

May 19, 2016

## IMPORTANT PRODUCT CORRECTION NOTIFICATION

### Invalid Calibration using Specific Lots of VITROS® Immunodiagnostic Products AFP Reagent Packs

*Please distribute this information to the appropriate personnel at your facility*

Dear Valued Customer,

Product Name (Unique Device Identifier No.)	Product Code	Affected Lot No. (Expiry Date)
VITROS Immunodiagnostic Products AFP Reagent Pack (10758750006489)	1925551	<b>1430</b> (07-Jul-2016) <b>1440</b> (02-Sep-2016)
VITROS Immunodiagnostic Products AFP Calibrators (10758750006540)	1515154	<b>1460</b> (08-Oct-2016) <b>1470</b> (13-Dec-2016)

Ortho Clinical Diagnostics (Ortho) confirmed that these lots exhibited an increase in reaction signal over time. Initial testing indicates that the unexpected signal increase is related to a specific lot of raw material used in the manufacture of these lots. The affected lots of VITROS AFP Reagent Packs met all quality assurance specifications upon release.

As a result of this issue, please discontinue using and discard the affected lots. If your laboratory is able to successfully calibrate VITROS AFP Reagent Packs, and your quality control results are acceptable, you may continue using your existing inventory of the affected lots until your replacement order arrives. In order to provide replacement product for all customers, product allocation may be necessary.

#### Impact to Result

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Our investigation indicates that there is the potential for sample concentrations to increase during the 28-day calibration timeframe and that the magnitude of the positive bias will decrease as sample concentrations increase. However, our data shows that quality control samples will remain within expected ranges throughout the 28-day calibration timeframe.

Previously reported patient results are valid providing that quality control results were within acceptable limits.

#### Actions Required from You

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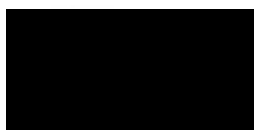
1. Discontinue using and discard all remaining inventory of the above-listed lots of VITROS AFP Reagent Packs (and their associated Calibrators). We will replace your remaining inventory or credit your account as indicated on your Confirmation of Receipt form.

**NOTE:** If you have a successful calibration, and quality control results are acceptable, you may continue using the affected lots until you receive your replacement order.)

2. Post this notification by each VITROS System that processes VITROS AFP Reagent Packs.
3. Complete the Confirmation of Receipt form and return within **(2) two business days** to indicate that you have been informed of this Product Correction.

If you have any questions, please contact Customer Technical Services at **1800 5646 766**.

Yours sincerely,



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Associate Manager Regulatory Affairs