

SYNBIOS® DENSITY GRADIENTS

GENERAL INFORMATION ON USE

SYNBIOS® Gradients is a gradient system for sperm preparation. SYNBIOS® Gradients consist of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution). SYNBIOS® Gradients system can be used in combination with IUI, IVF and ICSI.

MATERIALS SUPPLIED

20mL, 50mL & 100mL- 45% SYNBIOS® Gradients (REF: DG145020; DG145050, DG145100)
20mL, 50mL & 100mL- 80% SYNBIOS® Gradients (REF: DG180020; DG180050; DG180100)
20mL, 50mL & 100mL- 90% SYNBIOS® Gradients (REF: DG190020; DG190050; DG190100)
20mL, 50mL & 100mL- 100% SYNBIOS® Gradients (REF: DG100020; DG100050; DG100100)

MATERIALS REQUIRED BUT NOT SUPPLIED

Sperm freezing straws, 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® culture, sperm; Gamete, Flush, PVP, and Hyaluronidase media for cIVF / ICSI and HSA Solution

SPECIFICATIONS AND QUALITY CONTROL

pH: 7.20-7.90 (Release criteria: 7.20-7.60)

Osmolality:

310-340mOsm/kg (Upper layer)

320-350mOsm/kg (Lower layer)

310-330 mOsm/kg (80%)

Density:

1.1050-1.1150 g/ml (Lower layer)

1.097-1.107 g/ml (80%)

Viscosity: < 1.65 cP (Lower layer, 80%)

Endotoxin: < 0.5EU/ml

Sterility: SAL 10⁻³

Sperm Survival test: ≥ 80% survival after 4 hours exposure of spermatozoa to the test medium

Not MEA tested

A certificate of analysis and MSDS are available upon 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 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

G-FORCE CALCULATION

The g-force of your centrifuge can be calculated using this formula:

$$g = 1.118 \times r \times \text{rpm}$$

$$2 \text{ or rpm} = \text{Square root } \{g / (1.118 \times r)\}$$

r = radius of centrifuge in mm

rpm = rotations per minute / 1000

Example 1

r = 100 mm

rpm = 1800 rotations per minute

$$g = 1.118 \times 100 \times 3.24 = 362g$$

Example 2

r = 100 mm

g = 350g

$$\text{rpm} = \text{SQR} \{350 / (1.118 \times 100)\} = 1.77$$

rpm = 1770 rotations per minute

CAUTION

Gradients 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.

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

Standard measures to prevent infections from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded.

INSTRUCTIONS FOR USE WITH FRESH SEMEN SAMPLES.

1. Bring all components of the system and samples to room temperature or to 37°C.
2. Transfer 2.5ml of SYNBIOS® Gradients Upper Layer into a sterile disposable centrifuge tube.

3. Using a 3cc syringe with a 1 1/2" 21g needle, place 2.5ml of SYNBIOS® Gradients Lower Layer under the Upper Layer. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle on the bottom of the test tube and slowly dispensing the SYNBIOS® Gradients Lower Layer. This two layer gradient is stable for up to two hours.
4. Gently place up to 2.5ml of liquefied semen onto the upper layer using a transfer pipette or syringe.
5. Centrifuge for 15 to 18 minutes at 350g to 400g. When this centrifugation is completed you may not be able to visibly see a pellet. If so, it is essential to continue the procedure with a second centrifugation of 3 to 5 minutes.
6. Remove supernatant down to the pellet.
7. Using a syringe, add 2-3ml of sperm washing medium and re-suspend the pellet.
8. Centrifuge for 8 to 10 minutes at 300g. Higher sperm concentration will require the maximum 10 minutes centrifugation to ensure a complete and thorough sperm wash.
9. Remove supernatant down to the pellet and repeat steps 7 and 8.
10. Remove supernatant and replace with a suitable volume of appropriate medium.

INSTRUCTIONS FOR USE WITH FROZEN SEMEN SAMPLES.

1. Bring all components of the kit and samples to room temperature or to 37°C.
2. Transfer 1ml of SYNBIOS® Gradients Upper Layer into a sterile disposable centrifuge tube.
3. Using a 3cc syringe with a 1 1/2" 21g needle, place 1ml of SYNBIOS® Gradients Lower Layer under the Upper Layer. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle on the bottom of the test tube and slowly dispensing the SYNBIOS® Gradients Lower Layer. This two-layer gradient is stable for up to two hours.
4. Gently place the thawed semen sample onto the Upper Layer using a transfer pipette or syringe (0.5ml maximum).
5. Centrifuge for 15-20 minutes at 350g.
6. Remove supernatant down to no less than the 0.5ml mark above the pellet.
7. Using a syringe, add 2-3ml of sperm washing medium and resuspend the pellet.
8. Centrifuge for 8 to 10 minutes at 300g.
9. Remove supernatant down to the pellet and repeat steps 7 and 8.

10. Remove supernatant and replace with a suitable volume of appropriate medium. If samples do not liquefy and therefore do not pass through the layers, increasing the centrifugal force up to, but no more than, 500 g will help to separate the sperm.

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® GRADIENTS

20 Years of Research

Ensures Optimal Performance

SYNBIOS® MEDIA
Safety. Performance. Innovation

GMP-Manufactured

SYNBIOS® Gradients for sperm preparation.

Comes in 20mL, 50mL and 100mL, catalogue numbers given below in respective order.

REF: DG145020; DG145050, DG145100

REF: DG180020; DG180050; DG180100

REF: DG190020; DG190050; DG190100

REF: DG100020; DG100050; DG100100

SYNBIOS® GRADIENTS is sterilized by sterile filtration.