For the attention of the Head of Laboratory

(CITY), November 13th 2019

Reference: RC-19-0049

FIELD SAFETY NOTICE

Combined use of the following reagents

STA – UNICALIBRATOR (ref. 00675)
UNICALIBRATOR (ref. 00625)

and

STA – DEFICIENT VIII (ref. 00725)
STA – DEFICIENT IX (ref. 00724)

Dear Customer,

You are using the STA – Unicalibrator (00675) or Unicalibrator (00625) and STA – Deficient VIII (00725) and/or STA – Deficient IX (00724) and according to our records, you have ordered and received in your laboratory one or several kits of the calibrator plasmas listed in appendix 1.

Following the identification of a defect, please find below information about the reagents and lots listed in Appendix 1.

✓ Description:

Following a customer complaint, Stago has investigated and confirmed a positive bias on the (STA) Unicalibrator levels on test setups using STA - Deficient IX and STA - Deficient VIII reagents.

Stago has accordingly reassigned the concerned calibrator plasma levels (see new levels on the attached flyers).

According to our internal testing results, a lowered calibration plasma level results in a decrease of factor VIII and IX levels on normal and subnormal patient plasmas.
However, this change has no impact on the classification of hemophiliac patients (A and B) as either severe, moderate and minor.

The reassignment of the calibrator plasma levels leads to a change in the acceptance ranges on the corresponding Quality Control plasmas for factor VIII and IX parameters with the STA - Deficient VIII and STA - Deficient IX reagents.

You will find in the attachment the new flyers for each lot of the affected reagents.

✓ Actions:

Upon receipt of this letter, we ask you to:

- No longer use the values indicated on the flyers in your possession (reagents & lots listed in appendix 1) for STA - Deficient VIII and STA - Deficient IX.

- Use the attached new flyers:

  . For calibrator plasmas: you will find the procedure to implement this change in appendix 2. Please note the procedure will be dependent on the analyzer you are using and will require you to reload the calibrator values from the new flyer.

  . For Quality Controls plasmas: we ask you to manually change the acceptance ranges of the affected Quality Control plasmas for factor VIII and factor IX parameters with the STA - Deficient VIII and STA - Deficient IX reagents. The procedure to be applied according to your analyzer is indicated on appendix 3.

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

According to our clinical risk analysis, this defect has no clinical impact. Hence, it is not necessary to reassess patient results previously reported.

The Competent Administrative Authority of the country of origin (France) has been informed.
For additional information, please contact us.

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

Yours sincerely,

FIELD SAFETY NOTICE

APPENDIX 1 – LIST OF THE CONCERNED REFERENCES AND LOTS

Product	Reference	Lot number	Expiry date
Unicalibrator	00625	253178	2019-12-31
		253965	2020-06-30
		254722	2020-11-30
		255109	2021-02-28
STA - Unicalibrator	00675	253180	2019-12-31
		253964	2020-06-30
		254721	2020-11-30
		255108	2021-02-28
System Control N + P	00617	253417	2020-02-29
		254041*	2020-06-30
		254574	2020-10-31
		255515	2021-04-30
STA - System Control N + P	00678	253145	2019-11-30
		253416	2020-01-31
		253655*	2020-03-31
		254040*	2020-06-30
		254206	2020-07-31
		254401	2020-09-30
		254573	2020-10-31
		254760	2020-11-30
		255004	2021-01-31
		255359	2021-03-31
		255514	2021-04-30
STA – Quali-Clot I	00982	253156	2019-11-30
		253699	2020-03-31
		254007	2020-06-30
		254536	2020-10-31
		254867	2020-12-31
		255581	2021-05-31
STA – Quali-Clot II	00988	253157	2019-11-30
		253705	2020-03-31
		254049	2020-06-30
		254625	2020-10-31
		254868	2020-12-31
		255602	2021-05-31

**Only for STA - Deficient IX*

FIELD SAFETY NOTICE

APPENDIX 2 – PROCEDURE TO READ THE NEW STA- UNICALIBRATOR (00675) FLYER ON STAGO INSTRUMENTS

WARNING
These procedures will lead to the suppression of all the calibrations of all the parameters associated to the STA – Unicalibrator (00675) lot.

ON STA-R MAX

Refer to section ***8.7.3 Deleting a lot*** of your manual reference.

ON STA-R EVOLUTION

Refer to section ***4.11.3 Delete lot*** of your manual reference.

ON STA COMPACT OR STA COMPACT MAX

To simulate a lot change:

1. Open the product drawer.
2. Enter MANUALL Y the following information by using the keyboard :

Display on screen	Enter the following
ID / Identity	12350 then [ENTER]
Name (strictly respect the title)	STA-UNICALIB. then [ENTER]
Volume ml	1 then [ENTER]
Stability h	4 then [ENTER]
Lot number	Enter the last 3 digits of the lot number then [ENTER]

3. Load the vial on board.
4. Confirm lot change by entering YES.
5. Scan the new barcode sheet.

QUALITY INFORMATION

APPENDIX 3 – PROCEDURE OF MANUAL CHANGE OF THE CONTROL RANGES ON STAGO INSTRUMENTS

WARNING
These procedures will change the ranges on your past Quality Controls results. We advise you to save your QC results according to the current procedure in your laboratory and to record this event.

ON STA-R MAX

Refer to section ***4.3.7 Changing the threshold values for a quality control*** of your manual reference.

ON STA-R EVOLUTION

Refer to section ***3.5.9 Changing the values of the thresholds for a quality control*** of your manual reference.

ON STA COMPACT MAX

Refer to section ***4.3.2.3 Changing the threshold values for quality controls*** of your manual reference.

ON STA COMPACT

Refer to section ***9.4.3 Changing the Range of Acceptable Results for Quality Controls*** of your manual reference.