Ortho Clinical Diagnostics

March 2015

URGENT PRODUCT CORRECTION NOTIFICATION

Anomaly using Software Version 1.0.4 on the ORTHO VISION™ Analyser for ORTHO BioVue® Cassettes

Dear Valued Customer,

This notification is to inform you of an Urgent Product Correction involving the following product:

Affected System	Affected Software Version	Product Code
ORTHO VISION™ Analyser for ORTHO BioVue® Cassettes	1.0.4	6904579

Description of the Issue

Ortho-Clinical Diagnostics, Inc. (OCD) has identified an anomaly in ORTHO VISION™ Analyser for ORTHO BioVue® Cassettes software. Internal testing confirmed that it is possible for an operator to enter two different sets of patient information to be associated with the same Sample ID. As an example:

1. Sample ID **#101** was assigned patient information for Patient Name #1 and a test was ordered.
2. An operator inadvertently associated patient information for Patient Name #2 to the same Sample ID (**#101)** and a test was ordered.

Consequently, results from the first sample assigned to Sample ID #101 will be associated with both sets of patient information (i.e., Patient Name #1 and Patient Name #2), without operator awareness. This anomaly can only occur if manual entry is used to modify patient information.

For additional information, please refer to the Question and Answer section located on page two.

Impact to Results

If this anomaly is undetected by the operator, mis-associated results may occur. ***To date, we have had no customer complaints of this anomaly and no patient harm has been reported.***

Actions Required

- In accordance with good laboratory practices for clerical documentation, be cautious when manually entering and modifying patient information associated with a Sample ID. Always confirm that the patient information has been entered correctly *and is assigned to the intended Sample ID* before processing the sample on the analyser.
- Complete and return the Confirmation of Receipt form no later than ***insert date***.
- Post this notification by each ORTHO VISION™ Analyser in your facility or with the user documentation.
- Please contact an Ortho Clinical Diagnostics representative if you experience this anomaly.

Resolution

To address this issue, OCD has scheduled the release of new software to mitigate the risk associated with manual entry of patient information within a few months.

We apologize for the inconvenience this may cause your laboratory. If you have any additional questions, please contact our Technical Support Centre at *insert appropriate number.*

Sincerely,

Insert appropriate name & title

Questions and Answers

1. **How can this anomaly occur on the ORTHO VISION™ Analyser?**

   When a test order is created for a single Sample ID, the operator may enter selected patient information (for example, Patient Name).

   If a second test is ordered for the same Sample ID, the operator may inadvertently enter another set of patient information to be associated with the same Sample ID if using the manual entry option to modify patient information. If this occurs, the analyser will process that one sample with two different Patient Names.

2. **If the anomaly occurs, what is the impact to results when searching by "Patient Name"?**

   If the anomaly occurs and an operator searches on the "*Results Search by Patient Name"* screen, only the specific Patient Name requested will be displayed; other names associated to the same Sample ID will not be displayed. Results will only be displayed for the specific Patient Name entered for the search; the analyser will not display any other Patient Names that are associated with that sample ID and therefore results may not be for the target patient.

3. **If the anomaly occurs, what is the impact to results when searching by "Sample ID"?**

   If the anomaly occurs and an operator searches on the "*Result Search by Sample ID"* screen, results for all Patient Names associated with that specific Sample ID will be displayed.

4. **How was this anomaly identified?**

   This anomaly was identified during our internal testing. We have had no customer complaints of this anomaly and no patient harm has been reported. Please contact an Ortho Clinical Diagnostics representative if you experience this anomaly.

5. **What can I do to help prevent this issue from occurring on my ORTHO VISION™ Analyser?**

   In accordance with good laboratory practices for clerical documentation, be cautious when manually entering and modifying patient information associated with a Sample ID. Always confirm that the patient information has been entered correctly *and is assigned to the intended Sample ID* before processing the sample on the analyser.

6. **When will this issue be addressed?**

   This anomaly will be addressed in a future software version that is scheduled to be released within a few months. We will also issue a notification upon software availability.

   In the interim, we will issue a Technical Bulletin containing the information in this notification.