

Certificate of Analysis

Human Serum Normal from Defibrinated Plasma
Catalog Number: SP1000 Lot Number: I02001

Storage: -20 °C
Filtration: 0.22 µm
Preservative: None
Manufacture Date: February 2024
Expiration Date: February 2027
Country of Origin: USA
Source: Human Defibrinated Plasma

Product Performance Specifications

Test	Results	Specifications	Unit of Measure	Methodology
Glucose	76	65 – 105	mg/dL	Hexokinase
B.U.N.	7	7 – 14	mg/dL	Berthelot
Creatinine	0.9	0.7 – 1.4	mg/dL	Jaffe
Albumin	3.5	2.5 – 4.5	g/dL	BCG Dye-binding
Sodium	135	131 – 151	mmol/L	ISE
Potassium	4.1	3.5 – 5.5	mmol/L	ISE
Chloride	101	85 – 108	mmol/L	ISE
Calcium	7.3	5.0 – 10.0	mg/dL	Arsenazo III
Total Protein	5.8	5.5 – 6.5	g/dL	Biuret
Cholesterol	115	As Found	mg/dL	Enzymatic
Triglycerides	45	As Found	mg/dL	GPO
Phosphorus	3.3	3.0 – 4.0	mg/dL	Phosphomolybdate
Uric Acid	3.5	2.5 – 4.5	mg/dL	Uricase/Trinder
Progesterone	0.39	As Found	ng/mL	Immunoassay
Bioburden	<10	≤100	CFU/mL	USP/BAM
pH	7.2	7.0 – 7.5	Not Applicable	pH Meter

Testing

Each unit of plasma used in the preparation of this material was tested and found negative or non-reactive for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT), and RPR by FDA approved methods.

Caution

In-vitro use only. Products are intended for research or manufacturing of non-injectable products only. This material was tested as stated above in the testing section. Nevertheless products of human origin should be considered potentially infectious and handled according to universal precautions. The safe and responsible handling of the product listed above is the responsibility of the customer. We accept no liability for injury or illness resulting from the use and/or handling of the product. The customer assumes responsibility for the proper disposal of all materials in accordance with Federal and State regulations.

Warranty

Golden West Diagnostics, LLC makes no claim or warranty that this product will perform or is suitable for use in a customer's application. It is the customer's responsibility to evaluate and qualify the product's suitability for the customer's intended use or application. Furthermore, this product is a biological material and lots may vary so it is the customer's responsibility to determine if an evaluation of each lot is warranted.

Prepared By: PS
Date: 2/27/24

Approved By: [Signature]
Date: 27 Feb 24



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