



# VETERINARY VACCINE PRODUCTION

# SUMMARY

## Products and services for

## VETERINARY VACCINE PRODUCTION

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# Products and services for veterinary vaccine production

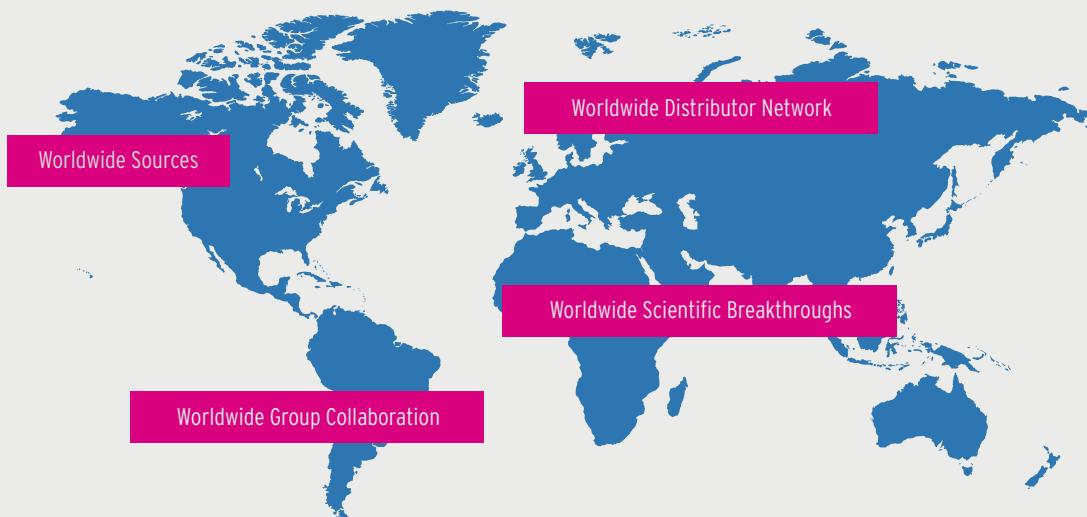
## A BIOWEST INTRODUCTION

Founded in 1987, Biowest is a **global leader** in the manufacture of animal sera, providing the **widest range of sera and cell culture media available on the market**.

Our products are used in the production of biopharmaceuticals and vaccines as well as in the academic, governmental and industrial research diagnostics.

Biowest sources its animal by-products only from companies with the highest standards of quality and traceability. As a result, Biowest controls the production of the sera throughout the **entire process**, from the collection around the world, to the final shipment of bottled serum from our warehouses, thus guaranteeing a **vertically integrated** system of production, quality control and documentation. Using specialized equipment and detailed SOP's, Biowest ensures the **quality** at every stage, thereby securing a consistently high quality with minimal batch-to-batch variation.

Biowest guarantees the best quality: We are ISO 9001 and ISO 13485 certified. Biowest is registered with the French Ministry of Agriculture (regulation (EC) n° 1069 / 2009) under the agreement n° FR 49.231.001 for the production of animal sera. Our facilities are auditable.



# Serum is the essential fuel for industrial cell culture applications

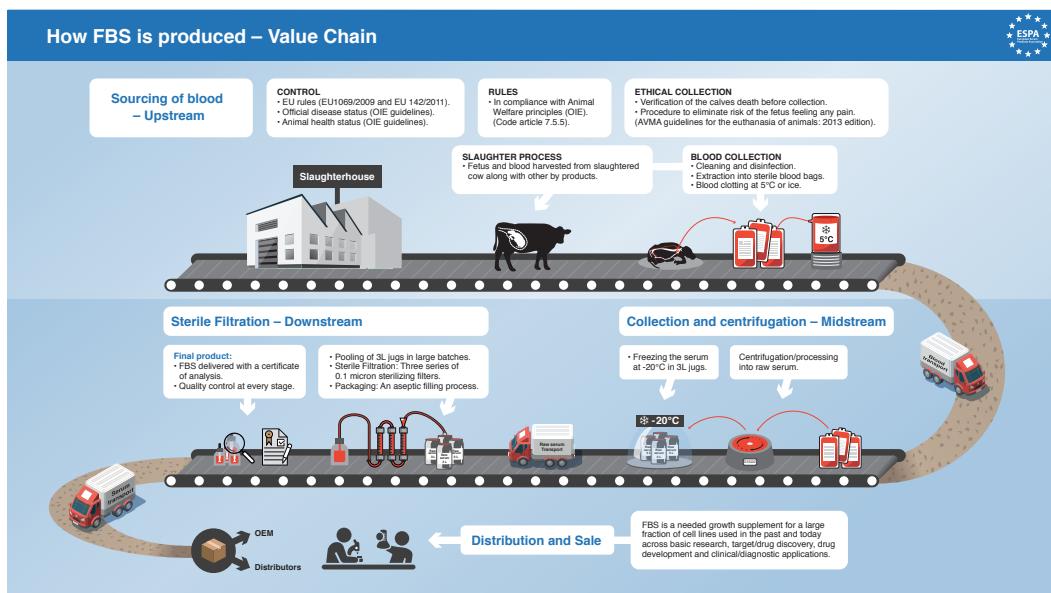
## Serum

Serum is a needed growth supplement for a large percentage of cells used for the production of therapeutics basic research, target/drug discovery, drug development, and clinical/diagnostic applications.

Serum provides nearly all of the components required for both adherent and suspension cell cultures, most of which are not yet chemically defined, such as growth factors, attachment factors, carrier proteins, lipids and hormones.

## FBS

FBS is the most widely used supplement for *in vitro* mammalian cell culture, and contributes to almost all parts of the life science industry. It is commonly used in the production of vaccines.



## How does the world benefit from serum ?

The number of serum dependent cell culture applications is increasing rapidly :

- Human vaccines
- Animal and pet vaccines
- Cancer research
- HIV treatments
- Production of life saving orphan drugs
- Treatment of burned people
- Virus diagnosis
- Treatment of leukemia

New developments require the use of FBS based cell culture in the areas of :

- Diabetes
- Cardiac diseases
- Neurodegenerative disease
- Musculoskeletal diseases
- Regenerative medicine

# Products



## FBS South America

Cat N°	Unit/Size	Storage	Shelf Life
S1810 - 100	100 ml		
S1810 - 500	500 ml		

## FBS EU ORIGIN

		Storage	Shelf Life
S1400 - 100	100 ml		
S1400 - 500	500 ml		

## FBS USA

		Storage	Shelf Life
S1520 - 100	100 ml		
S1520 - 500	500 ml		

## FBS CENTRAL AMERICA \*

		Storage	Shelf Life
S1600 - 100	100 ml		
S1600 - 500	500 ml		

## FBS URUGUAY \*\*

		Storage	Shelf Life
S1580 - 100	100 ml		
S1580 - 500	500 ml		

## FBS SOUTH AFRICA ORIGIN

		Storage	Shelf Life
S1300 - 100	100 ml		
S1300 - 500	500 ml		

\* Sourced from USDA approved countries and available for the USA from our Florida facility

\*\* Eligible for China from our facility in Uruguay

## OTHER ANIMAL SERA

Biowest has the widest range of animal sera

Bovine Sera are defined as the liquid fraction of clotted blood derived from healthy animals, deemed fit for human consumption by ante-and/or post-mortem inspection. It is collected in abattoirs inspected by the competent authority of the country of collection. There are no deletions nor additions (including preservatives) allowed.

### Bovine Serum

Slaughtered cattle 12 months of age or older.

### Calf Serum

Slaughtered bovine calves, aged from 20 days up to 12 months.

### Adult Bovine Serum (France Origin)

Cat N°	Unit/Size			
S0250 - 100	100 ml			
S0250 - 500	500 ml			

### Calf Serum

S0400 - 500	500 ml			
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### Horse Serum

S0910 - 500	500 ml			
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### Donor Horse Serum

S0900 - 100	100 ml			
S0900 - 500	500 ml			

### Dog (Canine) Serum

S2900 - 050	50 ml			
S2900 - 100	100 ml			

### Pig Serum

S2400 - 500	500 ml			
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### Rabbit Serum

S2500 - 500	500 ml			
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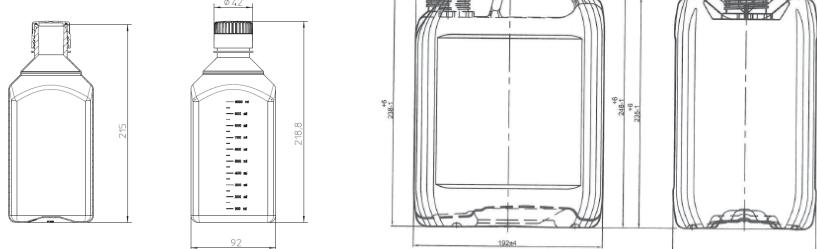
## I Other species available on request.

## I Choose the format of your packaging for convenience

PRODUCTS	FORMAT
SERUM	- 1L - 5L
FBS	- 500ml recommended, 1L available

## I Features & Benefits :

- Optimized and gain space
- Less manipulation
- Packaging for convenience
- More efficiency = less time
- Less packaging material



# FILTRATION

## ■ Filtration options according to your specification :

- 0.45 µm filtered clarification
- 0.22 µm sterile filtered
- Triple 0.1 µm only for FBS

# DOCUMENTATION

Each product is delivered with different documentations: Certificate of Analysis, Health Certificate, EDQM Certificate, Certificate of Origin.

 <b>CERTIFICATE OF ANALYSIS</b> <b>Fetal Bovine Serum (South America), Tetracycline free - 500ml</b>		Certificat Vétérinaire Sanitaire / Veterinary Sanitary Health Certificate n°  Certificat Vétérinaire Sanitaire pour l'exportation de sérum Veterinary/Sanitary Health Certificate for export of serum																																																																																																
Batch N° S00H8 ID N° S00H810101 Material N° S181T-500 Validation date 04-FEB-2021 Expiry date 03-FEB-2026		A) Description du chargement Exporter à : BIOWEST SAS Rue de la Caille 49340 NUAILLE - France Tél. N° / Tel No : 00 33 241 46 42 42 Agrément sanitaire n° N° d'agrément vétérinaire : FR-49 231 001																																																																																																
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**Certificate of suitability**  
**No. R1-CEP 2007-074-Rev 02**

1 **Name of the substance:**  
**FOETAL BOVINE SERUM**

3 **Name of holder:**  
**BIO WEST SAS**  
 4 Rue De La Caille  
 5 France-49340 Nuillé

7 **Site(s) of production:**  
**BIO WEST SAS**  
 8 Rue De La Caille  
 9 France-49340 Nuillé

11 **BIO NUTRIENTES DO BRASIL LTDA**  
 12 Av Etiópia  
 13 437 - Vila Morelato  
 14 Brazil-06408-030 Barueri, São Paulo

15 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
 16 **R1-CEP 2007-074-REV 01**

17 After examination of the information provided on the origin of raw material(s) and type of tissue(s)  
 18 used and on the manufacturing process for this substance on the site(s) of production mentioned  
 19 above, we certify that the substance **FOETAL BOVINE SERUM** meets the criteria described in  
 20 the current version of the monograph Products with risk of transmitting agents of animal  
 21 spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including  
 22 supplements.

23 – Country(ies) of origin of source materials:  
 24 Brazil, Chile, Colombia, Costa Rica, Denmark, France, Ireland, Mexico, The Netherlands,  
 25 Panama, Paraguay, Spain, United States of America and Uruguay

26 – Nature of animal tissues used in manufacture:  
 27 Foetal bovine blood

28 The submitted dossier must be updated after any significant change that may alter the quality,  
 29 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform  
 30 encephalopathy agents.

Address: 7 Allée Kastner, CS 39026  
 F-67081 Strasbourg (France)  
 Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu  
 Internet: <http://www.edqm.eu>

## EDQM Certificate

### CERTIFICAT D'ORIGINE / CERTIFICATE OF ORIGIN

**N° 80010874-10**

#### **I. Identification de la marchandise / Identification of products**

Description des produits / Products description:

**Sérum de Veau Fetal (Origine Amérique du Sud), Testé Tétracycline Négatif - 500ml**

Origine des matières premières / Origin of the raw materials:

**Argentina**

Nombre d'unités d'emballage / Quantity of packaging units:

**3 BOT**

Référence du lot / Batch number:

**500HB**

#### **II. Provenance de la marchandise / Origin of products**

Agrément des établissements enregistrés par les autorités vétérinaires responsables/ Agreement of registered establishments which have been controlled by the veterinary authority: FR-49-231-001

#### **III. Destination de la marchandise / Destination of products**

Les produits sont expédiés à / The products have been sent to:

#### **IV. Attestation / Attestation**

1. Ces produits ne proviennent pas / The products don't come from:
  - a) De cadavres d'animaux, y compris les animaux mort-nés / animals which have died in farms, including deadborn animals;
  - b) D'animaux qui ont été mis à mort afin d'éradiquer des maladies épidotiques / animals which have been killed to eradicate epizootic diseases;
  - c) D'animaux qui présentent, lors de l'inspection au moment de l'abattage, des signes ou des lésions de maladies contagieuses / animals showing any clinical signs and/or lesions of contagious disease.
2. L'origine des produits a été approuvée par les autorités européennes / The origin of the products has been approved by the european authorities.
3. Ces produits ont été manipulés de façon à éviter toute contamination / The products have been handled to prevent contamination.
4. Ces produits sont destinés exclusivement à un usage scientifique (Ces produits ne sont pas destinés à un usage pharmaceutique, humain ou vétérinaire) / The products are intended only for scientific purposes (Not for drug, human or veterinary use).

Délivré par / Issued by:

The Quality Department

27-mai-2021 / 15:44:21



## QUALITY CONTROL

Our high standard operating procedures ensures that a sterility assurance level of  $10^{-4}$  is met on all our batches of serum.

The filtration and dispensing are performed under positive pressure in HEPA-filtered environmentally controlled rooms.

Despite rigorous standard operation procedures slight batch-to-batch variations may occur. At Biowest, we allow you to test each batch for its suitability and performance in each of your applications.

The European Agency for Medicinal Products (EMA) and the Code of Federal Regulation (CFR) has issued a directive that apply to the use of bovine serum in the production veterinary vaccines. Biowest can provide you the EMEA/CVMP/743/00 or 9CFR compliant quality control if needed.

EMEA-CVMP-743-00-Rev.2 – Veterinary	
	Explanation
1. <a href="#">EP2262 Sterility (Bacteria and Fungi)</a>	Sterility test by membrane filtration "STERITEST" over 14 days in line with EP (§ 2.6.1) and US (USP 71).
2. <a href="#">EP2262 Mycoplasma</a>	Cultivation in cell cultures for at least 21 days with 3-5 subcultures in 2 cell lines (duplicates each) - MDBK (bovine kidney cells) + Vero (African green monkey) with final immunofluorescence for the detection of pestiviruses (incl. BVDV-1, BVDV-2, BVDV-3, BDV)
3. <a href="#">Virus culture in cell culture (adapted to 9 CFR / EMA) (abbreviation VI)</a>	Cultivation of test virus on cells maintained with test FBS for at least 3 passages followed by comparative titration of the test virus with standard batch (evaluation with immunofluorescence)
4. <a href="#">Serum inhibition test (adapted to 9 CFR / EMA) (abbreviation Sixx)</a>	Incubation of 3 cell lines (L cells, Vero or Hela, MRC-5) with test medium (culture medium with 10% test FBS) over three passages with assessment of cell morphology and cell density as well as determination of the cell number compared to standard approach.
5. <a href="#">cell culture test (abbreviation ZK)</a>	Detection of neutralizing antibodies (nAk) against viruses using the serum neutralization test
6. <a href="#">Serum neutralization tests</a> S301/302 nAk gegen BVDV-1 und BVDV-2 S01 nAk gegen BHV-1 S05 nAk gegen Pi-3	Detection of rabies virus antigen in cells after 21 days of culture (3-5 subcultures in Vero cells)
7. <a href="#">Antigen detection of rabies virus (adapted to 9 CFR) (abbreviation IF)</a>	Hemadsorption on culture cells after cultivation with test FBS (21 days)
8. <a href="#">Hemadsorption (adapted to 9CFR)</a>	Detection of viral nucleic acids by PCR in FBS / in culture cells after culture
9. <a href="#">Nucleic Acid Detection (PCR)</a> P05 Bovine Herpes viruses 1/5 P06 Bovine respiratory Syncytial virus P20 Parainfluenzavirus-3 P52 Reovirusses (pan) P75 Bluetongue Virus (pan) P80 Adenovirus (pan) P81 Bovine Parvovirus 1 P82 Bovine Parvovirus 2 More testing on request available	
10. <a href="#">30 kGy Irradiation</a>	This document is a summary of most internationally available adventitious agents inactivation studies by using gamma irradiation. These data have been the basis for EMA to go for a minimum irradiation dose of 30 kGy. End-users believe, by misinterpretation / misunderstanding, that each supplier has to redo such inactivation study. This is incorrect.
<b>Supporting Documents</b>	
1. <a href="#">Gamma Irradiation of Animal Serum: Validation of Efficacy for Pathogen Reduction and Assessment of Impacts on Serum Performance</a> By Mark Plavsic, Raymond Nims, Marc Wintgens, and Rosemary Versteegen Summer 2016 BioProcessing Journal [Vol.15/No.2]	On the other hand, suppliers need to validate the dosimetry. This means that the supplier needs to validate that in all parts of the irradiation carrier, a minimum irradiation dose of 30 kGy is reached. This validation needs to be carried out with each of the irradiation suppliers and needs to be done for each type of packaging, for each configuration of the positioning of the packaging in the irradiation carrier. Such dosimetry needs to be repeated after each change to the cobalt source.
2. <a href="#">Gamma Irradiation of Frozen Animal Serum: Dose Mapping for Irradiation Process Validation</a> By Bart Croonenborghs, Andy Pratt, Lorraine Bone, and Mara Senescu Fall 2016 BioProcessing Journal [Vol.15/No.3]	This validation file from Ionisos shows evidence that the treatment, as described, results in a minimum dose of 30 kGy, all over the irradiation carrier.
3. <a href="#">Latest Dose Mapping Summary for given packaging for requested minimum dose of 30 kGy</a>	This Certificate of Irradiation (CoI) guarantees the minimum dose of 30 kGy for the treated bottles of a specific serum batch. It also states the maximum dose attained.
4. <a href="#">Batch specific 30 kGy Certificate of Irradiation from Ionisos</a>	

## REGULATORY

Biowest guarantees compliance with the ethics code established by the serum industry along with all regulatory obligations. By rigorously controlling its sourcing and processes as well as using state-of-the-art IT software, Biowest guarantees the accuracy on the Certificate.

Biowest is also fully certified by the International Serum Industry Serum Association (ISIA) Traceability Audit Process. This certification verifies that Biowest sera are manufactured under the highest traceability standards.

### Biowest is member of ESPA :

ESPA Members share the goal of providing adequate access for life-saving life science researchers and biotech companies, to top quality products at stable prices, through a free and open market for animal sera, based on harmonized regulations for the trade and use of serum.

### It is ESPA's position that:

- "Serum is serum" and "Serum saves lives", wherever it is collected, as long as QA and regulatory rules are strictly adhered to.
- Promotional information and product descriptions must be based on accurate and relevant scientific information, avoiding misleading claims, e.g. relating to BSE



**SERUM SAVES LIVES**

### I More information on :

- ISIA : [www.serumindustry.org](http://www.serumindustry.org)
- ESPA : [www.serumproducts.eu/index.php/news-and-events](http://www.serumproducts.eu/index.php/news-and-events)

## TREATMENTS

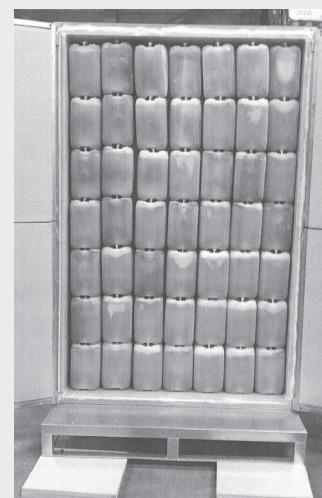
Biowest offers a variety of treatments for your applications.

TREATMENTS	DESCRIPTION/GUIDELINES
<b>Gamma Irradiation</b>	<ul style="list-style-type: none"> <li>- Inactivation of viruses</li> <li>- Maintain growth promotion potential</li> <li>- Minimizes risk associated with use of animal product</li> <li>- Protection against low levels of microbial contaminants</li> </ul>
<b>Heat inactivation</b>	<ul style="list-style-type: none"> <li>- Destruction of «complement»</li> <li>- Avoid interference with some experiments</li> <li>- Inactivation of viruses</li> </ul>
<b>Iron supplementation</b>	<ul style="list-style-type: none"> <li>- Addition of 1% sterile Ferric citrate to serum at 0.216% (v/v)</li> <li>- Transferrin is normally 20 to 40% saturated iron</li> </ul>
<b>Lyophilisation</b>	<ul style="list-style-type: none"> <li>- Storage at +4°C</li> <li>- Facilitates the preparation of gamma irradiated cell culture media treated</li> <li>- No freezing / thawing process required</li> </ul>

## GAMMA IRRADIATION

Our highly configurable Gamma Irradiation will surely match your needs.

Irradiation dose : according to your specifications



## OTHER CELL CULTURE PRODUCTS

Biowest offers a large range of culture cell media, buffers, antibiotics and reagents, as well as custom-made formulations for specific applications, using its outstanding knowledge of cell culture products. Biowest offers highest quality and premium service, ability to address special requirements and full traceability and security enabled by vertical integration.

**Cell Culture Media:** A wide range of Biowest Cell Culture Media formulations, manufactured according to original publications, standards set by the Tissue Culture Association. Some vary from set standards by substituting hydrated, chlorinated and/or the salt forms of certain compounds to deliver improved solubility and product performance.

MEDIA FORMAT
- 5KG
- 10KG
- 20KG
- 25KG

**Salt Solutions:** Biowest balanced salt solutions are sterile physiological balanced solutions intended to safeguard mammalian cells. They are used for preparation of organ parts and during dissociation of cells. The range includes DPBS, HBSS.

### Dulbecco's Phosphate Buffered Saline w/o Calcium w/o Magnesium

P0750 - N1L  
P0750 - N10L

For 1L  
For 10L



Room temp.

48 m

### HBSS w/o Calcium w/o Magnesium w/o Sodium Bicarbonate w/o Phenol Red

P0153 - N1L  
P0153 - N10L

For 1L  
For 10L



Room temp.

48 m

### HBSS w/ Calcium w/ Magnesium w/o Sodium Bicarbonate w/ Phenol Red

P0154 - N1L  
P0154 - N10L

For 1L  
For 10L



Room temp.

48 m

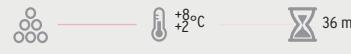
### Covid-19:

With the current Covid-19 pandemic, the demand for cell culture media has increased dramatically, leading to supply chain deficiencies. In order to guarantee your agility and responsiveness, we are in constant contact with the actors of our supply chain. Don't hesitate to contact us.

**Antibiotics :** Biowest manufactures and supplies a full range of antibiotics used in cell culture to avoid the growth of micro-organisms.

Penicillin G Sodium Salt - 1 Million Units

P0018 - 1MU 1 Million units



G-418 Sulfate

P0017 - 10GR 10 g



Gentamicin Sulfate

P4020 - 1GR 1 g  
P4020 - 5GR 5 g



Amphotericin B

P4030 - 250MG 250 mg



Nanomycopulitine Concentrat 20 x

L - X16 - 010 10 ml  
L - X16 - 100 100 ml



**Cell Culture Reagents**

Trypsin - EDTA 1X Lyophilised w/ Sodium Chloride

P0940 - 100GR 100 g



Trypsin 1:250 powder (porcine)

P5957 - 100GR 100 g



Trypsin-EDTA 1X in solution w/o Calcium w/o Magnesium  
w/ Phenol Red

L0930 - 100 100 ml  
L0930 - 500 500 ml



MEM Vitamins 100X w/o L-Glutamine

X0556 - 100 100 ml



MEM non Essential Amino Acids 100X w/o L-Glutamine

X0557 - 100 100 ml



L-Glutamine

P1012 - 100GR 100 g  
P1012 - 1KG 1 kg



HEPES, cell culture tested

P5455 - 100GR 100 g  
P5455 - 500GR 500 g  
P5455 - 1 KG 1kg



