IDEXX **LaserCyte**® Hematology Analyzer Performance and Reliability

Jeremy Hammond, LaserCyte R&D Manager
Chris Lee, LaserCyte Product Manager

Introduction

IDEXX is committed to the continual development of its LaserCyte® and ProCyte Dx® in-house hematology analyzers. Since its introduction to the market in 2002, several software, hardware, and sample processing improvements have been made to ensure the LaserCyte analyzer's performance and accuracy. This document describes the rigorous quality assurance methods used during the manufacturing and service processes and beyond that ensure the LaserCyte analyzer's performance and reliability.

Quality Assurance in Manufacturing

During quality assurance, each instrument is standardized to the predetermined production settings. During the production process, well-characterized samples are used to make adjustments to the sensitivity of the photo detectors, ensuring that each analyzer has a consistent and reproducible response. The standardization process is critical for ensuring proper classification of cell populations by the LaserCyte classification algorithm.

After the standardization process, the analyzer is calibrated to ensure consistent and accurate results for a broad range of values. This is done by running a significant number of samples with large and small populations of various cell types, comparing the results to veterinary-specific reference laboratory analyzers, and then calibrating the LaserCyte analyzer so that the results are consistent with the reference analyzers.

Quality Assurance in the Field: Advanced Diagnostic Software

In 2010, the LaserCyte analyzer gained the capability to determine when it is no longer standardized to the factory settings. Due to the great variabiliity of samples related to different species, sample handling, and individual patient health status, these cannot be used to determine if the response of the photo detectors is in alignment with the factory settings. To make this determination, each CBC5R tube contains standard-sized particles called qualiBeads®. The instrument evaluates the signal from the qualiBeads to determine if there are shifts in the beads' scatter pattern. If shifts are detected, the analyzer's Advanced Diagnostic Software will return the optics to the factory settings. This automated process ensures the integrity of the optics.

Quality Assurance in the Field: The Hammond Principle

Once an analyzer is standardized, the need for calibration must be assessed. This is necessary because automated hematology analyzers are complex systems, measuring particles smaller than the width of a human hair, and fluctuations in the fluidics and/or optics can sometimes result in minor response drift during normal operation. To prevent this from occurring, large reference laboratory hematology analyzers undergo a regular assessment by trained technicians to determine if an analyzer needs to be restandardized, recalibrated, or if the optics need to be realigned.

IDEXX developed a veterinary-specific algorithm known as the Hammond Principle (patent pending) to ensure the performance of the LaserCyte analyzer.[1] The Hammond Principle was adapted from Bull's algorithm, a process developed in the 1970s to ensure that automated hematology analyzers were accurate between quality-control runs. The LaserCyte analyzer incorporates a vigorous quality-assurance process using Advanced Diagnostics Software and the Hammond Principle to constantly monitor the analyzer performance so that any shift can be identified rapidly and automatically resolved. IDEXX is the only company that employs this technology within its hematology systems.

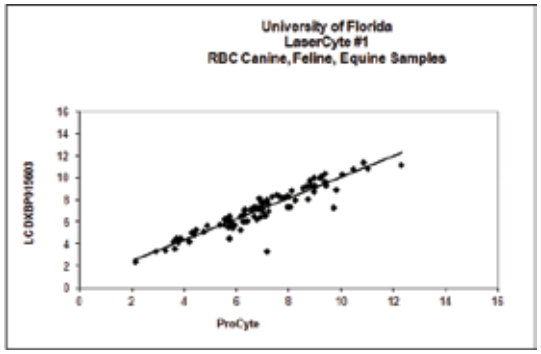
[1] Hammond JM, Lee WC, DeNicola DB, Roche J. In press: Patient-based feedback control for erythroid variables obtained using in-house automated hematology analyzers in veterinary medicine. *Vet Clin Pathol.* 2012;41(2).

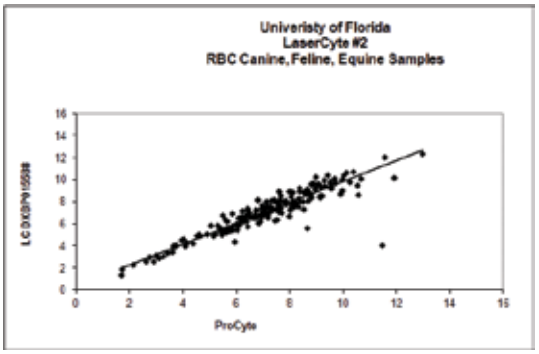
Comparing the LaserCyte to the ProCyte Dx analyzer

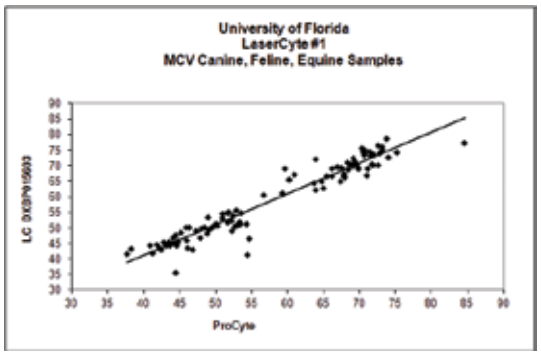
In 2010, IDEXX partnered with Purdue University, The University of Florida, Tufts University, and Michigan State University to compare the performance of the LaserCyte® Hematology Analyzer to the ProCyte Dx® Hematology Analyzer. The ProCyte Dx analyzer uses laser flow cytometry, optical fluorescence, and Laminar Flow Impedance™ to provide simple, fast, high-quality hematology results.

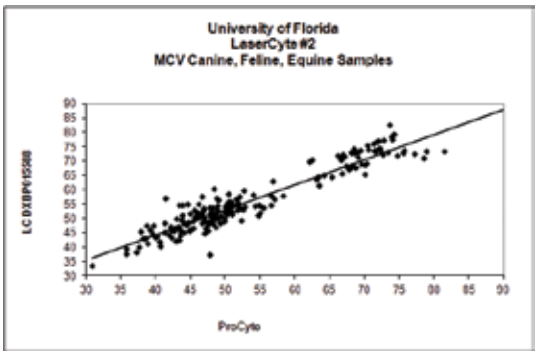
The following graphs compare the results obtained using two LaserCyte analyzers and a ProCyte Dx analyzer at the University of Florida. The data includes canine, feline, and equine samples (totaling 100 of each species split across the two LaserCyte analyzers). These results indicate good correlation between the LaserCyte and the ProCyte Dx for canine, feline, and equine samples. Information about the comparison of ProCyte Dx accuracy to reference laboratory methods can be obtained from abstracts presented at ACVIM in 2010 or from IDEXX Laboratories.

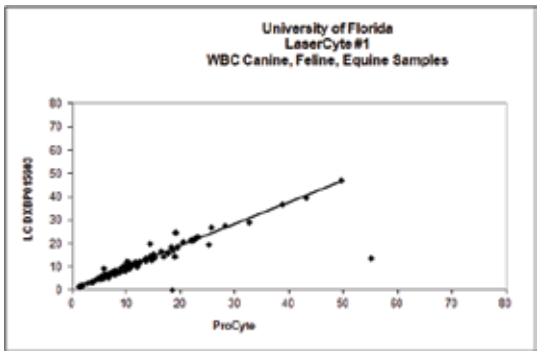
Note: The closer the data points are to the line on a given graph, the more closely the results from the two analyzers corrrelate.

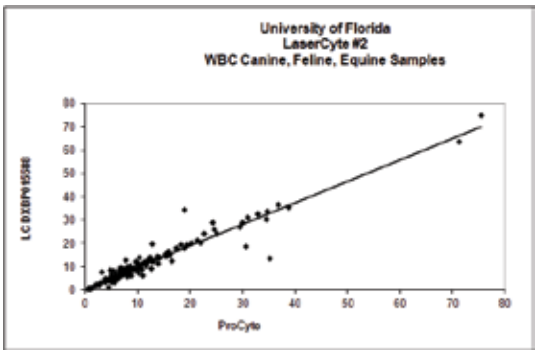


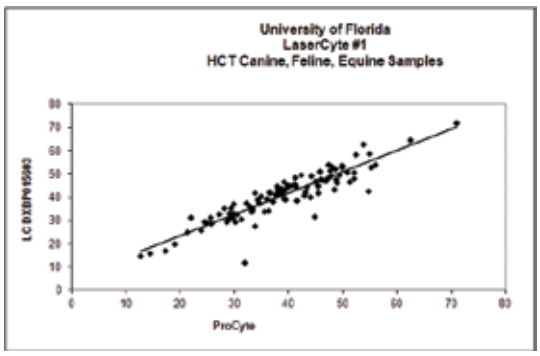


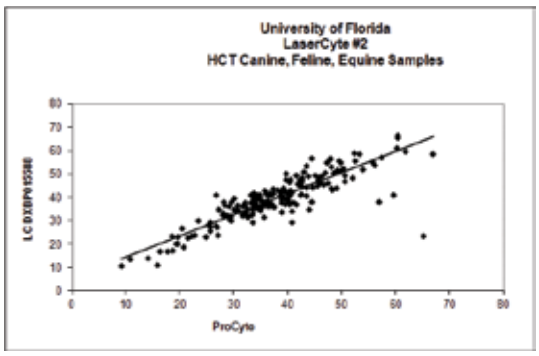


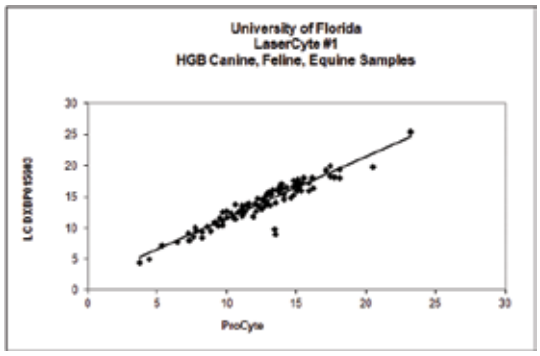


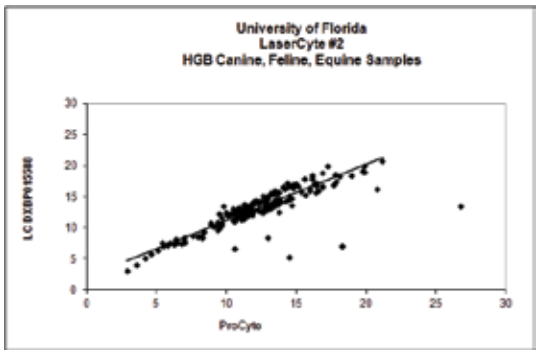


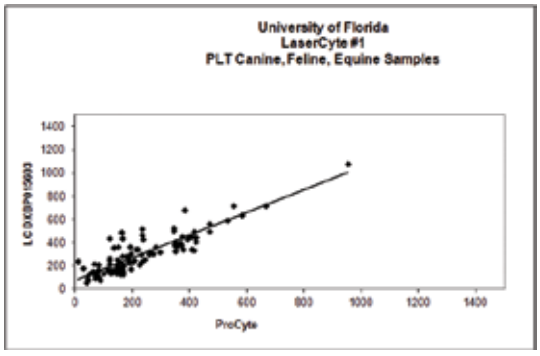


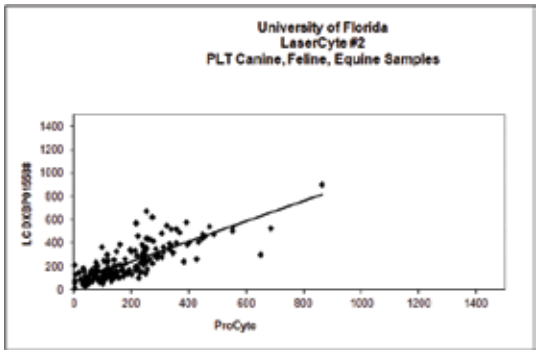












Conclusions

With our ongoing multi-million dollar investment in research and development each year, IDEXX continues to develop and enhance products, including the LaserCyte analyzer, with advanced technology, such as the Hammond principle, Advanced Diagnostics Software, and more.

For more information about LaserCyte performance and reliability, please contact Chris Lee (LaserCyte Product Manager) at 207-556-8499.

IDEXX LABORATORIES