

SYNBIOS[®] MEDIA

Safety. Performance. Innovation

SYNBIOS[®] IUI MEDIUM

GENERAL INFORMATION ON USE

SYNBIOS[®] IUI Medium is for preparing sperm intrauterine insemination. It can also be used for 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 a synthetic medium with surfactant macromolecules. It is also ready to use.**

MATERIALS SUPPLIED

50 mL SYNBIOS[®] IUI Medium with Phenol Red, Gentamicin and HSA (Ref: UM10050) OR

50 mL SYNBIOS[®] IUI Medium with Phenol Red and Gentamicin but without HSA (Ref: UM10050.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[®] HSA Solution is needed for [UM10050.SYN IUI medium](#)

SPECIFICATIONS AND QUALITY CONTROL

SYNBIOS[®] IUI 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 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

IUI 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 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.

IUI SAFETY PRECAUTION

IUI is not a simple routine procedure as it is thought to be. There are potentially serious risks involved such as fatal anaphylactic shock or debilitating infections. These side-effects are very rare nevertheless workers must bear in mind of the potential for the same. These side-effects are not entirely due to the medium used but also depend on the quality of the work procedures. All categories of ART workers must be aware of the risks and are advised to look out for signs of anaphylactic shock in patients immediately after IUI. Patients must be counselled on possible delayed anaphylactic shock or infections. There are at least two deaths reported (but this was not with the SYNBIOS[®] IUI Medium). Negative outcomes are seldom reported. These two deaths occurred most likely due to anaphylactic shock. *These incidents occurred 20 to 30 years ago; one reported in the USA and another in Asia, but is still pertinent.* Workers are cautioned of the risks and are advised to adhere to good practices [GLP and GCP] to avoid mortality and morbidity. It is safer to cancel IUI treatment if the sperm preparation is not clean and is "dirty" in appearance or if there are doubts about its safety.

INSTRUCTIONS FOR USE

1. The SYNBIOS[®] IUI Medium need not be pre-equilibrated in 6% CO₂ prior to use.
2. The SYNBIOS[®] IUI Medium can be used for: (a) preparation of sperm for intrauterine insemination; (b) conventional IVF and ICSI insemination; (c) for testicular spermatozoa aspiration; (d) short-term handling of oocytes in absence of 6% CO₂; (e) short-term handling of embryos in absence of 6% CO₂. Warm the medium to 37°C prior to use.
3. Briefly, the **gradient method is recommended** over the swim-up because the gradient method, when performed properly, will provide a clean specimen of spermatozoa only; which is not always the case with the swim-up technique.

DENSITY GRADIENT METHOD

4. Perform the sperm preparation for IUI as per the instructions given in the inserts for the SYNBIOS[®] Gradients Media products. The harvested sperm following density gradient centrifugation must be washed using pre-warmed (37°C) SYNBIOS[®] IUI Medium.
5. The principle of the density gradient technique as well as the swim-up methods of sperm preparation is given elsewhere (*Please refer to: 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.

6. It is essential that the sperm separation procedure is witnessed by one other worker to prevent specimen or pipette mix-up.
7. The labware used should be clearly labeled with a minimum of three unique identifiers for the specific patient, e.g. full name, date of birth, hospital number.

SWIM-UP METHOD

8. It is reiterated the density gradient technique is the recommended method for sperm preparation for IUI.
9. The swim-up method is also performed by numerous workers to harvest spermatozoa for IUI although the density gradient method is safer.
10. The swim-up method of sperm preparation must be performed very carefully to ensure the final is clean and free of cells and debris.
11. Perform the swim-up technique as per your protocol.
12. It is stressed it will be safer to cancel treatment so as to avoid mortality or morbidity rather than proceed with sperm preparation that is not completely clean and are not devoid of cells and debris.

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 any 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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Mar 2017

786

SYNBIOS[®] IUI 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 UM10050
Ref: 50 mL UM10050.SYN

SYNBIOS[®] IUI MEDIUM is sterilized by sterile filtration and comes with HSA (Ref: UM10050) or without HSA (Ref: UM10050.SYN).