UTAK

Troubleshooting Guide: Abnormal Appearances in Quality Control Material (QCM)

1. Initial Assessment

- **Observation**: The QCM shows abnormal appearances, such as cloudiness, discoloration, or particulates.
- **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 Visual Inspection and Documentation

- **Check for Abnormalities:** Inspect for cloudiness, particulates, or discoloration.
- **Document:** Take notes and photos of the abnormal appearance.
- **Compare:** Compare with a fresh or known sample.

2.2 Inspect the Sample for Handling Errors

- **Check Handling Procedures**: Ensure the QCM was handled according to the instructions on the IFU or CoA. Improper handling or contamination (e.g., dirty pipettes, containers, contaminated solvents) can lead to abnormal appearances.
- **Review Equipment Used**: Ensure that all equipment used (pipettes, containers, etc.) was clean and free from contaminants. Dirty or improperly cleaned equipment may introduce physical changes in the QCM's appearance.
- **Use a Fresh Aliquot**: Discard the suspect sample and use a fresh aliquot from the same QCM batch to see if the abnormal appearance persists.

2.3 Sample Storage Conditions

- **Confirm Proper Storage**: Review how the QCM was stored both before and after receipt to ensure it was kept under the proper conditions (e.g., temperature, light exposure, humidity). Incorrect storage can lead to physical changes in the material.
- **Verify Expiry Date**: Ensure the QCM has not exceeded its expiration date. Degradation over time can lead to changes in appearance.

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3. Retest with a Fresh Sample

- **Reconstitute or Prepare a New Sample**: If applicable, reconstitute or prepare a new sample from a sealed container following the IFU. Incorrect reconstitution (e.g., using the wrong solvent or volume) may cause abnormalities.
- **Use Fresh Reagents**: If the QCM was reconstituted or diluted, prepare a new sample using fresh reagents or solvents to rule out contamination from those sources.
- **Monitor for Consistency**: Retest the fresh sample and compare the results with those from the abnormal sample. If the abnormal appearance recurs, it could indicate a batch-related issue.

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4. Batch and Lot Review

- **Check Other Aliquots from the Same Batch**: Test additional aliquots from the same QCM lot to see if the abnormal appearance is consistent across the batch. If all aliquots have similar issues, this may point to a batch-wide problem.
- **Review Historical Data**: Check if similar issues have been reported with the same QCM lot or with previous batches. Recurring issues with the same lot may indicate a stability, storage or preparation issue.

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5. Contact UTAK

5.1 Report the Issue

- **Provide information:** Provide all relevant details, including the QCM lot number, description of the abnormal appearance, and storage/handling information. Attach any photos of the abnormal appearance for reference.

5.2 Request Additional Steps

- **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.