For submission to the Head of Laboratory

(CITY), January xxth 2017

Reference: RC-16-0082

URGENT – FIELD SAFETY NOTICE

LOTS RECALL (SEE LIST ON THE APPENDIX): DISPOSABLE STA®-CUVETTES (REF. 38669) FOR HAEMOSTASIS ANALYSERS STA-R®, STA R MAX®, STA COMPACT®, STA COMPACT MAX®

Dear Madam, Dear Sir,

According to our records you have ordered and received in your laboratory one or several lots of STA®-Cuvettes (reference 38669) used on our haemostasis analysers STA-R®, STA R Max®, STA Compact® or STA Compact Max®.

Please find hereafter details of an issue which has been detected regarding some lots of STA®-Cuvettes.

✓ **Identification and description of the defect:**

Following a customer complaint, Diagnostica Stago investigated a report of erroneous APTT results when using several lots of STA®-Cuvettes (listed in the appendix).

Internal investigations have shown that this is a random issue with a low occurrence. For example, with a standard customer test profile, the average rate of outliers is 0.4 %. All erroneous results observed during investigations have shortened clotting times, with a mean relative deviation of 30 % on APTT tests.

The affected clotting parameters are the following: APTT, Factor VIII, Factor IX, Protein S and Protein C clotting assays. The issue is not related to the type and the lot of reagent and has been reproduced both with Quality Control as well as patient plasmas.

The chromogenic, immunoturbidimetric and clotting tests other than those listed above are not affected.

✓ **Actions:**

If you have in your laboratory, any of the lots of STA®-Cuvettes among those listed in the appendix, Diagnostica Stago is asking you to:

- Identify and quarantine the concerned STA®-Cuvettes lot(s). The quarantined lots will be collected by your local distributor at an agreed time.
- Use other lots of STA®-Cuvettes in your stock until the affected lots can be replaced.
- Contact your local distributor as soon as possible in order to obtain without delay a lot exchange.

As patient results are interpreted in a global clinical context in association with other biological tests we leave at your discretion the decision to review previous patient results on a case by case basis.

Please can you complete the coupon attached acknowledging receipt of this letter. The return of this coupon will initiate the replacement process for the affected lots.

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

For additional information, please contact your local distributor

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

Yours sincerely,

APPENDIX – LIST OF CONCERNED LOTS

Reference: RC-16-0082

URGENT – FIELD SAFETY NOTICE

LOTS RECALL:
DISPOSABLE STA®-CUVETTES (REF. 38669) FOR HAEMOSTASIS ANALYSERS STA-R®, STA R MAX®, STA COMPACT®, STA COMPACT MAX®

Lot number	Date of first sale
A11716	25/08/2016
A11916	09/09/2016
A12816	08/11/2016
A41016	01/06/2016
A42016	28/09/2016
A42116	13/09/2016
A42516	22/09/2016
A42616	22/09/2016
A52916	16/11/2016
A53516	17/11/2016
A54016	08/12/2016
S51816	29/08/2016
S51916	12/09/2016
S52016	26/09/2016
S52116	26/09/2016
S52316	30/09/2016
S52416	06/10/2016
S62215	22/09/2015
S61916	04/08/2016
S62016	21/09/2016
S62416	01/09/2016
S62516	13/10/2016
S62616	27/10/2016
S62716	18/10/2016
S62916	08/11/2016