



April 26, 2021

URGENT FIELD SAFETY NOTICE

**VITROS® Black Reference Slides with Incorrect Part Number on Box
Potentially Leading to Incorrect Part Being Received**

Dear Customer,

VITROS® Black Reference Slides are used to calibrate the reflectometer of the VITROS® 250/350 Chemistry System. As part of a Field Safety Corrective Action, this notification is to inform you that some sales units of two lots of the VITROS® Black Reference Slides have the incorrect part number on the box. The correct part number should be J02316. The impacted boxes are labeled J02315, which is the part number for VITROS® White Reference Slides. This may have led to your facility receiving VITROS Black Reference Slides in place of VITROS White Reference Slides in your order. All other information on the box is correct, including the associated correction values.

Affected Product	Product Code (Unique ID No.)
VITROS® 250 Chemistry System	8132086 (10758750004409)
VITROS® 250AT Chemistry System	1758143 (10758750000036)
VITROS® 250 Chemistry System Refurbished	6801759 (10758750001330)
VITROS® 350 Chemistry System	6802153 (10758750002054)

Impacted Part Number	Impacted Part Description	Lot Number	Expiration
J02316	VITROS® Black Reference Slides	9252-0058-3361 9252-0058-3362	2022-10-01
VITROS Black Reference Slides are used with VITROS® 250/350 Chemistry Systems only.			

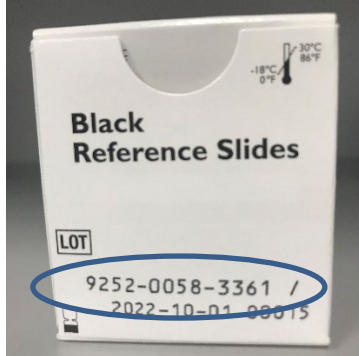
Note: not all boxes of the lot numbers above are affected.

Impact to Your Facility

The two lots VITROS Black Reference Slides listed above were incorrectly labeled with the part number of VITROS White Reference Slides (J02315).

All other information on the VITROS Black Reference Slide box is correct, including the associated correction values and, therefore, the VITROS Black Reference Slides are suitable for use as intended.

Lot No.



Incorrect
Part No.



If your facility received an affected lot of VITROS Black Reference Slides with the incorrect part number in place of the VITROS White Reference Slides in your order, your facility may not have the expected inventory of VITROS White Reference Slides. This could cause a delay in completing routine maintenance, which may temporarily prevent results from being reported until this part is shipped to and received by your facility.

Note: If you received an affected lot of VITROS Black Reference Slides with the correct part number, no further action is required.

REQUIRED ACTION

- Review your inventory of both VITROS Black/White Reference Slides and, depending on the VITROS System(s) you have in your laboratory, ensure you have sufficient inventory of the appropriate parts.
- **If you received affected product and have not already received replacement**, indicate this on your Confirmation of Receipt form and destroy the affected product. Ortho will replace your affected VITROS Black Reference Slides with VITROS White Reference Slides.
- Complete the enclosed Confirmation of Receipt form no later than **May 05, 2021**.
- Please forward this notification if the product was distributed outside of your facility.

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 0800 895 963.

Ricardo Escolá

Senior Manager Quality, Regulatory & Compliance