UTAK

Troubleshooting Guide: Degradation of Analytes in Quality Control Material (QCM)

1. Initial Assessment

- **Observation:** One or multiple analytes in the QCM panel show lower results over time, indicating possible degradation.
    - One analyte is degrading: Focus on potential individual anomalies such as instrument calibration or handling errors specific to that analyte.
    - Multiple analytes degrading: Investigate broader issues such as batch quality, reagent problems, systemic testing errors, or issues with the reconstitution or preparation process. Ensure the QCM was prepared correctly, as errors here can lead to widespread low 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

- **Instrument Calibration Check:** 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 affect results.
- **Test on a Different Instrument:** If possible, test the QCM on a different instrument to confirm if the low result persists. If results vary significantly, this might indicate an instrument-specific issue.

2.2 Verify Sample Integrity

- **Check for Contamination or Degradation:** Inspect the QCM for any signs of contamination or degradation, such as cloudiness, color changes, or particulates. **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. Incomplete mixing or improper reconstitution can lead to low analyte concentrations and erroneous results.
- **Check Environmental Conditions:** Confirm that the laboratory environment (e.g., temperature, humidity) was within acceptable limits during testing. Environmental deviations can affect instrument performance and sample stability.

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2.3 Review Reconstitution or Preparation Process

- **Reconstitute According to the IFU:** Ensure the QCM was reconstituted or prepared according to the IFU. Errors like adding too much solvent can result in diluted samples and low analyte concentrations.
- **Dilution Error Check:** Verify that dilutions were performed correctly. Over-dilution can result in analytes being under-concentrated, leading to low results.

2.4 Check Equipment, Reagents and Consumables

- **Inspect Equipment:** Ensure that all equipment used (pipettes, containers, etc.) is clean and calibrated. Errors in pipetting or contamination in the equipment can result in lower concentrations being measured.
- **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 low results. If there's any uncertainty about their quality, use fresh reagents to avoid inaccurate readings.

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 if 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 low 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 low. This helps rule out preparation or handling errors that may have caused the reduced results.
    - **If one analyte is degrading**, retest that analyte to confirm whether the result is reproducible.
    - **If multiple analytes are degrading**, 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 result to those. If other lots produce acceptable results, this may indicate an issue with the specific batch.
- **Check Previous Results:** Review past data for consistent degradation trends over time, indicating stability issues with the batch.

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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 troubleshooting efforts fail and the issue remains unresolved, contact UTAK to request replacement material for the QCM batch. Additionally, consider requesting a revised part design with single-use aliquots tailored to your testing needs (e.g., 1 mL fill size if 1 mL is used per test run).

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