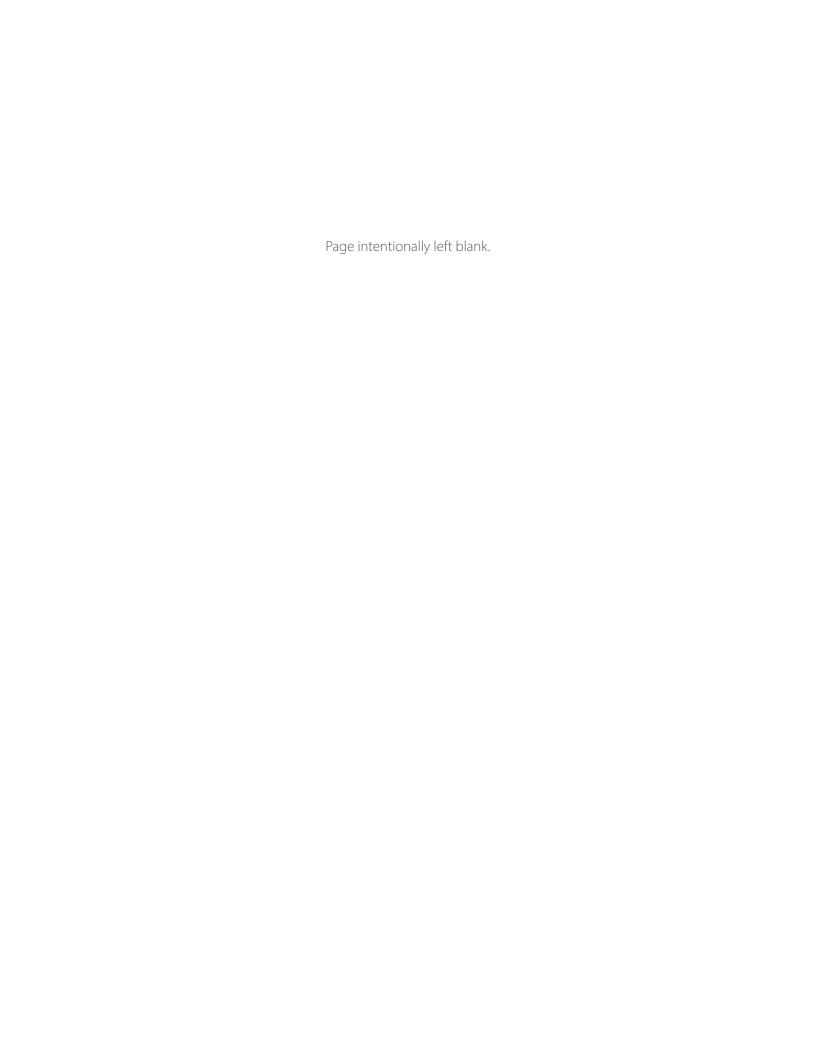




# Element HT5+Veterinary Hematology Analyzer







#### Precision

Precision is the foundational requirement for analytical reliability. If a system demonstrates high precision, is calibrated to a standard, and calibration is monitored by a quality control program, then the user can be assured of analytical reliability. This eliminates or reduces the need for individual facilities to replicate accuracy studies. Precision measures random error and is determined by comparing the results from assaying replicate aliquots of the same blood sample analyzed multiple times in succession. Without excellent precision, it is inherently not possible to achieve accuracy.

Precision								
Parameter	Units	Canine sample (mean +/- SD)	Canine sample CV%	Feline sample (mean +/- SD)	Feline sample CV%	Target CV%*	Pass/Fail	
WBC	10³/μL	9.4 (0.146)	1.5	13.4 (0.18)	1.4	= 5.0</td <td>Pass</td>	Pass	
NEU	10³/μL	5.89 (0.10)	1.7	8.10 (0.12)	1.6	= 3.75</td <td>Pass</td>	Pass	
LYM	10³/μL	2.17 (0.05)	2.4	3.7 (0.11)	3	= 3.75</td <td>Pass</td>	Pass	
MON	10³/μL	0.49 (0.03)	6.3	0.35 (0.03)	10.7	= 15</td <td>Pass</td>	Pass	
EOS	10³/μL	1.15 (0.04)	3.9	1.2 (0.04)	3.9	= 12.5</td <td>Pass</td>	Pass	
RBC	10 <sup>6</sup> /μL	7.11 (0.04)	0.6	9.12 (0.08)	0.8	= 3.33</td <td>Pass</td>	Pass	
HGB	g/dL	16.9 (0.09)	0.6	12.9 (0.07)	0.6	= 2.5</td <td>Pass</td>	Pass	
HCT	%	49.6 (0.34)	0.7	38.8 (0.42)	1.1	= 2.5</td <td>Pass</td>	Pass	
PLT	10³/μL	246 (4.16)	1.7	343 (5.11)	1.5	= 6.25</td <td>Pass</td>	Pass	
RET	10³/μL	29.5 (1.77)	6.1	42.9 (1.9)	4.1	= 5% (RET 60,000) >5% (RET < 60,000)	Pass	

<sup>\*</sup>Nabity MB, Harr KE, *et al.* ASVCP guidelines: Allowable total error hematology. Vet Clin Pathol 2018: 47: 9–21. NOTE: Target CV% for precision studies = 25% (0.25) X TEa.

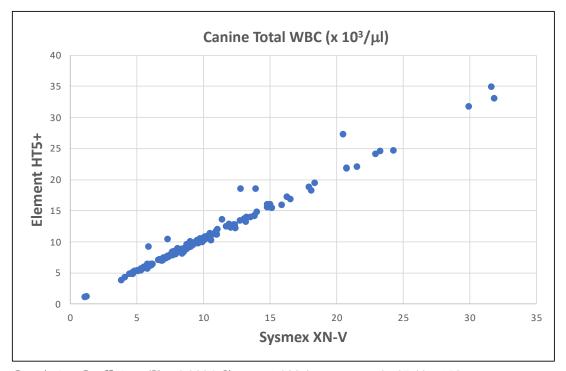
## Method Comparison Studies

Results from the Element HT5+® Hematology Analyzer were compared to a Sysmex XN-V hematology analyzer within a well established, large, referral hospital laboratory. Data represented here reflects results of paired aliquots of EDTA blood samples from 151 dogs and 69 cats representing patients with a wide variety of medical and surgical conditions.

### Canine

#### Leukocytes

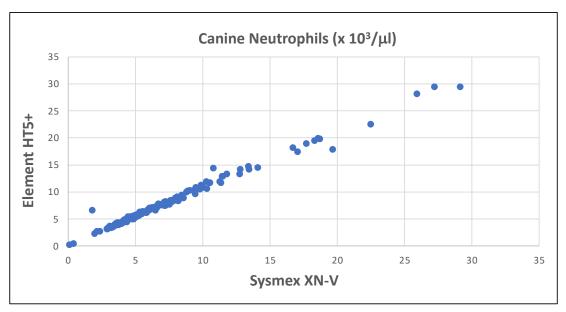
The canine total leukocyte concentration comparison is shown below. The many superimposed data points represent excellent correlation.



Correlation Coefficient (R) = 0.9886; Slope = 1.082; Intercept = -0.197; N = 152

#### Neutrophils

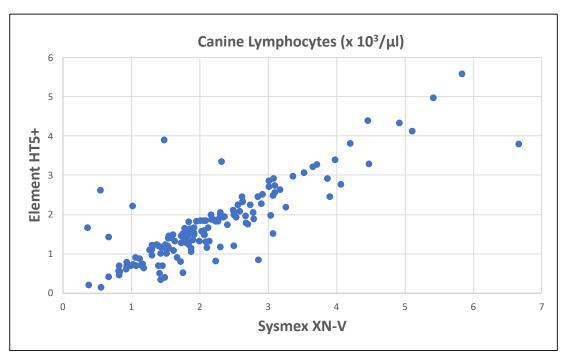
The canine neutrophil concentration comparison is shown below. Note the excellent correlation for neutrophils.



Correlation Coefficient (R) = 0.9888; Slope = 1.029; Intercept = 0.541; N = 151

#### Lymphocytes

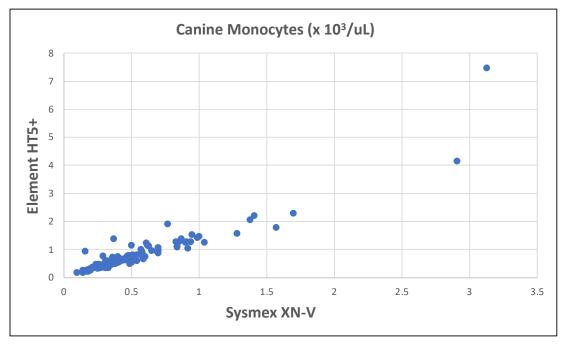
The canine lymphocyte comparison is shown below. This comparison includes both normal animals and animals with a variety of hematological abnormalities. Results which deviate from the dominant line of identity may reflect animals with hematological abnormalities that may be evidenced in the leukocyte scattergram and require examination of a blood film for definitive diagnosis.



Correlation Coefficient (R) = 0.7661; Slope = 0.817; Intercept = -0.065; N = 151

#### Monocytes

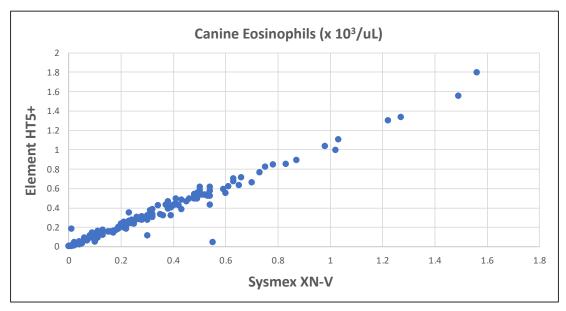
Canine monocyte comparison is shown below. Monocyte counts correlated well within the normal range of monocyte counts. There is some divergence at higher levels of monocyte values. This may reflect ill animals with hematological abnormalities that could be detected in WBC scattergram. In these instances, evaluation of a blood smear is needed to make a definitive diagnosis.



Correlation Coefficient (R) = 0.9329; Slope = 1.888; Intercept = -0.172; N = 151

#### Eosinophils

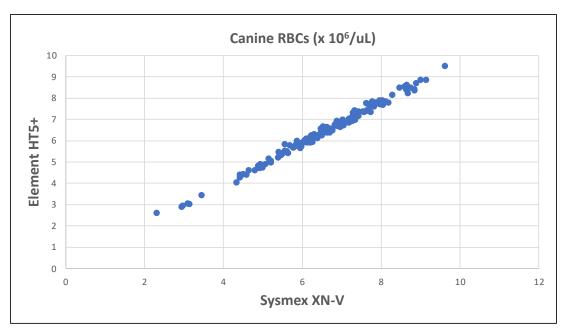
Canine eosinophil comparison is shown below. There is excellent correlation in eosinophil counts throughout the range of results assayed.



Correlation Coefficient (R) = 0.9804; Slope = 1.065; Intercept = 0.000; N = 151

#### **Erythrocytes**

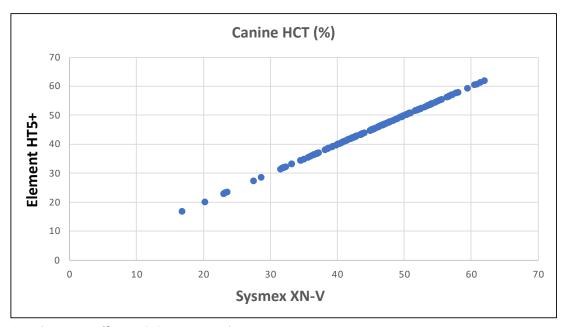
The canine total RBC concentration comparison is shown below. There is excellent correlation in RBC count between the two analyzers as evidenced by the number of superimposed points.



Correlation Coefficient (R) = 0.9953; Slope = 0.972; Intercept = 0.046; N = 151

#### Hematocrit (HCT)

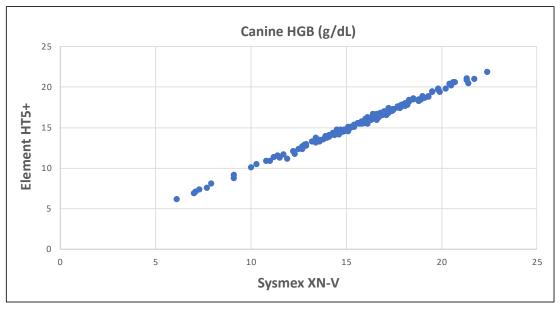
Hematocrit (HCT) is the most frequently used value to rapidly assess the patients' red blood cell mass. HCT is calculated from the RBC concentration and mean cell volume (MCV). Both direct measurements must be reliable to derive a reliable HCT. Canine HCT comparison is shown below. Note the excellent correlation.



Correlation Coefficient (R) = 0.9917; Slope = 1.036; Intercept = -2.28; N = 151

#### Hemoglobin Concentration (HGB)

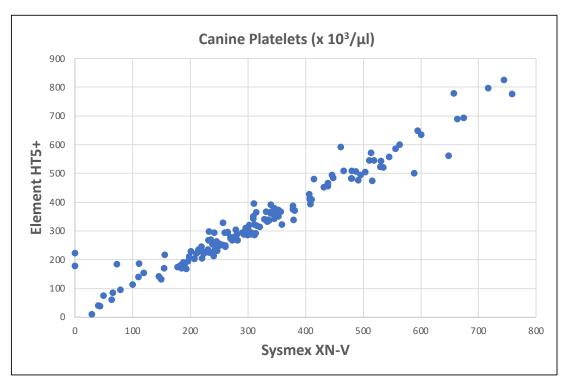
The hemoglobin comparison scatterplot is shown below. Because of the physiologic relationship between HGB and hematocrit (HCT) these measurements corroborate each other. There is excellent correlation between the two analyzers as evidenced by the abundance of superimposed points.



Correlation Coefficient (R) = 0.9980; Slope = 0.976; Intercept = 0.22; N = 152

#### **Platelets**

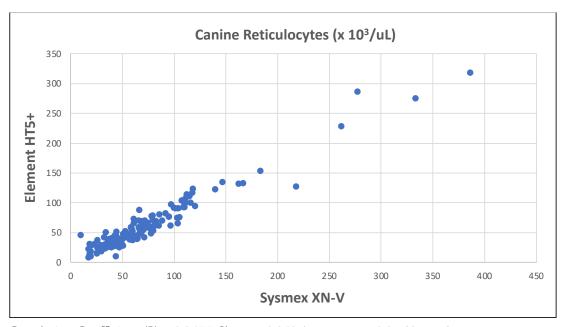
The platelet comparison scatterplot below shows good correlation between platelet counts from the two analyzers. Note the excellent correlation. Platelet clumping, common in animal samples, will cause some noise in the scatterplot.



Correlation Coefficient (R) = 0.9812; Slope = 1.049; Intercept = -3.3; N = 150

#### Reticulocytes

The canine total reticulocyte concentration comparison is shown below. There is good to excellent correlation between reticulocyte counts from the two analyzers with many superimposed points.

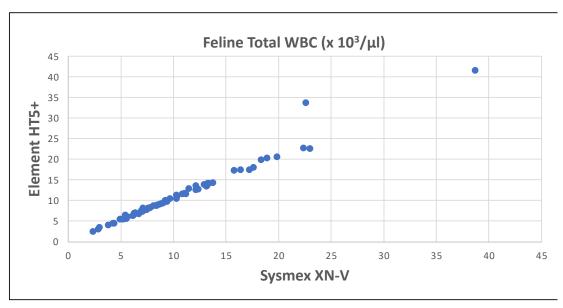


Correlation Coefficient (R) = 0.9675; Slope = 0.862; Intercept = -0.01; N = 148

#### **Feline**

#### Leukocytes

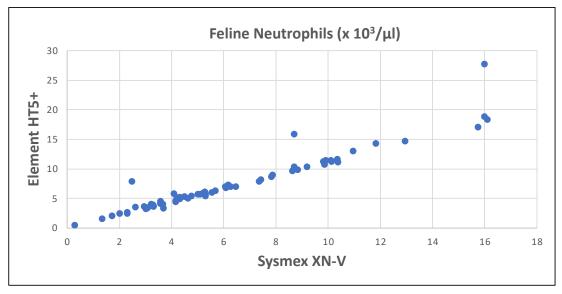
The feline total leukocyte concentration comparison is shown below. The many superimposed data points represent excellent correlation.



Correlation Coefficient (R) = 0.9832; Slope = 1.117; Intercept = -0.405; N = 69

#### Neutrophils

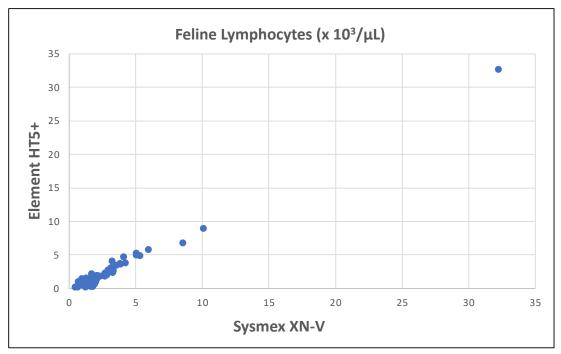
The feline neutrophil concentration comparison is shown below. There are many superimposed data points. Note the excellent correlation. The divergent points could reflect animals with hematological abnormalities which may be evidenced by abnormalities in the leukocyte differential scattergram of the analyzer. In these cases, a blood smear examination is warranted.



Correlation Coefficient (R) = 0.9520; Slope 1.306; Intercept = -0.732; N = 69

#### Lymphocytes

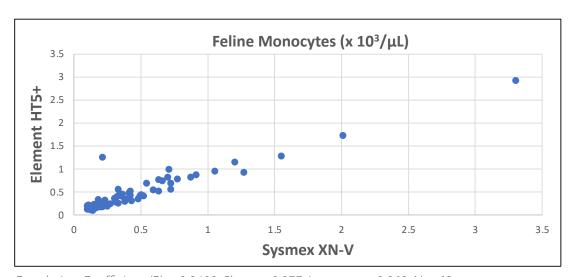
The feline total lymphocyte comparison is shown below. There is excellent correlation in lymphocyte numbers between the two analyzers.



Correlation Coefficient (R) = 0.9930; Slope = 1.015; Intercept = -0.310; N = 68

#### Monocytes

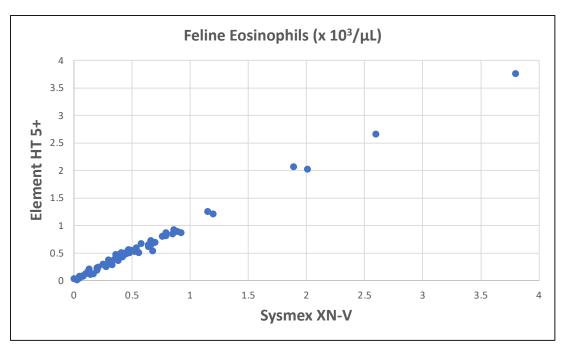
Feline monocyte comparison shown below. There is excellent correlation between the Element HT5+ and the Sysmex XN-V for monocyte counts. There are a few divergent points which may represent animals with hematological abnormalities. The leukocyte differential scattergram should always be evaluated for abnormalities and, if present, warrant evaluation of a blood smear.



Correlation Coefficient (R) = 0.9409; Slope = 0.877; Intercept = 0.069; N = 68

#### Eosinophils

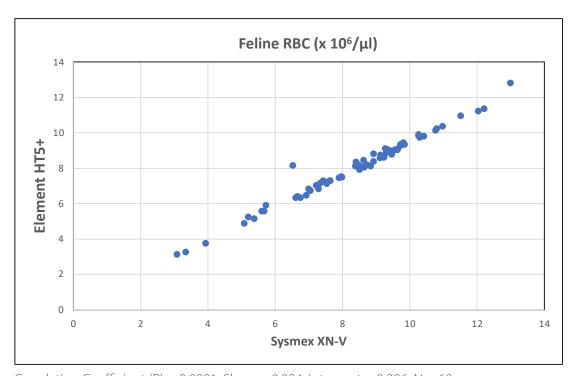
Feline eosinophil comparison is shown below. There is excellent correlation between the Element HT5+ and Sysmex analyzers.



Correlation Coefficient (R) = 0.9970; Slope = 1.008; Intercept = 0.021; N = 69

#### Erythrocytes

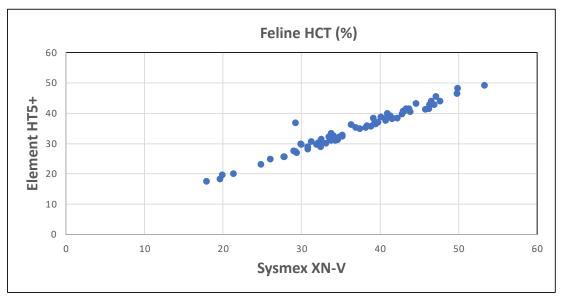
The feline total RBC concentration comparison is shown below. There are many superimposed data points. Note the excellent correlation.



Correlation Coefficient (R) = 0.9891; Slope = 0.924; Intercept = 0.286; N = 69

#### Hematocrit (HCT)

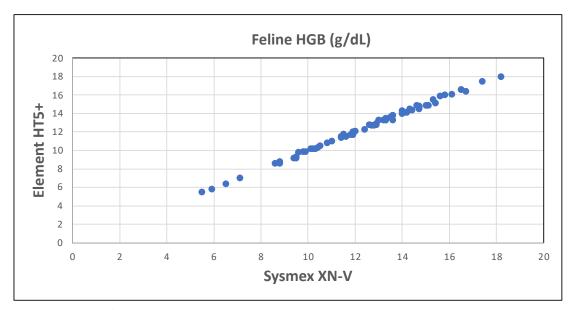
HCT is the most frequently used value to rapidly assess the patients' red blood cell mass. HCT is calculated from the RBC concentration and mean cell volume (MCV). Both direct measurements must be reliable to derive a reliable HCT. Feline HCT comparison is shown below. There are many superimposed data points. Note the excellent correlation.



Correlation Coefficient (R) = 0.9798; Slope = 0.918; Intercept = 0.92; N = 69

#### Hemoglobin (HGB)

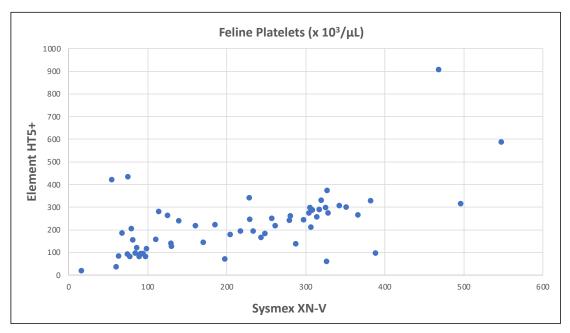
Because of the physiologic constant relationship between HGB and HCT, these measurements corroborate each other. There are many superimposed data points. Note the excellent correlation.



Correlation Coefficient (R)=0.9983; Slope 1.011; Intercept=-0.13; N=69

#### **Platelets**

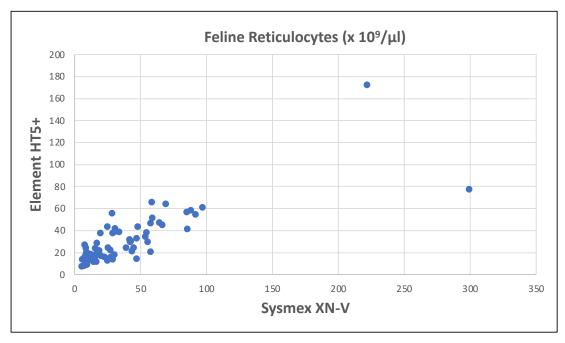
Feline platelet comparison seen below. Feline platelet enumeration is confounded by the presence of platelet aggregates. There may be less of a tendency for platelet aggregates to confound platelet counts in the Element HT5+ analyzer.



Correlation Coefficient (R) = 0.5898; Slope = 1.236; Intercept = 44.1; N = 59

#### Reticulocytes

The feline total reticulocyte concentration is shown below. The majority of reticulocyte counts were in the normal range. The differences between the reticulocyte counts between the two analyzers is reflected in their respective reference ranges.



Correlation Coefficient (R)=0.7608; Slope=0.440; Intercept=14.316; N=69

## Summary

These method comparisons show the Element HT5+ analyzer performs on a par with a reference lab analyzer for all hematology parameters.

# Sample Processing

Sample Processing					
Analysis time	~ 90 seconds after sample introduction				
Sample type	Whole blood from arterial or venous source				
Sample containers	Purple-top (EDTA) collection tube				

# Reportable Ranges (Linearity) and Precision

The Reportable Range is the span of test results over which the accuracy can be verified.

Parameter	Linearity Range (US)	Precision (US)	
	0~100.00 × 10³/μL	$\pm 0.20 \times 10^{3}/\mu L \text{ or } \pm 3\%$	
WBC	100.01~350.00 × 10³/μL	± 6%	
	350.01~500.00 × 10 <sup>3</sup> /μL	± 11%	
RBC	0~8.0 × 10 <sup>6</sup> /μL	$\pm 0.03 \times 10^{6}$ /µL or $\pm 2\%$	
MDC	8.01~16.99 × 10 <sup>6</sup> /μL	$\pm 0.06 \times 10^{6}$ /µL or $\pm 4\%$	
HCT	0-75%	±1.0 (HCT) or ± 2%	
HGB	0~26 g/dL	±0.2 g/dL or ± 2%	
PIT	$0\sim1000\times10^{3}/\mu$ L	$\pm 10 \times 10^{3}/\mu L \text{ or } \pm 5\%$	
PLI	1001~5000 × 10³/μL	± 6%	
RET# 0~800 × 10³/μL		$\pm 15 \times 10^{3}/\mu L \text{ or } \pm 20\%$	
RET% 0.00-30.00%		±0.30 (RET%) or ± 20%	

Parameter	Linearity Range (SI)	Precision (SI)	
	0~100.00 × 10 <sup>9</sup> /L	$\pm 0.20 \times 10^{9}$ /L or $\pm 3\%$	
WBC	100.01~350.00 × 10 <sup>9</sup> /L	± 6%	
	350.01~500.00 × 10 <sup>9</sup> /L	± 11%	
RBC	$0 \sim 8.0 \times 10^{12}/L$	$\pm 0.03 \times 10^{12}$ /L or $\pm 2\%$	
MDC	$8.01\sim16.99\times10^{12}/L$	$\pm 0.06 \times 10^{12}$ /L or $\pm 4\%$	
HCT	0–75%	1.0 (HCT) or ± 2%	
HGB 0~260 g/L		±2 g/L or ± 2%	
PIT	0~1000 × 10 <sup>9</sup> /L	$\pm 10 \times 10^{9}$ /L or $\pm 5\%$	
PLI	1001~5,000 × 10 <sup>9</sup> /L	± 6%	
RET#	0~800 × 10 <sup>9</sup> /L	$\pm 15 \times 10^{9}$ /L or $\pm 20\%$	
RET%	0.00-30.00%	±0.30 (RET%) or ± 20%	

