Ortho Clinical Diagnostics

<mark>xx May 2015</mark>

URGENT FIELD SAFETY NOTICE

Software Anomaly Affecting User Defined Protocol Feature on ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes

Dear Valued Customer,

As part of a Field Safety Corrective Action, this notification is to inform you of an Urgent Field Safety Notice involving the following product:

Affected System	Affected Software Version	Product Code
ORTHO VISION™ Analyzer	1.0.4	6904579

Description of the Issue

Ortho-Clinical Diagnostics, Inc. (OCD) has identified an anomaly in ORTHO VISION™ Analyzer software that may occur when an operator modifies an assay column name when using the User Defined Protocol (UDP) feature. When a User Defined Protocol (UDP) is created, if the operator modifies the cassette selection and changes the column names in the UDP test, under specific conditions the column name for the test template may get changed until the system is restarted. After the system is restarted, the name that was modified by the operator will be cleared and the column name of the test template will return to the default configuration for the standard assay template.

Impact to Results

If a result is reported solely based on a column result of a test template affected by this issue using the Graphical User Interface (GUI) or Order Report, an erroneous test result could be reported.
To date, no customer complaints or patient injury due to this issue have been reported to OCD.

Resolution

This issue has been resolved in ORTHO VISION™ Analyzer Software Version 1.2.10, which will be released imminently. The UDP feature should not be used until Software Version 1.2.10 is installed and validated according to your local requirements.

Actions Required

- Do not use the User Defined Protocol (UDP) feature of your ORTHO VISION™ Analyzer until Software Version 1.2.10 is installed and validated according to your local requirements.

- Complete and return the Confirmation of Receipt form no later than <mark>**May xx, 2015**</mark>.

- Post this notification by each ORTHO VISION™ Analyzer or with the user documentation.

We sincerely apologize for the inconvenience this may cause your laboratory. If you have any additional questions, please contact Customer Technical Services at <mark>*insert appropriate number.*</mark>

Sincerely,

<mark>Insert appropriate name</mark>
<mark>Insert appropriate title</mark>

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