UTAK

Troubleshooting Guide: High Analyte Results in Quality Control Material (QCM)

1. Initial Assessment

- **Observation**: One or multiple analytes in the QCM panel are higher than the acceptable range.
    - One Analyte Out of Range: Focus on potential individual issues like instrument calibration or handling errors specific to that analyte.
    - Multiple Analytes Out of Range: Investigate broader issues such as batch quality, reagent problems, systemic testing errors, or issues with reconstitution or preparation. Ensure the QCM was prepared correctly, as errors may cause widespread high analyte concentrations across the panel.
- **Details to Record**:
    - QCM lot number
    - Storage conditions before and after receipt (e.g., Frozen, Lyophilized, Liquid)
    - Testing instrument and method used
    - Date and time of testing

2. Immediate Steps

2.1 Instrument Calibration and Cross-Check

- **Verify Calibration:** Ensure the instrument was calibrated recently and properly with appropriate standards. Review the calibration logs to confirm calibration was completed before testing, as incorrect calibration can lead to inaccurate results.
- **Test on a Different Instrument:** If possible, run the QCM on a different instrument to confirm whether the high result persists. If the result changes significantly, this may indicate an issue with the original testing system.

2.2 Verify Sample Integrity

- **Check for Contamination or Degradation**: Inspect the QCM for any signs of contamination (e.g., cloudiness, particulates) or degradation. Contaminants may artificially inflate analyte concentrations. – **Contact UTAK if any changes or abnormal appearances are noted.**
- **Ensure Proper Mixing**: Verify that the QCM sample was mixed thoroughly, particularly if it was reconstituted from a lyophilized form. Improper mixing can cause uneven distribution of analytes, leading to higher readings.

- **Check Environmental Conditions**: Verify that the lab conditions (e.g., temperature, humidity) during testing were within the appropriate limits. Deviations in environmental factors can affect testing outcomes and result in high readings.

2.3 Review Reconstitution or Preparation Process

- **Reconstitute According to the IFU**: Double-check that the reconstitution or preparation of the QCM was done according to the IFU. Errors such as adding less solvent than recommended could lead to overly concentrated samples and high results.
- **Dilution Error Check**: Verify that dilutions were performed correctly. Under-dilution can result in analytes being over-concentrated, leading to high results.

2.4 Check Equipment, Reagents and Consumables

- **Inspect Equipment**: Ensure that all equipment (pipettes, containers, etc.) used in testing is clean and calibrated. Contaminated equipment or errors in pipetting could contribute to high readings.
- **Review Reagents and Consumables:** Ensure all reagents and consumables are within their expiration date, stored correctly, and free from contamination. Degraded or improperly stored reagents can lead to high results. If there's any uncertainty about their quality, use fresh reagents to avoid potential inaccuracies.

2.5 Use an Alternative Lot or Reference Material – Contact UTAK if troubleshooting samples are needed

- **Test with a Different Lot or Reference Material:** If available, test a different lot of the QCM or a reliable reference material. Compare the results to determine whether the issue is specific to the current QCM batch.
- **Run Parallel Testing:** Run both the suspect QCM and a known, reliable control material in parallel. If the high results are only observed in the suspect QCM, the issue may lie with that specific lot.

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3. Retest the Sample

- **Retest Protocol**: Retest the same QCM sample or, if possible, prepare a fresh aliquot from the same lot to confirm whether the analyte levels are still high. This helps rule out preparation or handling errors that may have caused the elevated results.
    - **If one analyte is out of range**, retest that specific analyte to confirm if the high result is reproducible.
    - **If multiple analytes are out of range**, retest the entire panel to check for systemic issues.

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4. Batch and Lot Review

- **Compare to Other Batches**: If other QCM lots are available, compare the high result to those. If other lots produce acceptable results, this may point to an issue with the specific batch.
- **Check Previous Results:** Review past results from the same QCM lot to identify trends. Consistently high readings over time could suggest a production or stability issue with the batch.

5. Contact UTAK

- **Request Additional Information or Technical Documentation:** If any additional information is needed that could make the QCM usable, contact a UTAK representative
- **Request Third-Party Testing:** If needed, request UTAK to send the QCM batch to a third-party testing facility for independent analysis. This is particularly useful if the third-party results could validate the product's usability or if there is uncertainty whether the QCM is the source of the issue.
- **Request Replacement Material:** If all troubleshooting efforts fail and the issue remains unresolved, contact UTAK to request replacement material for the QCM batch.

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