

TECHNICAL DATASHEET

- General informations

Product : Plasma Substrate R1

Code n° : 10.PS1 (10 mL vial);

Batch sizes : from 200 to 5000 mL

Filling sizes : 10 mL vial

Origin : Italy, from adult and healthy sheep

Shelf life : 2 years from date of production if the product is stored at

proper temperature and without any cycle of freeze and thaw

Storage Temperature $: -10 \, ^{\circ}\text{C}$ to $-20 \, ^{\circ}\text{C}$

Use: Heparin Assay. Not for human or animal consumption.

The product is manufactured by following the European Pharmacopea

Stability and storage: The product must be stored in a temperature range within -10 °C and -20 °C. If stored at this temperature range the serum is stable for two years from the date of production. It is recommended to not make more than one cycle of freeze and thaw, but to make various aliquots.

Turbid material or flocculation can be observed if the product is thawed or stored for a long time at cold temperatures, this is common concerning serum, and it is not detriment of its functionality.

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- Biological specifications

Assay		
Test	Specifications	Results
pH (pHmeter)	7,0 – 9,0	
Coaugulation time (s)	S (report value in sec)	
Blank coagulation time (s)	< 60 s	
Coagulation time for 1 EU heparin/mL	S (report value in sec)	