Abbott GmbH & Co. KG
Max-Planck-Ring 2
Wiesbaden Hessen, GERMANY 65205

Product Correction

Immediate Action Required

Date Issued

July 06, 2018

Product

Product	List Number (LN)	UDI
Alinity s System	06P16-01	N/A

Explanation

During in-house Alinity s System assay testing, Abbott identified the possibility of unexpected low RLU (Relative Light Units) values on sample results for all Alinity s assays.

Donor/ Patient Safety Impact

There is a potential for incorrect test results should unexpected low RLU values be generated. A historical review of available data through AbbottLink from all laboratories was performed from 30 May 2017 to 04 July 2018 and did not identify any occurrences of this event at your laboratory.

If this event were to occur during calibration, assay control, or at release control, a message code would be generated and no results would be reported.

Necessary Actions

Until the permanent solution is implemented, you must perform the following actions to mitigate potential impact. The review of sample RLU values applies to ongoing operations as well as all previously generated results, in the event they may not all have been transmitted to AbbottLink.

Low RLU values are an indicator this issue potentially has occurred. All sample results with RLU values greater than 20 are considered acceptable. Abbott recommends retest in duplicate of all samples with RLU values less than or equal to 20. If all three results are nonreactive, this verifies the disposition of the initial nonreactive result. If either retest replicate is reactive, please follow the respective assay retest procedure in the instructions for use.

If any additional previous results indicate this occurrence has taken place we recommend the blood products associated with these samples be placed on quality hold per your laboratory procedures. To confirm the nonreactive results of these samples please retest per instructions provided above. Should this testing be performed by your laboratory, please provide the testing outcome(s) to your Abbott ambassador to help facilitate the root cause investigation.

The RLU results may be viewed using the following methods:

- RLU results from multiple samples may be viewed using the archive function (Refer to Appendix A).
- RLU results for individual samples may be viewed on the Released tab of the sample results screen.
- As a third option RLU results are transmitted to the host and may be viewed at the host level.

Necessary Actions – Cont.	Please review results and perform necessary retests prior to final acceptance of results in your laboratory. This approach will address results that may be impacted by this issue and provides verification of the result. Retesting will effectively mitigate any impact in the event this issue should occur in your laboratory.
Contact Information	We sincerely regret any inconvenience this may have caused your laboratory. If you or any of your customers or health care providers you serve have any questions regarding this information please contact your local area Customer Service.

Appendix A: Reviewing RLU Results per the Archive Function

- Tap on “Results” screen
- Tap on “Released Results”
- Place a check mark next to Nonreactive.
- Tap on Search. Search “nonreactive” results
- Tap “Select all”
- Tap on Archive
- Tap on “only Archive”
    - A proper USB must be connected to any USB port
    - Then Tap “Archive”
- File type is xlsx. Open the file using a spreadsheet
- Sort results from low to high based on column labeled “Instrument Response Value (RLU)”
- Identify any results with RLU $\leq$20
- Sample information will be in the column labeled “Sample ID”. Other information regarding the sample rack, Assay Name, and date and time of completion are available in other columns.