



URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

ORTHO Optix™ Reader Displaying Incorrect QC Status When Using Multiple Quality Control Kits

Dear Customer,

This notification provides important information regarding incorrect Quality Control (QC) status displayed on the ORTHO Optix™ Reader software when using multiple QC kits.

Affected Product Name	Product Code (Unique Device Identifier)
ORTHO Optix™ Reader – BioVue with Software Version 1.0.0 and above	6842223 (10758750032853)

Issue Description

Ortho Clinical Diagnostics received a complaint regarding an incorrectly displayed passing QC status for a test (see example in table below), without the site having processed the multiple QC kits configured for the test.

Ortho confirmed that any test processed with multiple QC kits may encounter this issue. If one QC kit out of the multiple QC kits configured for the test has successfully passed, the software will automatically assign a passing QC status to the test even if the other QC kit configured for the test is not run or does not pass.

Below is an example of a test that may requires multiple kits.

Test Name	Assay	Analysis	Require Minimum Multiple Kits
Newborn	Anti-A, Anti-B, Anti-A+B, Anti-D, Control, IgG	ABO, Rh, IgG	<u>Scenarios Where Issue Occurs</u> - Ortho Confidence Whole Blood & non-Ortho samples - Non-Ortho samples configured across two QC kits

Impact to Results

Please Note: If multiple QC kits are used for a test and all samples in each QC kit receive a passing QC result, then the system provides the accurate passing QC status.

The premature passing status of the QC kit could cause a site to miss the detection of defective reagents leading to erroneous test results which may lead to potential incompatible transfusion.

To date, no patient impact was reported associated with this product issue.

Ortho recommends a lookback on QC results on the ORTHO Optix Reader with software version 1.0.0 and above for systems with the following configuration:

- 1) The QC feature is enabled.
- 2) One or more tests are enabled for Method Based Control (MBC) QC.
- 3) Multiple QC kits are configured for use at the same time.



4) A test enabled for MBC QC is configured to use more than one QC kit to control for the test.

For systems with this configuration, the lookback should review QC results for tests that are configured to use more than one QC kit to control for the test. During the review, ensure all QC samples for tests meeting the criteria have been processed successfully.

Discuss any concerns you may have regarding previously processed QC kits that potentially meet this failure mode and any patients tested associated to that QC with your Laboratory Medical Director to determine the appropriate course of action.

Investigation

Upon investigation it was determined this issue is due to an anomaly in the current design of the System's QC software.

Workaround

To avoid the QC software anomaly if the Optix Reader is configured as described in this letter (now or in the future) user must create a single QC Kit containing all necessary QC samples and complete QC testing using a single QC kit prior to testing patient samples.

Please contact your local OrthoCare representative for guidance on how to set up a Single QC Kit.

Resolution

Ortho is dedicated to providing a resolution to this issue in a future software update for the ORTHO Optix™ Reader.

REQUIRED ACTION

- To avoid the QC software anomaly if the Optix Reader is configured as described in this letter (now or in the future) user must create a single QC Kit containing all necessary QC samples and complete QC testing using a single QC kit prior to testing patient samples. Please contact your local OrthoCare representative for guidance on how to set up a Single QC Kit.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY**.
- Please forward this notification if the affected 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 **insert number**.

Insert signatory if required in your regions

Enclosure: Confirmation of Receipt Form