Medonic™ M32 hematology analyzer helps ensure secure and efficient use of blood donations

Efficient processing of donated blood and ensuring its safe use in transfusions require stringent hematology testing combined with rapid and accurate results. This work aims to evaluate that the Medonic M32 blood bank application meets the performance claims. The Medonic M32 analyzer was run with associated reagents and checked with dedicated quality control material. Correlation studies with platelet (PLT) and red blood cell (RBC) concentrates were performed in collaboration with a Swedish University Hospital Blood bank against a reference analyzer. The results show good correlation between instruments, indicating the suitability of Medonic M32 for use in blood bank applications.

Introduction

Pre-donor testing helps confirm donor suitability. Key questions to answer include whether or not the individual is suitable for donation, what is the exact platelet (PLT) count (needed for optimal processing) and does the donor have a possible infection. Accurate monitoring of platelet concentrate facilitates optimal pooling, and the equivalent information for red blood cells (RBC) is needed to define the number of cells in each concentrate bag.

Medonic M32 is an automated hematology analyzer intended for *in vitro* diagnostic testing of human PLT and RBC concentrates under laboratory conditions. The blood bank application resides in the Medonic M32 analyzer as a special analysis profile. The factory default blood bank profile is named PLT-C (PLT-Concentrate). This profile is pre-installed in the instrument and can be activated by the service technician upon delivery of the instrument. The erythrocyte concentrate (RBC-C) is analyzed in the Open Tube inlet mode, using the normal blood profile.

In the PLT-C profile, several parameters are blocked, and no value is displayed on the screen or printed. In PAS (Print All Settings) the blocked parameters are removed, whereas RBC, PLT, MPV, WBC, PCT, PDW, P-LCC and P-LCR values are displayed and printed. Suggested normal ranges for the active parameters are preset as the default (for a PLT concentrate), but levels may be altered by the user. Two calibration factors are available when the blood bank option is activated, PLT-C and MPV-C.

Medonic M32 features micro-pipette adapter (MPA) sampling (Figure 1). Simply make a finger stick, draw blood into a special 20 µL micro-capillary tube, slide it into the adapter, and insert in the analyzer. About one minute later, all key results can be viewed on the touchscreen. No preparation, pre-dilution, vacuum tubes, or needles are required. In addition to making fast pre-donation blood cell determinations, MPA also saves the vein for donation.

In this work, the performance of the Medonic M32 blood bank application was compared with the corresponding application in CA620 CellGuard.

(A) (B)

(C)

Figure 1. MPA function offers fast pre-donation testing. (A) Take a finger-stick blood sample. (B). The MPA adapter lets you analyze capillary samples directly and saves the vein for donation. (C) In one minute, key results can be viewed on the touchscreen.

Materials and methods

The following materials were used in this study:

- Medonic M-series M32 Hematology Analyzer (1420024)
- Medonic M-series Diluent (1504122)
- Medonic M-series Lyse (1504123)
- Boule Con-Diff Normal (1504019)
- Boule Con-Diff High (1504021)

Medonic M32 (test instrument) was co-calibrated with CA620 CellGuard (reference instrument) for the correlation study. PLT and RBC concentrates used for the evaluation were taken from the routine concentrate production. After analysis on the reference instrument, samples were run in the open tube (OT) inlet of the Medonic M32 analyzer.

Single assays on the test and reference analyzers were compared and results presented in scatter plots with the 95% confidence interval (confidence and prediction bands) of the linear regression indicated. Linearity testing was performed using a linearity kit with 10 levels, covering the range of the linearity claim in accordance with CLSI Standard EP06-A. The study was performed in accordance with the standard SS-EN 13612 for compliance with the demands in the European IVD directive (98/79/EC).

Results

Medonic M32 quickly generated accurate PLT-C and RBC-C results, all presented in an easy-to-read manner. Specification limits for the study are listed in Table 1. Correlation of test instrument with reference instrument for PLT and RBC concentrates are visualized in Figures 2 and 3.

Table 1. Specifications limits

	Correlation	Linearity	
Parameter	R (correlation coefficient)	Difference (whichever is greater)	Linearity range
PLT	≥ 0.95	± 10 × 10^9/L or ± 3%	20–5000 × 10^9/L
RBC	≥ 0.95	± 0.05 × 10^{12}/L or ± 2%	0.30–8.00 × 10^{12}/L

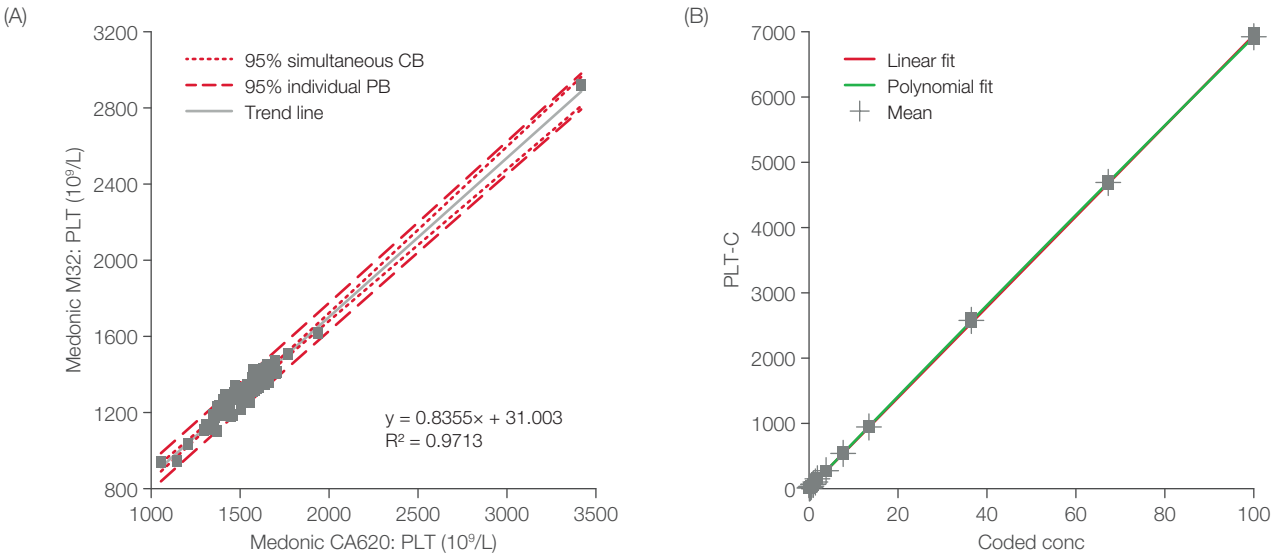

Figure 2. (A) Correlation of PLT concentrates between test system and reference system (n = 82). (B) PLT linearity: recovered vs theoretical value.

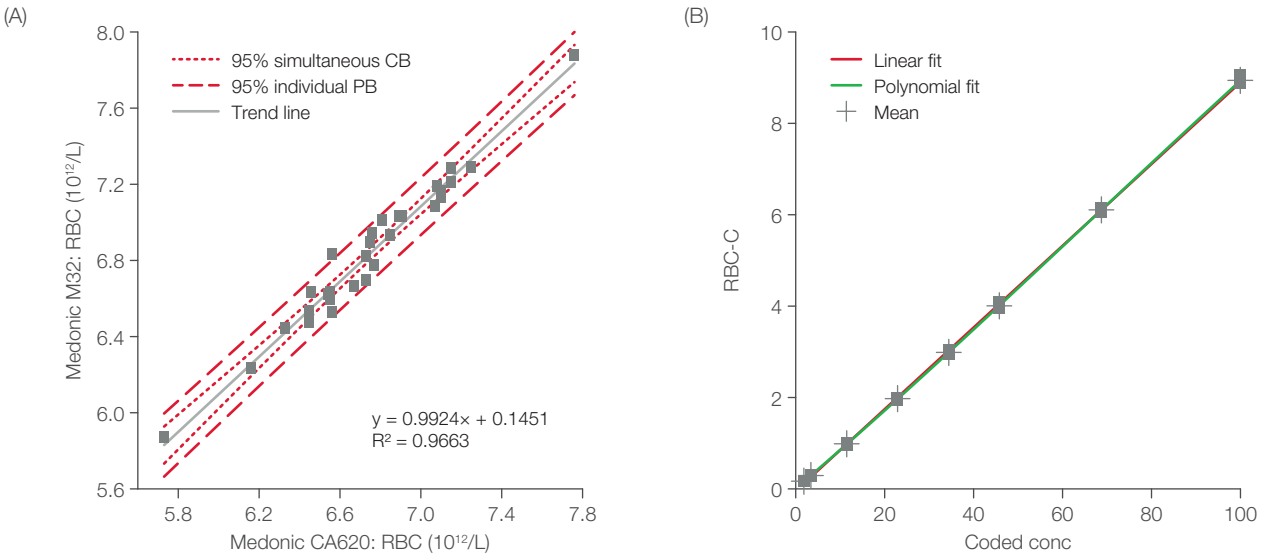

Figure 3. (A) Correlation of RBC concentrates between test system and reference system (n = 30). (B) RBC linearity: recovered vs theoretical value.

Conclusion

The results from this study shows good correlation and linearity of Medonic M32 with reference analyzer in blood bank application measurement of PLT and RBC concentrations. MPA sampling allowed fast and user-friendly operation. Enabling quick pre-donation blood cell testing, the Medonic M32 analyzer can be a useful tool for efficient processing of donated blood and ensuring its safe use in transfusion.

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.

boule.com

TR 22837
Boule Diagnostics AB, Domnarvsgatan 4, SE-163 53 Spånga, Sweden
ANM31881-1 03/2019