URGENT

Ortho Clinical Diagnostics

Insert Date

URGENT FIELD SAFETY NOTICE

Ortho BioVue® System ABD Confirmation Cassette, Lot ACC054H

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information that Ortho Clinical Diagnostics received reports from customers regarding false negative reactions for the Anti-D (RH1) reagent when using Ortho BioVue® System ABD Confirmation Cassettes, Lot ACC054H.

Product Name	Product Code (Unique Identifier No.)	Lot Number	Expiry Date
Ortho BioVue® System ABD Confirmation Cassettes	**707135** (10758750008018)	ACC054H	2019-10-13
Ortho BioVue System ABD Confirmation Cassette is a qualitative test for confirmation of the A (ABO1), B (ABO2) and D (RH1) antigens on human red blood cells FOR IN VITRO DIAGNOSTIC USE.			

Issue Description

Some customers have reported false negative results for the Anti-D (RH1) reagent. Although column 3 and column 6 contain the same reagent, the issue has only been reported when using column 6.

Instructions for Use Summary and Explanation

Testing with both Anti-A and Anti-B is necessary to determine if red blood cells possess or lack A (ABO1) and/or B (ABO2) blood group antigens. Normal adult individuals whose red cells lack A and/or B antigens usually have the corresponding antibody in their serum. The potentially serious consequences of ABO incompatible transfusions require that both transfusion recipient and donor red cells be reliably tested for the presence of A and B antigens.

The D (RH1) antigen is capable of stimulating production of Anti-D in persons lacking the D antigen. Anti-D is a clinically significant antibody capable of causing red blood cell destruction and may result in hemolytic disease of the newborn (HDN) and transfusion reactions. The D antigen, therefore, is commonly considered in the routine selection of blood for transfusion and Anti-D immunoglobulin therapy.

As stated in the Instructions for Use (IFU):

- Results can only be used to **confirm** ABO group and D type.
- **Laboratory policy may require confirmation of the initial ABO, D typing and this cassette is intended for that purpose.** Any use of this cassette should comply with regulatory and accrediting agency requirements associated with confirmational testing for ABO grouping and D typing.

Impact to Results

According to the IFU, the blood group determination obtained with the Ortho ABD Confirmation Cassette must be compared to another method that includes an appropriate negative control. Results from this test are valid only if they agree with another method.

Therefore, if your laboratory performs confirmational testing as per standard procedures, a review of previous results is not required. Consult with your medical director for the appropriate course of action for your facility.

REQUIRED ACTIONS

- It is acceptable to continue using Lot ACC054H providing that blood group results are compared to an alternate method that includes a negative control.
- Complete the enclosed Confirmation of Receipt form no later than August xx,2019.
- Please forward this notification if the product was distributed outside of your facility.

Root Cause Investigation

Our root cause investigation into this issue is ongoing.

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 appropriate number/signatory if required

Confirmation of Receipt – Response Required

Communication ID: _____ Date of Issue: 2019-xx-xx

URGENT FIELD SAFETY NOTICE

Ortho BioVue® System ABD Confirmation Cassette, Lot ACC054H
Product Code 707135

*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **DD-MM-2019**

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 regarding false negative reactions for the Anti-D (RH1) reagent when using Ortho BioVue System ABD Confirmation Cassettes, Lot ACC054H.

I understand that blood group determination obtained with the Ortho BioVue System ABD Confirmation Cassette must be compared to another method that includes an appropriate negative control. Results from this test are valid only if they agree with another method.

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

Print Name: _____

Phone Number: _____ Date: _____

Your Comments: _____