



HemaTrue™

Veterinary Hematology Analyzer

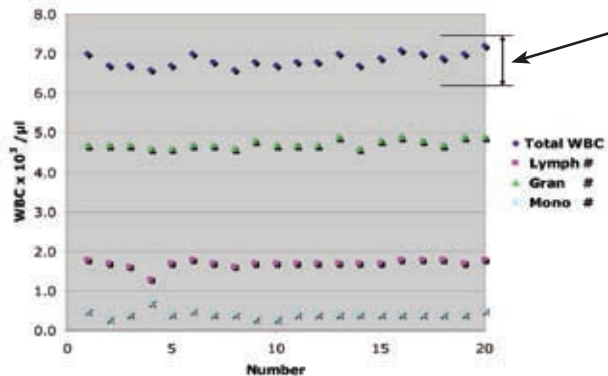
Performance Expectation Summary



Reproducibility—Is Simply Unsurpassed

Solid reproducibility is the essential foundation requirement for analytical reliability. If a system has good demonstrated reproducibility, 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. Perspectives on reproducibility and use of quality control programs in veterinary in-hospital laboratories have recently been summarized.^{1,2}

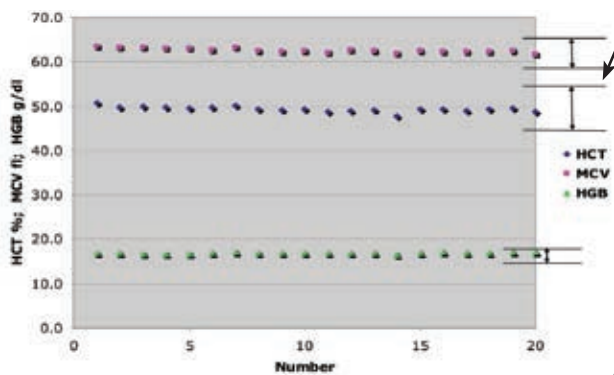
Reproducibility is easily tested by repeated analysis of the same sample. Below are plots of representative reproducibility of 20 sequential replicate analyses of dog blood run on the HemaTrue™ Veterinary Hematology Analyzer.



Typical performance range of QC program at this value is indicated by bracketed range.

Plotted sample points:

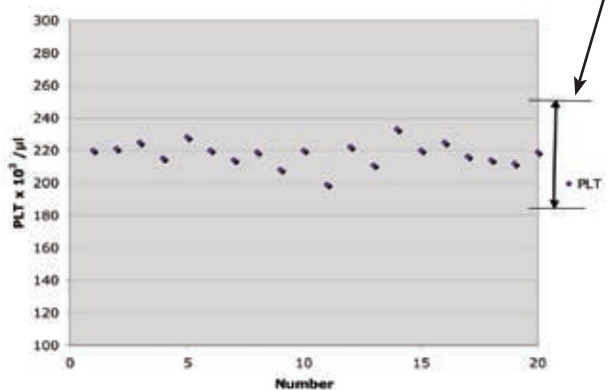
- Total WBC Range = 6.6–7.2 x 10³/μl
- Granulocyte Range = 4.6–4.9 x 10³/μl
- Lymphocyte Range = 1.3–1.8 x 10³/μl
- Monocyte Range = 0.3–0.7 x 10³/μl



Typical performance range of QC program at these values are indicated by bracketed ranges.

Plotted sample points:

- MCV Range = 61.7–63.5 fl
- HCT Range = 47.8–50.1 %
- HGB Range = 16.5–17.1 g/dl



Typical performance range of QC program at this value is indicated by bracketed range.

Plotted sample points:

- PLT Range = 199–233 x 10³/μl

Summary Points:

- Good reproducibility is expected to be tighter than the tolerance limits of a QC program.
- Without excellent reproducibility, it is inherently not possible to achieve accuracy!
- Excellent reproducibility delivered by shear valve dilution technology.
- Similar reproducibility is achieved with the microcapillary sampling mode. Below are results of 20 sequential replicate analyses of a different sample using the microcapillary sampling mode.

	WBC	LYM	MONO	GRAN	HCT	MCV	HGB	RBC	PLT
Mean	10.9	3.4	0.9	6.7	37.2	67.0	14.5	5.55	379
Min	10.4	3.0	0.7	6.3	35.9	66.3	14.2	5.39	354
Max	11.4	3.7	1.0	6.9	38.2	67.7	14.9	5.73	392

References: Reproducibility and quality control information.

1. Weiser, MG, Vap LM, Thrall, MA: Perspectives and Advances in In-Clinic Laboratory Diagnostic Capabilities: Hematology & Clinical Chemistry. In Veterinary Clinics of North America: Small Animal Practice. Issue title: Clinical Pathology and Diagnostic Techniques. Vol 37, (March 2007), pp. 221-236.
2. Weiser, MG, Thrall, MA: Quality Control Recommendations and Procedures for In-Clinic Laboratories. In Veterinary Clinics of North America: Small Animal Practice. Issue title: Clinical Pathology and Diagnostic Techniques. Vol 37, (March 2007), pp. 237-244.

Correlation Study Results

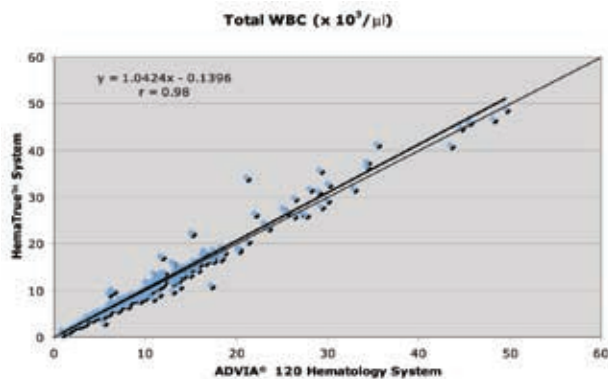
In a major veterinary teaching hospital setting, the HemaTrue™ analyzer was tested with established procedures for the analysis of dog, cat, and horse blood from animals with a wide variety of medical and surgical conditions. Blood from these animals represented a wide variety of hematologic abnormalities. Comparative procedures included blood analysis on a Bayer ADVIA® 120 system and differential results performed by 100 cell microscopy counts.

Data presented here include analysis of blood from 225 dogs, 82 cats, and 60 horses. Scatterplots consist of >360 points and therefore contain superimposed points.

Leukocytes

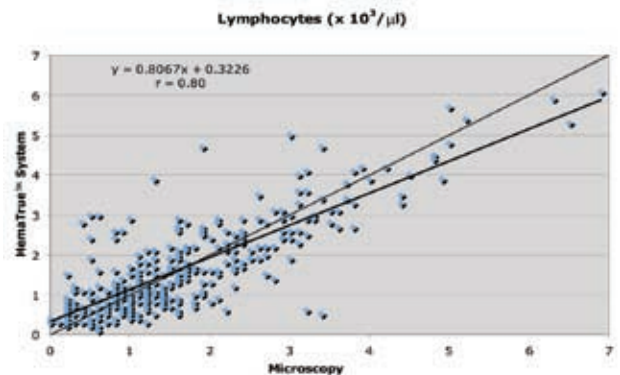
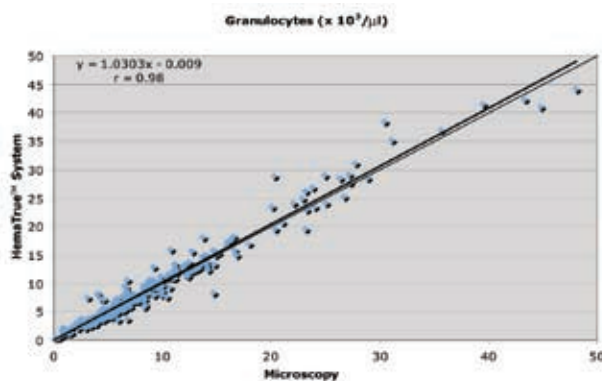
Total WBC Concentration

The Total WBC concentration scatterplot including 367 dog, cat, and horse samples is shown below. There are many superimposed data points. Note excellent correlation.



Granulocytes and Lymphocytes

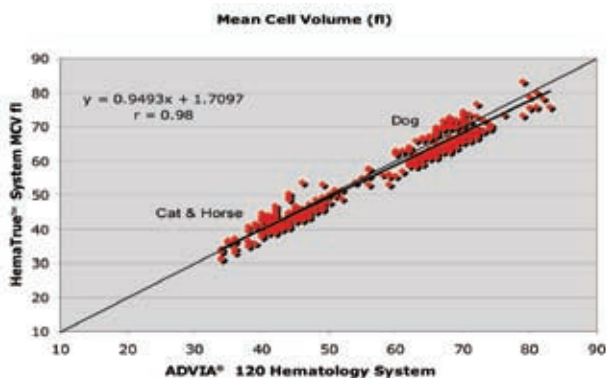
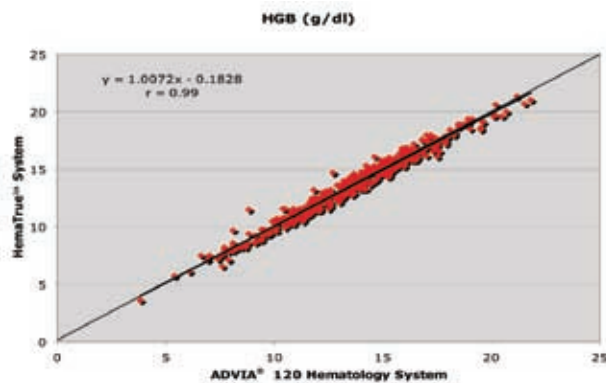
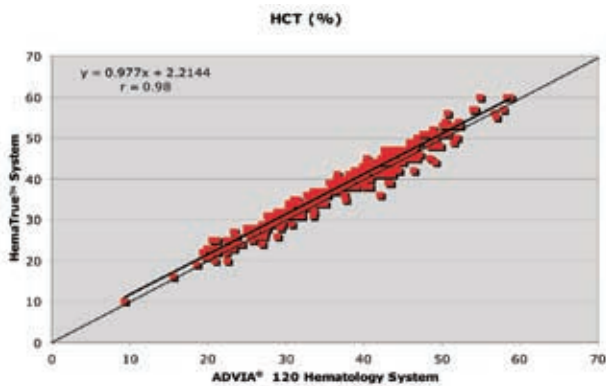
The granulocyte and lymphocyte concentration scatterplots including 367 dog, cat, and horse samples are shown below. Note excellent correlation for granulocytes. The lymphocyte correlation scatter is expected because of imprecision in the microscopy measurement of a minority cell type. However, the correlation is regarded as good for clinical interpretation purposes.



Summary Points:

- There is excellent performance for total WBC and granulocyte measurements.
- The lymphocyte performance is regarded as excellent; correlation is limited by the imprecision in the microscopy count of a minority cell over a minimal concentration range.
- As for all hematology systems, NRBC will be included in the total WBC and lymphocyte region. Blasts and other abnormal cells are unpredictable in where they will occur in the automated differential.

Erythrocytes



Derivation of Hematocrit (HCT)

HCT is the most frequently used value to rapidly assess the patient's red 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. HCT comparison to the ADVIA® system is shown at left; 367 dog, cat, and horse samples are plotted. The slight positive bias is attributable to calibration differences between two independent systems that are both in tolerance. Note excellent correlation.

Measurement of Hemoglobin Concentration (HGB)

Some prefer to interpret HGB to rapidly assess red cell mass. HGB is a completely independent measurement in a different analyzer subsystem. Because of the physiologic constant relationship between HGB and HCT, these measurements corroborate each other. 367 dog, cat, and horse HGB values are shown in the scatterplot at left. Note excellent correlation.

Measurement of Mean Cell Volume (MCV) and Volume Distribution

MCV and the RBC volume distribution histogram are used to assess disturbances in red cell production in disease. The scatterplot at left shows MCV for 367 dogs, cats, and horses. Note excellent correlation between two methods.

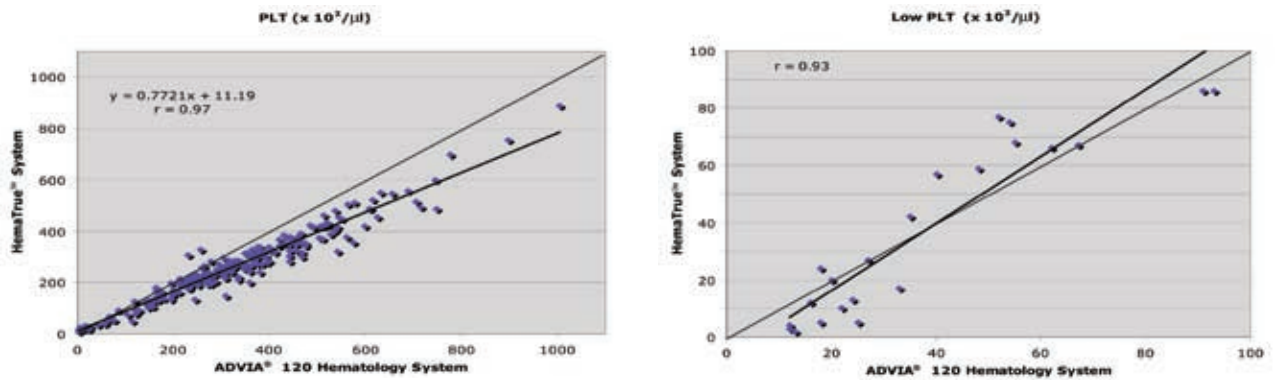
Summary Point:

- There is excellent performance for all erythrocyte measurements.

Platelets

The first scatterplot below shows PLT for 367 dogs, cats, and horses. Note excellent correlation between two methods. Platelet clumping, common in animal samples, will cause some noise in the scatterplot.

The second scatterplot shows 22 platelet concentration measurements below 100,000/ μ l.



Summary Points:

- There is excellent correlation for a population of animals measured on two different technologies.
- Dynamic platelet clumping contributes to scatter in all platelet correlation studies.
- Clean background on the HemaTrue™ Veterinary Hematology Analyzer assures good detection of decreased platelets in animals on chemotherapy or at risk for a bleeding disorder due to thrombocytopenia; sub 100,000/ μ l range.

For assistance, call Technical Support Services at 1-800-464-3752, opt 3.



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