

	Document ID:	TDS-S-HUH-US-031	Version:	002
	Date of Issue:	10-JAN-2023	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2025	Signature:	
	Title:	TECHNICAL DATASHEET		

Human Male AB Plasma-Derived Serum. Gamma Irradiated

Filtration, Treatment	Manufactured with Human Thrombin/Triple 0.1 µm sterile filtered. Gamma Irradiated
Origin	US
Product Code	S-HUH-US-031
Preservative	None
Shelf Life	5 years from DOM
Storage Temperature	<-15°C
Shipping Temperature	dry ice

QC Specifications

Physical and Chemical Analysis	Method	Specifications	Units
Identity	Internally Validated	Human	n/a
Appearance	Visual	Straw yellow to clear amber	n/a
pH at RT	Electronic pH Meter	7.0 - 9.0	n/a
Osmolality	Osmometer	260 - 350	mOsm/kg
Endotoxin	LAL Kinetic	≤ 10.0	EU/ml
Hemoglobin	Colorimetric	≤ 30	mg/dl
Sterility			
Aerobic Bacteria	9CFR113.26	Not detected	n/a
Anaerobic Bacteria	9CFR113.26	Not detected	n/a
Fungi (yeast & Mold)	9CFR113.26	Not detected	n/a
Mycoplasma	PCR	Not detected	n/a
Protein Profile			
Total Protein	Chemistry analyzer	4.0 - 9.0	g/dl
Albumin	Chemistry analyzer	Test and Report	g/dl
Globulin	Chemistry analyzer	Test and Report	g/dl
A/G Ratio (Calc)	Chemistry analyzer	Test and Report	n/a
Anti-A/Anti-B testing		Not detected	n/a
Biochemistry			
AST (SGOT)	Chemistry analyzer	Test and Report	U/L
ALT (SGPT)	Chemistry analyzer	Test and Report	U/L
Total Bilirubin	Chemistry analyzer	Test and Report	mg/dL
Blood Urea Nitrogen (BUN)	Chemistry analyzer	Test and Report	mg/dL
Cholesterol	Chemistry analyzer	110 - 210	mg/dL
Glucose	Chemistry analyzer	60 - 140	mg/dL
Triglyceride	Chemistry analyzer	35 - 175	mg/dL
Creatinine	Chemistry analyzer	Test and Report	mg/dL
Albumin/Creatinine Ratio	Chemistry analyzer	Test and Report	g/mg Cr
Carbon Dioxide	Chemistry analyzer	Test and Report	mEq/L
Calcium	Chemistry analyzer	< 12	mg/dL
Potassium	Chemistry analyzer	Test and Report	mEq/L
Sodium	Chemistry analyzer	100 - 200	mmol/L
Chloride	Chemistry analyzer	85 - 130	mmol/L
Alkaline Phosphate	Chemistry analyzer	Test and Report	U/L
Phosphorus	Chemistry analyzer	Test and Report	mg/dL
Iron	Chemistry analyzer	Test and Report	µg/dL
IgG	Chemistry analyzer	Test and Report	mg/dL
Fibrinogen	Chemistry analyzer	Test and Report	mg/dL
Uric acid	Chemistry analyzer	Test and Report	mg/dL
GGT	Chemistry analyzer	Test and Report	U/L
Viral Markers			
Anti-HIV I/II	9CFR113.53	Negative / Non-reactive	n/a
HBsAg	9CFR113.53	Negative / Non-reactive	n/a
Anti-HCV	9CFR113.53	Negative / Non-reactive	n/a
HIV p24 Ag	9CFR113.53	Negative / Non-reactive	n/a
HTLV I/II	9CFR113.53	Negative / Non-reactive	n/a
Syphilis	9CFR113.53	Negative / Non-reactive	n/a

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Anti-HBc	9CFR113.53	Negative / Non-reactive	n/a
Atypical Antibody	9CFR113.53	Negative / Non-reactive	n/a
HIV-1 RNA	9CFR113.53	Negative / Non-reactive	n/a
HBV DNA	9CFR113.53	Negative / Non-reactive	n/a
HCV RNA	9CFR113.53	Negative / Non-reactive	n/a
HAV RNA	9CFR113.53	Negative / Non-reactive	n/a
Parvovirus B19 DNA	9CFR113.53	Negative / Non-reactive	n/a
WNV RNA	9CFR113.53	Negative / Non-reactive	n/a
Chagas	9CFR113.53	Negative / Non-reactive	n/a
Zika Virus RNA	9CFR113.53	Negative / Non-reactive	n/a
Species Identification			
Cat		Not detected	n/a
Cattle		Not detected	n/a
Deer		Not detected	n/a
Dog		Not detected	n/a
Goat		Not detected	n/a
Horse		Not detected	n/a
Mouse		Not detected	n/a
Pig		Not detected	n/a
Rabbit		Not detected	n/a
Rat		Not detected	n/a
Sheep		Not detected	n/a

All units of Human AB serum have been collected from the whole blood donation of healthy male donors in the USA in FDA licensed facilities and tested for infectious diseases with FDA approved test systems. The number of donors will be mentioned for each batch in the issued Certificate of Analysis.

Gamm irradiation is performed through a validated process.

The product is intended for In vitro, further manufacturing use, or cell culture.

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RECOMMENDED USE:

Storage

To effectively preserve the integrity of animal serum, it should be stored frozen and protected from light. The recommended storage temperature is <-15°C.

Multiple thaw/freeze cycles should be avoided, as they will accelerate the degradation of serum nutrients and can encourage the formation of insoluble precipitates. For this reason, serum should never be stored in “frost-free” freezers. These types of freezers periodically warm themselves to avoid internal ice deposits and are detrimental to the stability of frozen serum products.

Suggested Thawing Procedure

1. Remove the serum bottles from the freezer and allow them to adjust to room temperature for approximately 10 minutes.
2. Place each container in a 30 to 37 °C water bath or incubator. Excessive temperatures will degrade heat labile nutrients. If using a water bath, prevent the bottle caps from being submerged.
3. Gently agitate the bottles every 10 – 15 minutes until the serum is completely thawed.

Efficient and Effective Usage

After thawing, use the serum promptly. Liquid serum may be stored refrigerated (2 to 8 °C) up to four weeks. To avoid thaw/freeze cycles or long periods of refrigeration, it is recommended that any unused serum be immediately dispensed into small, useful aliquots and refrozen for future use.