



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.



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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



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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.