CERTIFICATE OF ANALYSIS

Article Number	Product Name	Lot Number	
206101	Seronorm Immunoassay Lyo L-2	2402803	
Matrix	**Form**	**Manufacturing Date**	**Expiry Date**
Human Serum	Freeze-dried	2024-04-30	2028-04-30
Filling Volume (mL)	**Storage Temperature (°C)**	**Shipping Conditions (°C)**	
3,00	2-8	15-25	
Country of Origin	**Intended Use**		
Norway	Quality Control for use in hospitals by trained Professional only		
Preservative added			
None			

Tests	Method	Acceptance Criteria	Results
Filling Precision (weight,%CV)	Gravimetry	≤ 0,5	0,14
Residual Water (%)	Karl Fischer Coulometric Titration	≤ 2,0	0,55
Vial to vial variation (%CV)			
	C-peptid	≤ 2,5	0,7
	Troponin T	≤ 3,0	2,4
	hsTroponin I	≤ 3,2	2,9
Bioburden (CFU/mL)	Plate Count Method	≤100	≤100

The matrix is produced from blood collected from voluntary blood donors at government approved Blood Centres and contains some human additives. Certificates from Blood Centres and human additive suppliers confirme that each blood unit and additives are tested and found negative for HBs antigen, HIV p24 antigen, HIV-1/HIV-2antibodies and HCV antibodies.

Packaging conforms to SERO's packaging specifications.
The above mentioned products meets the specification stated in this certificate.

Signature: Julie Dee Qian
Julie Dee Qian (Sep 5, 2024 14:02 GMT+2)
Email: j.qian@sero.no
Kvalitetssjef - Head of Quality

2402803_CoA_v.01

Final Audit Report 2024-09-05

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