

## ABOUT US

Founded in 1997, Tecnoblen is a family company dedicated to animal by-products located in Canelones, Uruguay.

The company operates two owned processing plants authorized by the Uruguayan government (Ministry of Livestock, Agriculture and Fisheries, M.G.A.P.)

#### SINCE 2016...

our biopharmaceutical unit has the fetal bovine serum as its main product

We process blood obtained from bovine fetus of animals born, raised and slaughtered in Uruguay into raw serum

Raw serum is

afterwards filtered in

order to obtain our final

product



We are one of the largest serum company in Uruguay

Our production is 120.000 to 150.000 bottles per year



Encourage good
manufacturing practices
while preserving natural
resources and
developing our
employees capacities





## VISION

Pioneer the industry, grow economically and expand based on our compromise, quality and well established working processes

## PURPOSE



Collect, process and provide raw materials under strict quality standards, standardized processes and guaranteed regularity, seriousness and quality to all of our clients



#### ISO 9001 CERTIFICATION





# FACILITIES







灭菌室







The materials previously cleaned are sterilized in the autoclave at 121°C for 30 minutes and then placed in the oven at 55°C for 2 hours

All areas are cleaned and sanitized every day according to the recommended procedures, using solutions of sodium hypochlorite, benzalkonium chloride, 70% ethyl alcohol and ultraviolet light



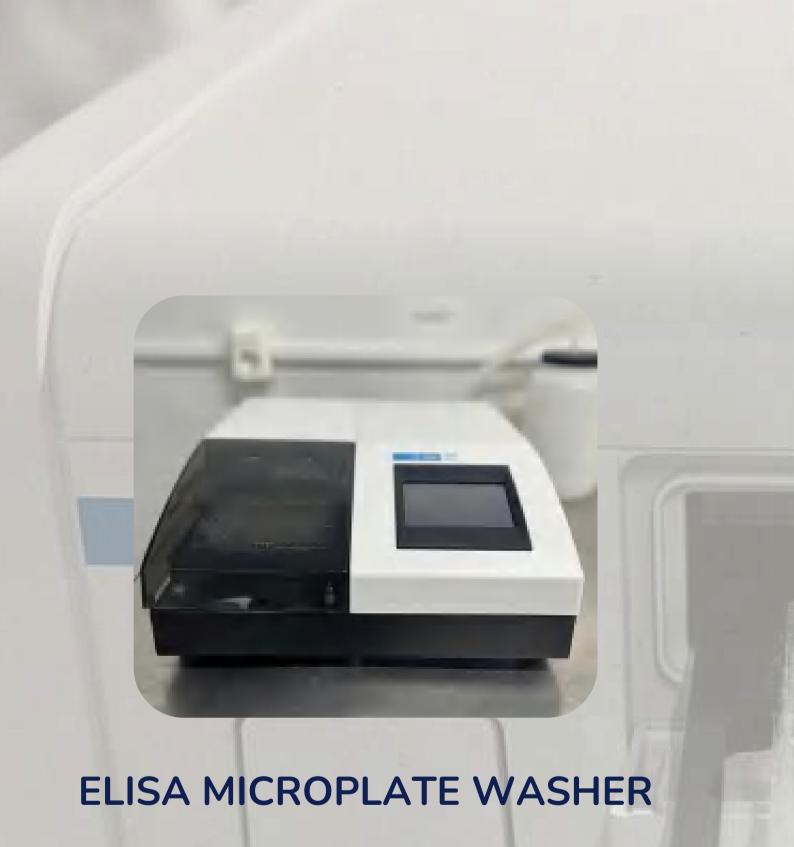
#### QUALITY CONTROL LABORATORY



#### **BIOTEK EPOCH 2**



Endotoxin, hemogoblin, IgG and Total protein determination



Effective microplate washer



#### **OSMOMETER**

Osmolarity determination



### ADVANCED pH AND BENCHTOPMETER

ph Determination

#### Tecnoblen 1 GT-Group Report

Assay Information

7/3/2024 (2-16:00 PM Started At-

40 Senso

abonatono Tecnoblesi. Operator

Assay Time 60 Omin.

Management.

Wavelength (WLI

Measurement Method Kimensc Teil Record Name 03.2024 L 11.2023-2 (Rev. 0)

Tent Record Comment.

7/3/2024 1:17:03 PM Finished At

> Time Interval 40sec.

Reference Wavelength

650mm

W1.2 F

Calculate concentration Value Culculate Average

nstrument Information

Serial Number Name 24012510 Epuch2

Kinetic Data Processing Parameter

Reduction Type 0.01500 Onesat OID I(lames) dilwer. Wait Time Count

Littuate interpolate

Ulmod 2 pourts nearly

ouset OD:

Achiestor Time Ta

Regression Type

for Linearity

Base Count

tandard Curve Parameter

Time/Com/Anny Regression Type Type for inear for Concentration

Log(X) Log(Y) Concentration

Time Cone Axia Same Concentration

Log(X) Log(Y)Type for Linearity

El /ml. Lise Mean Value Not Used Endorson Lint.

tandard Curve Information

Lyne Insernal

Cone Range EU/mL 432 = 1440sec (0, i+10, m=1). Cone, Unit

Regression for Log(Ta) = -0.25/1952 Log(C) = 2.89938 Linearaty

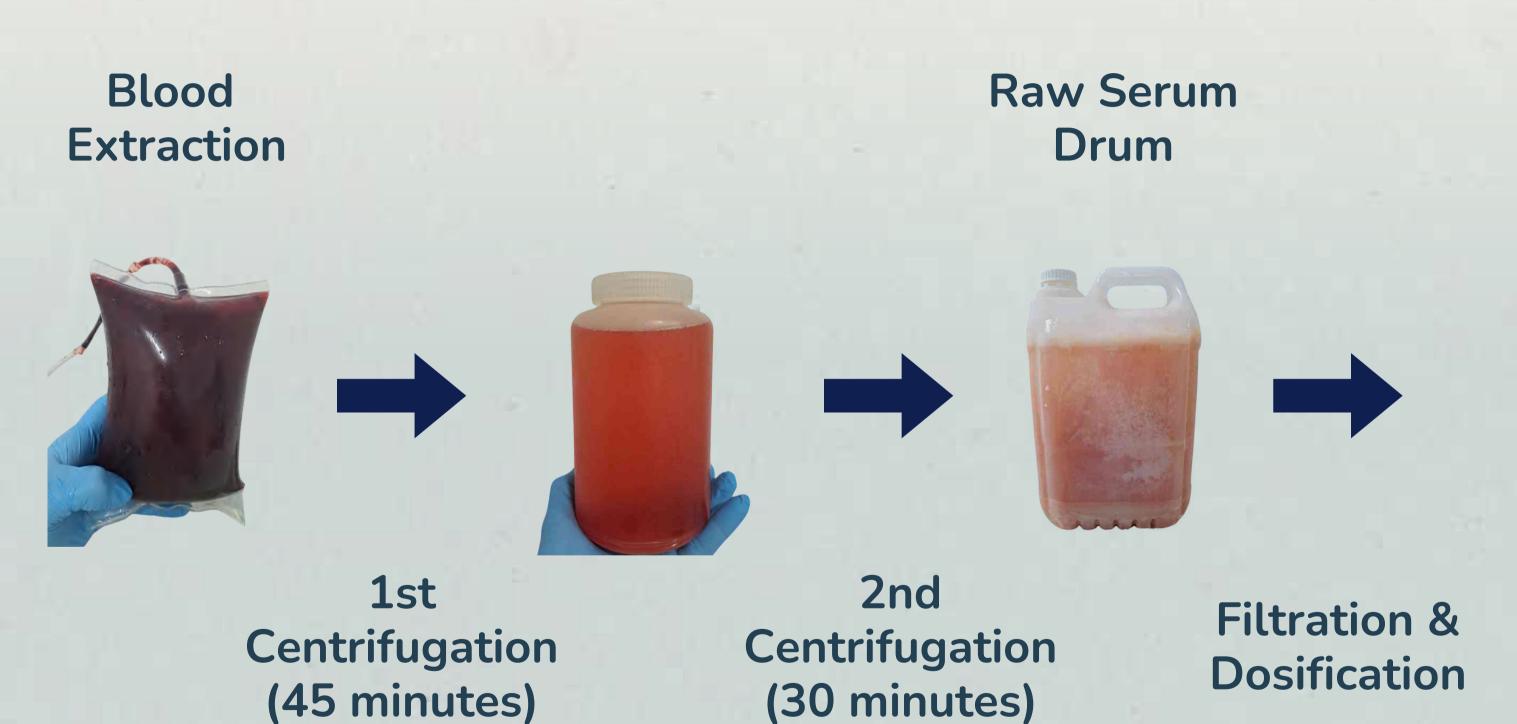
Hegressian for Log(Ta) - 0.254952 Log(C) 12.59938 Concentration

+1.000-1.0000Longardy r. Concentration to

Our measurement equipment guarantees 100% accuracy in the results

# PRODUCTION PRODUCESS

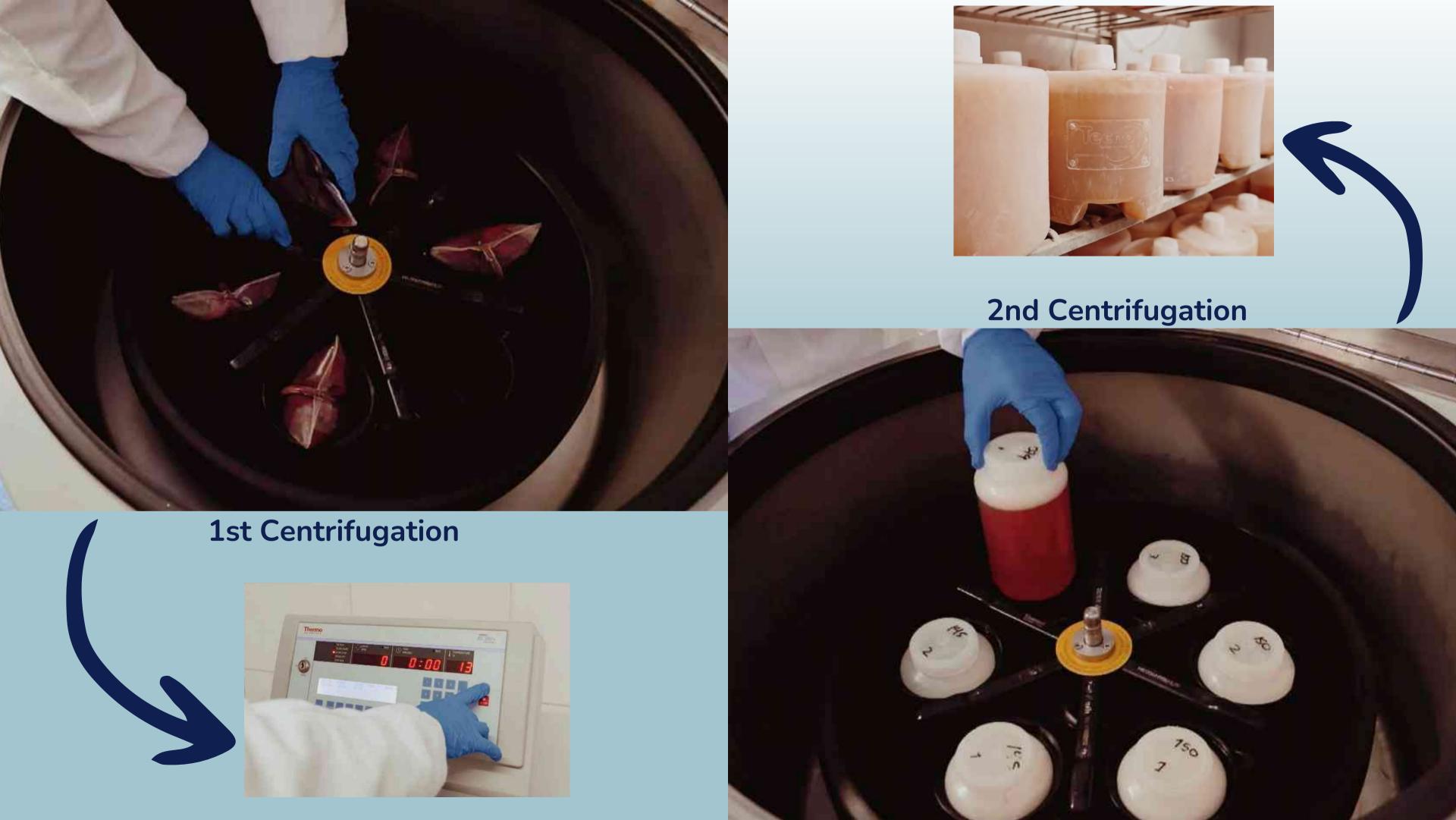
#### FROM BLOOD TO FILTERED SERUM...





**Final Product** 

# SERUM PRODUCTION







# RAWSERUM STORAGE



Raw serum is placed in 4.25 kg containers and storaged in the raw material chamber at -18°C \*\*





Raw material is defrosted prior filtering in the defrosting chamber at 1°C. Samples are taken and analized in our quality laboratory

# FILTRATION PROCESS



Prefiltration system is assembled by connecting the hoses of the peristaltic pump to the biocontainer bag of the tank

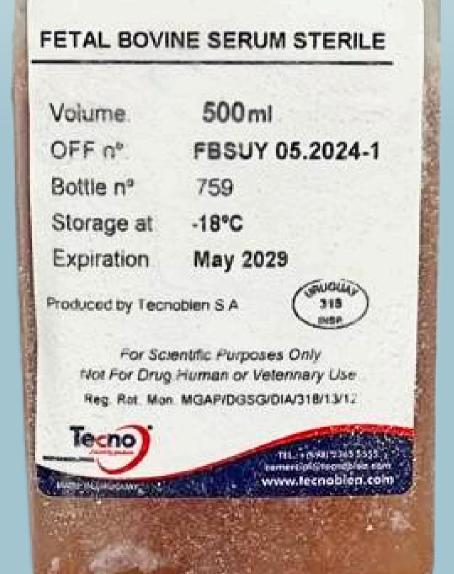
Our closed triple 0.1  $\mu$ m filtering system ensures sterility in the process.

Dosification of the 500 mL bottles.

# FINAL PRODUCT



# highest quality standards



- Low endotoxin
- Triple 0.1µm filtered
- Gamma Irradiated

#### PRODUCT SPECIFICATIONS



- < 25 mg/100ml Hemogoblin content
- < 10 UE/ml Endotoxin level</li>
- < 300 μg/ml lgG
- 2.50 4.50 g/dL Total protein
- 280 340 mOsm/kg Osmolarity
- 6.9 7.8 pH





#### PRESENTATIONS

**Bottles:** 

• 500 ml

• 125 ml

#### APLICATIONS

For scientific purposes such as immunology, virology, genetic engineering, pharmacology and other areas of biomedical research. Not for human or verterinary application.



### CERTIFICATE OF ANALYSIS (COA)

Production batches
guaranteed by our quality
control manager and
approved by Uruguayan
authorities.



#### Certificate of Analysis

Batch N°: FBSUY 05.2024-1 Filtration Date: 03/05/2024 Expiration Date: May 2029 Country of origin: Uruguay Country of final processing: Urugua

 Manufactured by:
 Expiration Date: May 2029

 Tecnoblen Company
 Country of origin: Uruguay

 Address: Route 67 s/n PTC Las Piedras
 Country of final processing: Use of final process

TEST	TEST ID	SPECIFICATION	RESULT	UNITS
Bacteria and Fungi	STERIO006	Not detected	Not detected	UNITS
Endotoxin	ENDO0007	0.0-10.0	2.4	EU/ml
Hemoglobin	HAEMO0002	0.0-25.0	10	mg/dL
Osmolality	OSMO0002	280-340	332	mOsm/k
PH	PH0003	6.9-7.8	7.39	-
Total protein	PROTEI0001	3.0-5.0	3.5	g/dL
1gG	EUSA	<30	· Pi	mg/dL
/T - BVDV Fluorescent Antibody	VIRUS0005	Not detected	Not detected	-

All fetal bovine blood is collected from fetuses derived from healthy dams that have passes pre and post-mortem verified veterinary inspection.

All fetal bovine sera is traceable by date and location of collection.

QUALITY CONTROL
Eugenia Pommerenck Date: 27-may-

#### REFERENCES

STERI0006: USP <71

ENDO0007: Analytical technique for the dtermination of bacterial endotoxins by turbidimetric kinetic method. USP<85> Bacterial Endotoxins Test

HAEMO0002: Three Wavelenght Polychromatic Analysis.

OSMO0002: USP <785>.

PH0003: USP <791>.
PROTEIN001: Tietz, Norhert V

PROTEI0001: Tietz, Norbert W.: Biuret Method for the Determination of Total Protein in Serum and Exudates Fundamentals of Clinical Chemistry, 1976, pages 302-304.

Fundamentals of Clinical Chemistry, 1976, pages 30.

VIRUS0005: viral isolation or RT-PCR



#### Certificate of Analysis

Fetal Bovine Serum

Manufactured by:

Tecnoblen Company

-Address: Route 67 s/n PTC Las Piedras

·Tel: +(598) 2365 5555 ·

www.tecnoblen.com

Batch Nº: FBSUY 05.2024-1
Filtration Date: 03/05/2024
Expiration Date: May 2029
Country of origin: Uruguay

Country of final processing: Uruguay

Storage Temp: -189C

For research use or further manufacturing use only. Secum and blood proteins are not for direct administration into humans or animals.

Sterile filtered (triple 0,1um)

TEST	TEST ID	SPECIFICATION	RESULT	UNITS
Bacteria and Fungi	STERIO005	Not detected	Not detected	
Endotoxin	ENDODD07	0.0-10.0	2.4	EU/mL
Hemoglobin	HAEMO0002	0.0-25.0	10	mg/dL
Osmolality	OSMODDDZ	280-340	332	mOsm/kg
PH	PH0003	6.9-7.8	7.39	
Total protein	PROTEIDD01	3.0-5.0	3.5	g/dL
lgG .	ELISA	<30		mg/dL
VT - BVDV Fluorescent Antibody	VIRUS0005	Not detected	Not detected	

# FINAL PRODUCT STORAGE









## LOADING PROCESS

Bottles are prepared in the conservators with dry ice and a temperature controller. A thermal blanket is added to finalize the process





Ensuring the safe transfer of our production towards the airport

# Our fleet of trucks transporting Tecnoblen products







### CONTACT US

Email: fbs@tecnoblen.com
Or through our official distributors



