Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Urgent Field Safety Notice

Product Correction

Immediate Action Required

Date Issued August 27, 2018

Product

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

Explanation

Abbott Hematology has identified the following issues with the Alinity hq Analyzer:

(1) Lab temperatures exceeding 22° Celsius (C) may cause false positive or elevated Nucleated Red Blood Cell (NRBC) counts and corresponding falsely decreased White Blood Cell (WBC) counts. In addition, increased WBC differential "boundary not found" invalidating flags may occur. The frequency of occurrence increases with temperature up to 30° C (the upper limit of the operating temperature range of the system).

(2) Mean Cell Volume (MCV) may be biased for MCV values above approximately 105 femtoliters (fL) and below approximately 70 fL. This could occur after one or more MCV calibration events. The calculated parameters, Hematocrit (HCT) and Mean Corpuscular Hemoglobin Concentration (MCHC), may also be impacted.

Patient Impact

Patient results may be impacted. Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported patient results.

(1) This quality issue has the potential to generate false positive or elevated NRBC counts and corresponding falsely decreased WBC counts.

(2) Internal data has shown that patient samples with MCV values greater than approximately 105 fL or less than 70 fL may show bias of ≥5% or 4 fL whichever is greater. For some analyzers, a bias as much as 10% could occur at especially low (< 65) or high (> 120) MCV values. If MCV shows a bias, HCT and MCHC will also be impacted as these parameters are calculated using MCV.

Necessary Actions

(1) Necessary NRBC-related actions when room temperature is above 22° C:

- Samples that are positive for NRBC must be validated using another method to confirm. WBC (including differential, when reported) must also be validated using an alternative method for NRBC positive samples, if the NRBC count could have a significant impact on WBC. For example, if the NRBC count exceeds 10% of the WBC count or is > 0.2x10_9/L, whichever is greater, WBC validation would likely be necessary. This would depend upon your laboratory practices.

Necessary Actions continued

- Where possible, maintain laboratory room temperatures between 15^{o} – 22^{o} C.
- Per the Alinity h-series Operations Manual, ensure that review and validation of affected results is performed before reporting if a data invalidating flag marks a parameter result as suspect. In addition, ensure validation of pathological findings indicated by any morphology flag and of all impacted and associated parameters is performed by using appropriate reference methodology, before affected results are reported.
- This issue will be addressed by software and/or hardware upgrades. Your Abbott representative will contact you to schedule upgrades starting in October 2018.

(2) Necessary MCV-related actions:

- Contact your customer service representative if you have calibrated the MCV parameter. Your representative will perform a service visit to verify the calibration. If you did not calibrate MCV since system installation, then the MCV bias issue should not exist.
- If your instrument performance indicates that MCV requires calibration, contact your customer service representative to request assistance. The service representative will assist you with MCV calibration until a software solution is made available.

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

Please return the Reply Form and 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 that you serve have any questions regarding this information, please contact your local area Customer Service.