QuidelOrtho™

URGENT

Month XX, 2023

URGENT FIELD SAFETY NOTICE

Potential for Incorrect Rh Results on the ORTHO VISION® Analyzers and Ortho Optix™ Reader for BioVue® Cassettes

Dear Customer,

The purpose of this notification is to inform you of potential erroneous results for Rh (Anti-D) Interpretation Results when performing Test ID 10023 (4 ABO(FWD)-44 + (RVS)-A1,A2,B) on the ORTHO VISION® Analyzer, ORTHO VISION® Max Analyzer or ORTHO Optix™ Reader for BioVue® Cassettes.

Affected Product	**Product Code** (Unique Device Identifier)
ORTHO VISION® Analyzer for BioVue	6904579 (10758750012831)
ORTHO VISION® Max Analyzer for BioVue	6904578 (10758750012848)
ORTHO Optix™ Reader for BioVue	6842223 (10758750032853)

Issue Description
During an internal review, QuidelOrtho identified that Test ID 10023 included a calculated Rh (Anti-D or RhD) Interpretation Result when in fact, no Anti-D column was used for the test.

Since no Rh (Anti-D) column is used for Test ID 10023, the Interpretation Result is erroneously determined only via the Control column in the cassette. If the Control column interpretation is Negative, then the Rh result is Rh "Pos" (positive). If the Control column interpretation is Positive, then the Rh result is a "?".

Impact to Results
A false positive RhD typing may result in an incorrect transfusion of RhD-positive blood to a RhD-negative recipient or a patient not considered eligible for anti-D immunoglobulin therapy, resulting in RhD alloimmunization.

In women of child-bearing potential, RhD alloimmunization carries the risk of hemolytic disease of the fetus and newborn (HDFN) in subsequent pregnancies, which requires specialized and advanced care. Erroneous typing of fetal blood as Rh-positive may result in transfusion with Rh-positive blood, resulting in fetal alloimmunization. Likewise, Rh-negative mothers of an erroneously Rh-antigen-typed fetus will inadvertently be treated with anti-D immunoglobulin to prevent RhD immunization. Though anti-D immunoglobulin has potential

side effects, it is considered safe and well-tolerated. The risk of serious injury is remote in all scenarios.

Additionally, a false positive RhD typing of a donor sample may result in an erroneous shortage of available RhD-negative blood for transfusion.

QuidelOrtho acknowledges that this failure mode may have implicated donor blood typed and stored in the blood bank. As a result, QuidelOrtho is recommending a one-time retrospective review of stored donor blood using the BioVue test ID 10023 that may be erroneously identified as RhD positive. If you have further concerns, you may discuss them with your Laboratory Medical Director to determine the appropriate course of action.

No complaints have been reported against these products for false positive Rh reactions associated with BioVue Test ID 10023.

Root Cause
The assignable root cause of this deviation has been determined to be a process related error as the Rh Interpretation Result was inadvertently introduced into the Test ID during the Assay Data Disk (ADD) development.

An additional review of all tests was performed, and we did not find additional anomalies.

Resolution
The impacted ADD will be corrected and made available to the impacted VISION Analyzers and the Optix Reader to resolve the issue, estimated for Q1 of 2024.

Until the ADD fix is released, discontinue the use of Test ID 10023 for Blood Grouping and Rh Typing. The following Test IDs must be used as an alternative:

Test ID	Test Name
10021	4 ABO(FWD/RVS)/Rh-00
10022	08 ABO(FWD/RVS)/Rh-00

REQUIRED ACTION

- Until the ADD with the fix is released, discontinue the use of test ID 10023 (4 ABO(FWD)-44 + (RVS)-A1,A2,B) for Blood Grouping and Rh Typing.
- As an alternative, Test ID 10021 or 10022 must be used when performing Blood Grouping and Rh Typing.
- QuidelOrtho is recommending a one-time retrospective review of stored donor blood using the BioVue test ID 10023 that may be erroneously identified as RhD positive.
- Acknowledge your understanding of this notification by completing the enclosed Confirmation of Receipt form no later than **Month DD, 2023**.
- If your laboratory has experienced the issue described in this notification and you have not already done so, please report the occurrence to your local Global Services Organization (Previously Ortho Care).

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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 applicable in your region.

Enclosure: Confirmation of Receipt Form

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.