

January xx, 2014

FOLLOW UP URGENT FIELD SAFETY NOTICE

Revised Risk Assessment & Interpretation Data for Improperly Positioned Labels on ORTHO BioVue® System Cassettes

Dear Customer:

This is a follow up to a prior Field Safety Corrective action that was issued in December 2013 (Ref. CL13-339) regarding an improperly positioned cassette label on ORTHO BioVue® System Cassettes. This notification contains revised information regarding the risk assessment information about the rate of occurrence and the potential impact to results for each type of cassette.

Background Information

In June 2013, Ortho Clinical Diagnostics, Inc. (OCD) received one customer complaint regarding an improperly positioned cassette label on an ORTHO BioVue® System Cassette, in October we received one additional complaint. OCD completed a review of customer complaints and has confirmed that only these two complaints have been reported or could be associated with improperly positioned cassette labels over a five year period.

Revised Risk Assessment

Enclosed with the previous notification issued in December, we provided a comprehensive assessment of the medical risks associated with using an improperly labeled ORTHO BioVue® System Cassette. It has come to our attention that there was an error in data previously provided for the RH & K typing cassette:

Type of Cassette	Clinical Utility	Potential Incorrect Results	Potential Population Affected	Overall Probability of Incorrect Result ¹	Comments / Observed Conditions
Data provided with previous notification:					
RHP	Rh & K typing	Incorrect Rh & K typing R2r K+ as R0r or rr R0r K+ as R2r or r''r	Approximately 1.5%	Remote (1 in 33 Million)	R2r: 11% in Caucasian (9% in Blacks) R0r: 25% in Blacks (2% in Caucasian) Total % of population that could potentially be affected is around 1.5% (11%*9% + 25%*2%)^{2,7}
Revised data is indicated in red:					
RHP	Rh & K typing	Incorrect Rh & K typing ccEe K- as ccee K+ ccee K+ as ccEe K-	Approximately 13%	Remote (1 in 3.8 Million)	DccEe: 11% in Caucasian (9% in Blacks); ccEe: 1% in Blacks (0.9% in Caucasian); Dccee: 25% in Blacks (2% in Caucasian); ccee: 15% in Caucasian (6.5% in Blacks) Total % of population that could potentially be affected is around 13% (11%*9% + 1%*98% + 25%*2% + 15%*9%)^{2,7}

Revised Impact to Results

The revised information also affects the probability that was listed in Impact to Results section of the previously issued customer letter. The revised probability should be 1 in 3.8 Million.

Type of Result	Probability of Incorrect Result	Comments
Data provided with previous notification:		
Rh & Kell typing	Between 1 in 3 Million - 1 in 33 Million	Probability is dependent upon the intended use of the cassette type.
Revised data is indicated in red:		
Rh & Kell typing	Between 1 in 3 Million - 1 in 3.8 Million	Probability is dependent upon the intended use of the cassette type.

Revised Cassette Interpretations for Improperly Positioned Cassette Labels

OCD also determined that the interpretation data provided for the **ABO-Rh/Reverse Cassette** was listed as “A Pos” and it should have been “**A Neg**” as shown below and in the enclosure:

	Correct Label						Interpretation		Reverse Label						Interpretation
	1	2	3	4	5	6			1	2	3	4	5	6	
REAGENT	A	B	D	CTL	Rev	Rev	Interpretation	R	Rev	Rev	CTL	D	B	A	Interpretation
LABEL	A	B	D	CTL	Rev	Rev		L	A	B	D	CTL	Rev	Rev	
O Pos	0	0	+	0	+	+	O Pos		0	0	0	+	+ or 0	+ or 0	Invalid Ctl
O Neg	0	0	0	0	+	+	O Neg		0	0	0	0	+ or 0	+ or 0	O NEG or F/R discrepancy
A Pos	+	0	+	0	0	+	A Pos		0	0	0	+	0	+ or 0	Invalid Ctl
A Neg	+	0	0	0	0	+	A Pos Neg		0	0	0	0	0	+ or 0	Invalid F/R
B Pos	0	+	+	0	+	0	B Pos		0	0	0	+	+ or 0	0	Invalid Ctl & F/R
B Neg	0	+	0	0	+	0	B Neg		0	0	0	0	+ or 0	0	Invalid F/R
AB Pos	+	+	+	0	0	0	AB Pos		0	0	0	+	0	0	Invalid Ctl & F/R
AB Neg	+	+	0	0	0	0	AB Neg		0	0	0	0	0	0	Invalid F/R

Required Actions

- Discard the previous enclosures provided in the **December 2013** notification and replace with the following enclosed revised documents:
 - Revised Risk Assessment Evaluation for Improperly Positioned Cassette Labels
 - Revised Cassette Interpretations for Improperly Positioned Cassette Labels
- Complete the Confirmation of Receipt form to confirm that you have been provided the revised documents (listed above). Please return no later than **February xx, 2014**.
- Forward this notification if you have provided this product outside of your facility.

As a reminder from our previous notification:

- 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.

Conclusion

Based on this revised information and a review of complaint data from the last five years, OCD concluded that the rate of occurrence is consistent with the previous notification.

If you have any additional questions regarding this issue, please contact our Customer Technical Service representatives at **insert appropriate number**.

Sincerely,

insert appropriate name & title

Enclosures:

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

Confirmation of Receipt - Important Response Required
FOLLOW UP URGENT FIELD SAFETY NOTICE
Revised Risk Assessment & Interpretation Data for
Improperly Positioned Labels on ORTHO BioVue[®] System Cassettes

So that we can complete our records, please return this form to us no later than **February xx, 2014.**

FAX TO: *insert appropriate name*

FAX: *insert appropriate number*

Section I: Confirmation

I received the Follow Up Urgent Field Safety Notice (Ref. CL2014-043_EU) and I have been provided the revised Risk Assessment and Cassette Interpretation data.

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: _____