QuidelOrtho™

URGENT

November XX, 2023

URGENT FIELD SAFETY NOTICE

Potential False Positive Test Results Due to Carryover of ORTHO Sera Anti-Jk^{b} in Specific Tests on the ORTHO VISION® and VISION® Max Analyzers for ORTHO BioVue® Cassettes

Dear Customer,

The purpose of this notification is to inform you of the potential for intermittent false positive results to be generated on the ORTHO VISION® or VISION® Max Analyzers for ORTHO BioVue® Cassettes due to reagent antibody carryover when specific tests are pipetted after ORTHO Sera Anti-Jk^{b} Blood Grouping Reagent.

Affected Product	**Product Code** (Unique Device Identifier)
ORTHO VISION® Analyzer for BioVue when Processing ORTHO™ Sera Anti-Jk^{b} Blood Grouping Reagent (Software 5.14.5 and below)	6904579 (10758750012831) 6904489 (10758750013166)
ORTHO VISION® Max Analyzer for BioVue when Processing ORTHO™ Sera Anti-Jk^{b} Blood Grouping Reagent (Software 5.14.5 and below)	6904578 (10758750012848) 6904489 (10758750013166)

Summary

Ortho Clinical Diagnostics (QuidelOrtho™) identified a trend regarding false positive results for specific tests (listed below) processed after ORTHO Sera Anti-Jk^{b} tests, on the ORTHO BioVue Cassettes when tested on the ORTHO VISION Analyzer.

It is important to note that this issue is intermittent because several factors must interact across a series of events for a false positive test result due to ORTHO Sera Anti-Jk^{b} carryover to occur.

- One of the five tests listed below must be performed on the ORTHO VISION/ VISION Max Analyzer in conjunction with or after the ORTHO Sera Anti-Jk^{b} testing.

And

- ORTHO Sera Anti-Jk^{b} must be pipetted one or two steps before a sample or reagent in one of the tests listed below.

And

- The red blood cells in the test pipetted after ORTHO Sera Anti-Jk^{b} must express the Jk^{b} antigen. The likelihood of occurrence is higher with red cells with higher antigen expression.

And

Summary Cont'd

- The intermittent occurrence of ORTHO Sera Anti-Jk^{b} carryover is also dependent on several factors specific to pipetting operations on the ORTHO VISION/ VISION Max Analyzer such as the volume of reagents and samples pipetted, and the amount of time they are retained in the probe between aspiration and dispense which are determined by the analyzer processing steps.

List of Impacted Tests:

Given the requisite sequence of events occur, the following tests may become false positive due to carryover of ORTHO Sera Anti-Jk^{b}:

1. ORTHO Sera tests performed in the Reverse Diluent (Anti-Jk^{a}, -Le^{a}, -Le^{b}, -DVI, -K, -P_1) and Anti-IgG Cassettes (Anti-S, -s, -Fy^{a}, -Fy^{b}, -D(IAT))
2. Antibody screening, identification, and autocontrol tests
3. Reverse Grouping tests
4. Crossmatch tests
5. Dilution Series tests

Root Cause

The wash protocol for ORTHO Sera Anti-Jk^{b} on the ORTHO VISION / VISION Max BioVue Analyzer does not sufficiently clean the internal surface of the probe to prevent false positive test results due to carryover of ORTHO Sera Anti-Jk^{b}. An effective wash protocol has been identified and will be implemented in an upcoming modification.

At this time, Ortho's investigation is ongoing and, to date, has not identified carryover issues related to any of the remaining ORTHO Sera specificities when tested on the ORTHO VISION / VISION Max BioVue Analyzers.

Impact to Results

Potential Impact to Patient Results

Extended Antigen Typing Tests – A patient who lacks the antigen and is mistakenly identified as antigen positive may receive antigen positive blood. This could lead to sensitization and/or a transfusion reaction if the patient has an antibody against that antigen.

Reverse Grouping Tests – A false positive reverse grouping is unlikely to be consistent with the forward grouping which may lead to complications in determining the patient's ABO blood type. A false positive result in a reverse grouping test when run without the forward grouping may lead to incorrect anti-A and/or anti-B detection.

Antibody Screening and Crossmatch Tests – A false positive result does not represent a transfusion risk for patients.

Antibody Identification Tests – If one or more cells are false positive within the antibody identification test, delay in the identification of an unexpected antibody may occur.

Dilution Series Tests – Unexpected results in the dilution series tests, such as a false positive control column or a higher-than-expected antibody titer, may result in follow up and/or investigative testing in antibody identification and prenatal studies. As per ORTHO

VISION/VISION Max Reference Guide* (Section 9-18), results of the dilution series test are invalidated if the control column is positive. In the context of prenatal studies, a single higher-than-expected antibody titer is unlikely to result in an invasive fetal procedure as these decisions are made in the context of many additional clinical tests.

Potential Impact to Donor Results

Antigen Typing Tests – A false positive result does not represent a transfusion risk for patients because the transfusion of antigen negative blood to an antigen -positive patient is of no clinical significance.

Reverse Grouping Tests, Antibody Screening, and Antibody Identification Tests – False positive results with donor samples in these tests are likely to be detected and pose no transfusion risk.

Review of Previous Results

If your facility chooses to perform a lookback to identify potentially impacted test results, please perform the following steps.

1. - Identify dates where ORTHO Sera Anti-Jk^{b} testing was performed on your ORTHO VISION/ VISION Max Analyzer using the Search feature, the procedure is outlined in the ORTHO VISION/VISION Max Reference Guide* (Section 10-14).
   - Configure the search to include the date ranges of interest to your facility. Please note that the maximum data retention timeframe is six months. For dates beyond this six-month window, a backup must be restored. The procedure for restoring from a backup can be found in the ORTHO VISION/ VISION Max Reference Guide* (Section 15-7).
2. For dates where the use of ORTHO Sera Anti-Jk^{b} was identified, review the results of potentially impacted tests as listed above that were performed in conjunction with or after the ORTHO Sera Anti-Jk^{b} test(s).
3. If a false positive result is identified, please contact our Global Services Organization to discuss any concerns you may have. Additionally, you should contact your Laboratory Medical Director to determine the appropriate course of action, regarding false positive test results, you may have found.

*Reference:

J55655: ORTHO VISION BioVue Cassettes Reference Guide

J55657: ORTHO VISION Max BioVue Cassettes Reference Guide

Resolution
Ortho is actively working to modify the wash protocol used for ORTHO Sera Anti-Jk^{b} testing on the ORTHO VISION/VISION Max Analyzer. A follow-up communication will be issued when the modification is released.

To ensure proper results when processing tests in conjunction with ORTHO Sera Anti-Jk^{b} tests, it is important to follow the directions provided below until the wash protocol is modified for the ORTHO VISION/VISION Max Analyzer:

- Test the ORTHO Sera Anti-Jk^{b} in isolation (consider batch order testing) – do not process other profiles while testing the ORTHO Sera Anti-Jk^{b} test.
- Perform daily maintenance at the completion of processing ORTHO Sera Anti-Jk^{b} tests on the ORTHO VISION/ VISION Max Analyzer.

Manual BioVue technique may be used for ORTHO Sera Anti-Jk^{b} as an alternative to following the above automated use recommendation.

REQUIRED ACTION
Until the wash protocol is modified.

- The continued use of ORTHO Sera Anti-Jk^{b} on the ORTHO VISION/VISION Max Analyzer must only be done using the directions provided in the Resolution Section of this letter.
- Review the content of this communication with your Medical Director and retain this letter for your laboratory.
- Complete the enclosed Confirmation of Receipt form no later than **November XX, 2023.**

Contact Information
We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at insert number.

Insert signatory if required in your region.

Enclosure: Confirmation of Receipt Form

Questions and Answers (Q&A)

1. **Can I observe false positive results with Patient, Donor, and Quality Control Samples**?

   A: There is the potential for false positive results to be observed with patient, donor, and Quality Control samples in the test types listed above.

2. **If my Quality Control for the profiles listed in the communication are acceptable, can false positive patient/donor tests still occur if Ortho Sera Anti-Jk^{b} was used?**

   A: Due to the intermittent nature of this issue, there is the potential for quality control to be accurate followed by a false positive result generated with a patient/donor sample.

3. **Will carryover only be seen with cells that are Jk(b+)?**

   A: Yes, false positive test results due to carryover of ORTHO Sera Anti-Jk^{b} may occur with red blood cells expressing the Jk^{b} antigen in the test types listed above.

4. **Can ORTHO Sera Anti-Jk^{b} test results be impacted?**
   A: No. Jk(b-) red blood cells cannot test as false positive due to carryover of ORTHO Sera Anti-Jk^{b}.

5. **Is this issue related to sample carryover?**
   A: No, this issue is specifically related to ORTHO Sera Anti-Jk^{b}. It is important to note that antibody characteristics between patient/donor samples and manufactured reagents are different, therefore the information related to carryover outlined in the reference guide is applicable only to high-titer patient/donor samples. (Section 9-14 Antibody Titers**)

6. **Why is ORTHO Sera Anti- Jk^{b} the only antisera impacted at this time?**
   A: Our investigation, while continuing, has indicated that the wash protocol specific to ORTHO Sera Anti-Jk^{b} reagent requires modification. Our investigation has not identified any other ORTHO Sera wash protocols as insufficient at this time.

** Reference:
J55655: ORTHO VISION BioVue Cassettes Reference Guide
J55657: ORTHO VISION Max BioVue Cassettes Reference Guide

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Confirmation of Receipt – Response Required

Communication ID: CL2020-257a_EU Date of Issue: DD-MMM-2023

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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-MMM-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.CL2023-257a_EU) regarding the potential for intermittent false positive results for several assays being generated on the ORTHO VISION/ VISION Max BioVue Analyzers as a result of antibody carryover when these assays are tested after processing ORTHO Sera Anti-Jk^{b}.

I understand the continued use of ORTHO Sera Anti-Jk^{b} on the ORTHO VISION/ VISION Max Analyzer must only be done using the directions provided in the Resolution Section of the customer letter.

Please choose from the following:

☐ My laboratory processes ORTHO Sera Anti-Jk^{b} on a VISION analyzer.
☐ My laboratory does not process ORTHO Sera Anti-Jk^{b} on a VISION analyzer.

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

Print Name: _____
Phone Number: _____ Date: _____

Your Comments: _____