

Summary of Clinical Data, correlation between Medonic M-series M32 and Sysmex XE-5000 hematology systems

Introduction

The purpose of this document is to summarize the outcome of the clinical evaluations to validate that the Medonic M-series M32 meet the performance claims in comparison to the reference instrument Sysmex XE-5000¹. The Medonic M-series M32 instrument was run with reagents and checked with quality control material as indicated below.

Materials

Medonic M-series M32 Hematology Analyzer, art no 1420024

Medonic M-series Diluent; art no 1504122

Medonic M-series Lyse; art no 1504123

Boule Con-Diff Normal; art no 1504019

Boule Con-Diff Low; art no 1504020

Boule Con-Diff High; art no 1504021

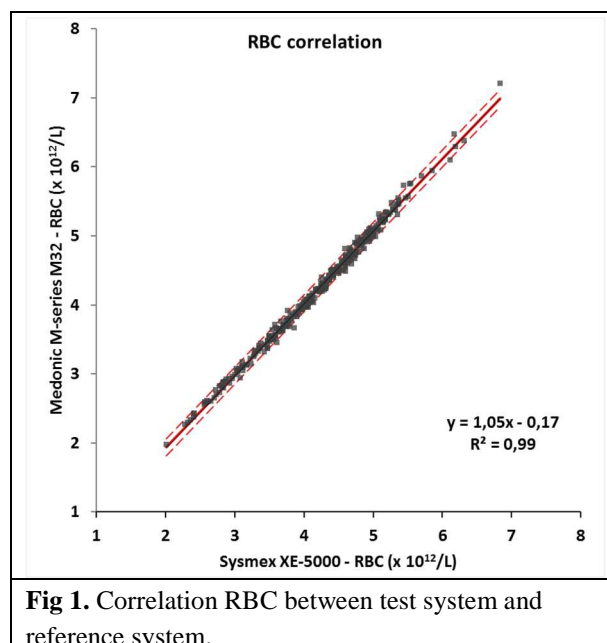
Clinical samples

The evaluation was performed in collaboration with a Swedish Hospital against the reference instrument Sysmex XE-5000, in accordance with the standard SS-EN 13612 for compliance with the demands in the European IVD directive (98/79/EC).

The correlation studies are based on >340 samples taken from the normal routine. After analysis on the reference instrument samples were run in the open tube (OT) inlet on the Medonic M-series M32 system. Single assays on the test and reference instruments are compared and results are presented in scatter plots with the 95% confidence interval (prediction interval) of the linear regression indicated.

Results of correlation study

Erythrocytes, concentration (red blood cells, RBC)



¹ The full data set is found in Doc# 21966 with references including original graphs

Erythrocytes, mean cell volume (MCV)

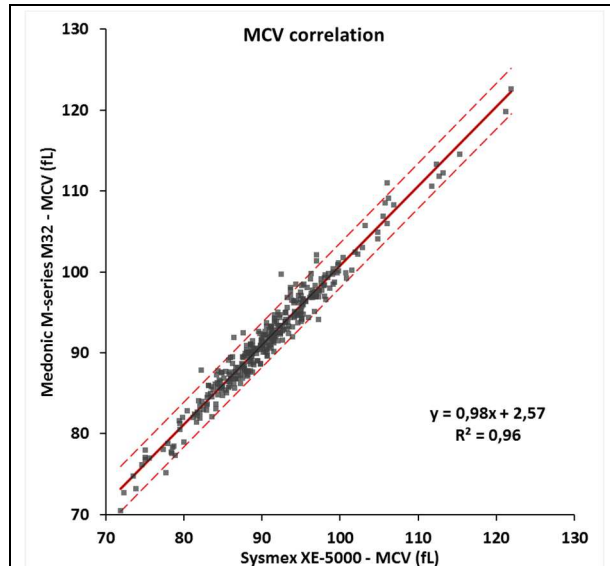


Fig 2. Correlation MCV between test system and reference system.

Thrombocytes, concentration (platelets, PLT)

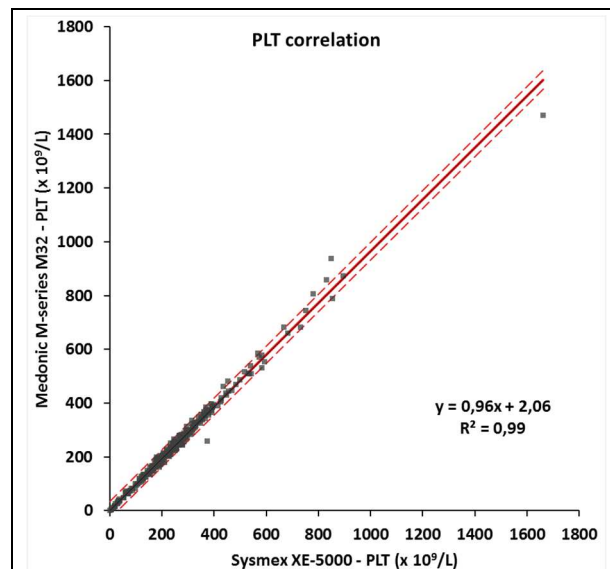
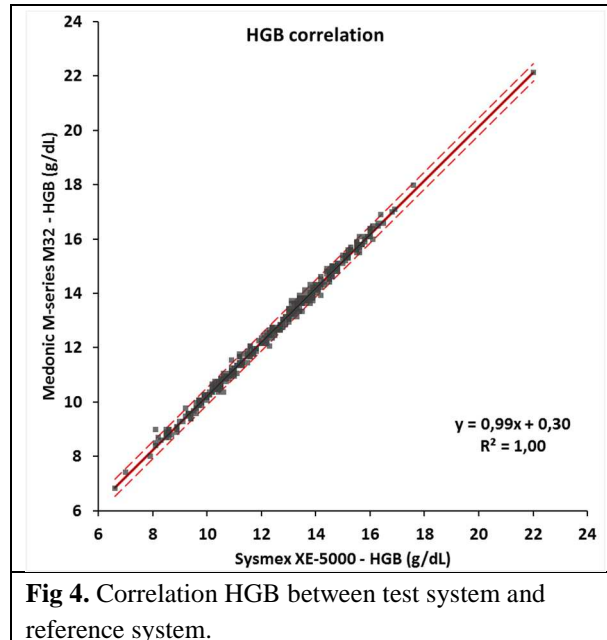
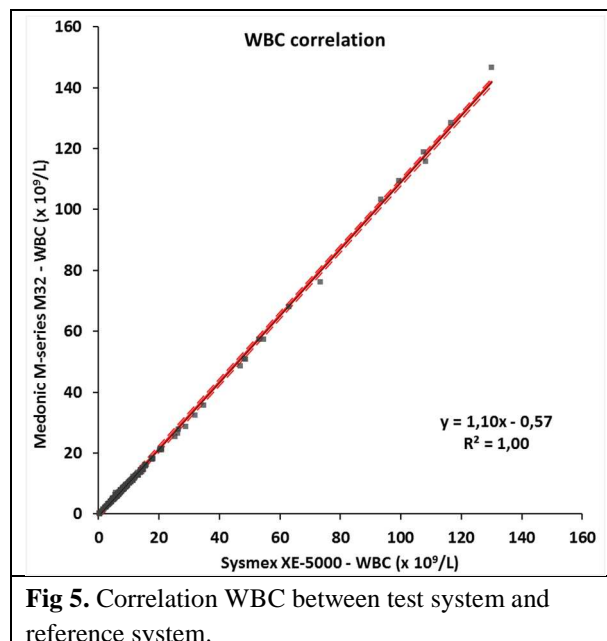


Fig 3. Correlation PLT between test system and reference system.

Hemoglobin, concentration (HGB)



Leucocytes, concentration (white blood cells, WBC)



Lymphocytes, concentration (Lymph)

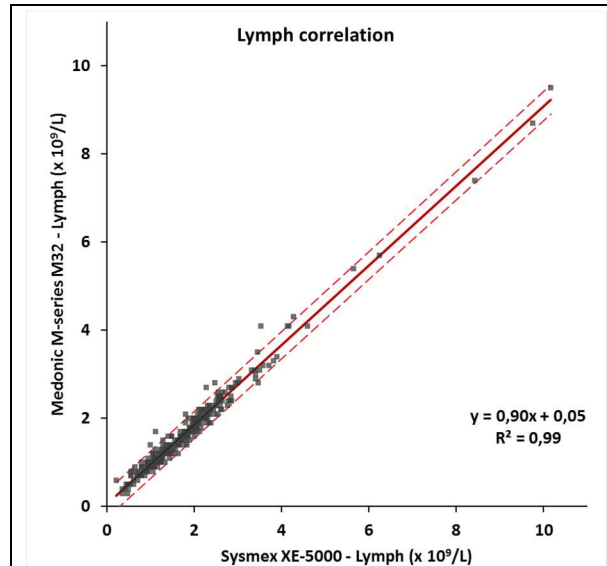


Fig 6. Correlation Lymph (non-flagged samples) between test system and reference system.

Granulocytes, concentration (Gran)

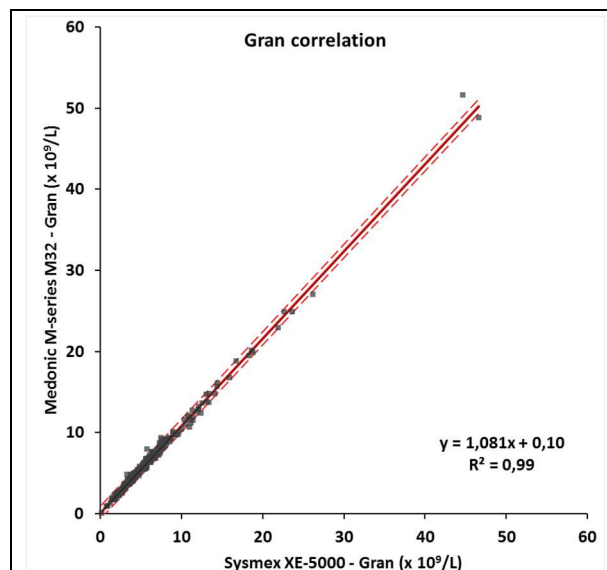


Fig 7. Correlation Gran (non-flagged samples) between test system and reference system.

Summary

| Result/specification | RBC | MCV | PLT | HGB | WBC | Lymph | Gran |
|------------------------------------|-------------|-------------|-------------|-------------|-------------|-----------------------|-----------------------|
| R (correlation coefficient) | 1.00 | 0.98 | 0.99 | 1.00 | 1.00 | 0.99 | 1.00 |
| R, specification | ≥ 0.98 | ≥ 0.98 | ≥ 0.95 | ≥ 0.98 | ≥ 0.97 | ≥ 0.90 | ≥ 0.90 |
| Bias% | 0.56 | 1.04 | -4.03 | 1.69 | 2.75 | -1.80 ¹⁾ | 4.68 ¹⁾ |
| Bias%, specification | ± 2.5 | ± 2.5 | ± 6 | ± 2 | ± 3 | ± 5 ¹⁾ | ± 5 ¹⁾ |

1) Deviation and specification is given as the deviation of the % distribution of non-flagged samples.

Conclusion

The present study shows that the Medonic M-series M32 performance fulfills the specifications.