

(CITY), March 28th 2024

Reference : RC-24-0001

QUALITY INFORMATION

Use of primary microtubes (0.8 mL / 1.0 mL) on STA R EVOLUTION, STA R MAX and STA COMPACT MAX

Dear Customer,

According to our traceability records, you are users of screw microtainer adaptors (ref. 89434 and 89318) on your analyzer STA R EVOLUTION/ STA R MAX/ STA COMPACT MAX. You might be affected by this Quality Information, concerning the combined use of microtubes MiniCollect® 1.0 mL from GREINER (item 450539) and PAED44 0.8 mL from ISS or any other equivalent primary microtube of the same supplier (when their material, dimensions, capacity volume are identical) on our analyzers.

✓ **Description :**

Following a customer complaint about abnormal presence of red cells in the measurement cuvettes, Stago has investigated and confirmed a potential risk of pipetting close to or into the packed red blood cells when using these primary microtubes.

This risk depends on the actual blood volume in the microtube, the patient sample hematocrit level and on the number and type of test to perform.

According to our internal tests, pipetting into the packed red blood cells has no impact on colorimetric and immunologic tests (pipetting red cells leads to a technical error message) but could lead to prolonged clotting times on chromometric tests.

Prothrombin time (PT) and activated partial thromboplastin time (PTT) are mildly prolonged. According to our analysis, the main identified risk is a lowering of the fibrinogen level which could then be normalized. However, this risk remains moderate, considering the attention that is paid to the volume present in this type of tube, the results of other tests and the clinical context.

✓ **Actions :**

Stago have decided to update the instructions for use of those primary microtubes in order to optimize the volume of plasma usable by the analyzer as follows :

| Microtube | Rack | Stago Adapter | Sample Identification |
|---|--|--|-----------------------|
| GREINER MiniCollect® 1.0 mL (item 450539) | STA R MAX / STA R Evolution | | |
| | - <u>Manual Identification</u> : 39147 STANDARD RACK 89330 STANDARD RACK WITH INSERTS 89381 RACK 11-13 | 89434 SCREW MICROTAINER ADAPTER | Pediatric |
| | - <u>Automatic Identification</u> : 89318 SCREW MICROTAINER RACK | | |
| | STA Compact MAX | | |
| <i>Not applicable</i> | | <i>Not applicable</i> | Pediatric |
| ISS PAED44 0.8 mL | STA R MAX / STA R Evolution | | |
| | - <u>Manual Identification</u> : 39147 STANDARD RACK 89330 STANDARD RACK WITH INSERTS 89381 RACK 11-13 | 89434 SCREW MICROTAINER ADAPTER | Pediatric |
| | - <u>Automatic Identification</u> : 89318 SCREW MICROTAINER RACK | | |
| | STA Compact MAX | | |
| <i>Not applicable</i> | | <i>Not applicable</i> | Pediatric |

In any case, due to the limited volume of these microtubes, it is advisable to check the available volume before starting the tests.

According our risk analysis, the defect is not likely to cause harmful consequences for the patients' health. Therefore, previous reported patient results should not necessarily be reviewed.

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 Stago affiliate.

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

Yours sincerely,