URGENT

Ortho Clinical Diagnostics

Month ##, 2020

URGENT FIELD SAFTEY NOTICE

Potential Intermittent False Positives on ORTHO VISION and ORTHO VISION Max BioVue Analyzers When Testing High Titer Samples

Dear Customer,

This notification is regarding the potential for intermittent false positive results being generated on ORTHO VISION® or ORTHO VISION® Max BioVue analyzers when processing ORTHO Sera anti-D (IAT) and Indirect Antiglobulin Test (IAT) crossmatch (XM) tests after pipetting high titer plasma or serum samples.

Affected Product	Product Code Unique Device Identifier No.
ORTHO VISION® Analyzer for ORTHO® BioVue Cassettes	**6904579** (10758750012831)
ORTHO VISION® Max Analyzer for ORTHO® BioVue Cassettes	**6904578** (10758750012848)

You are receiving this communication because Ortho has identified your analyzer as potentially being affected.

Issue Description

Ortho Clinical Diagnostics received complaints of discordant positive reactions for healthy donor and patient samples when using ORTHO Sera anti-D (IAT) (Product No. 6904493) with AHG Anti-IgG Ortho BioVue® System cassettes (Product No. 707400/707450) and IAT XM tests with Anti-Human Globulin Anti-IgG, -C3d; polyspecific Ortho BioVue System® cassettes (Product No. 707300/707350). Ortho estimates based on a review of complaints that this issue has impacted less than 3.1 % of ORTHO VISION Max and 0.4% for ORTHO VISION customers analyzers.

Impact to Results

Carryover of high titer (≥1024) ABO antibodies may cause a false positive result with the Ortho Sera anti-D (IAT) test and IAT XM results.

Unexpected positive results may lead the blood bank laboratory to perform additional testing to confirm the sample is a Rh(D) variant, or if the Ortho Sera anti-D(IAT) test is used as the primary Rh(D) typing test, it is possible that a sample may incorrectly be typed as Rh(D) positive.

If a high titer ABO antibody sample (>1024) is suspected of being processed it is recommended to review column results for all plasma and/or cell dispenses that occurred after the high titer sample. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Carryover Claims

The Carryover Claims were established using an Anti-D antibody and state: *Testing of the ORTHO VISION® Analyzer indicated that a sample with a high-titered antibody (>1024) when tested may intermittently cause carryover in the subsequent sample test columns. The number of columns affected is dependent on the magnitude of the high titer sample. Testing also indicated that carryover was not observed in samples with antibody titers of 512 or 1024.*

During an investigation on low frequency intermittent false positive results it was concluded that the potential for intermittent carryover exists for Anti-A at an antibody titer equal to 1024 and may generate a false positive result with red blood cells that express higher copy number of A antigen, while having no observable effect on the expected negative results with red blood cells expressing lower copy number of A antigen.

Investigation

The current investigation is focusing on the potential of antibody carryover on ORTHO VISION systems and its impact on results of ORTHO Sera anti-D (IAT) and IAT XM tests. The investigation has shown that false positive results may be caused by carryover of ABO antibodies from previously pipetted samples into subsequently pipetted tests on the ORTHO VISION systems. Carryover may occur when high titer (≥1024) antibody from previously pipetted plasma or serum samples is not completely washed from the pipettor and contaminates subsequently pipetted test fluids.

This investigation has determined that generation of false positives due to ABO antibody carryover is dependent on the following factors, which must interact simultaneously to cause a false positive in a susceptible test.

- Performing the Weak D or IAT XM Test on ORTHO VISION and ORTHO VISION Max systems.
- Concentration of ABO antibodies in the previously pipetted serum or plasma sample.
- A and or B antigen copy number of the Red Blood Cells (RBCs) in the subsequently pipetted test.
- Aspiration volume of previously pipetted serum of plasma sample, and of the subsequently pipetted test fluids.
- The amount of time subsequently pipetted test fluids reside in the pipettor between aspiration and dispense.

Resolution

While no carryover is observed with anti-D antibody of titer levels at 1024 in line with Ortho's initial design verification of the ORTHO VISION and ORTHO VISION Max Analyzers, we have observed false positives due to ABO antibody carryover at titer levels of 1024.

As a consequence, ORTHO recommends following the mitigations defined in the ORTHO VISION/ VISION Max reference guides, if a plasma sample with ABO antibody titer equal to or greater than 1024 has been processed.

Ortho is actively working on further mitigations to mitigate carryover of ABO antibodies into subsequently pipetted fluids.

REQUIRED ACTIONS

- Please refer to ORTHO VISION/ORTHO VISION Max reference guide recommendations (Pub No. J55655/Pub. No. J55657) if you suspect carryover has occurred. Specifically, If a high titer antibody sample (>1024) is suspected of being processed it is recommended to review column results for all plasma and/or cells dispenses that occurred after the high titer sample and to perform the Daily Probe Maintenance procedure."
- Complete the enclosed Confirmation of Receipt form no later than **Month XX, 2020**.
- Please forward this notification if the product was relocated outside of your facility.
- Save this notification with your user documentation.

Contact Information

If you have questions, please contact Ortho Care™ Technical Solutions Center at insert number.

Insert signatory if appropriate in your region.

Confirmation of Receipt – Response Required

Communication ID: CL2020-206a_EU Date of Issue: 2020-MM-DD

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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:* **DD-MM-YYYY**

Send to: Name e-Mail Address: email address Fax: Fax Number

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

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

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2020-206a_EU) regarding the potential for intermittent false positive results being generated on ORTHO VISION® or ORTHO VISION® Max BioVue analyzers with ORTHO Sera anti-D (IAT) and Indirect Antiglobulin Test (IAT) crossmatch tests after pipetting high titer plasma or serum samples.

I understand that I am advised to refer to ORTHO VISION/ ORTHO VISION Max reference guide recommendations (Pub No. J55655/Pub. No. J55657) if I suspect carryover has occurred. Specifically, If a high titer ABO or D antibody sample (>1024) is suspected of being processed it is recommended to review column results for all plasma and/or cells dispenses that occurred after the high titer sample and to perform the Daily Probe Maintenance procedure.

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

Print Name: _____

Phone Number: _____ Date: _____

Your Comments: _____