For submission to the Head of Laboratory

(CITY), January 28th 2019

Reference: RC-18-0003

FIELD SAFETY NOTICE

STA® – VWF:RCo (ref. 01191)

Lot 202469 – *Exp. 2018-08-31*
Lot 202470 – *Exp. 2019-03-31*
Lot 202473 – *Exp. 2019-09-30*
Lot 202474 – *Exp. 2020-03-31*

Dear Customer,

You are a user of the **STA® – VWF:RCo** reagent (ref. 01191) and according to our records, you have ordered and received in your laboratory one or several kits of the above listed lots.

Following the detection of a defect, you will find below the new instructions for use to apply on the above listed lots and on the next lots.

✓ Identification and description of the defect:

Following customer complaints, Stago has investigated and confirmed a non-systematic underestimation of the ristocetin cofactor activity of von Willebrand factor on some plasmas with a level above 85%.

The root cause investigations have found a disturbance of these measures at the standard dilution of the plasma only (1:4 dilution).
These disturbances affect the calculation of the level, which is then underestimated by a half (on average) and consequently found with a level below 85%. Hence, the instrument does not automatically rerun the 1:10 dilution defined for plasmas with a level above 85%.
During our internal testing, 38% of the tested plasmas with a level above 85% were impacted.

The Quality Controls in the kit, considering their respective levels, do not allow the detection of the defect.

✓ Actions:

As the 1:10 dilution is not impacted, we ask you from now on to test your samples in the following order:

1. **For all samples, test at the 1:10 dilution** by using a dependent test linked to the STA® – VWF:RCo Test Setup.

2. **If the result is in error (V>VMax or M>MMax) or < 85% at the 1:10 dilution, test at the 1:4 dilution** by using the STA® – VWF:RCo Test Setup.

N.B.: if the result is < 30% at the 1:4 dilution, the 1:2 dilution will be automatically performed as defined by the STA® – VWF:RCo Test Setup.

Calibration and Quality Controls are still to be tested according to the STA® – VWF:RCo Test Setup.

According to our risk analysis, as patient results are interpreted in a global biological and clinical context, it is unlikely that this defect has had a significant clinical impact.
However, we leave to your discretion the decision to review previous patient results on a case by case basis and to potentially control the results with a new blood sample.

Please return to your local distributor, by fax or e-mail, the completed enclosed form confirming that you have read this letter.

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.

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

Yours sincerely,