

The World Resource for Diagnostic Products







### **About Monobind**

Since its inception in 1978 Monobind, an ISO 13485 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 110+ countries in both developed and emerging markets, Monobind is a global brand and leader 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 Raw Materials**

Because of the lack of quality materials, Monobind decided to commercially offer its processed bio-matrices and materials to diagnostic companies and researchers. The market favorably responded and today Monobind produces essential materials for the majority of top diagnostic firms, maintaining coveted approved-vendor status.

# **Key Suppliers**

Monobind has supply partnerships build on trust with the world's largest blood fractionators. This gives us priority access to Human Albumin, IVIG and other fractions for our usage and channeling into the diagnostic market. We can meet small-to-large scale production requirements with batch sizes into the thousands of liters.

# **High-Quality Matrices with Exact Specifications**

Processing up to 30,000 liters of human plasma per year for both internal use and worldwide customers, Monobind ranks among the largest producers. With expertise perfected through its immunoassay product line, Monobind is able to remove endogenous hormones and antigens thereby meeting exact material-profile specifications.

Based on the use-application, such may be accomplished with defibrination, charcoal or resin stripping, with or without dilapidation. In addition, Monobind has proprietary procedures that can essentially eliminate endogenous proteases and many endotoxins, which are detrimental to sensitive proteins and/or peptides. Further, Monobind may provide preshipment samples for functionality testing and approval.

# **MONOBIND BIOMATERIALS**

Human IGIV - 20% Solution

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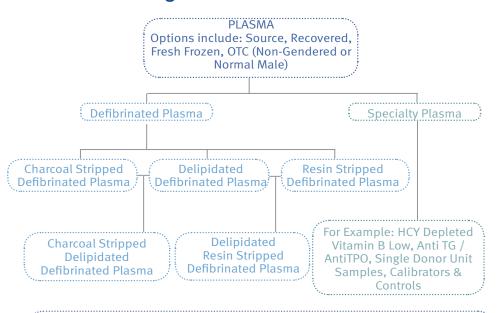
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#### **Monobind Biomaterial Advantage**

Key Suppliers	Largest fractionators & specialty blood banks - all FDA approved facilities
Testing & Traceability	Strict collection & testing criteria with plasma-lookback programs
Priority Access	Trusted channel for source plasma & fractionated materials
Selection	Extensive inventory of characterized materials, large lot sizes
Material Quality	Exceptional standards for diagnostic, non-injectable usage only
Certifications	Monobind is ISO 13485 certified and FDA registered
Expertise	Internal product portfolio of 120+ immunoassays
Key Accounts	Renown IVDs for bio-matrices, processed fractions, calibrators &
	QC controls

# **Plasma Processing Chart**



Monobind typically stocks Raw Plasma, Defibrinated Plasma,
Charcoal Stripped Defibrinated (2x),
Delipidated Defibrinated (2x) All other materials made per customer request and
to exact specs, including salt and total protein count, pre-shipment samples and
customer authorization made prior to release of final product.



Human Plasma Decision Guide (Item Number Selection)

Determine Your Base Material				
	Source	Recovered	Fresh Frozen	Off The Clo
Protein Content (typical native)	5-5.3%	5.5-6%	5.5-6%	7%
Select The Product That Matches Your Needs:				
Gendered	Yes/No	Yes/No	Yes/No	Yes/No
Unprocessed plasma (Pooled or Single Donor)	173RM	177RM	174RM	245RN
Defibrinated Protease free Protease free	174CM 200CM	018CM 204CM	170CM	245CN
Single Charcoal Stripped Protease free	099CM	098CM 208CM	101CM	
2X Charcoal Stripped Protease free	103CM	100CM 209CM	104CM	
Charcoal Stripped, Delipidated Protease free	176CM 202CM	180CM 206CM	182CM	
2X Charcoal Stripped, Delipidated Protease free	177CM 203CM	190CM 207CM	191CM	
Delipidated Protease free	175CM 201CM	198CM 205CM	171CM	246CN
Resin Stripped Protease free	173CM	097CM	096CM	
Delipidated, Resin Stripped Protease free	183CM	185CM	095CM	
Speciality HCY Depleted,Low B12,Anti-Tg/TPO, 15% T-Uptake, Calibrator Matrix etc.	Call Us	Call Us	Call Us	Call Us

3 Sodium Azide as a Preservative?	4 Analyte Profile
☐ Yes (We recommend 0.1% sodium azide) ☐ No ☐ Custom preservative (let us know)	☐ Total protein count ☐ Specific analyte values (enzyme, calcium, ALP) ☐ pH, electrolytes and other analytes ranges (provide targets)
5 Pack Size?	
☐ 3.5 liter jugs (recommended to reduce freight/☐ 10 liter jugs☐ Other (1, 2, 3 liter or custom)	ensure transport temp)



# Human Albumin DECISION GUIDE (ITEM NUMBER SELECTION)

2 Select The Product That Matches YourNeeds:  Pooled HA05S HA10S HA20S Single Charcoal Stripped HA05CS HA10CS HA20CS Fatty Acid Free HA05FAF HA10FAF HA20FAF Low Folate HA05SLB HA10SLB HA20SLB Low Vitamin B12 HA05SLB HA10SLB HA20SLB	]	25%		Lyophilized	
Pooled HA05S HA10S HA20S  Single Charcoal Stripped HA05CS HA10CS HA20CS  Fatty Acid Free HA05FAF HA10FAF HA20FAF  Low Folate HA05SLB HA10SLB HA20SLB  Low Vitamin B12 HA05SLB HA10SLB HA20SLB					
Single Charcoal Stripped HA05CS HA10CS HA20CS  Fatty Acid Free HA05FAF HA10FAF HA20FAF  Low Folate HA05SLB HA10SLB HA20SLB  Low Vitamin B12 HA05SLB HA10SLB HA20SLB					
Fatty Acid Free HA05FAF HA10FAF HA20FAF  Low Folate HA05SLB HA10SLB HA20SLB  Low Vitamin B12 HA05SLB HA10SLB HA20SLB		HA25S		HA00D	
Low Folate HA05SLB HA10SLB HA20SLB  Low Vitamin B12 HA05SLB HA10SLB HA20SLB		HA25CS		HAOCD	
Low Vitamin B12 HA05SLB HA10SLB HA20SLB		HA25FAF		HAODFAF	
		HA25SLB		HAODLB	
		HA5SLB		HAODLB	
Low Vitamin D Call Us Call Us Call Us		Call Us		Call Us	
Low Endotoxin Call Us Call Us Call Us		Call Us		HAODEU	
High Purity					

3 Sodium Azide as a Preservative
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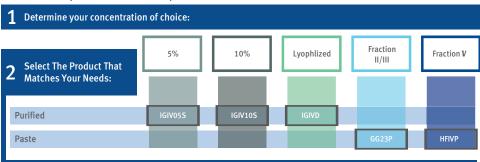
☐ Yes (We recommend (	0.1%	sodium	azide
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□ No
□ Custom preservative (let us know)



#### **Human IGIV**

DECISION GUIDE (ITEM NUMBER SELECTION)



3 Sodium azide as a preservative?

- ☐ Yes (We recommend 0.1% sodium azide)
- □No
- ☐ Custom preservative (let us know)

# **Human Urine**

DECISION GUIDE (ITEM NUMBER SELECTION)

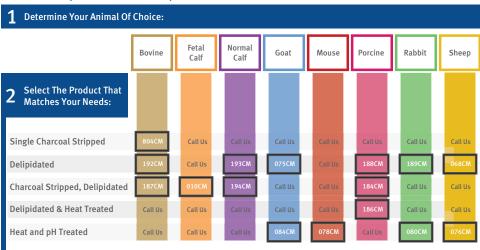
1 Determine the Human Urine of Your Choice

Drug Free Urine – Raw & Pooled	011RM
Drug Free Urine Matrix – pH Treated	004CM
Drug-Free Urine Matrix - Sodium Azide pH - Treated	014CM
EtG/Cotinine Drug Free Urine Matrix – Sodium Azide & pH Treated	043CM
Custom Description	Х



#### **Animal Plasma**

DECISION GUIDE (ITEM NUMBER SELECTION)



#### Sodium Azide as a Preservative?

г	Yes	(We	recommer	nd	0.1%	sodium	azide)	١

□No

Custom preservative (let us know)

# Purified Antigens & Antibodies Products Decision Guide (Item Number Selection)

#### **Product Key Features**

Quality	Standard & affinity purified grades
Validated	Commercially proven reagents in Monobind assay products for manufacturing or research use
ITEM#	Description
1925015RM	AFP
2525015RM	lgE
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

#### Human Serum: Defibrinated, Charcoal Stripped

Product: Defibrinated, Charcoal Stripped, Non-Lipid Stripped Human Serum

Item#-Lot#: 3 Liters/Bottle

Preservative: None

Microbial: <10cfu/mL or no growth

Filtration: Filtered through a 0.22micron absolute membrane filter prior to bottling

Shelf Life & Storage: Five years at -20°C from date of manufacture

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	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.

#### Human Serum: Defibrinated, Double Charcoal Stripped

Product: Defibrinated, Double Charcoal Stripped Human Serum

Item#: 177CM or 190CM
Preservative: As required
Microbial: < 10 cfu/ml

Filtration: Filtered through a 0.22micron absolute membrane filter prior to bottling

Shelf Life & Storage: Five years at -20°C from date of manufacture

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.

#### Human Serum: Resin Stripped

Product: Resin Stripped, Non-Lipid Stripped, Human Serum

MB Part#: 097CM or 173CM
Preservative: As required
Microbial: <10 cfu/ml

Filtration: Filtered through a 0.22micron absolute membrane filter prior to bottling

Shelf Life & Storage: Five years at -20°C from date of manufacture

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.

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

#### Human Serum: Off the Clot

Product: Human Serum, Off The Clot

Item#-Lot#: 245CM-24L05

Preservative: None

Microbial: <10cfu/mL or no growth

Shelf Life & Storage: Five years at -20°C from date of manufacture

Filtration: Filtered through a 0.22micron 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	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
	D 11	
Analyte	Result	
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.

#### Human Albumin: 20% Solution

Product: Human Albumin 20% Solution

Item#: HA20S

Lot#: 100RM-MBB-75616

Fractionation Method: Cohn-Oncley Cold Alcohol Procedure

Shelf Life & Storage: Ten years at -20°C from date of manufacture

Purity: > 97% by SPE Gel Electrophoresis

Appearance: Faint yellow-white color Plasma Type: Phoresis Plasma

Origin Of Plasma: FDA Licensed Facilities

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

• HBsAg

HCV Antibodies

• ALT (SGPT)

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

• HIV I & II Antibodies

• HBV, HCV, HIV-1 & HIV-2

HCV Antibodies

(NAT Testing)

HBsAg

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.

#### Human Albumin: Lyophilized

Product: Human Albumin Lyophilized

Item#: HA00D

Lot#: 089RM-MBB-58D16

Shelf Life & Storage: Ten years at -20°C from date of manufacture

Fractionation Method: Cohn-Oncley Cold Alcohol Procedure

Purity: >96% by SPE Gel Electrophoresis

Appearance: Cream Powder

Plasma Type: Phoresis Plasma
Origin Of Plasma: FDA Licensed Facilities

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

HBsAg

• HCV Antibodies • ALT (SGPT)

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

HIV I & II Antibodies

• HBV, HCV, HIV-1 & HIV-2

HCV Antibodies

(NAT Testing)

HBsAg

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.

#### Human Albumin: Lyophilized, Low B12

Product: Human Albumin Lyophilized, Low B12

Item#: HAODLB

Lot#: 089RM-MBB-59G16

Shelf Life & Storage: Ten years at -20°C from date of manufacture

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

Origin Of Plasma: FDA Licensed Facilities

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
 HBV, HCV, HIV-1 & HIV-2
 (NAT Testing)

HBsAg

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.

#### Human Albumin: Lyophilized, Fatty Acid Free

	•
D 1 .	11 411 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Product:	Human Albumin Lyophilized, Fatty Acid Free
Item #:	HAODFAF
Lot#:	088RM-MBB-59G16
Fractionation Method:	Cohn-Oncley Cold Alcohol Procedure
Shelf Life & Storage:	Ten years at -20°C from date of manufacture
Purity:	>96% by SPE Gel Electrophoresis
Key Analytes:	Fatty Acid 0.0mg/g
Appearance:	Cream Powder
Plasma Type:	Phoresis Plasma
Origin Of Plasma:	FDA Licensed Facilities

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 AntibodiesHCV AntibodiesHCV AntibodiesHBSAgALT (SGPT)

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

• HIV I & II Antibodies • HBV, HCV, HIV-1 & HIV-2

HCV Antibodies (NAT Testing)

HBsAg

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.



# Human IGIV: 10% Solution Product: Human Gamma Globulin – IGIV – 10% Item#: IGIV10S Lot#: 105RM-47D16 Shelf Life & Storage: Ten years at – 20°C from date of manufacture 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 Origin Of Plasma: FDA Licensed Facilities

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 AntibodiesHCV AntibodiesHBsAgALT (SGPT)

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

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

HBsAg

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.



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

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