

xx March 2015

## URGENT FIELD SAFETY NOTICE

### Partially Used Cassettes\* Anomaly using Software Version 1.0.4 on the ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes

Dear Valued Customer,

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

Affected System	Affected Software Version	Product Code
ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes	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 if a partially processed cassette\*\* has been placed in the Manual Review Rack after a shutdown and then moved manually by the user to the Load Area of the Dual Purpose Drawer for reuse. With these partially processed cassettes, columns with punched foil can potentially be reused to generate results when the cassette is reintroduced to the analyzer. It is possible that no error code will be displayed if this occurs. If this anomaly occurs undetected, incorrect results may be reported.

This anomaly can only occur after a specific sequence of events takes place. Please refer to the *Question and Answer* section located on Page 3 for a description of this sequence of events. This anomaly does not occur:

- When cassettes have been fully processed and advance past the centrifugation step.
- When partially used cassettes are not presented to the Manual Review Rack of the Dual Purpose Drawer.

Until this anomaly is resolved, do not manually re-introduce partially used cassettes to the Load Area of the Dual Purpose Drawer of the ORTHO VISION™ Analyzer. **NOTE:** As a reminder, per the *ORTHO VISION™ Analyzer BioVue® Cassettes Reference Guide* (J55655), do not place partially used cassettes with unused columns in the Supply Drawer.

#### Actions Required

- Do not manually re-introduce partially used cassettes to the ORTHO VISION™ Analyzer.
  - ✓ Do not manually place partially used cassettes with unused columns in the Load Area of the Dual Purpose Drawer.
  - ✓ If the system has placed partially used cassettes in the Manual Review Rack of the Dual Purpose Drawer, do not manually reintroduce these cassettes via the Load Area of the Dual Purpose Drawer.
- Complete and return the Confirmation of Receipt form no later than insert date.
- Post this notification by each ORTHO VISION™ Analyzer in your facility or with the user documentation.
- Please contact an Ortho Clinical Diagnostics representative if you experience this anomaly.

\*partially used cassettes contain some columns that are punched and others that are not punched and available for use  
\*\*partially processed cassettes are cassettes that have been punched and have some fluids dispensed BUT NOT centrifuged.

## **Impact to Results**

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If this anomaly is undetected by the operator, false results may be reported. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

## **Resolution**

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ORTHO VISION™ software will be updated in the future to enable partially used cassettes to be safely reintroduced manually on the analyzer. In the interim, OCD will release a modification to disable the Load Area of the Dual Purpose drawer as well as provide a technical bulletin (interim instructions) about this issue.

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

Sincerely,

*Insert appropriate name & title*

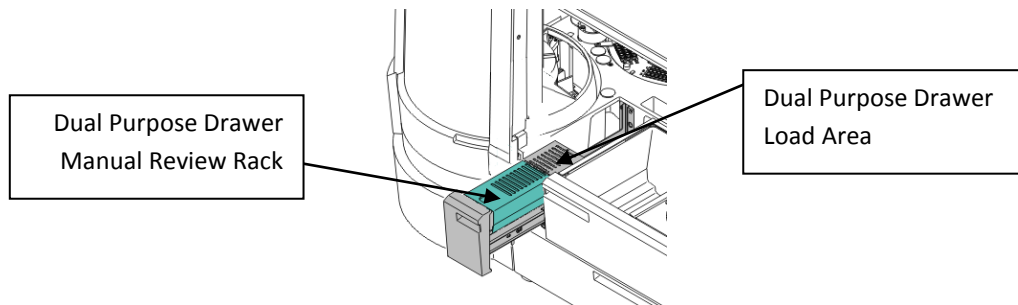
## Questions and Answers

### 1. How can this anomaly occur on the ORTHO VISION™ Analyzer?

The following sequence of events *must occur* in order for punched columns in partially processed cassettes to be reused to generate results, with the possibility that no error code is presented to the operator:

1. On the analyzer, foil has been punched on some but not all columns on a cassette.
2. The partially processed cassette has some sample or reagent fluid dispensed in the punched columns, but the cassette *has not been centrifuged*.
3. An event (e.g., a software exception) occurs such that the partially processed cassette is placed in the Manual Review Rack of the Dual Purpose Drawer.
4. The user manually re-introduces the partially processed cassette from the Manual Review Rack to the Load Area of the Dual Purpose Drawer.
5. The red cells contained in the punched column have settled between the upper and lower chamber of the column.
6. An air gap is maintained in the punch column such that red cells are not detected.

Below is an illustration of the Dual Purpose Drawer:



### 2. What is the impact to results if this anomaly occurs?

If this anomaly occurs undetected, false results may be reported. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

### 3. How do I prevent this anomaly from occurring?

To prevent this anomaly from occurring, do not manually re-introduce partially used cassettes to Load Area of the Dual Purpose Drawer of the ORTHO VISION™ Analyzer.

### 4. How will OCD compensate our facility for cassette columns that could not be used?

Please maintain a record of the number of cassettes that could not be used for testing due to this issue. OCD will provide reimbursement in the form of either replacement cassettes at no charge or credit to your account based on the needs of your laboratory. Please contact Customer Technical Services at **insert appropriate number** and reference this document.

### 5. When will this anomaly be resolved?

OCD is currently investigating the changes that will be necessary to correct the anomaly in a future version of ORTHO VISION™ Analyzer software. In the interim, OCD will release a modification to the software disable the Load Area of the Dual Purpose Rack as well as provide a technical bulletin (interim instructions) about this issue.