How to Limit Patient Harm from Erroneous Results, QC Strategies Based on Risk Management

Questions and Answers

Quality Control

1. **Is possible use QC strategy design at blood bank? For example, in my country once a day QC for serology test.**

2. **How do you monitor qualitative assays?**

   As these questions have the same answer, I am grouping them. Quantitative QC strategy design requires quantitative results. If the test method has no quantitative performance metrics, you cannot do quantitative QC strategy design.
   Basic best practices for QC do still apply:

   - Bracket patient specimens with QC specimens to ensure that patient specimens are not tested in the presence of a persistent error
   - Make sure that the number of patient specimens between QC's is small enough so that you can recover from a malfunction detected by the closing QC in a timely manner (this generally means ending the day with a QC).
   - Run QC before an event that will lose the system state (like calibration) so that a hidden malfunction is not missed.
   - Use a third-party, unbiased QC material.

   Qualitative QC practices (like quantitative QC practices) should ensure that you can identify and correct circumstances where erroneous test results were produced. Most labs will have a problem recovering from a malfunction that is identified in the morning, but happened the day before, after their QC was accepted yesterday when they are only doing QC once a day.

3. **How do you monitor molecular QC's?**

   Start with an unbiased QC material that allows you to control extraction and amplification. For qualitative tests that have no performance indicators available, use the suggestions above for qualitative QC.
   If performance metrics like cycle thresholds are available, they can be used to monitor test method performance. For a stable specimen and a stable test method, the cycle threshold should be stable – significant changes in cycle thresholds (like ±3) may indicate performance issues with the test method.

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The following questions were asked during the presentation. Please see the webinar recording for the responses.

4. How should harm be categorized when there are multiple clinical applications for an analyte?

5. Is there any reference for risk in general by test, since all laboratory measure the same analyte?

6. What should we do when we have no quality specifications available like for Molecular testing or serology?

7. Do I really need to design my QC for each analyte? How can I manage that in my lab.

8. Our lab reports patient results all through the day, how can you manage the risk?

9. When I have a 1-3s error, but my results are still within my TEa limits, can I report my patient results?