Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **User Defined Test Templates on ORTHO VISION® and VISION Max Analyzers with Software Version 3.6.0 and Below** **Immediate Action Required**

Date Issued 23 November 2016

Issue

Ortho Clinical Diagnostics (Ortho) is issuing this Urgent Field Safety Notice because Ortho confirmed that if incubation time parameters are changed when creating a User Defined Protocol (UDP) test, then the incubation time of the Ortho test template and other UDP tests created from the same test template may change. The system will update the incubation time with the latest selection for all UDPs that use the same template, and will also update the Ortho test template, as described in the example below:

- UDP Test 1 is defined with the *Ortho test 08 ABScr Surg Poly*, and the minimum incubation time parameter is set at the default time of **15 minutes**.
- An additional UDP, UDP Test 2, is subsequently defined with the same *Ortho test 08 ABScr Surg Poly,* and the minimum incubation time is set to **30 minutes**.
- The minimum incubation time for UDP Test 1 and the template test *Ortho test 08 ABScr Surg Poly* is unexpectedly changed by the system software to the default time of **30** minutes (i.e., the minimum incubation time parameter of UPD Test 2). The user is not notified of the change.

The incubation time parameters will reset back to the values from the Assay Data Disk (ADD) for the Ortho test template and the associated UDPs will be reset to the original validated parameters during restart of the analyzer.

Product

Product Name	Product Code	Software Version
ORTHO VISION® Analyzer for ORTHO BioVue® Cassettes	6904579	3.6.0 and Below
ORTHO VISION® Max Analyzer for ORTHO BioVue® Cassettes	6904578	3.6.0 and Below

Impact to Results

The unintentional change to the UDP assay incubation time parameter on the Ortho VISION and VISION Max Analyzer may cause over- or under-incubation for tests, potentially leading to false positive or false negative test results. The affected UDP assays may include antibody screening and identification tests, DAT, antigen typing, as well as Ortho Sera (IgG) or other Antisera tests.

Required Actions

- After adjusting the incubation time parameters of a UDP test, make sure to restart the system prior to processing samples so that the incubation time parameters will reset back to the values from the Assay Data Disk (ADD) for the Ortho test template and the associated UDPs will be reset to the original validated parameters during restart of the analyzer.
- Post this notification by your ORTHO VISION Analyzer or with your user documentation.
- Complete and return the Confirmation of Receipt form by **6th December 2016**.

Resolution

This issue will be addressed in software version 4.8.0 (MOD 16) that is targeted to be released by year end 2016.

Contact Information	Please contact your Ortho Care™ Technical Solutions Center at **+33 388 65 4763** if you have further questions or require additional information. Fergal Connolly Barbara Riall