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

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m HBV Assay

March 3, 2022

Dear Health Care Provider,

Molecular Diagnostics at Abbott has received reports of falsely elevated results when using the Alinity m HBV Assay. Carryover events may cause samples that are positioned near high positive samples in the assay tray to produce falsely elevated (misquantitation high) HBV results.

Abbott plans to update the Carryover and Limitations of the Procedure sections of the associated package insert with the following information:

> **Limitations of the Procedure:**
> Unexpected HBV DNA levels due to carry over may occur. If results are inconsistent with patient history and other diagnostics through patient monitoring, a retest of the sample should be considered by the physician or healthcare provider.

Abbott is continuing to evaluate additional corrective actions in association with this issue and may send additional updates to this notification at a later date.

Results from the Alinity m HBV Assay must be interpreted within the context of all relevant clinical and laboratory findings. If results are inconsistent with patient history and other diagnostics through patient monitoring, a retest of the same sample should be considered. Please contact your laboratory if you choose to retest a patient sample.

We apologize for any inconvenience this may have caused you.

Thank you,

3-3-22

Ray Bastian
Senior Director, Quality Assurance
Molecular Diagnostics at Abbott