

G-IVF™ PLUS

Vitrolife

US

EN: Indication for use

Medium for preparation and handling of gametes and for in vitro fertilisation.

Product Description

SUPPLEMENTED WITH HSA

G-IVF™ PLUS is a bicarbonate buffered medium containing human serum albumin and gentamicin as an antibacterial agent.

Ready to use after equilibration at +37 °C and 6 % CO₂ atmosphere.

Storage instructions and stability

Store dark at +20 to +8 °C.

G-IVF™ PLUS is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

For Non-EU: Media bottles should not be stored after opening. Discard excess media after completion of the procedure.

EU: Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Record the opening date on the bottle. Discard excess media no later than two weeks after first opening.

Directions for use

Sperm preparation:

Swim-up migration method for semen samples with a good sperm count and motility.

Pipette 1.0 mL of semen into the tube. Overlay 2.0 mL of medium onto the top of the semen. Incubate in an air-tight container in the incubator at +37 °C and 6 % CO₂ for 30–60 minutes. Aspirate the top medium without touching the underlying semen and transfer to a clean tube. Add 5.0 mL of G-IVF™ PLUS, mix and centrifuge for 10 minutes at 300–600 g.

Aspirate the supernatant and re-suspend the pellet in 5.0 mL of equilibrated G-IVF™ PLUS and repeat the centrifugation. Discard the supernatant and resuspend the pellet in the 0.5–1.0 mL of equilibrated G-IVF™ PLUS. Determine motility and concentration of spermatozoa in the washed sample.

Density gradient centrifugation method.

This method can be used to wash all samples regardless of quality.

Mix SpermGrad™ with G-IVF™ PLUS in separate tubes to obtain 90% and 45% stock solutions. For 50 mL of semen, add 10 mL of G-IVF™ PLUS and 1.0 mL of G-IVF™ PLUS. For 45% stock solution mix 4.5 mL SpermGrad™ with 5.5 mL of G-IVF™ PLUS. Mix the solutions thoroughly. Store in sterile non-toxic tubes or sterile culture tanks. Label and refrigerate at +20–30 minutes at +37 °C and 6 % CO₂ atmosphere.

Transfer the supernatant and re-suspend the pellet in 5.0 mL of equilibrated G-IVF™ PLUS and repeat the centrifugation. Discard the supernatant and resuspend the pellet in the 0.5–1.0 mL of equilibrated G-IVF™ PLUS. Determine motility and concentration of spermatozoa in the washed sample.

Oocyte identification:

Wash the oocytes first pre-warmed supernatant G-IVF™ PLUS and then in equilibrated G-IVF™ PLUS. The washing procedure should include at least two steps with 1.0 mL of G-IVF™ PLUS in each step. Transfer the oocytes to the dishes with equilibrated G-IVF™ PLUS and return the dishes to the incubator immediately.

Insemination:

Transfer the oocytes to insemination dishes and leave at +37 °C and 6 % CO₂ overnight.

Alternatively: Add equilibrated sperm suspension to equilibrated dishes with the oocytes already present.

It is recommended to inseminate in 0.5–1 mL volume without oil overlay. If overlay is used, droplets of at least 100 µL are recommended.

Specifications

STERILE filtered SAL 10⁺

Mouse embryo assay (1-cell) [% expanded blastocyst within 96 hours] ≥ 80

Bacterial endotoxins (LAL assay) [EU/mL] < 0.25

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Precutions

Discard product if bottle integrity is compromised. Do not use G-IVF™ PLUS if it appears cloudy.

G-IVF™ PLUS contains human serum albumin and gentamicin as an antibacterial agent. Known hypersensitivity/allergy to any of the components.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for HIV-1, HIV-2, HCV, HBsAg, HCV and HTLV I and non-reactive for HSV-1, HSV-2, CMV, Toxoplasma and syphilis. No known methods can offer assurance that products derived from human blood will not transmit infectious agents.

To prevent transmission of disease, strongly recommends that media should be opened and used only with aseptic technique.

The risk of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife's IVF media, have not been determined and are uncertain.

Not for injection.

Caution: (US) law restricts this device to sale or by the order of a physician.

CHINA

CN: 洗精受精液-G-IVF™ PLUS产品说明书

产品名称: 洗精受精液

适用范围: 本产品适用于配子准备和处理以及体外受精培养。

产品型号及规格: 型号: G-IVF PLUS, 1x30 mL, 1x60mL。

产品注册证及技术要求书: 产品注册证编号: 国食药监械(进)20153183137

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产品组成及主要功能构成

产品组成: 加入人血清白蛋白。

G-IVF™ PLUS是一种含有人血清白蛋白和杀菌剂庆大霉素的非免疫性基础培养液。

在+37 °C和二氧化碳浓度为6%的环境中平衡后即可使用。

产品有效期及贮存条件

产品有效期: 自生产之日起25年。

储存条件: 温度: +20 ~ +8 °C。

运输温度: 在运输过程中温度不得超过8 °C, 不得超过12 °C, 最长不得超过48小时。

G-IVF™ PLUS在使用前应将产品在+20~60 °C的温箱中平衡后打开。将平衡好的产品取出后，将产品包装打开后再继续储藏，使用后丢弃剩余产品。

生产日期: 见标签。

使用期限: 见标签。

使用方法:

1. 上面对精子质量及活力较好的液体样本。

吸取1.0 mL精液或冲洗液的试管中，在+上室温小心加入1.0 mL G-IVF™ PLUS，轻轻摇匀，使精子与G-IVF™ PLUS充分接触，直到精子活力恢复到+37 °C和6%CO₂的平衡状态。

吸出1.0 mL后，再用1.0 mL平衡后的G-IVF™ PLUS冲洗，混匀，300~600 g离心10分钟。

吸出上层培养液并丢弃，将平衡好的产品重新平衡后，再用1.0 mL平衡后的G-IVF™ PLUS冲洗，混匀，300

