

November XX, 2012

URGENT FIELD SAFETY NOTICE

Calibration Failures when using VITROS[®] Immunodiagnostic Products Anti-HBs Reagent Packs Lots 2220, 2225 and 2230 (CAT No. 1787753)

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you that Ortho Clinical Diagnostics, Inc. (OCD) has received customer complaints regarding an inability to obtain a valid calibration when using VITROS[®] Immunodiagnostic Products Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230 on some VITROS[®] ECi/ECiQ Immunodiagnostic Systems, VITROS[®] 3600 Immunodiagnostic Systems and VITROS[®] 5600 Integrated Systems. As a result of this issue, OCD is requesting that you discontinue using and discard VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230.

Please be assured that patient results are not affected by this issue. If your laboratory is able to successfully calibrate VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230, and your quality control results are acceptable, you may continue using your existing inventory of the affected lots until you receive your replacement order.

Investigation Summary

Our internal investigation confirmed that VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230 met all quality assurance release specifications. Subsequently, the affected lots exhibited an increase in background signal that may exceed the Calibrator Signal Index (CSI) or Delta Ratio 2 (DR2) limits, resulting in failed calibrations on some VITROS[®] ECi/ECiQ, 5600 and 3600 Systems.

Although our investigation is ongoing, our initial testing indicates that the unexpected rise in signal is related to a new lot of raw material used in the manufacture of the affected lots of VITROS[®] Anti-HBs Reagent Packs. At this time, this issue is limited to VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230.

Required Actions:

Our records indicate that your laboratory was previously sent VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230 (CAT No. 1787753).

Please do the following:

- Discontinue using VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230, and discard any remaining inventory.
- Complete and return the attached Confirmation of Receipt form upon receipt of this notification. Please return this form no later than **November XX, 2012**.
- Forward the information in this notification if you have distributed VITROS[®] Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230 outside of your facility.

Once we receive the completed Confirmation of Receipt form, OCD will process your replacement order as quickly as possible. Your replacement order will consist of VITROS[®] Anti-HBs Reagent Packs and Calibrators, Lots 2250 and above, which will be supported on the Assay Data Diskette (ADD), beginning with Data Release Version (DRV) 570601.

Please note that ADD DRV 570601 will be available on VITROS® 5600 and/or VITROS® 3600 System(s) that are e-connected beginning on 26 October 2012. We anticipate that customers with VITROS® Systems that are *not* e-connected will receive ADD DRV 570601 the week of 12 November 2012.

We apologize for any inconvenience this may cause your laboratory. If you have technical questions please contact Customer Technical Services at *<insert appropriate number>*. If you have questions about your replacement order, please call our Customer Service Center at *<insert appropriate number>*.

Sincerely,

<insert appropriate name and title>

Enclosures:

Confirmation of Receipt

Confirmation of Receipt

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VITROS® Immunodiagnostic Products Anti-HBs Reagent Packs
Lots 2220, 2225 and 2230 (CAT No. 1787753)**

So that we can complete our records, please return this form to us by **November XX, 2012**.

FAX TO: <insert appropriate name>

FAX: <insert appropriate number>

Section I – Confirmation

I received the Urgent Field Safety Notice (Ref. CL12-280_EU) regarding the inability to obtain a valid calibration when using VITROS® Anti-HBs Reagent Packs, Lots 2220, 2225 and 2230 on some VITROS® ECi/ECiQ Immunodiagnostic Systems, VITROS® 3600 Immunodiagnostic Systems and VITROS® 5600 Integrated Systems.

Please check one of the following:

- My laboratory does *not* currently use VITROS® Anti-HBs Reagent Packs and is not affected by this issue.
- My laboratory does use VITROS® Anti-HBs Reagent Packs, but does not have any Lots 2220, 2225 or 2230 remaining in inventory.
- My laboratory does use VITROS® Anti-HBs Reagent Packs. I have discontinued using and discarded the following quantity of VITROS® Anti-HBs Reagent Packs and Calibrators, Lots 2220, 2225 and 2230.

Quantity Discarded (Lots 2220, 2225 and 2230)	
VITROS® Anti-HBs Reagent Packs	VITROS® Anti-HBs Calibrators

Your Name: _____

Job Title (optional): _____

Signed*: _____

Date: _____

Fax Number: _____

Telephone Number: _____

**Your signature provides confirmation that you have received and understood this notification.*

Your comments are always welcome:

Section II – Verify Your Name and Address

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: _____

Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Telephone: _____ FAX: _____