

April 2024

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**VITROS® Immunodiagnostic Products HIV Combo Control (HIV p24 Antigen) Not Stable Up To 13 Weeks When Stored at 2-8°C**

Dear Valued Customer,

This notification is to inform you that QuidelOrtho™ has confirmed an issue involving the performance of VITROS® Immunodiagnostic Products HIV Combo Control (HIV p24 Antigen), not meeting the stability specifications defined in the Instructions For Use (IFU).

Affected Product	Product Code (Unique Device Identifier)	Affected Lots*	Expiry
VITROS Immunodiagnostic Products HIV Combo Control (HIV p24 Antigen)	691 2257 (10758750033140)	90	04-Jan-2024
		100	23-Jan-2024
		120	26-Mar-2024
		130	28-May-2024
		140	18-Jun-2024
		150	26-Jul-2024
		160	13-Sep-2024
		170	08-Oct-2024
		180	08-Nov-2024
		190	01-Jan-2025
		200	27-Jan-2025
		210	14-Feb-2025

**\*Until further notice, future lots are also affected by this issue.**

**Summary**

QuidelOrtho has received complaints of failed Quality Control (QC) testing, with results below the expected 2SD range, when using the above listed lots of VITROS HIV Combo Control (HIV p24 Antigen).

Our investigation found that, when thawed and stored at 2-8°C, VITROS HIV Combo Control (HIV p24 Antigen) does not maintain stability up to 13 weeks as defined in the IFU and will experience a signal reduction and decrease in performance over time.

The IFU states that once thawed and opened, VITROS HIV Combo Control (HIV p24 Antigen) can maintain stability through 7 freeze-thaw cycles for up to 13 weeks. However, due to this issue, QuidelOrtho can only assure stability for up to 1 freeze-thaw cycle after the initial thaw.

**Until further notice, please implement one of the following options:**

1. Store unopened vials of VITROS HIV Combo Control (HIV p24 Antigen) at  $\leq -20^{\circ}\text{C}$ . Store thawed vials at  $2-8^{\circ}\text{C}$ , use within 24 hours after thawing and discard.

**OR**

2. Store unopened vials of VITROS HIV Combo Control (HIV p24 Antigen) at  $\leq -20^{\circ}\text{C}$ . Thawed vials can be re-frozen *once* and stored at  $\leq -20^{\circ}\text{C}$  for up to 13 weeks. After 1 freeze-thaw cycle, store thawed vials at  $2-8^{\circ}\text{C}$ , use within 24 hours after thawing and discard.

**OR**

3. Store unopened vials of VITROS HIV Combo Control (HIV p24 Antigen) at  $\leq -20^{\circ}\text{C}$ . Subaliquot a thawed vial into multiple sample containers and store the subaliquots at  $\leq -20^{\circ}\text{C}$  for up to 13 weeks. After 1 freeze-thaw cycle, store thawed subaliquots at  $2-8^{\circ}\text{C}$ , use within 24 hours after thawing and discard.

**Impact to Results**

Decreased performance of VITROS HIV Combo Control (HIV p24 antigen) due to signal reduction from long-term storage at  $2-8^{\circ}\text{C}$  may cause QC results to drift lower than the target mean value, resulting in QC failure. Troubleshooting or investigating the cause of failure may result in potential delay in patient sample testing or result reporting. In most cases, a delay would not pose a health risk to the patient. In urgent situations, the lack of an HIV test result would be unlikely to postpone a lifesaving procedure. Serious health risk due to this issue is not anticipated.

In rare cases, a falsely elevated p24 signal in patient samples (due to sub-optimal calibration or reagent bias) may be missed due to a reduced HIV p24 antigen control signal that was inappropriately accepted due to being within range when the control should have been low. Such a patient result will be discordant with an HIV antibody test result in an HIV antibody-positive patient. Per the IFU and clinical guidelines, a reactive result would go through a confirmation test, such as an RNA test. In this scenario, there is no risk of serious patient injury.

QuidelOrtho does not recommend a review of previously reported QC results generated using VITROS HIV Combo Control (HIV p24 antigen), or associated patient results, due to the unlikelihood of significant impact on patient management that may result in serious adverse patient effects.

**REQUIRED ACTIONS**

- VITROS HIV Combo Control (HIV p24 Antigen) should not be stored long-term at 2-8°C. Long-term storage is defined as longer than 24 hours.
- Select and implement Options 1, 2, or 3 detailed in the Summary section above.
- Complete the enclosed Confirmation of Receipt form no later than **10 May 2024**.
- Save this notification with your User Documentation or post this notification near your laboratory's storage area until the issue has been resolved.
- Please forward this notification if the affected product was distributed outside of your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your QuidelOrtho representative or our local Global Services Organisation.

**Resolution**

QuidelOrtho's investigation is on-going, and we are currently working to identify root cause. We will communicate again after root cause has been determined and the issue has been resolved.

**Contact Information**

We apologise for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Global Services Organisation.

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)

*Enclosure: Confirmation of Receipt form (Ref. CL2024-109\_Conf)*

## Questions and Answers

**1. What is the sample volume I should use when creating a subaliquot?**

As each VITROS® System may require a different sample volume, refer to your VITROS® System Reference Guide or Operator's Manual to determine the appropriate sample volume for the sample containers used by your laboratory.

**2. Are new lots of VITROS HIV Combo Control (HIV p24 Antigen) not listed in this communication affected by this issue?**

Yes, until further notice, all future released lots are also affected by this issue.

**3. Are the other VITROS Immunodiagnostic Products HIV Combo Controls affected by this issue?**

No, this issue affects *only* the HIV p24 Antigen Control. All other VITROS Immunodiagnostic Products HIV Combo Controls perform as intended with no impacts to storage or stability.

**4. How long can subaliquots be stored at  $\leq -20^{\circ}\text{C}$ ?**

Subaliquots of VITROS HIV Combo Control (HIV p24 Antigen) can be stored at  $\leq -20^{\circ}\text{C}$  for up to 13 weeks.