



## IMPORTANT

Ortho Clinical Diagnostics

February 2018

### IMPORTANT PRODUCT CORRECTION NOTIFICATION

#### Revised Assay Sheets for VITROS Chemistry Products %A1c Performance Verifiers I & II

Dear Customer,

This notification is to inform you that the assay sheets used to support VITROS Chemistry Products %A1c Performance Verifiers I & II will be revised.

Affected Product	Product Code	Unique Device Identifier No.	Affected Lots
VITROS Chemistry Products %A1c Performance Verifiers I & II	6801750 6801751	10758750006960 10758750006977	This revision will affect all in-date and future lots released
<b>Note:</b> VITROS %A1c Performance Verifiers are assayed controls used on the VITROS Systems to monitor performance of the VITROS HbA1c Reagent Kit.			

#### Background

Beginning in 2014, Ortho Clinical Diagnostics (Ortho) announced that VITROS Chemistry Products HbA1c Reagent was replacing VITROS Chemistry Products d%A1c Reagent.

To determine the % glycated haemoglobin (HbA1c), the VITROS System haemolyses whole blood samples and both the HbA1c and total Hb concentrations are measured. %A1c (NGSP) and HbA1c (SI) are calculations derived from these measurements.

- With the previous VITROS d%A1c Reagent: Measurements of total Hb and HbA1c components were obtained from two separate reaction cuvettes.
- With the current HbA1c Assay: Total Hb and HbA1c component measurements are obtained from a single reaction cuvette thereby eliminating a source of potential variation in the determination of glycated haemoglobin proportion (HbA1c).

The VITROS %A1c Performance Verifier I and II assay sheets contain a Range of Means (ROM) and a within-lab Standard Deviation (SD) for %A1c (NGSP) and HbA1c (SI) as well as the individual components, Hb and A1c. The values for the components were relevant to the previous assay since it utilized separate reaction cuvettes for each component.

#### Investigation

Based upon customer complaints of higher than expected within lab SDs for the Hb and A1c components listed on the VITROS %A1c Performance Verifiers I & II assay sheets, Ortho performed an investigation.

We determined the within-lab Standard Deviation (SD) for the Hb and A1c components on the assay sheets are not appropriate for use with the current assay. Since the current VITROS HbA1c Assay measures both the total Hb and HbA1c components from a single reaction cuvette, monitoring QC results for glycated haemoglobin proportion (HbA1c) is sufficient to verify the assay's performance.

## Resolution

As a result of our investigation, Ortho no longer recommends monitoring the quality control results of the Hb or A1c components when using the current VITROS HbA1c Assay.

The Hb and A1c components will be removed from the assay sheets for VITROS %A1c Performance Verifiers I & II for all current and future lots in approximately three months.

**Note:** When using the VITROS HbA1c Reagent Kit, results for the Hb and A1c components are not reported by the VITROS System for patient samples.

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## REQUIRED ACTIONS

- Acknowledge the information contained in this notification by completing the Confirmation of Receipt form no later than **February 21, 2018**.
- Post this notification by each VITROS System in your facility or with the user documentation.
- Please forward this notification if the product was distributed outside of your facility.

## Contact Information

If you have questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,



Jon Wong

QA MANAGER