UTAK

Troubleshooting Guide: Analyte Not Present in Quality Control Material (QCM)

1. Initial Assessment

- **Observation**: Analyte is not detected or is reported as absent in the QCM.
- **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, especially for the missing analyte.
- **Test on a Different Instrument**: If possible, test the QCM on a different instrument to confirm whether the absence of the analyte persists. If the analyte is detected on another instrument, 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. If the analyte has degraded, it may not be detectable. **Contact UTAK if any changes or abnormal appearances are noted.**
- **Ensure Proper Mixing**: Confirm that the QCM was mixed thoroughly before testing, especially if it was reconstituted from a lyophilized form. Incomplete mixing may cause uneven distribution of analytes, leading to some analytes not being detected.
- **Check Environmental Conditions**: Verify that lab conditions (e.g., temperature, humidity) during testing were within acceptable limits. Deviations in environmental conditions may impact the stability and detectability of certain analytes.

2.3 Review Reconstitution or Preparation Process

- **Reconstitute According to the IFU**: Double-check the reconstitution or preparation process to ensure it was done precisely according to the IFU. Failure to properly reconstitute the QCM may cause the analyte to be undetectable.

- **Dilution Error Check**: Verify that any dilutions were performed correctly. Over-dilution may result in analytes being below the detection limit, leading to a "not present" result.

2.4 Check Equipment, Reagents and Consumables

- **Inspect Equipment**: Ensure that all equipment (pipettes, containers, etc.) used in testing is clean and calibrated. Contamination or calibration issues could interfere with analyte detection.
- **Review Reagents and Consumables**: Ensure all reagents and consumables are within their expiration date, stored properly, and free from contamination, as degraded or improperly stored reagents can affect analyte detection. If there is any uncertainty about the quality of the reagents, use fresh ones to avoid potential issues.

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 that contains the missing analyte. 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 (which contains the analyte) in parallel. If the analyte is present in the control but absent in the QCM, the issue may lie with the QCM.

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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 is still absent and to rule out preparation or handling errors.

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4. Batch and Lot Review

- **Compare to Other Batches**: If other QCM lots are available, compare the results to those. If the analyte is present in other lots but missing in the current batch, this may indicate an issue with the specific lot.
- **Check Previous Results**: Review previous data from the same QCM lot to determine if the analyte has been consistently detected before. If it was previously detected, this could indicate a degradation or stability issue 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 all troubleshooting efforts fail and the issue remains unresolved, contact UTAK to request replacement material for the QCM batch.

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