



Monobind Inc.®

The World Resource for Diagnostic Products



BioMaterials Product Catalog



About Monobind

Since its inception in 1978 Monobind, an ISO 13485 & 9001 certified-company, has pioneered in providing diagnostic tools to healthcare professionals. The expertise acquired through years of hard work has allowed Monobind significant penetration into the immunoassay market. With a distributor network spanning established and emerging worldwide markets in 90+ countries, Monobind looks forward to an even brighter future. As a global brand and leading manufacturer, our company is a major player in the field of diagnostic immunoassay systems.

To achieve product integrity and value, Monobind has always manufactured all essential reagents in-house. Over the years, we've refined our methods to create superlative materials custom-fit to our product line, using the latest manufacturing technology and materials from only the best sources.



Commercializing our Raw Materials

Because of the lack of quality materials, we decided to commercially offer our raw reagents to developers and researchers. The market has strongly responded and we now produce essential ingredients for the majority of the leading biomedical manufacturers.

Essential Elements

Monobind has manufacturing partnerships with some of the US's largest blood fractionators. This gives us priority access to Human Albumin, IVIG and other fractions for our usage and supply into the diagnostic market. We can meet small-to-large scale production requirements.

High Quality Matrices Exact Specifications

We provide customers worldwide with raw plasma or process it into serum. With batch sizes in the thousands of liters, Monobind ranks as one of the largest manufacturers of human serum. We remove endogenous hormones and antigens using expertise perfected in our development of immunoassay products. Using charcoal or resin stripping, with or without delipidation, we routinely refine materials to exact specifications. In addition, we utilize proprietary procedures to essentially eliminate endogenous proteases and the many endotoxins that are detrimental to sensitive proteins and/or peptides.



Plasma & Serum PRODUCT LIST

Monobind Advantage

PRODUCT KEY FEATURES

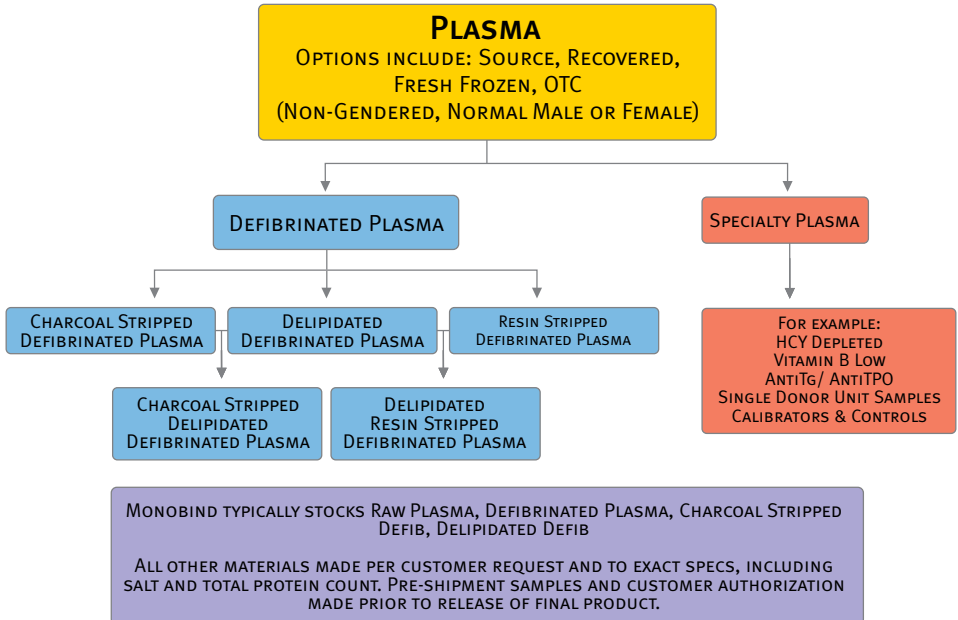
Partners	Talecris (Frm Bayer Corp), Baxter, ZLB Berhing, Specialty Blood Banks
Access	Direct & priority access to source plasma, disease states & more
Quality	Some formerly for fractionation, exceptional standards
Processing	Monobind is FDA & ISO approved; one of the industries largest processors
Expertise	Monobind manufactures calibrators & controls for other leading diagnostic firms. Monobind is an IVD company w > 70 immunoassays
Price	Subject to market conditions, please inquire with volume & specs

Human Plasma

PRODUCT KEY FEATURES

Grade	Diagnostic Use Only
Source	US patient donors with strict collection and testing criteria (NAT-HCV, NAT-HIV, NAT-HBV)
Records	Robust donor and testing records available
CAT #	DESCRIPTION
Inquire	Source, Recovered, Fresh Frozen human plasma in bags, bottles, jugs as based on availability

Plasma Processing Chart





Human Serum

PRODUCT KEY FEATURES

Grade	Diagnostic Use Only
Source	US patient donors with strict collection and testing criteria (NAT-HCV, NAT-HIV, NAT-HBV)
Specs	Provided in more detail upon request; plasma can be manufactured per customer requirements

CAT #	DESCRIPTION	REMOVED ELEMENTS	REMOVAL METHOD	PROTEASE FREE CAT#
174CM	Defibrinated plasma, source units	Fibrinogen	Precipitation	200CM
018CM	Defib plasma, recovered units	Fibrinogen	Precipitation	204CM
170CM	Defib plasma, fresh frozen units	Fibrinogen	Precipitation	204CM
099CM	Charcoal/defib, source units	Small Molecules	Surface absorption	
098CM	Charcoal/defib, recovered units	Small Molecules	Surface absorption	208CM
101CM	Charcoal/defib, fresh frozen units	Small Molecules	Surface absorption	
103CM	2XCharcoal/defib, source units	Small Molecules	Surface absorption	
100CM	2XCharcoal/defib, recovered units	Small Molecules	Surface absorption	209CM
104CM	2X Charcoal/defib, fresh frozen units	Small Molecules	Surface absorption	
173CM	Resin/defib plasma, source units	Thyroid Hormones	Anionic exchange	
097CM	Resin/defib plasma, recovered units	Thyroid Hormones	Anionic exchange	
096CM	Resin/defib plasma, fresh frozen units	Thyroid Hormones	Anionic exchange	
175CM	Delip/defib plasma, source units	Lipids	Surface absorption	201CM
179CM	Delip/defib plasma, recovered units	Lipids	Surface absorption	205CM
171CM	Delip/defib plasma, fresh frozen units	Lipids	Surface absorption	
176CM	Delip/charcoal/defib plasma, source units	Lipids	Surface absorption	202CM
180CM	Delip/charcoal/defib plasma, recovered units	Lipids, Small Molecules	Surface absorption	206CM
182CM	Delip/charcoal/defib plasma, fresh frozen units	Lipids, Small Molecules	Surface absorption	
177CM	Delip/2Xcharcoal/defib plasma, source units	Lipids, Small Molecules	Surface absorption	203CM
190CM	Delip/2Xcharcoal/defib plasma, recovered units	Lipids, Small Molecules	Surface absorption	207CM
191CM	Delip/2Xcharcoal/defi plasma, fresh frozen units	Lipids, Small Molecules	Surface absorption	
183CM	Delip/resin/defib plasma, source units	Lipids	Anionic exchange	
185CM	Delip/resin/defib plasma, recovered units	Lipids	Anionic exchange	
095CM	Delip/resin/defib plasma, fresh frozen units	Lipids	Anionic exchange	
245CM	Off the clot serum	-		
246CM	Off the clot serum - delip	Lipids		
039CM	Delip/defib plasma, homocysteine free	Small Molecules	Proprietary	

Source: Plasma used was not subject to variable temperatures that may lead to sensitive protein denaturing
 Fresh Frozen: Plasma from whole blood collection and frozen within e.g. 18 hours results in higher protein levels than source plasma
 Recovered: Plasma used may have been subject to variable temperatures that may lead to sensitive protein denaturing



Human Serum Project Checklist

1. Identify base plasma type

- a. Source (typically 5-5.3% total protein)
- b. Fresh Frozen (higher total protein, typically 5.5-6%)
- c. Recovered (higher total protein, typically 5.5-6% with less intact enzymes/ protein)
- d. Off the Clot (higher total protein, typically 7% due to anticoagulant content)
 - i. Pooled (individual units approx 5ml each combined)
 - ii. Single Donor (individual units approx 275ml each)
- e. Gendered (the above may be sorted by gender as available)

2. Choose processing technique, or if unsure, tell us the intended use or other product specs (per #3 below).

- i. Available filtration methods after plasma defibrination are
 1. Charcoal Stripped (removes small molecules and some proteins from serum)
 2. Single process

Double process (removes a higher percentage of molecules/proteins)

- ii. Delipidated (removes triglycerides and cholesterol from serum)
- iii. Charcoal Stripped, Delipidated (removes small molecules and some proteins as well as triglycerides and cholesterol)
 1. Single charcoal + delipidized
 2. Double charcoal + delipidized
- iv. Resin Stripped (removes thyroid hormones from serum)
- v. Resin Stripped, Delipidated (removes thyroid hormones as well as triglycerides and cholesterol from serum)

3. Specify analyte content levels, if available (this may affect the choice of base material or filtration methods), chemistry profile may include

- a. Total protein count
- b. Specific analyte values (eg enzymes, calcium, ALP etc)
- c. apH, electrolytes and other analytes ranges (provide targets)

4. If desired, request preservatives be added (Monobind does not typically include therefore manufactured serum is shipped frozen)

5. If desired, request specific product packaging

- a. Typically serum is packed in 3.5 liter jugs to reduce freight and ensure temperature consistency during transport
 - i. Other sizes available
 1. 1, 2, 3, or 10 liter
 2. Custom



Blood Fractions PRODUCTS LIST

Monobind Advantage

PRODUCT KEY FEATURES

Partners	Largest US Fractionators
Access	Direct & priority access to HSA, IGIV, Source Plasma
Quality	Formerly therapeutic, exceptional standards
Processing	At ISO 13485 & 9001 certified company <small>We concentrate, refine & package per customer needs</small>
Price	Subject to market conditions, please inquire with volume & specs

Human Albumin -- HSA

PRODUCT KEY FEATURES

Grade	Diagnostic Use Only
Source	US patient donors with strict collection and testing criteria (NAT-HCV, NAT-HIV, NAT-HBV)
Purity	> 98%

LIQUID

CAT #	DESCRIPTION	WEIGHT PER LITER
HA05S	HSA 5% Solution	50 grams
HA05SLB	HSA 5% Solution, Low B12 Folate	50 grams
HA20S	HSA 20% Solution	200 grams
HA20SLB	HSA 20% Solution, Low B12 Folate	200 grams
HA25S	HSA 25% Solution	250 grams
HA25SLB	HSA 25% Solution, Low B12 Folate	250 grams

POWDER

CAT #	DESCRIPTION
HA00D	HSA Lyophilized
HA0DLB	HSA Lyophilized with low B12/folate
HA0DHP	HSA Lyophilized with high purity 99%
HA0DEU	HSA Lyophilized with low endotoxin units
HA0FAF	HSA Lyophilized with fatty acid free

PASTE

CAT #	DESCRIPTION
HA00P	HSA Fraction V Paste

Human Gamma Globulin -- IGIV

PRODUCT KEY FEATURES

Grade	Diagnostic Use Only
Source	US patient donors with strict collection and testing criteria (NAT-HCV, NAT-HIV, NAT-HBV)
Purity	> 99%

LIQUID, POWDER, PASTE

CAT #	DESCRIPTION	WEIGHT PER LITER
IGIV10B	IGIV 10%	100 grams
IGIVD	hlgg Lyophilized (dried)	
GG23P	Fraction II/III Paste	



Bovine Albumin -- BSA

PRODUCT KEY FEATURES

POWDER	Grade	Diagnostic Use Only
	CAT #	DESCRIPTION
	BA7D	BSA, Cohn Fraction V, pH 7
	BA7DFAL	BSA, Cohn Fraction V, pH 7, Fatty Acid Low
	BA7DPF	BSA, Cohn Fraction V, pH 7, Protease Free
	Inquire	BSA Customer Specific

Other Biomaterials PRODUCT LIST

Human Urine

PRODUCT KEY FEATURES

Quality	Clear stable matrix produced using proprietary filtration and treatment
Source	US patient donors with strict collection & FDA testing criteria (HIV-1/2, HCV, HIV/Ag, HbAg)
CAT #	DESCRIPTION
011RM	Human Raw Urine Pool
004CM	Human Urine pH Treated
014CM	Drug Free Human Urine Matrix (pH 10&4)
012CM	Drug-Ethanol Free Human Urine, pH treated

Animal Serum

PRODUCT KEY FEATURES

Grade	Diagnostic Use Only
Quality	Processed to customer spec, including 0.2µ absolute filter
CAT #	DESCRIPTION
192CM	Bovine Serum Delipidated
193CM	Normal Calf Serum Delipidated
194CM	Normal Calf Serum Delipidated, Charcoal Stripped
188CM	Porcine Serum Delipidated
184CM	Porcine Serum Delipidated, Charcoal Stripped
189CM	Rabbit Serum, Delipidated

Purified Antigens & Antibodies

PRODUCT KEY FEATURES

Quality	Standard & affinity purified grades
Validated	Proven reagents for research and commercial use by means of Monobind immunoassays business
CAT #	DESCRIPTION
1925015RM	AFP
2525015RM	IgE
1825015RM	CEA
625015RM	LH Intact
425015RM	FSH Intact
626015RM	LH Subunits
426015RM	FSH Subunits
725015RM	PRL
825015RM	hCG Intact
2125015RM	PSA
2025015RM	hCG Subunits
325015RM	TSH Intact
1725015RM	HGH
326015RM	TSH Subunits

Sample Certificate of Analysis

PRODUCT:	DEFIBRINATED, CHARCOAL STRIPPED, NON-LIPID STRIPPED HUMAN SERUM
LOT#:	099CM-01C05
FILL:	3 LITERS/BOTTLE
PRESERVATIVE:	NONE
BIOBURDEN:	<10CFU/ML OR NO GROWTH
FILTRATION:	FILTERED THROUGH A 0.22MICRON ABSOLUTE MEMBRANE FILTER PRIOR TO BOTTLING
STORAGE:	-20°C
D.O.M.:	03-28-2005
EXPIRATION DATE:	03-2010
BLEED TESTING:	ALL UNITS USED IN THIS POOL WERE TESTED NEGATIVE OR NON-REACTIVE FOR ANTIBODIES: HIV1&2, HCV, HBsAg, HIV1-Ag AND RPR BY FDA APPROVED METHOD.

ANALYTE	RESULT	METHOD	ANALYTE	RESULT	METHOD
Calcium	4.4 mg/dL	SMAC	Bun	3 mg/dL	SMAC
Phosphorus	1.5 mg/dL	SMAC	Creatinine	<0.1 mg/dL	SMAC
Uric Acid	<2.0 mg/dL	SMAC	Glucose	<30 mg/dL	SMAC
Alkaline Phosphatase	17 IU/L	SMAC	Total Iron	73 µg/dL	SMAC
LDH	37 IU/L	SMAC	Chloride	110 meq/L	SMAC
SGOT/AST	<4 U/L	SMAC	Sodium	139 meq/L	SMAC
Billirubin, Total	<1.0 mg/dL	SMAC	Potassium	1.6 meq/L	SMAC
SGPT/ALT	<4 U/L	SMAC	Triglycerides	57 mg/dL	SMAC
GGTP	13 IU/L	SMAC	Cholesterol	104 mg/dL	SMAC
Total Protein	5.0 g/dL	SMAC	Ionized Calcium	2.2 mg/dL	SMAC
Albumin	3.0 g/dL	SMAC	Osmorality	260 mOSM/Kg	SMAC
Globulin	2.0 g/dL	SMAC			

Caution: For use in research or manufacturing in non-injectable products only. Not for use in human or clinical diagnosis.

Sample Certificate of Analysis

PRODUCT:	DELIPIDATED, DOUBLE CHARCOAL STRIPPED, HUMAN SERUM
MB PART#:	177CM OR 190CM
PRESERVATIVE:	AS REQUIRED
MICROBIAL:	< 10 CFU/ML
FILTRATION:	FILTERED THROUGH A 0.22µM ABSOLUTE MEMBRANE FILTER PRIOR TO BOTTLING
STORAGE:	-20°C
BLEED TESTING:	ALL UNITS WERE TESTED AT THE DONOR LEVEL BY FDA APPROVED TESTS FOR ANTI-HIV1&2, HCV, HTLV-1, HBsAg AND RPR WERE FOUND TO BE NEGATIVE OR NON-REACTIVE.

ANALYTE	NORMAL RANGE	ANALYTE	NORMAL RANGE
Calcium	5.0 – 10 mg/dl	Creatinin	0.7 – 1.4 mg/dl
Phosphorus	2.5 – 4.5 mg/dl	Glucose	65 – 114 mg/dl
Uric Acid	1.9 – 8.4 mg/dl	Total Iron	34 – 185 µg/dl
Alkaline Phosphatase	30 – 130 IU/L	Cholride	95 – 110 mEQ/L
LDH	60 – 225 IU/ml	Sodium	130 – 150 mEQ/L
SGOT/AST	0.0 – 48 U/L	Potasium	1.0 – 5.5 mEQ/L
Total Bilirubin	0.1 – 1.4 mg/dl	Triglycerides	< 15 mg/dl
SGTP/ALT	0.0 – 52 U/L	Cholesterol	< 15 mg/dl
GGTP	0.0 – 65 IU/L	Ionized Calcium	1 – 4.7 mg/dl
Total Protein	5.0 – 8.0 gm/dl	Serum Osmolality	260 – 310 mOSM/Kg
Albumin	3.0 – 5.0 gm/dl	Ammonia	< 300 µmol/L
Globulin	2.0 – 4.0 gm/dl	T3 Value	0.0 ng/dl
A/G Ratio	1.0 – 2.2	T4 Value	0.0 µg/ml
BUN	8.0 – 26 gm/dl	Cortisol	0.0 µg/ml

CAUTION: For use in research or manufacturing in non-injectable products only. Not for use in human or clinical diagnosis.

Sample Certificate of Analysis

PRODUCT:	RESIN STRIPPED, NON-LIPID STRIPPED, HUMAN SERUM
MB PART#:	097CM OR 173CM
PRESERVATIVE:	AS REQUIRED
MICROBIAL:	< 10 CFU/ML
FILTRATION:	FILTERED THROUGH A 0.22UM ABSOLUTE MEMBRANE FILTER PRIOR TO BOTTLING
STORAGE:	-20°C
BLEED TESTING:	ALL UNITS WERE TESTED AT THE DONOR LEVEL BY FDA APPROVED TESTS FOR ANTI-HIV1&2, HCV, HTLV-1, HBSAG AND RPR WERE FOUND TO BE NEGATIVE OR NON-REACTIVE.

ANALYTE	NORMAL RANGE	ANALYTE	NORMAL RANGE
Calcium	5.0 – 10 mg/dl	Creatinin	0.7 – 1.4 mg/dl
Phosphorus	2.5 – 4.5 mg/dl	Glucose	65 – 114 mg/dl
Uric Acid	1.9 – 8.4 mg/dl	Total Iron	34 – 185 µg/dl
Alkaline Phosphatase	30 – 130 IU/L	Chloride	95 – 110 mEQ/L
LDH	60 – 225 IU/ml	Sodium	130 – 150 mEQ/L
SGOT/AST	0.0 – 48 U/L	Potassium	1.0 – 5.5 mEQ/L
Total Bilirubin	0.1 – 1.4 mg/dl	Triglycerides	10 – 190 mg/dl
SGTP/ALT	0.0 – 52 U/L	Cholesterol	118 – 200 mg/dl
GGTP	0.0 – 65 IU/L	Ionized Calcium	1 – 4.7 mg/dl
Total Protein	5.0 – 8.0 gm/dl	Serum Osmolality	260 – 310 mOSM/Kg
Albumin	3.0 – 5.0 gm/dl	Ammonia	< 300 µmol/L
Globulin	2.0 – 4.0 gm/dl	T3 Value	0.0 ng/dl
A/G Ratio	1.0 – 2.2	T4 Value	0.0 µg/ml
BUN	8.0 – 26 gm/dl		

CAUTION: For use in research or manufacturing in non-injectable products only. Not for use in human or clinical diagnosis.

Sample Certificate of Analysis

PRODUCT:	HUMAN SERUM, OFF THE CLOT
LOT#:	245CM-24L05
PRESERVATIVE:	NONE
BIOBURDEN:	<10CFU/ML OR NO GROWTH
SHELF LIFE:	FIVE YEARS AT -20°C FROM DATE OF MANUFACTURED
FILTRATION:	FILTERED THROUGH A 0.22MICRON ABSOLUTE MEMBRANE FILTER PRIOR TO BOTTLING
STORAGE:	-20°C
BLEED TESTING:	DONORS USED IN THIS POOL WERE TESTED NEGATIVE OR NON-REACTIVE FOR: HIV-1/2, CV, HBSAG, HIV1-AG, ALT WITHIN ACCEPTABLE RANGE AND RPR BY FDA APPROVED METHOD.

ANALYTE	RESULT	METHOD
Calcium	9.1 mg/dL	SMAC
Phosphorus	3.7 mg/dL	SMAC
Uric Acid	4.8 mg/dL	SMAC
Alkaline Phosphatase	13 IU/mL	SMAC
LDH	54 IU/mL	SMAC
SGOT/AST	4 U/L	SMAC
Total Bilirubin	0.0 mg/dL	SMAC
SGTP/ALT	<4 U/L	SMAC
GGTP	35 IU/mL	SMAC
Total Protein	6.7 g/dL	SMAC
Albumin	4.2 g/dL	SMAC
Globulin	2.5 g/dL	SMAC

ANALYTE	RESULT	METHOD
A/G Ratio	1.7	SMAC
BUN	12 mg/dL	SMAC
Creatinine	0.8 mg/dL	SMAC
Glucose	124 mg/dL	SMAC
Total Iron	59 mg/dL	SMAC
Chloride	124 meq/L	SMAC
Sodium	155 meq/L	SMAC
Potassium	4.1 meq/L	SMAC
Triglycerides	108 mg/dL	SMAC
Cholesterol	156 mg/dL	SMAC
Ionized calcium	4.1 mg/dL	SMAC
Osmolality	321 mOSM/Kg	SMAC

CAUTION: For use in research or manufacturing in non-injectable products only. Not for use in human or clinical diagnosis.

Sample Certificate of Analysis

PRODUCT:	HUMAN ALBUMIN 20% SOLUTION
CATALOG NUMBER:	HA20S
LOT NUMBER:	100RM-MBB-75610
FRACTIONATION METHOD:	COHN-ONCLEY COLD ALCOHOL PROCEDURE
EXPIRATION AND STORAGE:	JULY 2019 AT -20°C
PURITY:	> 97% BY SPE GEL ELECTROPHORESIS
APPEARANCE:	FAINT YELLOW-WHITE COLOR
PLASMA TYPE:	PHORESIS PLASMA
COUNTRY OF ORIGIN OF PLASMA:	FDA LICENSED FACILITIES IN USA

Each plasma unit used in the preparation of human albumin was tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- ALT (SGPT)

The plasma pool(s) were tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- HBV, HCV, HIV-1 & HIV-2 (NAT Testing)

The antibody screening is performed on all Rh negative donors.

Source plasma is collected from donors who have not been hyperimmunized to produce specific antibodies.

Ashatola

Quality Control

7-6-2010

Date

Sample Certificate of Analysis

PRODUCT:	HUMAN ALBUMIN LYOPHILIZED
ITEM NUMBER:	HA00D
LOT NUMBER:	089RM-MBB-58D09
EXPIRATION AND STORAGE:	APRIL 2019 AT -20°C
FRACTIONATION METHOD:	COHN-ONCLEY COLD ALCOHOL PROCEDURE
PURITY:	>96% BY SPE GEL ELECTROPHORESIS
APPEARANCE:	CREAM POWDER
PLASMA TYPE:	PHORESIS PLASMA
COUNTRY OF ORIGIN OF PLASMA:	FDA LICENSED FACILITIES IN USA

Each plasma unit used in the preparation of (human) IVIG was tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- ALT (SGPT)

The plasma pool(s) were tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- HBV, HCV, HIV-1 & HIV-2 (NAT Testing)

The antibody screening is performed on all Rh negative donors.

Source plasma is collected from donors who have not been hyperimmunized to produce specific antibodies.

Ashatola

Quality Control

4-27-2009

Date

Sample Certificate of Analysis

PRODUCT:	HUMAN ALBUMIN LYOPHILIZED, LOW B12
ITEM NUMBER:	HAODLB
LOT NUMBER:	089RM-MBB-59G09
EXPIRATION AND STORAGE:	JULY 2019 AT -20°C
FRACTIONATION METHOD:	COHN-ONCLEY COLD ALCOHOL PROCEDURE
PURITY:	>96% BY SPE GEL ELECTROPHORESIS
KEY ANALYTES:	FOLATE <1.0 NG/ML & VITAMIN B12<80 PG/ML
APPEARANCE:	CREAM POWDER
PLASMA TYPE:	PHORESIS PLASMA
COUNTRY OF ORIGIN OF PLASMA:	FDA LICENSED FACILITIES IN USA

Each plasma unit used in the preparation of (human) IVIG was tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- ALT (SGPT)

The plasma pool(s) were tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- HBV, HCV, HIV-1 & HIV-2 (NAT Testing)

The antibody screening is performed on all Rh negative donors.

Source plasma is collected from donors who have not been hyperimmunized to produce specific antibodies.

Ashatola

Quality Control

07-15-2009

Date

Sample Certificate of Analysis

PRODUCT:	HUMAN ALBUMIN LYOPHILIZED, FATTY ACID FREE
CATALOG NUMBER:	HAODFAF
LOT NUMBER:	088RM-MBB-59G09
FRACTIONATION METHOD:	COHN-ONCLEY COLD ALCOHOL PROCEDURE
EXPIRATION AND STORAGE:	JULY 2019 AT -20°C
PURITY:	>96% BY SPE GEL ELECTROPHORESIS
KEY ANALYTES:	FATTY ACID 0.0MG/G
APPEARANCE:	CREAM POWDER
PLASMA TYPE:	PHORESIS PLASMA
COUNTRY OF ORIGIN OF PLASMA:	FDA LICENSED FACILITIES IN USA

Each plasma unit used in the preparation of human albumin was tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- ALT (SGPT)

The plasma pool(s) were tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- HBV, HCV, HIV-1 & HIV-2 (NAT Testing)

The antibody screening is performed on all Rh negative donors.

Source plasma is collected from donors who have not been hyperimmunized to produce specific antibodies.

Ashatola

Quality Control

07-30-2009

Date



Sample Certificate of Analysis

PRODUCT:	HUMAN GAMMA GLOBULIN – IVIG – 10%
ITEM NUMBER:	IGIV10S
LOT NUMBER:	105RM-47D05
EXPIRATION AND STORAGE:	05/2010 AT 2 – 8°C
FRACTIONATION METHOD:	COHN-ONCLEY COLD ALCOHOL PROCEDURE
PURITY:	> 98% BY SPE GEL ELECTROPHORESIS
APPEARANCE:	CLEAR TO OPALESCENT COLORLESS TO PALE YELLOW
PLASMA TYPE:	PHORESIS PLASMA
COUNTRY OF ORIGIN OF PLASMA:	FDA LICENSED FACILITIES IN USA

Each plasma unit used in the preparation of (human) IVIG was tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- ALT (SGPT)

The plasma pool(s) were tested and found negative, for the following, by FDA licensed reagents.

- HIV I & II Antibodies
- HCV Antibodies
- HBsAg
- HBV, HCV, HIV-1 & HIV-2 (NAT Testing)

The antibody screening is performed on all Rh negative donors.

Source plasma is collected from donors who have not been hyperimmunized to produce specific antibodies.

A. Shatola

Quality Control

5-3-2005

Date

For more information about any of the products, or to discuss your unique needs, please contact us:

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