Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

*xx* November 2012

# URGENT FIELD SAFETY NOTICE

## Discontinuance of VITROS® Chemistry Products HPT Reagent
## Product Code: 6802214

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 complaints of the inability to calibrate the VITROS® Chemistry Products HPT Reagent. We have also had reports of an increase in U91-274 condition codes. Our records indicate that you were sent one or more of the affected lots of VITROS® HPT Reagents. The lots affected are listed below:

| VITROS® Chemistry Products HPT Reagent Product Code 6802214 | Lots Affected | Expiration Date |
|---|---|---|
| | 1533-19-2133 **GEN 19, Lot 2133** | 20-NOV-2012 |
| | 1533-20-2314 **GEN 20, Lot 2314** | 11-FEB-2013 |

### Investigation Summary

Customers have reported the inability to calibrate VITROS® HPT Reagent, Lot 1533-19-2133 and Lot 1533-20-2314 due to an increase in "U91-274" condition codes. In cases of successful calibration, some customers have also reported an increase in "U91-274" condition codes that prevented results when processing patient samples and quality control fluids.

The affected lots met all release testing specifications prior to distribution. Our investigation has confirmed an increased occurrence of condition codes and calibration failures when using these lots over a period of time. Although OCD has received no complaint for biased results, our testing of the affected lots has found that as the reagent ages, a potential for biased results exists if you are able to obtain a valid calibration. Quality Control (QC) may not detect the issue. Refer to the Question and Answer section of Page 3 for additional information.

In the range of 20-64 mg/dL (0.20-0.64 g/L) an average bias of +7.9 mg/dL (+0.08 g/L) using GEN 19 and an average bias of +7.7 mg/dL (+0.08 g/L) using GEN 20 may be observed. Minimal average biases of -1.0 mg/dL (-0.01 g/L) using GEN 19 and +2.0 mg/dL (+0.02 g/L) using GEN 20 may be observed in the range of 65-229 mg/dL (0.65-2.29 g/L). In the range of 230–300 mg/dL (2.30–3.00 g/L) an average bias of -23.6 (-0.24 g/L) using GEN 19 and an average bias of +10.5 mg/dL (+0.11 g/L) using GEN 20 may be observed.

### Required Actions

This issue affects *all in-date lots of* VITROS®HPT Reagent.

***Please do the following:***

- **Immediately discontinue using and discard your remaining inventory of VITROS® HPT Reagent.**
- Complete and return the Confirmation of Receipt form upon receipt of this notification so that we can credit your account accordingly. Please return this form no later than **xx November 2012**.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action
- Forward this notification if you have provided this product outside of your facility.

## Product Availability

OCD is unable to release new product at this time or to provide you with any VITROS® HPT Reagents. We are continuing to investigate the root cause of this issue and recommend that you use an alternate method until further notice. We regret that we are unable to provide you with a timeframe for re-establishing sufficient supply levels at this time. We are making every attempt to resolve this situation as soon as possible and will notify you when replacement product is available.

We apologize for the inconvenience this will cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions, please contact Customer Technical Services at *phone*.

Sincerely,

*Insert appropriate name*
*Insert appropriate title*

## Questions and Answers

1. **What VITROS® HPT Reagent lots are affected by this issue?**

   All current lots of VITROS® HPT Reagent (Lots 1533-19-2133 & 1533-20-2314) may be affected by this issue.

2. **What is the impact to previously reported results using the VITROS® HPT assay?**

   Although OCD has had no complaints for biased results, our testing of the affected lots has found that as the reagent ages, there is a potential for biased results.

   The results of the VITROS® HPT assay or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture. Please refer to the VITROS® HPT Reagent Pack Instructions for Use for additional information and consult your Laboratory Medical Director and requesting physician to resolve any concerns you may have regarding previously reported patient results.

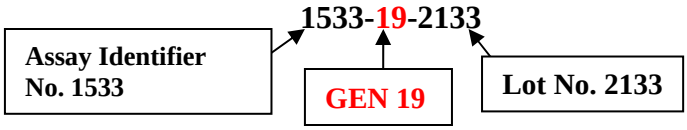
3. **What is the bias that has been observed when using VITROS® HPT Reagent?**

   If calibration is successful, our internal testing determined that biased results comparable to those summarized below could be observed. Your results may vary slightly depending upon your current system performance.

| VITROS® HPT Reagent | | | | |
|---|---|---|---|---|
| GEN | Conventional Units (mg/dL) | | SI Units (g/L) | |
| | Concentration | Average Bias | Concentration | Average Bias |
| 19 | 20-64 | +7.9 | 0.20-0.64 | +0.08 |
| 20 | | +7.7 | | +0.08 |
| 19 | 65-229 | -1.0 | 0.65-2.29 | -0.01 |
| 20 | | +2.0 | | +0.02 |
| 19 | 230-300 | -23.6 | 2.30-3.00 | -0.24 |
| 20 | | +10.5 | | +0.11 |

4. **How can I determine the lot number of VITROS® HPT Reagent in my inventory?**

   Use the example below to determine the Generation (GEN) and Lot number on the product packaging:




5. **What is OCD doing to help resolve this issue?**

   We are working to identify root cause, resolve this issue, and re-establish our inventory of VITROS® HPT Reagent. We will issue a follow up notification regarding future product availability.

6. **Will the Assay Data Disk (ADD) continue to support the VITROS® HPT assay on my system?**

   OCD will remove the VITROS® HPT assay from a future version of the ADD. In the meantime, you will continue to see the HPT assay target on your system. If you use the on board quality control program on your VITROS® System, we recommend that you perform a back up of the current quality control results. Once the ADD no longer includes HPT, you will not be able to access the HPT quality control data.

7. **Our laboratory uses VITROS® AAT Reagent. May we continue to use VITROS® Calibrator Kit 99 and VITROS® AAT/HPT Performance Verifiers with the VITROS® AAT assay?**

   Yes. You may continue to use VITROS® Calibrator Kit 99 and VITROS® AAT/HPT Performance Verifiers only when processing the VITROS® AAT assay.

# Confirmation of Receipt - Important Response Required

# URGENT FIELD SAFETY NOTICE

## Discontinuance of VITROS® Chemistry Products HPT Reagent
## Product Code: 6802214

So that we can complete our records, please return this form to us no later than **November xx, 2012**.

**FAX TO:** *insert appropriate name*
**FAX:** *insert appropriate number*

### Section I: Confirmation

I received the Urgent Product Correction Notification (Ref. CL12-283_EU) and agree to immediately discontinue using and discard VITROS® HPT Reagents remaining in my inventory.

***Please choose from the following options:***

□ My laboratory no longer uses VITROS® HPT Reagent and is not affected by this issue.

□ My laboratory uses VITROS® AAT Reagent*
**NOTE:** *You may continue to use* VITROS® Calibrator Kit 99 *and* VITROS® AAT/HPT Performance Verifiers

□ My laboratory uses VITROS® HPT Reagent and has discarded the following:

| Product Code | Product Name | Affected Lots | Quantity Discarded |
|---|---|---|---|
| 6802214 | VITROS® HPT Reagent | 1533-19-2133 | |
| | | 1533-20-2314 | |

***Please complete the information in the table below only if you do not use VITROS® AAT Reagent**

| Product Code | Product Name | Affected Lots | Quantity Discarded |
|---|---|---|---|
| 6802310 | VITROS® Calibrator Kit 99 | 9962 | |
| 6802311 | VITROS® AAT/HPT Performance Verifiers I | All in-use lots | |
| 6802312 | VITROS® AAT/HPT Performance Verifiers II | | |
| 6802313 | VITROS® AAT/HPT Performance Verifiers II | | |

*OCD will credit your account for all products that you have discarded.*

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

Your Name: _____ Job Title (optional): _____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number: _____

J Number: _____ Institution: _____

*Your comments are always welcome:*

_____

### Section II – Verification of your Name and Address

Verify your name and mailing 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: _____