

Certificate of Analysis

GMP Human Serum - Type AB from Human Male AB Whole Blood

Product Information

Product #:	humanabsrmcg-1
Lot# / Sample ID#:	23B0276
Storage temperature:	-20°C
Expiration Date:	2/28/2028
Date of Manufacture:	2/8/2023
Number of Donors:	212

Quality Control

Test	Specification	Result
Physical Appearance	Clear, straw yellow	Clear, straw yellow
pH (room temp.)	7.0-9.0	8.4
Osmolality	260-330 mOsm/kg	291 mOsm/kg
Hemoglobin	<25 mg/dl	2.0 mg/dl
Sterility	Sterile	Sterile
Mycoplasma	Negative	Negative
Endotoxin	<10 EU/mL	2.1 EU/mL
Glucose	60-140 mg/dl	110 mg/dl
Sodium	110-160 mEq/L	140 mEq/L
Potassium	3.0-5.5 mEq/L	4.4 mEq/L
Chloride	100-130 mEq/L	102 mEq/L
Calcium	6.5-11.5 mg/dl	9.2 mg/dl
Phosphorus	2.2-7.0 mg/dl	4.1 mg/dl
Iron	Result	72 ug/dl
Creatine	Result	1.00 mg/dl
Total Protein	4.8-8.3 gm/dl	7.1 gm/dl
Albumin	3.0-5.5 gm/dl	4.0 gm/dl
Total Bilirubin	0.0-1.5 mg/dl	<0.2 mg/dl
Cholesterol	80-200 mg/dl	159 mg/dl
Triglyceride	30-160 mg/dl	96 mg/dl
ALT	Result	5 U/L
AST	Result	10 U/L
BUN	Result	13 mg/dl
GGT	Result	26 U/L
Uric Acid	Result	5.3

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Xeno (BSE/TSE)	Result	Negative

Regulatory

Test	Specification	Result
HIV 1/2 RNA	Non-reactive	Non-reactive
Anti HIV 1/2	Negative	Negative
HBV NAT	Non-reactive	Non-reactive
Anti HBsAg	Non-reactive	Non-reactive
HCV RNA	Non-reactive	Non-reactive
Anti HCV	Negative	Negative
WNV RNA	Negative	Negative
Syphilis	Negative	Negative
Chagas	Negative	Negative
HTLV I/II	Negative	Negative
Anti Hbc	Negative	Negative
HAV-RNA	Non-reactive	Non-reactive
HIV p24	Negative	Negative
Hepatitis E	Negative	Negative
Plasmodium	Negative	Negative

Male donors blood type AB, collected in FDA registered commercial donor establishments located in the USA and processed in an FDA registered facility located in the USA, in accordance with applicable regulatory and ethical standards.

This product is being sold for further manufacturing only. It is not to be used in humans or animals. For in vitro use only. The user assumes all responsibility for its usage and disposal in accordance with all regulations. The material should be handled as if capable of transmitting infectious agents. Please use universal precautions. No test method can provide total assurance against Hepatitis Virus, Human Immunodeficiency Virus, or other infectious agents that are absent. All blood products should be handled at the Bio-Safety Level 2.

> Jazzmyn Bower **Quality Control Specialist**

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DATE: 09May2023

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BioIVT is committed to sourcing human and animal biological material in accordance with the highest ethical and regulatory standards.

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