



**Urgent Field Safety Notice
Molecular Diagnostics at Abbott**

Products: Alinity m SARS-CoV-2 AMP Kit Emergency Use Authorization,
Alinity m SARS-CoV-2 AMP Kit,

Alinity m Resp-4-Plex Amp Kit Emergency Use Authorization,
Alinity m Resp-4-Plex Amp Kit

List Numbers: 09N78-095, 09N78-090, 09N78-091,
09N79-096, and 09N79-090

Not Lot Specific

Unique Device Identifiers (UDIs): See Appendix A

September 2, 2021

Dear Abbott Customer,

This letter contains important information regarding potential false positive results when using Alinity m SARS-CoV-2 AMP Kit Emergency Use Authorization (EUA), List Number 09N78-095, Alinity m SARS-CoV-2 AMP Kit, List Numbers 09N78-090 or 09N78-091, Alinity m Resp-4-Plex AMP Kit Emergency Use Authorization (EUA), List Number 09N79-096, or Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090. Please review this information carefully.

Background

Abbott Molecular Inc. has received reports of Alinity m SARS-CoV-2 EUA false positive results. Preliminary investigation has identified that potential carryover in the assay tray may contribute to false positive results. An increase of false positive rate was observed in July 2021 going from a historical rate of 0.002% (235 reported false positives/12,022,419 total tests performed) to a rate of 0.015% (552 reported false positives/3,590,490 total tests performed). However, the rate in the field may be higher than this. An evaluation of the current mixing protocol used during preparation of the PCR reaction mixture determined the current mixing parameters may result in potential overflow that could carry over into neighboring wells in the assay reagent tray. Because the assay parameters and the presence of the SARS-CoV-2 analyte are similar, Alinity m Resp-4-Plex customers are being included in this communication.

Potential Impact

Carryover events may cause true negative samples that are positioned near positive samples in the assay tray to produce false positive SARS-CoV-2 results.

Updates in the SARS-CoV-2 Application Specification file version 5 adjusted the mixing parameters to directly aid in the control of any potential carryover events.

Similar updates will be made to the Alinity m Resp-4-Plex Application Specification file.

Necessary Actions

Please complete and return the customer reply form.

All positives are to be considered presumptive until the Alinity m SARS-CoV-2 Application Specification file version 5 or the updated Alinity m Resp-4-Plex Application Specification file is implemented at your site. Consider retesting SARS-CoV-2 positive patient specimens generated in the last two weeks on another platform until an updated file is implemented.



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A Molecular Diagnostics Abbott Representative will be contacting you regarding the availability and installation of the updated application specification file.

This recall is to be carried out at the user/customer level. If this product has been further distributed by your facility, please notify any additional impacted customers.

Please review this information with your Medical Director or physicians as appropriate and retain this communication for future reference. Please review positive patient results generated with the Alinity m SARS-CoV-2 and determine if retesting is required taking patient medical history and previous treatment into consideration.

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,

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Unique Device Identifiers (UDIs): See Appendix A

Appendix A

| Unique Device Identifiers (UDIs) | | | |
|---|------------|------------|----------------|
| (01)00884999049222 | (10)511810 | (17)210918 | (240)09N78-095 |
| (01)00884999049222 | (10)512026 | (17)210921 | (240)09N78-095 |
| (01)00884999049222 | (10)512900 | (17)211014 | (240)09N78-095 |
| (01)00884999049222 | (10)513146 | (17)211014 | (240)09N78-095 |
| (01)00884999049222 | (10)513583 | (17)211118 | (240)09N78-095 |
| (01)00884999049222 | (10)513959 | (17)211123 | (240)09N78-095 |
| (01)00884999049222 | (10)514176 | (17)211123 | (240)09N78-095 |
| (01)00884999049222 | (10)514216 | (17)211201 | (240)09N78-095 |
| (01)00884999049222 | (10)514819 | (17)211217 | (240)09N78-095 |
| (01)00884999049222 | (10)515052 | (17)220105 | (240)09N78-095 |
| (01)00884999049222 | (10)515653 | (17)220128 | (240)09N78-095 |
| (01)00884999049222 | (10)515949 | (17)220205 | (240)09N78-095 |
| (01)00884999049222 | (10)516085 | (17)220211 | (240)09N78-095 |
| (01)00884999049222 | (10)516611 | (17)220222 | (240)09N78-095 |
| (01)00884999049222 | (10)517139 | (17)220301 | (240)09N78-095 |
| (01)00884999049222 | (10)517355 | (17)220308 | (240)09N78-095 |
| (01)00884999049222 | (10)517999 | (17)220319 | (240)09N78-095 |
| (01)00884999049222 | (10)518266 | (17)220322 | (240)09N78-095 |
| (01)00884999049222 | (10)518435 | (17)220322 | (240)09N78-095 |
| (01)00884999049222 | (10)518670 | (17)220401 | (240)09N78-095 |
| (01)00884999049222 | (10)519124 | (17)220503 | (240)09N78-095 |
| (01)00884999049222 | (10)519583 | (17)220511 | (240)09N78-095 |
| (01)00884999049222 | (10)519785 | (17)220518 | (240)09N78-095 |
| (01)00884999049222 | (10)519968 | (17)220525 | (240)09N78-095 |
| (01)00884999049222 | (10)520216 | (17)220608 | (240)09N78-095 |
| (01)00884999049222 | (10)520699 | (17)220630 | (240)09N78-095 |
| (01)00884999049222 | (10)521106 | (17)220713 | (240)09N78-095 |
| (01)00884999049222 | (10)521654 | (17)220723 | (240)09N78-095 |
| (01)00884999049222 | (10)521842 | (17)220727 | (240)09N78-095 |
| (01)00884999049222 | (10)521857 | (17)220727 | (240)09N78-095 |
| (01)00884999049215 | (10)511468 | (17)210915 | (240)09N78-090 |
| (01)00884999049215 | (10)511504 | (17)210915 | (240)09N78-090 |
| (01)00884999049215 | (10)511505 | (17)210915 | (240)09N78-090 |
| (01)00884999049215 | (10)512025 | (17)210921 | (240)09N78-090 |
| (01)00884999049215 | (10)512416 | (17)210918 | (240)09N78-090 |
| (01)00884999049215 | (10)512417 | (17)210918 | (240)09N78-090 |
| (01)00884999049215 | (10)512705 | (17)210921 | (240)09N78-090 |
| (01)00884999049215 | (10)512712 | (17)211007 | (240)09N78-090 |



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|---|------------|------------|----------------|
| (01)00884999049215 | (10)512898 | (17)211007 | (240)09N78-090 |
| (01)00884999049215 | (10)513147 | (17)211014 | (240)09N78-090 |
| (01)00884999049215 | (10)513629 | (17)211118 | (240)09N78-090 |
| (01)00884999049215 | (10)514359 | (17)211201 | (240)09N78-090 |
| (01)00884999049215 | (10)514762 | (17)211217 | (240)09N78-090 |
| (01)00884999049215 | (10)515053 | (17)220105 | (240)09N78-090 |
| (01)00884999049215 | (10)515415 | (17)220115 | (240)09N78-090 |
| (01)00884999049215 | (10)515416 | (17)220115 | (240)09N78-090 |
| (01)00884999049215 | (10)515948 | (17)220128 | (240)09N78-090 |
| (01)00884999049215 | (10)516084 | (17)220205 | (240)09N78-090 |
| (01)00884999049215 | (10)516430 | (17)220217 | (240)09N78-090 |
| (01)00884999049215 | (10)516431 | (17)220218 | (240)09N78-090 |
| (01)00884999049215 | (10)516612 | (17)220225 | (240)09N78-090 |
| (01)00884999049215 | (10)516636 | (17)220301 | (240)09N78-090 |
| (01)00884999049215 | (10)516910 | (17)220304 | (240)09N78-090 |
| (01)00884999049215 | (10)516911 | (17)220211 | (240)09N78-090 |
| (01)00884999049215 | (10)517009 | (17)220218 | (240)09N78-090 |
| (01)00884999049215 | (10)517138 | (17)220225 | (240)09N78-090 |
| (01)00884999049215 | (10)517354 | (17)220308 | (240)09N78-090 |
| (01)00884999049215 | (10)517876 | (17)220319 | (240)09N78-090 |
| (01)00884999049215 | (10)517998 | (17)220319 | (240)09N78-090 |
| (01)00884999049215 | (10)518668 | (17)220401 | (240)09N78-090 |
| (01)00884999049215 | (10)518669 | (17)220420 | (240)09N78-090 |
| (01)00884999049215 | (10)518878 | (17)220420 | (240)09N78-090 |
| (01)00884999049215 | (10)519022 | (17)220430 | (240)09N78-090 |
| (01)00884999049215 | (10)519122 | (17)220430 | (240)09N78-090 |
| (01)00884999049215 | (10)519372 | (17)220503 | (240)09N78-090 |
| (01)00884999049215 | (10)519373 | (17)220511 | (240)09N78-090 |
| (01)00884999049215 | (10)519784 | (17)220518 | (240)09N78-090 |
| (01)00884999049215 | (10)519967 | (17)220525 | (240)09N78-090 |
| (01)00884999049215 | (10)520221 | (17)220608 | (240)09N78-090 |
| (01)00884999049215 | (10)520387 | (17)220615 | (240)09N78-090 |
| (01)00884999049215 | (10)520388 | (17)220615 | (240)09N78-090 |
| (01)00884999049215 | (10)520563 | (17)220618 | (240)09N78-090 |
| (01)00884999049963 | (10)520596 | (17)220618 | (240)09N78-091 |
| (01)00884999049390 | (10)514074 | (17)211106 | (240)09N79-096 |
| (01)00884999049390 | (10)519243 | (17)220510 | (240)09N79-096 |
| (01)00884999049338 | (10)513424 | (17)211013 | (240)09N79-090 |
| (01)00884999049338 | (10)513771 | (17)211013 | (240)09N79-090 |
| (01)00884999049338 | (10)513861 | (17)211106 | (240)09N79-090 |



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|---|-------------------|-------------------|-----------------------|
| (01)00884999049338 | (10)514503 | (17)211119 | (240)09N79-090 |
| (01)00884999049338 | (10)515652 | (17)211202 | (240)09N79-090 |
| (01)00884999049338 | (10)516411 | (17)211106 | (240)09N79-090 |
| (01)00884999049338 | (10)517877 | (17)211202 | (240)09N79-090 |
| (01)00884999049338 | (10)518436 | (17)211210 | (240)09N79-090 |
| (01)00884999049338 | (10)518877 | (17)211210 | (240)09N79-090 |
| (01)00884999049338 | (10)519091 | (17)211106 | (240)09N79-090 |
| (01)00884999049338 | (10)519582 | (17)220510 | (240)09N79-090 |
| (01)00884999049338 | (10)519969 | (17)220510 | (240)09N79-090 |
| (01)00884999049338 | (10)520356 | (17)220510 | (240)09N79-090 |
| <u>(01)00884999049338</u> | <u>(10)520695</u> | <u>(17)220708</u> | <u>(240)09N79-090</u> |