

Letter to the Editor

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Response to: Shift happens: The utility of external quality assessment data in evaluating folate lot changes. doi.org/10.1515/cclm-2025-1569

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To the Editor,

We read with great interest the letter from the UK NEQAS for Haematinics team and appreciate their comprehensive presentation of EQA data supporting the recent observations regarding shifts in serum folate results obtained with the Roche Folate III assay. Their contribution highlights the value of structured post-market surveillance and the importance of collaborative interpretation of analytical performance.

We fully agree that both patient-based statistical tools – such as patient medians – and EQA programs play essential and complementary roles in the early detection of assay drift or Lot-to-Lot variation. Patient median monitoring enables laboratories to detect subtle shifts using real-world clinical samples with high temporal resolution, while EQA data provide an independent, standardised, and externally benchmarked view of analytical performance across platforms, laboratories, and reagent lots. When used together, these approaches strengthen laboratories' ability to identify potential risks earlier, refine clinical interpretation, and ensure continuity in patient care.

The dataset presented by UK NEQAS for Haematinics further illustrates the importance of transparency regarding reagent and calibrator Lot information, as well as the need for improved digital infrastructure to support automated sharing of such metadata. As the authors note, full visibility of Lot-specific effects is essential not only for understanding analytical changes but also for assessing downstream clinical impact. We strongly support efforts toward greater collaboration among manufacturers, laboratories, EQA providers, and clinicians, and agree that harmonised analytical performance specifications for Lot-to-Lot variation would be beneficial for all stakeholders.

We appreciate the authors' dedicated work in disseminating these findings and believe their contribution provides an important complement to patient median data and other internal laboratory monitoring strategies. Together, these tools enhance our collective ability to detect analytical shifts, mitigate clinical risk, and ultimately safeguard patient care.

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