



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 $\geq 5\%$ 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 $> 0.2 \times 10^9/L$, 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° – 22° 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.

Attachment A
FA27AUG2018
Alinity hq Temperature and MCV Issues

hq00102	hq00103	hq00104	hq00105	hq00106	hq00107	hq00108
hq00109	hq00113	hq00115	hq00116	hq00118	hq00119	hq00120
hq00121	hq00124	hq00125	hq00126	hq00127	hq00129	hq00130
hq00132	hq00133	hq00134	hq00135	hq00136	hq00137	hq00138
hq00139	hq00140	hq00141	hq00142	hq00144	hq00146	hq00147
hq00148	hq00149	hq00150	hq00151	hq00153	hq00157	hq00160
hq00161	hq00165	hq00166	hq00167	hq00168	hq00169	hq00171
hq00172	hq00173	hq00175	hq00176	hq00178	hq00181	hq00182
hq00183	hq00184	hq00185	hq00186	hq00187	hq00188	hq00189
hq00190	hq00194	hq00196	hq00197	hq00198	hq00199	hq00202
hq00203	hq00204	hq00206	hq00208	hq00209	hq00210	hq00214
hq00217	hq00218	hq00222				