

26 April 2022

Biomedical Data Solutions are writing to inform of an**URGENT FIELD SAFETY NOTICE****ORTHO CONNECT™ Displaying Incorrect QC Status When Using Multiple Kits**

This notification provides important information regarding the Quality Control (QC) status displayed on ORTHO CONNECT™ software version 3.0 and above when using multiple QC kits.

Affected Product Name	Product Code
ORTHO CONNECT Enterprise Single Instrument BioVue	6904413
ORTHO CONNECT Enterprise Multi Instrument BioVue	6904414
ORTHO CONNECT Enterprise Version Upgrade BioVue	6904415

Identified Issue

It has been identified that an end user site had attempted to perform QC on a single test using multiple QC kits.

The Quality Control module was not designed to support testing of multiple QC Kits for a single Test, and it is required that all QC Samples used to validate a Test are contained in a single QC Kit in ORTHO CONNECT™.

If a test is processed across multiple QC kits, the QC Status will be based on the results of only a single QC Kit – if a single QC Kit has a passing QC status, the status will be considered as passing for the Test.

It is noted that in practice, labs use Ortho QC kits (for example, Ortho Confidence) which bundle the results, so one kit can be used to cover multiple analyses.

Below is an example of a test that contains analysis results that are not able to be fully QC checked by a single Ortho QC kit.

Test Name	Assay	Analysis
Newborn Cassette Test	Anti-A, Anti-B, Anti-A+B, Anti-D, Control, IgG	ABO, Rh, IgG

Impact to Results

If a test is processed across multiple QC kits, the QC Status will be based on the results of only a single QC Kit – if a single QC Kit has a passing QC status, the status will be considered as passing for the Test.

This could lead to incorrect QC status being applied to patient samples if:

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- a QC Kit for a test **fails** validation,
- and a second QC Kit for the same test receives a passing validation,

the passing validation from the second QC Kit would be applied to patient samples, even though the first kit received a failing result.

Additionally, if multiple QC kits are configured a passing status will be determined based on the results of a single QC Kit.

For example;

- QC Kit for a test **passes** validation,
- and a second QC Kit is **not run**,

this would result in a **passing** QC status being reported.

To date, no patient harm has been reported associated with this product issue.

Investigation

Upon investigation it was determined that the software is behaving as per the intended design of the QC software system. However, the software does not prevent configuration of multiple QC kits for one test and does not force all analysis for the test to be covered by the samples in the QC kit.

Workaround

In order for tests to be QC checked properly, QC samples must exist in a single QC kit that contain all analysis results required for the test.

For the specific tests noted above, since these results are not contained in a single ORTHO QC kit, a single user defined kit must be created in order to process these tests.

Please ensure good practices are followed to verify all components of the required QC are passing prior to performing tests.

Resolution

A resolution to this issue is being provided in a future software update for ORTHO CONNECT™

Required Action

To satisfy global requirements for regulatory reporting, please complete and return the accompanying form within 10 business days of receipt and email to QAG@Biomedical-DS.com

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Contact Information

If you require further information or assistance with this notification, please contact:

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