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

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Products: Alinity m Resp-4-Plex AMP Kit CE &
Alinity m Resp-4-Plex AMP Kit
List Numbers: 09N79-090 & 09N79-096
Lot Numbers: See Appendix A
Unique Device Identifiers (UDIs): See Appendix A

November 22, 2022

Dear Abbott Customer,

This letter contains important information regarding Alinity m Resp-4-Plex Amplification (AMP) Kit (CE), List Number 09N79-090, and Alinity m Resp-4-Plex AMP Kit (US), List Number 09N79-096, utilized with the Alinity m System. Please review this information carefully.

Background:
Abbott has received reports of an increase in reactive negative controls and false positive results, with certain lots of Alinity m Resp-4-Plex AMP Kit (CE), List Number 09N79-090 and of the Alinity m Resp-4-Plex AMP Kit (US), List Number 09N79-096 on the Alinity m System. Specifically, an increase in the amount of reactive negative controls and false positive results have been reported for the influenza B virus (Flu B) and Respiratory Syncytial Virus (RSV) targets. Based on internal evaluation, false positive results and reactive negative controls manifest as a weak signal with a late cycle number for these targets. Internal evaluation has not shown impact to influenza A virus (Flu A) and SARS targets.

Potential Impact:
There is a potential for false positive results for Flu B and RSV while using the list numbers and lot numbers referenced above associated with the manufacture of these lots. There is also a potential for delayed results when using these lots as reactive negative controls invalidate the sample run. Additional quality control mitigations have been put in place to prevent reoccurrence. All subsequent lots of Alinity m Resp-4-Plex AMP kits are not impacted.

Necessary Actions:

- Discard inventory of any lots listed in Appendix A below. Contact Abbott Customer Support for credit of any unused kit(s).
- If you have forwarded any kits of these lots to other laboratories, please inform them of this Urgent Field Safety Notice, and provide a copy of this letter.
- Return the associated Customer Reply form.

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,

Ray Bastian 11-22-22

Ray Bastian
Divisional Vice President, Quality Assurance
Molecular Diagnostics at Abbott

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Appendix A

09N79-090 Impacted Lots		
525460 (exp Dec 09, 2022)	526393 (exp Dec 21, 2022)	531612 (exp Jun 28, 2023)
525766 (exp Dec 21, 2022)	526483 (exp Jan 15, 2023)	527142 (exp Jan 21, 2023)
527403 (exp Jan 29, 2023	527602 (exp Feb 08, 2023)	381177 (exp Aug 24, 2023)

09N79-096 Impacted Lots
381465 (exp Aug 24, 2023)
524433 (exp Jan 15, 2023)
526710 (exp Jan 21, 2023)
527845 (exp Feb 08, 2023)

Unique Device Identifiers (UDIs)	
(01)00884999049338(10)525460(17)221209(240)09N79-090	(01)00884999049338(10)527403(17)230129(240)09N79-090
(01)00884999049338(10)525766(17)221221(240)09N79-090	(01)00884999049338(10)527602(17)230208(240)09N79-090
(01)00884999049338(10)526393(17)221221(240)09N79-090	(01)00884999049338(10)531612(17)230628(240)09N79-090
(01)00884999049338(10)526483(17)230115(240)09N79-090	(01)00884999049390(10)524433(17)230115(240)09N79-096
(01)00884999049338(10)527142(17)230121(240)09N79-090	(01)00884999049390(10)526710(17)230121(240)09N79-096
(01)00884999049390(10)381465(17)230824(240)09N79-096	(01)00884999049390(10)527845(17)230208(240)09N79-096
(01)00884999049338(10)381177(17)220828(240)09N79-090	