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

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Products: Alinity m EBV AMP Kit, Alinity m CMV AMP Kit,
Alinity m EBV Application Specification File (Whole Blood) and
Alinity m CMV Application Specification File (Whole Blood)
List Numbers: 09N43-090, 09N46-090, 09N43-03A, and 09N46-03B
Not Lot Specific
Unique Device Identifiers (UDIs): 00884999049642, 00884999049581,
(01)00884999049680(240)09N43-03A(8012)1.00, and
(01)00884999050105(240)09N46-03B(8012)2.00

March 31, 2022

Dear Abbott Customer,

This letter contains important information regarding Alinity m EBV and Alinity CMV Amplification (AMP) Kits, List Numbers (LNs) 09N43-090 and 09N46-090, and the Alinity m EBV and Alinity CMV Application Specification Files **(Whole Blood)**, LNs 09N43-03A and 09N46-03B utilized with the Alinity m System. Please review this information carefully.

Background
Abbott has received reports of under-quantitation of the Alinity m EBV and Alinity m CMV assays versus the Abbott RealTime EBV and CMV assays (LNs 08N54 and 05N23). This issue was reported and confirmed for fresh whole blood samples only when processed by the Alinity m EBV Application Specification File **(Whole Blood)**, LN 09N43-03A and/or the Alinity m CMV Application Specification File **(Whole Blood)**, LN 09N46-03B, and not for plasma samples.

Per the Alinity m EBV AMP Kit Package Insert 53-608243/R1 Clinical Performance – Method Correlation, Alinity m EBV compared with Abbott RealTime EBV for whole blood samples showed a mean bias between the two assays for whole blood samples of -0.13 Log IU/mL (95% CI: -0.16 to -0.09). Data analysis determined the current mean bias between the two assays to be -1.25 Log IU/mL (95% CI: -1.12 to -1.38).

Per the Alinity m CMV AMP Kit Package Insert 53-608185/R1 Clinical Performance – Method Correlation, Alinity m CMV compared with Abbott RealTime CMV for whole blood samples showed a mean bias between the two assays for whole blood samples of 0.32 Log IU/mL (95% CI: 0.28 to 0.37). Data analysis determined the current mean bias between the two assays to be -0.77 Log IU/mL (95% CI: -0.65 to -0.89).

Potential Impact
EBV and CMV in whole blood samples may be mis-quantitated/under-quantitated when processed using the Alinity m EBV Application Specification File **(Whole Blood)**, LN 09N43-03A or the Alinity m CMV Application Specification File **(Whole Blood)**, LN 09N46-03B.

While there is potential impact to results for Alinity m EBV or Alinity m CMV, there is no impact or change to the assay reagents as the reagents may continue to be utilized with the Alinity m EBV Application Specification File **(Plasma)**, LN 09N43-01A or Alinity m CMV Application Specification File **(Plasma)**, LN 09N46-01A. There have been zero (0) reports received to-date of harm associated with this issue.

Necessary Actions
Please complete and return the Customer Reply Form.

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- Discontinue use of the Alinity m EBV AMP Kit with the Alinity m EBV Application Specification File **(Whole Blood)**, LN 09N43-03A and/or the Alinity m CMV AMP Kit with the Alinity m CMV Application Specification File **(Whole Blood)**, LN 09N46-03B immediately.

- Abbott plans to remove the Alinity m EBV Application Specification File **(Whole Blood)**, LN 09N43-03A and/or the Alinity m CMV Application Specification File **(Whole Blood)**, LN 09N46-03B from your Alinity m System. An Abbott Representative will contact you to schedule the removal of the **Whole Blood** Application Specification File(s) at your site.

- The Alinity m EBV and CMV AMP Kits may continue to be used only with the Alinity m EBV Application Specification File **(Plasma)**, LN 09N43-01A and/or Alinity m CMV Application Specification File **(Plasma)** LN 09N46-01A, respectively.

This field action 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 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,

3-31-22

Ray Bastian
Senior Director, Quality Assurance
Molecular Diagnostics at Abbott