

# Access Biologicals LLC

# The Access Biologicals Advantage

Gold standard in plasma and blood collection, manufacturing & worldwide distribution

FDA licensed & registered, CLIA & ISO certified

Distinct, closed-loop supply of human based blood products. Serving the diagnostic & life science industries

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# **ABOUT US**

Access Biologicals is a market leader in the collection & manufacturing of an extensive portfolio of biological products. Combined with closed-loop material sourcing, we are able to provide critical support for various markets such as: in-vitro diagnostic manufacturing, biopharmaceutical and cell culture. Manufacturing capabilities include a variety of plasma and serum processing in fully auditable facilities with on-site monitored storage

# **Our Business Units**

Access Biologicals LLC is comprised of business units that provide a comprehensive closed-loop response to our customers' product requirements

- Access Plasma: Our dedicated plasma donation center, Saturn Biomedical, which includes human plasma & serum collection as well as clinical collections
- Access Biologicals: Our corporate management, quality, sales & manufacturing infrastructure
- Access Cell Culture: Our portfolio of quality human and animal sera for cell culture & cell therapy applications
- Access Manufacturing: Our processed plasma and serum manufacturing business unit

## **Locations**

Headquarters, manufacturing facility, shipping and comprehensive donor recruitment offices: Vista, CA

Sales offices: Dartmouth, MA, Philadelphia, PA and Charleston, SC

Saturn Biomedical: Plasma and blood collection center in Indianapolis, IN





# **Capabilities**

The Access group of companies provides a dynamic, closed-loop response to the needs of our customers in the Life Science and Diagnostic Industry:

- Serum production
- Disease state plasma & serum
- Whole blood products
- Clinical Collections & Biospecimens
- Analytical testing
- Animal serum
- Human Male AB serum
- Dedicated donor center, Saturn Biomedical

#### FDA/CLIA/ISO licenses

- FDA Registration # 3006118943
  - Access Biologicals
- CLIA Certification ID # 15D0891286
  - Access Plasma dba Saturn Bio
- FDA License # 1193
  - Access Plasma dba Saturn Bio
- ISO 9001 Certified

# **Saturn Biomedical, dedicated donor collection center**

Access Biologicals' dedicated donor center exceeds 1,000 donations per week, increasing supply of high-quality plasma and serum products catered to meet customer specifications.

FDA licensed since 1998, Saturn Biomedical is able to collect both injectable & non-injectable blood products such as:

- ToRCH
- Infectious and Autoimmune Diseases
- Cancer Markers
- Coagulation Plasma
- Therapeutic-grade Source Plasma
- Red Cell Antibodies
- Whole Blood Normal and Diabetic
- Other Specialty Products



# COVID-19



Offering COVID-19 positive serum and plasma

# **COVID-19 POSITIVE & NEGATIVE PANELS**

Access Biologicals is actively collecting serum and plasma from patients that have been diagnosed with COVID-19.

- Our COVID-19 (30 member) panel contains 1mL of serum from 30 unique donors. This panel includes both an ELISA IgG and IgM POS or NEG result as well as IgG and IgM units and concentration information. Date symptoms subsided is also included. This panel is collected under an IRB approved protocol.
- Our COVID-19 Matched set (20 member) panel contains 1mL of serum and 1mL of K2 EDTA from 20 unique donors. This panel contains a COVID-19 IgG result as well as the date symptoms subsided. This panel is collected under an IRB approved protocol.
- Our COVID-19 (20 member) panel contains 1mL of serum from 20 unique donors. This panel includes COVID-19 IgG results from the Diasorin Liason and results from the Siemens Centaur. This panel is collected under an IRB approved protocol.
- Our Normal, Healthy Serum (87 member)
   panel contains 2mL per member of OTC serum
   collected pre-pandemic era (bleed dates are
   from March 2017-Nov 2018). Age, gender,
   bleed date and blood type are provided.

# Sample Inclusion Criteria for COVID-19 Positive Panels:

- Any gender
- Age ≥18 to ≤90 years
- Confirmed infection with COVID-19 determined by a Positive Swab result or an MD diagnosis

#### **Donor Data Provided:**

- Age
- Gender
- Race
- Date of draw
- Date of onset of symptoms
- Date of positive swab or MD Diagnosis

# **COVID-19 SEROCONVERSION PANEL**

The COVID-19 Seroconversion Panel consists of 14 members with each member containing 1 vial of 1.0 mL of human plasma. Panel members collected in this longitudinal series are from a single donor during the progression of a SARS-CoV-2 infection. This panel illustrates the onset and decline of IgM, IgG and Ig total SARS-CoV-2 virus antibody titers over a period of 87 days. Panel members are undiluted, naturally occurring plasma samples collected in 4% sodium citrate. Units were aseptically filtered. No preservative has been added. All panel members are ready to use.

COVID-19 Seroconversion Panel

Panel member	Day	Bleed date	Gold Standard Diagnostics <sup>a</sup>		DiaSorin, Inc. <sup>b</sup>	Progenika Biopharma SA c	VITROS <sup>d</sup>	
			SARS- CoV-2 IgG	SARS- CoV-2 IgM	LIAISON SARS-CoV- 2 S1/S2 IgG	Anti-SARS- CoV-2 (IgG)	Anti-SARS- CoV-2 IgG	Anti-SARS- CoV-2 Total
1	1	03/04/20	0.6	1.5	8.34	0.0	0.01	0.04
2	3	03/06/20	0.5	1.1	8.22	0.0	0.01	0.07
3	10	03/13/20	0.4	1.4	8.36	0.0	0.01	0.05
4	15	03/18/20	0.5	1.5	8.14	0.0	0.01	0.05
5	17	03/20/20	0.5	0.9	7.79	0.0	0.01	0.05
6	24	03/27/20	0.4	1.9	8.32	0.0	0.01	0.05
7	31	04/03/20	0.4	1.3	8.63	0.1	0.01	0.06
8	36	04/08/20	0.6	2.5	6.18	0.1	0.01	0.53
9	50	04/22/20	22.7	33.5	20.80	2.8	2.16	17.89
10	64	05/06/20	39.4	21.4	40.90	6.0	9.14	41.18
11	71	05/13/20	30.8	15.1	45.10	6.9	7.53	47.66
12	78	05/20/20	27.0	11.5	42.60	4.8	6.96	56.74
13	80	05/22/20	25.9	10.7	37.70	4.5	5.65	53.57
14	87	05/29/20	20.7	7.2	32.30	3.9	4.98	62.12

°Units are qualitative. They are defined by the manufacturer; Units < 9.0 are considered negative; Units 9.0 − 11.0 are considered equivocal; Units > 11.0 are considered positive. 

°Arbitrary units (AU/mL) Units < 15.0 are considered negative; Units ≥ 15.0 are considered negative; Units ≥ 15.0 are considered positive. 

°Units < 0.8 are considered negative; units ≥ 0.8 to < 1.1 are considered equivocal, units ≥ 1.1 are considered positive. 

°Units < 0.8 are considered non-reactive for anti-SARS-CoV-2; S/C ≥ 1.00 is considered reactive for anti-SARS-CoV-2.

# **BULK COVID-19 POSITIVE & NEGATIVE**

- Convalescent bulk plasma units of 690-880 mL per donor are available using the same criteria as above.
- Pooled defib/delip material available, negative via NAT for COVID-19.
- All panels, bulk units and processed pools are shipped frozen, on dry ice.

# **COVID-19 Vaccine Panels**

- 15 Subject Panel
  - O 3 samples per subject
    - Sample 1: ≤ 2 days prior to the first vaccination
    - Sample 2: ≤ 2 days prior to their second vaccination
    - Sample 3: 13-15 days post their second vaccination
- No previous COVID infections
- Serum only
- 1mL samples
- Methodology: DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG
- 30 Subject Panel
  - O 3 samples per subject
    - Sample 1: ≤ 2 days prior to the first vaccination
    - Sample 2: ≤ 2 days prior to their second vaccination
    - Sample 3: 13-15 days post their second vaccination
- Some subjects with previous COVID infections
- Serum and Plasma
- 1mL samples
- Methodology: DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG

# **Access Biologicals Panels**

- ANA (Antinuclear Antibody)
- Anti-CCP ((cyclic citrullinated peptide) antibodies in the blood)
- APLS (antiphospholipid antibody syndrome)
- Celiac
- HSV I & II
- MMRV (measles, mumps, rubella and varicella)
- ToRC
- Vasculitis
- Vitamin D

Custom panels available upon request

# **Human Plasma & Whole Blood Products**

Access Biologicals provides a variety of human plasma, whole blood & protein products to fill your IVD, R&D and bioprocess needs. Choose from human plasma, human whole blood products, human serum albumin and gamma globulin.

### **Human Plasma Products:**

Pooled or single units of human plasma are available with various anticoagulants such as:

- EDTA
- Sodium Citrate
- Na Heparin
- Na EDTA
- Custom anticoagulants also available

Flash Frozen Plasma is available as single units, freshly collected and flash frozen within a maximum of 30 minutes of collection.

- All units are collected at FDA licensed facilities within the US
- All units are tested for FDA required viral markers using FDA approved test methods
- Collected in sodium citrate

## **Human Derived Proteins:**

Available in both liquid or powder form

**Human Serum Albumin** is the most common protein found in human blood plasma and makes up about half of the human serum protein. It is commonly used to treat patients who have experienced trauma, such as burns or surgery, as it helps to replace lost fluid and restore blood volume. It's also used as a supplement for cell culture media and promotes cell growth by delivering nutrients and binding toxins.



Human serum albumin is available in the following forms & concentrations suitable for therapeutics, excipient use, diagnostics or cell culture applications:

5%, 20%, 25%

Diagnostic Grade Human Serum Albumin is available in powder or liquid and comes in concentrations of:

5% Liquid only

20% Liquid and powder

### 25% Liquid and powder

- Powders are soluble, off-white, diagnostic grade of ultra-high purity, and fractionated according to Cohn Cold Alcohol techniques from fully traceable, documented US plasma
- Solutions are available in a variety of concentrations, suitable for diagnostic or cell culture processes
- All units of plasma used to manufacture HSA are collected at FDA licensed blood centers within the US and have been tested and found to be non-reactive for HBsAg, Anti-HCV, Anti-HIV-1 and 2, HIV RNA, HBV DNA and HCV RNA

#### Performance:

- 98% protein with albumin purity levels >97%
- Viral inactivated, low endotoxin and with low protease levels
- Ideal choice for sensitive diagnostic assays and applications
- Extensively tested for a full panel of safety and analytical data

## **Gamma Globulin:**

Available at 5% or 10% as either a diagnostic-grade powder or solution. This is an ideal choice for sensitive diagnostic assays and applications.

- Powders are soluble, off-white, diagnostic grade of ultra-high purity, and fractionated according to Cohn Cold Alcohol techniques from fully traceable, documented plasma
- All units of plasma used to manufacture gamma globulin have been collected at FDA licensed centers within the United States, have been tested and found to be non-reactive for HBsAg, Anti-HCV, Anti-HIV-1 and 2, HIV RNA, HBV DNA and HCV RNA

# **Human Serum Production**

Our plasma and serum processing techniques are widely varied from standard products to custom processing.

# Plasma and Serum Processing Capabilities

Our plasma and serum processing techniques are widely varied. They include, but are not limited to:



### The Access Biologicals Manufacturing Standard of Excellence:

- Fully auditable facilities & on-site monitored storage, ensuring that only the highest quality plasma is used in production
- Plasma is collected at FDA licensed facilities, with complete quality control, donor traceability and a validated software system
- Standard fill sizes: 1 liter and 3 liters
- Custom processing and custom fill sizes are available

- Defibrination
- Charcoal Stripping
- Large scale filtration
- Lipid stripping
- Diafiltration
- Heat Inactivation
- Gamma Irradiation

**Defibrinated Serum** is created by defibrinating plasma. It is available delipidized (meaning the lipids have been removed and the serum is optically clear), charcoal stripped (meaning the hormone proteins have been removed) or as a combination of the two serum production methods as well.

**Serology Negative Serum** is serum that has been screened and declared negative for serology disease state markers.

**Hepatitis Negative Serum** is a custom serum that is derived from plasma that has a bulk pool of negative or non-reactive viral markers as found by chLIA and PCR methodology. This variety of serum production is suitable for negative control matrices.

**Off-The-Clot Serum** is collected from whole blood and allowed to coagulate naturally. There is no anticoagulant added.

**Standard Human Serum** – Our standard human serum is a proprietary product that is a replacement for OTC serum and can be used as a negative base matrix. It can be manufactured with or without sodium citrate and can be manufactured to customer specifications.

**Custom Produced Sera** – Can't find the material you're looking for? Our specialty is custom-produced sera. Just contact us with your specifications or acceptance criteria for pricing and production lead time.

# PERSPECTIVE AND REMNANT IRB APPROVED BIOSPECIMENS FOR:

FDA Submissions
Quality control
Research and Development

# & BIOSPECIMENS

Access Biologicals provides specialty collections from our FDA Licensed and Registered Blood Center, Saturn Biomedical. Collections are IRB compliant with informed consent.

Additionally, we offer Perspective collections and Remnant samples through our extensive Physician and Laboratory Network.

- Matched sets, representative samples from bulk material, large donor base, prescreened donors and repeat donors as well as specialty and customer directed collections
- All samples are provided with basic demographic data; age, gender, race (if available)
- Additional data may include: collection date/ time, freeze date & time, redacted labs &/or medical records, current medications, ICD-10 code, methodology and titer result

# IRB compliant sample types:

- Normal/disease free collections
- Infectious disease
- Endocrinology
- Oncology
- Cardiac
- Pregnancy and Hormones
- Diabetics
- Autoimmune disease markers
- Serology
- Virology



## **IRB Compliant Protocol**

## In-house Biospecimen Repository

- Our in-house sample repository contains IRB approved samples:
- Single samples, 2-way matched sets, 3-way matched sets from various markers such as:
  - AFP with gestational week
  - ALT
  - AST
  - BNP
  - Anti-CCP
  - CEA
  - CPK

- CRP
- HbA1c
- NTproBNP
- PSA
- RF
- Free T3 Free T4
- Folate

- Ferritin
- dsDNA
- Iron
- FSH
- VIT D
- INR
- Cardiolipin

- VIT D25
- Normal Healthy
- Post-Menopausal
- OTC Healthy

Consultation services are available prior to issuance of Statement of Work to assure study accomplishes goals within budget.

Contact your Access Biologicals sales representative or the Access Clinical collection department at 1-760-931-8444 or Biospecimens@accessbiologicals.com for additional information.



# **DISEASE STATE PLASMA & SERUM**

Access Biologicals offers specialty antibody positive and negative plasma available in single donor units that can be drawn to meet your specifications:

- Numerous disease states available including viral positive, infectious, autoimmune and others
- Many items available as plasma or serum, for use as diluents in the manufacture of positive and negative controls
- Bulk-pooled material and services such as defibrination, delipidization and heat inactivation are also available

## Complete Traceability and Quality Control

- Complete traceability and quality control; raw, bulk serum and plasma collected from single donors within our closed-loop collection network
- Our units of serum or plasma are obtained from FDA registered and licensed facilities, from qualified blood donors. Characterized units collected from paid, U.S. plasmapheresis donors requiring informed consent
- All units collected under relevant ethical procedures

### Disease State Plasma/Serum available:

#### Autoimmune Disease Markers:

- Saccharomyces (ASCA)
- C-ANCA
- Anti-Cardiolipin (IgG, IgM, IgA)
- B2 Glycoprotein (IgG, IgM, IgA)
- Gliadin
- Jo-1
- Microsomal (TPO)
- Mitochondrial (AMA)
- Nuclear Ab (ANA)
- Parietal
- Pm-Scl-70
- RNP
- Smith
- Smooth muscle (AMSO)
- SSa, SSb
- Thyroglobulin
- DNA/Histone
- dsDNA and ssDNA
- Ribosomal Nuclear Protein
- Tissue Transglutaminase (tTG)
- Rheumatoid Arthritis (RF)
- Systemic Lupus

#### **Interfering Substance:**

- Lipemic
- Icteric
- Hemolyzed

#### Infectious Disease:

- Chagas (anti T. cruzi)
- Chlamydia (IgA, IgG, IgM)
- CMV (IgG, IgM)
- Coag/INR
- COVID-19
- EBV (VCA, EA, EBNA)
- H. Pylori (IgA, IgG, IgM)
- HAV (Total, IgG, IgM)
- HBc (Total, IgG, Igm)
- HBeAg, HBe (total, IgM)
- HBsAg (AY, AD)
- HBV DNA
- HCV RNA
- HIV-1 Ag (p24 and other WB patterns)
- HIV-1 Ab (group M,O, genotypes)
- HIV-1/2, HIV-1(WB), HIV-2
- HIV-1 RNA
- HSV-1 (IgG, IgM) HSV-2(IgG, IgM)
- Influenza A/B
- Lyme (IgG, IgM)
- Mononucleosis
- Mumps (IgG, IgM)
- Mycoplasma (IgG, IgM)
- Parvovirus
- Rubella (IgG, IgM)
- Rubeola (IgG, IgM)
- Rocky Mountain Spotted
   Fever
- Syphilis (RPR and anti-Treponema)
- Tetanus
- Toxoplasmosis (IgG, IgM)
- VZV (IgM)
- West Nile Virus (IgM)
- Zika Virus

#### Other Conditions:

OB/GYN: Pregnancy

#### Immune/Serology:

- ASO
- Allergy
- IgA, IgD, IgE, IgG, IgM (allergen specific and total IgE)

### Inflammatory:

- Elevated CRP
- hCG (bulk)
- HLA B-27

#### **Red Cell Antibodies:**

- Anti-K
- Anti-Fya
- Anti-Fyb
- Anti-C
- Anti-c
- Anti-M
- Anti-D
- Anti-E
- Anti-Vel
- Anti-Jka
- Anti-S
- Anti-U

**100% PURE FBS, PERFECT FOR:** 

Viral Vector Production Cell Therapy Mammalian Cell Culture

# **FETAL BOVINE SERUM**

Access Cell Culture, a member of the ISIA (International Serum Industry Association), offers a range of Fetal Bovine Serum products tailored to meet the unique needs of a variety of cell culture systems.

All Bovine Sera are produced following stringent manufacturing & finished product specifications to ensure extraordinary quality at exceptional value.



- EU approved sources
- Collected aseptically at South American licensed facilities
- Complete traceability to original source by collection date and location
- Triple.1 micron filtered, Endotoxin <5EU/mL,</li>
   Mycoplasma negative, Low hemoglobin
- 9CFR Tested
- Produced under cGMP guidelines in an ISO certified facility
- Heat inactivation available upon request
- EU142/2011 approved





- US & USDA approved sources
- Collected aseptically at USDA licensed facilities
- Complete traceability to original source by collection date and location
- Triple . 1 micron filtered, Endotoxin <5EU/mL,</li>
   Mycoplasma negative, Low hemoglobin
- 9CFR Tested
- Produced under cGMP guidelines in an ISO certified facility
- Heat inactivation and gamma irradiation available upon request
- EU 142 approved
- Korean eligible
- Oritain origin certified

# cGMP HUMACELL, PERFECT FOR:



Replacing FBS
Gene Therapy
Monoclonal Antibody
Production

# **HUMACELL SERUM**

Humacell is a non-AB human serum meant for use on human cells where FBS is being used. It is 100% mixed gender, mixed blood type human serum manufactured using our proprietary process under cGMP.

Suitable for use in regenerative medicine, cryopreservation media and therapeutic applications.

- Each unit is tested and found negative for all viral markers via FDA-approved methods:
  - Testing at CLIA and FDA approved labs
    - HIV-1, HCV and HBV by Nucleic Acid Test, Parvo B19, WNV, Zika, Chagas and HAV by Nucleic Acid Test, Anti-HIV 1 / 2, Anti-HCV, HBsAg & Syphilis
    - Additional testing provided: Anti-HBc, Mycoplasma, Endotoxin, USP Sterility, Hemoglobin, Osmolality, pH, Chemistry, Species Testing, Anti-HTLV I/II, Atypical Antibodies and HIV 1 p 24 Antigen
  - Additional testing available upon request
  - 0.1μm sterile-filtered
- Heat inactivation and gamma irradiation available upon request:
  - Gamma Irradiation is through a validated process
  - Virus inactivation study completed March 2019



# **HUMAN MALE AB OTC SERUM**

# The Access Advantage:

Human Male AB OTC Serum is collected from the whole blood donation of healthy male AB donors at FDA-licensed centers within the US.

The whole blood is allowed to coagulate naturally after collection and once clotted, the material is centrifuged to remove the clot and serum is separated and virally tested. The individual units are then pooled, filtered and bottled.

- Each individual unit is tested and found negative for all required viral markers via FDA-Approved methods:
  - Testing at CLIA and FDA approved labs
    - HIV-1, HCV and HBV by Nucleic Acid Test, Parvo B19, WNV, Zika, Chagas and HAV by Nucleic Acid Test, Anti-HIV 1/2, Anti-HCV, HBsAg & Syphilis
  - Additional testing provided: Anti-HBc, Mycoplasma, Endotoxin, USP Sterility, Hemoglobin, Osmolality, pH, Chemistry, Species Testing, Anti-HTLV I/II, Atypical Antibodies and HIV 1 p 24 Antigen
    - Additional testing available upon request
  - 0.1μm sterile filtered
- Higher protein content than standard plasma
- Custom donor pools available
- Heat Inactivation and gamma irradiation available upon request
  - Gamma Irradiation is through a validated process
  - Virus inactivation study completed March 2019

# **HUMAN MALE AB SERUM**

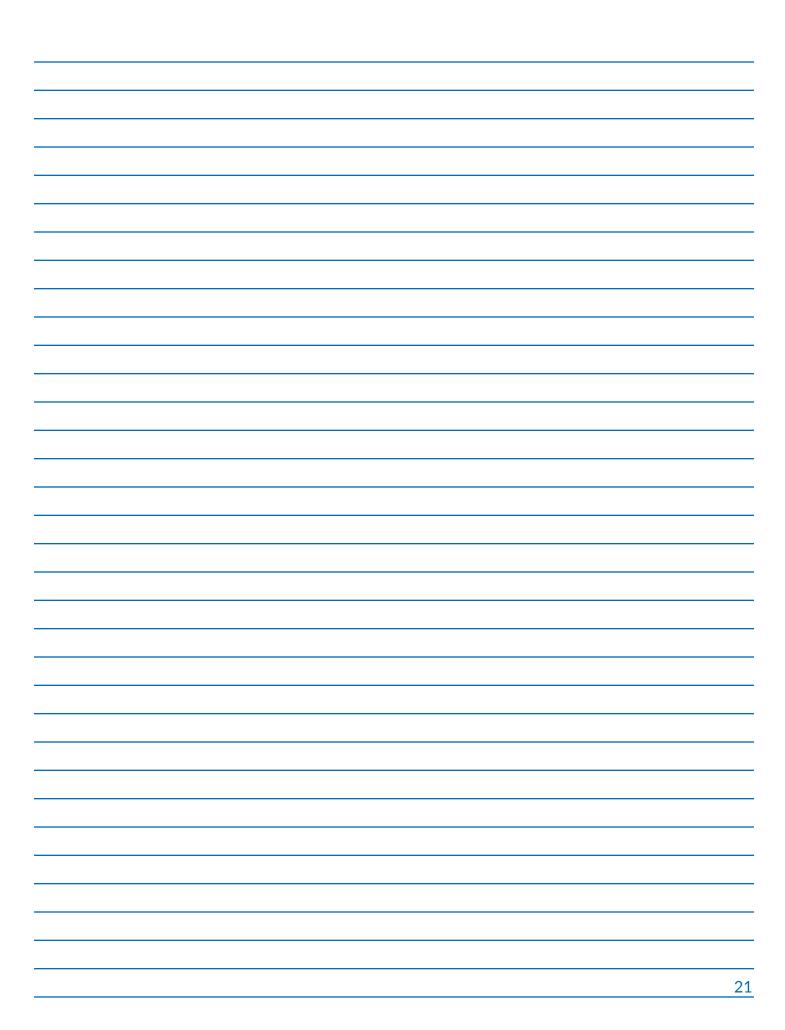
# **The Access Advantage:**

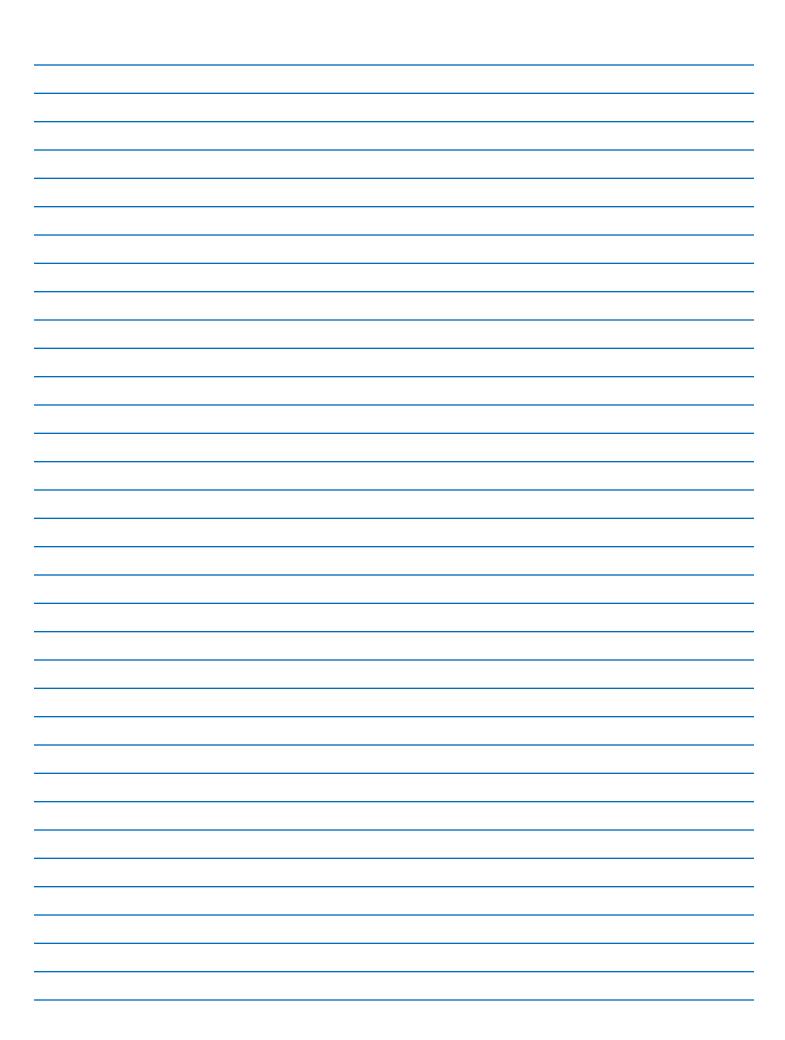
Our Human Male AB Serum is a proprietary product manufactured with either human or bovine thrombin following a cGMP process.

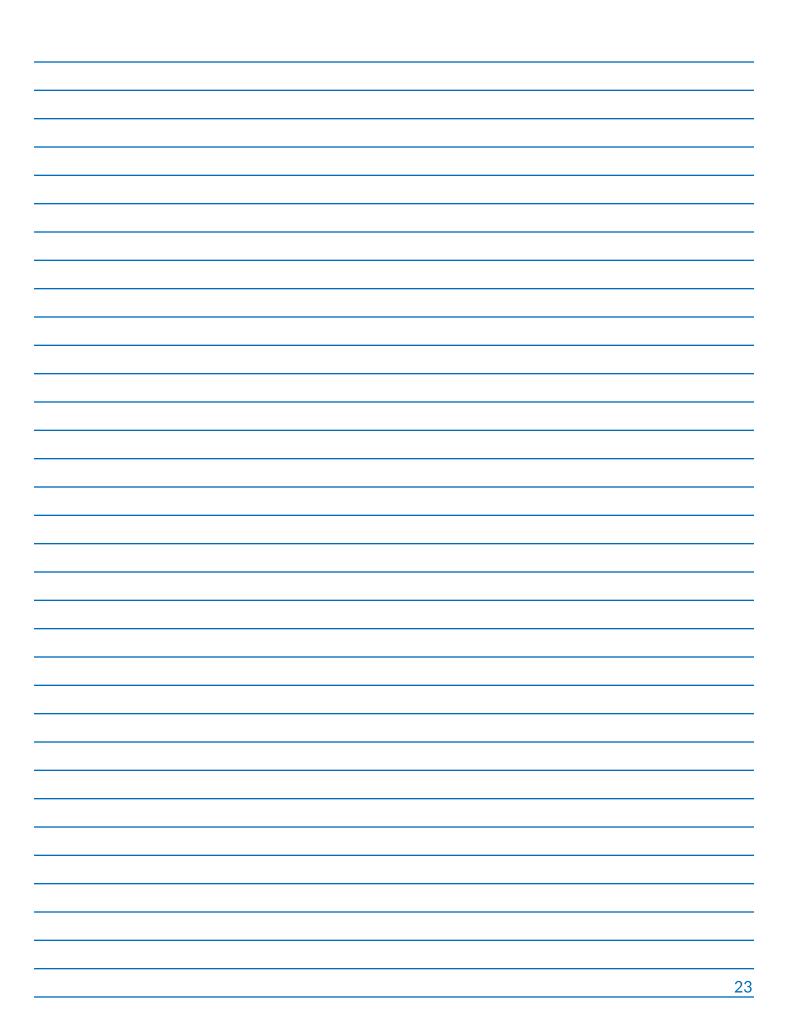
We collect and manufacture internally, allowing us to offer a product using a fully closed-loop system from plasma donation to finished product.

- Access Biologicals directly collects our Human Male AB plasma from FDA licensed centers within the US
- Our donors are monitored using a DMS (donor management system) which is a 510K licensed medical device
- Each unit is tested and found negative for all viral markers via FDA-approved methods:
  - Testing at CLIA and FDA approved labs
    - HIV-1, HCV and HBV by Nucleic Acid Test, Parvo B19, WNV, Zika, Chagas and HAV by Nucleic Acid Test, Anti-HIV 1 / 2, Anti-HCV, HBsAg & Syphilis
    - Additional testing provided: HEV, Chagas, Anti-HBc, Mycoplasma, Endotoxin, USP Sterility, Hemoglobin, Osmolality, pH, Chemistry, Species Testing, Anti-HTLV I/II, Atypical Antibodies and HIV 1 p 24 Antige
    - Additional testing available upon request
  - 0.1μm sterile-filtered
  - Heat inactivation and gamma irradiation available upon request
  - Gamma Irradiation process is through a validated process
  - Virus inactivation study completed March 2019









# Access Biologicals has built a reputation for providing a comprehensive portfolio of diagnostic sera, plasma-derived reagents and cell culture products.

Operating state-of-the-art facilities that incorporate the industry's highest quality standards, Access Biologicals remains committed to meeting the stringent demands of our customers in the global life sciences industry by:

- Consistently identifying and fulfilling our customers' needs and expectations.
- Satisfying customer and regulatory requirements and continually anticipating industry needs.
- Fostering an environment of continuous improvement and innovation, leading to better products and services for our customers.

#### DISCOVER THE ACCESS BIOLOGICALS ADVANTAGE...

- Gold standard in plasma & blood collection, manufacture and distribution
- Excellent compliance with FDA, CLIA and State Regulations
- Direct-from-donor material sourcing
- Commitment to our customers through strategic partnerships

#### **CORPORATE OFFICE**

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#### **GENERAL INFO**

info@accessbiologicals.com

### **DONOR RECRUITING:**

info@accessclinical.com

## **SALES & MARKETING OFFICE**

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