



October 2019

IMPORTANT PRODUCT CORRECTION NOTIFICATION**Revised On-Analyser Stability Time for VITROS® Chemistry Products 7% BSA and Urine Electrolyte Diluent on VITROS® 250/350 Chemistry Systems**

Dear Valued Customer,

Cc: Chairman Medical Board and relevant Head of Department

The On-Analyzer Stability (OAS) time for VITROS 7% BSA and VITROS Urine Electrolyte Diluent has been revised when using them on VITROS 250/350 Chemistry Systems. This change affects the use of 7% BSA or UED with 2mL cup storage on the VITROS 250/350 diluent tray.

| Affected Product | Product Code (Unique ID No.) | Affected Lots |
|--|------------------------------------|---|
| VITROS® Chemistry Products 7% BSA | 8262487 (10758750004652) | This issue affects all expired, in-date and future lots released. |
| VITROS® Chemistry Products Urine Electrolyte Diluent (UED) | 1110352 (10758750008421) | |

Issue Description

Ortho Clinical Diagnostics has found that VITROS 7% BSA and VITROS Urine Electrolyte Diluent (UED) do not meet the current recommended OAS time of up to 7 days when stored on the VITROS 250/350 System in a 2mL cup.

Impact to Results

Ortho's internal testing compared results from samples diluted with diluent stored on the analyser versus fresh diluent. When using 7% BSA or UED stored in a 2mL cup for 7 days, the differences in the results vs fresh diluent were >10% for some assays. Refer to the Questions and Answers section for the affected assays and maximum % difference observed for the analyte concentrations tested.

7% BSA: A review of previous patient results is not recommended since the results of the undiluted sample should exceed or be close to the upper limit of the reportable range and well above any relevant reference intervals. Therefore, the result after dilution is not likely to alter a physician's medical decision. Discuss any concerns regarding previously reported results with your Laboratory Medical Director.

Urine Electrolyte Diluent: Since urine samples have a large standard dilution (1:5), if the diluent was stored on the analyser in a 2mL cup for >24 hours, Ortho recommends assessing the need for a review of patient results with your Laboratory Medical Director.

REQUIRED ACTIONS

- When using 7% BSA and UED in 2mL cups on VITROS 250/350 Systems, replace after ≤24 hours.
- Post this notification by each VITROS 250/350 System in your laboratory until the IFUs have been updated.
- Complete the Confirmation of Receipt form and return by October 22, 2019.

Resolution

- **The OAS of 7% BSA and UED in 2mL cups has been revised to ≤24 hours.**
- Current OAS time remains at ≤7 days for storage in 5mL and 10 mL bottles.
- The Instructions for Use and appropriate User Documentation will be revised at a future date.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Enclosure:

Confirmation of Receipt Form

QUESTIONS AND ANSWERS

1. What is the potential impact to results?

The table below shows the difference in sample results when samples are diluted using 7%BSA or UED stored in 2mL cups for 7 days versus results when diluted using fresh diluent:

| 7% BSA | |
|------------------------------|---|
| Assay | Maximum % POSITIVE Result Difference Observed |
| ALC | 11 - 15% |
| TRIG, Li | 16 - 25% |
| Assay | Maximum % NEGATIVE Result Difference Observed |
| CHE, URIC, ALKP, CHOL | 11 - 15% |
| AST, BU, BC, THEO, ALT, PHYT | 16 - 25% |
| CK, LIPA | 26 - 30% |
| DGXN, CKMB | 31 - 60% |
| Urine Electrolyte Diluent | |
| Assay | Maximum % POSITIVE Result Difference Observed |
| Urine K+ | 11 - 15% |
| Urine Na+ | 115 - 120% |

2. Is VITROS Specialty Diluent affected?

No, the IFU for VITROS Specialty Diluent currently states ≤24 hours.

3. Are other VITROS Systems affected by this change?

No, other VITROS Systems are not affected because they do not use a 2mL cup for on-analyser diluent storage.