External Quality Assurance for Cells in Body Fluid

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Introduction

Quality assurance for automatic counting and differentiating cells in body fluid is challenging primarily due to the sample stability.

The existing external quality assurance (EQA) scheme for counting cells in body fluid did not fulfil the laboratories' needs and several laboratories were dissatisfied with the quality of the material.

In addition to this some customers wanted to report erythrocytes and the different leukocyte subtypes, which was not possible in other known EQA schemes.

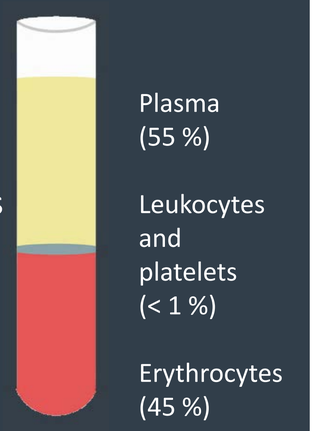
The main goal of our project was to produce a more suitable EQA-material stable for more than 48 hours. Thus making shipment to the laboratories in due time for analysis.
The sub-goal was to investigate the possibility to ship at ambient temperature by regular mail.

Materials

To imitate the matrix of the human cerebrospinal fluid, the EQA-material was made using cells from buffy coats of multiple fresh EDTA samples with moderate elevated leucocyte count, which were added to of mix of DCL reagent (Sysmex), albumin and preservative.

DCL reagent was chosen because most of the laboratories in Denmark use Sysmex instruments.

The EQA-material was distributed to 22 laboratories in Denmark by regular mail and by courier to one in Iceland and one in Germany.

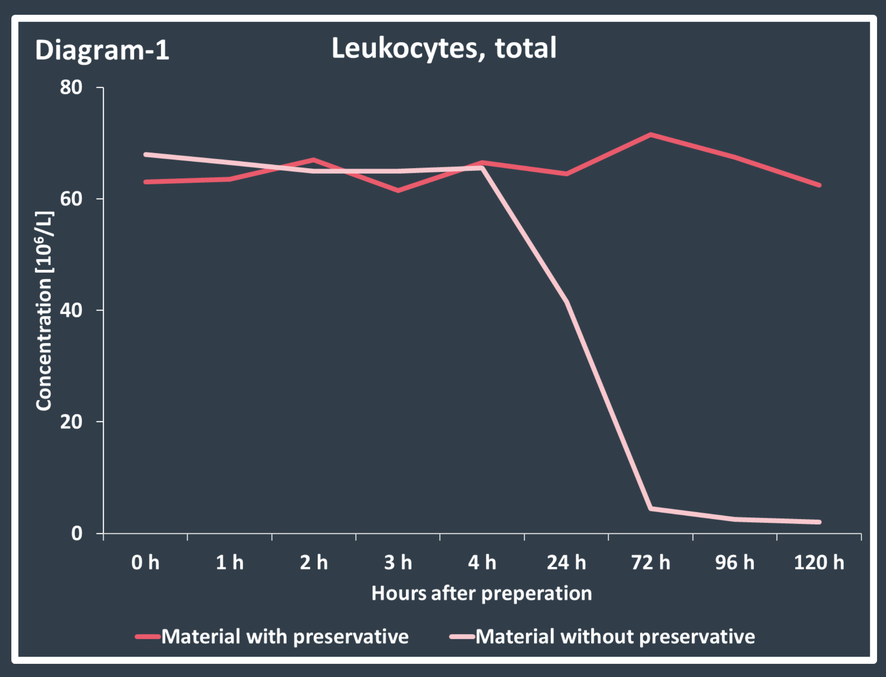


Results I

The results below show the effects of temperature and shipment of the material with preservative.

Our laboratory experiments show increased stability with added preservative - shown in the diagram-1 below.

The material without preservative was stable for less than 24 hours as shown in publications – e.g. [1].



When adding preservative and stored at 4 – 8 °C the material was stable for up to 4 days when the material is not exposed to the effects of shipment.

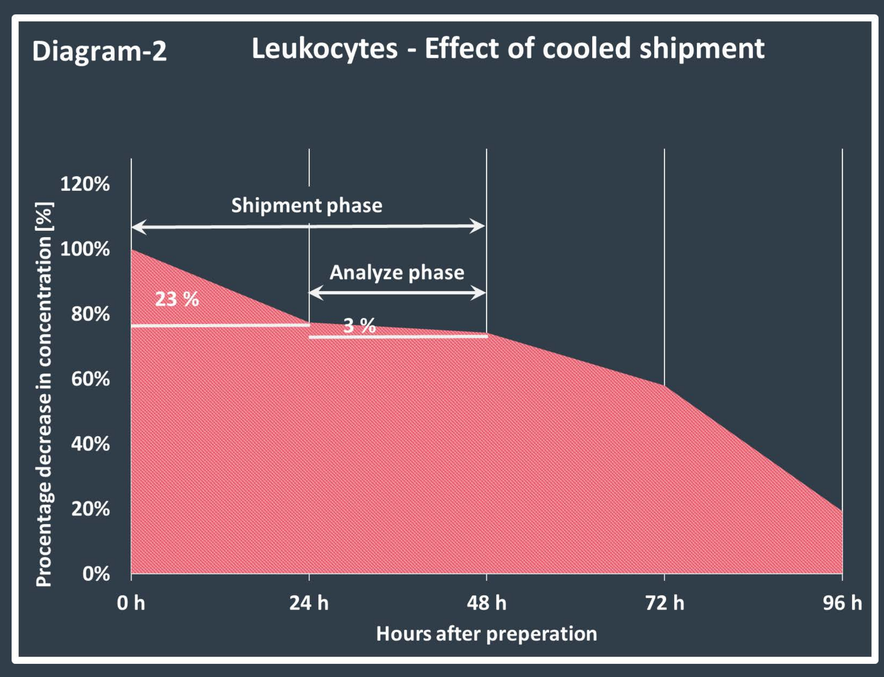
Our experiments showed that Erythrocytes are incredibly stable, whether stored at room temperature or at 4 to 8 °C, therefore we only show data from the experiments with Leukocytes.

Results II

As shown in diagram-2 the Leukocyte's concentration is in a steady state from 24 hours to 48 hours.

In contrast a decrease of 23 % is seen from 0 hours to 24 hours.

The laboratories usually receive the material 24 hours to 48 hours after preparation, which is in the steady state.
When the material were affected by shipment, the Leukocytes were only stable for 48 hours.

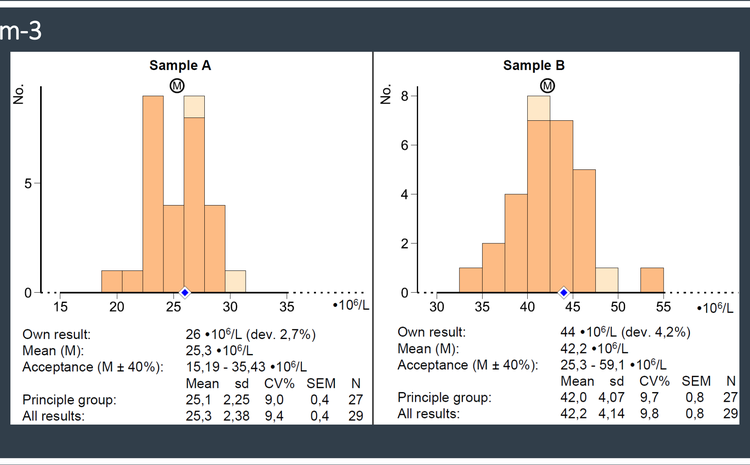


Due to the large fluctuations in the temperature in Denmark (-23 °C to +33 °C) [2] shipment by regular mail at ambient temperature was not possible.
Therefore, we chose to ship the materials cooled by using small cooling elements.

Results III

Results from 29 instruments, showed that stability was obtained for 48 hours when shipped with cooling elements.

Diagram-3



As shown in diagram-3 the results are within the normal distribution with relatively low coefficient of variations (CV%).

Conclusion

We have succeeded making a programme for external quality assurance for cells in body fluid.

Only results from analysis 24 hours to 48 hours after preparation are included in the data analysis for the report and the laboratory comparison. Use of the overall mean value as the "true" target value allows ignoring the natural decay in the shipment phase (0 hours to 24 hours).

When shipped with cooling element the material is proved suitable for measuring on the Sysmex systems. Experiments were also made on the Advia system unfortunately without success.

This EQA program can compare whether laboratories are measuring the cells in body fluid at the same level.

References

1: Mlinarić, A., Vogrinc, Ž., & Drenšek, Z. (2018). Effect of sample processing and time delay on cell count and chemistry tests in cerebrospinal fluid collected from drainage systems. *Biochemia medica*, *28*(3).
2: Danish Meteorological Institute (DMI), www.dmi.dk