URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

Unexpected Contamination Identified in ORTHO BioVue Cassettes Which May Generate Potential Erroneous Results

Dear Valued Customer,

The purpose of this notification is to provide important information regarding unexpected contamination that may be identified in the reaction chamber or column of the ORTHO BioVue Cassettes lots listed below.

Affected Products ORTHO Blood Grouping Reagents	**Product Code** (Unique Device Identifier)	**Affected Lot(s)**	**Expiry**
Ortho BioVue® System Reverse Diluent (ABD/Reverse Cassette)	**6986736** (10758750032112)	ABF056F	02-Oct-2023
Ortho BioVue® System Control (Rh/K Cassette)	**707250/707280** (10758750008117) (10758750008087)	RHP123J	30-Sep-2023
Ortho BioVue® System Control (Rh/K II Cassette)	**6986735** (10758750031634)	RHK049J	30-Sep-2023
Ortho BioVue® System Anti-Human Globulin Anti-IgG-C3d; polyspecific Neutral Solution (Poly/ Neutral Cassette)	**707310/707355** (10758750008148) (10758750008179)	PLN079F	01-Sep-2023
Ortho BioVue® System Control Reverse Diluent (ABO-Rh/Reverse Grouping Cassette)	**707100/707155** (10758750007943) (10758750008049)	ABR390F	06-Sep-2023

Issue Description

During a routine internal inspection, Ortho identified a red/brown residue within the reaction chamber/column of the cassette, which may or may not be visible to the end user. Upon further investigation, it was determined that the contamination occurred intermittently and was isolated to a single cavity from Ortho's supplier's molding tool presenting as either column 3 or 4 of the cassette depending on the orientation of the cassette at the point of fill. The contamination has the potential to impact the reaction strength of the affected column.

Probability of Occurrence

Ortho's estimate of the probability of occurrence that the contamination would have occurred in the cassette undetected is 1:200,000.

Impact to Results

The contamination observed in columns 3 or 4 of the affected cassette lots may cause false positive or false negative results of the corresponding reactions.

- If the patient's previous type and screening results (i.e. crossmatch, ABO, Rh phenotyping) are available, the false positive or false negative results may lead to additional confirmation testing.
- If the patient's previous type and screening results are unavailable, the false positive or false negative results caused by the contamination could result in erroneous test results, for which the user may not be aware.

Ortho recommends a look back on patient/donor screening results that used the affected cassette lots and:

1. Produced a potential weak Rh D result.
2. And/or created potential discrepant result checks.

Identification of the affected patient/donor results produced from the affected cassette lots are not easily identifiable without the patient's history; thus, a review of previous results may be impractical. Please consult with your Laboratory Medical Director to determine the appropriate course of action.

To date, Ortho is not aware of any misreported patient results associated with this issue.

Root Cause Investigation

It was determined that this issue is due to a defect in the supplier's cassette molding tool, impacting columns 3 or 4. The affected molding tool has been removed from production, pending remedial action. Maintenance work was completed by the supplier across all tools, no other molding tool is affected at this time.

REQUIRED ACTION

- Stop using and discard your remaining inventory of the affected products listed above. Ortho will replace or credit your account. Indicate quantities to be replaced or credited via the Confirmation of Receipt form.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY.**
- Please forward this notification if the affected product was distributed outside of your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care Technical Solutions Center at *insert number.*

Insert signatory if required in your region.

Enclosure: Confirmation of Receipt Form

Confirmation of Receipt – Response Required

Communication ID: 2023-065a_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** Fax: **Fax Number**

Verification Request

☐ ***I confirm this contact information and no changes are required***

Institution: _____ UCN: _____

Contact: _____

Address: _____

City: _____ State/Prov: _____

Zip/Postal Code: _____ Phone: _____

e-Mail: _____ Fax: _____

Please complete this section if any of this information has changed

Institution: _____

Contact: _____

Address: _____

City: _____ State/Prov: _____

Zip/Postal Code: _____ Phone: _____

e-Mail: _____ Fax: _____

Please Confirm

I received the Urgent Field Safety Notice (Ref.CL2023-065a_EU) regarding unexpected contamination that may be identified in the reaction chamber or column of the ORTHO BioVue Cassettes lots listed in the customer letter.

I understand I must stop using and discard the remaining inventory of the affected cassette lots.

Please choose from the following:

☐ My laboratory uses the affected BioVue Cassette lots but does not have any of the affected lots remaining in inventory.

☐ My laboratory has the affected BioVue Cassette lots. I have discontinued using and discarded the quantity listed in the table below.

Please indicate your choice of credit or replacement:

☐ Credit my account (Credit only will be issued for discarded partial sales units, credit can also be issued for discarded full sales units.)

☐ Send a replacement order for the number of discarded full sales units to the address listed above. (We can ship full sales units only.)

For reference: One Sales Unit for ORTHO BioVue Cassettes = 1 Pack containing 100 cassettes

Product Name / Product Code / LOT	Quantity of Full Sales Units Discarded (unopened)	Quantity of Cassettes remaining in partially used (opened) pack

Print Name: _____

Phone Number: _____ Date: _____

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

Your Comments:

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent:

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

Content ID: _____