Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No...٥٥..... dated ١٠/١/٢٠٢٤ Regarding NCMDR Field Safety Corrective Action of Ortho BioVue System Cassette products from (Ortho-Clinical Diagnostics).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

dg-padc@moh.gov.om : البريد الإلكتروني - فاكس: ٢٢٣٥٨٤٨٩ - هاتف: ٢٢٣٥٧١١١ - الرمز البريدي: ١٠٠ - ص . ب: ٣٩٣ مسقط
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 05 / 2021

27-05-1442 H

10-01-2021

Field Safety Corrective action of Ortho BioVue System Cassette products from Ortho-Clinical Diagnostics.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15483
Product	Ortho BioVue System Cassette products.
Description	Instrument/analyser IVDs.
Manufacturer	Ortho-Clinical Diagnostics.
Local Agent	Al Hashar Pharmacy.
The affected products	1-Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly) cassette: - Product Code: 707300, 707350 - Affected Lots: AHC171J, AHC172J, AHC181J, AHC179H, AHC180H, AHC182J - Expiry Date: 21 Mar 2021, 26 Mar 2021, 16 May 2021, 18 May 2021, 22 May 2021, 30 May 2021 2- Ortho BioVue® System Anti-Human Globulin Anti-IgG (Rabbit) Anti-Human Globulin Anti-C3b, -C3d (Monoclonal) Control (DAT/IDAT) cassette: - Product Code: 707165 - Affected Lots: DAT015F, DAT016H, DAT017F. - Expiry Date: 21 Jan 2021, 09 Mar 2021, 19 Apr 2021 3- Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly/Neutral) cassette: - Product Code: 707310, 707355.
Reason	A non-specific reactivity was identified in a few Ortho BioVue System cassette lots. When processing patient or Quality Control (QC) samples on the ORTHO VISION/ORTHO VISION Max or Ortho AutoVue Systems, customers reported a 0.5+ or Indeterminate (IND) result where the result was expected to be negative. In some instances, customers also reported Haze when using the Ortho BioVue System DAT/IDAT Cassette.
Action	1. Be aware unexpected reactivity issues may result in additional repeat testing, please follow your laboratory Standard Operating Procedures. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

IMPORTANT

Ortho Clinical Diagnostics

December XX, 2020

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Increased Incidence of Non-Specific Reactivity for Several ORTHO BioVue® System Cassette Products

Dear Customer,

Ortho recently issued a letter (Ref. 2020-286a) regarding the effect of a raw material lot on several Ortho BioVue® System Cassette products. The letter (Ref.2020-286a) related to customers experiencing intermittent false Mixed Field (MF) gradings on their ORTHO AutoVue Systems caused by small agglutinates present in the supernatant of Anti-A and Anti-A, B columns of some Ortho BioVue® System Cassettes. When processing on an Ortho AutoVue System only, the agglutinates were incorrectly interpreted as Mixed Field (MF) reactions by the Ortho AutoVue Image Processing System (IPS) algorithm. These were not true MF patterns as there were no dual population of agglutinates. ORTHO VISION systems were **not** affected by this issue.

This notification is to inform you that you may observe intermittent false positive or indeterminate results while testing on ORTHO VISION®/ORTHO VISION® Max or Ortho AutoVue® Systems with Ortho BioVue® System Cassette products and lots listed below:

Affected Product	Product Code Unique Device Identifier No.	Affected Lots	Expiry Date
Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly) cassette	**707300** **707350** (10758750008124)	AHC171J AHC172J AHC181J AHC179H AHC180H AHC182J	21 Mar 2021 26 Mar 2021 16 May 2021 18 May 2021 22 May 2021 30 May 2021
Ortho BioVue® System Anti-Human Globulin Anti-IgG (Rabbit) Anti-Human Globulin Anti-C3b, -C3d (Monoclonal) Control (DAT/IDAT) cassette	**707165** (10758750008063)	DAT015F DAT016H DAT017F	21 Jan 2021 09 Mar 2021 19 Apr 2021
Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly/Neutral) cassette	**707310** **707355** (10758750008148)	PLN036F	01 Jun 2021

Note: Ortho is actively working to manufacture additional inventory to replenish product availability.

Description of Issue

Ortho received complaints where non-specific reactivity was identified in a few Ortho BioVue® System cassette lots. When processing patient or Quality Control (QC) samples on the ORTHO VISION®/ORTHO VISION® Max or Ortho AutoVue® Systems, customers reported a 0.5+ or Indeterminate (IND) result where the result was expected to be negative. In some instances, customers also reported Haze when using the Ortho BioVue® System DAT/IDAT Cassette.

Impact to Results

The complaints have been assessed using standard procedures; the likelihood of serious injury to patient as a result of this failure mode is remote. Observations of unexpected reactivity may force customers to perform additional and repeat testing, which could lead to a delay in treatment.

Investigation

Based on the information gathered during *both* investigations there appears to be one specific raw material lot that is the likely cause of the intermittent false positive or indeterminate results *and* the false MF gradings in these Ortho BioVue® System Cassettes. This raw material lot is no longer being used to manufacture product.

Now that we have identified the root cause issue, Ortho has implemented additional controls to secure the performance of future released lots while we continue to progress the investigation to address the raw material lot issue.

REQUIRED ACTION

- Be aware unexpected reactivity issues may result in additional repeat testing, please follow your laboratory Standard Operating Procedures.
- Complete the enclosed Confirmation of Receipt form no later than Month XX, 2020.
- Please forward this notification if the product was distributed outside of your facility.

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.*

IMPORTANT

Ortho Clinical Diagnostics

December 16, 2020

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Increased Incidence of Non-Specific Reactivity for Several ORTHO BioVue® System Cassette Products

Dear Distributor,

Ortho recently issued a letter (Ref. 2020-286a) regarding the effect of a raw material lot on several Ortho BioVue® System Cassette products. The letter (Ref.2020-286a) related to customers experiencing intermittent false Mixed Field (MF) gradings on their ORTHO AutoVue Systems caused by small agglutinates present in the supernatant of Anti-A and Anti-A, B columns of some Ortho BioVue® System Cassettes. When processing on an Ortho AutoVue System only, the agglutinates were incorrectly interpreted as Mixed Field (MF) reactions by the Ortho AutoVue Image Processing System (IPS) algorithm. These were not true MF patterns as there were no dual population of agglutinates. ORTHO VISION systems were **not** affected by this issue.

This notification is to inform customers that they may observe intermittent false positive or indeterminate results while testing on ORTHO VISION®/ORTHO VISION® Max or Ortho AutoVue® Systems with Ortho BioVue® System Cassette products and lots listed below:

Affected Product	Product Code Unique Device Identifier No.	Affected Lots	Expiry Date
Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly) cassette	**707300** **707350** (10758750008124)	AHC171J AHC172J AHC181J AHC179H AHC180H AHC182J	21 Mar 2021 26 Mar 2021 16 May 2021 18 May 2021 22 May 2021 30 May 2021
Ortho BioVue® System Anti-Human Globulin Anti-IgG (Rabbit) Anti-Human Globulin Anti-C3b, -C3d (Monoclonal) Control (DAT/IDAT) cassette	**707165** (10758750008063)	DAT015F DAT016H DAT017F	21 Jan 2021 09 Mar 2021 19 Apr 2021
Ortho BioVue® System Anti-Human Globulin Anti-IgG, -C3d; polyspecific (Poly/Neutral) cassette	**707310** **707355** (10758750008148)	PLN036F	01 Jun 2021

Note: Ortho is actively working to manufacture additional inventory to replenish product availability.

Description of Issue

Ortho received complaints where non-specific reactivity was identified in a few Ortho BioVue® System cassette lots. When processing patient or Quality Control (QC) samples on the ORTHO VISION®/ORTHO VISION® Max or Ortho AutoVue® Systems, customers reported a 0.5+ or Indeterminate (IND) result where the result was expected to be negative. In some instances, customers also reported Haze when using the Ortho BioVue® System DAT/IDAT Cassette.

REQUIRED ACTION

- Send the customer letter (Ref.CL2020-306a) to all customers who were shipped the affected lots of the affected products mentioned above from your facility.
- Complete the enclosed Confirmation of Receipt form no later than December 23, 2020.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care™ Technical Solutions Center.

Enclosure: Customer Letter (Ref.CL2020-306a)