

SYNBIOS® MEDIA

Safety. Performance. Innovation

SYNBIOS®SPERM ACTIVATION MEDIUM

For the activation of immotile sperm (esp. in asthenozoospermia, testicular, frozen-thawed, etc) that will enable selection of viable sperm for ICSI

COMPOSITION

Media are SYNBIOS®
1,3-Dimethylxanthine (Theophylline), Cysteine, Adenosine in SYNBIOS Hepes buffered Gamete Medium.

MATERIAL INCLUDED

SA10005	Sperm activation med+HSA	5ml
SA10010	Sperm activation med+HSA	10ml
SA10005.SYN	Sperm activat.med w/out HSA	5ml
SA10010.SYN	Sperm activat med w/out HSA	10ml

Two types are available. Product with HSA and without (synthetic)

MATERIAL NOT INCLUDED WITH THE KIT

- Dishes ICSI & embryo culture sterile, non-toxic;
- Embryo handling pipets
- Laminar flow hood
- Zoom stereo microscope
- Laminar flow hood
- Lab timer
- Hand-held micro heat sealer
- SYNBIOS Embryo culture, Flush and Gamete handling media

SYNBIOS®ASSISTED OOCYTE ACTIVATION kit is compatible for use with SYNBIOS vitrification cooling and warming kits, SYNBIOS Hypoosmotic, Culture, Gamete and Flushing media to select viable sperm, culture, wash oocytes and embryos and for the cryopreservation of embryos.

PRODUCT SPECIFICATIONS

- Chemical composition
- pH: 7.20 – 7.40
- Osmolality (mOsm/kg):Pre-incubation med: 270-290
- Sterility: Sterile (SAL 10-3)
- Endotoxins: < 0.25 EU/ml
- Sperm survival assay ≥ 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 medium. Do not freeze. Aseptic technique is adhered to at all times during handling and it is stored at 2-8°C. Do not use after expiry date. Expiry 6 months from date of manufacture. *Low temperature storage conditions may cause precipitation but will dissolve at room temperature.*

INSTRUCTIONS FOR USE

Read instructions carefully, prepare the necessary dishes and keep handy all required utility items before commencing.

- 1.Oocytes were stripped of its cumulus and corona cells using hyaluronidase or Disperse (SYNBIOS® Media) as per standard methods at 4 hours after oocyte retrieval.
- 2.Incubate denuded oocytes at 37°C in a 6% CO₂ air atmosphere in equilibrated SYNBIOS® embryo culture medium.
- 3.Metaphase II oocytes were selected for ICSI at 5-6 hours after retrieval.
4. The ICSI dish was prepared as per standard methods containing SYNBIOS PVP and droplets of Hepes buffered SYNBIOS Gamete medium with the following additional item, namely a 5ul droplet of SYNBIOS Gamete medium containing 1:20 times dilution of Sperm activation medium (diluted Sperm activation medium). Keep dish warm at 37°C.
5. To perform dilution stated in (4) above add 50ul of Sperm activation medium to 950ul ml of SYNBIOS Gamete medium, mix and use it to make the droplet.
- 6.About 1ul of washed spermatozoa specimen is resuspended into the droplet containing the diluted Sperm activation medium previously prepared ICSI dish.
7. Incubate or keep the ICSI dish warm at 37°C for 10 minutes.
8. At 10 minutes examine the dish for motile sperm. Normally motility will commence very soon after addition of sperm to the sperm activation medium.
9. Select motile sperms and transfer to another droplet of Gamete medium using the injection needle
10. The selected motile sperms are washed thoroughly to remove all trace of the sperm activation medium. Sperm activation medium is toxic.
11. Selected sperm are individually picked up and taken to the PVP droplet and washed thoroughly at a marked spot within the PVP spread.

- 12.After thorough wash in PVP move the sperm to another part of the PVP spread that is not contaminated by the sperm activation medium.
13. The selected sperm is inflicted with a tail injury using the injection needle as per standard methods.
14. If no motile sperm are available, use the SYNBIOS® Hypoosmotic medium (SH10005plus HSA or SH10005.SYN without HSA) using protocol of the manufacturer to select live or viable sperms.
15. The selected sperm is drawn into an injection pipette.
16. Then move and position the injection pipet towards the oocyte for the ICSI procedure.
17. Inject the spermatozoa into the oocyte.
18. Transfer the injected oocyte into the previously equilibrated SYNBIOS® embryo culture medium and then return dish to the CO₂ incubator for overnight culture.
- 18.Next morning oocytes are examined for fertilization.
19. Oocytes with normal 2 pronuclei are separated for further culture until embryo transfer as per standard procedure.
- 20.Normal embryos obtained following sperm activation are examined and selected for embryo transfer and the remaining quality embryos are cryopreserved for the patient's later use.
21. End of instructions

WARNINGS AND PRECAUTIONS

This product must be used only by laboratory personnel competent in laboratory human Assisted Reproduction Technology (ART). All human and organic material is potentially infectious; including this product, 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. •The product must not be used if any of the media supplied is cloudy and also do not use the product if the seal has been removed or is defective.

IMPORTANT: It is not possible to sterilize HSA with 100% certainty (Truyen et al., 1995) thus HSA must be treated as potentially infectious. ART Lab personnel are urged to wear personnel protective apparel including goggles for their safety. Lab Personnel must adhere to Good Laboratory Practices (GLP) for optimizing outcome and to avoid mishaps.

CAUTION: All media exposed to the elements or above 8°C for >8 hours may be unfit for use for human ART treatment due to possible formation of toxic free radicals and products of putrefaction.

IMPORTANT: The biosafety of the active ingredients of the sperm activation medium namely Theophylline, Cysteine and Adenosine remains to be fully elucidated. This technique is still experimental. Workers are cautioned of possible adverse outcome as a direct consequence of this technique although no adverse outcome is known at this moment. Decision to use this technique/product have to considered carefully..

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.

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

Custom-manufactured for ANDROCRYOGENICS, Malaysia

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**SYNBIOS® SPERM
ACTIVATION MEDIUM**

**20 Years of Research
Ensures Optimal Performance**

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GMP-Manufactured

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SYNBIOS® SPERM ACTIVATION is sterilized by sterile filtration. Comes with and without HSA.