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FIELD SAFETY NOTICE

Software version 4.06 on STA R Max®

Number of pages: 2 + 3 enclosed documents

Dear Distributors,

According to our traceability records, your customers are using a STA R Max® analyzer. This field safety notice is related to a potential rinsing anomaly of needles # 2 and # 3 on software version 4.06. 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 more difficult to detect.

✓ **Actions:**

A software fix is already available: version 4.07.01, we ask you to install it as soon as possible.

While waiting the instrument update, in order to limit the risk of an LLD error on the reagent bottles, we recommend to the customers that they do not unload-reload their 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.

✓ **Customer information:**

For all your customers who have a STA R® Max analyzer, we ask you :

- ☐ To inform them about the issue and the measures to adopt using the Field Safety Notice attached (attachment 03) and to send them the associate coupon answer (attachment 04).
- ☐ To install as soon as possible the software version 4.07.01 at customers who have a STA R Max analyzer on software version 4.06 (see **TB-STR-134**)

Please return to us, by fax or by e-mail, the completed enclosed form (appendix 02) when you will have contacted all your customers about this matter.

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

If requested by your current local regulations, we let you inform your Competent Administrative Authority about this issue in accordance with timing provided by your regulations.

For additional information, please contact us.

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

Yours sincerely,

Marc BORENSZTEJN
Operational Director
Qualification & Complaint Management
Diagnostica Stago