



FertiCult™ IVF medium



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FertiCult™ IVF medium

FEU020 5 x 20ml FertiCult™ IVF medium
FEU050 5 x 50ml FertiCult™ IVF medium
FEU100 3 x 100ml FertiCult™ IVF medium

FertiCult™ IVF medium with phenol red

FEU020PHR 5 x 20ml FertiCult™ IVF medium with phenol red
FEU050PHR 5 x 50ml FertiCult™ IVF medium with phenol red
FEU100PHR 3 x 100ml FertiCult™ IVF medium with phenol red

FertiCult™ IVF medium with phenol red and gentamicin

FEU020PHRG 5 x 20ml FertiCult™ IVF medium with phenol red and gentamicin
FEU050PHRG 5 x 50ml FertiCult™ IVF medium with phenol red and gentamicin
FEU100PHRG 3 x 100ml FertiCult™ IVF medium with phenol red and gentamicin

1 Conaghan J (2014). pH control in the embryo culture environment. In: Quinn P, editors. Culture media, solutions, and systems in Human ART. Cambridge University Press. P. 142-154

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FertiCult™ IVF medium

INDICATIONS FOR USE

FertiCult™ IVF medium is intended for washing and holding of human oocytes, performing fertilization by IVF or ICSI (until 2PN).

For professional use only.

GENERAL INFORMATION

The medium is complete and needs no further additives. As with all IVF media, FertiCult™ IVF medium has to be pre-incubated in a CO₂ incubator with 5-6% CO₂ for at least 5 hours, but ideally, dishes should be prepared the day before use and incubated overnight (with lid opened) to obtain an optimal pH for oocyte washing/holding.

COMPOSITION

FertiCult™ IVF medium is a ready-to-use bicarbonate-buffered balanced salt solution, supplemented with glucose (5.55mM), lactate, pyruvate, and human serum albumin (4.0g/l); medicinal substance derived from human blood plasma). The product is also available with phenol red and/or gentamicin (1.0mg/l; medicinal substance).

PRODUCT SPECIFICATIONS

- Chemical composition
- pH: 7.20 - 7.50 (37 °C - 6% CO₂)
- Osmolality: 270 - 290 mOsm/kg
- Sterility test by the current Ph. Eur. 2.6.1 / USP <71>; No growth
- Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>); < 0.25EU/ml
- Mouse Embryo Assay (% blastocysts after 96h after IVF in test medium); ≥ 80%
- Use of Ph Eur or USP grade raw materials if applicable
- Certificates of analysis and MSDS are available upon request or can be downloaded from our website (www.fertipro.com).

WARNINGS BEFORE USE

- Do not use the product if:
 - it becomes discoloured (if medium contains phenol red), cloudy, or shows any evidence of microbial contamination;
 - seal of the container is opened or defect when the product is delivered;
 - expiry date has been exceeded.
- Do not freeze before use.
- Product which include gentamicin should not be used on a patient that has a known allergy to gentamicin or similar antibiotics.
- Depending on the number of procedures that will be performed on one day, remove the required volume of medium under aseptic conditions in an appropriate sterile recipient. This is in order to avoid multiple openings/ warming cycles of the medium. Discard excess (unused) media.
- Keep in its original packaging until the day of use

METHOD

MEDIUM PRE-EQUILIBRATION / DISH PREPARATION

Incubate the medium (in culture dishes or flasks with loosened screw tops) in a CO₂ incubator at 37 °C and 5-6% CO₂. Ideally the medium should be pre-incubated overnight before use (or at least 5 hours).

Important: Read the note on optimal pH, CO₂ and atmospheric pressure below carefully.

When pre-equilibration is performed in culture dishes, follow the instructions below:

- For small droplets: 6-8 droplets of 25-250µl of FertiCult™ IVF medium may be dispensed around the 6cm culture dish/well. To maintain pH, temperature and osmolality, make sure that the droplets are completely covered with oil (e.g. FertiCult™ Mineral Oil, FertiPro NV). 1-5 oocytes are usually placed per micro-droplet.

Alternatively, the medium can also be used for fertilization in an open system such as with the Falcon / Nunc dishes. About 1ml of medium is placed in each well. Additional medium is placed in the reservoir surrounding the wells. This helps to maintain humidity as well as providing medium which can be used for washing of the oocytes. Up to 5 oocytes per dish/well may be cultured together. In the open system, paraffin oil is not necessary, but sometimes a 1mm layer of mineral oil may be added over the medium in the inner well. When using such an open system the incubator must be humidified.

Washing/holding of oocytes and fertilization by IVF or ICSI

After equilibration of the medium, the prepared dishes are ready for use. During oocyte collection, oocytes are identified in the follicular aspirates and then washed before placing into the wells or droplets in the dish. After oocyte collection, oocytes will be checked and may be re-washed, before being placed into fresh droplets/wells for further culture. Generally, within 6 hours of oocyte collection, oocytes will be fertilized by IVF or ICSI with prepared sperm and then left overnight in the incubator. The presence of 2 pro-nuclei (2PN) is checked 16-20 hrs after fertilization. Once embryos have been identified by the presence of 2PN, they are placed into fresh dishes containing a fresh embryo culture medium (e.g. GAIN™ Medium, FertiPro NV) for further embryo culture and embryo transfer.

Notes:

- Test tube culture is now rare, but for those still using this method, place 1ml of FertiCult™ IVF medium in each tube and then follow the same procedure as for Falcon or Nunc dishes.
- Each laboratory should consult its own validated procedures, optimized for its individual medical program.

Note on optimal pH, co₂ and atmospheric pressure

For optimal embryo culture, FertiCult™ IVF medium should be used at a pH of 7.20-7.35. Different factors like the CO₂ concentration in the incubator and atmospheric pressure (which decreases at higher altitudes) may have an effect on the pH after equilibration in the incubator. Therefore, we strongly advise to measure the pH under culture conditions with 6% CO₂ in the incubator in order to determine the CO₂ concentration settings of the incubator which result in an optimal pH of 7.20-7.35.

STORAGE/DISPOSAL INSTRUCTIONS

- Store FertiCult™ IVF medium without gentamicin between 2-25 °C. Once opened: store between 2-8 °C.
- Store FertiCult™ IVF medium with gentamicin between 2-8 °C.
- The products can be used up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8 °C.
- Keep away from sunlight.
- The devices need to be disposed in accordance with local regulations for disposal of medical devices.

PRECAUTIONS

- Aseptic technique should be used to avoid possible contamination, even when the products contain gentamicin.
- All blood products should be treated as potentially infectious. Source material used to manufacture this product was tested and found non-reactive for HbsAg and negative for anti-HIV-1/2, HIV-1, HBV, and HCV. Furthermore, source material has been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.
- Standard measures to prevent infections resulting 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 activation/ removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infectious agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albums manufactured to European Pharmacopoeia specifications by established processes. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.

Important: lire attentivement la remarque sur les conditions optimales quant au CO₂, à la pression atmosphérique et au pH figurant ci-dessous.

Important: le pré-équilibrage est effectué dans des boîtes de culture. Veuillez lire les instructions ci-dessous.

- Pour les micro-gouttes: 6 à 8 gouttes de 25 à 250µl de FertiCult™ IVF medium peuvent être distribuées autour de la boîte / puces de culture de 6cm. Pour maintenir le pH, la température et l'osmolalité, assurez-vous que les gouttes sont complètement recouvertes d'huile (par exemple, FertiCult™ Mineral Oil, FertiPro NV). 1 à 5 ovocytes sont généralement placés par micro-gouttes.

Le milieu de culture peut aussi être utilisé comme milieu de fécondation en système ouvert en utilisant des boîtes multi-puits de type Falcon / Nunc. Placer environ 1ml de milieu dans chaque puit. Un volume additionnel de milieu peut aussi être déposé dans l'espace central inter-puits. Cette opération permet de contribuer à un meilleur maintien du degré hygrométrique dans la boîte. Elle peut aussi servir à laver les ovocytes. Cinq ovocytes au maximum peuvent alors répartis dans chaque puit. Dans le système ouvert, l'huile minérale n'est pas nécessaire, mais le milieu du puit intérieur est parfois recouvert d'une couche d'huile minérale de 1ml. L'incubateur doit être humidifié lorsqu'un tel système ouvert est employé.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The SSCP for FertiCult™ IVF medium describes safety and performance characteristics for the media and is available on the website of FertiPro NV (www.fertipro.com) or by downloading the following QR code:

For further questions regarding the safety and performance, please contact FertiPro NV for customer or technical support.

METHOD

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Incubate the medium (in culture dishes or flasks with loosened screw tops) in a CO₂ incubator at 37 °C and 5-6% CO₂. Ideally the medium should be pre-incubated overnight before use (or at least 5 hours).

Important: Read the note on optimal pH, CO₂ and atmospheric pressure below carefully.

When pre-equilibration is performed in culture dishes, follow the instructions below:

- For small droplets: 6-8 droplets of 25-250µl of FertiCult™ IVF medium may be dispensed around the 6cm culture dish/well. To maintain pH, temperature and osmolality, make sure that the droplets are completely covered with oil (e.g. FertiCult™ Mineral Oil, FertiPro NV). 1-5 oocytes are usually placed per micro-droplet.

Alternatively, the medium can also be used for fertilization in an open system such as with the Falcon / Nunc dishes. About 1ml of medium is placed in each well. Additional medium is placed in the reservoir surrounding the wells. This helps to maintain humidity as well as providing medium which can be used for washing of the oocytes. Up to 5 oocytes per dish/well may be cultured together. In the open system, paraffin oil is not necessary, but sometimes a 1mm layer of mineral oil may be added over the medium in the inner well. When using such an open system the incubator must be humidified.

Notes:

- Test tube culture is now rare, but for those still using this method, place 1ml of FertiCult™ IVF medium in each tube and then follow the same procedure as for Falcon or Nunc dishes.

Réservez à un usage professionnel.

INFORMATIONS GÉNÉRALES

Le milieu est complet et ne requiert pas d'additif. Comme tous les milieux pour la FIV, FertiCult™ IVF medium doit être préincubé dans un incubateur à CO₂ contenant 5-6 % de CO₂ pendant un minimum de 5 heures, mais idéalement, les boîtes sont préparées la veille et pré-incubées pendant la nuit (couvercle ouvert) afin d'obtenir un pH optimal pour le lavage/manipulation des ovocytes.

COMPOSITION

FertiCult™ IVF medium est une solution salée, équilibrée, tamponnée au bicarbonate, prête à l'emploi, additionnée de glucose (5.55mM), d'acide lactique, d'acide pyruvique et de sérum-albumine humaine (4.0g/l), substance médicamenteuse dérivée du plasma sanguin humain. Le produit est également disponible avec du rouge de phénol et/ou de la gentamicine (1.0mg/l, substance médicamenteuse).

INSTRUCTIONS RELATIVES AU STOCKAGE ET A L'ÉLIMINATION

- Conserver le FertiCult™ IVF medium sans gentamicine entre 2 et 25 °C. Une fois ouvert : le conserver entre 2 et 8 °C.
- Conserver le FertiCult™ IVF medium avec gentamicine entre 2 et 8 °C.
- Les produits peuvent être utilisés jusqu'à 7 jours après ouverture si les conditions de stérilité sont respectées et si les produits sont conservés entre 2 et 8 °C.
- Tenir à l'écart de la lumière (du soleil).
- Les dispositifs doivent être éliminés conformément aux réglementations locales en matière d'élimination des dispositifs médicaux.

PRÉCAUTIONS

- Utilisation de produits de qualité Ph Eur ou USP le cas échéant
- Un certificat d'analyse et une fiche de données de sécurité sont disponibles sur demande ou peuvent être téléchargés sur notre site Internet (www.fertipro.com).

MISES EN GARDE AVANT UTILISATION

- Ne pas utiliser le produit si :
 - il est décoloré (dans le cas où il contient du rouge de phénol), trouble ou s'il présente des signes de contamination microbienne;
 - l'opercule du contenant est rompu ou abîmé à la livraison;
 - la date de péremption est dépassée;
 - Ne pas congeler avant utilisation.
 - Ne pas résteriliser après ouverture.
- Les produits contenant de la gentamicine ne doivent pas être utilisés chez des patients allergiques à la gentamicine ou à des antibiotiques similaires.
- Prélever le volume de milieu requis dans un récipient stérile approprié, en conditions aseptiques, en fonction du nombre de procédures qui seront effectuées dans la journée. Cela évitera une multitude d'ouvertures et de cycles de réchauffement du milieu. Éliminer le milieu en excès (non utilisé).
- Conserver dans son emballage d'origine jusqu'au jour de l'utilisation.

VORINKEBULATION DES MEDIUMS / SCHALENPRAPARATION

Inkubieren Sie das Medium (in Kulturschalen oder Flaschen mit gelösten Schraubverschlüssen „Vent Position“) in einem CO₂-Incubator bei 37 °C und 5-6% CO₂. Idealerweise sollte das Medium vor der Verwendung über Nacht vorinkubiert werden. Allerdings vor dem Inkubieren müssen die Platten mit Albumin vor, das nach den Spezifikationen des Europäischen Arzneibuches (Pharmacopoeia) durch etablierte Prozesse hergestellt wurde. Alle Proben sind so zu handhaben, als könnten sie HIV oder Hepatitis übertragen.

MÉTHODE

VORINKEBULATION DES MEDIUMS / SCHALENPRAPARATION

Inkubieren Sie das Medium (in Kulturschalen oder Flaschen mit gelösten Schraubverschlüssen „Vent Position“) in einem CO₂-Incubator bei 37 °C und 5-6% CO₂. Idealerweise sollte das Medium vor der Verwendung über Nacht vorinkubiert werden. Allerdings vor dem Inkubieren müssen die Platten mit Albumin vor, das nach den Spezifikationen des Europäischen Arzneibuches (Pharmacopoeia) durch etablierte Prozesse hergestellt wurde. Alle Proben sind so zu handhaben, als könnten sie HIV oder Hepatitis übertragen.

Wichtig: Lesen Sie den folgenden Hinweis zum optimalen pH-Wert, CO₂ und atmosphärischen Druck sorg-fältig durch.

Wenn die Vorinkubierung in Kulturschalen durchgeführt wird, befolgen Sie die folgenden Anweisungen:

- Für Mikrotropfchen: 6-8 Tröpfchen von 25-250µl FertiCult™ IVF medium beschreibt die Merkmale der Sicherheit und Leistungsfähigkeit des Mediums und ist auf der Website von FertiPro NV (www.fertipro.com) oder durch Scannen des QR-Codes erhältlich:

Für weiteren Fragen zur Sicherheit und Leistungsfähigkeit kontaktieren Sie bitte den Kundenservice oder Technischen Support von FertiPro NV.

ZUSAMMENFASSUNG DER SICHERHEIT UND KLINISCHEN LEISTUNGSFÄHIGKEIT (SSCP)

