

**Date** *Insert Date***Product** This Urgent Field Safety Notice is in reference to the following products:

Product Name	Product Code
VidimSoft OrthoScan™ System	300.0122
ORTHO™ Workstation for BioVue® Cassettes	6904629

The OrthoScan System (OrthoScan), manufactured by VidimSoft, is used to capture electronic images of the agglutination patterns of ORTHO BioVue® System Cassettes (BioVue Cassettes) and assist in interpretation, security and storage of the images.

The ORTHO Workstation, manufactured by Ortho Clinical Diagnostics (Ortho), supports the *in vitro* immunohematology testing of human blood through the incubation and centrifugation of BioVue Cassettes.

**Issue Explanation** As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics (Ortho) initiated this Urgent Field Safety Notice having been made aware that, due to the requirement to manually apply up to six (6) barcode labels to BioVue Cassettes when using OrthoScan, there is the possibility that if labels are applied to a cassette incorrectly (with gaps and/or creases with one or multiple labels applied), the cassette may not be positioned properly in the ORTHO Workstation Centrifuge Cassette Holder.

**Impact to Results** Centrifugation of BioVue Cassettes that are not positioned properly (i.e. level) into the ORTHO Workstation Centrifuge Cassette Holder may produce incorrect (false positive) results. Affected sample results occurring prior to this communication are not easily identifiable; thus, a review of previous results may be impractical.

- Required Actions**
- If your laboratory adds VidimSoft labels to BioVue Cassettes and uses a ORTHO Workstation, operators should ensure that:
    - Labels are applied without a significant gap at the bottom of the cassette and without creases in the label after it is applied to the cassette to help assure the cassette is positioned correctly in the Workstation Centrifuge Cassette Holder. *Refer to Illustrations on Page 2.*
    - Cassettes are positioned level in the ORTHO Workstation Centrifuge Cassette Holder prior to the initiation of the centrifugation cycle. *Refer to Illustrations on Page 2.*
  - Post this notification by your ORTHO Workstation or with your user documentation.
  - Complete and return the Confirmation of Receipt form by **xx May 2017**.

**Contact Information** Please contact the Ortho Care™ Technical Solutions Center at *insert phone number* if you have further questions or require additional information.

*Signature if required*

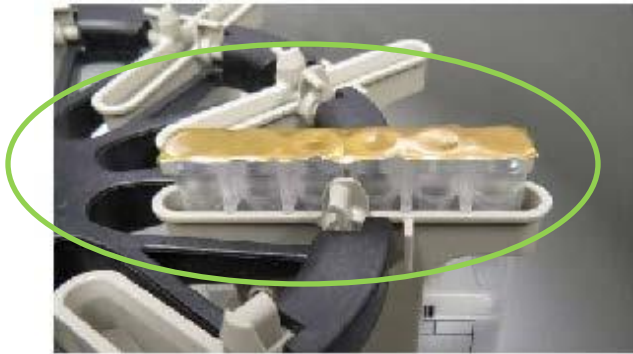
**Illustrations  
of Proper  
Label  
Application  
and  
Cassette  
Positioning**



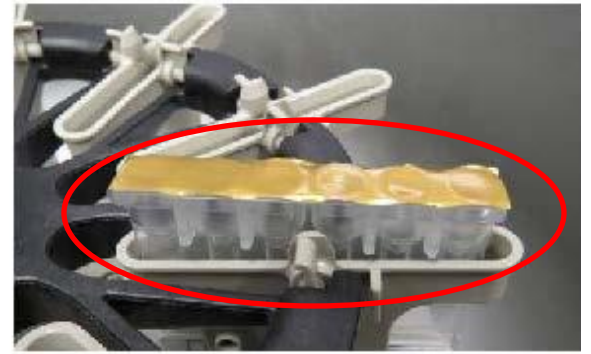
Incorrectly applied label



Correctly applied label



Cassette correctly  
positioned in  
Centrifuge Holder



Cassette incorrectly  
positioned in  
Centrifuge Holder