



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

cc Chairman Medical Board and relevant Head-of-Department

Date Issued February 07, 2019

Product
Product Name: Alinity hq Analyzer
List Number: 09P68-01
UDI Number: Not applicable
Serial Numbers: See Attachment A

Explanation Abbott has identified the following issue:

A patient sample result with an “MCHC Out of Range. Check Sample Integrity” flag on the Alinity hq analyzer may indicate that the processed sample contained a clot. If the analyzer is not halted by the user, the system will continue to process samples. Subsequent results may be impacted and may not be flagged.

Immediate action is required by the user.

Abbott is continuing to investigate this issue and future system upgrades are in development.

Patient Impact Patient CBC results that are generated following the aspiration of a clot may be incorrect (falsely decreased).

Necessary Actions

1. When the “MCHC Out of Range. Check Sample Integrity” flag is triggered, this message may indicate a short sample or a clotted sample. Pause the system when the notification is detected. Check the sample that triggered the flag for the presence of clots. If no clot is found, resume operation of the analyzer and no further actions are needed.

If a clot is found, perform the daily (5001) AutoClean maintenance procedure and run background and Quality Controls. Samples processed after the “MCHC Out of Range. Check Sample Integrity” data invalidating flag and before the Quality Control values are confirmed should be re-tested, even if no flags, invalid results, delta checks or results outside of the reference range were generated.

**Necessary
Actions
continued**

2. Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
3. Clots in specimens are a condition that may affect CBC results. Although the Alinity hq has been designed to flag such samples, it may not always be possible to do so. To minimize the risk of clot formation, follow the instructions in the Alinity h-series Operations Manual, "Requirements for handling the specimens." Collect all whole blood specimens according to laboratory procedures. Follow the recommendations of the collection tube manufacturer. Comply with all precautions for blood collection by venipuncture to prevent clotting or specimen hemolysis.

NOTE: No changes are required to the recommended maintenance schedule.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please retain this letter for your laboratory records.

**Contact
Information**

We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.
