URGENT

Ortho Clinical Diagnostics

Month XX, 2020

URGENT FIELD SAFETY NOTICE

Potential for Erroneous Results Due to Incorrect Placement of Reagent Bottles for VITROS Anti-SARS-CoV-2 Assays Reagent Pack

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information regarding the potential for erroneous patient sample results, calibration errors and QC failures with some reagent packs of VITROS Anti-SARS-CoV-2 Total assay.

Affected Product Name	Product Code (Unique Identifier)	Lot No.	Expiry Dates
VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent	**6199922** (10758750033386)	**0010 - 0037**	**08-Oct-20 to 23-Dec-20**

Note: No other lots are affected.

Description of Issue

- Ortho internally identified a VITROS Anti-SARS-CoV-2 Total Reagent Pack in which the reagent bottles were swapped within the reagent pack. When this occurs, all reported results for that pack are affected.
- Ortho used VITROS e-Connectivity® technology to review field data, which indicates approximately 0.06% of packs were affected.
- **No other VITROS assays are affected**.

Impact to Results

If the two reagent bottles are switched in their positions, the correct reaction scheme does not occur. This can result in:

- False negative results for a sample that is reactive.
    - False negative serology test results can lead to an incorrect assessment that the tested person has not had an adaptive immune response to SARS-CoV-2 and has not had recent or prior infection with SARS-CoV-2, which may lead to a restriction of activities potentially deemed acceptable for individuals with evidence of an antibody response to SARS-CoV-2. A false negative serology test result may also lead to additional unnecessary diagnostic evaluations, and in the context of the current public health emergency, incorrect serological test results could negatively impact the effectiveness of infection control activities.
- Calibration failures, if the affected pack is used during calibration. This could lead to a delay in testing.
- Quality Control failures for the Reactive control, if the affected pack is used for testing quality control samples. This could lead to a delay in testing or releasing results.

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.

Re-evaluate previous negative results that were not consistent with clinical symptoms or other test results. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Resolution

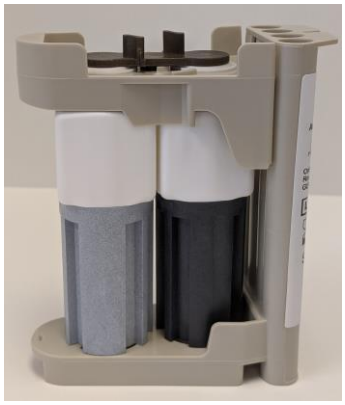
VITROS Anti-SARS-CoV-2 Total Reagent Packs are now manufactured on our automated line with automated digital quality controls that prevent this issue from occurring in the future.

REQUIRED ACTIONS

- Visually inspect affected VITROS Anti-SARS-CoV-2 Total Reagent Packs, Lots 0010-0037, to ensure correct reagent bottle configuration.

✓

CORRECT CONFIGURATION
black bottle near wells



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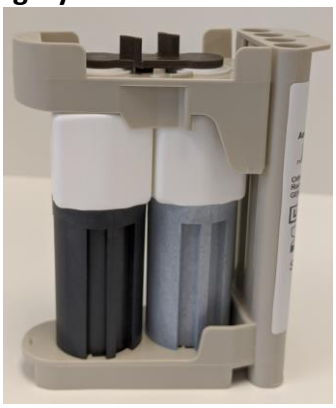
INCORRECT CONFIGURATION
grey bottle near wells



- Set aside any pack in which the reagent bottles are positioned incorrectly, so the lot number and pack id can be provided to Ortho. Complete and submit the enclosed Request for Credit Form, including the pack information, to receive credit for an affected pack.
- Complete the Confirmation of Receipt form no later than **Month XX, 2020.**
- Post this notification by each system that processes an affected lot.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact Ortho Care Technical Solutions Center at insert number.

Insert signatory if appropriate in your region.

Enclosure:
Request for Credit Form