For the attention of the Head of Laboratory

Asnières, June 16th 2021

Reference: RC-21-0021

FIELD SAFETY NOTICE

Software version 4.06 on STA R Max®

Dear Customer,

According to our traceability records, you are using a STA R Max® analyzer. If your instrument is on software version 4.06, you are concerned by this safety information, relating to a potential rinsing anomaly of needles # 2 and # 3. All other STA R Max software versions are not affected by this information.

✓ Description:

Customer feedback has highlighted an unusual frequency of abnormally shortened APTT clotting times on STA R Max instruments, since the software version 4.06 update.

Internal investigation has identified an issue on “special” or “special plus” washes with STA-Desorb U on reagent needles (#2 and #3) when a level detection error (LLD) occurs. This washing anomaly is most commonly present in a specific context of non-recommended use (unloading and reloading of bottles of reagents already used, with entry of an incorrect residual volume by the user).

If a LLD error appears on a test with a special wash, cross-contamination may occur with different test combinations.

According to our risk analysis, the most critical case would be the contamination of an APTT test by Fibrinogen reagents because the shortening of APTT clotting times is significant. Additionally, since APTT and Fibrinogen are routine tests, it increases the likelihood of occurrence.
The shortening of the APTT result in normal patient plasma is detectable because the time obtained will be abnormally short (shorter than the laboratory reference time). The shortening of an APTT on a pathological patient plasma could be difficult to detect.

✓ Actions:

A software fix is already available: version 4.07.01 and will be installed shortly by your Stago representative.

While waiting for your instrument to be updated, in order to limit the risk of an LLD error on the reagent bottles, we recommend that you do not unload-reload your reagents from the STA R Max® before the end of the bottle. Or, if it is necessary, ensure the correct entry of the residual volume is made when reloading a vial that has already been used and has not yet been completed. This good practice will allow optimal management of volumes by the instrument and therefore avoid the risk of occurrence of the anomaly described.

According to our risk analysis, as patient results are interpreted in a global clinical-biological context, and if you do not unload-reload reagents on your STA R Max without entering the exact residual

volume, it is unlikely that this defect has occurred or could have harmful consequences for the patient's health. Consequently, review of previous patient results is not required.

Please return to your Stago affiliate, by fax or by e-mail, the completed enclosed form confirming that you have read this letter and will apply the instructions.

The Competent Administrative Authority of the country of origin (France) has been informed.

For additional information, please contact your Stago affiliate.

Please accept our apologies for this inconvenience. We thank you in advance for your support.

Yours sincerely,