Private Laboratory Feedback On Draft Study Report

Peter Arth

Joint Stakeholder Advisory Committee & Expert Science Panel Meeting

September 6, 2023

Report Comments

- A significant portion of the data analysis focused on mean control production and control CV- a greater emphasis placed on comparability of point estimates (especially EC25) or statistically significant responses to samples among labs would be a better measure of inter lab variability and performance
  - While minimal control performance is critical, control performance is relative to sample performance
  - Were labs that had known culture issues removed prior to making the data comparisons?
- For clarity, all data tables and graphs should have a footnote for laboratories that self reported culture or other significant testing issues that may have impacted the results
  - While this is narrated in the report, data tables must include this qualifier so a reader can clearly link the text to the tables

Report Comments

- Limitations to the study state that none of the testing recommendations could be identified as being more or less impactful than another.
  - It is noted throughout the report that generally labs tended to perform consistently between rounds and to historical standards, absent of noted issues; while one lab is noted to have measurably improved, others appear to have had poorer performance in the second ILS with the recommendations being implemented
  - Only recommendations which are clearly defined in the method as requirements should be made
- Recommendation #1- The plus or minus 1 hour window for termination is not consistent with the test method
  - The method clearly states the 2 hour window in section 13.10.9 is for the analyst to complete all observations while ending the test
    - Intent was to limit the window of time for which an analyst can end a test to prevent reproduction from occurring in later replicates relative to the ones counted first
- Recommendation #7- Please provide rationale for how this recommendation reduces variability
  - All neonates produced within the testing window are counted, therefore this recommendation has no impact on the final neonate counts.

Report Comments

- Recommendations should be enumerated by section in the body of the report and not continuously
  - A more clear delineation should be made for required and recommended testing procedures and a statement in each testing recommendation should clearly state whether it is required in the test method
  - Any non method required recommendations should have data driven rational
- What is the panel's view on the urgency for completion of accreditation and training recommendations?
- Given the 5th limitation of time in the conclusion, and the acknowledgements on the limitations for the panels findings and recommendations, if the window for the study was extended (or a second study was commissioned), do you feel a more robust set of recommendations could be made, implemented, and verified?