PERFORMANCE SUMMARY

Element HT5 Veterinary Hematology Analyzer

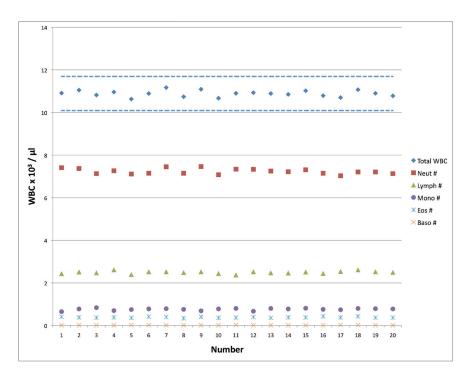




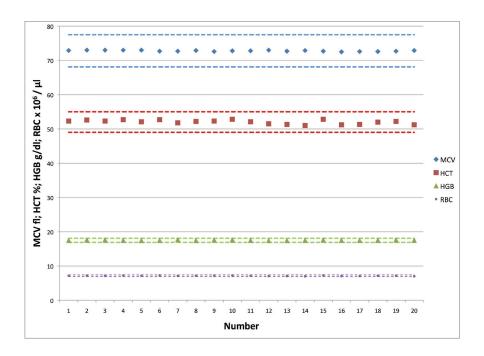
Excellent Reproducibility

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 been summarized.^{1,2}

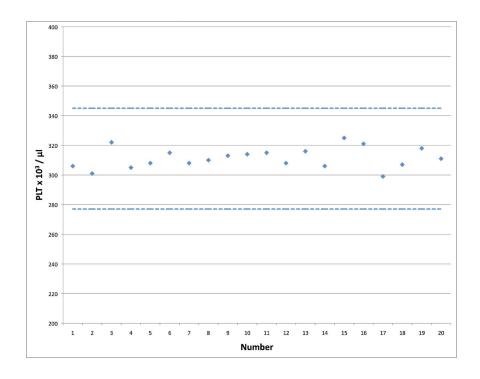
Reproducibility is easily tested by repeated analysis of the same sample. Below are plots of representative reproducibility of 20 sequential replicate analyses of dog blood run on the Element HT5 Veterinary Hematology Analyzer.



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



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



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

The mean, minimum and maximum values of 20 sequential replicate analysis of dog blood:

	WBC	Neut	Lymph	Mono	Eos	Baso	HCT	RBC	MCV	HGB	PLT
Mean	10.89	7.24	2.49	0.76	0.39	0.01	52.0	7.15	72.8	17.5	311
Min	10.63	7.03	2.37	0.65	0.34	0.01	51.0	6.99	72.5	17.4	299
Max	11.17	7.45	2.61	0.84	0.43	0.02	52.8	7.26	73.0	17.7	325

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!

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

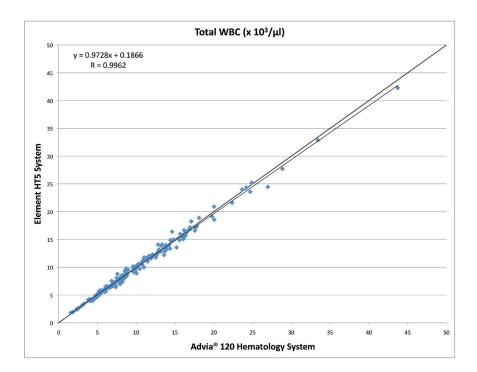
In a major veterinary teaching hospital setting, the Element HT5 Analyzer was tested with established procedures for the analysis of dog, cat, and horse blood from animals with a wide variety of medical and surgical conditions. Blood from these animals represented a wide variety of hematologic abnormalities. Comparative procedures included blood analysis on a Bayer ADVIA® 120 Hematology System and differential results performed by 100 cell microscopy counts.

Data presented here include analysis of blood from 97 dogs, 60 cats, and 49 horses. Scatterplots consist of >200 points and therefore contain superimposed points.

Leukocytes

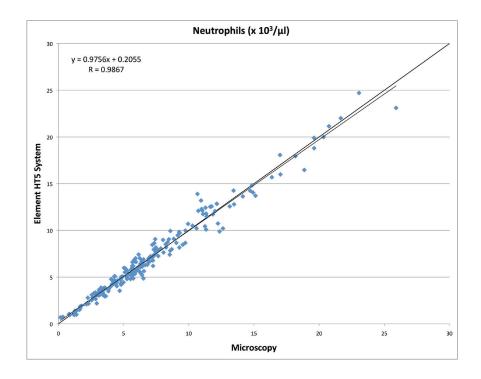
Total WBC Concentration

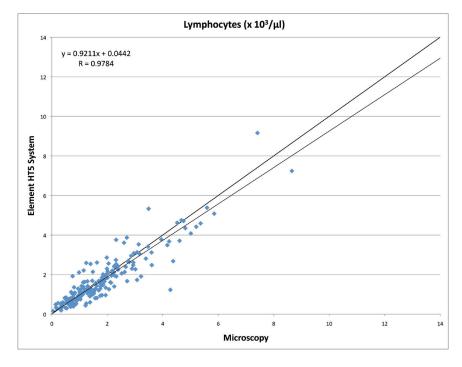
The Total WBC concentration scatterplot including 206 dog, cat, and horse samples is shown below. There are many superimposed data points. Note the excellent correlation.



Neutrophils and Lymphocytes

The granulocyte and lymphocyte concentration scatterplots including 206 dog, cat, and horse samples are shown below. Note excellent correlation for neutrophils. The lymphocyte correlation scatter is expected because of imprecision in the microscopy measurement of a minority cell type. However, the correlation is regarded as very good for clinical interpretation purposes.





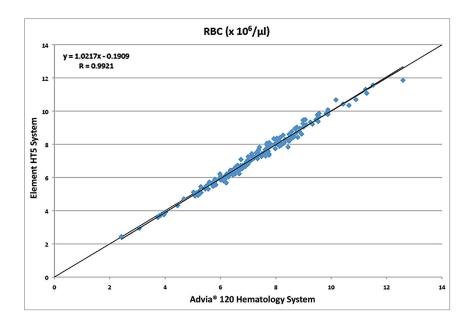
Summary Points

- There is excellent performance for total WBC and neutrophil 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, blasts and other abnormal cells are unpredictable in where they will occur in the automated differential.

Erythrocytes

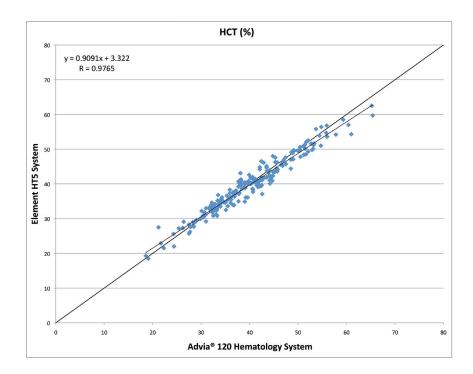
Total RBC Concentration

The Total RBC concentration scatterplot including 206 dog, cat and horse samples is shown below. There are many superimposed data points. Note the excellent correlation.



Derivation of Hematocrit (HCT)

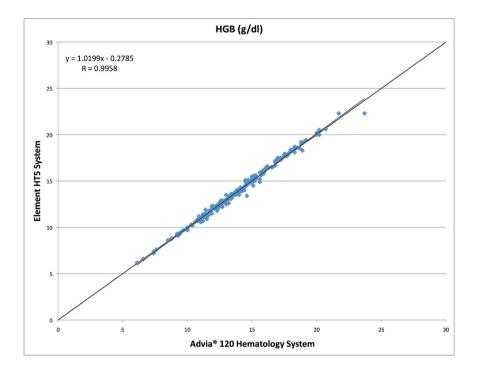
HCT is the most frequently used value to rapidly assess the patient's red cell mass. HCT is calculated from the RBC concentration and mean cell volume (MCV). Both direct measurements must be reliable to derive a reliable HCT.



HCT comparison to the ADVIA® system is shown above; 206 dog, cat, and horse samples are plotted. Note excellent correlation.

Measurement of Hemoglobin Concentration (HGB)

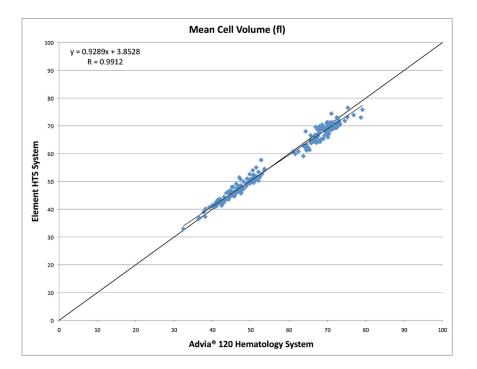
Some prefer to interpret HGB to rapidly assess red cell mass. HGB is a completely independent measurement in a different analyzer subsystem. Because of the physiologic constant relationship between HGB and HCT, these measurements corroborate each other.



HGB comparison to the ADVIA® system is shown at above; 206 dog, cat, and horse samples. 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.



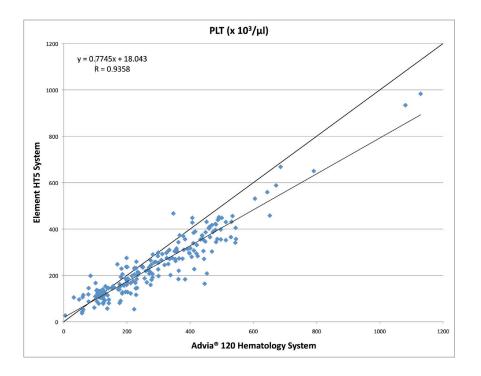
The scatterplots above show MCV for 206 dogs, cats, and horses. Note excellent correlation between two methods.

Summary Point

• There is excellent performance for all erythrocyte measurements.

Platelets

The scatterplots below show PLT values for 206 dogs, cats, and horses. Note excellent correlation between two methods. Platelet clumping, common in animal samples, will cause some noise in the scatterplot.



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 Element HT5 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/µl range.

