



**SYNBIOS® HUMAN SERUM
ALBUMIN (HSA)**

For ART laboratory use

COMPOSITION

SYNBIOS® Human Serum Albumin contains 100 mg/mL made up in normal saline.

MATERIAL INCLUDED

**HA1000 Human Serum Albumin (HSA)
5ml**

Product use:

This preparation of Human Serum Albumin is intended for use in therapeutic assisted reproduction technology

PRODUCT SPECIFICATIONS

- pH (7.4 ± 0.2)
- Osmolality (mOsm/kg): 280-290mOsmols
- Sterility: Sterile (SAL 10-3)
- Endotoxins: < 0.25 EU/ml
- MEA (blastocysts >120h) ≥ 80%
- Use of Ph Eur or USP grade products if applicable
- Certificate of analysis and MSDS are available upon request

STORAGE INSTRUCTIONS

Product must be stored in original package between 2-8°C. It must not be aliquoted into smaller containers for storage. Once removed from container, discard excess water. Do not freeze. Aseptic technique is adhered to at all times during handling. Do not use after expiry date. Expiry 6 months from date of manufacture.

WARNINGS AND PRECAUTIONS

This product must be used only by ART Laboratory, Medical and Nursing personnel competent in Clinical Human Assisted Reproduction Technology Treatment (ART). All human and organic material is potentially infectious if it contains HSA. All specimens must be handled as capable of transmitting harmful viral or prion diseases or hitherto unknown pathogenic agents. Wear protective garments. Strict aseptic techniques must be employed to avoid contamination. Medium may contain antibiotic Gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

The HSA is extracted from donor human blood consequently is potentially a hazardous material. Every individual donor for preparing the HSA has been confirmed non-reactive nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by methods approved by regulatory authorities. The donors have also screened negative for the CreutzfeldtJakob disease (CJD).

IMPORTANT: It is not possible to sterilize HSA with 100% certainty (Truyen et al., 1995) thus HSA must be treated as potentially infectious. In spite of exhaustive screening this product may still carry a remote risk of viral load of potentially hazardous viruses. In addition there also be a theoretical risk of CJD transmission. There has been no report of viral or prion disease transmission in ART to date from plasma protein fraction.

Do not use this product if:

- The medium appears cloudy or shows signs of microbial contamination.
- The product has expired.
- The seal of product is broken.
- The container is damaged.
- Cold chain has been broken during transport and handling.

DISCLAIMER:

Every effort has been taken to ensure quality of the product. We have no control over the products during transport. Shippers are aware of the cold-chain protocol. Nevertheless product could be damaged for any reason during transport (e.g. inspection by Border Security). End users must ensure products received are in good condition by internal QC/QA prior to use.

Good Laboratory Practices

ART Lab personnel are urged to adhere to Good Laboratory Practices (GLP) for optimizing the treatment outcome. Dishes must not be out of incubator for more than 3 mins at any one time.

Note: This product is classified as a medical device. US Federal Law restricts its sale by or on order of a physician (Rx only).

Custom-produced under GMP quality standards
For ANDROCRYOGENICS, Malaysia

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**SYNBIOS[®] HUMAN SERUM
ALBUMIN**

**20 Years of Research
Ensures Optimal Performance**

SYNBIOS[®] MEDIA
Safety. Performance. Innovation

GMP-Manufactured

**HA10005 Human Serum Albumin 5mL
(100mg/mL)**

SYNBIOS[®] Human Serum Albumin is
filter sterilized