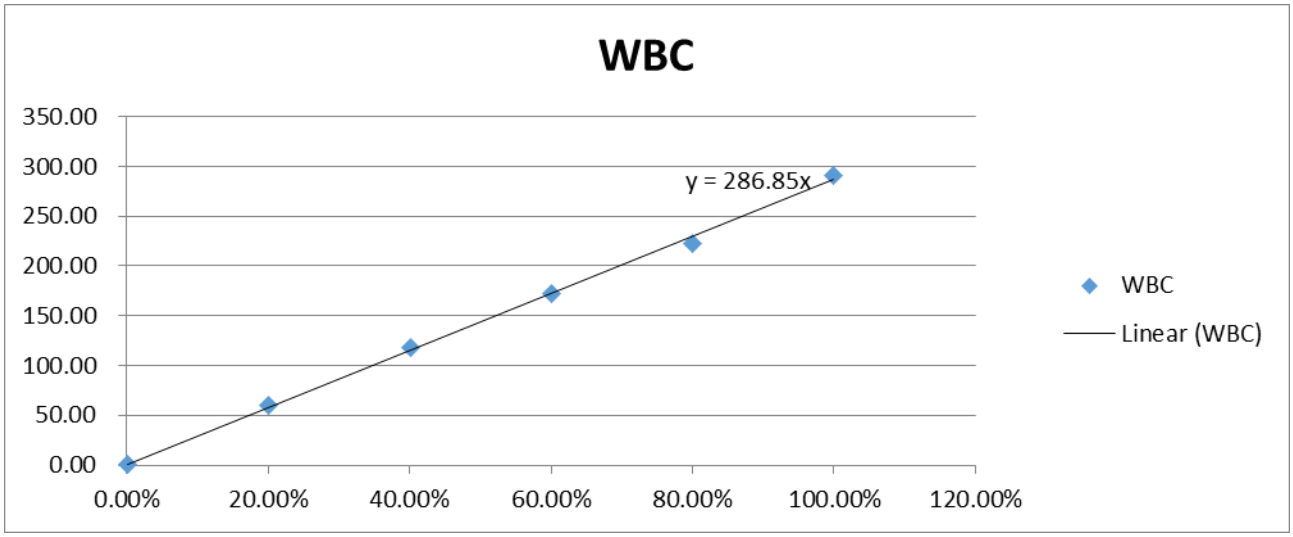
WBC:

1	2	3	Mean Value Y
0.5	0.5	0.6	0.53
59.4	59.4	59.9	59.57
117.5	116.8	118.6	117.63
169.7	171.9	173.9	171.83

221.7	223	224.6	223.10
292	292.1	288.7	290.93

Linear Regression	**Slope**	a	286.846
	Intercept	b	0.000
Linear Regression Equation	y = 286.846 * x		
Correlation Index	R	0.999407049	

Low Value	High Value	Concentration Gradient (X)	Linear Regression Theoretical Value Z	Z-Y	Deviation (Z-Y) / Z*100%	Allowable Deviation	Result	Description	Allowable Deviation
6	0	0.18%	0.53	-0.007	-1.42%	±0.3	Passed	WBC≤10	≤±0.3
4.8	1.2	20.15%	57.79	-1.78	-3.07%	±5%	Passed	WBC＞10	≤±5%
3.6	2.4	40.11%	115.05	-2.58	-2.24%	±5%	Passed	WBC＞100	≤±9%
2.4	3.6	60.07%	172.32	0.48	0.28%	±5%	Passed		
1.2	4.8	80.04%	229.58	6.48	2.82%	±5%	Passed		
0	6	100.00%	286.85	-4.09	-1.42%	±5%	Passed		

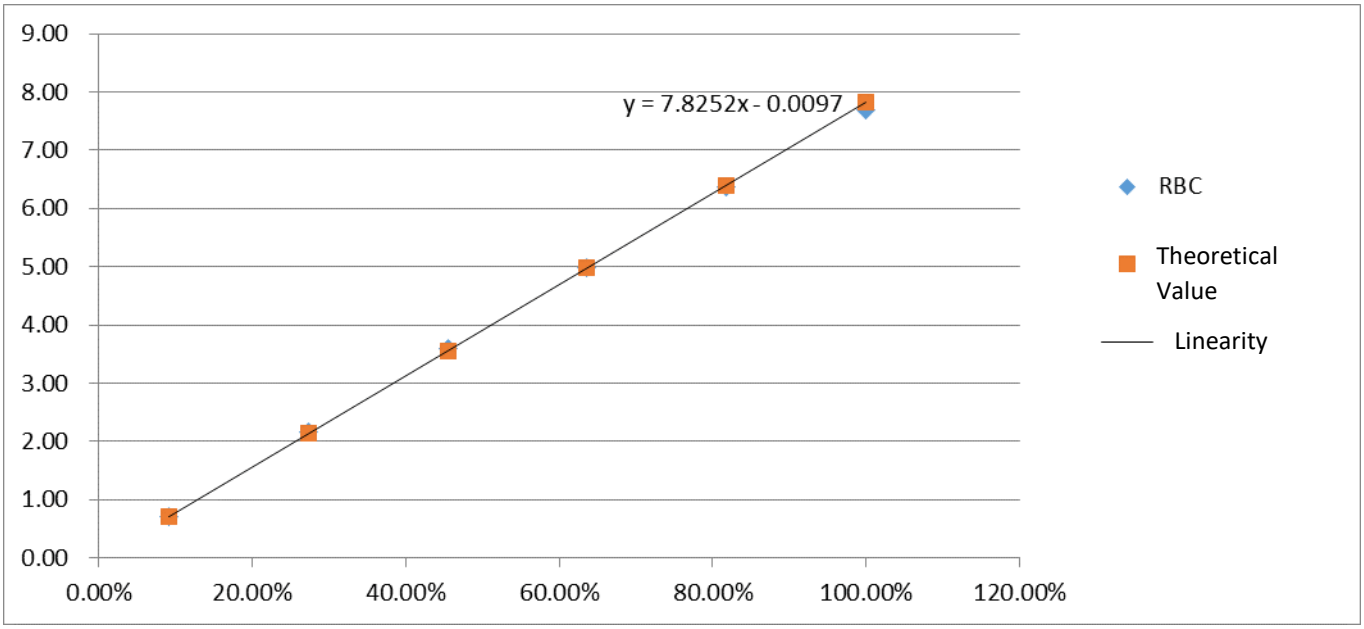


RBC:

Original Data				
	1	**2**	**3**	**Mean Value Y**
1	0.7	0.71	0.7	0.70
2	2.15	2.15	2.17	2.16
3	3.62	3.57	3.58	3.59
4	4.97	4.98	4.99	4.98
5	6.36	6.33	6.43	6.37
6	7.67	7.69	7.69	7.68

Linear Regression	**Slope**	a	7.83
	Intercept	b	-0.010
Linear Regression Equation	y = 7.825 * x + (-0.010)		
		R	R^2
Correlation Index	R	0.9999	0.9997

Low Value	**High Value**	**Concentration Gradient (X)**	**Linear Regression Theoretical Value Z**	**Z-Y**	**Deviation (Z-Y) / Z*100%**	**Allowable Deviation**	**Result**	**Description**	**Allowable Deviation**
100%	0%	9.15%	0.71	0.003	0.47%	±0.05	Passed	RBC≤1	≤±0.05
80%	20%	27.32%	2.13	-0.028	-1.33%	±6%	Passed	RBC＞1	≤±6%
60%	40%	45.49%	3.55	-0.040	-1.12%	±6%	Passed		
40%	60%	63.66%	4.97	-0.008	-0.16%	±6%	Passed		
20%	80%	81.83%	6.39	0.020	0.32%	±6%	Passed		
0%	100%	100.00%	7.82	0.132	1.69%	±6%	Passed		

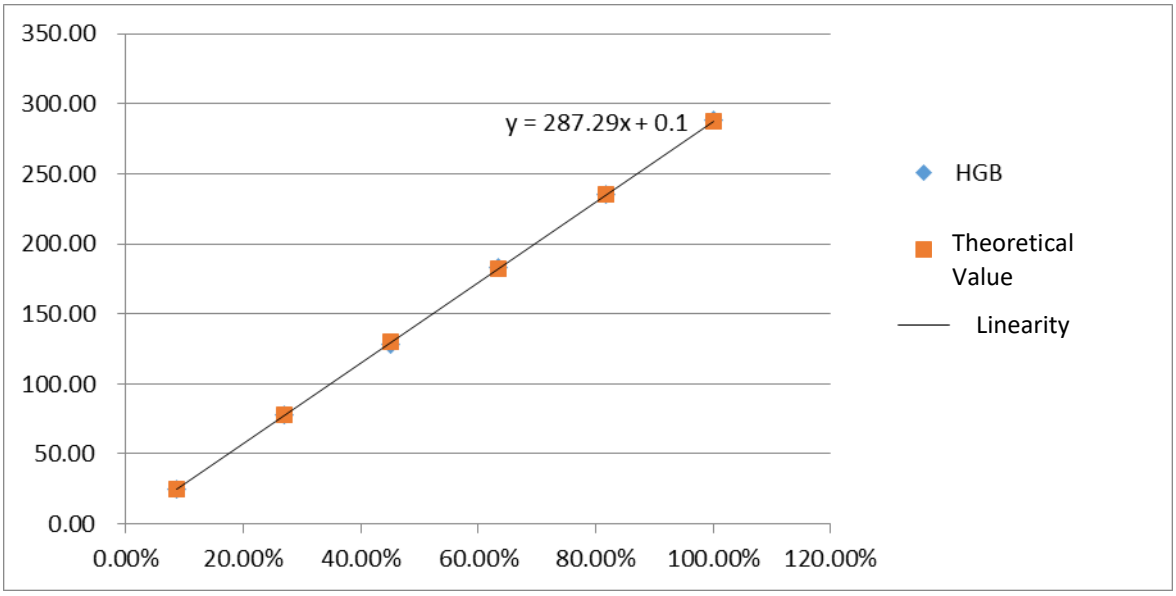


HGB:

Original Data				
	1	**2**	**3**	**Mean Value Y**
1	25	25	25	25.00
2	79	76	79	78.00
3	128	128	129	128.33
4	184	183	182	183.00
5	235	235	235	235.00
6	288	289	288	288.33

Linear Regression	**Slope**	a	287.29
	Intercept	b	0.100
Linear Regression Equation	y = 287.290 * x + (0.100)		
		R	R^2
Correlation Index	R	1.0000	0.9999

Low Value	High Value	Concentration Gradient (X)	Linear Regression Theoretical Value Z	Z-Y	Deviation (Z-Y) / Z*100%	Allowable Deviation	Result	Description	Allowable Deviation
100%	0%	8.67%	25.01	0.010	0.04%	±3	Passed	HGB≤70	≤±3
80%	20%	26.94%	77.49	-0.514	-0.66%	±3%	Passed	RBC>70	≤±3%
60%	40%	45.20%	129.96	1.629	1.25%	±3%	Passed		
40%	60%	63.47%	182.44	-0.562	-0.31%	±3%	Passed		
20%	80%	81.73%	234.91	-0.086	-0.04%	±3%	Passed		
0%	100%	100.00%	287.39	-0.943	-0.33%	±3%	Passed		



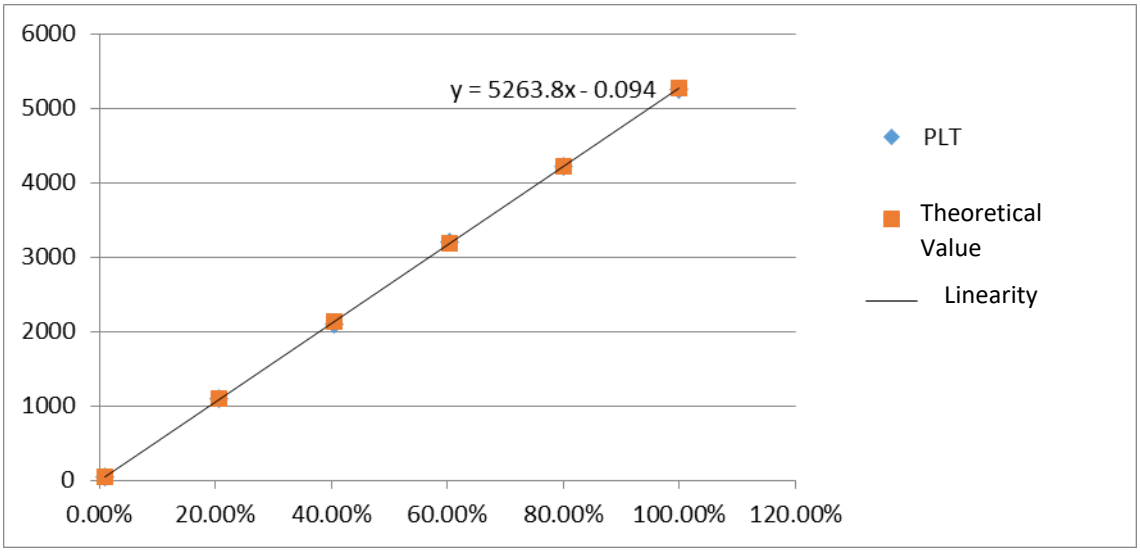
PLT:

Original Data				
	1	2	3	Mean Value Y
1	52	49	46	49
2	1097	1099	1121	1105.666667
3	2087	2108	2113	2102.666667

4	3210	3193	3193	3198.666667
5	4225	4203	4225	4217.666667
6	5245	5234	5278	5252.333333

Linear Regression	**Slope**	a	5263.79
	Intercept	b	-0.094
Linear Regression Equation	y = 5,263.793 * x + (-0.094)		
		R	R^2
Correlation Index	R	1.0000	0.9999

Low Value	High Value	Concentration Gradient (X)	Linear Regression Theoretical Value Z	Z-Y	Deviation (Z-Y) / Z*100%	Allowable Deviation	Result	Description	Allowable Deviation
100%	0%	0.93%	49	0.0	0.03%	±15	Passed	PLT≤100	≤±15
80%	20%	20.75%	1092	-13.7	-1.26%	±12%	Passed	PLT>100	≤±12%
60%	40%	40.56%	2135	32.2	1.51%	±12%	Passed		
40%	60%	60.37%	3178	-20.8	-0.66%	±12%	Passed		
20%	80%	80.19%	4221	3.1	0.07%	±12%	Passed		
0%	100%	100.00%	5264	11.4	0.22%	±12%	Passed		



3.4 Carryover

3.4.1 Test Method

Carryover was tested in Customs 3 mode to represent the carryover of the instrument.

Take the high level control material in the range of the following table and mix it well. Test it 3 times in Custom 3 whole blood mode. The test values are H_1, H_2, H_3. Then, take the low level control material in the range of the following table and mix it well. Test it 3 times in Custom 3 whole blood mode. The test values are L_1, L_2, L_3. Calculate the carryover (CR) using formula (4).

Parameter	High Concentration Sample Range	Low Concentration Sample Range
WBC	＞90.0×10^9/L	＞0～＜3.0×10^9/L
RBC	＞6.20×10^{12}/L	＞0～＜1.50×10^{12}/L
HGB	＞180g/L	＞0～＜50g/L
PLT	＞900×10^9/L	＞0～＜30×10^9/L

The results should meet the requirements in the following table:

Parameter	Measurement Result
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
PLT	≤1.0%

$$CR = \frac{|L_1 - L_3|}{H_3 - L_3} \times 100\% \quad \textbf{(4)}$$

CR - Carryover

L_1 - The first test value of low concentration sample

L_3 - The third test value of low concentration sample

H_3 - The third test value of high concentration sample

3.4.2 Test Data

V3-1#	Name	WBC (×10∧9)	RBC (×10∧12)	HGB (g/L)	PLT (×10∧9)
High Concentration Value	H_1	100.61	8.16	252	2251
	H_2	101.87	8.5	253	2296
	H_3	100.76	8.13	255	2267
Low Concentration Value	L_1	0.52	0.14	3	40
	L_2	0.54	0.14	3	29
	L_3	0.43	0.14	2	22
Carryover (%)		0.08%	0.00%	0.40%	0.80%
Standard Request ≤		0.5%	0.5%	0.6%	1.0%
Conclusion		Pass	Pass	Pass	Pass

4. Conclusion

The test results meet the basic performance of the technical requirements of InSight V3 PLUS Veterinary Haematology Analyser.