Frimley Health NHS Foundation Trust

Berkshire and Surrey Pathology Services

Internal Quality Assessment in the absence of an EQA scheme.

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Introduction

Participation in External Quality Assessment (EQA) schemes is mandatory for ISO:15189 accreditation and is the gold standard in assessing and monitoring performance of diagnostic devices. In the absence of an EQA scheme alternative methods must be devised to ensure quality and reduce any risk in using this equipment.

The BSPS Point of Care Testing (POCT) Team use Horiba Yumizen H500s Full Blood Count (FBC) Analysers across nine clinical units.

In 2022 we had challenges with our EQA performance in the UK NEQAS Full Blood Count and Automated Differential Leukocyte Count schemes, specifically with Lymphocytes. Discussions were in progress between the manufacturer and the EQA scheme as to the analysis mode that should be used for these samples. In the interim we needed a way to assure the quality of our investigations.

Methods

A comparison exercise was designed that used the Horiba Difftrol IQC as a substitute for EQA material. This was selected because

- Multiple levels are available from the manufacturer to cover analytical range
- All five sites had IQC material of the same lot number available
- Difficulty in supplying whole blood samples to 5 sites within a reasonable timeframe may have led to result differences due to sample degradation.

Set up of cross site comparison exercise:

An initial comparison between patient results on the POCT Horiba Yumizen and the local Laboratory (Abbott Alinity) was run to ensure that the POCT device and the Laboratory were giving comparable results.

The NEQAS EQA used on these devices was run in patient analysis mode, as per the participant instructions. Horiba advised that using EQC control mode would give more accurate results with fixed cells such as EQA material or IQC. This exercise was initially completed using both modes to establish the best mode for our comparison.

The following parameters were measured: Total White Blood Cells, Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils.

Scoring method:

- Each month a day was selected, and sites were asked to run an IQC sample on the devices three times and return the results.
- A mean, SD and CV for each device (n=3) were calculated
- Results for each parameter (n=42. 14 devices x 3 results) were checked and outliers excluded[1]
- A robust mean, SD and CV (%) for each parameter (n=42) was then calculated
- A Standard Deviation Index (SDI) for each parameter on each device was then calculated and scoring applied as follows
- SDI <1 = Good performance
- SDI between 1 and 2 = Acceptable performance
- SDI >2 = Poor performance that required investigation

References

GraphPad Outlier Calculator. Available from: https://www.graphpad.com/quickcalcs/Grubbs1.cfm [Accessed September 2022]

Acknowledgements

Many thanks to all of the BSPS POCT team for participating in and collecting data for this cross site comparison exercise

Results

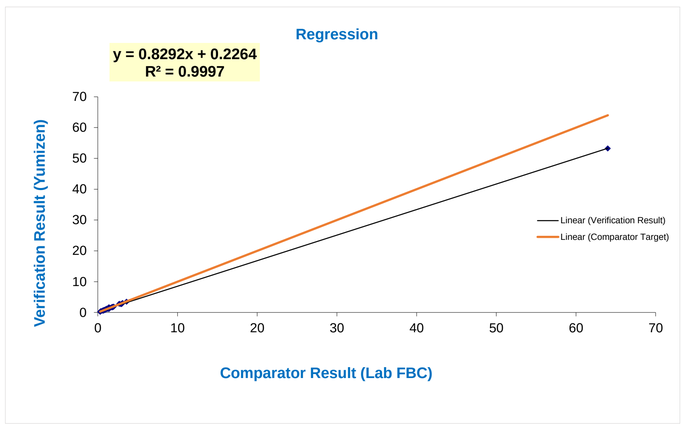

Figure 1. Graph showing regression of patient results run on both the POCT Horiba and the Local laboratory Full blood count (Abbott Alinity).

A comparison between the POCT device (Horiba Yumizen) using patient mode, and the device in use at the local Laboratory (Abbott Alinity) showed that patient results were comparable and that the performance issues we were seeing with EQA were likely related to the running mode and the use of fixed cells.

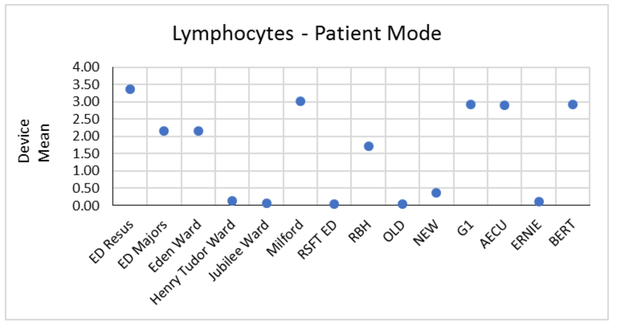

Figure 2. Graphs showing the mean value obtained (n=3) when running the Difftrol IQC on Horiba Yumizens in Patient analysis mode.

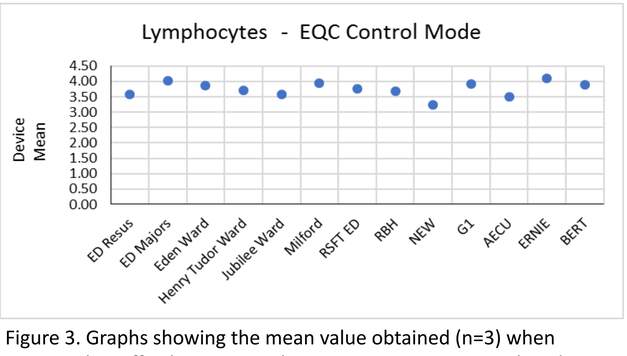

Figure 3. Graphs showing the mean value obtained (n=3) when running the Difftrol IQC on Horiba Yumizens in EQC Control analysis mode.

When running the IQC material in patient mode, a dual population can be seen in the Lymphocytes. When running in EQC control mode, this is not seen and results are more comparable. EQC control mode was selected for this comparison study. NEQAS EQA samples continued to be run in patient mode as per the participant instructions.

With 14 machines as participants, we were able to produce reports on the intra-network comparability of the devices each month for three months. We had 8 instances of poor performing parameters in those three comparisons. We were able to follow these up as we would any EQA poor performance.

Table 1. Example of cross site comparison results for one analyser. Results were presented in this format to POCT coordinators for any follow up.

	Group Mean	Group SD	Analyser Mean	Analyser SD	Analyser CV (%)	SDI
WBC	8.06	0.22	8.11	0.14	1.71	0.21
Neutrophils	4.10	0.19	4.10	0.10	2.52	0.03
Lymphocytes	3.23	0.11	3.28	0.04	1.37	0.44
Monocytes	0.34	0.05	0.31	0.01	4.07	-0.69
Eosinophils	0.28	0.04	0.33	0.02	6.55	1.05
Basophils	0.11	0.07	0.09	0.01	9.07	-0.30

Discussion / Conclusions

For Point of Care, where EQA is not always available, and as intra-laboratory comparison becomes more important for ISO 15189 accreditation, finding ways to run intra-laboratory or in house comparisons is increasingly important.

This exercise demonstrates that an EQA style intra-laboratory comparison can be quick and easy to set up. In this instance we were able to set up an EQA style comparison and monitor our device performance. This gave us assurance that devices were performing well despite seeing poor performance in an EQA scheme.

We were able to perform a results comparison with our local laboratory. However, this intra-device comparison method may also be useful where laboratory comparison is not available, or, as in this case, it is not feasible to compare each individual analyser to a secondary method, which may often be the case for Point of Care devices.