
	Document ID:	TDS-HUO-EU-011	Version:	001
	Date of Issue:	10-JAN-2023	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2025	Signature:	
	Title:	TECHNICAL DATASHEET		

Human Male AB Off The Clot Serum

Filtration, Treatment	0.2µm sterile filtered
Origin	EU Eligible
Product Code	S-HUO-EU-011
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	Clear yellow-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 EU/mL	EU/ml
Hemoglobin	Colorimetric	< 30	mg/dl
Sterility			
Aerobic Bacteria	Internally Validated	Not detected	n/a
Anaerobic Bacteria	Internally Validated	Not detected	n/a
Fungi (yeast & Mold)	Internally Validated	Not detected	n/a
Mycoplasma	qPCR	Not detected	n/a
Protein Profile			
Total Protein	Beckmann Coulter	5.0 - 9.0	g/dl
Albumin	Turbidimetric Immunoassay	3.5- 5.5	g/dl
IgG	Turbidimetric Immunoassay	5.8-15.2	mg/dl

Virology and Infectivity Analysis

Each individual blood donation is being tested for HIV-1/2 antibodies, HCV antibodies, HBs antigen and HBc antibodies with methods cleared in compliance with the European Directive 98/79/EC, Annex II, List A and must be found negative or non-reactive. Additionally, the pool is being tested for HTLV I and II antibodies and West-Nil-Virus PCR (RNA) and must be found negative.



These statements will appear on all Certificates of Analysis issued.

Ethical Remarks

The samples are gained, processed and verified in a way that is ethically and legally compliant for the purposes of diagnostic research and development, production and quality assurance. All products are from human source resulting in variances of state, colour and turbidity that do not diminish their quality.

Intended Use and Disclaimer

This Product is for research or manufacturing purposes only and are not for direct therapeutic or diagnostic use in humans or animals. The samples are not for identifying genetic analysis. Biospecimens should be treated as potentially infectious. Therefore, standard precautions for a safe handling and disposal are advised.

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Instructions For 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.

Product use: This product is not intended for human or animal consumption or therapeutic use.