



July 6, 2023

Ministry of Health, Vietnam  
Department of Medical Device & Construction  
Departments of Health

## Letter of Explanation - ORTHO™ Anti-Sera Product Names LOA / IFUs VS LABELS and CFS

Dear Officer,

This is in relation to the product names listed on the LOA and IFUs, differing with the product names listed on the labels and Certificate of Free Sale.

The product names in terms of full description in the LOA and IFUs have the cell line added (i.e. (Anti-FY1)) for additional information and does not form part of the product name.

Please be assured that there is no difference in the product as the product codes appearing on the CFS/Labeling and the LOA/IFUs are identical.

We request that you refer to product codes and names on the CFS for this situation.

Code	Product Name
6904623	ORTHO™ Sera Anti – D (DVI)
6904493	ORTHO™ Sera Anti – D (IAT)
6904488	ORTHO™ Sera Anti – Jk <sup>a</sup>
6904489	ORTHO™ Sera Anti – Jk <sup>b</sup>
6904497	ORTHO™ Sera Anti – Le <sup>a</sup>
6904498	ORTHO™ Sera Anti – Le <sup>b</sup>
6904490	ORTHO™ Sera Anti – S
6904491	ORTHO™ Sera Anti – s
6904486	ORTHO™ Sera Anti – Fy <sup>a</sup>
6904487	ORTHO™ Sera Anti – Fy <sup>b</sup>
6904492	ORTHO™ Sera Anti – K
6904494	ORTHO™ Sera Anti – M
6904495	ORTHO™ Sera Anti – N
6904496	ORTHO™ Sera Anti – P1



Yours Sincerely

*Janine S. Robb*

**Janine Robb**  
**Head of ALBA Product Development & Support**