



Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m System
List Numbers: 08N53-002
Not Serial Specific
Unique Device Identifiers (UDIs): 00884999048034

March 19, 2024

Dear Abbott Customer,

This letter contains important information regarding your Alinity m System List Number 08N53-002. Please review this information carefully.

Background

Abbott has identified an issue concerning the use of certain third-party Universal Transport Medium (UTM) tubes on the Alinity m System. This issue has been observed with Copan® UTM-RT 3 mL Without Beads Transport & Preservation Medium for Viral Molecular Diagnostics Testing, Part Number (PN) 3Co47N. However, it is possible that other third party manufactured tubes could experience the same issue.

The Alinity m System camera detects whether tubes are “capped.” If the camera detects a cap and the retention bar is not present on the sample rack, the system will generate the message “Error – 6013: Has cap, no retention bar.” Any color other than black or white within the Keep-Out Zone (See Appendix A) on the tube label can cause the camera to falsely detect a cap, resulting in generation of the error code. Because this is an incorrectly generated error code, the corrective action associated with Message Code: 6013 of “Remove sample rack and add the retention bar with the rack” will not remediate the issue. The correct method to remediate this error code is outlined in the Necessary Actions section of this letter.

Potential Impact

There is no impact to patient results. However, this issue may cause a potential delay in results. If encountered, Message Code 6013 will invalidate the sample rack and will not allow further processing of samples until it has been resolved. Assays which currently allow use of Universal Transport Medium tubes are Alinity m SARS-CoV-2, Alinity m Resp-4-Plex, and Alinity m HSV 1 & 2 / VZV.

Necessary Actions

Please complete and return the Customer Reply Form.

If error code 6013 occurs and uncapped sample tubes are present on the sample rack, one of the following options can be used to resolve the error:

1. Aliquot the sample into another tube permitted by the assay package insert and ensure the sample tube label requirements in Appendix A are met.

OR

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Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

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2. Cover colored portion of tube label that is present in the Keep-Out Zone, depicted in Appendix A, with white opaque material (e.g. white sticker) where the barcode is located. Avoid covering any needed sample information when applying an additional sticker to the sample tube.



Uncovered



Covered with white
opaque material

OR

3. Reach out to manufacturer of the tube that is triggering the error to discuss alternative tube types that meet the specifications documented within the Abbott assay specific package insert and do not have color within the required color free space (Keep-Out Zone) as depicted in Necessary Action #2 and provided image in Appendix A.

If you have further distributed or transferred the Alinity m System, List Number 08N53-002, please inform them of this Urgent Field Safety Notice, provide a copy of this letter to them, and have them take the necessary actions listed here.

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,



Julie Strom
Global Director of Compliance
Molecular Diagnostics at Abbott

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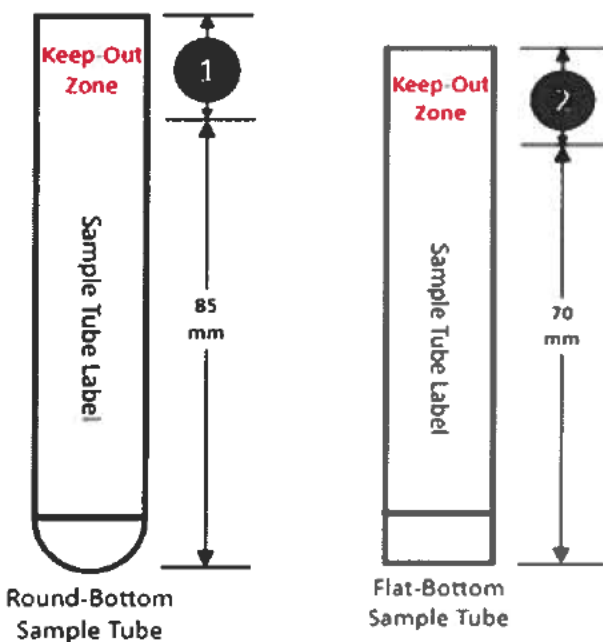
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Appendix A

Aliquot the sample from the sample tube that is experiencing the error to a different sample tube, as permitted by the assay package insert, and ensure the following sample tube label requirements are met:



Legend:

1. This area defined as ① is the keep-out zone for the round-bottom sample tube. The keep-out zone is the area where the sample tube label cannot contain colors other than white and black, above a maximum of 85 mm from the bottom of the tube.
2. The area defined as ② is the keep-out zone for the flat-bottom sample tube. The keep-out zone is the area where the sample tube label cannot contain colors other than white and black, above a maximum of 70 mm from the bottom of the tube.