InSight V5 Veterinary Haematology Analyser

Clinical Performance Verification Report – Guinea Pig

Contents

Chapter 1 Overview

1.1 Purpose of Experiment

The main performance indicators of the InSight V5 Veterinary Haematology Analyser and its supporting reagents meet the specifications required by the instrument and whether it can meet the effectiveness and safety of clinical use.

1.2 Evaluation Items

- Background
- Precision
- Carry-over Rate
- Linearity
- 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.
- Linearity – The linearity meets the specification requirements.
- Correlation – The correlation meets the specification requirements.

1.4 Applicable Scope and Species

This clinical test is applicable to the InSight V5 Veterinary Haematology Analyser.

Species: Guinea Pig

Reference Standard: Performance metrics refer to new metrics developed with the InSight V5 Veterinary Haematology Analyser, mainly reflected in batch precision and correlation.

Chapter 2 Resource Allocation for Clinical Trials

2.1 Instrument and Reagent Information

2.1.1 Test Machine and Reagents

Test Machine: InSight V5 Veterinary Haematology Analyser (selected at random)

Table 1 Reagent Information of the Test Machine

Reagent Name	V5 DIL Diluent	V5 LY1 Lyse	V5 LY2 Lyse
Lot No.	2020080901	2020040201	2020042101
Expiry Date	08.08.2022	01.04.2022	20.04.2022

Table 2 Version Information of the Test Machine

Component Version	0.5.20.21780	Software Release	5
Technical File Version	A8.0	Analyser Type	1108
Application Software	0.8.0.1781	Algorithm	0.1.1.5949
Guide Software	0.11.9.16974	MLO	0.11.9.16974
MCU	1.3.0.10950	FPGA	0.1.0.1289
Fluidics Sequence	3.1108.020.002	Operating System	3.2.0.20008
LIBS	0.1.0.14974	HPCBA	0.0.0.0
RF Card Reader MCU	1.1.0.2865		

2.2 Sample Information

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

2.3 Experiment Base

Experiment Base: Clinical laboratory

Experiment Temperature: 20-25°C

Chapter 3 Experiment Results and Analysis

3.1 Background Test

3.1.1 Test Method

The dilution is used as a sample or air is directly absorbed as a sample and three tests are carried out on the analyser. The maximum value of these three tests is the result of blank count and the results should meet the requirements in Table 3.

Table 3 Background Requirements

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

3.1.2 Test Results

Table 4 Test Results of InSight V5 Background

Pattern	WBC x 10^9/L	RBC x 10^{12}/L	HGB g/L	HCT%	PLT x 10^9/L
Whole Blood – Guinea Pig	0	0	0	0	0
	0	0	0	0	0
	0	0	0	0	0
Enterprise Standard (<=)	0.2	0.02	1	0.5	10
Conclusion	PASS	PASS	PASS	PASS	PASS

3.1.3 Data Analysis Conclusion

It can be seen from 3.1.2 that the background test results of the InSight V5 Veterinary Haematology Analyser are within the range of product specifications and meet the requirements.

3.2 Precision

3.2.1 Test Method

Samples of fresh anticoagulant venous blood that meet the requirements of the test range were selected for ten consecutive measurements at the counting interface and the variation coefficient (CV%), standard deviation (SD) and absolute deviation (d) of the ten test results were calculated. The results should meet the requirements in Table 5.

Table 5 Requirements for the InSight V5 Precision Indexes

Parameters	Whole Blood – Guinea Pig
WBC	≤3.0% (5.00 ~ 15.00) x 10^9/L
Neu%	±4.0(Absolute deviation) (31.33% ~ 54.45%)
Lym%	±4.0(Absolute deviation) (40.42% ~ 65.20%)
Mon%	±3.0(Absolute deviation) (1.89% ~ 4.05%)
Eos%	±3.0(Absolute deviation) (1.10% ~ 3.31%)
Bas%	±1.0(Absolute deviation) (0.08% ~ 0.20%)
RBC	≤2.0% (3.97 ~ 5.00) x 10^{12}/L
HGB	≤2.0% (101 - 180) g/L
MCV	≤1.0% (77 ~93) fL
PLT	≤6.0% (293 ~593) x 10^9/L
MPV	≤4.0% (4 ~12)

3.2.2 Test Results

Mode	Guinea Pig						
Parameter	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Enterprise Standard (CV/d)	Conclusion
WBC	0.7%	1.9%	0.9%	1.5%	0.9%	3.0%	PASS
Neu%	1.09	1.26	0.91	1.35	0.57	4.0	PASS
Lym%	1.55	1.18	1.46	1.02	1.61	4.0	PASS
Mon%	0.85	0.4	0.87	0.63	0.3	3.0	PASS
Eos%	0.31	0.33	0.27	0.2	0.21	3.0	PASS
Bas%	0	0.13	0.09	0.1	0.11	1.0	PASS
RBC	0.4%	0.7%	0.6%	0.5%	0.5%	2.0%	PASS
HGB	0.4%	0.5%	0.4%	1.2%	0.9%	2.0%	PASS
MCV	0.2%	0.2%	0.1%	0.1%	0.2%	1.0%	PASS
PLT	1.6%	1.2%	1.6%	1.6%	1.9%	6.0%	PASS
MPV	1.4%	1.0%	1.7%	1.3%	1.8%	4.0%	PASS

3.2.3 Data Analysis Conclusion

It can be seen from the test results that the precision of the InSight V5 Veterinary Haematology Analyser meets the requirements for product specifications.

3.3 Carry-over Rate

3.3.1 Test Method

Perform continuous tests on the high and low value samples conforming to the requirements specified in the table below. Test the sample 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 6 Requirements for InSight V5 Carry-over Rate Indexes

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 7 Carry-over Rate Test Results (Guinea Pig)

Mode	WBC	RBC	HGB	HCT	PLT
H-01	30.73	7.81	267	84.7	484
H-02	31.42	8	274	87.4	501
H-03	31.52	8.03	275	87.8	499
L-01	0	0.01	0	0.1	0
L-02	0	0	0	0	0
L-03	0	0	0	0	0
Carry-Over Rate (%)	0.00	0.12	0.00	0.11	0.00
Enterprise Standard (%)	0.5	0.5	0.5	0.5	1
Conclusion	PASS	PASS	PASS	PASS	PASS

3.3.3 Data Analysis Conclusion

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

3.4 Linearity

3.4.1 Test Method

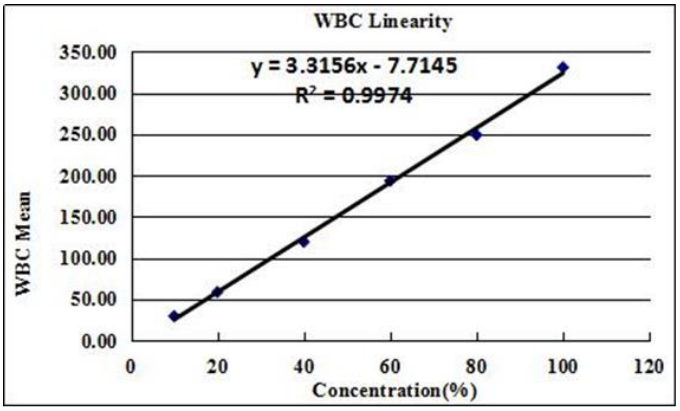
Take one high value sample of WBC, RBC, HGB, HCT and PLT, respectively. Perform gradient dilution on the samples by a concentration gradient of 10% from 100% to 0%. Test WBC, RBC, HGB, HCT and PLT by means of open sampling under whole blood mode. Measure each sample at different concentration levels three times. Take the mean values as 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 should meet the requirements specified in Table 8.

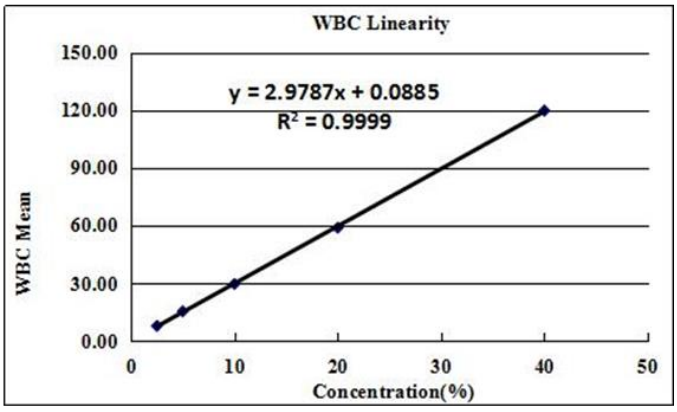
Table 8 Requirements for the InSight V5 Linearity Indexes

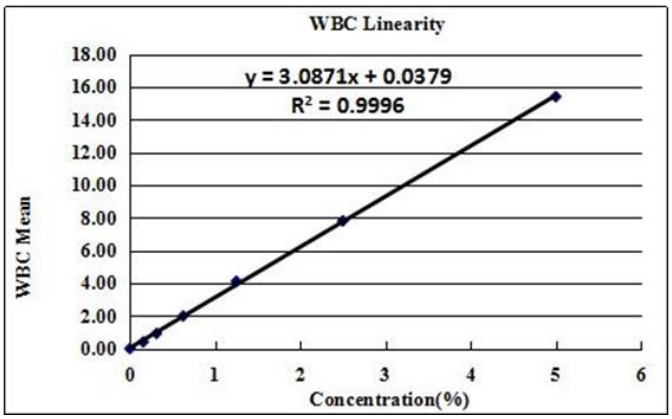
Parameters	Range of Measurement	Venous Blood
WBC	0.00~100.00 x 10^9/L	±0.30 x 10^9/L ±5%
	100.01~300.00 x 10^9/L	±10%
RBC	0.00~14.50 x 10^{12}/L	±0.05 x 10^{12}/L ±5%
HGB	0~250 g/L	±2 g/L ±2%
PLT	0~1000 x 10^9/L (1.0 ≤ RBC ≤ 7.0)	±10 x 10^9/L ±8%
	1001~3000 x 10^9/L (1.0 ≤ RBC ≤ 7.0)	±12%
HCT	0~67%	±2% (HCT Value) ±3% (Percentage Error)

3.4.2 Test Results

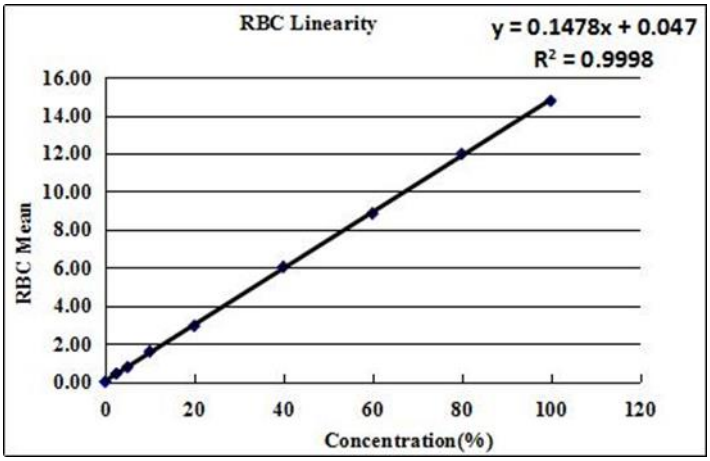
3.4.2.1 WBC Parameter



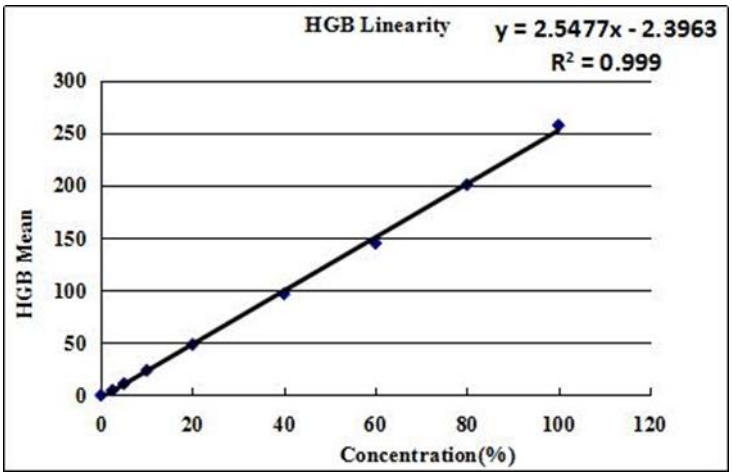




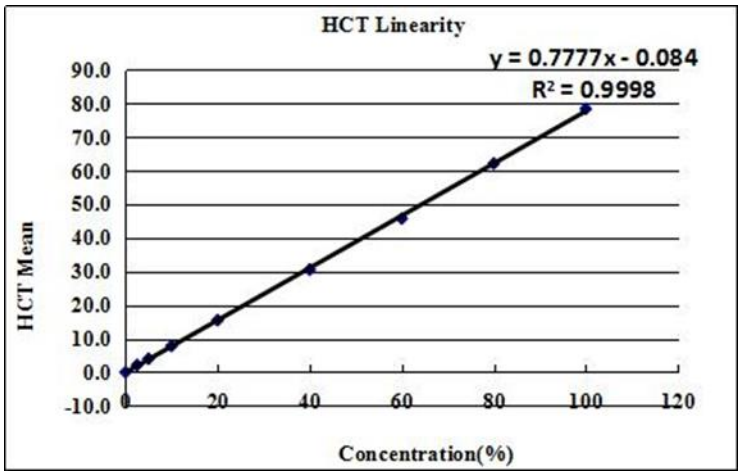
3.4.2.2 RBC Parameter



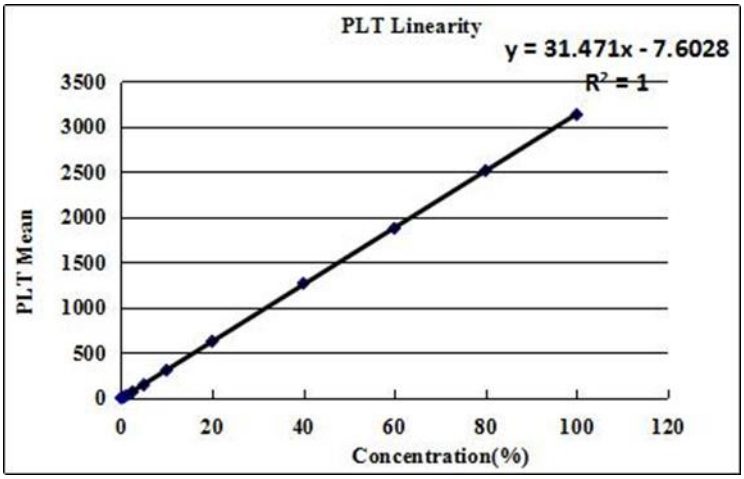
3.4.2.3 HGB Parameter



3.4.2.4 HCT Parameter



3.4.2.5 PLT Parameter



3.4.3 Data Analysis Conclusion

Table 9 Linear Test Total Results of InSight V5

Parameters	Range of Measurement	Correlation
WBC	0.00 – 300.00	0.00 – 15.40
		7.81 – 119.66
		58.81 – 330.89
RBC	0.00 – 14.50	0.00 – 14.76
HGB	0 – 250	0 – 257
HCT	0 – 67	0.0 – 78.4
PLT	0 – 3000	0 – 3134

3.4.4 Test Results

It can be seen from the test results that the linearity of the InSight V5 Veterinary Haematology Analyser meets the requirements of product specifications.

Note: This species is customised and modified according to the characteristics of collected blood sample data. For other research species, please contact Woodley Equipment Company.

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