

Date Issued November 2016

Issue Previously, Ortho Clinical Diagnostics (Ortho) issued an Urgent Product Correction Notification due to the intermittent presence of marked haemolysis caused by microbial contamination in some Ortho Reagent Red Blood Cell (RRBC) products as well as Quality Control products containing red blood cells. The notification 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.
- 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.

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 haemolysis or evidence of contamination is observed.***

Product List Inaccuracies The list enclosed with the original letter included some inaccuracies, including an incomplete listing of products, some incorrect product naming conventions, and missing lots. *The following affected products were missing 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 haemolysis detected at your facility, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

**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 haemolysis or evidence of contamination is observed.***
- Contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre to report a product in which marked haemolysis is observed so that the product can be credited.

In addition:

- Complete and return the Confirmation of Receipt form by **6 December 2016**. ***If you already submitted a Confirmation of Receipt form based upon the previous 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 your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,



Jon Wong, 30 Nov 2016
QA Manager

Enclosure:
Confirmation of Receipt Form

Confirmation of Receipt – Response Required

FOLLOW-UP TO URGENT PRODUCT CORRECTION NOTIFICATION

Ortho Clinical Diagnostics

Increased Haemolysis Reported for Reagent Red Blood Cell Products

Please return completed form by **fax or scan to PDF** and email so that we can complete our records no later than: **6-DEC-2016**

Send to: Anthony Leung

e-Mail Address: anthony.leung@orthoclinicaldiagnostics.com

Fax: 6486 1186

Please Confirm

I received the follow-up to the Urgent Product Correction Notification (Ref. CL2016-212ea_fu) informing me that subsequent to the issuance of the earlier Product Correction Notification (Ref. CL2016-212ea), additional lots have been identified as potentially affected by haemolysis due to microbial contamination.

I understand that the potential for microbial contamination exists in products with expiry dates up to **2017-01-24**. We will continue to inspect all products prior to use for each day of use, and, per the Instructions for Use, will not use red cell products if marked haemolysis or evidence of contamination is observed.

Please choose from the following:

- My laboratory has reviewed the Follow up to the Urgent Field Safety Notice and our response has not changed since we submitted the Confirmation of Receipt form included with the original communication.
- My laboratory has reviewed the Follow up to the Urgent Field Safety Notice. Since submitting the Confirmation of Receipt form included with the original communication, we have identified additional products with marked haemolysis in our inventory and will contact Ortho Care for credit of affected products.

Your signature provides confirmation that you have received and understand this notification.

Your Name: _____

Signature: _____

Phone Number: _____

Date: _____

Required if sent by
fax or a scanned PDF

Your Comments: _____

Your Name and Address

Please complete this section

Institution/
Contact Name: _____

Address: _____

City: _____

State/Prov: _____

Zip/Postal Code: _____

Phone: _____

Fax: _____

e-Mail: _____