

For submission to the Head of Laboratory

Asnières, January XXth, 2013

Reference: RC-11-0100

IMPORTANT - FIELD SAFETY NOTICE
COMBINED USE OF THE REAGENT STA LIATEST® VWF (CAT N°. 11777033)
WITH STA-R® / STA-R EVOLUTION®

Dear Madam, Dear Sir,

You are a user of the reagent STA Liatest® VWF on our automated instruments STA-R® / STA-R Evolution® for the measurement of von Willebrand factor (VWF:Ag).

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

Following customer complaints concerning random low results with the STA Liatest® VWF reagents used on STA-R® / STA-R Evolution® instrument, Diagnostica Stago has investigated and confirmed that sometimes the measure performed by the instrument may be disturbed, leading to a lowered result in %.

This information does not concern the use of the reagent STA Liatest® VWF in combination with STA Compact® analysers.

This event is not systematic, it has been observed mainly on quality control samples (QC) but also, more seldom, on some patient samples.

When it appears, the probability to observe a falsely low value is variable and the results are about 50% of their expected value.

- If QC are affected, results are always out of the defined ranges and are to be run again.
- For patients samples: according to the current recommendations for the diagnosis of von Willebrand disease, the antigenic assay is performed in parallel with other tests so the defect is not likely to lead to a misdiagnosis.

✓ **Actions to implement in the laboratory:**

Pending the availability of the solution, we are asking you **to confirm all the results obtained in the abnormal range (under 50%)** either with a manual rerun or by the creation of a dependant test at a 1:2 dilution (same as SOP original dilution) linked to the Standardized Operating Procedure (SOP) of STA Liatest® VWF:Ag.

However, if your tests are performed in double determination, the probability of the defect becomes negligible. Thus, it is not necessary to apply the above mentioned measure.

Your Competent Administrative Authority has been informed regarding this issue.

For additional information, please contact (the hot line).

Please accept our apologies for this inconvenience. We are thanking you in advance for your confidence.

Sincerely yours,