GRIFOLS

GRIFOLS BIO SUPPLIES INC.
995 Park Center Drive, Vista, CA 92081

800-510-4003
Fax 760-931-8456

CERTIFICATE OF ANALYSIS

Human Male AB Serum
Heat Inactivated

Lot #: A24005-HI

Manufactured with Bovine Thrombin
Manufacture Date: February 22, 2024
Expiration Date: February 28, 2029
Country of Origin: United States
Country of Final Processing: United States
Shipping: Material shipped by Air Freight or Truck at ≤ -20°C

Part Number: 515-HI
GBS Specification: ACC-PS-515-I Rev. 06
Preservative: None
Filtration: Triple 0.1µm Sterile Filter
Heat Inactivated: 56°C for ≥30 minutes
Storage: ≤ -20°C

TEST	SPECIFICATION	RESULTS	UOM
Appearance	Straw yellow to amber liquid	Pass	N/A
Hemoglobin	≤ 30	5.7	mg/dL
Endotoxin	≤10.0	<0.30	EU/mL
Mycoplasma	Negative	Negative	N/A
Osmolality	260 – 350	274	mOsm/kg
Bioburden	Negative for Growth	Negative for Growth	N/A
pH	7.0 – 9.0	7.6	N/A
Anti-A/Anti-B Testing	Not Detected	Not Detected	N/A

BIOCHEMICAL ASSAY			
AST (SGOT)	Report result	14	U/L
ALT (SGPT)	Report result	6	U/L
Total Bilirubin	Report result	0.2	mg/dL
Blood Urea Nitrogen (BUN)	Report result	2	mg/dL
Cholesterol	110 – 210	134	mg/dL
Glucose	60 – 140	84	mg/dL
Triglyceride	35 – 175	90	mg/dL
Creatinine	Report result	<0.5	mg/dL
Total Protein	4.0 – 9.0	5.1	g/dL
Albumin	Report result	3.6	g/dL
Globulin	Report result	1.5	g/dL
A/G Ratio (Calc)	Report result	2.4	N/A
Albumin/Creatinine Ratio	Report result	7.2	g/mg Cr
Carbon Dioxide	Report result	2	mEq/L
Calcium	< 12	8.5	mg/dL
Potassium	Report result	4.7	mEq/L
Sodium	100 – 200	132	mmol/L
Chloride	85 – 130	110	mmol/L
Alkaline Phosphatase	Report result	6	U/L
Phosphorus	Report result	3.1	mg/dL
Iron	35 – 180	72	ug/dL
IgG	Report result	543	mg/dL
Fibrinogen	Report result	<25	mg/dL
Uric Acid	Report result	0.6	mg/dL
GGT	Report result	19	U/L

LOT NUMBER: A24005-HI

HUMAN MALE AB SERUM, HI

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TEST	SPECIFICATION	RESULTS	UOM
VIRAL MARKERS			
Anti-HIV I/II	Negative / Nonreactive	Negative / Nonreactive	N/A
HBsAg	Negative / Nonreactive	Negative / Nonreactive	N/A
Anti-HCV	Negative / Nonreactive	Negative / Nonreactive	N/A
HTLV I/II	Negative / Nonreactive	Negative / Nonreactive	N/A
Syphilis	Negative / Nonreactive	Negative / Nonreactive	N/A
Anti-HBc	Negative / Nonreactive	Negative / Nonreactive	N/A
Atypical Antibody	Negative / Nonreactive	Negative / Nonreactive	N/A
HIV-1 RNA	Negative / Nonreactive	Negative / Nonreactive	N/A
HBV DNA	Negative / Nonreactive	Negative / Nonreactive	N/A
HCV RNA	Negative / Nonreactive	Negative / Nonreactive	N/A
HAV RNA	Negative / Nonreactive	Negative / Nonreactive	N/A
Parvovirus B19 DNA	Negative / Nonreactive	Negative / Nonreactive	N/A
WNV RNA	Negative / Nonreactive	Negative / Nonreactive	N/A
Chagas	Negative / Nonreactive	Negative / Nonreactive	N/A
ZIKA Virus RNA	Negative / Nonreactive	Negative / Nonreactive	N/A

SPECIES IDENTIFICATION			
Cat	Not Detected	Not Detected	N/A
Cattle	Not Detected	Not Detected	N/A
Deer	Not Detected	Not Detected	N/A
Dog	Not Detected	Not Detected	N/A
Goat	Not Detected	Not Detected	N/A
Horse	Not Detected	Not Detected	N/A
Mouse	Not Detected	Not Detected	N/A
Pig	Not Detected	Not Detected	N/A
Rabbit	Not Detected	Not Detected	N/A
Rat	Not Detected	Not Detected	N/A
Sheep	Not Detected	Not Detected	N/A

Bovine viruses were not found in bovine thrombin lot # VS6P210, which was used to manufacture lot A24005-HI. BT bovine cells and VERO cells were inoculated with bovine thrombin lot # VS6P210 and studied in strict compliance to 9CFR 113.53c analysis requirement.

Lot A24005-HI was manufactured using a total of 30 donors.

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

All units have been collected in the USA in FDA licensed facilities and tested for infectious diseases with FDA approved test systems.

Prepared By: Ernest Schrepfer
Print Name: Ernest Schrepfer
Date: 14 FEB 2025

Approved By: Jennifer Goodman
Print Name: Jennifer Goodman
Date: 14 Feb 2025

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Bioburden Reporting

Product Name: Human Male AB Serum
Lot Number(s): A24005-HI
Date of Test: 15-Mar-2024

Test Performed By: Quality Control Laboratory

1. Sample Information:

- **Sampling Method:** Sterile pipette transfer from sealed bottle
- **Number of Samples:** One 100 ml bottle
- **Sampling Locations:** Random sample from middle of lot.

2. Test Method:

- **Growth Medium:**
  Fluid Thioglycolate Media
  Tryptic Soy Broth
- **Incubation Conditions:**
  FTM: 30-35°C for 14 days
  TSB: 20-25°C for 14 days

3. Results:

- **Sample 1:** 0 CFU/100 ml (bacteria), 0 CFU/100 ml (fungi)

4. Summary:

Bacteria
- **Total CFU:** 0 CFU/100 ml
- **Average CFU per Sample:** 0 CFU /100 ml

Fungi
- **Total CFU:** 0 CFU/100 ml
- **Average CFU per Sample** 0 CFU/100 ml

5. Conclusion: The bio-burden levels for the batch of Human Male AB Serum are within the acceptable limits for both bacteria and fungi.

6. Remarks: No deviations from the standard testing procedures were observed.

Approved By:

14FEB2025

Ernest Schrepfer, Quality Assurance Manager

LOT NUMBER: A24005

HUMAN MALE AB SERUM