Molecular Diagnostics at Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m Resp-4-Plex AMP Kit
List Number: 09N79-090
Lot Numbers: 409383, 410627, 411921
Unique Device Identifiers (UDIs): See table below

April24, 2025

Dear Abbott Customer,

This letter contains important information regarding the Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090 Lot Numbers 409383, 410627, and 411921, utilized with the Alinity m System. Please review this information carefully.

LIST NUMBER	LOT NUMBER	UDI
09N79-090	409383	(01)00884999049338(10)409383(17)251030(240)09N79-090
09N79-090	410627	(01)00884999049338(10)410627(17)260103(240)09N79-090
09N79-090	411921	(01)00884999049338(10)411921(17)260103(240)09N79-090

Background:
Abbott has received reports of an increase in reactive negative controls and false positive results, with Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090 Lot Numbers 409383, 410627, and 411921, on the Alinity m System. Specifically, an increase in the amount of reactive negative controls and false positive results have been reported for the Respiratory Syncytial Virus (RSV) and Influenza B virus (flu B) and 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.

To date, there have been 13 customer complaints associated with these lots, and no reported injuries.

Potential Impact:
There is a potential for delayed results and false positive results for RSV and flu B when using these lots. All subsequent lots of Alinity m Resp-4-Plex AMP kits are not impacted.

Necessary Actions:
- Discard inventory of the lots listed in the above table. Contact Abbott Customer Support for replacement 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.

Abbott

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.

Pamela Yip
Divisional Vice President, Quality Assurance
Molecular Diagnostics at Abbott