Comparison of capillary and venous blood samples on Medonic™ M32 hematology analyzer

As a finger-stick is largely painless, the micro-pipette adapter (MPA) method is well-suited to take and analyze blood samples from children and other patients. For blood banks, MPA is an excellent tool for making fast pre-donation blood cell determinations. The method also saves the vein for donation. Here, we summarize the outcome of internal and external evaluations to demonstrate equivalency of results, within defined limits, on the Medonic M32 system (analyzer and reagents, set-up with Boule Cal) for samples collected by venipuncture and capillary collection methods.

Introduction

Commonly, laboratory reference values are set using venous blood samples. For many applications, however, capillary blood samples are preferred. A finger-stick is easier on the patient, especially for elderly and pediatric patients, and the smaller blood volume is easier to handle in a near-patient setting. It is also in the capillaries that oxygen and nutrients from the arterial blood are distributed, and from where deoxygenated blood flows back to the heart through the veins. Hence, capillary blood is a combination of arterial and venous blood. Consequently, the correlation between venous and finger-stick capillary blood is heavily debated.

Medonic M32 hematology analyzer is trusted for its high reliability and ease-of-use (Figure 1). From doctors' offices and small labs to medium-sized clinical units, the system delivers 22 parameters, including complete blood count (CBC) and a 3-part differential of the white blood cells (WBC), with outstanding speed and precision. Most importantly, Medonic M32 analyzer offers a wide choice of sampling inlets: open tube, pre-dilute, cap-piercing, auto sampler, and micro-pipette adapter (MPA) sampling. The MPA method—based on a simple finger-stick sample taken directly from the patient—is widely used with the Medonic M32 hematology analyzer today (Figure 2).

This work compares the results from samples collected by the capillary methods for analysis using MPA with samples collected by venipuncture.

Figure 1. Medonic M32 hematology analyzer with the MPA module.

(A) (B)

(C)

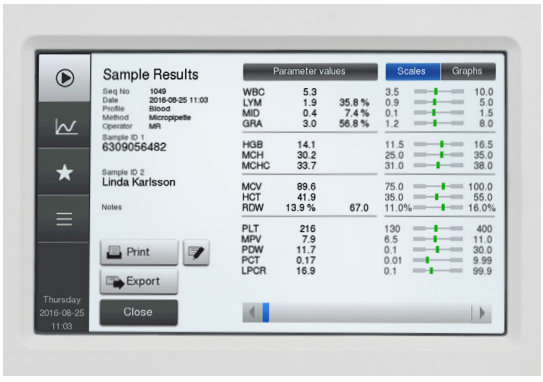

Figure 2. MPA function offers fast pre-donation testing. (A) Take a finger-stick blood sample. (B). The MPA adapter lets you analyze capillary samples directly and saves the vein for donation. (C) In one minute, key results can be viewed on the touchscreen.

Materials and methods

The following material was used in this study:

- Medonic M-series M32 Hematology Analyzer
- Medonic M-series Diluent
- Medonic M-series Lyse
- Boule Con-Diff Low
- Boule Con-Diff Normal
- Boule Con-Diff High
- Boule Cal
- Boule MPA Micro Pipettes Plastic, EDTA

In this study, results obtained for capillary blood samples collected in Boule micro-pipettes as well as micro-collection tubes were compared with results for venous blood samples. From each donor, venous and capillary K_2EDTA anticoagulated whole blood samples were collected by venipuncture and finger stick, respectively. All samples were analyzed in single assays to obtain CBC and WBC differential results using the open tube (OT) sampling method for both the venous and capillary samples.

Parameter mean value bias was determined using venous whole blood as reference for the following comparisons:

1) Capillary blood in micropipette (MPA) with venous blood (OT).
2) Capillary blood in micro-collection tubes (OT) with venous blood (OT).

Results were compared with pre-defined acceptance criteria.

The following standards and guidelines were followed for design and implementation of the studies:

- CLSI H26-A2. Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard - Second Edition; 2010.
- CLSI GP41-A6. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition; 2007.
- GP42-A6. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition; 2008.

Results

The outcome of the comparative studies for capillary versus venous blood are presented separately in Tables 1 and 2.

Table 1. Comparison of capillary blood collected in micropipettes (MPA mode) versus venous blood (OT mode)

Parameter	Unit	N	Range (venous)		Mean venous	Mean capillary	Bias	Bias%	Specification limit		Result
			Low	High					Bias	Bias%	
WBC	10^9/L	60	3.3	10.4	6.5	6.5	0.0	-0.1%	NA	± 7%	Pass
LYM%	%	60	15.4	39.7	27.7	29.8	2.1	7.7%	± 5	NA	Pass
MID%	%	60	4.5	7.8	6.3	7.8	1.5	24.3%	± 5	NA	Pass
GRAN%	%	60	52.5	80.1	66.0	62.7	-3.4	-5.1%	± 5	NA	Pass
RBC	10^{12}/L	60	3.92	5.83	4.7	4.8	0.1	2.2%	NA	± 4%	Pass
HGB	g/dL	60	12.1	16.6	14.1	14.3	0.2	1.1%	NA	± 4%	Pass
MCV	fL	60	79.1	99.2	90.6	91.7	1.1	1.2%	NA	± 2.5%	Pass
HCT	%	60	35.7	51.6	42.6	44	1.4	3.3%	± 2	NA	Pass
RDW%	%	60	11.1	14.8	12.5	12.2	-0.4	-2.8%	± 2	NA	Pass
PLT	10^9/L	60	125	340	208	190	-18	-8.6%	NA	± 10%	Pass
MPV	fL	60	7.0	10.5	8.4	8.9	0.5	-5.6%	NA	± 10%	Pass

NA = not applicable

Table 2. Comparison of capillary blood collected in bullet tube (OT mode) versus venous blood (OT mode)

Parameter	Unit	N	Range (venous)		Mean venous	Mean capillary	Bias	Bias%	Specification limit		Result
			Low	High					Bias	Bias%	
WBC	10^9/L	52	3.6	11.6	7.2	6.9	-0.3	-3.7%	NA	± 5%	Pass
LYM%	%	52	14.4	46.7	31.9	31.5	-0.4	-1.4%	± 5	NA	Pass
MID%	%	52	4.9	10.1	7.2	6.9	-0.3	-4.5%	± 5	NA	Pass
GRAN%	%	52	44.8	80.3	60.8	61.6	0.8	-1.3%	± 5	NA	Pass
RBC	10^{12}/L	52	3.6	5.72	4.9	4.8	0.0	-0.6%	NA	± 2.5%	Pass
HGB	g/dL	52	11.9	17.1	14.7	14.6	-0.1	-0.6%	NA	± 2.5%	Pass
MCV	fL	52	76.4	99.7	87.4	86.5	-0.9	-1.1%	NA	± 2.5%	Pass
HCT	%	52	34.8	51.5	42.4	41.7	-0.7	-1.7%	± 2	NA	Pass
RDW%	%	52	12	14.6	13.1	13.1	0.0	-0.3%	± 2	NA	Pass
PLT	10^9/L	52	132	358	220	207	-13	-5.8%	NA	± 7%	Pass
MPV	fL	52	7.2	10.4	8.9	9.2	0.4	4.4%	NA	± 10%	Pass

NA = not applicable

Conclusion

Analysis of the data shows that the Medonic M32 System meets performance specifications and provides comparable results for samples collected by venipuncture and capillary collection methods. The study demonstrates the suitability of the MPA method for determination of blood status from a simple finger-stick sample taken directly from the patient.

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.

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