Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **Potential for False Positive Results Using ORTHO BioVue® System (Rh/K Cassette), Lot RHP020F**

Date Issued

xx July 2017

Issue

As part of a Field Safety Corrective Action, this Urgent Field Safety Notice is in reference to the following products:

Product Name	Product Code	Lot Number	Expiry
Blood Grouping Reagents Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti-c̄ (Anti-RH4) (Monoclonal) Anti-e (Anti-RH5) (Monoclonal) Anti-K ORTHO BioVue® System (Rh/K Cassette)*	**707280 (400 Cassettes) 707250 (100 Cassettes)**	**RHP020F**	**18-OCT-17**

*ORTHO BioVue System (Rh/K Cassette) is a qualitative test for recognition of the C (RH2), E (RH3), c̄ (RH4), e (RH5) and K (K1) antigens on human red blood cells

Ortho has confirmed the potential for unexpected false positive 3+ or 4+ results for either anti-c̄ (column 3) or anti-e (column 4) in a limited number of ORTHO BioVue® System (Rh/K Cassettes), Lot RHP020F only. The unexpected results are caused by a dried column that is located in either the anti-c̄ (column 3) or anti-e (column 4). If the cassette is affected, the dried column is located in either the anti-c̄ (column 3) or anti-e (column 4), but not both.

Ortho determined that up to 0.6% of 405,000 total cassettes produced for this lot only may be affected. If an affected cassette is used for testing:

- On ORTHO AutoVue® *Innova* or *Ultra* Systems, unexpected false positive results may occur without operator notification.
- On ORTHO VISION® and ORTHO VISION® Max Analyzers, the system automatically detects dried columns and rejects affected cassettes prior to using them for testing.
- In manual BioVue cassette testing, unexpected false positive results may occur.

Please refer to Questions and Answers on Page 3 for additional information.

Required Actions

- Immediately discontinue using and discard your remaining inventory of ORTHO BioVue System (Rh/K Cassette), Lot RHP020F. **NOTE:** If you have no alternative lot in your inventory, you may use the affected lot until you receive your replacement order if:
  1. Using Ortho VISION or ORTHO VISION Max Analyzers or
  2. You manually inspect cassettes from the affected lot for dried columns prior to use if performing:
     a. manual BioVue cassette testing, or
     b. testing on ORTHO AutoVue® *Innova* or *Ultra* Systems.

Required Actions, continued

- Complete and return the Confirmation of Receipt form no later than **xx July 2017** Upon receiving your Confirmation of Receipt form, Ortho will credit your account or send a replacement order for discarded product.
- Forward this notification if you have provided this product outside of your facility.

Impact to Results

Use of cassettes with either a dried anti-c̄ column or dried anti-e column for testing could potentially mistype patients who are antigen negative as being c̄ or e antigen positive and erroneously suitable to receive c̄ or e positive blood. If the cassette is affected, the dried column is located in either the anti-c̄ (column 3) or anti-e (column 4), not both.

Please review previous results generated from testing with this product lot and consult with your Medical Director to determine whether any follow-up activities are required for samples that produced 3+/4+ anti-c̄ or anti-e results only for patients who have no previous clinical history.

If visual inspection was performed prior to use, and dried columns were identified and rejected for use, previous results utilizing this lot should not be affected. As a reminder, the Precautions Section of the Instructions for Use currently states:

Do not use cassettes that appear damaged (i.e., break in foil seal or break, crack or bubble in the column) or exhibit drying (i.e., liquid level is at or below the top of the glass beads) or exhibit discoloration (due to bacterial contamination which can cause false reactions).

Investigation

Ortho became aware of this quality issue from customers who contacted us after either finding dried columns when manually checking cassettes prior to use or after obtaining unexpected false positive results when using their ORTHO AutoVue *Innova* or *Ultra* Systems.

Ortho's root cause investigation in coordination with our plastic cassette supplier has traced this issue to a defect in the plastic molding of a limited number of cassettes produced at the supplier's facilities. Only lot RHP020F is affected by this issue.

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* / *insert signatory if required*

Enclosure: Confirmation of Receipt Form

Questions and Answers

1. **Is there any impact to previously reported results if I used cassettes from the affected lot?**

   A dried column could cause a false positive or erroneous result. If the cassettes from Lot RHP020F were inspected prior to use and the result was as expected, no further action is required. If you suspect that an erroneous result occurred (i.e., 3+/4+ anti-c̄ or anti-e reaction only for patients who have no previous clinical history), please consult with your Medical Director and report the occurrence to our Ortho Care™ Technical Solutions Center at *insert appropriate number*.

2. **Are any other products affected by this issue?**

   Ortho has determined that this issue is limited to 0.6% of the cassettes manufactured from ORTHO BioVue System (Rh/K Cassette), Lot RHP020F only. The affected cassettes contain a plastic molding defect that occurred during a single, identified manufacturing event that occurred at the supplier of our plastic cassettes.

3. **Will this issue be detected if I am using an ORTHO VISION Analyzer or ORTHO VISION Max Analyzer or BioVue manual testing?**

   As part of their design, ORTHO VISION and VISION Max Analyzers perform a quality pre-check and reject cassettes identified with dried columns (Error Code CIMS21) prior to use. Unlike ORTHO VISION and ORTHO VISION Max Analyzers, ORTHO AutoVue *Innova* and *Ultra* Systems do not have the functionality to detect dried columns prior to cassettes being used for testing.

   The ORTHO BioVue System (Rh/K Cassette) IFU cautions against using cassettes for testing that exhibit drying (i.e., liquid level is at or below the top of the glass beads).

4. **When can I expect my replacement order?**

   For your convenience, Ortho will either process your product replacement or credit your account upon receipt of your Confirmation of Receipt Form. Please choose your replacement or credit preference on the Confirmation of Receipt Form included with this communication.

5. **I do not have an alternative lot in my inventory. May I continue to use the affected lot until I receive my replacement order?**

   Yes. If you have no alternative lot in your inventory, you may use the affected lot until you receive your replacement order if:

   1. Using Ortho VISION or ORTHO VISION Max Analyzers, or
   2. You manually inspect cassettes from the affected lot for dried columns prior to use if performing:
      a. manual BioVue cassette testing, or
      b. testing on ORTHO AutoVue® *Innova* or *Ultra* Systems.

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

Ortho Clinical Diagnostics

Potential False Positive Results Using ORTHO BioVue® System (Rh/K Cassette), Lot RHP020F

*Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than*: **xx-July-2017**

Send to: **Insert name** e-Mail Address: **insert email** Fax: **Insert number**

Please Confirm

I received the Urgent Field Safety Notice regarding a limited number of Ortho BioVue System Rh/K Cassettes, Lot RHP020F, that may contain a dried column, and, if used, may cause unexpected positive 3+ or 4+ results for either anti-c̄ (column 3) or anti-e (column 4), but not both. I understand that according to the Instructions For Use for this product I must visually inspect all cassettes to ensure that I do not use a cassette that exhibits dried columns.

NOTE: It is acceptable to use your remaining inventory provided you do not use cassettes that show signs of drying.

Please choose from the following:** **Credit will be applied to partial sales units. Replacement of product can only be provided for full sales units that are discarded.

- ☐ My laboratory does not currently use Ortho BioVue System Rh/K Cassettes and is not affected by this issue.
- ☐ My laboratory uses Ortho BioVue System Rh/K Cassettes, but does not have any of Lot RHP020F remaining in inventory.
- ☐ **For Replacement of Product:** My laboratory uses Ortho BioVue System Rh/K Cassettes. We have discontinued using and discarded the quantity of the affected lot listed in the table below. Please provide a replacement for the quantity indicated. (**NOTE:** Ortho will replace complete sales units only.)
- ☐ **For Credit of Product:** My laboratory uses Ortho BioVue System Rh/K Cassettes. We have discontinued using and discarded the quantity of the affected lot listed in the table below. Please credit my account for the quantity indicated.

Product Name / LOT	Quantity of Individual Cassettes (only) Discarded
Ortho BioVue System Rh/K Cassettes, Lot RHP020F, Product Code 707280 (400 cassettes per sales unit)	
Ortho BioVue System Rh/K Cassettes, Lot RHP020F, Product Code 707250 (100 cassettes per sales unit)	

One Sales Unit for Product Code 707280=400 Cassettes. One Sales Unit for Product Code 707250=100 Cassettes

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

Your Name: _____

Phone Number: _____ Date: _____

Signature: Required if sent by fax or a scanned PDF

Your Comments: _____

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: _____