InSight V5R Clinical Performance Validation Report – Rabbit, Cow, Horse & Sheep

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Chapter 1 Overview

1.1 Purpose of Experiment

To verify whether the main performance indicators of the InSight V5R Analyser and its accompanying reagents in the Rabbit, Bovine, Equine and Sheep models meet the specifications claimed by the instrument, and whether they can satisfy the effectiveness and safety requirements for clinical use.

1.2 Evaluation Items

Background, carry-over rate, precision, daily quality control and correlation.

1.3 Conclusion of Experiment

- Background: The background meets the specification requirements.
- Precision: The precision meets the specification requirements.
- Carry-over Rate: The carry-over rate meets the specification requirements.
- Correlation: The correlation meets the specification requirements.

1.4 Applicable Scope and Species

This clinical test is applicable to InSight V5R.

Species: Rabbit, Bovine, Equine and Sheep.

Chapter 2 Resource Allocation for Clinical Trials

2.1 Instrument and Reagent Information

2.1.1 Test Machine and Reagents

Test Machine: InSight V5R

Table 1 Reagent Information of the Test Machine

Reagent Name	V5 DIL Diluent	V5 LY1 Lyse	V5 LY2 Lyse
Lot No.	2025070902	2024090401	2024090701
Exp. Date	2027.07.08	2026.09.03	2026.09.06

Table 2 Calibration and Controls Information of the Test Machine

Type	Calibrator	Controls		
		Low Level	Normal Level	High Level
Lot No.	NK0326	BC0326L	BC0326N	BC0326H
Exp. Date	2026.04.10	2026.05.10	2026.05.10	2026.05.10

Table 3 Version Information of the Test Machine

Software Full Version	0.5.20.22921	**Software Release Version**	5
Technical File Version	A2.7	**Machine Type**	7003
Application Software	0.2.0.2921	**Algorithm**	0.1.18948.26038
Boot Software	0.11.9.22149	**MLO**	0.11.9.22149
MCU	1.3.0.18706	**FPGA**	0.101.0.11
Fluidics Sequence	3.7003.010.003	**Operating System**	3.2.0.21818
LIBS	0.1.0.21676	**RF Card Reader MCU**	3.2.0.21597

2.2 Sample Information

Select fresh Rabbit, Bovine, Equine and Sheep anticoagulant venous whole blood and use EDTA-K_2 as the anticoagulant whose concentration ranges from 1.5 mg/mL to 2.2 mg/mL for clinical application. The sample size should be greater than 1.0ml. No abnormalities should occur to the samples, such as haemolysis, agglutination, etc.

2.3 Experiment Base

- Experiment Base: Clinical laboratory
- Experiment Temperature: +22°C to +25°C

Chapter 3 Experiment Results and Analysis

3.1 Background Test

3.1.1 Test Method

A background test should be conducted prior to each test. Note down the background during daily startup for statistical collection.

Table 4 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 5 Background Test Results – Rabbit

Mode	WBC	RBC	HGB	HCT	PLT
Venous Whole Blood – CBC+DIFF	0.00	0	0	0	0
	0.00	0	0	0	0
	0.00	0	0	0	0
Enterprise Standard (≤)	**0.20**	**0.02**	**1**	**0.5**	**10**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 6 Background Test Results – Bovine

Mode	WBC	RBC	HGB	HCT	PLT
Venous Whole Blood – CBC+DIFF	0.00	0	0	0	0
	0.00	0	0	0	0
	0.00	0	0	0	0
Enterprise Standard (≤)	**0.20**	**0.02**	**1**	**0.5**	**10**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 7 Background Test Results – Equine

Mode	WBC	RBC	HGB	HCT	PLT
Venous Whole Blood – CBC+DIFF	0.00	0	0	0	0
	0.00	0	0	0	0
	0.00	0	0	0	0
Enterprise Standard (≤)	**0.20**	**0.02**	**1**	**0.5**	**10**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 8 Background Test Results – Sheep

Mode	WBC	RBC	HGB	HCT	PLT
Venous Whole Blood – CBC+DIFF	0.00	0	0	0	0
	0.00	0	0	0	0
	0.00	0	0	0	0
Enterprise Standard (≤)	**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 meets the specification requirements.

3.2 Carry-over Rate

3.2.1 Test Method

Perform continuous tests on the 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:

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

Table 9 Concentration Ranges of Samples for Carry-over Rate Tests

Parameter	High Concentration Range	Low Concentration Range
WBC	>90.00 x 10^9/L	<3.00 x 10^9/L
RBC	>6.20 x 10^{12}/L	<1.500 x 10^{12}/L
HGB	>220 g/L	<50 g/L
PLT	>900 x 10^9/L	<30 x 10^9/L
HCT	>65.0%	>0 ~ <12.0%

3.2.2 Test Results

Table 10 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Rabbit

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	109.33	8.35	290	78.5	1280
H-2	107.23	8.2	286	77.3	1270
H-3	110.17	8.24	287	77.9	1310
L-1	0.63	0.24	6	2.4	8
L-2	0.52	0.24	6	2.4	8
L-3	0.51	0.24	5	2.4	9
Carry-over (%)	0.1%	0.0%	0.4%	0.0%	0.1%
Enterprise Standard (%)	**0.5**	**0.5**	**0.5**	**0.5**	**1**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 11 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Bovine

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	100.76	6.41	219	69.7	1336
H-2	102.43	6.49	222	70.9	1436
H-3	102.36	6.46	222	70.5	1395
L-1	1.05	0.43	13	5.1	23
L-2	1.06	0.44	13	5.1	25
L-3	1.11	0.44	13	5.1	22
Carry-over (%)	0.1%	0.2%	0.0%	0.0%	0.1%
Enterprise Standard (%)	**0.5**	**0.5**	**0.5**	**0.5**	**1**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 12 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Equine

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	106.3	8.31	273	78.3	1333
H-2	108.69	8.2	274	77.4	1360
H-3	107.64	8.23	275	77.7	1328
L-1	0.57	0.21	6	2.1	8
L-2	0.57	0.21	5	2.1	8
L-3	0.53	0.21	5	2.1	7
Carry-over (%)	0.0%	0.0%	0.4%	0.0%	0.1%
Enterprise Standard (%)	**0.5**	**0.5**	**0.5**	**0.5**	**1**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Table 13 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Sheep

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	102.93	6.5	221	71	1416
H-2	100.09	6.31	220	68.9	1356
H-3	101.94	6.45	221	70.2	1434
L-1	0.88	0.43	13	5.1	24
L-2	0.82	0.44	13	5.1	22
L-3	0.84	0.43	12	5	24
Carry-over (%)	0.0%	0.0%	0.5%	0.2%	0.0%
Enterprise Standard (%)	**0.5**	**0.5**	**0.5**	**0.5**	**1**
Conclusion	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

3.2.3 Conclusion and Analysis

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

3.3 Daily Quality Control

3.3.1 Test Method

Use the same batch number and the different level of quality control objects, and test them on the quality control test interface every day. Statistic data and calculate CV/d, Sd.

3.3.2 Test Results

Testing Type	Blood Routine
Batch	BC0326L
Detection Level	Low
Bottling Date	05/03/2026
Testing Date	05/03/2026 - 24/03/2026
Number of Tests	20

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	3.28	2.35	57.45	17.77	75.72	24.43	322.80	61.65
CV/d	2.5%	1.1%	1.1%	1.1%	0.7%	0.9%	0.7%	5.6%
Enterprise Standard	6.0%	2.5%	2.0%	4.0%	2.5%	2.5%	3.0%	8.0%
Conclusion	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	Neu%	Lym%	Mon%	Eos%	Bas%	Neu#	Lym#	Mon#	Eos#	Bas#
MEAN	51.7	38.25	4.29	5.77	2.06	1.7	1.26	0.14	0.19	0.07
Conclusion	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	14.06	45.29	9.01	10.79	0.06
Conclusion	Under control	Under control	Under control	Under control	Under control

Testing Type	Blood Routine
Batch	BC0326N
Detection Level	Normal
Bottling Date	05/03/2026
Testing Date	05/03/2026 - 24/03/2026
Number of Tests	20

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.96	4.63	134.1	38.98	84.26	28.98	344.10	271.6
CV/d	1.7%	1.1%	0.9%	0.8%	0.8%	1.0%	0.6%	2.0%
Enterprise Standard	6.0%	2.5%	2.0%	4.0%	2.5%	2.5%	3.0%	8.0%
Conclusion	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	Neu%	Lym%	Mon%	Eos%	Bas%	Neu#	Lym#	Mon#	Eos#	Bas#
MEAN	57.48	29.75	4.01	8.77	1.71	4.58	2.37	0.31	0.7	0.14
Conclusion	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	13.03	46.96	8.84	11.89	0.24
Conclusion	Under control	Under control	Under control	Under control	Under control

Testing Type	Blood Routine
Batch	BC0326H
Detection Level	High
Bottling Date	05/03/2026
Testing Date	05/03/2026 - 24/03/2026
Number of Tests	20

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	17.92	5.35	172.8	48.38	90.53	32.34	357.45	480.45
CV/d	1.5%	1.0%	0.8%	0.9%	0.8%	0.7%	0.8%	2.0%
Enterprise Standard	6.0%	2.5%	2.0%	4.0%	2.5%	2.5%	3.0%	8.0%
Conclusion	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS
Control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	Neu%	Lym%	Mon%	Eos%	Bas%	Neu#	Lym#	Mon#	Eos#	Bas#
MEAN	66.33	16.35	7.13	10.2	1.13	11.89	2.93	1.27	1.82	0.2
Conclusion	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control	Under control

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	12.37	47.9	9.32	12.54	0.45
Conclusion	Under control	Under control	Under control	Under control	Under control

3.3.3 Conclusion and Analysis

The data showed that all parameters are within the deviation limit when the quality control objects were tested and evaluated at different levels.

3.4 Precision Testing

3.4.1 Test Method

Venous Whole Blood Test Method:

Select fresh anticoagulant venous whole blood samples that meet the requirements of the detection range, measure them 10 times under the counting interface, and calculate the coefficient of variation (CV%) or standard deviation (SD) or absolute deviation (d) of the 10-times-results.

Table 14 Repeatability Requirement

Parameters	Reference Range	Enterprise Standard (CV/d)
WBC	(7.3~20.4) x 10^9/L	≤3.0%
RBC	(4.5~17.0) x 10^12/L	≤1.5%
HGB	(90~180) g/L	≤1.5%
MCV	(32~69) Fl	≤1.0%
PLT	(150~576) x 10^9/L	≤6.0%

3.4.2 Test Results

Table 15 Test Results of Repeatability – Rabbit

Mode	Rabbit						
Parameter	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Enterprise Standard (CV/d)	Conclusion
WBC	1.9%	1.4%	1.5%	1.2%	0.8%	**3.0%**	PASS
RBC	0.5%	0.8%	0.7%	0.7%	1.2%	**1.5%**	PASS
HGB	0.5%	0.4%	0.6%	0.4%	0.6%	**1.5%**	PASS
MCV	0.2%	0.2%	0.2%	0.2%	0.2%	**1.0%**	PASS
PLT	1.7%	2.0%	1.9%	0.8%	2.8%	**6.0%**	PASS

Table 16 Test Results of Repeatability – Bovine

Mode	Bovine						
Parameter	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Enterprise Standard (CV/d)	Conclusion
WBC	1.4%	1.0%	1.3%	1.6%	1.2%	**3.0%**	PASS
RBC	0.4%	1.0%	0.8%	0.5%	0.7%	**1.5%**	PASS
HGB	0.6%	0.8%	0.5%	0.4%	0.5%	**1.5%**	PASS
MCV	0.1%	0.2%	0.3%	0.2%	0.2%	**1.0%**	PASS
PLT	1.8%	3.3%	3.5%	2.0%	2.0%	**6.0%**	PASS

Table 17 Test Results of Repeatability – Equine

Mode	Equine						
Parameter	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Enterprise Standard (CV/d)**	**Conclusion**
WBC	1.6%	1.0%	1.7%	1.1%	1.5%	**3.0%**	PASS
RBC	0.6%	0.5%	0.5%	0.8%	0.7%	**1.5%**	PASS
HGB	0.7%	0.4%	0.5%	0.5%	0.5%	**1.5%**	PASS
MCV	0.2%	0.3%	0.2%	0.2%	0.2%	**1.0%**	PASS
PLT	2.7%	2.6%	2.3%	2.8%	2.6%	**6.0%**	PASS

Table 18 Test Results of Repeatability – Sheep

Mode	Sheep						
Parameter	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Enterprise Standard (CV/d)**	**Conclusion**
WBC	1.7%	1.4%	1.8%	1.3%	2.2%	**3.0%**	PASS
RBC	0.7%	1.2%	1.1%	0.5%	0.8%	**1.5%**	PASS
HGB	0.6%	0.6%	0.8%	0.6%	0.8%	**1.5%**	PASS
MCV	0.2%	0.2%	0.1%	0.2%	0.3%	**1.0%**	PASS
PLT	3.4%	1.6%	1.0%	2.0%	3.0%	**6.0%**	PASS

3.4.3 Conclusion and Analysis

It can be seen from the test results that the precision of InSight V5R meets the requirements for product specifications.

3.5 Correlation

3.5.1 Test Method

The correlation of blood count was evaluated by selecting two top-grade five type models. The comparison instrument and BC5000 Vet are required to be calibrated according to their respective requirements before counting correlation evaluation and statistical regression equation is required. In the statistical process, it is required to remove samples with limited measurement accuracy due to the limitation of principle, such as small red blood cells and samples with nuclear red cells. Statistical regression equation: Y= aX + b; Calculate the correlation coefficient r.

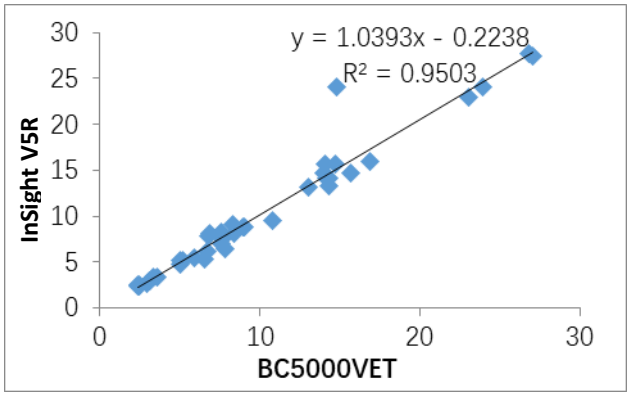
Table 19 Requirement of Correlation Index of Venous Whole Blood Count

	Parameters	**Rabbit**	**Bovine**	**Equine**	**Sheep**
Count Correlation (Y = aX + b)	WBC	r≥ 0.90	r≥ 0.90	r≥ 0.90	r≥ 0.90
	RBC	r≥ 0.90	r≥ 0.85	r≥ 0.90	r≥ 0.90
	HGB	r≥ 0.90	r≥ 0.85	r≥ 0.90	r≥ 0.90
	MCV	r≥ 0.85	r≥ 0.90	r≥ 0.90	r≥ 0.50
	PLT	r≥ 0.50	r≥ 0.85	r≥ 0.50	r≥ 0.75

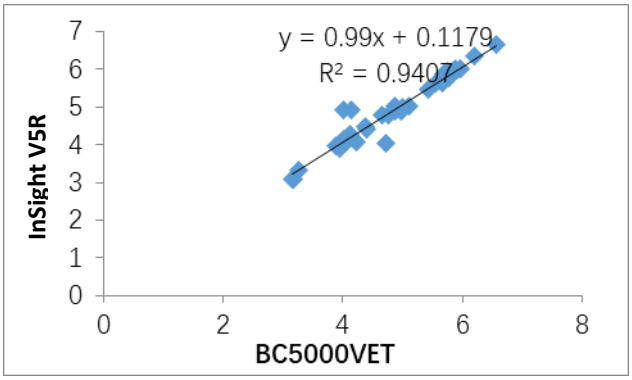
3.5.2 Test Results

Figure 1 Diagram for the Correlation Between InSight V5R and BC5000VET (Rabbit)

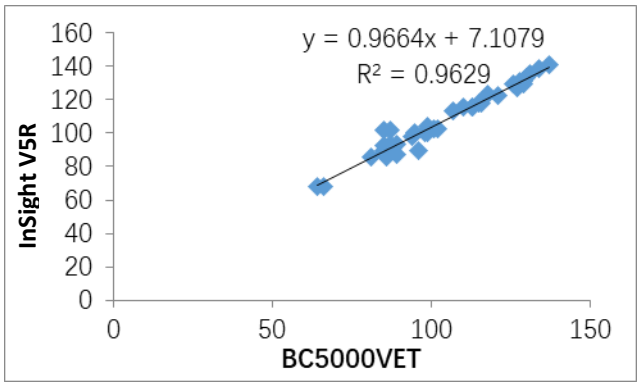
WBC



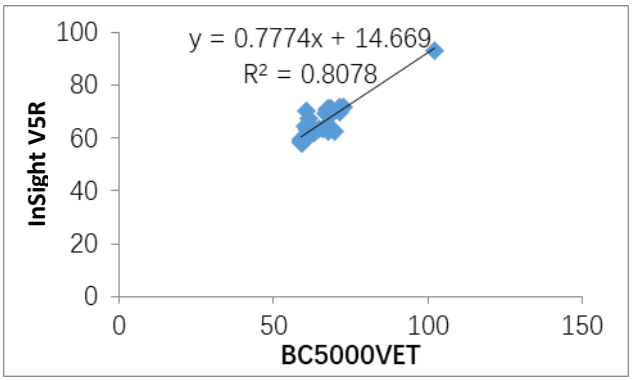
RBC



HGB



MCV



PLT

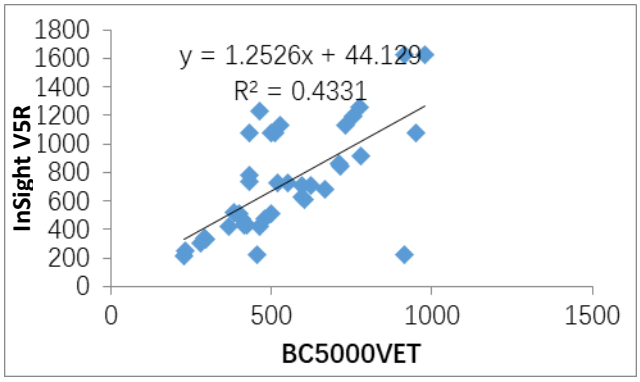
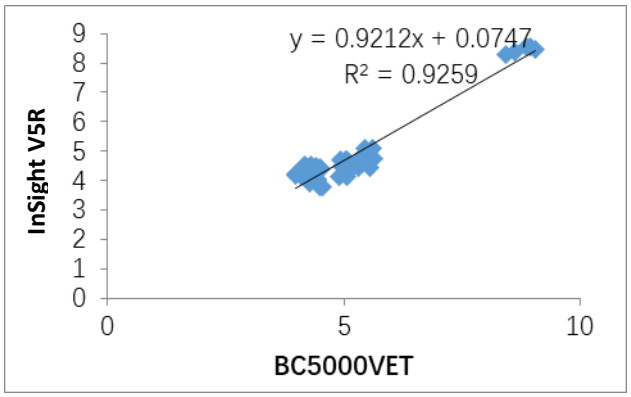
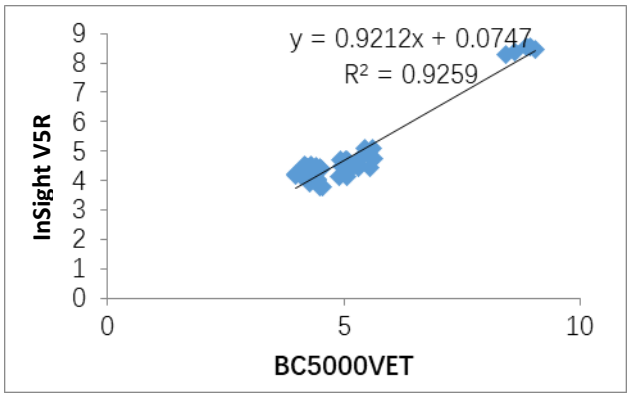


Figure 2 Diagram for the Correlation Between InSight V5R and BC5000VET (Bovine)

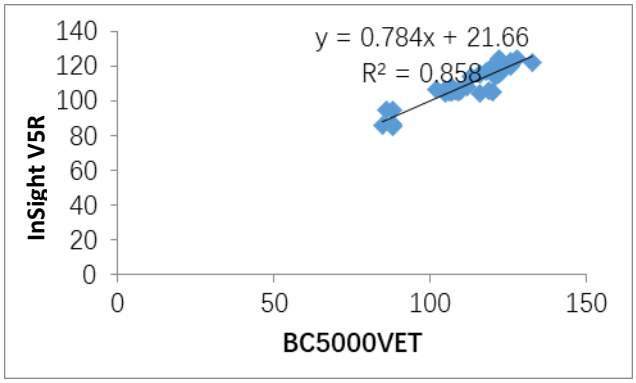
WBC



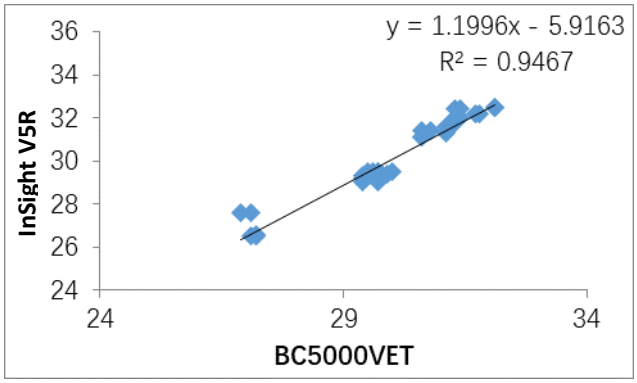
RBC



HGB



MCV



PLT

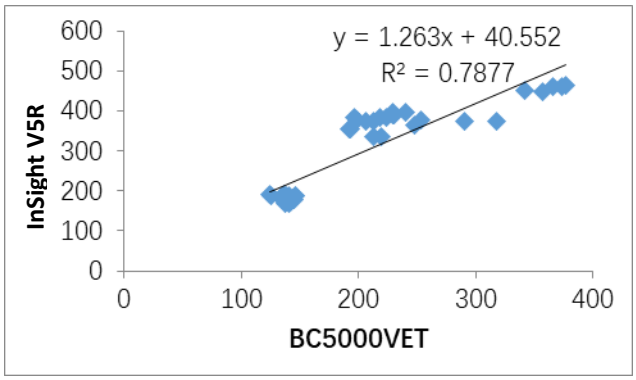
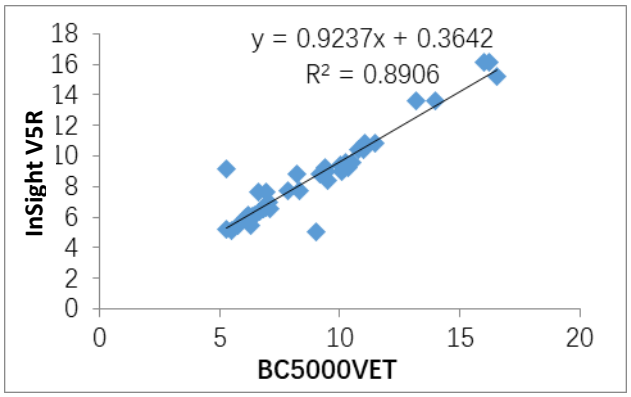
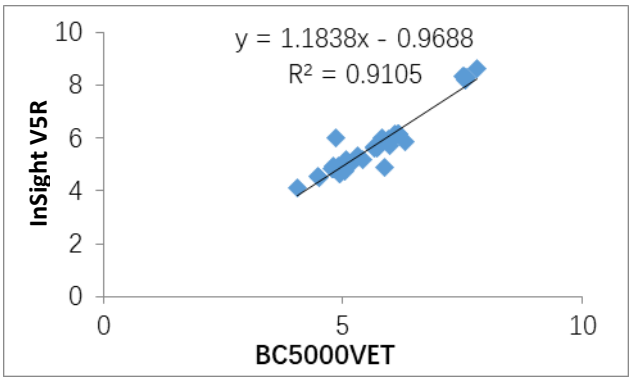


Figure 3 Diagram for the Correlation Between InSight V5R and BC5000VET (Equine)

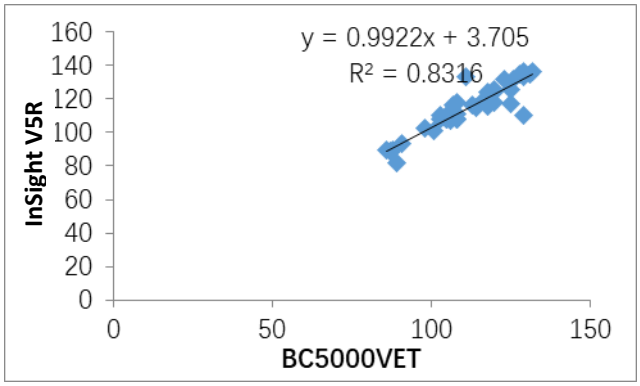
WBC



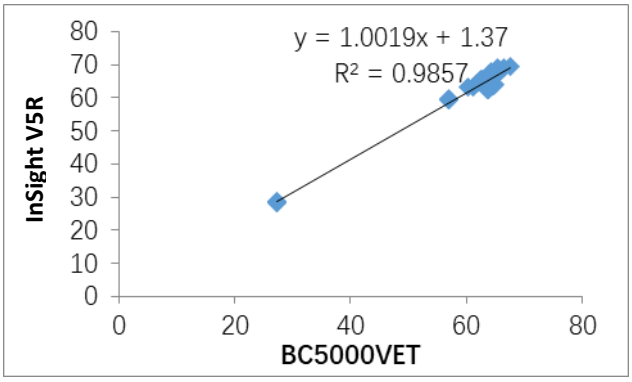
RBC



HGB



MCV



PLT

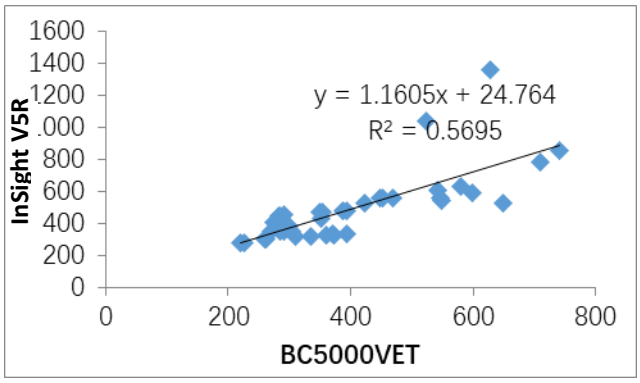
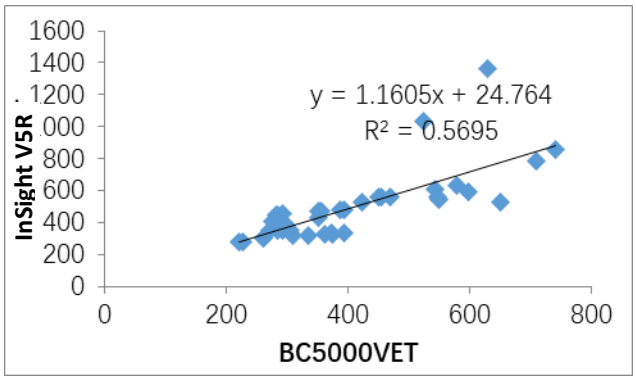
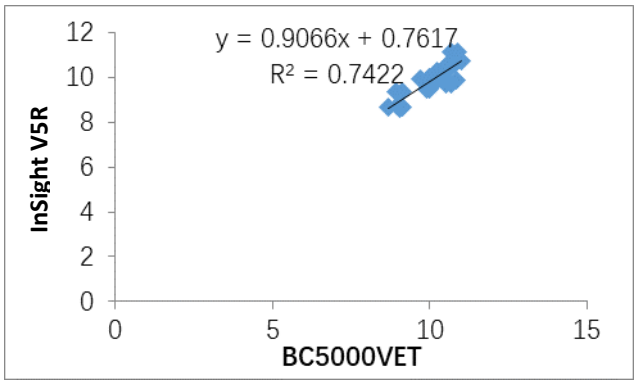


Figure 4 Diagram for the Correlation Between InSight V5R and BC5000VET (Sheep)

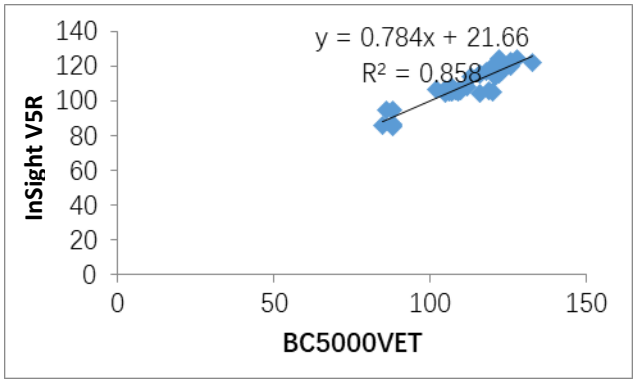
WBC



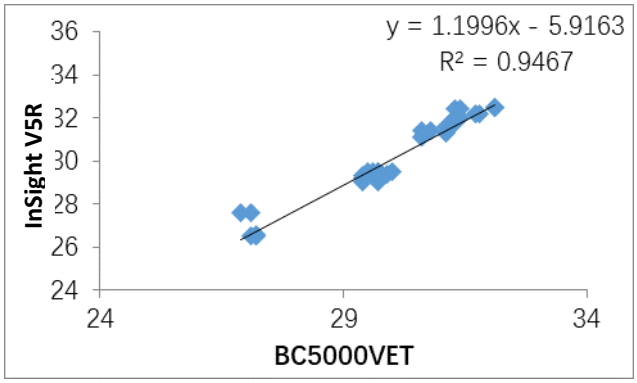
RBC



HGB



MCV



PLT

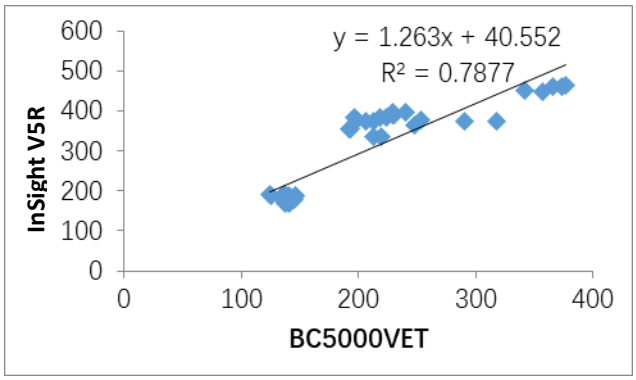


Table 20 Correlation Results of InSight V5R and BC5000VET

Mode	Parameters	WBC	RBC	HGB	MCV	PLT
Rabbit	Correlation	0.975	0.970	0.981	0.899	0.658
	Enterprise Standard (≥)	**0.90**	**0.90**	**0.90**	**0.85**	**0.50**
Mode	**Parameters**	**WBC**	**RBC**	**HGB**	**MCV**	**PLT**
Bovine	Correlation	0.962	0.862	0.926	0.973	0.888
	Enterprise Standard (≥)	**0.90**	**0.85**	**0.85**	**0.90**	**0.85**
Mode	**Parameters**	**WBC**	**RBC**	**HGB**	**MCV**	**PLT**
Equine	Correlation	0.944	0.954	0.912	0.993	0.755
	Enterprise Standard (≥)	**0.90**	**0.90**	**0.90**	**0.90**	**0.50**
Mode	**Parameters**	**WBC**	**RBC**	**HGB**	**MCV**	**PLT**
Sheep	Correlation	0.991	0.978	0.986	0.713	0.810
	Enterprise Standard (≥)	**0.90**	**0.90**	**0.90**	**0.50**	**0.75**

3.5.3 Data Analysis Conclusion

It can be seen from the test results that the correlation index meets the requirements of the product specifications.