



**MARCH 2022 UPDATE TO
Urgent Field Safety Notice
Molecular Diagnostics at Abbott**

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

Products: Alinity m SARS-CoV-2 AMP Kit, Alinity m Resp-4-Plex AMP Kit,
Alinity m SARS-CoV-2 Application Specification File, and
Alinity m Resp-4-Plex Application Specification File
List Numbers: 09N78-090, 09N78-091, 09N79-090, 09N78-01E, and 09N79-01D
Not Lot Specific

Unique Device Identifiers (UDIs): 00884999049215, 00884999049963,
00884999049338, (01)00884999050228(240)09N78-01E(8012)5.00, and
(01)00884999050235(240)09N79-01D(8012)4.00

March 30, 2022

Dear Abbott Customer,

This is a follow-up to Urgent Field Safety Notice FA-AM-SEP2021-260 regarding potential false positive results when using Alinity m SARS-CoV-2 AMP Kit, List Numbers 09N78-090 or 09N78-091 and/or Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090. Please review this information carefully.

This follow-up is to inform you of updates to the Application Specification files for the Alinity m SARS-CoV-2 and Resp-4-Plex assays to further reduce the potential for carryover.

Background

Abbott informed you via Urgent Field Safety Notice FA-AM-SEP2021-260 of reports of Alinity m SARS-CoV-2 false positive results. Because the assay parameters and the presence of the SARS-CoV-2 analyte are similar, Alinity m Resp-4-Plex customers were included in this communication.

Updates in the Alinity m SARS-CoV-2 and Resp-4-Plex Application Specification files adjusted the mixing parameters to directly aid in the control of any potential carryover events. Since the introduction of the updated Application Specification files in September 2021, a decrease in the false positive rate for Alinity m SARS-CoV-2 was observed, from a historical rate of 0.0164% to a rate of 0.0016%. A decrease in the false positive rate for Alinity m Resp-4-Plex was also observed, from a historical rate of 0.0078% to a rate of 0.0016%.

Necessary Actions

Please complete and return the Customer Reply Form.

Abbott has updated the existing Application Specification files for Alinity m SARS-CoV-2 and Resp-4-Plex to further reduce the potential for carryover.

A Molecular Diagnostics Abbott Representative will be contacting you once the updated Application Specification files are available.

If you have any questions regarding this communication, please contact your local Molecular Diagnostics Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,



Ray Bastian
Senior Director Quality Assurance
Molecular Diagnostics at Abbott