

Evaluation of the Yumizen H500 FBC analyser and potential clinical improvements for point of care testing for paediatric patients groups

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Introduction

The Automated haematology laboratory at UHW, Cardiff currently processes FBC samples from the Paediatric oncology and associated departments for both outpatients (Rocket Ward) and Inpatients (Rainbow Ward).

The possibility of increasing the availability of PoCT could reduce delays, improve overall turnaround, decrease unnecessary clinician contact time and improve patient prognostic pathways including potential prevention of hospitalisation in some patient groups.

Due to the nature of the patient groups; including newly diagnosed haematological malignancies, those undergoing chemotherapy treatment and some atypical haemoglobinopathies they may present with abnormal FBCs comprising of leucocytopenia, anaemia, thrombocytopenia and atypical blood cells. It is therefore important that the application of PoCT in this setting ensures the quality of the results generated.

The H500 is a recent, compact FBC instrument (HORIBA Medical) with just three reagents and a redesigned touch screen user interface. It offers a collection of clinically key parameters such as a 5-population WBC differential, red cell parameters and platelet count.

Methods

Routine Full Blood Counts (K₂EDTA) from 200 patients were run using the Pentra DX120 analyser before repeated using the Yumizen H500 analyser over 5 days.

The study was conducted between January and March 2018

The data obtained was statistically analysed to assess correlation, uncertainty measurement and performance characteristics. The instrument was also assessed for user accessibility and ease of conformance to the requirements of ISO standards; namely 15189:2012 standard and corresponding aspects of ISO 22870:2016.



Results

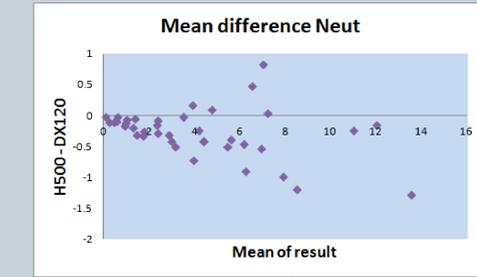
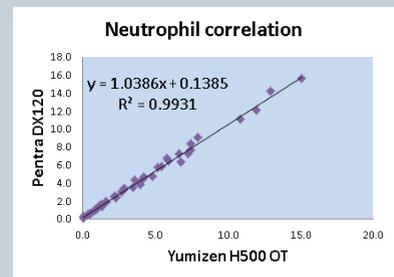
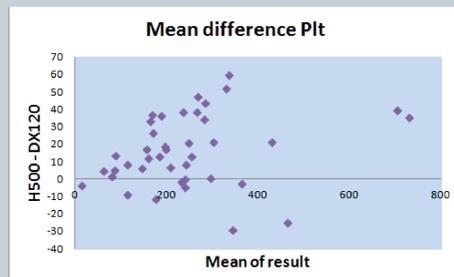
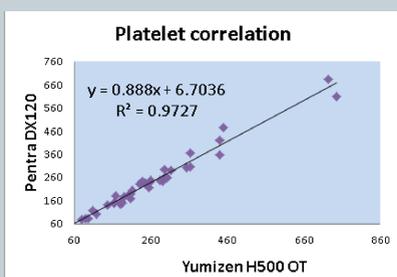
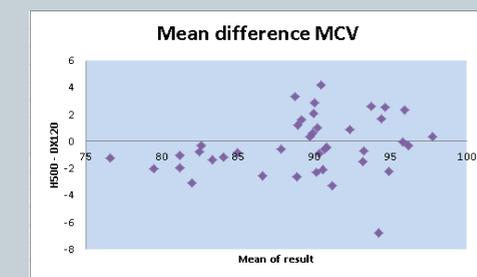
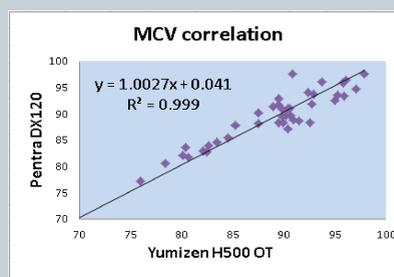
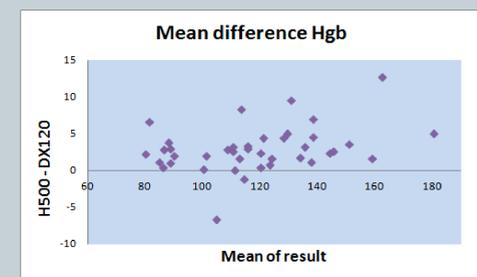
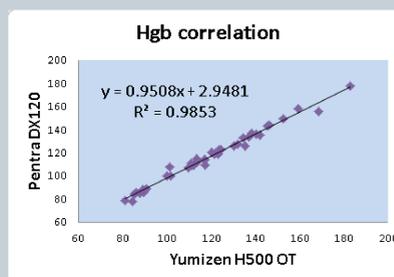
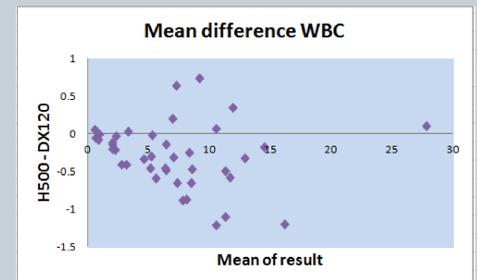
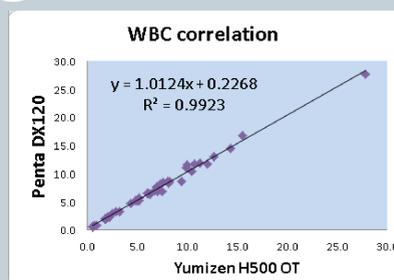
The results gathered include patients with clinically key parameters for paediatrics, White cell count (WBC), Neutrophils (Neuts), Haemoglobin (Hgb), Platelets (Plts) and mean [red] cell volume (MCV).

| Parameter | Range | R ² | CV (%) | UM (+/- where k = 2) | Selected range | UM obtained |
|-----------------------------|------------|----------------|--------|----------------------|---------------------------|-------------|
| WBC (x10 ⁹ /L) | 0.5 - 27.8 | 0.99 | 1.69 | 1.1 | <1.5 x 10 ⁹ /L | 0.3 |
| Hgb (g/L) | 78 - 183 | 0.98 | 0.64 | 7 | <130 g/L | 5 |
| MCV (fl) | 76 - 108 | 0.99 | 0.32 | 3 | N/A | N/A |
| Plts (x10 ⁹ /L) | 14 - 746 | 0.97 | 2.49 | 49 | <150 x10 ⁹ /L | 11 |
| Neuts (x10 ⁹ /L) | 0.1 - 15.6 | 0.99 | 1.84 | 0.9 | <1.5 x10 ⁹ /L | 0.2 |

Both CV and Uncertainty measurement of the performance characteristics were within expected limits and proved to be even tighter at clinically significant levels

The H500 sample cycle was 1 minute 20 seconds and requires only 20 µL of whole blood per cycle. It gave clear pop-up instructions and prompts on the screen on how operate and maintain the instrument. The reagent update is simple, guided and fully traceable. Processing samples is straight forward and includes instructions for adequate mixing which is vital to ensure validity of results for the clinical teams. The H500 provides a preventative function and visual cue where QC are out of consensus and if essential maintenance tasks have not been completed.

This type of analysis ensures that patients' treatment is expedited and directed with a workforce that does not necessarily rely on staff who have technical instrumentation expertise.



Conclusions

Horiba Yumizen H500 has exceptional correlation with the Horiba Pentra DX120, and the performance characteristics and uncertainty measurement exceed the claims of the manufacturer and local acceptable requirements.

The design and functionality of the analyser would mean ease of application to conform to applicable ISO standards (both 15189:2012 and 22870:2016).

In CAVHB the potential for clinical improvement is potentially vast, average TAT (vein to report) for FBC is ~4 hours this could be reduced to < 15 minutes.

This would mean that in certain patient groups (thrombocytopenic and anaemic) they request blood components earlier and be transfused more quickly, this in turn would reduce hospital stays. In neutropenic patients their treatment options could be considered more readily and reduce hospital/clinic exposure time in those that would not be appropriate for chemotherapy.

The H500 would be suitable for use in point of care settings for paediatric care and chemotherapy patients with potential expanded applications in other paediatric or clinical settings.

References & Contacts:

A comparison between the Horiba Yumizen H500 PoC Haematology analyser with a 5 part cell differential and the Horiba Pentra 120; T. Woolley *et al.*; *Point of Care*; 16 (2); June 2017
New methodical solution in haematology analyser (Yumizen 500 – Horiba Medical) and clinical practice; Lena Bielawska *et al.*; *Clinical chemistry and laboratory medicine*; 54 (10); Oct. 2016

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