A Clinical Validation Study of the New Diatron Aquila Hematology Analyzer

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Introduction

The Aquila Hematology analyzer is a new, compact 3 part differential analyzer specially designed for potential use in Non-Centralized Laboratories (e.g. Outpatient clinics, Physician offices and other Point of Care (POC) setting). It has many new features that include: a unique small sampling method, a single on-board reagent pack and a simple to use, operating interface which was designed specifically for a non-expert user. The purpose of this study was to validate the clinical performance of the analyzer, to demonstrate comparability with a reference laboratory hematology analyzer (Abbott Cell Dyn 3700) and to generate clinical data for regulatory submissions.

Methods

Linearity, repeatability, carryover and accuracy of the Aquila analyzer were performed on commercial linearity blood material, commercial control blood material and 245 clinical samples with a wide value range (e.g. low, normal and high). The validation process of the Diatron Aquila hematology analyzer complied to EN 13612:2002, CLSI H26-A2 and CLSI EP9-A3 standards.

Results

The Aquila passed the acceptance criteria for all the parameters tested, both on control blood material and clinical samples with the following CVs respectively for the measured parameters of WBC, RBC & Platelets e.g. <3.00% & <6.00%.
The carryover performance was very good and well within the acceptance criteria for a 3 part hematology analyzer. The WBC, RBC, HGB and PLT linearity tests passed at all levels.
Data and graphs below show performance on the key measured parameters.

Repeatability testing

This was performed by repeating 21 replicates of commercial control material on one Aquila analyzer.
The system passed on all acceptance criteria for repeatability.

Parameter	SD Criteria	CV Criteria
WBC (10^3/µL)	0.18	2.70%
GRA% (%)	3.50	6.00%
LYM% (%)	3.10	6.00%
MID% (%)	2.00	12.00%
RBC (10^6/µL)	0.11	1.70%
HGB (g/dL)	0.20	2.00%
MCV (fL)	1.00	1.70%
HCT (%)	1.20	2.40%
RDW (%)	0.40	2.50%
PLT (10^3/µL)	20.00	6.00%
MPV (fL)	0.45	8.70%
PDW (%)	0.50	2.00%

Table for Repeatability Acceptance Criteria

Carryover Testing

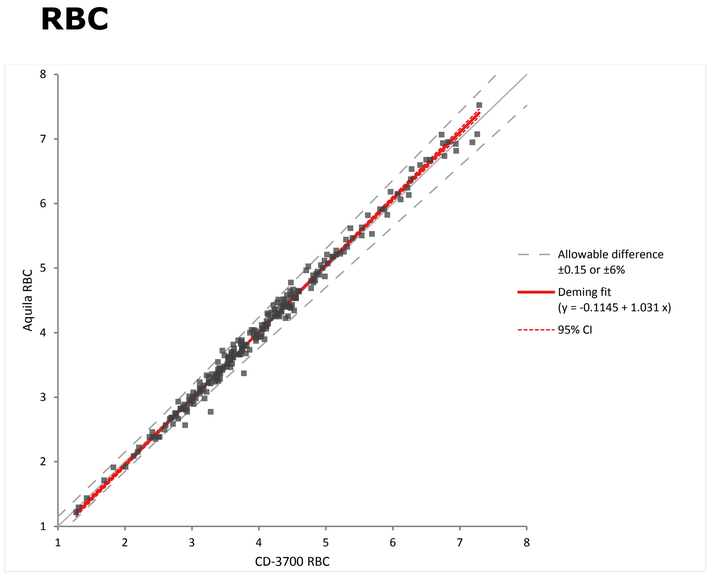
For each parameter, a high and low concentration sample was selected or prepared. The high concentration sample was run in triplicate followed by the low concentration sample in triplicate.

Aquila Carryover Test				
	WBC	RBC	HGB	PLT
Criteria	1.00%	0.50%	0.80%	1.00%
Measured	0.16%	0.20%	0.00%	0.06%
Pass/Fail	Pass	Pass	Pass	Pass
Overall Pass/Fail	Pass			

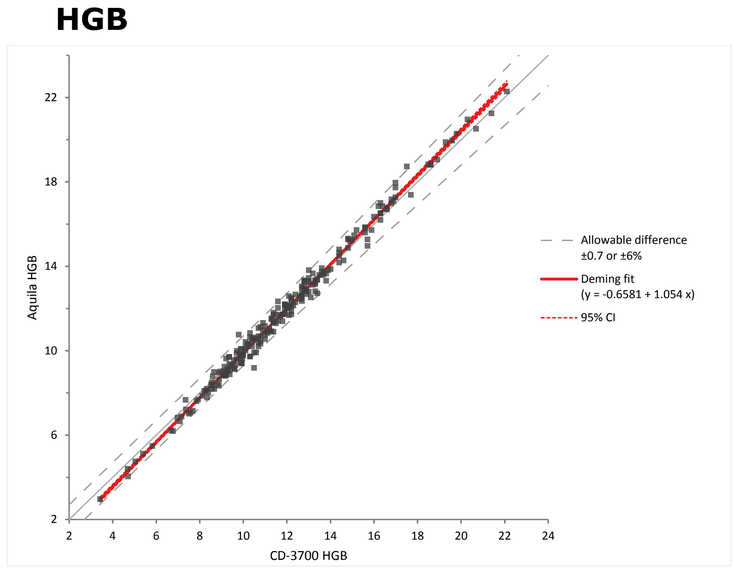
Table for Aquila Carryover Test

Method Comparison Plots with Cell Dyn 3700 on Clinical Samples

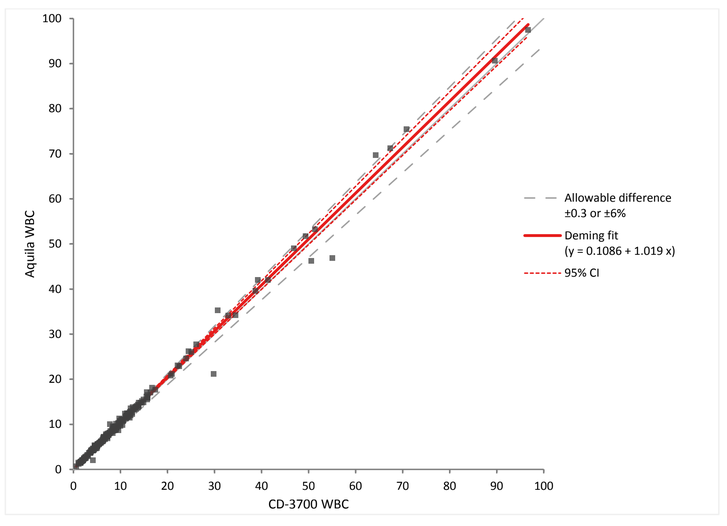
RBC



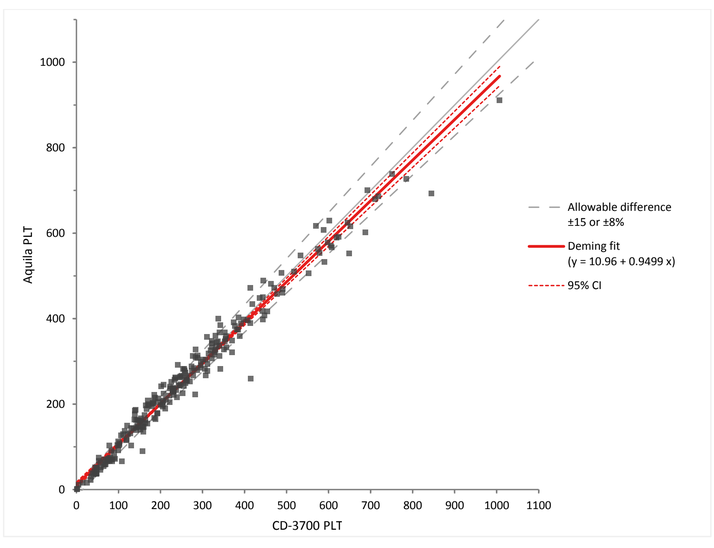
HGB



WBC



PLT



Conclusion

The Diatron Aquila Hematology Analyzer, utilising only a small blood sample volume and low reagent consumption met all criteria in line with current CLSI standards and provided good results when compared to a well recognised 5 part differential laboratory analyzer - the Abbott Cell Dyn 3700 system thus making it suitable for use in a variety of testing sites and especially in a decentralized POC setting.

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