CERTIFICATE OF ANALYSIS

Article Number	Product Name	Lot Number	Matrix	Preservative added
200805	Seronorm Human	2506866	Human Serum	None
Form	**Filling Volume**	**Storage Temp.**	**Shipping Conditions**	**Country of Origin**
Freeze-dried	5,0 mL	2-8 °C	15-25 °C	Norway
Manufacturing Date	**Expiry date**	**Vials in Kit (pcs)**		
2025-10-31	2029-10-31	10		
Comment				

Intended Use

Quality Control for use in clinical laboratories by trained Professionals only.

Test	Instrument	Method	Unit	Acceptance Criteria	Results
Bioburden		Manual counting	CFU/mL	≤100	≤100
Residual Water	Karl Fischer Coulometer	Karl Fischer titration	%	≤2	0,613
Filling Precision			%	≤0,5	Approved
Uniformity					
Bilirubin, total	Roche cobas c501	DPD	% CV	≤3,3	1,8
CK, total	Roche cobas c501	IFCC (37 °C)	% CV	≤2,9	2,2
LDH	Roche cobas c501	IFCC (37 °C)	% CV	≤2,8	1,3
Phosphorus	Roche cobas c501	Ammonium phosphomolybdate	% CV	≤2,9	0,8

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 confirm 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: Guri S. Børhaug
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Head of Quality and RA