

InSight V5R Clinical Performance Validation Report – Rat and Mouse

Table of Contents

Chapter 1 Overview	2
1.1 Purpose of Experiment	2
1.2 Evaluation Items	2
1.3 Conclusion of Experiment.....	2
1.4 Applicable Scope and Species.....	2
Chapter 2 Resource Allocation for Clinical Trials	3
2.1 Instrument and Reagent Information	3
2.1.1 Test Machine and Reagents.....	3
2.2 Sample Information	3
2.3 Experiment Base	3
Chapter 3 Experiment Results and Analysis.....	4
3.1 Background Test.....	4
3.1.1 Test Method	4
3.1.2 Test Results	4
3.1.3 Conclusion and Analysis	4
3.2 Carry-over Rate	5
3.2.1 Test Method	5
3.2.2 Test Results	5
3.2.3 Conclusion and Analysis	6
3.3 Daily Quality Control.....	6
3.3.1 Test Method	6
3.3.2 Test Results	6
3.3.3 Conclusion and Analysis	6
3.4 Precision Testing	6
3.4.1 Test Method	6
3.4.2 Test Results	8
3.4.3 Conclusion and Analysis	8
3.5 Correlation	9
3.5.1 Test Method	9
3.5.2 Test Results	9
3.5.3 Data Analysis Conclusion.....	10

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 mouse and rat 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: Rat and Mouse.

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.	NK0825	BC0725L	BC0725N	BC0725H
Exp. Date	2025.09.10	2025.09.10	2025.09.10	2025.09.10

Table 3 Version Information of the Test Machine

Software Full Version	0.5.20.22912	Software Release Version	5
Technical File Version	A1.4	Machine Type	7003
Application Software	0.1.0.2912	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	0.1.0.21363	RF Card Reader MCU	1.0.0.18383

2.2 Sample Information

Select fresh Rat and Mouse anticoagulant venous whole blood and use EDTA-K₂ 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	$\leq 0.20 \times 10^9/L$
RBC	$\leq 0.02 \times 10^{12}/L$
HGB	$\leq 1 \text{ g/L}$
HCT	$\leq 0.5\%$
PLT	$\leq 10 \times 10^9/L$

3.1.2 Test Results

Table 5 Background Test Results – Rat

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 (\leq)	0.20	0.02	1	0.5	10
Conclusion	PASS	PASS	PASS	PASS	PASS

Table 6 Background Test Results – Mouse

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 (\leq)	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:

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

Table 7 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 8 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Rat

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	111.88	8.12	276	78.6	1021
H-2	112	8.05	271	78.3	1010
H-3	113.05	8.05	271	78.3	1010
L-1	0.26	0.16	12	1.7	12
L-2	0.23	0.15	12	1.6	10
L-3	0.22	0.15	12	1.6	10
Carry-over (%)	0.0%	0.1%	0.0%	0.1%	0.2%
Enterprise Standard (%)	0.5	0.5	0.5	0.5	1
Conclusion	PASS	PASS	PASS	PASS	PASS

Table 9 Test Results of Carry-over Rate (Venous Whole Blood – CBC+DIFF) – Mouse

Sample No.	WBC	RBC	HGB	HCT	PLT
H-1	112.68	7.85	274	74.2	1157
H-2	113.84	7.87	273	74.3	1165
H-3	113.64	7.78	270	73.7	1180
L-1	0.28	0.15	12	1.6	13
L-2	0.27	0.15	12	1.6	12
L-3	0.3	0.15	12	1.6	14
Carry-over (%)	0.0%	0.1%	0.0%	0.0%	0.1%
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	BC0725L
Detection Level	Low
Bottling Date	30/07/2025
Testing Time	2025/07/30 - 2025/08/05
Number of Tests	5

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	3.4	2.08	57	16.72	80.24	27.34	340.6	52.2
CV/d	1.70%	0.50%	0.00%	0.70%	0.30%	1.00%	0.90%	5.70%
Enterprise Standard	6.00%	2.50%	2.00%	4.00%	2.50%	2.50%	3.00%	8.00%
Conclusion	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	53.72	35.34	5.76	5.18	4.48	1.83	1.21	0.19	0.17	0.15
Conclusion	Under control									

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	14.82	53.84	8.18	7.44	0.04
Control	Under control	Under control	Under control	Under control	Under control

Testing Type	Blood Routine
Batch	BC0725N
Detection Level	Normal
Bottling Date	30/07/2025
Testing Time	2025/07/30 - 2025/08/05
Number of Tests	6

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	8.36	4.16	130.5	36.5	87.67	31.32	357.33	217.83
CV/d	1.10%	0.80%	0.60%	1.00%	0.30%	0.50%	0.60%	2.40%
Enterprise Standard	6.00%	2.50%	2.00%	4.00%	2.50%	2.50%	3.00%	8.00%
Conclusion	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	57.5	29.23	6.17	7.1	3.85	4.81	2.45	0.51	0.59	0.32
Conclusion	Under control									

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	12.68	50.77	7.55	9.13	0.16
Control	Under control	Under control	Under control	Under control	Under control

Testing Type	Blood Routine
Batch	BC0725H
Detection Level	High
Bottling Date	30/07/2025
Testing Time	2025/07/30 - 2025/08/05
Number of Tests	6

Parameters	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	17.77	4.76	161.33	44.33	93.1	33.92	364.33	434.33
CV/d	1.30%	0.70%	0.60%	0.80%	0.30%	0.50%	0.60%	1.40%
Enterprise Standard	6.00%	2.50%	2.00%	4.00%	2.50%	2.50%	3.00%	8.00%
Conclusion	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	63.47	19.32	7.53	9.68	2.1	11.29	3.44	1.33	1.72	0.37
Conclusion	Under control									

Parameters	RDW-CV	RDW-SD	MPV	PDW	PCT
MEAN	12.18	51.87	7.68	9.47	0.33
Control	Under control	Under control	Under control	Under control	Under control

Venous Whole Blood Test Method:

Select fresh anticoagulant (EDTA-K₂) 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 10 Repeatability Requirement

Parameters	Reference Range (Mouse)	Enterprise Standard (CV/d)
WBC	(4.00-15.00) x 10 ⁹ /L	≤5.0%
Neu%	(10.0%~21.0%)	±5.0 (Absolute deviation)
Lym%	(70.0%~96.0%)	±5.0 (Absolute deviation)
Mon%	(0.0%~10.0%)	±4.0 (Absolute deviation)
Eos%	(0.0%~5.0%)	±3.0 (Absolute deviation)
Bas%	(0.0%~2.0%)	±3.0 (Absolute deviation)
RBC	(6.00-12.50) x 10 ¹² /L	≤2.0%
HGB	(100-190) g/L	≤2.0%
MCV	(41.0-73.0) fL	≤4.0%
PLT	(540-1240) x 10 ⁹ /L	≤8.0%
Parameters	Reference Range (Rat)	Enterprise Standard (CV/d)
WBC	(5.00-20.00) x 10 ⁹ /L	≤5.0%
Neu%	(1.2%~30.0%)	±5.0 (Absolute deviation)
Lym%	(70.0%~96.0%)	±5.0 (Absolute deviation)
Mon%	(0.0%~10.0%)	±4.0 (Absolute deviation)
Eos%	(0.0%~5.0%)	±3.0 (Absolute deviation)
Bas%	(0.0%~2.0%)	±3.0 (Absolute deviation)
RBC	(5.00-10.50) x 10 ¹² /L	≤2.0%
HGB	(100-190) g/L	≤2.0%
MCV	(41.0-63.0) fL	≤4.0%
PLT	(540-1540) x 10 ⁹ /L	≤8.0%

3.4.2 Test Results

Type	Sample No.	WBC	Neu%	Lym%	Mon%	Eos%	Bas%	RBC	HGB	MCV	PLT
Mouse	1	PASS									
	2	PASS									
	3	PASS									
	4	PASS									
	5	PASS									
	6	PASS									
	7	PASS									
	8	PASS									
	9	PASS									
	10	PASS									
Quantity		10	10	10	10	10	10	10	10	10	10
Number of Non-Compliant Cases		0	0	0	0	0	0	0	0	0	0
Percent of Pass		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Type	Sample No.	WBC	Neu%	Lym%	Mon%	Eos%	Bas%	RBC	HGB	MCV	PLT
Rat	1	PASS									
	2	PASS									
	3	PASS									
	4	PASS									
	5	PASS									
	6	PASS									
	7	PASS									
	8	PASS									
	9	PASS									
	10	PASS									
Quantity		10	10	10	10	10	10	10	10	10	10
Number of Non-Compliant Cases		0	0	0	0	0	0	0	0	0	0
Percent of Pass		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

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 11 Requirement of Correlation Index of Venous Whole Blood Count

Count Correlation ($Y = aX + b$)	Parameters	Rat	Mouse
	WBC	$r \geq 0.90$	$r \geq 0.90$
	RBC	$r \geq 0.90$	$r \geq 0.85$
	HGB	$r \geq 0.90$	$r \geq 0.90$
	MCV	$r \geq 0.80$	$r \geq 0.75$
	PLT	$r \geq 0.80$	$r \geq 0.80$
	Mon% (0-10)	± 3 (Laboratory result comparability)	± 3 (Laboratory result comparability)
	Mon% (>10)	40% (Laboratory result comparability)	40% (Laboratory result comparability)
	Eos% (0-10) / (0-5)	± 3 (Laboratory result comparability)	± 3 (Laboratory result comparability)
	Eos% (>10) / (>5)	40% (Laboratory result comparability)	40% (Laboratory result comparability)

3.5.2 Test Results

Correlation Results of InSight V5R and BC5000VET – Mouse							
Parameter	WBC	Neu%	Lym%	RBC	HGB	MCV	PLT
Correlation (r)	0.997	0.975	0.981	0.945	0.989	0.945	0.938
Enterprise Standard (\geq)	0.90	0.80	0.80	0.85	0.90	0.75	0.80
Conclusion	PASS						

Correlation Results of InSight V5R and BC5000VET – Rat							
Parameter	WBC	Neu%	Lym%	RBC	HGB	MCV	PLT
Correlation (r)	0.997	0.976	0.969	0.910	0.983	0.964	0.936
Enterprise Standard (\geq)	0.90	0.80	0.80	0.90	0.90	0.80	0.80
Conclusion	PASS						

Laboratory Result Comparability – Mouse							
Total Number of Cases: 49	Test Item	Concentration Range		Quantity Requirement	Number of Test Cases	Number of Non-Compliant Cases	Percent of Pass
		Lower Limit	Upper Limit				
Mon%		0	10	≥40	30	0	100%
		10.1	Above		19	0	
Eos%		0	10	≥40	48	1	98%
		10.1	Above		0	0	

Laboratory Result Comparability – Rat							
Total Number of Cases: 48	Test Item	Concentration Range		Quantity Requirement	Number of Test Cases	Number of Non-Compliant Cases	Percent of Pass
		Lower Limit	Upper Limit				
Mon%		0	10	≥40	29	0	100%
		10.1	Above		19	0	
Eos%		0	5	≥40	48	1	98%
		5.1	Above		0	0	

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.