Asnières, July 1st, 2025

For the attention of the Head of Laboratory

Reference : RIS-25-0006

FIELD SAFETY NOTICE

Use of STA®-LIQUID ANTI-Xa (REF. 00311 / 00322) UFH and LMWH applications on STA SATELLITE® and STA SATELLITE MAX® (all references)

Dear customer,

According to our traceability records, you are using the STA®-LIQUID ANTI-Xa reagent and you have a STA SATELLITE® or STA SATELLITE MAX®.

You may be concerned by this Field Safety Notice regarding the use of STA®-LIQUID ANTI-Xa in UFH and LMWH applications on STA SATELLITE® / STA SATELLITE MAX®.

✓ **Concerned Products :**

Device	Code	UDI
STA®-LIQUID ANTI-Xa	00311 00322	3607450003116 3607450003222
STA SATELLITE®	All references	03607450581041 03607450581027
STA SATELLITE MAX®	All references	03607450590043 03607450580303

✓ **Description :**

As part of normal post-market surveillance, Stago studied the risks of cross-reagents contamination on its single-needle analyzers, the STA SATELLITE® and the STA SATELLITE MAX®.

Following internal tests, contamination of STA®-LIQUID ANTI-Xa by Stago Fibrinogen reagents was identified in UFH and LMWH applications. The Fondaparinux application is not affected.
Contamination occurs when one or several tests with the contaminating reagent are performed before the STA®-LIQUID ANTI-Xa test. It induces an underestimation of heparin levels which could lead to a heparin treatment change, and an overdose risk for the patient.
It is important to note that Stago has never recorded a complaint or incident in relation with this problem.

The contamination is detectable by quality controls (QC). Consequently, if you perform a series of STA®-LIQUID ANTI-Xa tests with QCs running before and after the series, there is no risk to underestimate the results.

✓ **Actions :**

Pending a corrective solution on both instruments, and if you perform assays on STA®-LIQUID ANTI-Xa UFH and LMWH applications on your STA SATELLITE® or STA SATELLITE MAX®, we temporarily ask you to systematically run a quality control just before series of UFH or LMWH.

Please return to your local distributor or Stago affiliate, by e-mail, the enclosed response coupon duly completed and signed.

According to our risk analysis, considering the regular monitoring of patients on heparin and the duration of treatment, it does not seem necessary to us to review the results previously reported.

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

Your Competent Administrative Authority has also been informed regarding this issue.
For additional information, please contact your local distributor or Stago affiliate.

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

Yours sincerely,