Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

June xx, 2013

URGENT FIELD SAFETY NOTICE

Inspection of ORTHO BioVue® System Cassettes

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information that Ortho Clinical Diagnostics (OCD) has identified isolated occurrences of improperly positioned cassette labels for the products listed in the enclosure. Our records indicate that you were shipped some of the *potentially* affected products. The purpose of this notification is to inform you of the issue and provide instructions for the inspection of the potentially affected product remaining in your facility.

Background Information

An investigation confirmed that the cause of the issue occurred on one of our three manufacturing lines following a particular sequence of events. The investigation concluded that the occurrence rate of the issue is very low.

The use of an affected multi-reagent cassette may lead to false negative or false positive results causing a potential misclassification of the patient or donor blood groups or incorrect antibody detection results. There is no risk associated with the use of an affected single-reagent cassette since all wells contain the same reagent.

Required Actions

- Inspect all cassettes from the potentially affected lots remaining in your facility prior to use. Refer to the enclosed ORTHO BioVue® System Cassette Inspection Procedure for detailed visual instructions.
- Do not use cassettes with an incorrectly positioned label. Contact your Customer Technical Support representatives for to report the issue and request assistance. Discard the affected cassette in accordance with your local regulations.
- Complete and return the Confirmation of Receipt form no later than **July xx, 2013**.
- Post this notification and inspection procedure in your facility.
- Forward this notification if you have provided this product outside of your facility

Resolution

We have identified the root cause of this issue and we have implemented corrective actions to mitigate a reoccurrence.

We apologize for the inconvenience this will cause your laboratory. We have anticipated some questions you may have in the following Question and Answers section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number.*

Sincerely,
insert appropriate name
insert appropriate title

Enclosures:

Potentially Affected ORTHO BioVue® System Cassettes
ORTHO BioVue® System Cassette Inspection Procedure

Questions & Answers

1. Is there any impact to previously reported results if I used a cassette from one of the affected lots?

Our assessment determined that the likelihood an incorrect result obtained using an affected cassette is remote. This assessment is based on the following:

- Low probability of the occurrence of the issue
- Presence of a Control reagent in most blood grouping and phenotyping cassettes
- Use of Quality Control samples
- Laboratory procedures and/or specific regulations that require samples to be tested in duplicate or results are compared to previously obtained results

If you suspect that erroneous result occurred, please consult with your medical director and report the occurrence to our Customer Technical Service representatives.

2. Are all lots affected by this issue?

No, only the lots listed in the enclosure are subject to the inspection. Our investigation confirmed that the issue occurred on one of our three manufacturing lines following a particular sequence of events; not all types of cassettes are manufactured on this line. A thorough review of all data concluded the rate of the defect is very low.

3. How can I determine the proper label position if I have an affected lot?

Follow the instructions provided in the enclosed ORTHO BioVue® System Cassette Inspection Procedure. The procedure sheet contains examples of both a properly and improperly positioned cassette label.

Performing the inspection prior to use will help to mitigate the occurrence and allow the use of the product.

4. What action should I take if I identify an improperly positioned label cassette?

If you identify an affected cassette in your facility, do not use the cassette. We advise that you contact your Customer Technical Support representatives to report the issue and request assistance. Discard the affected cassette in accordance with your local regulations.

5. Does OCD recommend performing the inspection all at once?

We recommend that you perform the inspection *prior to use* to minimize cassette handling so as not to induce other potential defects caused by excess handling.

6. What is OCD doing to prevent this issue from reoccurring on other lots?

We have identified the root cause of this issue and we have implemented preventative and corrective actions to mitigate a reoccurrence.

Confirmation of Receipt - Important Response Required

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So that we can complete our records, please return this form to us no later than **July xx, 2013**.

FAX TO: ***insert appropriate name***
FAX: ***insert appropriate number***

Section I: Confirmation

I received the Urgent Field Safety Notice (Ref. CL13-198_EU) and understand that I must inspect all potentially affected cassettes (listed in the enclosure) for proper label orientation prior to use. If I identify an affected cassette, I am advised to not use it and contact my Customer Technical Support representatives to report the issue.

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

Your Name:_____ Job Title (optional):_____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number:_____

J Number: _____ Institution: _____

Your comments are always welcome:

Section II – Verification of your Name and Address

Verify your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: _____

Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Telephone: _____ FAX: _____