

Troubleshooting Guide: Product Arriving Thawed, with Compromised Storage Conditions, or Damaged in Transit

1. Initial Assessment

- **Observation:** The product arrived thawed, with compromised storage conditions, or damaged (e.g., cracked packaging, leaks, physical damage to containers).
 - **Details to Record:**
 - Product lot number
 - Storage conditions upon arrival (e.g., thawed, liquid, or improper temperature)
 - Condition of the packaging and any visible damage
 - Date and time of receipt
 - Any physical changes (e.g., condensation, leaks, unusual appearance, broken vials)
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2. Immediate Actions Upon Discovery

2.1 Document the Condition

- **Visual Inspection:** Check the product and packaging for any physical damage (e.g., broken containers, cracks, leaks, discoloration). Photograph any damage for documentation and sharing with UTAK.
- **Record Receipt Time and Temperature:** Immediately note the time and temperature upon arrival to track any potential exposure to improper conditions.
- **Inspect for Shipping Damage:** Look for signs of damage to both outer and inner packaging, such as crushed boxes or leaks, which may indicate environmental exposure during shipping.

2.2 Review Storage and Shipping Requirements

- **Review Products Storage Recommendations:** Confirm the storage requirements (e.g., Frozen at -20°C, Deep Frozen at -60°C, Refrigerated at 2-8°C). Compare the product's current condition to these recommendations to determine the extent of the deviation.

2.3 Return Product to Proper Storage Conditions

- Depending on the product's storage requirements, return the product to the proper storage (e.g., freezer, deep freezer, or refrigerator) to stabilize it before testing.
 - Follow the technical documentations (IFU or COA) guidance on whether the product can be re-frozen or should remain refrigerated if it has been thawed or exposed to improper conditions.
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3. Sample Testing Procedure

- **Test the Sample for Performance:** Follow standard testing procedures, ensuring that all analytes are tested according to the expected results.
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4. Evaluate Test Results

- **Compare to Expected Ranges:** Cross-check the results with the expected range provided by the Certificate of Analysis (CoA) or IFU. Watch for any results outside the expected range, which may indicate a loss of product integrity.
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5. Contact UTAK for Out-of-Range Results or Additional Documentation

- **Alert UTAK for Out-of-Range Results:** If test values fall outside the expected range, contact UTAK immediately. Please provide:
 - Product lot number
 - Details of the compromised storage condition or damage during transit (e.g., thawed, damaged containers, improper temperature)
 - Test results and how they compare to the expected target values
 - Photos and documentation of the product's condition upon arrival, including damage or temperature deviations
 - **Request replacement, technical documentation, or further testing**
- **Request Additional Documentation:** If results are in range but further documentation is needed for regulatory purposes, contact UTAK with:
 - Product lot number
 - Details of the compromised storage condition or damage during transit (e.g., thawed, damaged containers, improper temperature)
 - Test results and how they compare to the expected target values
 - Photos and documentation of the product's condition upon arrival, including damage or temperature deviations
 - What documentation is required