Ortho Clinical Diagnostics

July 17, 2014

URGENT FIELD SAFETY NOTICE

VITROS® Immunodiagnostic Products CA19-9 Calibrators, Lot 1320 (Product Code 6800035)
VITROS® Immunodiagnostic Products CA19-9 Reagent Packs, Lot 1320 (Product Code 6800040)

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you of an Urgent Field Safety Notice involving the following products:

Product Code	VITROS® Immunodiagnostic Products	Affected Lot	Expiry Date
6800035	VITROS® Immunodiagnostic Products CA 19-9 Calibrators	1320	12- Sep-2014
6800040	VITROS® Immunodiagnostic Products CA 19-9 Reagent Pack		

Our records indicate that you were shipped the products listed above. This Urgent Field Safety Notice has been initiated due to the potential for positively biased results when using VITROS® CA 19-9 Reagent Packs, Lot 1320. **As a result of this issue, you must immediately discontinue using and discard all remaining inventory of VITROS® CA 19-9 Reagent Packs and Calibrators, Lot 1320.**

Impact to Results

VITROS® CA 19-9 Reagent Packs are used on VITROS® ECi/ECiQ Immunodiagnostic Systems, VITROS® 3600 Immunodiagnostic Systems and VITROS® 5600 Integrated Systems for the quantitative measurement of 1116-NS-19-9 defined antigen in human serum and plasma. Our internal testing confirmed positively biased results generated using VITROS® CA19-9, Lot 1320 as shown below.

VITROS®CA 19-9 Results	
Concentration Range (U/mL)	**Average Bias Observed**
≤ 37 (Reference Interval)	30%
>37	17%

Results for patient samples and proficiency samples were positively biased for Lot 1320 compared to previous lots. As a result, you must immediately discontinue using and discard all remaining inventory of VITROS® CA19-9, Lot 1320. In addition, we advise that you review all previously reported results that were generated using VITROS® CA19-9, Lot 1320.

Required Actions

- Immediately discontinue using and discard all remaining inventory of VITROS® CA19-9 Calibrators and Reagent Packs, Lot 1320.
- Review previously reported results using VITROS® CA 19-9 Reagent Packs, Lot 1320. Discuss any concerns regarding previously reported results with your Laboratory Medical Director or the requesting physician to determine the appropriate course of action.
- Complete the enclosed Confirmation of Receipt Form no later than July 24, 2014. Upon receipt of your form, OCD will credit your account or replace any product you are unable to use.
- Forward this information if you have distributed this product outside of your facility.

We apologize for any inconvenience this may cause your laboratory and are working diligently to resolve this issue. We have anticipated some questions you may have in the following Questions and Answers section. For additional information, please contact our Customer Technical Service representatives at *0800 895 963.*

Sincerely,

Commercial Services Manager

Questions and Answers

1. **What is the magnitude of the observed bias for results when using VITROS® CA 19-9 Reagent Packs, Lot 1320?**

   The average bias observed for Lot 1320 is shown below:

VITROS®CA 19-9 Results	
Concentration Range (U/mL)	**Average Bias Observed**
≤ 37 (Reference Interval)	30%
>37	17%

2. **What is the impact to my previously reported results using VITROS® CA 19-9 Reagent Packs, Lot 1320?**

   If you suspect that patient results were affected at your facility, consult with your Laboratory Medical Director or requesting physician to determine the appropriate course of action.

3. **Will this issue be detected by running Quality Control samples?**

   Quality control and proficiency samples will be similarly affected by this issue.

4. **Are other lots affected by this issue?**

   OCD is not aware of any other affected lots. Lot 1320 met all product specifications at the time of release; our data suggests that this particular lot has shifted since the time of release. We are continuing to actively investigate this issue to determine the root cause.

5. **What should I do with my current inventory of VITROS® CA19-9 Reagent Packs, Lot 1320?**

   OCD advises that you immediately discontinue using and discard all remaining VITROS® CA 19-9 Calibrators and Reagent Packs, Lot 1320. Once you return the enclosed Confirmation of Receipt form, OCD will credit your account or replace any product that you were unable to use.

Confirmation of Receipt – Response Required

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VITROS® IMMUNODIAGNOSTIC PRODUCTS CA19-9 CALIBRATORS, LOT 1320 (PRODUCT CODE 6800035)
VITROS® IMMUNODIAGNOSTIC PRODUCTS CA19-9 REAGENT PACKS, LOT 1320 (PRODUCT CODE 6800040)

Please return completed form by fax or scan to PDF and email so that we can complete our records no later than: xx-July-2014

Send to: Name e-Mail Address: email address Fax: Fax Number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2014-197_EU) regarding the potential for positively biased results when using VITROS® CA 19-9 Reagent Packs, Lot 1320.

I understand that OCD will replace my remaining inventory of VITROS® CA 19-9 Reagent Packs, Lot 1320 upon receipt of this Confirmation of Receipt form.

Please choose from the following:

☐ My laboratory does not have any VITROS® CA 19-9 Reagent Packs, Lot 1320 remaining in my inventory.

☐ My facility has the following quantity of VITROS® CA 19-9 Reagent Packs, Lot 1320 and will immediately discontinue using and discard all remaining inventory. Please indicate in the table below the number of sales units that you have discarded and indicate your choice of credit or replacement:

☐ Credit my account

☐ Send a replacement order to the address listed below.

Product name/Product Code/LOT	# Sales Units Discarded
VITROS® Immunodiagnostic Products CA 19-9 Calibrators/ Product Code 6800035/Lot 1320	
VITROS® Immunodiagnostic Products CA 19-9 Reagent Packs/ Product Code 6800040/Lot 1320	
One Sales Unit for VITROS CA 19‑9 Calibrators (Product Code 6800035) = 1 set of 1, 2, and 3 Calibrators **One Sales Unit for VITROS CA 19‑9 Reagent Packs (Product Code 6800040) = 1 Pack containing 100 Well**	

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

Your Name: _____ Signature: _____
Required if sent by fax or a scanned PDF

Phone Number: _____ Date: _____

Your Comments: _____

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____