WOODLEY
EQUIPMENT COMPANY LTD.

InSight™ V5

Veterinary Haematology Analyser Evaluation

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Chapter 1 Overview

1.1 Purpose of Evaluation

The evaluation aims to test whether the performance of the InSight V5 meets the specification requirements.

1.2 Evaluation Items

Background, Repeatability, Carry-over rate, Comparability, Linearity, and Correlation.

1.3 Conclusion of Experiment

- **Background:**

  The background meets the specification requirements.

- **Repeatability:**

  The repeatability meets the specification requirements;

  All pre-dilution modes meet the specification requirements.

- **Carry-over rate:**

  The Carry-over rate meets the specification requirements.

- **Comparability:**

  The comparability meets the specification requirements.

- **Linearity:**

  The linearity meets the specification requirements.

- **Correlation:**

  The correlation meets the specification requirements.

1.4 Product name

Auto Haematology Analyser Model：InSight V5

Chapter 2 Materials Information

2.1 Instrument and Reagent Information

2.1.1 Test machine and reagents (InSight V5)

Test Machine: A clinical prototype (InSight V5) is selected at random.

Table 1 Reagent Information of the Test Machine

Reagent Name	V5 DIL Diluent	V5 LY1 Lyse	V5 LY2 Lyse
Lot No.	20160920	20161017	20161011
Exp. Date	20180919	20181016	20181010

Table 2 Version Information of the Test Machine

Boot Software	0.11.9.13558	**Application Software**	0.1.0.133/171
FPGA	0.1.0.1240	**MCU**	1.3.0.3368/3562
Algorithm	1.0.0.0/1.0.1.0	**Fluidics Sequence**	0.1.9.5
Operating System	3.2.0.13516	**Component Version**	0.5.20.13518/13520
Machine Type	1108	**RF Card Reader MCU**	1.1.0.2865

2.1.2 Comparison machine and reagents

Comparison Machine: Mindray BC-5000 Vet Haematology Analyser

Table 3 Reagent Information of the Control Machine

Reagent name	Diluent	M-52LH Lyse	M-52DIFF Lyse
Lot No.	2016030501	2016011101	2016011001
Exp. Date	2018-03-04	2018-01-10	2017-01-09

Table 4 Version Information of the Control Machine

Version details	Boot software	1.5	**Hardware**	Digital FPGA	3.0.1.46
	Core CPU	V1.06.75		Driver FPGA	1.0.3.12

	System version	V01.06.00.3783		Driver MCU	01.06.00.2828
	Printing driver	1.6.0		Disk	1.6
	Printing template	01.06	/	/	
	Time sequence	1.2.258GENERAL	/	/	/
	Algorithm	1.0.0.392	/	/	/

2.2 Sample Information

Fresh venous whole blood samples in EDTA anticoagulant were used for the evaluation. The sample size was greater than 1.0ml.

Chapter 3 Experiment Results and Analysis

3.1 Background Test

3.1.1 Test method

A Background test shall be conducted prior to each test. Note down the background during daily startup for statistical collection. The background during startup shall meet the requirements specified in Table 1.

Table 1 InSight V5 Background Requirements

Determined Parameters	Background Requirements
WBC	≤0.20×10^9/L
RBC	≤0.02×10^{12}/L
HGB	≤1 g/L
HCT	≤0.5%
PLT	≤10×10^9/L

3.1.2 Test results

Table 2 Summary of InSight V5 Background Test Results during Daily Startup

Sample No.	Counting mode	Testing mode	WBC	RBC	HGB	HCT	PLT
background	CBC	VWB	0.02	0.00	0	0.0	0
background	CBC	VWB	0.00	0.00	0	0.0	0
background	CBC	VWB	0.00	0.00	0	0.0	0
Result	/	/	0.02	0.00	0	0.0	0
Background requirement (≤)	/	/	0.20	0.02	1	0.5	10
Conclusion	/	/	PASS	PASS	PASS	PASS	PASS

3.1.3 Conclusion and analysis

It can be seen from the results shown in 3.1.2 that the background of InSight V5 meets the specification requirements.

3.2 Repeatability

3.2.1 Test method

Conduct 10 repeated measurements on venous whole blood samples in compliance with the requirements specified in the table below, under the whole blood mode and pre-dilution mode respectively. The results shall meet the requirements specified in the table below.

Table 3 Requirements for the InSight V5 Repeatability

	Parameters	Whole Blood Repeatability	Pre-dilution Repeatability
Repeatability (≤%)	WBC	≤2.0% (4.0-15.0×10^9/L)	≤4.0% (4.0-15.0×10^9/L)
	Neu%	±4.0 (absolute deviation) (50.0% ~ 60.0%)	±8.0 (absolute deviation) (50.0% ~ 60.0%)
	Lym%	±3.0 (absolute deviation) (25.0%~35.0%)	±6.0(absolute deviation) (25.0%~35.0%)
	Mon%	±2.0(absolute deviation) (5.0%~10.0%)	±4.0(absolute deviation) (5.0%~10.0%)
	Eos%	±1.5(absolute deviation) (2.0%~5.0%)	±2.5(absolute deviation) (2.0%~5.0%)
	Bas%	±0.8(absolute deviation) (0.5%~1.5%)	±1.2(absolute deviation) (0.5%~1.5%)
	RBC	≤1.5% (3.5-6.0×10^12/L)	≤2.0% (3.5-6.5×10^12/L)
	HGB	≤1.5% (110-180g/L)	≤2.0% (110-180g/L)
	PLT	≤6.0% (100-149×10^9/L)	≤8.0% (100-500×10^9/L)
		≤4.0% (150-500×10^9/L)	
	MCV	≤1.0% (70-120 fL)	≤1.5% (70-120 fL)
	MPV	≤4.0%	≤8.0%

3.2.2 Test results

Table 11 Summary of Repeatability Data in the CBC+DIFF Mode

Sample	WBC	Neu%	Lym%	Mon%	Eos%	Bas%	RBC	HGB	MCV	PLT	MPV
Sample 1	1.6%	2.34	-1.34	1.44	1	-0.24	0.8%	0.4%	0.2%	2.0%	0.9%
Sample 2	1.7%	0.74	-0.97	-0.46	0.69	-0.3	1.0%	0.9%	0.3%	2.0%	3.0%
Sample 3	1.8%	1.1	-1.37	0.63	0.6	-0.36	0.8%	0.6%	0.2%	1.2%	2.4%

Standard (≤ CV/d)	**2.0%**	**±4.0**	**±3.0**	**±2.0**	**±1.5**	**±0.8**	**1.5%**	**1.5%**	**1.0%**	**4.0%**	**4.0%**
Conclusion	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS

Table 12 Summary of Repeatability Data in the Pre-dilution CBC+DIFF Mode

Sample	WBC	Neu%	Lym%	Mon%	Eos%	Bas%	RBC	HGB	MCV	PLT	MPV
Sample 1	1.7%	-1.76	1.71	1.75	0.58	-0.28	0.6%	0.3%	0.2%	6.0%	2.8%
Sample 2	2.3%	-3.49	1.03	-1.19	-1.36	-0.59	0.3%	0.6%	0.3%	2.3%	1.6%
Sample 3	1.3%	-3.38	1.8	-1.61	-0.5	-0.91	1.0%	0.9%	0.3%	4.7%	2.8%
Standard (≤ CV/d)	4.0%	±8.0	±6.0	±4.0	±2.5	±1.2	2.0%	2.0%	1.5%	8.0%	8.0%
Conclusion	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS

3.2.3 Conclusion and analysis

Repeatability in the whole blood mode:

Meets the requirements for product specifications.

Repeatability in the pre-dilution mode:

Meets the requirements for product specifications.

3.3 Carry-over Rate

3.3.1 Test method

Perform continuous tests on high- and low-value samples conforming to the requirements specified in the table below. Test the samples three times by using the high value, and then another three times by using the low value. Calculate the carry-over rate according to the following formula:

$$\text{Carry-over Rate (\%)} = \frac{\text{First Low Value} - \text{Third Low Value}}{\text{Third High Value} - \text{Third Low Value}} \times 100\%$$

Table 4 Concentration Ranges of Samples for Carry-over Rate Tests

Parameter	High Concentration Range	Low Concentration Range
WBC	>15.00×10^9/L	<3.00×10^9/L
RBC	>6.00×10^{12}/L	<2.00×10^{12}/L

HGB	>200g/L	<40g/L
PLT	>300×10^9/L	<100×10^9/L

Table 5 Requirements for InSight V5 Carry-over Rate

Determined Parameter	Carry-over Rate Requirement
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
HCT	≤0.5%
PLT	≤1.0%

3.3.2 Test results

Table 6 Test Results of InSight V5 Carry-over Rate

Parameter	WBC	RBC	HGB	HCT	PLT
Result	**0.0%**	**0.1%**	**0.0%**	**0.1%**	**0.0%**
Standard (≤)	0.5%	0.5%	0.5%	0.5%	1.0%
Conclusion	PASS	PASS	PASS	PASS	PASS

3.3.3 Conclusion and analysis

It can be seen from the test results that the carry-over rate of InSight V5 meets the requirements for product specifications.

3.4 Comparability

3.4.1 Test method

Measure a fresh whole blood sample 5 times and calculate the mean value of each parameter on the InSight V5 and the comparison haematology analyser. Calculate the mean value deviation percentage of each measured parameter of the two haematology analysers.

Table 7 InSight V5 Comparability Requirements

Determined Parameters	Comparability Requirements
WBC	≤±5%

RBC	≤±2.5%
HGB	≤±2.5%
MCV	≤±3%
PLT	≤±8%

3.4.2 Test results

Table 8 Test Results of InSight V5 Comparability

Sample No	WBC	RBC	HGB	MCV	PLT
Result	**2.01%**	**-0.44%**	**-0.65%**	**-0.93%**	**1.29%**
Standard (≤)	±5%	±2.5%	±2.5%	±3%	±8%
Conclusion	PASS	PASS	PASS	PASS	PASS

3.4.3 Conclusion and analysis

It can be seen from the test results that the comparability of InSight V5 meets the requirements for product specifications.

3.5 Linearity

3.5.1 Test method

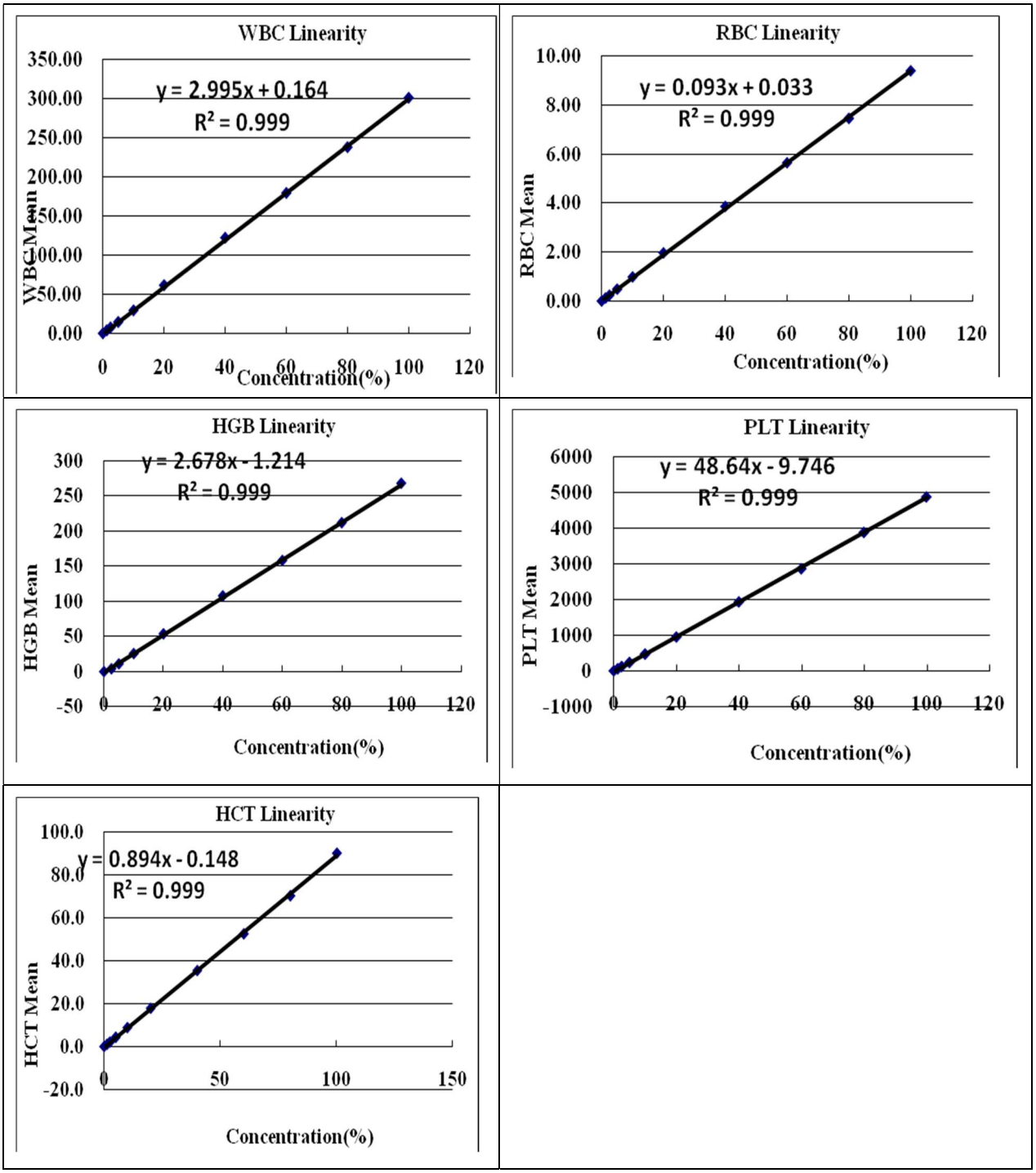
Take one high-value sample of WBC, RBC, HGB, HCT and PLT respectively. Perform gradient dilution on the samples by a concentration gradient of 10% from 100% to 0%. Test WBC, RBC, HGB, HCT and PLT sampling under the whole blood mode. Measure each sample at different concentration levels three times. Take the mean values of test results and perform linear regression analysis with sample concentration. Calculate the absolute error or relative percentage error between the mean value and theoretical value of measurement. The results shall meet the requirements specified in Table 10.

Table 9 Requirements for InSight V5 Linearity

Parameter	Linearity Range	Linearity Error
WBC	(0.00~100.00) $\times10^9$/L	No more than $\pm0.30\times10^9$/L or±5%
	(100.01~300.00) $\times10^9$/L	No more than±10%
RBC	(0.00~8.50) $\times10^{12}$/L	No more than$\pm0.05\times10^{12}$/L or ±5%
HGB	(0~250) g/L	No more than±2 g/L or ±2%
PLT	(0~1000) $\times10^9$/L RBC≤7.0	No more than$\pm10\times10^9$/L or ±8%

Parameter	Linearity Range	Linearity Error
PLT	(1001~3000) $\times 10^9$/L RBC≤7.0	No more than±12%
HCT	0~67%	No more than ±2% (HCT value) or±3% (percentage error)

3.5.2 Test results



3.5.3 Conclusion and analysis

The WBC linearity, whose measured values are within the range of 0.02 to 300.76, meets the specification requirements.

The RBC linearity, whose measured values are within the range of 0.00 to 9.41, meets the specification requirements.

The HGB linearity, whose measured values are within the range of 0.00 to 268 meet the specification requirements.

The HCT linearity, whose measured values are within the range of 0.0 to 90.5, meets the specification requirements.

The PLT linearity, whose measured values are within the range of 0 to 4880, meets the specification requirements.

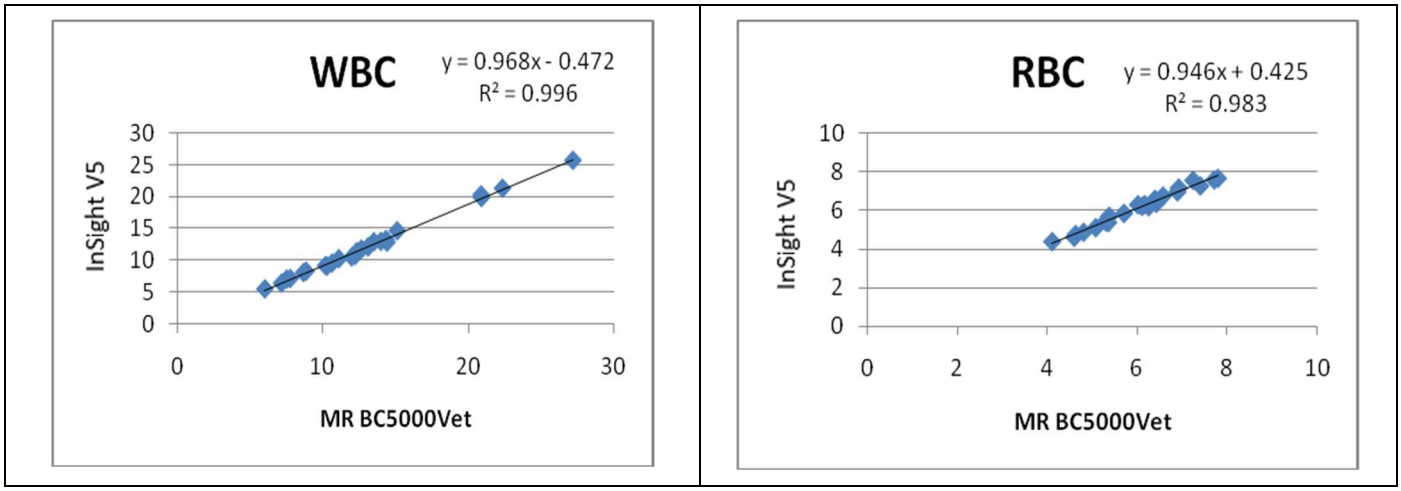
3.6 Correlation with Other Instruments

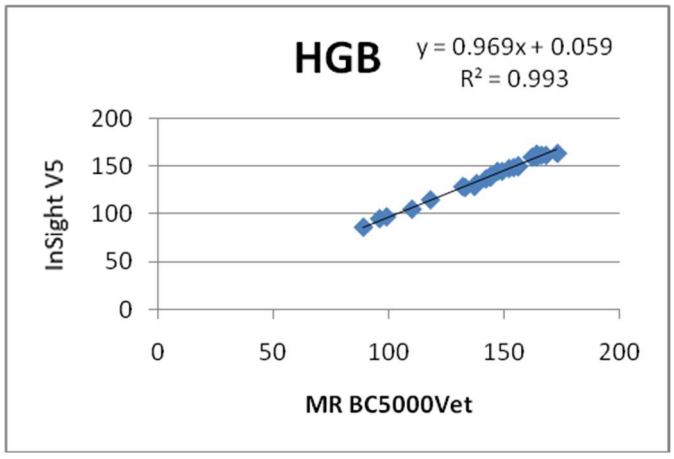
3.6.1 Test method

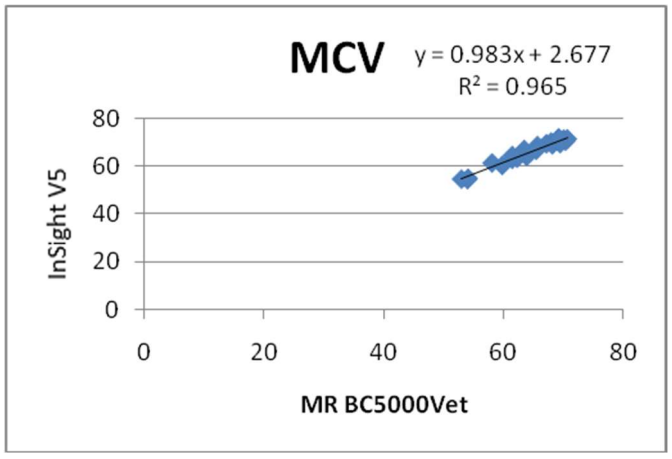
The comparison analyser shall be produced by a different manufacturer (Mindray MR BC5000 VET). The MR BC5000 Vet and the InSight V5 analysers shall be calibrated before running samples. Choose fresh venous EDTA whole blood samples at random every day (the samples are not selected according to disease). Measure the samples once on the InSight V5 and MR BC5000 Vet respectively. Note down each parameter result. Calculate the correlation coefficient (r) according to the statistical regression equation Y =aX + b

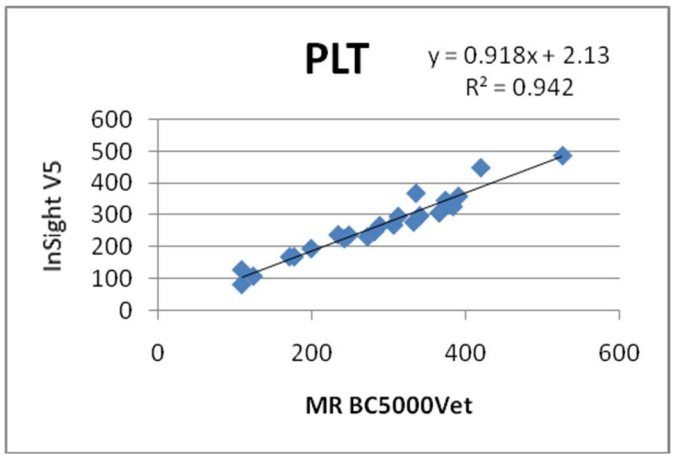
3.6.2 Test results

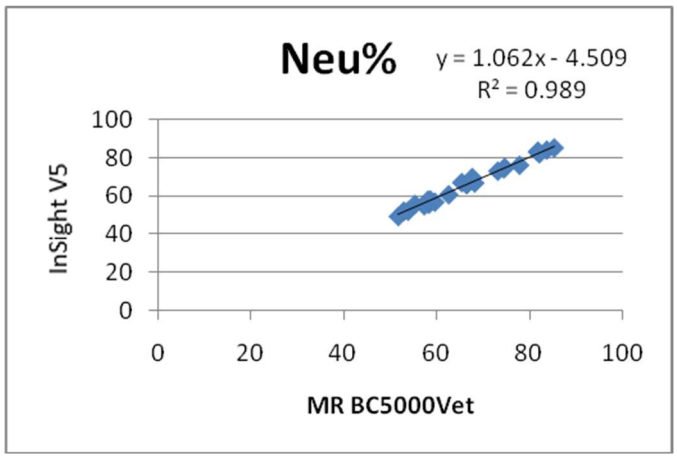
Fig 1 Diagram for the Correlation between InSight V5 and MR BC5000 VET Instruments

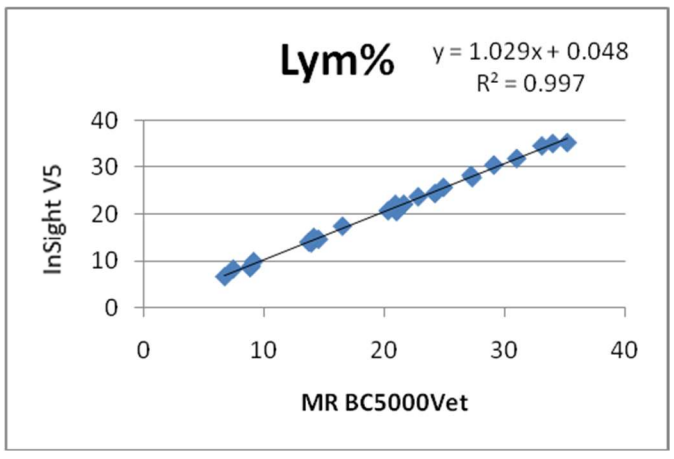


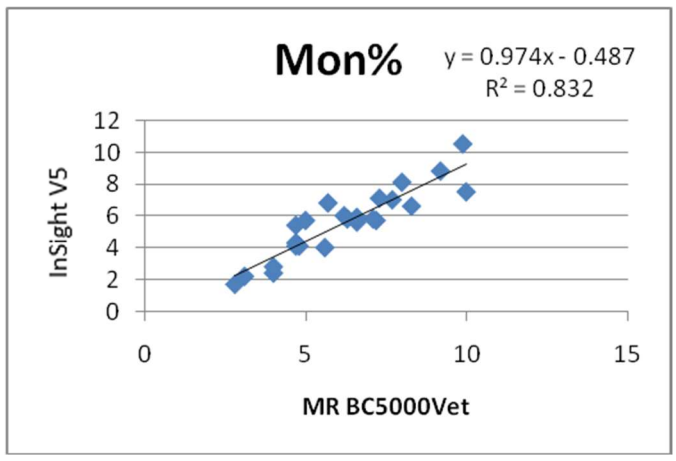

HGB
y = 0.969x + 0.059
R² = 0.993
InSight V5
MR BC5000Vet
0
50
100
150
200


MCV
y = 0.983x + 2.677
R² = 0.965
InSight V5
MR BC5000Vet
0
20
40
60
80


PLT
y = 0.918x + 2.13
R² = 0.942
InSight V5
MR BC5000Vet
0
100
200
300
400
500
600


Neu%
y = 1.062x - 4.509
R² = 0.989
InSight V5
MR BC5000Vet
0
20
40
60
80
100


Lym%
y = 1.029x + 0.048
R² = 0.997
InSight V5
MR BC5000Vet
0
10
20
30
40


Mon%
y = 0.974x - 0.487
R² = 0.832
InSight V5
MR BC5000Vet
0
2
4
6
8
10
12
15

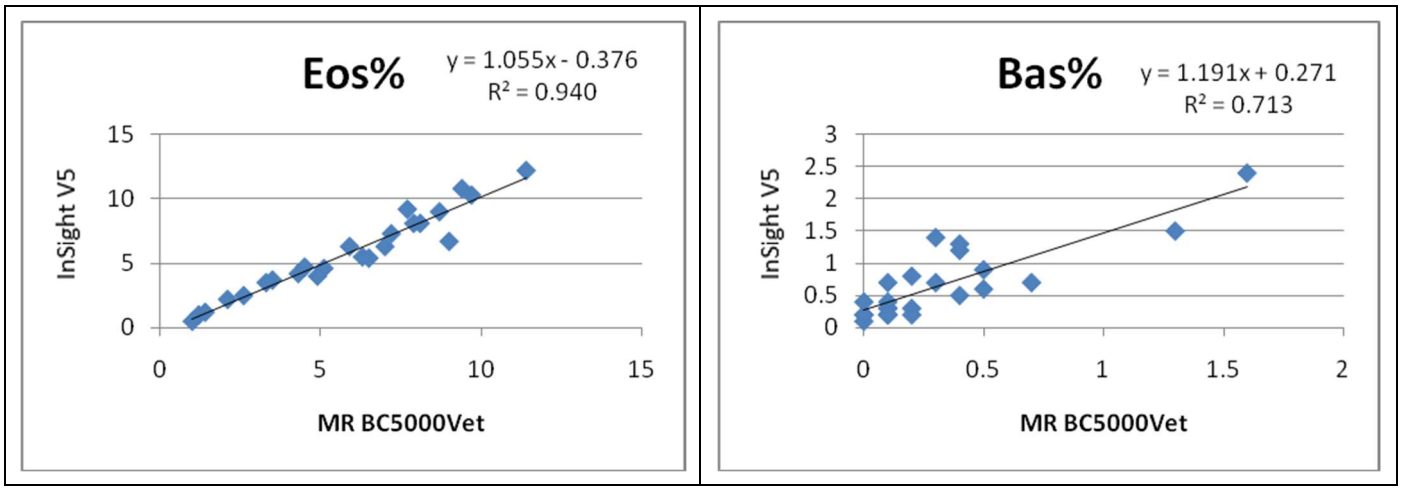


Table 10 Correlation Results of InSight V5 and MR BC5000 VET Instruments

Parameter	**WBC**	**RBC**	**HGB**	**MCV**	**PLT**
Correlation r	0.998	0.992	0.997	0.982	0.970
Standard (≥)	0.99	0.99	0.98	0.98	0.95
Conclusion	PASS	PASS	PASS	PASS	PASS
Parameter	Neu%	Lym%	Mon%	Eos%	Bas%
Correlation r	0.995	0.999	0.913	0.970	0.845

3.6.3 Conclusion and analysis

The correlation meets the specification requirements.

Chapter 4 Appendix of Figures and Tables