

SYNBIOS[®] GAMETE MEDIUM

GENERAL INFORMATION ON USE

SYNBIOS[®] GAMETE Medium is for gamete handling, preparation and transport which do not require a carbon dioxide atmosphere. **There are two types; one with HSA which is a complete medium that is ready-to-use; while the other is the synthetic medium with surfactant macromolecules. It is also ready-to-use.**

MATERIALS SUPPLIED

50 mL SYNBIOS[®] GAMETE Medium with Phenol Red, Gentamicin and HSA (Ref: GM10050) OR
50 mL SYNBIOS[®] GAMETE Medium with Phenol Red, surfactant macromolecules and Gentamicin but without HSA (Ref: GM10050.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; Flush, PVP, and Hyaluronidase media for cIVF / ICSI.

SPECIFICATIONS AND QUALITY CONTROL

SYNBIOS[®] Gamete Handling Medium may or may not contain human serum albumin (HSA) as described in the previous page. It contains carbohydrates, sugars, physiological salts, amino acids, vitamins, sodium pyruvate, sodium lactate, osmolytes such 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

Gamete 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[®] Gamete Medium need not be pre-equilibrated in 6% CO₂ prior to use.
2. The SYNBIOS[®] Gamete Medium can be used for (a) preparation of handling oocytes during oocyte aspiration; (b) during testicular spermatozoa aspiration; (c) short-term handling of oocytes stripped of the corona-cumulus complex in the absence of 6% CO₂ during the ICSI; (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 oocyte isolation and denuding as per your standard operating procedures (SOP) using SYNBIOS[®] Gamete Medium.

Oocyte Identification and Isolation

4. Briefly, the protocol for oocyte identification and isolation are as follows:
5. Put off the lab fluorescent lights. Put on the warm lights. Reduce intensity of warm light using a light dimmer. Lower the intensity of air flow in the laminar flow hood.
6. Take out the pre-warmed oocyte collection 4-well dish containing SYNBIOS[®] Gamete medium (0.8ml/well; 2ml in reservoir) from the incubator and place it on the laminar flow hood bench held at 37°C.

7. This step must be witnessed by one other IVF lab personnel to prevent mix-up.
8. Another 4-well oocyte dish containing pre-equilibrated SYNBIOS® Culture Medium (0.8ml/well; 2ml in reservoir) (EM10050) is kept close at hand under a gaseous phase of 10% CO₂ in air using a small glass bell jar attached to the gas source.
9. Fit a sterile non-embryo-toxic Pasteur pipette to a pipette-pump.
10. Rinse the Pasteur pipette 7 times in SYNBIOS® Gamete culture medium held in a tube prior to use.
11. Examine the aspirate under zoom stereo microscope.
12. Pick up the oocyte with the Pasteur pipette.
13. Wash it three times in SYNBIOS® Gamete culture medium or until all traces of blood has been washed off.
14. Washed oocytes are transferred to the SYNBIOS® Culture Medium held at 37°C under an atmosphere of 6%CO₂ in labelled 4-well dishes.
15. Record in the patient's IVF Laboratory Record form the quality of the oocyte.
16. Place immature eggs in well 3 and, post-mature and atretic eggs in well 4 (SYNBIOS® Culture Medium).
17. Place the egg dish in the incubator in an atmosphere of 6% CO₂ triple gas or in air until insemination.
18. With this step oocyte identification and isolation is completed.

Oocyte Handling During ICSI

19. Oocytes stripped/denuded of the corona-cumulus complex are held in SYNBIOS® Culture Medium until ICSI.
20. When ready to perform ICSI place 4 to 6 denuded oocytes, one per droplet of SYNBIOS® Gamete Medium under SYNBIOS® Mineral Oil in a previously prepared and warmed (37°C) ICSI dish.
21. Rinse and wash both injection and holding pipettes with Gamete Medium.
22. Equilibrate injection pipette with SYNBIOS® PVP Medium held in a 5ul droplet in the ICSI dish under Mineral Oil.
23. Proceed to immobilize a spermatozoon and inject it into the oocyte held in gamete medium.
24. Likewise inject all remaining eggs.
25. The injected eggs are washed 3-times in micro-drops of pre-equilibrated SYNBIOS® Culture Medium under mineral oil held in a culture dish.
26. The washed injected oocytes are cultured as per standard operating procedures (SOP).
27. The ICSI procedure is completed.

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 except during ICSI.

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® GAMETE MEDIUM

20 Years of Research
Ensures Optimal Performance

SYNBIOS® MEDIA
Safety. Performance. Innovation

GMP-Manufactured

Gamete medium formulation for handling oocytes and the preparation of sperm

Ref: 50 mL GM10050

Ref: 50 mL GM10050.SYN

SYNBIOS® GAMETE MEDIUM is sterilized by sterile filtration and comes with HSA (Ref: GM10050) or with surfactant macromolecules without HSA (Ref: GM10050.SYN).