QuidelOrtho™

URGENT

October 2023

URGENT PRODUCT CORRECTION NOTIFICATION
Potential for Incorrect Rh Results on the ORTHO VISION® Analysers and Ortho Optix™ Reader

Dear Customer,

This notification is to inform you of the potential for incorrect Rh (Anti-D) Interpretation Results when performing Test ID 10023 (4 ABO(FWD)-44 + (RVS)-A1,A2,B) on the ORTHO VISION® Analyser, ORTHO VISION® Max Analyser or ORTHO Optix™ Reader.

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

Issue Description
During an internal review, QuidelOrtho identified that Test ID 10023 included 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 incorrectly 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 alloimmunisation.

In women of child-bearing potential, RhD alloimmunisation carries the risk of haemolytic disease of the foetus and newborn (HDFN) in subsequent pregnancies, which requires specialised and advanced care.

Incorrect typing of foetal blood as Rh-positive may result in transfusion with Rh-positive blood, resulting in foetal alloimmunisation. Likewise, Rh-negative mothers of an incorrectly Rh-antigen-typed foetus will inadvertently be treated with anti-D immunoglobulin to prevent RhD immunisation. 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, false positive RhD typing of a donor sample may result in a lowered availability of RhD-negative blood for transfusion.

QuidelOrtho acknowledges that this failure mode may have implications for donor blood typed and stored in the blood bank. As a result, QuidelOrtho is recommending a one-time retrospective review of donor blood that was originally tested using the BioVue test ID 10023 that may have been incorrectly 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 root cause has been found to be a process related error that allowed the Rh Interpretation Result to be incorrectly introduced into the Test ID during the Assay Data Disk (ADD) development.

A review of all other tests was performed, and no further anomalies were found.

Resolution
The affected ADD will be corrected and made available for VISION Analysers and the Optix Reader. The estimated availability of the revised ADD is Q1 of 2024.

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

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

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REQUIRED ACTIONS

- Until the revised ADD 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 may be used when performing Blood Grouping and Rh Typing.
- QuidelOrtho recommends a one-time retrospective review of donor blood that was originally tested using the BioVue test ID 10023 that may have been incorrectly identified as RhD positive.
- Acknowledge your understanding of this notification by completing the enclosed Confirmation of Receipt form no later than **10 November 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 QuidelOrtho representative or our Global Services Organisation (Previously Ortho Care).

Contact Information

We apologise for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Global Services Organisation.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

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.