

SYNBIOS[®] SPERM MEDIUM

GENERAL INFORMATION ON USE

SYNBIOS[®] SPERM Medium is for sperm preparation and transport which do not require a carbon dioxide atmosphere. **There are two types; one comes supplemented with HSA which is a complete medium and is ready-to-use; while the other is a synthetic medium with surfactant macromolecules. It is a synthetic medium which is ready-to-use and can be used without HSA.**

MATERIALS SUPPLIED

50 mL SYNBIOS[®] SPERM Medium with Phenol Red, Gentamicin and HSA (Ref: SM10050) OR

50 mL SYNBIOS[®] SPERM Medium with Phenol Red surfactant macromolecules and Gentamicin but without HSA (Ref: SM10050.SYN)

MATERIALS REQUIRED BUT NOT SUPPLIED

Test tubes & culture dishes; Oocyte and embryo handling pipettes; Laminar flow/Biological hoods, Stereo & Inverted Microscopes; Incubators, and other ART Lab equipment. Others include: SYNBIOS[®] Mineral Oil; Gamete, Flush, PVP, and Hyaluronidase media for cIVF / ICSI.

SPECIFICATIONS AND QUALITY CONTROL

SYNBIOS[®] Sperm Handling Medium may or may not contain human serum albumin (HSA) as described in previous page. It contains carbohydrates, sugars, physiological salts, amino acids, vitamins, sodium pyruvate, sodium lactate, osmolytes such as EDTA, and sodium bicarbonate. All products contain extremely minute quantities of Gentamicin Sulfate in the order of 1.5mg per Liter, and/or Phenol Red for pH balance. Quality is assured through testing for sterility, pH, osmolality, endotoxin <0.05 EU/mL (USP, PH Eur.) and Mouse Embryo Assay. A Certificate of Analysis for each batch is available on request.

STORAGE AND CONSERVATION

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. **IMPORTANT:** It is not possible to sterilize HSA with 100% certainty (Truyen et al., 1995) thus HSA must be treated as potentially infectious. **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.

CAUTION

Sperm medium 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.

DISCLAIMER:

This product is manufactured in compliance with the GMP quality standards. Every effort has been taken to ensure quality of the product. We have no control over the products during transport. Shippers are aware of cold-chain protocol. Product could be damaged for any reason during transport. End users must ensure products received are in good condition by internal QC/QA procedures prior to use.

WARNINGS AND PRECAUTIONS

This product must be used only by 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.

INSTRUCTIONS FOR USE

1. The SYNBIOS[®] Sperm Medium need not be pre-equilibrated in 6% CO₂ prior to use.
2. The SYNBIOS[®] Sperm Medium can be used for (a) preparation of sperm for insemination (conventional IVF and ICSI; (b) during testicular spermatozoa aspiration; (c) short-term handling of oocytes in the absence of 6% CO₂; (d) short-term handling of embryos in the absence of 6% CO₂; (e) for IUI spermatozoa preparation if IUI medium is not available.
3. Perform the sperm preparation as per your standard operating procedures (SOP) using pre-warmed (37°C) SYNBIOS[®] Sperm Medium.
4. Briefly, the protocol for sperm preparation for the swim-up method (*Ali, 2014: Sperm preparation. In: Male Infertility. Sperm Diagnosis, Management and Delivery. Mehta J and Woodward B, Eds. JP Medical Ltd, UK, p.37-44*) is described in subsequent sections (from point 5 onwards) whereas the differential centrifugation method of sperm preparation is described elsewhere (Ali, 2014; or the product insert for SYNBIOS[®] Gradients Media).

5. Mix one part of liquefied semen and two parts of sperm medium gently in a centrifuge tube and centrifuge at 200g (Mahadevan et al., 1983) for 5mins (first wash). Some workers use higher g-force. However bear in mind centrifugation beyond 800g (Jeulin et al., 1982) will damage the spermatozoa.

6. **IMPORTANT:** *Some workers may not be familiar with g-force calculation. Such workers normally use centrifugation speeds of 1500 to 2000rpm instead of g-force for sperm preparation which also appear to work well. While g-force is the recommended unit for centrifugation, however rpm can also be used instead.*

7. Pipet out supernatant into another labelled tube leaving 0.3 ml of the medium and pellet.

8. Re-suspend the pellet in the remaining 0.3 ml of medium. Then add more Sperm Medium (1.5 ml), and then mix the pellet gently with the medium.

9. Re-centrifuge the sample (second wash) as described earlier.

10. If the sperm preparation is for IUI two washes are mandatory.

11. Layer the re-suspended pellet gently in a 4-well NUNC dish with extreme care under 1 ml of SYNBIOS® Embryo Culture Medium.

12. Incubate the sample for a period of 45 minutes in carbon dioxide incubator at a humidified atmosphere of 6%CO₂ at 37°C.

13. Do not incubate beyond 45 minutes.

14. Record the results in the patient's sperm preparation form.

15. Store the harvested specimen in an atmosphere of 6% CO₂ at room temperature until insemination.

16. With this the sperm preparation protocol is completed.

17. Please note sometimes the best spermatozoa may be found in the supernatant. Therefore do not discard the supernatant until the insemination procedure is performed/ completed.

18. The spermatozoa in the supernatant can be retrieved if necessary by centrifugation at 350 to 400g for 5mins if volume is ≤5ml and for 10mins if volume is 6 to 10ml.

19. Examine the harvest for density and motility characteristics using an appropriate sperm counting chamber (eg: Makler, Horwell, or Neubeur chamber manually) or automated computerised sperm analysis technique.

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

www.synbiosmedia.com

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SYNBIOS® SPERM MEDIUM

20 Years of Research
Ensures Optimal Performance

SYNBIOS® MEDIA
Safety. Performance. Innovation

GMP Manufactured

Sperm medium formulation for handling and preparation of sperm

Ref: 50 mL SM10050
Ref: 50 mL SM10050.SYN

SYNBIOS® SPERM MEDIUM is sterilized by sterile filtration and comes with HSA (Ref: SM10050) or with surfactant macromolecules but without HSA (Ref: SM10050.SYN). Both are ready-to-use