

# InSight V5R Clinical Performance Validation Report – Dog and Cat

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## Chapter 1 Overview

### 1.1 Purpose of Experiment

The main performance indicators of the InSight V5R 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 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.
- 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 InSight V5R.

Species: Dog and Cat.

## 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 | V5 DIF-R Diluent | V5 FDF-R Dye |
|--------------|----------------|-------------|-------------|------------------|--------------|
| Lot No.      | 2023010502     | 2022082501  | 2022120701  | 2022120701       | 2022120701   |
| Exp. Date    | 2025.01.04     | 2024.08.24  | 2024.12.06  | 2024.12.06       | 2024.12.06   |

**Table 2 Version Information of the Test Machine**

|                        |                |                          |              |
|------------------------|----------------|--------------------------|--------------|
| Component Version      | 0.5.20.21647   | Software Release Version | 5            |
| Technical File Version | A0.2           | Machine Type             | 7003         |
| Application Software   | 0.0.0.1647     | Algorithm                | 0.1.1.17855  |
| Guide Software         | 0.11.9.21784   | MLO                      | 0.11.9.21784 |
| MCU                    | 1.3.0.17859    | FPGA                     | 0.101.0.10   |
| Fluidics Sequence      | 3.7003.100.012 | Operating System         | 3.2.0.21818  |
| LIBS                   | 0.1.0.18009    | RF Card Reader MCU       | 2.1.0.5926   |
| HPCBA                  | 4.0.0.0        |                          |              |

### 2.2 Sample Information

Select fresh anticoagulant venous whole blood and use EDTA-K<sub>2</sub> 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: +20°C to +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 the three test results 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                   | $\leq 0.20 \times 10^9/L$    |
| 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 4 Background Test Results – Dog**

| Mode   | WBC x $10^9/L$ | RBC x $10^{12}/L$ | HGB g/L     | HCT %       | PLT x $10^9/L$ |
|--|----------------|-------------------|-------------|-------------|----------------|
| Whole Blood – Dog                              | 0              | 0                 | 0           | 0.1         | 0              |
|  | 0              | 0                 | 0           | 0           | 0              |
|  | 0              | 0                 | 0           | 0           | 0              |
| <b>Enterprise Standard (<math>\leq</math>)</b> | <b>0.2</b>     | <b>0.02</b>       | <b>1</b>    | <b>0.5</b>  | <b>10</b>      |
| <b>Conclusion</b>                              | <b>PASS</b>    | <b>PASS</b>       | <b>PASS</b> | <b>PASS</b> | <b>PASS</b>    |

**Table 5 Background Test Results – Cat**

| Mode   | WBC x $10^9/L$ | RBC x $10^{12}/L$ | HGB g/L     | HCT %       | PLT x $10^9/L$ |
|--|----------------|-------------------|-------------|-------------|----------------|
| Whole Blood – Cat                              | 0              | 0                 | 0           | 0           | 0              |
|  | 0              | 0                 | 0           | 0           | 0              |
|  | 0              | 0                 | 0           | 0           | 0              |
| <b>Enterprise Standard (<math>\leq</math>)</b> | <b>0.2</b>     | <b>0.02</b>       | <b>1</b>    | <b>0.5</b>  | <b>10</b>      |
| <b>Conclusion</b>                              | <b>PASS</b>    | <b>PASS</b>       | <b>PASS</b> | <b>PASS</b> | <b>PASS</b>    |

#### 3.1.3 Conclusion and Analysis

It can be seen from the results of 3.1.2 that the background test results of the InSight V5R instrument 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 10 consecutive measurements at the counting interface, and the variation coefficient (CV%), standard deviation (SD) or absolute deviation (d) of the 10 results were calculated. The results should meet the requirements in table 6.

**Table 6 Requirements for the InSight V5R Precision Indexes**

| Parameters | Whole Blood – Dog                                      | Whole Blood – Cat                                      |
|------------|--|--|
| WBC        | ≤3.0% (7.28~16.58) x 10 <sup>9</sup> /L                | ≤3.0% (8.24~20.39) x 10 <sup>9</sup> /L                |
| RBC        | ≤1.5% (4.5-10.0) x 10 <sup>12</sup> /L                 | ≤1.5% (6.0-17.0) x 10 <sup>12</sup> /L                 |
| HGB        | ≤1.5% (90-180) g/L                                     | ≤1.5% (108-180) g/L                                    |
| MCV        | ≤1.0% (49~69) fL                                       | ≤1.0% (32~44) fL                                       |
| PLT        | ≤6.0% (156~576) x 10 <sup>9</sup> /L                   | ≤6.0% (150~350) x 10 <sup>9</sup> /L                   |
| MPV        | ≤4.0% (4~12)   | ±3.0 (Absolute deviation)                              |
| Retic#     | ≤15% (RBC≥3.00 x 10 <sup>12</sup> /L,<br>Retic% 1%-4%) | ≤15% (RBC≥3.00 x 10 <sup>12</sup> /L,<br>Retic% 1%-4%) |
| Retic%     | ≤15%   | ≤15%   |

### 3.2.2 Test Results

| Mode      | Dog      |          |          |          |          |                            |            |
|-----------|----------|----------|----------|----------|----------|----------------------------|------------|
| Parameter | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Enterprise Standard (CV/d) | Conclusion |
| WBC       | 1.1%     | 0.8%     | 1.3%     | 1.7%     | 1.1%     | 3.0%                       | PASS       |
| RBC       | 0.6%     | 0.7%     | 0.75%    | 0.6%     | 0.6%     | 1.5%                       | PASS       |
| HGB       | 0.6%     | 0.7%     | 0.7%     | 0.7%     | 0.5%     | 1.5%                       | PASS       |
| MCV       | 0.2%     | 0.1%     | 0.2%     | 0.3%     | 0.3%     | 1.0%                       | PASS       |
| PLT       | 1.3%     | 2.8%     | 2.7%     | 1.6%     | 1.5%     | 6.0%                       | PASS       |
| MPV       | 1.0%     | 2.0%     | 1.5%     | 1.9%     | 1.2%     | 4.0%                       | PASS       |
| Retic#    | 12.9%    | 10.1%    | 11.4%    | 10.5%    | 9.7%     | 15%                        | PASS       |
| Retic%    | 12.7%    | 10.0%    | 11.4%    | 10.5%    | 9.0%     | 15%                        | PASS       |

| Mode      | Dog      |          |          |          |          |                            |            |
|-----------|----------|----------|----------|----------|----------|----------------------------|------------|
| Parameter | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Enterprise Standard (CV/d) | Conclusion |
| WBC       | 0.9%     | 1.4%     | 1.9%     | 1.0%     | 2.0%     | 3.0%                       | PASS       |
| RBC       | 0.5%     | 0.7%     | 0.6%     | 0.8%     | 0.8%     | 1.5%                       | PASS       |
| HGB       | 0.7%     | 0.6%     | 0.5%     | 0.4%     | 0.5%     | 1.5%                       | PASS       |
| MCV       | 0.2%     | 0.2%     | 0.2%     | 0.2%     | 0.2%     | 1.0%                       | PASS       |
| PLT       | 1.4%     | 1.9%     | 2.3%     | 4.7%     | 2.1%     | 6.0%                       | PASS       |
| MPV       | 0.5%     | 0.5%     | 0.9%     | 2.2%     | 0.6%     | 4.0%                       | PASS       |
| Retic#    | 10.6%    | 11.6%    | 10.8%    | 9.4%     | 11.8%    | 15%                        | PASS       |
| Retic%    | 10.6%    | 11.4%    | 10.6%    | 9.3%     | 11.6%    | 15%                        | PASS       |

### 3.2.3 Conclusion and Analysis

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

### 3.3 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 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 Requirements for InSight V5R Carry-over Rate Indexes**

| Parameter | Carry-over Rate Requirements |
|-----------|------------------------------|
| WBC       | ≤0.5%                        |
| RBC       | ≤0.5%                        |
| HGB       | ≤0.5%                        |
| HCT       | ≤0.5%                        |
| PLT       | ≤1.0                         |

#### 3.3.2 Test Results

**Table 8 Test Carry-over Rate Test Results**

| Sample No.                     | WBC         | RBC         | HGB         | HCT         | PLT         |
|--------------------------------|-------------|-------------|-------------|-------------|-------------|
| Dog                            | 0.0%        | 0.1%        | 0.0%        | 0.0%        | 0.0%        |
| Cat                            | 0.1%        | 0.0%        | 0.0%        | 0.2%        | 0.1%        |
| <b>Enterprise Standard (%)</b> | <b>0.5</b>  | <b>0.5</b>  | <b>0.5</b>  | <b>0.5</b>  | <b>1</b>    |
| <b>Conclusion</b>              | <b>PASS</b> | <b>PASS</b> | <b>PASS</b> | <b>PASS</b> | <b>PASS</b> |

#### 3.3.3 Conclusion and Analysis

It can be seen from the test results that the carry-over rate of InSight V5R meets the requirements for 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 the 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 9.

**Table 9 Requirements for InSight V5R Linearity Indexes**

| Parameter | Range of Measurement                              | Venous Blood                                 |
|-----------|---|--|
| WBC       | 0.00 ~ 100.00 x 10 <sup>9</sup> /L                | ±0.30 x 10 <sup>9</sup> /L or ±5%            |
|           | 100.01 ~ 300.00 x 10 <sup>9</sup> /L              | ±10%   |
| RBC       | 0.00 ~ 17 x 10 <sup>12</sup> /L                   | ±0.05 x 10 <sup>12</sup> /L or ±5%           |
| HGB       | 0 ~ 250 g/L                                       | ±2 g/L or ±2%                                |
| PLT       | 0 ~ 1000 x 10 <sup>9</sup> /L                     | ±10 x 10 <sup>9</sup> /L or ±8%              |
|           | 1001 ~ 3000 x 10 <sup>9</sup> /L<br>(1.0≤RBC≤7.0) | ±12%   |
| HCT       | 0% ~ 67%  | ±2% (HCT Value) or ±3%<br>(Percentage Error) |
| Retic#    | 0.00 – 3.00 x 10 <sup>12</sup> /L                 | R≥0.90                                       |
| Retic%    | 0.0% – 23%  | R≥0.90                                       |

#### 3.4.2 Test Results

##### WBC

| Parameter             | WBC               | Sampling Mode | Open Vial            |        |            |                  |         |                 |        |
|-----------------------|-------------------|---------------|----------------------|--------|------------|------------------|---------|-----------------|--------|
| Test Resource         | Linearity Control | Blood Mode    | Whole Blood CBC+DIFF |        |            |                  |         |                 |        |
| Concentration (%)     | Test 1            | Test 2        | Test 3               | Mean   | Linear Fit | Bias             | Bias%   | Linearity Limit | Result |
| 100                   | 343.57            | 342.72        | 340.37               | 342.22 | 346.38     | -4.16            | -1.2    | 10%             | PASS   |
| 80                    | 279.44            | 287           | 278.38               | 281.61 | 277.02     | 4.59             | 1.66    | 10%             | PASS   |
| 60                    | 207.12            | 205.47        | 229.99               | 214.19 | 207.65     | 6.54             | 3.15    | 10%             | PASS   |
| 50                    | 168.92            | 169.09        | 167.77               | 168.59 | 172.97     | -4.38            | -2.53   | 10%             | PASS   |
| 40                    | 134.96            | 135.63        | 133.31               | 134.63 | 138.29     | -3.66            | -2.64   | 10%             | PASS   |
| 20                    | 71.2              | 69.38         | 69.38                | 69.99  | 68.93      | 1.06             | 1.54    | 5%              | PASS   |
| Regression Polynomial |                   |               |                      | Slope  | Intercept  | R <sup>2</sup> = |         | 0.99767         |        |
|                       |                   |               |                      | Y =    | 3.46814    | X +              | -0.4362 | R = 0.99883     |        |
| Concentration (%)     | Test 1            | Test 2        | Test 3               | Mean   | Linear Fit | Bias             | Bias%   | Linearity Limit | Result |
| 100                   | 122.37            | 120.86        | 122.1                | 121.78 | 122.06     | -0.28            | -0.23   | 10%             | PASS   |
| 80                    | 95.66             | 98.94         | 98.6                 | 97.73  | 97.64      | 0.09             | 0.09    | 5%              | PASS   |
| 60                    | 71.14             | 71.82         | 72.78                | 71.91  | 73.23      | -1.32            | -1.8    | 5%              | PASS   |
| 50                    | 66.67             | 64.66         | 60.38                | 63.9   | 61.02      | 2.88             | 4.72    | 5%              | PASS   |
| 40                    | 48.05             | 47.01         | 48.91                | 47.99  | 48.82      | -0.83            | -1.69   | 5%              | PASS   |
| 20                    | 23.14             | 23.92         | 24.47                | 23.85  | 24.4       | -0.56            | -2.28   | 5%              | PASS   |
| 0                     | 0                 | 0             | 0                    | 0.00   | -0.01      | 0.01             | -100.00 | 0.30            | PASS   |
| Regression Polynomial |                   |               |                      | Slope  | Intercept  | R <sup>2</sup> = |         | 0.99688         |        |
|                       |                   |               |                      | Y =    | 1.22067    | X +              | -0.0100 | R = 0.99844     |        |

**RBC**

| Parameter             | RBC               |        | Sampling Mode | Open Vial            |            |                  |         |                 |         |
|-----------------------|-------------------|--------|---------------|----------------------|------------|------------------|---------|-----------------|---------|
| Test Resource         | Linearity Control |        | Blood Mode    | Whole Blood CBC+DIFF |            |                  |         |                 |         |
| Concentration (%)     | Test 1            | Test 2 | Test 3        | Mean                 | Linear Fit | Bias             | Bias%   | Linearity Limit | Result  |
| 100                   | 17.88             | 17.97  | 18.01         | 17.95                | 18.26      | -0.3             | -1.66   | 5%              | PASS    |
| 80                    | 14.73             | 14.94  | 14.96         | 14.88                | 14.6       | 0.27             | 1.87    | 5%              | PASS    |
| 60                    | 11.14             | 11.03  | 11.21         | 11.13                | 10.95      | 0.17             | 1.59    | 5%              | PASS    |
| 40                    | 7.32              | 7.28   | 7.28          | 7.29                 | 7.3        | -0.01            | -0.1    | 5%              | PASS    |
| 20                    | 3.65              | 3.61   | 3.55          | 3.6                  | 3.65       | -0.05            | -1.24   | 5%              | PASS    |
| 10                    | 1.74              | 1.74   | 1.76          | 1.75                 | 1.82       | -0.08            | -4.18   | 5%              | PASS    |
| 5                     | 0.88              | 0.89   | 0.9           | 0.89                 | 0.91       | -0.02            | -2.18   | 0.05            | PASS    |
| 2.5                   | 0.45              | 0.44   | 0.45          | 0.45                 | 0.45       | -0.01            | -1.48   | 0.05            | PASS    |
| 1.25                  | 0.23              | 0.23   | 0.23          | 0.23                 | 0.23       | 0.00             | 2.15    | 0.05            | PASS    |
| 0.625                 | 0.12              | 0.11   | 0.11          | 0.11                 | 0.11       | 0.00             | 2.06    | 0.05            | PASS    |
| 0                     | 0                 | 0      | 0             | 0.00                 | 0.00       | 0.00             | -100.00 | 0.05            | PASS    |
| Regression Polynomial |                   |        |               | Slope                | Intercept  | R <sup>2</sup> = | 0.99952 |                 |         |
|                       |                   |        |               | Y =                  | 0.18259    | X +              | -0.0031 | R =             | 0.99976 |

**HGB**

| Parameter             | HGB         |        | Sampling Mode | Open Vial            |            |                  |         |                 |         |
|-----------------------|-------------|--------|---------------|----------------------|------------|------------------|---------|-----------------|---------|
| Test Resource         | Whole Blood |        | Blood Mode    | Whole Blood CBC+DIFF |            |                  |         |                 |         |
| Concentration (%)     | Test 1      | Test 2 | Test 3        | Mean                 | Linear Fit | Bias             | Bias%   | Linearity Limit | Result  |
| 100                   | 278         | 280    | 284           | 280.67               | 281.22     | -0.56            | -0.2    | 2%              | PASS    |
| 80                    | 226         | 224    | 228           | 226                  | 223.56     | 2.44             | 1.09    | 2%              | PASS    |
| 60                    | 163         | 164    | 164           | 163.67               | 165.9      | -2.23            | -1.35   | 2%              | PASS    |
| 20                    | 50          | 50     | 49            | 49.67                | 50.57      | -0.91            | -1.79   | 2.00            | PASS    |
| 10                    | 23          | 23     | 23            | 23                   | 21.74      | 1.26             | 5.78    | 2.00            | PASS    |
| Regression Polynomial |             |        |               | Slope                | Intercept  | R <sup>2</sup> = | 0.99972 |                 |         |
|                       |             |        |               | Y =                  | 2.88311    | X +              | -7.0878 | R =             | 0.99986 |
| Concentration (%)     | Test 1      | Test 2 | Test 3        | Mean                 | Linear Fit | Bias             | Bias%   | Linearity Limit | Result  |
| 20                    | 50          | 50     | 49            | 49.67                | 49.03      | 0.63             | 1.29    | 2.00            | PASS    |
| 10                    | 23          | 23     | 23            | 23                   | 23.57      | -0.57            | -2.4    | 2.00            | PASS    |
| 5                     | 10          | 10     | 10            | 10                   | 10.83      | -0.83            | -7.69   | 2.00            | PASS    |
| 2.5                   | 3           | 4      | 3             | 3.33                 | 4.47       | -1.13            | -25.37  | 2.00            | PASS    |
| 0                     | 0           | 0      | 0             | 0                    | -1.9       | 1.9              | -100    | 2.00            | PASS    |
| Regression Polynomial |             |        |               | Slope                | Intercept  | R <sup>2</sup> = | 0.99612 |                 |         |
|                       |             |        |               | Y =                  | 2.54667    | X +              | -1.9000 | R =             | 0.99806 |

**HCT**

| Parameter             | HCT               |        | Sampling Mode | Open Vial            |            |                  |         |                 |         |
|-----------------------|-------------------|--------|---------------|----------------------|------------|------------------|---------|-----------------|---------|
| Test Resource         | Linearity Control |        | Blood Mode    | Whole Blood CBC+DIFF |            |                  |         |                 |         |
| Concentration (%)     | Test 1            | Test 2 | Test 3        | Mean                 | Linear Fit | Bias             | Bias%   | Linearity Limit | Result  |
| 100                   | 66.3              | 66.7   | 67            | 66.67                | 66.93      | -0.26            | -0.39   | 3.00%           | PASS    |
| 80                    | 53.5              | 54.3   | 54.5          | 54.1                 | 53.5       | 0.6              | 1.13    | 2.00            | PASS    |
| 60                    | 40.2              | 39.9   | 40.3          | 40.13                | 40.06      | 0.07             | 0.18    | 2.00            | PASS    |
| 40                    | 26.2              | 26     | 26.1          | 26.1                 | 26.63      | -0.53            | -1.98   | 2.00            | PASS    |
| 20                    | 13.2              | 13     | 12.7          | 12.97                | 13.19      | -0.23            | -1.72   | 2.00            | PASS    |
| 10                    | 6.3               | 6.3    | 6.4           | 6.33                 | 6.48       | -0.14            | -2.21   | 2.00            | PASS    |
| 5                     | 3.2               | 3.2    | 3.2           | 3.2                  | 3.12       | 0.08             | 2.64    | 2.00            | PASS    |
| 2.5                   | 1.6               | 1.6    | 1.6           | 1.6                  | 1.44       | 0.16             | 11.24   | 2.00            | PASS    |
| 0                     | 0                 | 0      | 0             | 0                    | -0.24      | 0.24             | -100    | 2.00            | PASS    |
| Regression Polynomial |                   |        |               | Slope                | Intercept  | R <sup>2</sup> = | 0.99982 |                 |         |
|                       |                   |        |               | Y =                  | 0.67171    | X +              | -0.2410 | R =             | 0.99991 |

**PLT**

| Parameter             | PLT               |        | Sampling Mode | Open Vial            |            |           |                  |                 |        |
|-----------------------|-------------------|--------|---------------|----------------------|------------|-----------|------------------|-----------------|--------|
| Test Resource         | Linearity Control |        | Blood Mode    | Whole Blood CBC+DIFF |            |           |                  |                 |        |
| Concentration (%)     | Test 1            | Test 2 | Test 3        | Mean                 | Linear Fit | Bias      | Bias%            | Linearity Limit | Result |
| 100                   | 3140              | 3160   | 3114          | 3138                 | 3206.18    | -68.18    | -2.13            | 12.00%          | PASS   |
| 80                    | 2604              | 2609   | 2639          | 2617.33              | 2581.53    | 35.8      | 1.39             | 12.00%          | PASS   |
| 60                    | 2044              | 2008   | 2028          | 2026.67              | 1956.89    | 69.78     | 3.57             | 12.00%          | PASS   |
| 50                    | 1633              | 1678   | 1688          | 1666.33              | 1644.56    | 21.77     | 1.32             | 12.00%          | PASS   |
| 40                    | 1333              | 1318   | 1325          | 1325.33              | 1332.24    | -6.91     | -0.52            | 12.00%          | PASS   |
| 20                    | 662               | 650    | 654           | 655.33               | 707.6      | -52.26    | -7.39            | 8.00%           | PASS   |
| Regression Polynomial |                   |        |               | Y =                  | Slope      | Intercept | R <sup>2</sup> = | 0.99648         |        |
|                       |                   |        |               |                      | 31.23224   | X +       | R =              | 0.99824         |        |
| Concentration (%)     | Test 1            | Test 2 | Test 3        | Mean                 | Linear Fit | Bias      | Bias%            | Linearity Limit | Result |
| 100                   | 1026              | 1009   | 1002          | 1012.33              | 1016.42    | -4.09     | -0.4             | 12.00%          | PASS   |
| 80                    | 821               | 804    | 814           | 813                  | 813.31     | -0.31     | -0.04            | 8.00%           | PASS   |
| 50                    | 525               | 515    | 513           | 517.67               | 508.65     | 9.02      | 1.77             | 8.00%           | PASS   |
| 40                    | 405               | 406    | 419           | 410                  | 407.09     | 2.91      | 0.71             | 8.00%           | PASS   |
| 20                    | 198               | 197    | 197           | 197.33               | 203.98     | -6.65     | -3.26            | 8.00%           | PASS   |
| 0                     | 0                 | 0      | 0             | 0                    | 0.87       | -0.87     | -100             | 10.00           | PASS   |
| Regression Polynomial |                   |        |               | Y =                  | Slope      | Intercept | R <sup>2</sup> = | 0.99979         |        |
|                       |                   |        |               |                      | 10.15553   | X +       | R =              | 0.99989         |        |

**3.4.3 Conclusion and Analysis**

It can be seen from the test results that the linearity of the InSight V5R Analyser meets the requirements of 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 IDEXX Procyte ONE 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 10 Requirements for InSight V5R Correlation Indexes**

| Parameter | Dog           | Cat           |
|-----------|---------------|---------------|
| WBC       | $r \geq 0.85$ | $r \geq 0.85$ |
| RBC       | $r \geq 0.90$ | $r \geq 0.90$ |
| HGB       | $r \geq 0.90$ | $r \geq 0.90$ |
| MCV       | $r \geq 0.80$ | $r \geq 0.90$ |
| PLT       | $r \geq 0.85$ | $r \geq 0.75$ |
| Retic#    | $r \geq 0.90$ | $r \geq 0.90$ |
| Retic%    | $r \geq 0.90$ | $r \geq 0.90$ |

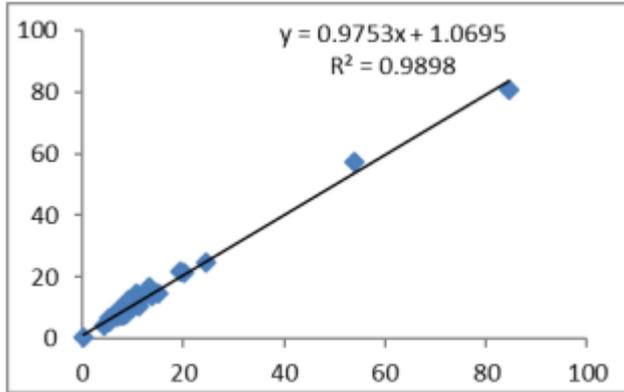
**NOTE:**

This standard is only applicable to the comparison IDEXX Procyte ONE and InSight V5R. Other models are only for reference.

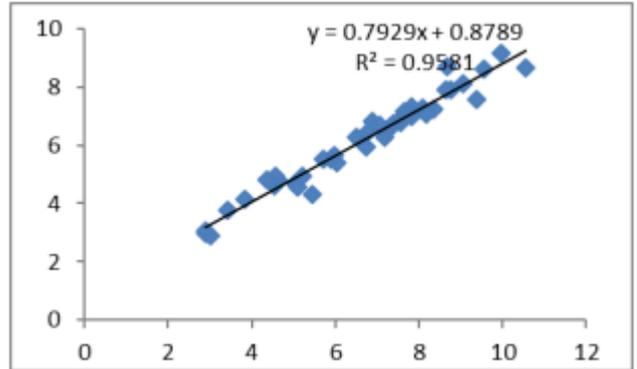
**3.5.2 Test Results**

**Diagram for the Correlation Between InSight V5R and IDEXX Procyte ONE (Dog)**

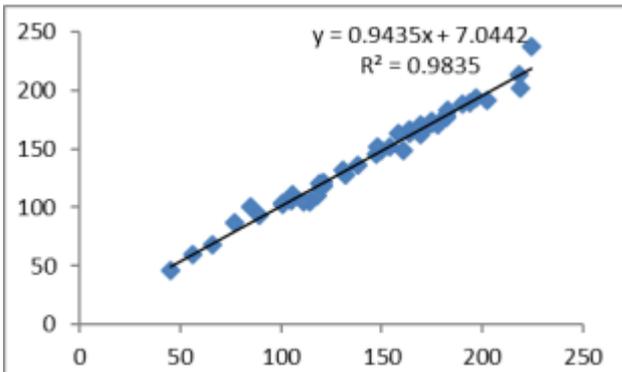
**WBC**



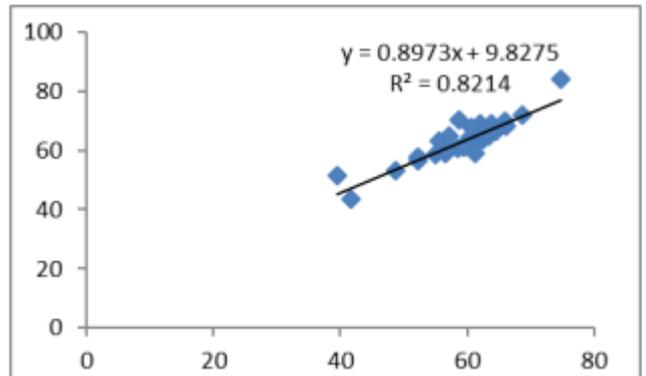
**RBC**



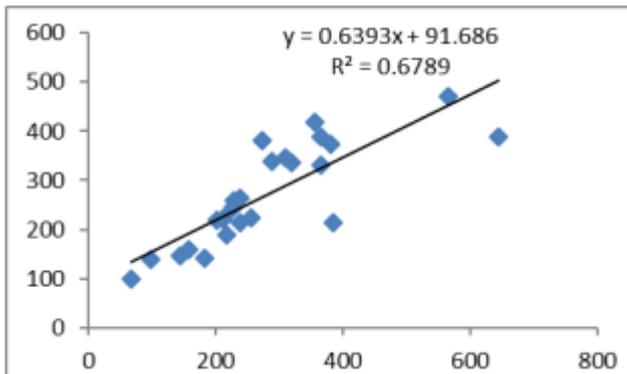
**HGB**



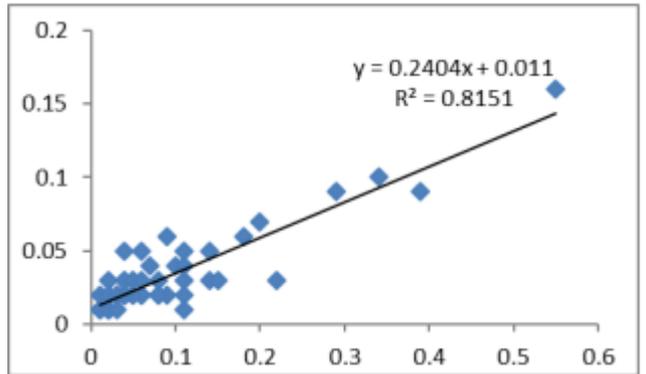
**MCV**



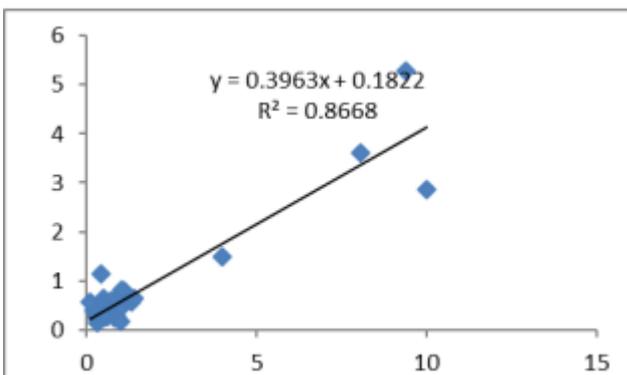
**PLT**



**Retic#**

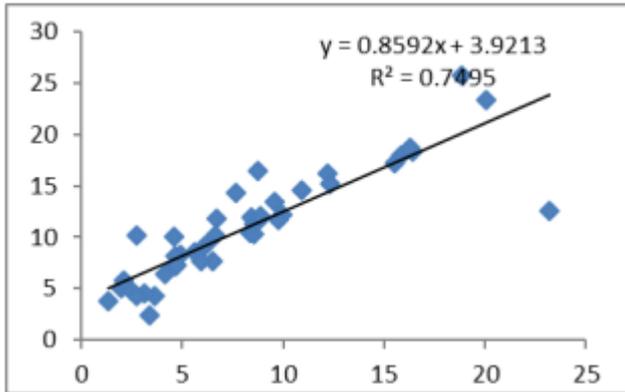


**Retic%**

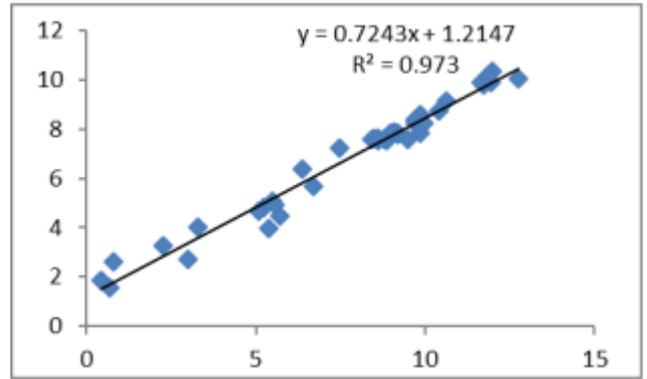


**Diagram for the Correlation Between InSight V5R and IDEXX Procyte ONE (Cat)**

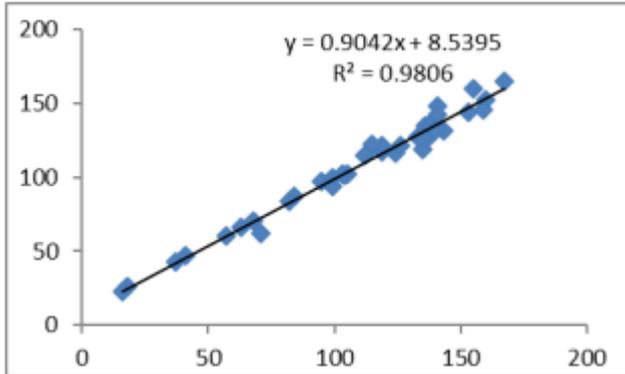
**WBC**



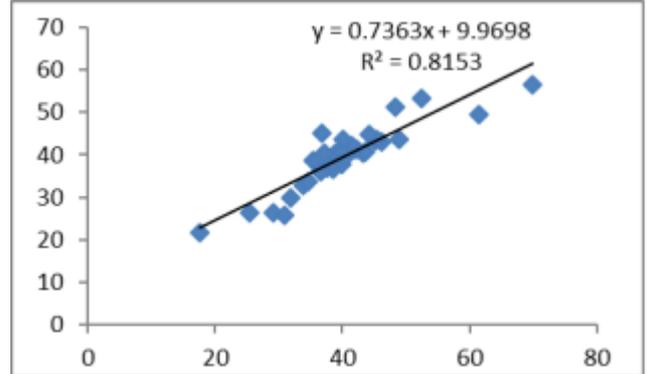
**RBC**



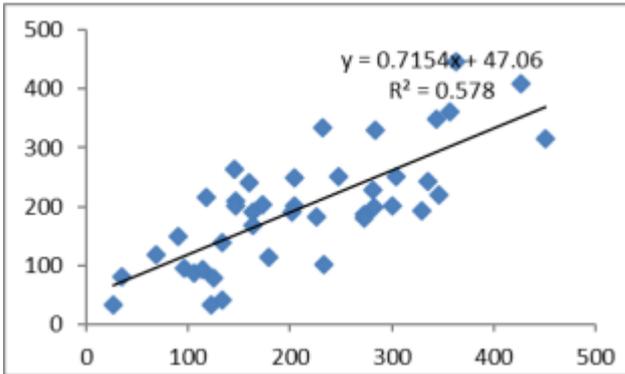
**HGB**



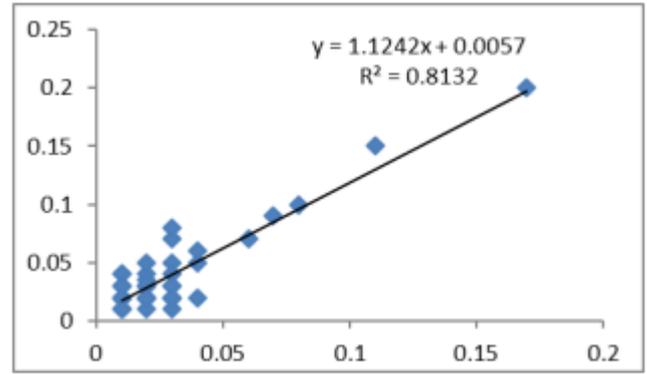
**MCV**



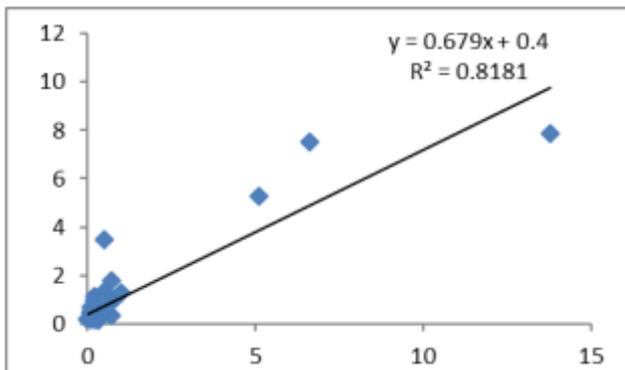
**PLT**



**Retic#**



**Retic%**



**Table 11 Correlation Results of InSight V5R and Procyte ONE**

| <b>Mode</b> | <b>Parameter</b>               | <b>WBC</b>  | <b>RBC</b>  | <b>HGB</b>  | <b>MCV</b>  | <b>PLT</b>  | <b>Retic#</b> | <b>Retic%</b> |
|-------------|--------------------------------|-------------|-------------|-------------|-------------|-------------|---------------|---------------|
| <b>Dog</b>  | Correlation                    | 0.995       | 0.979       | 0.992       | 0.906       | 0.870       | 0.903         | 0.943         |
|             | Enterprise Standard ( $\geq$ ) | <b>0.85</b> | <b>0.90</b> | <b>0.90</b> | <b>0.80</b> | <b>0.85</b> | <b>0.90</b>   | <b>0.90</b>   |
| <b>Mode</b> | <b>Parameter</b>               | <b>WBC</b>  | <b>RBC</b>  | <b>HGB</b>  | <b>MCV</b>  | <b>PLT</b>  | <b>Retic#</b> | <b>Retic%</b> |
| <b>Cat</b>  | Correlation                    | 0.866       | 0.986       | 0.990       | 0.903       | 0.760       | 0.902         | 0.905         |
|             | Enterprise Standard ( $\geq$ ) | <b>0.85</b> | <b>0.90</b> | <b>0.90</b> | <b>0.90</b> | <b>0.75</b> | <b>0.90</b>   | <b>0.90</b>   |

### 3.5.3 Data Analysis Conclusion

It can be seen from the test results that the correlation index of the InSight V5R Analyser meets the requirements of product specifications.