UTAK

Troubleshooting Guide: Random Deviations in Quality Control Material (QCM)

1. Initial Assessment

- **Observation**: QCM results show random deviations, with no clear pattern of high or low values.
- **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 recently calibrated with appropriate standards. Review calibration logs to confirm all necessary calibrations were completed before testing, as incorrect calibration can cause inaccurate results and contribute to random deviations.
- **Instrument Maintenance**: Confirm the instrument is properly maintained and functioning. Look for any signs of wear or parts nearing the end of their life, which can cause random errors.
- **Test on a Different Instrument**: If possible, test the QCM on a different instrument to see if the random deviations persist. If the results are stable on another instrument, the problem may be with the initial instrument.

2.2 Verify Sample Integrity

- **Check for Contamination or Degradation**: Inspect the QCM for any signs of contamination (e.g., particulates, cloudiness). If degradation has occurred, it could lead to inconsistent results. **Contact UTAK if any abnormalities are noted.**
- **Ensure Proper Mixing**: Confirm that the QCM was mixed thoroughly before each test. Random deviations may result from incomplete mixing, especially if the sample was reconstituted or thawed from a frozen state.
- **Check Environmental Conditions**: Verify that the testing environment (e.g., temperature, humidity) was stable during the testing process. Fluctuations in environmental conditions can affect instruments and cause random errors.

2.3 Review Reconstitution or Preparation Process

- **Reconstitute According to Instructions provided on the IFU**: Double-check the reconstitution or preparation process. Minor errors in reconstitution (e.g., variations in solvent volume) may lead to subtle, random fluctuations in concentration.
- **Avoiding Handling Variability**: Ensure consistency in sample handling, including pipetting and dilution. Inconsistent techniques during preparation can contribute to random deviations.

2.4 Check Equipment and Reagents

- **Inspect Equipment**: Ensure that all equipment (pipettes, containers, etc.) is clean and calibrated. Even minor wear in pipettes or variability in containers can introduce random errors into results.
- **Test with Fresh Reagents**: Ensure all reagents and consumables are within their expiration date, stored correctly, and free from contamination. Degraded or improperly stored reagents can lead to random deviations. If there's any uncertainty about reagent quality, use fresh ones to avoid inaccurate or inconsistent 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**: Test another lot of QCM or a known reference material. If the deviations only occur with the original lot, this could indicate an issue specific to that batch.
- **Run Parallel Testing**: Run both the suspect QCM and a reliable control in parallel. If random deviations are only present in the QCM, this might indicate a problem with that specific lot.

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3. Retest the Sample

- **Retest Protocol**: Retest the same QCM sample or prepare a fresh sample from the same lot. Monitor for any continuing random deviations to see if the issue is reproducible.
- **Sample Replication**: Prepare and test multiple samples from the same QCM lot to see if the random deviations can be isolated to certain aliquots or are consistent across the entire batch.

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4. Batch and Lot Review

- **Compare to Other Batches**: Compare results to other QCM lots in stock. If random deviations only appear in the current lot, the issue may be batch-specific.
- **Check Historical Results**: Review past results from the same lot to determine if these deviations have occurred previously. Random errors occurring over time could indicate a stability issue with the QCM 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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