

October 2014

IMPORTANT NOTIFICATION

VITROS® Immunodiagnostic Products Rubella IgM Reagent Packs, Lots 0740 & 0751 (Product Code 1484427)

Dear Customer,

This notification has been initiated by Ortho-Clinical Diagnostics, Inc. (OCD) due to the potential for false reactive results, when using VITROS® Immunodiagnostic Rubella IgM Reagent Packs, Lots 0740 and 0751. As a result of this issue, you must immediately discontinue using VITROS® Rubella IgM Reagent Packs and Calibrators, Lots 0740 and 0751. Our records indicate that you were shipped one or more of the affected lots listed below.

Product Code	VITROS® Immunodiagnostic Products	Lots	Expiry Date
1484427	VITROS® Rubella IgM Reagent Packs	0740	19-Nov-2014
		0751	12-Jan-2015

Impact to Results

Some customers have reported false reactive results for samples that were known to be negative when using Lots 0740 and 0751. Our internal investigation confirmed higher than expected results for patient samples that were negative or borderline when tested with VITROS® Rubella IgM Reagent Packs, Lots 0740 and 0751. The maximum bias expected from this issue is an increased signal/cutoff value (S/C) of 0.69 S/C which impacts reactive results in the range 1.20 - 1.90 (S/C) when tested using the affected lots, as the true result may be borderline or negative.

This issue may not be readily detectable unless the operator observes higher than expected results with quality control samples or a patient sample with a known result.

Required Actions

- Immediately discontinue using all remaining inventory of VITROS® Rubella IgM Reagent Packs and Calibrators, Lots 0740 and/or 0751.
- Review previously reported results that have a signal/cutoff value of 1.20 – 1.90 generated using VITROS® Rubella IgM Reagent Packs, Lots 0740 and/or 0751. Discuss any concerns regarding previously reported results with your Laboratory Medical Director or the requesting physician to determine the appropriate course of action.
- Forward this information if you have distributed this product outside of your facility.
- Complete the enclosed Confirmation of Receipt Form no later than **November 14, 2014**. Upon receipt of your form, OCD will credit your account for the product that you are unable to use.

We apologize for any inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you need additional information, please contact our Technical Support Centre representatives at **insert number**.

Sincerely,

Insert appropriate name & title

Questions and Answers

1. What is the impact to results when using VITROS® Rubella IgM Reagent Packs, Lots 0740 and/or 0751?

To aid in the diagnosis of an acute or recent Rubella infection, the IgM test result is often used in conjunction with the patient's signs and symptoms as well as history of a potential exposure to Rubella. Independent literature (i.e., Center for Disease Control Surveillance of Vaccine-Preventable Disease¹) often suggests a second blood draw 5-10 days later to retest both Rubella IgM and IgG and/or alternate test method to confirm Rubella infection for patients with an initial IgM positive result.

To date, no customer complaints have been reported to OCD indicating that patient harm have been associated with the affected lots.

2. What actions are required for previously reported Rubella IgM results?

OCD advises that you review previously reported results that have a signal/cutoff value of 1.20 – 1.90 generated using VITROS® Rubella IgM Reagent Packs, Lots 0740 and/or 0751. If you suspect that false reactive results were previously reported 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?

This issue may not be readily detectable unless the operator observes higher than expected results with quality control samples.

There may be an increase in the number of patient samples that are borderline or reactive compared to your laboratory's normal distribution may also indicate that your lot is affected. In addition, there may also be an increase in the mean S/C value for negative patient samples at your facility.

4. Are other lots affected by this issue?

Although we are continuing to actively investigate the root cause of this issue, the evidence available at this time does not indicate that other lots are affected.

5. What should I do with my remaining inventory of VITROS® Rubella IgM Reagent Packs, Lots 0740 and/or 0751?

Please discard all VITROS® Rubella IgM Reagent Packs and Calibrators and all previously opened, partial reagent packs from Lots 0740 and/or 0751. Once we receive the enclosed Confirmation of Receipt form, OCD will credit your account for any product that you were unable to use.

¹ <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt14-rubella.html>

Confirmation of Receipt – Response Required

Communication ID: CL2014-281

Date of Issue: 31-Oct-2014

IMPORTANT NOTIFICATION

Ortho Clinical Diagnostics

VITROS® Immunodiagnostic Products Rubella IgM Reagent Packs, Lots 0740 & 0751 (Product Code 1484427)

Please return completed form by **fax or scan to PDF** and email so that we can complete our records no later than: **14-November-2014**

Send to: **Insert name**e-Mail Address: **insert email**Fax: **insert number**

Please Confirm

I received the Important Notification (Ref. CL2014-281) regarding the potential for false reactive results, when using VITROS® Rubella IgM Reagent Packs, Lots 0740 and 0751. I understand that OCD will credit my account for my remaining inventory of VITROS® Rubella IgM Reagent Packs, Lots 0740 and/or 0751, upon receipt of this Confirmation of Receipt form.

Please choose from the following:

- My laboratory does not have any VITROS® Rubella IgM Reagent Packs, Lots 0740 or 0751 remaining in inventory.
- My facility has the following quantity of VITROS® Rubella IgM Reagent Packs, Lots 0740 and 0751 remaining in inventory. Please indicate in the table below the number of sales units of reagent packs and calibrators that you are unable to use.

Product Name/Product Code/LOT	# Sales Units
VITROS® Immunodiagnostic Products Rubella IgM Reagent Packs/Product Code 1484427/Lot 0740	
VITROS® Immunodiagnostic Products Rubella IgM Calibrator/Product Code 8017600/Lot 0740	
VITROS® Immunodiagnostic Products Rubella IgM Reagent Packs/Product Code 1484427/Lot 0751	
VITROS® Immunodiagnostic Products Rubella IgM Calibrator/Product Code 8017600/Lot 0751	

One Sales unit for VITROS Rubella IgM Reagent Pack (Product Code 1484427) = 100 Wells

One Sales unit for VITROS Rubella IgM Calibrator (Product Code 8017600) = 1 VITROS Rubella IgM Calibrator

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

Your Name: _____

Signature: _____

Phone Number: _____

Date: _____

Required if sent by
fax or a scanned PDFYour Comments: _____

Your Name and Address

Please complete this section

Institution/
Contact Name: _____

Address: _____

City: _____

State/Prov: _____

Zip/Postal Code: _____

Phone: _____

Fax: _____

e-Mail: _____