URGENT

Ortho Clinical Diagnostics

5 Aug 2019

URGENT PRODUCT CORRECTION NOTIFICATION

Ortho BioVue® System ABD Confirmation Cassette, Lot ACC054H

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

Ortho Clinical Diagnostics has 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 Aug 15, 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 1800 5646766.