



IMPORTANT

Ortho Clinical Diagnostics

August 2017

IMPORTANT PRODUCT CORRECTION NOTIFICATION VITROS® Immunodiagnostic Products Signal Reagent

Product	Product Code	Affected Lots	Expiry Date
VITROS® Immunodiagnostic Products Signal Reagent	1072693	4492 & Above	13-AUG-17 & Later*
*Until this issue is resolved, all future lots may be affected.			

Dear Customer,

Ortho Clinical Diagnostics updated the reagent pack (i.e., bottle) for VITROS Signal Reagent, beginning with Lot 4492. Some customers reported that their VITROS 3600 or 5600 System cannot detect the presence of the VITROS Signal Reagent pack when using Lot 4492 or above.

VITROS Signal Reagent is used for the generation of the luminescence signal on VITROS ECi/ECiQ Immunodiagnostic Systems, VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System.

Investigation

Our investigation determined that the sensors may not detect the base of the updated VITROS Signal Reagent Packs due to a larger indentation at the base of the reagent pack.

As a result, some VITROS 3600 or 5600 Systems may not be able to reliably detect VITROS Signal Reagent Packs in the load positions or during testing at the in-use position.

NOTE: VITROS ECi/ECiQ Systems are not affected.

Impact to Results

If the sensor cannot detect the base of the pack, that pack cannot be used to process samples. Refer to page two for information regarding associated condition codes.

Resolution

Ortho is working with our supplier to change the indentation of the bottle. Upon completion of the validation testing, we will implement the change in future lots. In the interim, Ortho has created a modification (MOD) C3 to adjust the sensors allowing the reagent pack to be detected by the system.

- If you have previously reported this issue, an Ortho trained service representative will contact you to schedule the installation of MOD C3.
- If you have experienced the issue but have not contacted Ortho, please indicate this on your Confirmation of Receipt form.
- If this issue occurs in the future, contact Ortho at any time to request MOD C3.

REQUIRED ACTIONS

- If your VITROS 3600 or 5600 System cannot detect the presence of VITROS Signal Reagent Packs, contact our Ortho Care™ Technical Solutions Centre for immediate assistance. An Ortho trained service representative will contact you to schedule the installation of MOD C3.
- Complete the enclosed Confirmation of Receipt form no later than **August 25, 2017**.
- Please forward this notification if the affected lots were distributed to a different location.

Contact Information

We apologize for the inconvenience that this may cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Sincerely,



Jon Wong, QA Manager

QUESTIONS AND ANSWERS

1. What condition codes are associated with this issue?

If the issue occurs, the system reports that a full or partially full VITROS Signal Reagent pack is unusable.

The following condition codes may be associated with this issue; however, these codes may also occur for other situations including normal operating conditions.

If you are experiencing an increase in these codes and/or an unexpected loss of signal reagent inventory on your system, you may require MOD C3.

Condition Code	Text Displayed
PU1-226	No Signal Reagent reserved for %s; %s; %s/%d
PVG-026	Insufficient SR volume to complete tests.
SBB-015	SR pack at scan cannot be used.
SBB-020	A usable SR pack is not available for pack change.
SB9-017	The SR Pack at metering is not valid.
NOTE: Additional codes may also occur.	

2. When does this issue occur?

When the issue occurs, the sensor may not be able to reliably detect VITROS Signal Reagent packs in the load positions or during testing at the in-use position.

3. What if I am not experiencing any condition codes now but they occur in the future?

If this issue occurs in the future, contact Ortho to request MOD C3 by contacting our Ortho Care Technical Solutions Centre or submitting the Confirmation of Receipt form.