URGENT

Ortho Clinical Diagnostics

September 21, 2022

URGENT PRODUCT CORRECTION NOTIFICATION

ORTHO VISION® Analyzer and ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards: Potential Use of Mismatched Camera Images During Routine Imaging Operations

Dear Customer,

The purpose of this Urgent Product Correction Notification is to provide you information of the potential for the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards to use mismatched camera images for routine imaging operations. These routine operations include:

- Inventory of cards when sleeves are loaded in the Supply Drawer or cards are loaded in the Dual-Purpose Loading Drawer
- Quality check of cards prior to assay processing
- Analysis of cards at the conclusion of assay processing
- ID-MTS™ column grading for result interpretation
- Inventory of card punch tools
- Health Checks to ensure proper functioning of the Card Imaging Subsystem

Affected Product	Product Code (Unique Device Identifier)
ORTHO VISION® Analyzer for ID-MTS™ Gel Cards	6904577 (10758750012817)
ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards	6904576 (10758750012824)

Issue Description

During normal operation of the ORTHO VISION analyzer, the Camera Imaging Subsystem (CIMS) interfaces with a hardware camera to request and retrieve camera images for column grading and results interpretation. The camera software uses a first-in, first-out queuing system to take and return images to the CIMS software.
Under an atypical software anomaly, a customer observed that images used for analysis of a test result did not come from the front and back sides of the same card. Ortho determined that the CIMS processed images out of synchronization (images captured earliest in sequence are placed at the top of the queue to be processed). As a result, image processing software utilized on the ORTHO VISION analyzer may use mismatched front of card and back of card images for column grading and result interpretation.

Impact to Results

When this software anomaly is observed the ORTHO VISION analyzer may:

- ✓ incorrectly identify the contents of sleeves of cards loaded in the Supply Drawer.
- ✓ reject cards during pre-processing quality check that do not have errors or accept cards that should have been rejected.
- ✓ assign the mismatched card barcode ID to one or more orders.
- ✓ reverse the orientation of a card prior to sample and reagent addition.
- ✓ perform grading from the images of two different cards.

There are numerous safeguards in place to protect against reporting interpretable results while using mismatched camera images. Some of these safeguards include, but are not limited to:

- ✓ Verification that the card is received for grading in the correct orientation.
- ✓ Verification that the card barcode ID on the analyzed card matches the ID associated with the order.
- ✓ Checks that all columns used on the test have an appropriate amount of sample and reagent based on what is expected for the test.
- ✓ Checks that column grades for each card side image are concordant.

The likelihood of reporting a test with an erroneous column grade and no error codes occurring is approximately 1 in 3.2 million tests.

It is important to note that there have been no reports of a discrepant result having been reported by the analyzer.

Identifying the Issue

The following error codes are encountered when the VISION analyzer is actively using mismatched camera images.

Error Code	Descriptive Text	ORTHO VISION® Automatic Recovery Action
CIMS28[1]	Duplicate Card barcode detected at process start	Aborts and restarts affected test
CIMS33[1]	Card reversed at process end	Aborts all tests
CIMS35[1]	Unexpected Card at process end	Aborts all tests
CIMS02[2]	Card cannot be read	Aborts affected test

[1] If one or more of these error codes post, it is likely that the analyzer has encountered this anomaly.

[2] CIMS02 error codes may post in addition to the three above-mentioned codes. Although CIMS02 error codes may post for other reasons, if posted independently, this code may indicate that the analyzer has encountered this anomaly.

The use of mismatched camera images can also be reviewed for any test which has had column level grading performed, even if the grading has resulted in an invalid test interpretation (e.g., Indeterminate or Wrong Liquid Level code is generated). When using mismatched camera images, the color images in the Results Details screen exhibit unusual color patterns, which may support the identification of the mismatched images for the order.

The following images are examples of an order Results Details screen where Figure 1 shows a normal image reviewed in color and figure 2 shows an unusual color pattern when reviewed in color. Figure 2 is an example of the use of mismatched MTS images by CIMS.

Figure1: Correct Image

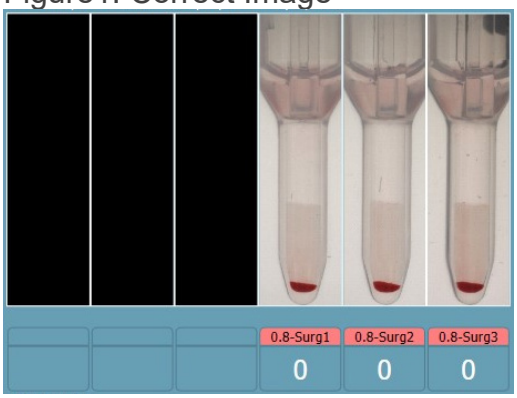
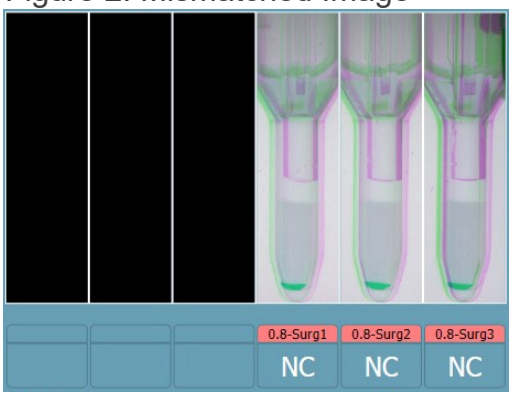


Figure 2: Mismatched Image



Process to Recover from the Error State

Until a software update is available, and when the ORTHO VISION analyzer posts a CIMS28, CIMS33, CIMS35, or a CIMS02 error code, please abort all tests in process, shut down the system and restart the analyzer. Restarting the analyzer will reset the software and resynchronize camera images to resolve the use of mismatched images.
Results generated around the time the error code was reported should be reviewed for concordance with known patient information, if available. Specifically, front, and back side color images for all results automatically accepted in the following time ranges should be reviewed:

1. Starting directly after the error code was posted, ending at the time the system was shut down and restarted.
2. Starting directly before the error code was posted, in reverse chronological order until images appear unaffected.

It is recommended that color column images from the Result Details screen are to be used for this review as they are a visually clear method of determining if mismatched images were used during the analysis process.

Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. In order to assist you with a process for reviewing impact to your analyzer, Ortho has provided the enclosed instructions to explain how to search previous error codes, results, and images. You may also contact Ortho Care® for any further questions or assistance. Please note that the ORTHO VISION analyzer is designed to continuously retain the most recent 6 months of data and images.

Resolution

This software anomaly will be resolved in the next software update, currently expected to be available before or during Q1 of 2023. Ortho will notify you when the software update is published for installation.

REQUIRED ACTION

- After a system shut down and restarting of the analyzer, automatically accepted results prior to the error code should be reviewed for concordance with known patient information, if available, and to detect evidence of the previous use of mismatched images.
- If your laboratory has experienced the issue which resulted in a discrepant result being reported, and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.
- Complete the enclosed Confirmation of Receipt form no later than **September 29, 2022**.
- Please forward this notification if the affected product was distributed outside of your facility.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care Technical Solutions Center at 1-800-421-3311.

Enclosure:
Confirmation of Receipt
Customer Look Back Instructions (Ref.CL2022-243_LookBackGuide)

Confirmation of Receipt – Response Required

Communication ID: 2022-243 Date of Issue: 21-SEP-2022

URGENT PRODUCT CORRECTION NOTIFICATION

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*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **29-SEP-2022**

Send to: **Joe Falvo** e-Mail Address: RA-OCDUS-CONFIRMAD@ORTHOCLINICALDIAGNOSTICS.COM Fax: 1.888.557.3759 or 1.585.453.4110

Verification Request

☒ ***I confirm this contact information and no changes are required***

Institution: KAISER SAN FRANCISCO UCN: 01085551
Contact:
Address: 2130 OFARRELL ST
City: SAN FRANCISCO State/Prov: CA
Zip/Postal Code: 94115 Phone: 415-833-3881
e-Mail: cara.h.lim@kp.org Fax: 415-833-2557

Please complete this section if any of this information has changed

Institution:
Contact:
Address:
City: State/Prov:
Zip/Postal Code: Phone:
e-Mail: Fax:

Please Confirm

I received the Urgent Product Correction Notification (Ref.CL2022-243) regarding the potential for the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards to use mismatched camera images for routine imaging operations.

I understand that after a system shut down and restarting of the analyzer, automatically accepted results prior to the error code should be reviewed for concordance with known patient information, if available, and to detect evidence of the previous use of mismatched images.

Print Name: Cara Lim

Signature: Required
Your signature confirms that you have received and understand this communication.

Phone Number: 415-833-3886 Date: 9/22/22

Your Comments: This facility has not encountered any mismatched camera images error described in CL2022-243 to my knowledge.

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent:

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

Content ID: CL2022-243