Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

December xx, 2013

FOLLOW UP URGENT FIELD SAFETY NOTICE
Improperly Positioned Labels on ORTHO BioVue® System Cassettes

Dear Customer:

This is a follow up to a prior Field Safety Corrective action to inform you that Ortho Clinical Diagnostics (OCD) has identified an additional occurrence of an improperly positioned cassette label on ORTHO BioVue® System Cassettes. This notification contains information regarding the additional complaint and provides risk assessment information about the rate of occurrence and the potential impact to results for each type of cassette.

Background Information

In June 2013, OCD received one customer complaint regarding improperly positioned cassette labels on an ORTHO BioVue® System Cassette. Upon detection of this issue, manufacturing of ORTHO BioVue® System Cassettes was placed on hold pending completion of our investigation.

Our investigation identified an issue isolated to one of our three manufacturing lines following a particular sequence of several failure modes, including the way cassettes were presented to the camera detection system designed to detect labeling anomalies. Customers who were shipped any of the affected products were issued Field Safety Notices Ref. CL13-198 & CL13-238. The occurrence rate of improperly positioned cassette labels on ORTHO BioVue® System Cassettes was stated as 1 in 11.5 million cassettes.

Recently, OCD received one additional customer complaint related to improperly positioned cassette labels on an ORTHO BioVue® System Cassette. As described below, the root cause of this second event was determined to be different from the first event (customer complaint).

OCD has also completed a review of customer complaints and has confirmed that only these two complaints have been reported for or could be associated with improperly positioned cassette labels over a five year period.

Investigation Summary

The root cause of this recent occurrence is due to a manufacturing line failure to reject a cassette with a labeling anomaly that was properly identified by the camera detection system. A comprehensive engineering evaluation has been performed on all manufacturing lines and immediate corrective actions have been implemented.

The risk of the failure to reject ORTHO BioVue® System Cassettes with improperly positioned cassette labels has been further reduced for all lots manufactured since November 2013.

Based upon this *new* information and a review of complaint data from the last five years, OCD concludes that the rate of occurrence is consistent with that stated in our previous notification.

Impact to Results

OCD has completed a comprehensive assessment of the medical risks associated with using an improperly labeled ORTHO BioVue® System Cassette. In this assessment, we used a conservative assessment of the rate of occurrence.

To facilitate risk assessment activities, detailed information regarding the impact to results is provided below. Based on population blood group distributions and the rate of occurrence determined from our internal inspection, the probability of an incorrect result was determined as follows:

Type of Result	Probability of Incorrect Result	Comments
ABO blood typing	Between 1 in 0.9 Million - 1 in 500 Billion	Probability is dependent upon the intended use of the cassette type. Refer to the enclosed risk assessment.
Rh & Kell typing	Between 1 in 3 Million - 1 in 33 Million	Probability is dependent upon the intended use of the cassette type. Refer to the enclosed risk assessment.
Antibody Screening	1 in 5 Billion	ORTHO BioVue® System Poly/Neutral Cassettes only. Refer to the enclosed risk assessment.

For cassettes containing a single type of reagent, the orientation of the labeling does not adversely affect product function since all wells contain the same reagent. Therefore, there is no risk associated with the use of an affected single-reagent cassette.

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. For specific types of affected multi-reagent cassettes, further mitigations are in place to prevent the reporting of erroneous results, such as:

- Presence of a Control reagent in most blood grouping and phenotyping cassettes
- Laboratory procedures and/or specific regulations that require samples to be tested in duplicate or comparison to previously obtained results

Enclosed is a Risk Assessment Evaluation for Improperly Positioned Cassette Labels, as well as Cassette Interpretations for Improperly Positioned Cassette Labels. These documents provide detailed information regarding the impact to results for each type of cassette for your risk assessment evaluation. Please contact our Customer Technical Service representatives at *insert appropriate number* if your facility has identified any instances of a miss-typed patient or donor result. This will enable OCD to perform any necessary investigation and regulatory reporting associated with such occurrences.

Required Actions

- Consider the need to review patient results. If you suspect that a previously reported result may have been affected, provide this information to your Laboratory Medical Director and the requesting physician or health care provider so that appropriate actions may be taken.
- Notify your Medical Director to assess the need to complete a risk assessment based on the information provided in this notification.
- Contact our Customer Technical Service representatives at *insert appropriate number* if your facility has identified any instances of a miss-typed patient or donor result using cassettes.
- Complete and return the Confirmation of Receipt form no later than **December xx, 2013**.
- Forward this notification if you have provided this product outside of your facility.

NOTE: Based on OCD's determination of root cause, the low rate of occurrence and additional mitigations, we are advising that an inspection of your current inventory is not necessary.

Customer satisfaction is our highest priority and we appreciate your time and patience. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions regarding this issue, please contact our Customer Technical Service representatives at *insert appropriate number*.

Sincerely,

insert appropriate name
insert appropriate title

Enclosures:

1. Risk Assessment Evaluation for Improperly Positioned Cassette Labels
2. Cassette Interpretations for Improperly Positioned Cassette Labels

Questions & Answers

1. **Why did OCD require a cassettes inspection in the previous notifications but it is not required now?**

   In June 2013, our investigation was in progress and we did not have enough data to determine the rate of occurrence. As a precaution, we advised customers to inspect all cassettes from the potentially affected lots remaining in their facility prior to use

   Upon completion of the investigation, our determination of root cause, the low rate of occurrence and additional mitigations, we are advising that an inspection of your current inventory is not necessary.

2. **Which lots are affected by this issue?**

   Our investigation concluded that the root cause and rate of occurrence are not product or lot specific.

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 **December xx, 2013**.

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

Section I: Confirmation

I received the Urgent Field Safety Notice (Ref. CL13-339_EU) and understand that I am advised to notify my Medical Director to assess the need to complete a risk assessment based on the information provided in this notification. If I identify an affected result, I am advised to 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: _____