| Ortho Clinical Diagnostics | **Follow-up to URGENT FIELD SAFETY NOTICE**<br>**Increased Hemolysis Reported for Reagent Red Blood Cell Products** |
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**Date Issued** ***30th November 2016***

**Issue**

On 2nd November 2016, Ortho Clinical Diagnostics (Ortho) issued an Urgent Field Safety Notice due to Ortho confirming the intermittent presence of marked hemolysis caused by microbial contamination in some Ortho Reagent Red Blood Cell (RRBC) products as well as Quality Control products containing red blood cells. The November letter indicated that this issue affects lots with expiration dates up to 2016-12-16.

The November communication included a list of affected products with corresponding lots that were identified to be potentially affected by contamination. Subsequently, additional lots that were missing from the list have been identified as potentially affected. Moreover, investigations have determined that the potential for microbial contamination exists in any Reagent Red Blood Cell products with expiry dates up to **2017-01-24** rather than the previously specified date of 2016-12-16.

As noted in the original letter, Ortho is requesting that you continue to visually inspect ***all products*** prior to use for each day of use; per the Instructions for Use, ***do not use red cell products if marked hemolysis or evidence of contamination is observed.***

**Product List Inaccuracies**

The list enclosed with the original letter dated *2nd November,* included some inaccuracies, including an incomplete listing of products sold in markets outside the US, some incorrect product naming conventions, and missing lots. The following affected products sold in some international markets were missing entirely from the original list:

| Product Code | Product Name from Instructions for Use (IFU) |
|---|---|
| 707910 | Affirmagen® 4 |
| 719000 | Reagent Red Blood Cells Ortho® Pooled Screening Cells |
| 719100 | Reagent Red Blood Cells Surgiscreen® |
| 719102 | 0.8% Surgiscreen® |
| 719201 | Reagent Red Blood Cells 0.8% AFFIRMAGEN® |
| 719210 | Reagent Red Blood Cells (Pooled Cells) Affirmagen® |
| 719410 | Reagent Red Blood Cells ORTHO Ficin Panel System Resolve® Panel C System |
| 719510 | Reagent Red Blood Cells Resolve® Panel A |
| 719520 | Reagent Red Blood Cells Resolve® Panel B |
| 719610 | Reagent Red Blood Cells Selectogen® |
| 719810 | Reagent Red Blood Cells (Pooled Cells) Ortho® Coombs Control |
| 6901861 | Affirmagen® |
| 6901862 | ORTHO® A2 Cells |
| 6902096 | ORTHO® Confidence System |
| 6902314 | Reagent Red Blood Cells Ortho® 0.8% Pooled Screening Cells |
| 6902315 | Reagent Red Blood Cells 0.8% Selectogen® |
| 6902316 | Reagent Red Blood Cells 0.8% Surgiscreen® |
| 6902317 | Reagent Red Blood Cells 0.8% Resolve® Panel A |
| 6902318 | Reagent Red Blood Cells 0.8% Resolve® Panel B |

**Product List Inaccuracies, continued**

Due to the number of products and lots affected, a revised List of Affected Products is not being included in this communication.

*If you require a Listing of Affected Products and Lots or have questions regarding hemolysis detected at your facility, please contact the Ortho Care™ Technical Solutions Center.*

**Required Actions**

As instructed in the original product correction notification, please continue to do the following:

- Visually inspect all products prior to use for each day of use; per the Instructions for Use, ***do not use red cell products if marked hemolysis or evidence of contamination is observed***.
- Contact the Ortho Care™ Technical Solutions Center to report a product in which marked hemolysis is observed so that the product can be replaced or credited.

***In addition:***

- Complete and return the Confirmation of Receipt form by 8 **December 2016**. ***If you already submitted a Confirmation of Receipt form based upon the 2nd November communication and no additional affected lots have been identified since that response please select the first box only on the enclosed Confirmation of Receipt form.***

**Contact Information**

We thank you and your staff for your patience and cooperation as we manage the resolution of this issue. If you have questions or require additional information, please contact Ortho Care™ Technical Solutions Center at **+33 388 65 4763.**

Enclosure:
Confirmation of Receipt Form