URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

Potential Weak or No Reactivity Observed for ORTHO Blood Grouping Reagent Anti-Le^a (Anti-LE1) (Murine Monoclonal) BioClone® 2.0

Dear Customer,

The purpose of this Urgent Field Safety Notice is to provide awareness regarding potential weak or no reactivity for several lots of ORTHO Blood Grouping Reagent Anti-Le^a (Anti-LE1) (Murine Monoclonal) BioClone® 2.0 (listed below). Our records indicate you were shipped at least one of the affected lots listed below.

ORTHO Blood Grouping Reagent Anti-Le^a (Anti-LE1) BioClone® 2.0		
Product Code (Unique Device Identification)	**Affected Lot(s)**	**Expiry**
6901859 (10758750007271)	LAB168AX	14-May-2023
	LAB169AX	23-Jul-2023
	LAB170AX	10-Sep-2023

Investigation Summary

During an internal investigation, Ortho identified that the Anti-Le^a (Anti-LE1) lot LAB170A was demonstrating weak to no reactivity with Le^a positive cells. The results of the investigation demonstrated that lot LAB170A was more than two dilutions lower than the control lot, thereby these lots were failing internal testing. This issue of weak/no reactivity of Anti-Le^a (Anti-LE1) antisera may be detectable in both Quality Control (QC) and patient samples based on weakened strength of reactivity.

The affected lots were all manufactured with the same Anti-Le^a (Anti-LE1) raw material.

To date, no patient impact has been reported due to this issue.

Further root cause investigation is ongoing.

Impact to Results

User may experience:

- Delayed results with valid Le^a phenotype determinations and potential delays with QC due to weakened reactivity.
- False negative reactions that may impact a patient or donor Le^a status. This could lead to uncertain determinations of phenotype, antibody identification and compatibility testing.

REQUIRED ACTION

- Stop using and discard your remaining inventory of ORTHO Blood Grouping Reagent Anti-Le^{a} (Anti-LE1) BioClone® 2.0 lots LAB168AX, LAB169AX, and/or LAB170AX.Ortho will replace or credit your account. Indicate quantities to be replaced or credited via the Confirmation of Receipt form.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY**.
- Please forward this notification if the affected product was distributed outside of your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

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 number.*

Insert signatory if required in your region.

Enclosure: Confirmation of Receipt Form