



## Technical data sheet Serum

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### Human Serum HIV tested

CAT N°: S4200

#### Collected from the source:

When searchers choose their serum, an important factor that should be taken into consideration is the source, which also emphasises the traceability of the serum.

Our system of vertical integration allows us to be certain of the origins and traceability of our human serum. The donors are volunteers.

Each manufactured batch is rigorously controlled, from the collection of serum in authorised organisms, and throughout all stages of its treatment and production through to final packaging on the authorised organisms and on our premises.

The serum is sourced from multiple blood types and multiple genders.

The serum is off-the-clot serum, processed from human blood that has had natural coagulation.

The serum is collected or imported and treated in agreement with the European regulations.

#### Country of Origin:

The country in which the blood was taken from the donor.

BioWest sera are sourced from Germany, Poland, United Kingdom, Lithuania, USA or France.

#### Storage conditions:

- 18°C to - 40°C, protected from light.

Bottles can be stored between -40°C and -80°C for a short period (few days).

#### Shelf life:

5 years.

#### Filtration:

Final Filter Size: 0.2µm x 2

#### pH:

pH specification: 8,0 ± 1,0

#### Osmolality:

Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions.

Osmolality specification: 300 ± 40 mOsm/kg

#### Endotoxin:

All sera are tested to determine the levels of endotoxins. BioWest carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia.

The endotoxin reagent is standardized against the US reference endotoxin.

Endotoxin specification: Not applicable

#### Haemoglobin:

The haemoglobin level is measured by spectrophotometer.

Haemoglobin specification: As low as possible

#### Cell Culture:

Biological performance is assessed using cell culture medium supplemented with the serum being tested.

During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum.

#### Cell Culture Tests:

Cell Growth



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### Cell Lines Tested :

HELA - Cancer Cell/Human  
MRC-5 - Human/Lung

### Total Protein:

Determined by Biuret Colorimetry.  
Total Protein specification: Not applicable

### Sterility tests:

All sera are tested for the absence of aerobic and anaerobic bacteria, fungi and yeast.  
The sera are tested for the absence of *Mycoplasma pneumoniae* by chimiluminescence.

### Virus test:

All of our human serum is tested negative or non-reactive for:

- Hepatitis B antigen (HBs Ag)
- Hepatitis C virus and antibodies (HCV)
- HIV Type 1 virus and antibodies HIV ½
- Syphilis

### Other tests:

#### Albumin:

Determined by Immunoturbidimetry.  
Albumin specification: Not applicable

### Alpha-globulins, Beta-globulins and Gamma-globulins:

Determined by Immunoturbidimetry.  
Globulins specification: Not applicable

### Treatments:

Not applicable

### Recommended use:

- Respect storage conditions of the serum
- Do not use the serum after its expiry date
- Store serum in an area protected from light
- Manipulate serum in aseptic conditions (e.g.: under laminar air flow)
- Wear clothes adapted to the manipulation of serum to avoid contamination (e.g.: gloves, mask, hygiene cap, overall...)
- In order to preserve all serum qualities, it is recommended to thaw out the flask, to aliquote, then to re-freeze the produced flasks rather than to thaw out and re-freeze the flask at each use.
- It is recommended to use the serum immediately after its thaw out. However, if it is not useful, it is possible to store thaw out serum, at +2°C / +8°C, until 26 weeks without significant decrease of its performances in cell culture.

The product is intended to be used in vitro for scientific purposes only and not for drug, human or veterinary use.

### Remarks:

Not applicable