URGENT

Ortho Clinical Diagnostics

Month DD, 2022

URGENT FIELD SAFETY NOTICE

Potential For False Repeat Reactive Results and False Negative Results Reported Using VITROS® Immunodiagnostic Products HIV Combo Reagent Pack

Dear Valued Customer,

The purpose of this notification is to inform you that Ortho Clinical Diagnostics has become aware of issues affecting VITROS Immunodiagnostic Products HIV Combo Reagent Pack, with certain lots having the potential to report false repeat reactive and false negative results. As a result, discontinue using and discard the affected lots listed below.

Note: Ortho's investigation is ongoing for the issues described in this communication and root cause has not yet been determined. We are proactively sending this communication to all customers who were shipped VITROS HIV Combo Reagent Packs.

Name	Product Code (Unique Device Identifier)	Affected Lots	Expiry
VITROS® Immunodiagnostic Products HIV Combo Reagent Pack	**6842779** (10758750031061)	0660	15-Sep-2022
		0670	15-Oct-2022
		0730	24-Feb-2023
VITROS® Immunodiagnostic Products HIV Combo Calibrators	**6842780** (10758750031078)	0740	21-Mar-2023
		0750	07-Apr-2023
		0760	20-Apr-2023

Intended Use: For the simultaneous qualitative detection of antibodies to Human Immunodeficiency Virus types 1, including group M and O, and/or 2 (anti-HIV-1 and anti-HIV-2) and HIV p24 antigen in human serum and plasma (heparin and EDTA) in adults, pregnant women, adolescents and children, using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

The results of the VITROS HIV Combo test, in conjunction with other serological evidence and clinical information, may be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in persons at high and low risk for HIV infection and as a screening test for the detection of HIV-1 and/or HIV-2 in blood donors.

Issue / Investigation Summary

Scenario 1:

Ortho received a customer complaint for false negative results generated from VITROS HIV Combo Reagent Pack, Lot 0670, when testing a proficiency sample identified to be reactive for the presence of HIV-1 p24 antigen and absent of antibodies to HIV (p24 antigen positive). Ortho's investigation confirmed this issue and identified five additional lots of VITROS HIV Combo Reagent Pack that also generated false negative results when tested using the same HIV-1 p24 positive sample. For this scenario, to date, Ortho's investigation has shown that this issue is limited only to HIV-1 p24 antigen detection and does not affect the antibody detection of anti-HIV-1 or anti-HIV-2 in VITROS HIV Combo Reagent Pack.

As of August 26, 2022, Ortho has received two confirmed reports regarding this issue.

Issue / Investigation Summary (continued)

Scenario 2:

During the investigation in Scenario 1, Ortho received complaints related to repeat reactive results for VITROS HIV Combo Reagent Pack. Ortho confirmed that known negative samples could produce reactive results. Ortho's data demonstrates a correlation to the same lots implicated in Scenario 1.

As of August 26, 2022, Ortho has received 136 confirmed reports regarding this issue.

Impact To Results

Scenario 1:

When used to screen donor samples for transfusion, VITROS HIV Combo Reagent Pack generating false negative results may not detect HIV from a donor with early HIV infection before seroconversion has occurred, which can lead to the transmission of HIV infection to blood recipients through the infected blood.

VITROS HIV Combo Reagent Pack generating false negative results may indicate to an individual with early acute HIV infection that they do not have an HIV infection, putting themselves and others they may come into contact with at risk. For pregnant women, if early acute HIV infection is not detected, there is an increased chance to transmit the infection to the fetus.

Scenario 2:

False repeat reactive results for an HIV negative patient will increase the burden of additional tests and may cause undue stress to the donor and/or the patient.

In circumstances where VITROS HIV Combo Reagent Pack is utilized in screening blood donor samples for transfusion, repeat false reactive results may cause deferral of the donation and the donor.

REQUIRED ACTIONS

- Immediately discontinue using and discard your remaining inventory of affected VITROS HIV Combo Reagent Pack and linked Calibrator lots listed above. Ortho will replace or credit your account. Indicate quantities to be replaced or credited via the Confirmation of Receipt form.
- Refer to the "*Interpretation of Results"* section of the Instructions for Use to ensure your laboratory performs the appropriate supplemental testing to confirm reactive results.
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2022**.
- Please forward this notification if the affected product was distributed outside of your facility.
- Save this notification with your user documentation or post this notification by each VITROS ECi/ECiQ/3600/5600/XT 7600 System until further notice.
- If your laboratory has experienced this issue with VITROS HIV Combo Reagent Pack and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

REQUIRED ACTIONS (CONTINUED)

- If your laboratory has concerns about previously reported results, discuss any concerns you may have with your Laboratory Medical Director to determine the appropriate course of action. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests.

Resolution

Ortho's investigation is ongoing, and we are monitoring newly manufactured lots for the presence of this issue. Additional information will be issued once root cause is determined.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care Technical Solutions Center at Insert Phone Number.

Insert signatory if applicable

Questions and Answers

1. **Can I continue using the affected lots of VITROS HIV Combo Reagent Pack until a replacement arrives?**

   No. If your laboratory is using any of the affected lots listed at the beginning of this communication, customers are advised to immediately discontinue using and discard the affected lots. Ortho will credit or replace your discarded inventory.

2. **How do I know the replacement lot I receive will not be affected by this issue?**

   Ortho has identified certain factors that may correlate to this issue, and we are monitoring newly manufactured lots for this occurrence.

3. **Will my QC detect this?**

   No. This issue cannot be detected by performing routine Quality Control testing.

4. **How soon can I expect replacement?**

   As soon as we receive your Confirmation of Receipt form, a replacement order will be processed as quickly as possible. Product is on allocation to ensure availability for all customers.

Confirmation of Receipt – Response Required

Communication ID: CL2022-227_EU Date of Issue: DD-MON-2022

URGENT FIELD SAFETY NOTICE

Potential For False Repeat Reactive Results Generated from VITROS® Immunodiagnostic Products HIV Combo Reagent Pack
Lots 0660, 0670, 0730, 0740, 0750, 0760 (Product Code 6842779)

*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **DD-MON-2022**

Send to: **Name** e-Mail Address: Email address Fax: Fax number

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: _____

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2022-227_EU) regarding the potential for false repeat reactive results and false negative results to be reported using certain lots of VITROS® Immunodiagnostic Products HIV Reagent Combo Pack.

Please choose from the following:

- ☐ My laboratory has not received VITROS® Immunodiagnostic Products HIV Combo Reagent Pack and therefore is not affected by this issue.
- ☐ My laboratory uses VITROS® Immunodiagnostic Products HIV Combo Reagent Pack but does not have any affected lots remaining in inventory.
- ☐ My laboratory has the affected lot(s) of VITROS® Immunodiagnostic Products HIV Combo Reagent Pack. I have discontinued using and discarded the quantity listed in the table below.
- ☐ My laboratory has the affected lot(s) of VITROS® Immunodiagnostic Products HIV Combo Calibrator. I have discontinued using and discarded the quantity listed in the table below.

Please indicate your choice of credit or replacement:

- ☐ Credit my account (Credit only will be issued for discarded partial sales units, credit can also be issued for discarded full sales units.)
- ☐ Send a replacement order for the number of discarded full sales units to the address listed above. (We can ship full sales units only.)

For reference: One Sales Unit for VITROS® Immunodiagnostic Products HIV Combo Reagent Packs (Product Code 6842779) = 1 Pack containing 100 wells. One Sales Unit for VITROS® Immunodiagnostic Products HIV Combo Calibrators (Product Code 6842780) = 1 box containing 1 set of calibrators.

Product Name / Product Code / Enter LOT	Quantity of Full Sales Units Discarded (unopened)	Quantity of wells remaining in partially used (opened) Packs
VITROS® Immunodiagnostic Products HIV Combo Reagent Packs / 6842779 /		
VITROS® Immunodiagnostic Products HIV Combo Reagent Packs / 6842779 /		
VITROS® Immunodiagnostic Products HIV Combo Calibrator/ 6842780 /		
VITROS® Immunodiagnostic Products HIV Combo Calibrator/ 6842780 /		

Print Name: _____

Signature: Required
Your signature confirms that you have received and understand this communication.

Phone Number: _____ Date: _____

Your Comments: _____