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June 2023

URGENT PRODUCT CORRECTION NOTIFICATION
Potential for ORTHO VISION® Analysers to Process Non-Validated Ortho Sera Anti-N Test when Regional Setting is Incorrectly Configured

Dear Customer,

This notification is to inform you that ORTHO VISION® Analysers may be able to process non-validated tests (for example ORTHO Sera Anti-N, except when run as part of User Defined Protocol (UDP)) if the regional setting is incorrectly configured.

Affected Product	**Product Code** (Unique Device Identifier)
ORTHO VISION® Analyser	6904579 (10758750012831)
ORTHO VISION® Max Analyser	6904578 (10758750012848)
Impacted Product	**Product Code** (Unique Device Identifier)
ORTHO™ Sera Anti-N	6904495 (10758750013227)

Summary

Ortho Clinical Diagnostics, Inc (QuidelOrtho™) internal investigation identified that the regional setting on a small population of ORTHO VISION Analysers was set to "OCD". This analyser configuration is intended for internal use only.

The regional setting is applied during analyser installation based on the location where the installation is being performed. If the regional setting is left as "OCD," all tests may be processed irrespective of your region's required accessibility.

For example, the setting allows the ORTHO Sera Anti-N test to be run on the analyser although it has not been validated for use on the ORTHO VISION platform.

ORTHO Sera Anti-N has been validated for use with manual cassette testing.

ORTHO Sera Anti-N must not be processed on an ORTHO VISION Analyser unless processed in a User Defined Protocol.

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Impact to Results
There may be a risk to patient results if ORTHO Sera Anti-N was processed on an analyser where it is not validated, and the ORTHO VISION could potentially produce incorrect results.

A false positive result could lead to patient injury if an antigen-negative individual is transfused with antigen-positive blood, potentially resulting in haemolytic transfusion reactions.

False negative results are unlikely to cause significant harm.

Blood screening is a real-time procedure, retrospective review has no mitigating effect on the likelihood of occurrence of serious injury to the patient. Thus, Ortho is not recommending a look back at previous results because of the nature of the risk. If you have further concerns, you may discuss them with your Laboratory Medical Director to determine the appropriate course of action.

Resolution

Ortho will confirm the correct configuration, either remotely or via site visit, to ensure that the correct configuration is present.

REQUIRED ACTION

- Do not process the Ortho Sera Anti-N assay on Vision BioVue Analysers unless it is part of a User Defined Protocol (UDP) - per labelling on the product insert.
- Complete the enclosed Confirmation of Receipt form no later than **7 July 2023**.

Contact Information

We apologize 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.