UTAK

Troubleshooting Guide: Interference in Quality Control Material (QCM)

1. Initial Assessment

- **Observation**: QCM results indicate possible interference (e.g., unexpected analyte levels, inconsistent or inaccurate results).
- **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 Assess the Interference Source

- **Review the Test Method**: Ensure the method being used is appropriate for the specific QCM and analytes involved. Some methods may be prone to interference from other substances in the matrix or sample.
- **Identify the Type of Interference**: Determine whether the interference is chemical (caused by reagents or matrix components) or physical (e.g., light scattering, temperature effects). Understanding the nature of the interference can help narrow down the source.
- **Run a Blank Sample**: Test a blank sample (e.g., solvent or buffer without the QCM) to check for background interference in the system. If interference is detected in the blank, this may point to contamination in the reagents or equipment.
- **Check for Matrix Effects**: Review whether the matrix (human or synthetic) used in the QCM is known to interfere with the test method. Matrix components (e.g., lipids, proteins) can interfere with analyte detection or measurement.
- **Dilution Test**: Dilute the sample and retest. In some cases, diluting the sample reduces matrix effects and interference, helping to isolate the problem.
- **Test with a Different Matrix**: If possible, use a QCM with a different matrix (e.g., synthetic instead of human or vice versa) to see if the interference is matrix-specific.
- **Environmental Conditions**: Check whether the lab environment (temperature, humidity, light exposure) was stable and within acceptable limits during testing. Environmental fluctuations can contribute to physical interference (e.g., light scattering or evaporation).

2.2 Check Equipment, Reagents and Consumables

- **Inspect Equipment:** Verify all testing equipment is properly cleaned and free from contamination.
- **Check Maintenance:** Review the instrument's condition and maintenance logs. Issues like drift or misaligned optics can introduce interference.
- **Verify Calibration:** Ensure the instrument was calibrated correctly, as improper calibration can amplify interference.
- **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 cause interference. If there's uncertainty about the quality of the reagents, use fresh ones to avoid potential issues.
- **Test on a Different Instrument:** If possible, test the QCM on another instrument. If the interference disappears, it is likely an instrument-specific issue.

2.3 Inspect Sample for Contamination

- **Visual Inspection**: Inspect the QCM for visible contamination (e.g., particulates, discoloration) that could contribute to interference. **Contact UTAK if any abnormal appearances are noted.**
- **Check for Cross-Contamination**: Ensure that there is no cross-contamination from previously used reagents or improperly cleaned equipment (e.g., pipettes, containers). Contamination from other substances can cause interference in the results.
- **Test a Fresh Aliquot**: Discard the current sample and use a fresh aliquot from the same batch to see if the interference persists. This helps rule out contamination introduced during handling or preparation.
- **Review Handling Procedures**: Verify that all handling steps, including pipetting and sample preparation, were performed correctly to avoid contamination or improper mixing.

2.4 Review Reconstitution or Preparation Process

- **Ensure Proper Reconstitution**: Confirm that the QCM was reconstituted or prepared according to the instructions on the IFU. Incorrect preparation (e.g., using the wrong solvent or concentration) can lead to interference in the assay.
- **Test with Fresh Reagents**: Prepare a fresh sample using new reagents to rule out contamination or interference from degraded or improperly stored reagents.

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 another lot of the QCM with the same matrix or a reliable reference material. If the interference is only observed with the suspect QCM, this may indicate a batch-specific issue.
- **Run Parallel Testing**: Run both the suspect QCM and a control material with the same matrix in parallel. If only the suspect QCM exhibits interference, the issue may be with that specific batch.

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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 interference persists. This helps rule out preparation or handling errors as potential causes of the interference.

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4. 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.