

Clinical performance of Exigo™ H400 4-part hematology analyzer compared with a reference 5-part instrument

Exigo H400 automated hematology analyzer is routinely used in laboratory diagnostics for determination of patients' blood status. This work demonstrates the performance of Exigo H400 4-part hematology analyzer in comparison with a more technically advanced 5-part reference analyzer in complete blood count (CBC) analyses of patient samples taken from the normal routine screening. The results show that the analyzers are in good agreement, indicating the suitability for use of Exigo H400 in veterinary clinics.



Fig. 1. Exigo H400 automated 4-part hematology analyzer.

Introduction

A CBC is highly useful in general screenings as a tool to aid in diagnosis and monitoring of disease conditions. Automated instruments for this type of analyses were developed as early as in the 1950s, with the first European cell counter developed by Erik Ohlin, the founder of the human Swelab Instruments (now part of Boule Diagnostics). Boule launched their first veterinary system 2004.

Before, blood cell counts were performed manually by microscopy. Although manual examination of blood smears is still used as a control method for verification of results from abnormal samples, the automated hematology analyzers have largely replaced the manual method for determination of hematology parameters in routine use.

The Exigo H400 system is an automated hematology analyzer for in vitro diagnostic use under laboratory conditions (Fig. 1). The analyzer is intended for determination of hemoglobin (HGB) concentration, for counting of red blood cells (RBC) and platelets (PLT), as well as for counting and differentiation of white blood cells (WBC) into four subpopulations, namely lymphocytes (LYM), monocytes (MONO), neutrophils (NEU), and eosinophils (EOS). The measurement principles of the Exigo H400 are based on impedance for cell counts and spectrophotometry for HGB. Although such a 4-part hematology analyzer provides enough information for the smaller local hospital laboratory, trends show an increased interest in 5-part laser instruments, typically used in larger reference labs, also for use in smaller clinics.

While a 5-part analyzer offers improved WBC assessment, differentiating them into neutrophils (NEU), lymphocytes (LYM), monocytes (MONO), eosinophils (EOS), and basophils (BASO), a 3-part or 4-part instrument can offer great cost benefits to general screenings of patients' blood status (1). Moreover, on the veterinary hematology side, BASO are known to show no correlation with reference manual microscope method on any hematology analyzer available today. Also, as for the possible links of diagnosis to BASO, neoplasia and heartworms tend to increase not only BASO but also EOS at the same time (2). The objective of this study was to evaluate the performance of Exigo H400 4-part hematology analyzer against a 5-part reference instrument.

Materials and methods

Exigo H400 4-part hematology analyzer and associated reagents, calibrator, and control material were used as test system. As reference system, the Sysmex™ XT-2000iV 5-part hematology analyzer and associated reagents, calibrator, and control material (Sysmex Corp.) were used. Control blood was analyzed in duplicates daily before and after sample runs. Fresh normal and abnormal dog, cat, and horse whole blood samples (n = 125 dog samples, n = 63 cat samples and n = 60 horse samples), collected for routine analyses, were analyzed in duplicate on the test analyzer and on the reference analyzer. Samples included in the study were primarily selected to support the main test parameters RCB, HGB, PLT, and WBC. The analyzers were co-calibrated prior to the statistical analyses using the first 5 normal (non-flagged) dog samples.

The strength of the relationship between the cell count in the test and the reference systems was measured using Pearson correlation coefficient (r). Passing-Bablok regression analysis and Bland-Altman difference plots for estimation of agreement and possible systematic bias between the test and the reference systems were performed on matched samples. For comparison with the Exigo H400 4-part system, results from the Sysmex 5-part differential were combined into granulocytes (GRAN)/NEU, MONO, LYM and EOS as given in Table 1. The evaluation was performed in collaboration with Evidensia Specialist Veterinary Hospital in Strömsholm (hereafter, Strömsholm), Sweden.

No outliers were deleted as they did not affect the results. Most of the flags obtained from the analyzers were related to WBC indices. The Sysmex XT-2000iV analyzer did not report MPV-values for the cat profile. For that reason, agreement between the Sysmex and the Exigo analyzers for MPV could not be evaluated.

Table 1. Correlation of parameters between 4-part and 5-part differential

Exigo H400	Sysmex XT-2000iV
GRAN/NEU	Neutrophils + basophils
MONO	Monocytes
LYM	Lymphocytes
EOS	Eosinophils

Results

Correlation results, with specification limits for the correlation coefficient (r) between test and reference systems, are given in Table 2. As shown, all parameters passed the correlation requirements, except for the mean cell volume (MCV), for which the correlation coefficient was just below the acceptance criterion. The specifications were applicable for dogs only. The results of the performance of the Exigo analyzer using cat and horse samples were presented for informational purposes.

Dogs

Correlation plots for the dog samples are shown in Fig. 2. According to the specifications, the Exigo H400 analyzer passed the correlation requirements when compared to the Sysmex analyzer, except for MCV, where the correlation coefficient was slightly below the acceptance limit. The diluents contain substances that make the cells spherical before analysis, and clinical conditions with high bilirubin can induce differences in membrane plasticity and swelling. Thus, MCV might be recorded differently in the two systems.

There were no observations of deviating samples in the plots for PLT, RBC, HGB, and WBC.

Table 2. Agreement between the Sysmex XT-2000iV and the Exigo H400 veterinary hematology analyzer CBC for dogs

Parameter	Unit	r_s	r specification
RBC	$10^{12}/L$	0.997*	≥ 0.98
HGB	g/L	0.995*	≥ 0.98
MCV	fL	0.937*	≥ 0.95
HCT	%	0.989*	
PLT	$10^9/L$	0.979*	≥ 0.95
MPV	fL	0.952*	
WBC	$10^9/L$	0.994*	≥ 0.97
LYM	$10^9/L$	0.736*	≥ 0.70
MONO	$10^9/L$	0.572*	
GRAN	$10^9/L$	0.960*	≥ 0.90
EOS	$10^9/L$	0.585*	

* Correlation is significant at the 0.01 level (2-tailed). r_s = Spearman rho.

The systems showed results comparable with manual microscopy (Table 3).

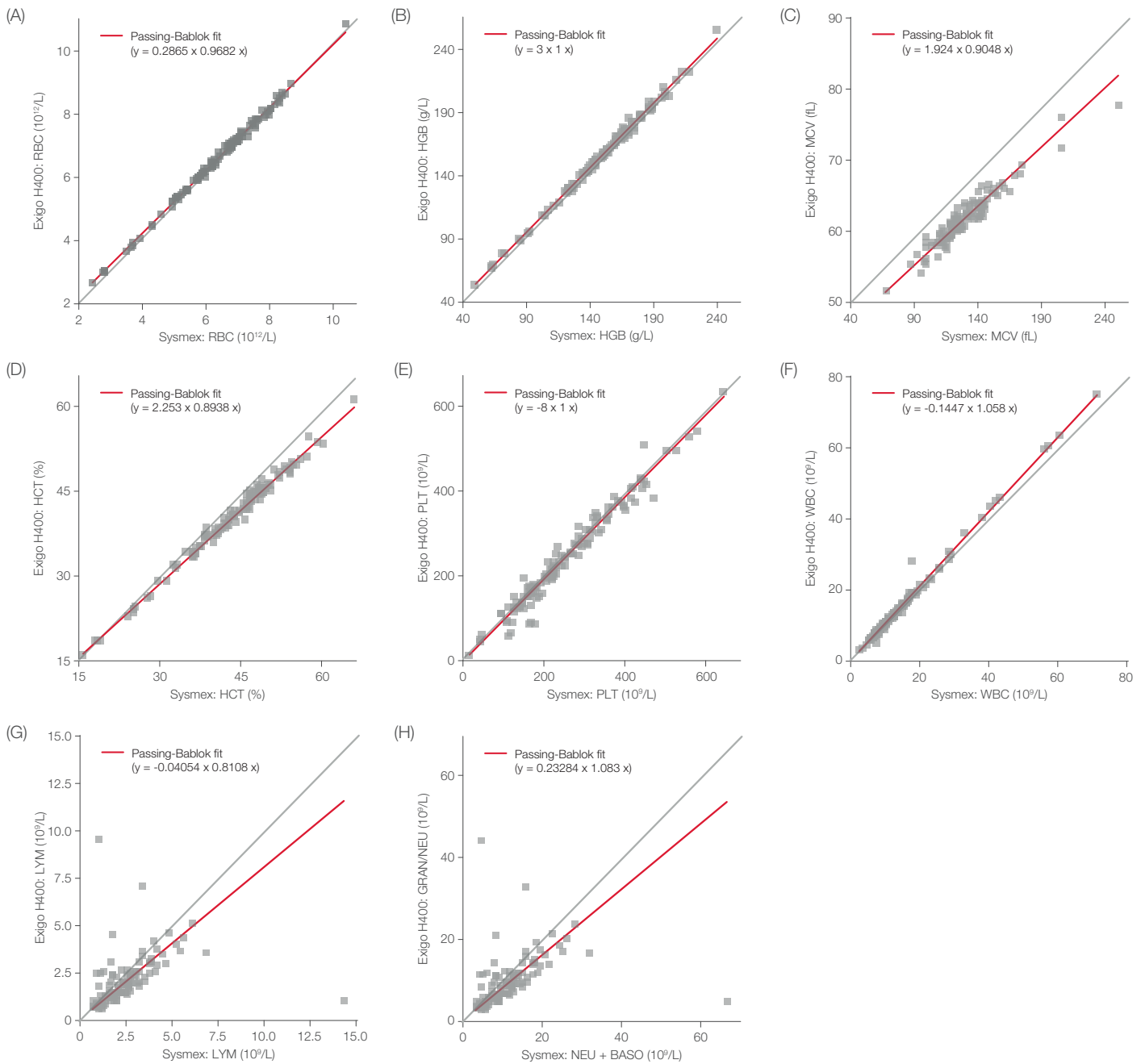


Fig. 2. Agreement between the Sysmex XT-2000iV (reference) and the Exigo H400 (test) hematology analyzer for dog CBC shown in Passing-Bablok regression graphs RBC (A), HGB (B), MCV (C), HCT (D), PLT (E), WBC (F), LYM (G), and GRAN (H). The thin line is the line of identity ($x = y$) and the thick line is the line of best fit.

Table 3. Agreement between the manual WBC differential count (reference method) and the automated count in the Sysmex XT-2000iV and the Exigo H400 veterinary hematology analyzers for dogs

	N		Spearman Correlation		Bias	
	Sysmex	Exigo	Sysmex	Exigo	Sysmex	Exigo
NEU/GRAN	118	122	0.995*	0.976*	-0.37	0.13
LYM	118	122	0.794*	0.700*	0.52	0.10
MONO	118	122	0.639*	0.434*	-0.34	-0.16
EOS	122	119	0.789*	0.701*	-0.01	-0.06

* Correlation is significant at the 0.01 level (2-tailed).

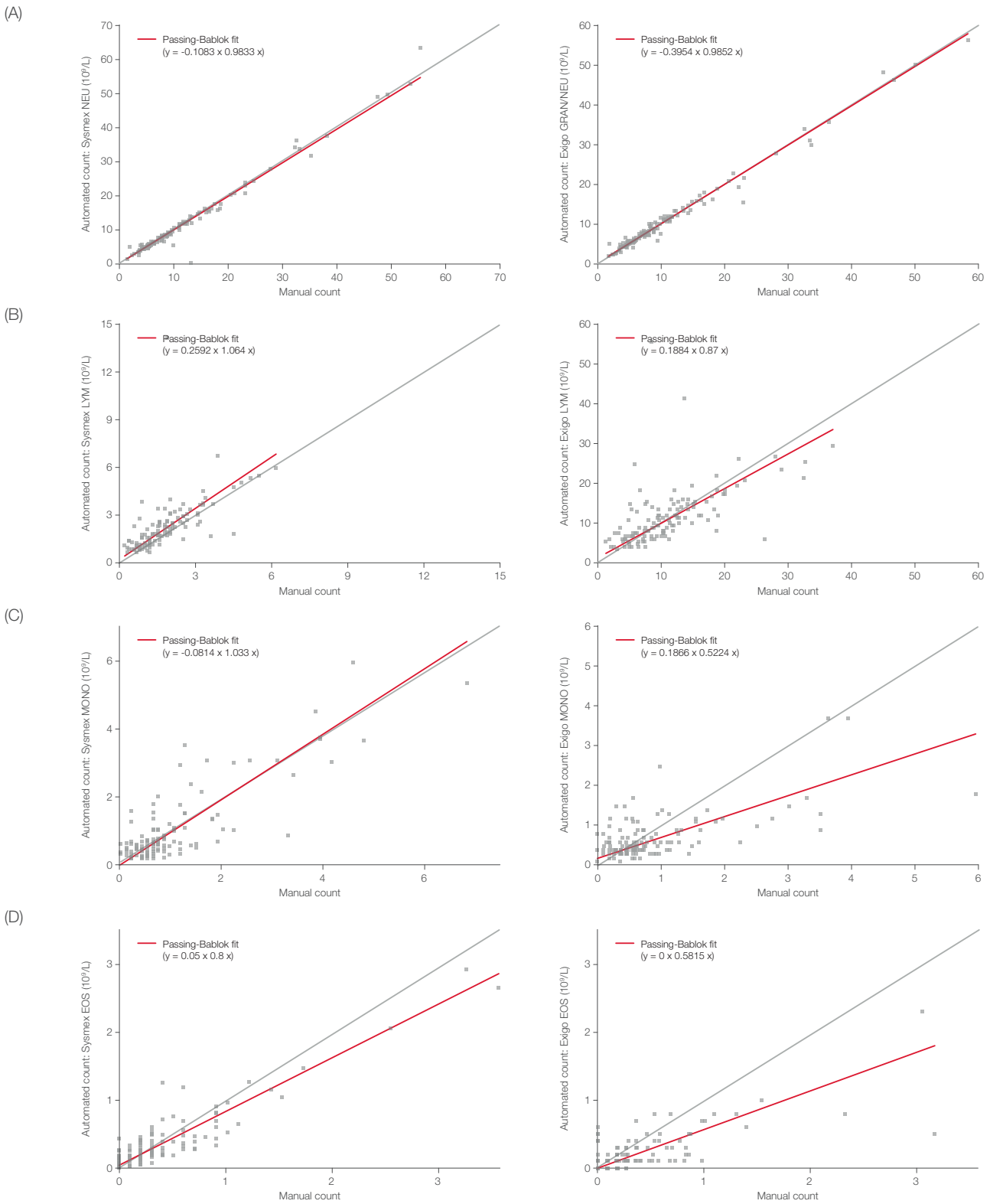


Fig. 3. Agreement between the manual WBC differential count and the automated count in the Sysmex XT-2000iV (left) and the Exigo H400 (right) veterinary hematology analyzers for dogs. Passing-Bablok regression graphs for NEU/GRAN (A), LYM (B), MONO (C), and EOS (D). The thin line is the line of identity ($x = y$) and the thick line is the line of best fit.

Cats

Correlation plots for the cat samples are shown in Fig. 4. The Exigo H400 showed good to excellent correlation when compared to the Sysmex analyzer (Table 4, Fig. 4), except for the MONO and LYM, where slightly lower correlation was observed. MONO are present at a substantially lower level in comparison to LYM and GRAN, which can also lower the correlation coefficient.

As for the MCV, where the correlation coefficient was slightly below the acceptance limit, with the same explanation as above for the dogs.

Table 4. Agreement between the Sysmex XT-2000iV and the Exigo H400 veterinary hematology analyzer CBC for cats

Parameter	Unit	r_s	r specification
RBC	$10^{12}/L$	0.986*	≥ 0.98
HGB	g/L	0.990*	≥ 0.98
MCV	fL	0.926*	≥ 0.95
HCT	%	0.966*	
PLT	$10^9/L$	0.642*	≥ 0.95
WBC	$10^9/L$	0.883*	≥ 0.97
LYM	$10^9/L$	0.521*	≥ 0.70
MONO	$10^9/L$	0.522*	
GRAN	$10^9/L$	0.969*	≥ 0.90
EOS	$10^9/L$	0.750*	

* Correlation is significant at the 0.01 level (2-tailed). r_s = Spearman rho.

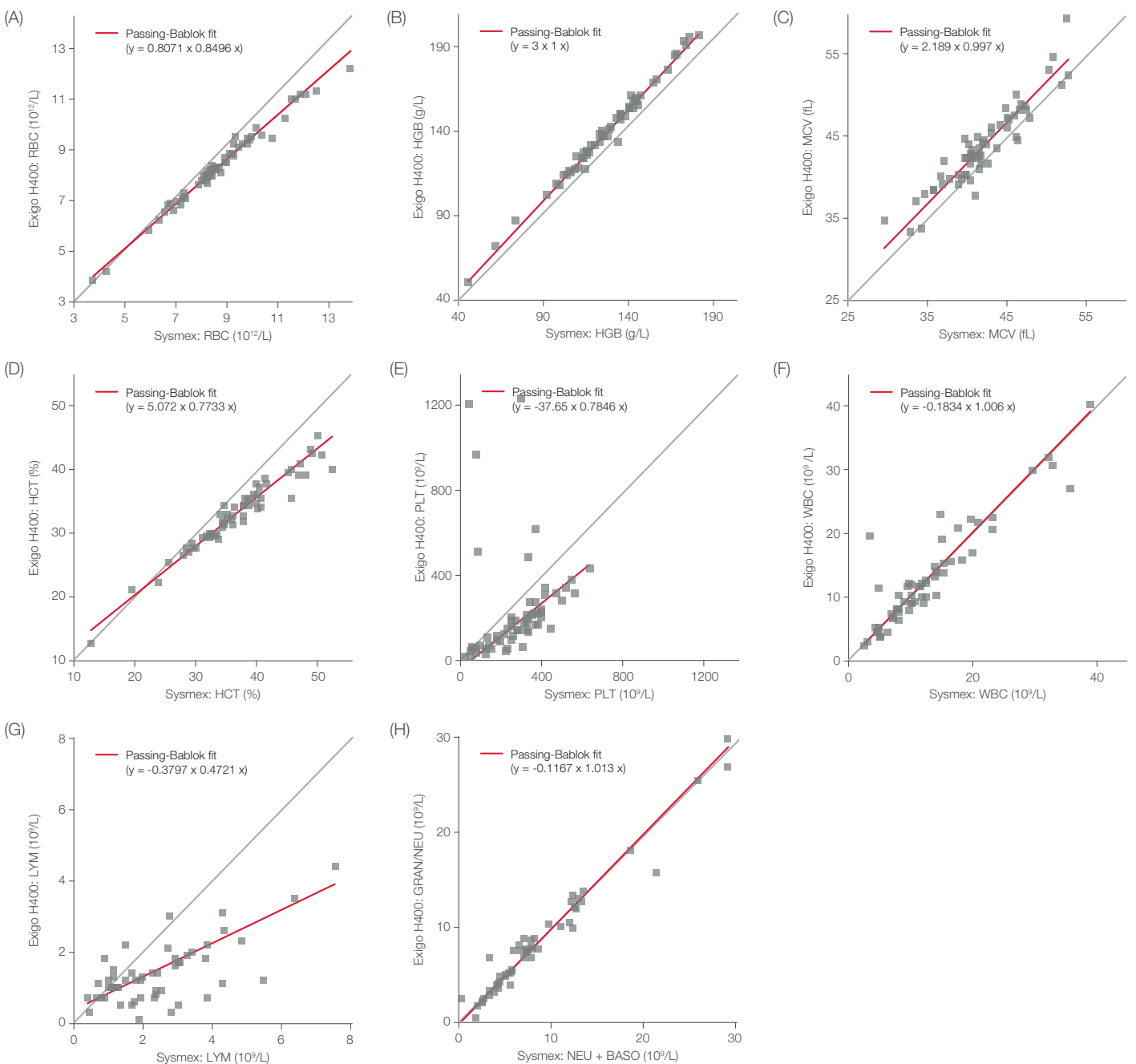


Fig. 4. Agreement between the Sysmex XT-2000iV (reference) and the Exigo H400 (test) hematology analyzer for cat CBC. Passing-Bablok regression graphs for RBC (A), HGB (B), MCV (C), HCT (D), PLT (E), WBC (F), LYM (G), and GRAN (H). The thin line is the line of identity ($x = y$) and the thick line is the line of best fit.

Horses

Correlation plots for the horse samples are shown in Fig. 5. The Exigo H400 showed good to excellent correlation when compared to the Sysmex analyzer, except for the MONO (Table 5, Fig. 5).

Table 5. Agreement between the Sysmex XT-2000iV and the Exigo H400 veterinary hematology analyzer CBC for horses

Parameter	Unit	r_s	r specification
RBC	$10^{12}/L$	0.996*	≥ 0.98
HGB	g/L	0.997*	≥ 0.98
MCV	fL	0.962**	≥ 0.95
HCT	%	0.989*	
PLT	$10^9/L$	0.822*	≥ 0.95
WBC	$10^9/L$	0.983*	≥ 0.97
LYM	$10^9/L$	0.891*	≥ 0.70
MONO	$10^9/L$	0.504*	
GRAN	$10^9/L$	0.986*	≥ 0.90
EOS	$10^9/L$	0.679*	

* Correlation is significant at the 0.01 level (2-tailed). r_s = Spearman rho.

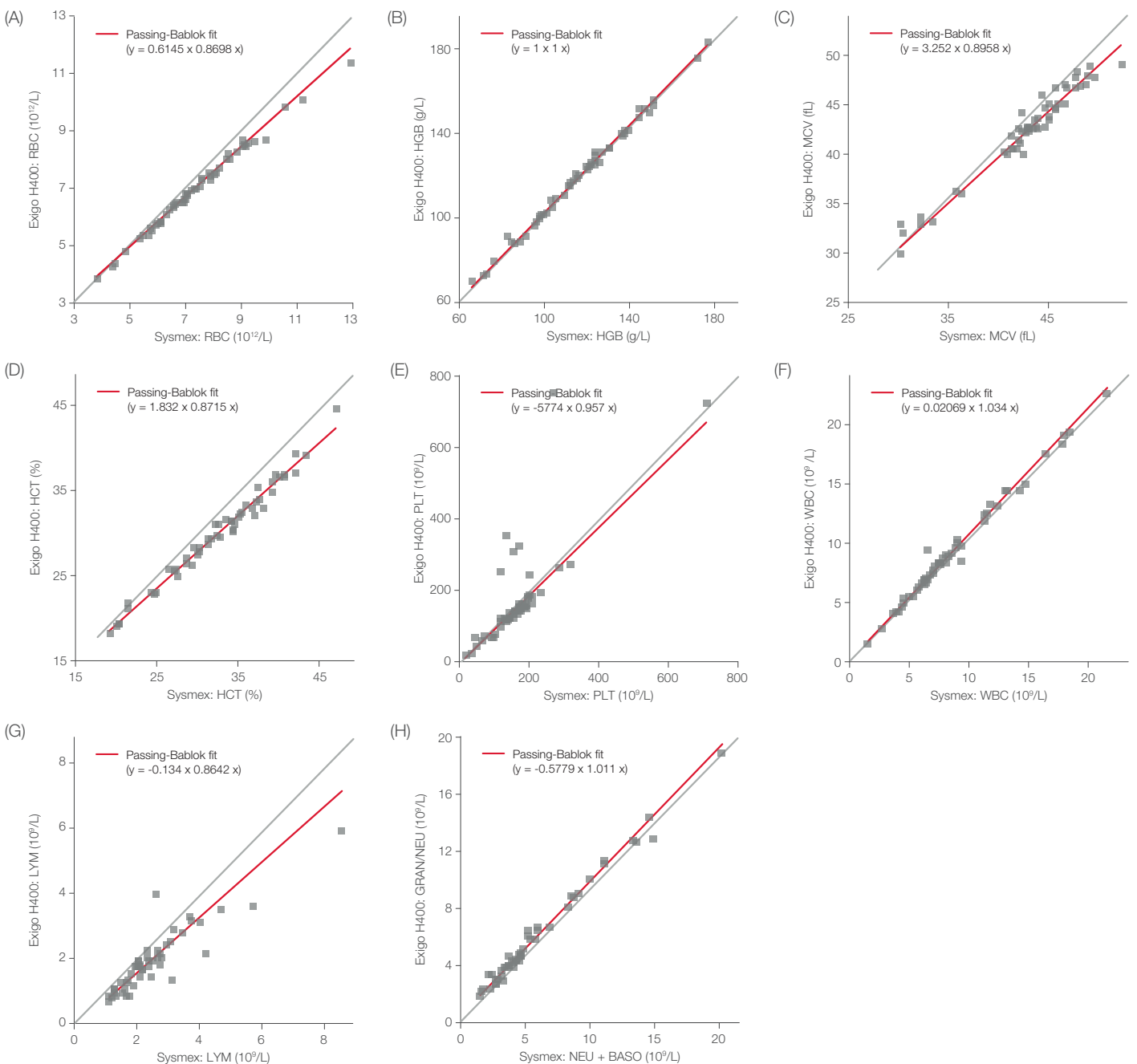


Fig. 5. Agreement between the Sysmex XT-2000iV (reference) and the Exigo H400 (test) hematology analyzer for horse CBC. Passing-Bablok regression graphs for RBC (A), HGB (B), MCV (C), HCT (D), PLT (E), WBC (F), LYM (G), and GRAN (H). The thin line is the line of identity ($x = y$) and the thick line is the line of best fit.

Conclusion

This study points to some of the differences between a more technically advanced 5-part analyzer, intended for use in a larger reference laboratory, and a 4-part analyzer, intended for use in general health screenings at local veterinary clinics. Although some samples included in this study were from patients with pathological states that are not applicable to the placement of a 4-part hematology analyzer, these samples provide the analytical parameter range necessary for the evaluation. The results from this study demonstrate that the performance of Exigo H400 hematology analyzer is in good agreement with that of the reference analyzer and the manual reference method, indicating the suitability of Exigo H400 for use in routine hematology analysis at veterinary clinics.

Disclaimer

The results and conclusions presented in this study are valid for this specific study only. Other study conditions and assumptions could have significant impact on the outcome.

References

1. White Paper: Hematology analyzers: 3-part or 5-part, that is the question. Boule Diagnostics, WP31183, Edition 1 (2019).
2. White Paper: Introduction of veterinary hematology parameters: factors affecting parameters, clinical relevance and inter-species variations. Boule Diagnostics, WP34071, Edition 2 (2019).

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