PEth EQA Performance: A fifteen Year-Perspective

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CONCLUSIONS

For more than a decade, the Equalis PEth EQA scheme has demonstrated stable performance, with low variation and high fulfilment of the quality goal. The sample material was confirmed to be both homogeneous and stable. These findings indicate that the scheme provides reliable EQA and supports comparability of PEth measurements across laboratories, thereby improving global patient safety.

INTRODUCTION

Phosphatidylethanol (PEth) is an alcohol biomarker belonging to a group of phospholipids in the cell membrane. Its formation requires the presence of ethanol, which ensures high analytical specificity. The PEth form most abundant in blood is Peth 16:0/18:1. This variant correlates strongly with the total PEth amount and is therefore used in routine clinical measurement, as well as in Equalis external quality assessment (EQA) scheme.[1, 2]

PEth was first identified in Sweden, and Equalis quickly established national harmonization in collaboration with the Swedish laboratories. A pilot EQA round in 2010, developed into a formal scheme starting in 2013. Initially, six Swedish laboratories participated. Over time, Equalis PEth program (article nr 295) has grown to include a total of 64 laboratories from 14 countries, of which 17 are based in Sweden.

The purpose of the EQA scheme is to evaluate comparability of results across laboratories and to monitor quality over time. For this scheme, a quality goal was established by Equalis in 2019, requiring that participants results should not deviate more than 20% from the total mean value.

The sample material consists of hemolyzed whole blood containing authentic PEth, thereby being as patient-like as possible. The quality of the sample material is essential for correctly evaluating EQA results. In addition to commutability, homogeneity and stability are key properties that contribute to quality and therefore they have been examined.

AIM

This study aimed to evaluate Equalis PEth EQA scheme, focusing on participants performance over time by assessing annual coefficient of variation (CV%), fulfilment of the quality goal, as well as the quality of the sample material in terms of homogeneity and stability.

METHODS

The PEth EQA scheme comprises four rounds annually, each including three samples, sent to participants in room temperature. In total, approximately 5000 results from 2013–2025 were evaluated. For each year, the CV% of the total mean value was calculated, together with the participating laboratories fulfilment of the quality goal.

The homogeneity and stability of the sample material were examined at both room temperature and refrigerated storage conditions (+2–8 °C) through repeated analysis of identical samples over several days. These investigations were complemented with data from previous rounds by evaluating participants results in relation to the day of analysis.

RESULTS

Across samples between 2013 and 2025, mean CV% showed minor variation, and the proportion of laboratories meeting the quality goal was consistently high (figure 1). The sample material was found to be homogeneous and stable for at least six days at room temperature and at least seven days in refrigerator (+2–8 °C), enabling global participation (figure 2). Analysis of participants results by day of measurement revealed no systematic differences, 95% confidence intervals overlapped across days.

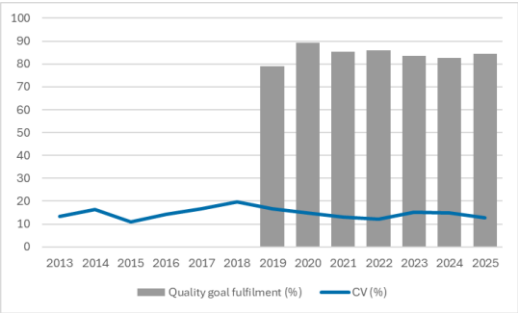

Figure 1. The line shows the mean CV% of participants results per year, while the bars represent annual quality goal fulfilment (%) from 2019 to 2025. CV remained relatively stable over time, and quality goal fulfilment was consistently high during the observed period.

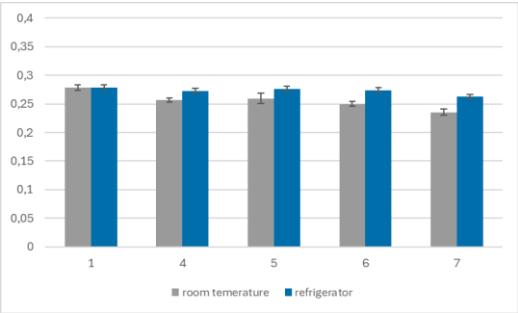

Figure 2. Mean concentration of PEth 16:0/18:1 (µmol/L) in identical samples analyzed on days 1, 4, 5, 6, and 7 after dispatch during a stability test. Bars represent mean ± standard deviation for storage at room temperature (gray) and in refrigerator (blue).

REFERENCES

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