

Date Issued*insert appropriate date***Issue**

Ortho Clinical Diagnostics (Ortho) is issuing this Urgent Field Safety Notice because Ortho has received an increase in customer complaints and has confirmed the intermittent presence of marked hemolysis in Ortho Reagent Red Blood Cell (RRBC) products as well as Quality Control products containing red blood cells.

Ortho conducted an extensive investigation, and the root cause for the marked hemolysis, as illustrated below, has been identified as microbial contamination.

**Affected Products**

The enclosed “List of Affected Red Blood Cell Products” indicates all product lots that Ortho has identified as potentially subject to microbial contamination.

Impact to Results

If markedly hemolyzed red cell products are used in testing, erroneous (false positive or false negative) results may be generated, which can potentially lead to patient harm. To date, Ortho has received no reports of erroneous patient/donor results due to this issue. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. As a reminder, the *Precaution* Section of the Instructions for Use for these products states:

“Do not use reagents if marked hemolysis or evidence of contamination is observed.”

Resolution

Corrective actions have been implemented and any RRBC product lots that expire after 2016-12-16 should not exhibit this hemolysis.

Required Actions

- Visually inspect all products prior to 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.
- Complete and return the Confirmation of Receipt form by **xx November 2016**.

**Contact
Information**

Ortho would like to apologize for the inconvenience and the increased workload that this issue may have caused your laboratory.

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 *<insert appropriate number.> (insert signatory with signature if required)*

Enclosure:

List of Affected Red Blood Cell Products