

PRODUCT CATALOGUE





Your partner in semen analysis and Assisted Reproductive Technologies

Founded in 1992, FertiPro is a reliable, independent manufacturer of in vitro diagnostics and cell culture media used in assisted reproductive technologies and the diagnosis of male infertility.

Product Range

We manufacture in vitro diagnostic kits for the determination of neutral alpha-glucosidase, fructose, anti-sperm antibodies, sperm vitality, white blood cells and sperm morphology in human semen samples. Our media range includes cell culture media for use in all stages of IVF and ICSI procedures as well as pre-washed, paraffin oils, a ready-to-use hyaluronidase solution, PVP solution, density gradients for sperm selection and media for cryopreservation of human oocytes, spermatozoa and embryos.

Manufacturing

Manufacturing takes place in our own, state-of-the-art, fully environmentally controlled, production facility in Beernem, Belgium.

Certification & quality assurance

FertiPro is an ISO 13485 certified company, that participates in the MDSAP program. We have product registrations in Europe, Brazil, Canada, United States of America and in increasingly more countries worldwide. A complete list of all distributors can be found on our website. All of our diagnostic kits and ART media are CE marked either as in vitro diagnostics or as medical devices. Certificates of analysis for all our products are available upon request.

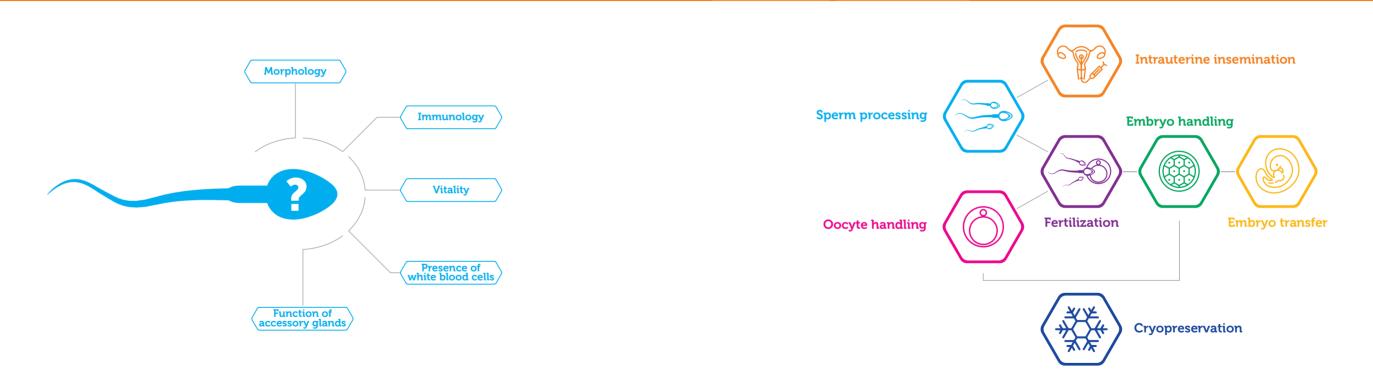
Contract manufacturing

Contact us for more information regarding contract manufacturing for your company.



Semen analysis: product range diagnostics

Assisted Reproductive Technologies: ART media







Semen analysis: product range diagnostics

Morphology os Spermac Stain 12 LeucoScreen Plus Immunology og SpermMar Test IgA & IgG 13 Fructose Test 14 EpiScreen Plus

Vitality

- 10 VitalScreen
- 11 Hypo-osmotic Swelling Test

Presence of white blood cells

Function of accessory glands

Spermac Stain Sperm morphology stain

Regulatory

USA: registered – Canada: registered Brazil: registered – Australia: registered Other regions: information available upon request

Storage

∬,**~ +25°C** Stable until expiry date specified on the

Product order codes

SPS050	Spermac	Stain	- 4>	c 50ml
SPS250	Spermac	Stain	- 4>	250ml

Product instruction video



An instruction film on the use of Spermac Stain is available on YouTube.



General information

Sperm morphology analysis is one of the basic semen examinations performed in the diagnosis and management of male infertility. Spermac Stain is an in vitro diagnostic staining kit consisting of a fixative and 3 staining solutions for human spermatozoa. Staining facilitates distinction between morphologically normal and abnormal spermatozoa, and enhances visualization of different parts of the sperm cell (head, acrosome, equatorial region, midpiece, tail).

Spermac Stain is a qualitative, non-automated, diagnostic kit

Intended use

for professional use for the staining of human spermatozoa.



ermMar Test Mar Test IgG Antisérum - 50 Tes WParticules de latex REF SPMG_L N SPMG_A 20G01 21-07 +20 2021-07 +20 EEZE / NE PAS CONG OT FREEZE / NE PAS CO enPro N.V., Industriepark No 8730 Beernem, Belgium

Intended use

As sperm does not come into contact with the blood circulation, the male reproductive system contains no antisperm antibodies in normal conditions. However, when the blood-testis barrier is breached, the immune system can detect mature sperm as antigenic and form antisperm antibodies that cause sub- or infertility. Anti-sperm antibodies belong to two immunological classes: immunoglobulin (Ig)A and IgG antibodies, and can be present in the semen sample as well as in male blood serum. Antisperm IgA and IgG antibodies are clinically associated with immunological infertility, and screening can therefore provide help in assessing the male fertility.

General information

The SpermMar Test IgA and IgG are both semiguantitative, non-automated diagnostic kits for detecting antisperm antibodies of respectively the IgA or IgG class on spermatozoa in human semen (or serum when using SpermMar Test IgG).

SpermMar Test IgA & IgG

Test for the detection of anti-sperm antibodies

Regulatory

Europe: CE-marked (IVDD) – USA: registered Canada: Health Canada License Brazil: registered – Australia: registered Other regions: information available upon request

Storage



Product order codes

SPMA_S	SpermMar Test IgA single kit	50 tests
SPMA_C	SpermMar Test IgA complete kit*	50 tests
SPMG_S	SpermMar Test IgG single kit	50 tests
SPMG_C	SpermMar Test IgG complete kit*	50 tests
SPMG_P	SpermMar Test IgG Positive Control	50 tests
SPMG_N	SpermMar Test IgG Negative Control	50 tests

Product instruction video



Instruction films on the use of SpermMar Test IgA & IgG are available on YouTube.

* The complete kit contains pipettes and

VitalScreen Sperm vitality test

Regulatory

Europe: CE-marked (IVDR) – USA: registered – Canada: registered Brazil: registered – Australia: registered Other regions: information available upon request

Storage



Product order codes

Product instruction video



An instruction film on the use of VitalScreen is available on YouTube.



General information

VitalScreen uses eosin-nigrosin staining to assess the percentage of live spermatozoa. The technique is based on the principle that dead cells take up eosin through their cell membrane, and as a result stain red. The nigrosin provides a dark background which makes it easier to evaluate the slides. Sperm vitality should be determined when less than 40% of spermatozoa are motile. In samples with poor motility, it is important to discriminate between immotile dead sperm and immotile live sperm.

Intended use

VitalScreen is a semiquantitative, non-automated diagnostic test to evaluate the vitality of spermatozoa in a semen sample by using an eosin-nigrosin staining.

General information

The Hypo-osmotic Swelling Test (HOS Test) is an in vitro diagnostic for professional use to evaluate the vitality of the spermatozoa in a semen sample. In contrast to dead spermatozoa, living cells have intact cell membranes which allow regulated water transport in hypo-osmotic conditions which will result in swelling or curling of the sperm tail upon incubation in HOST medium.

HOST-medium

LOT FP19HOS02

2020-09 FertiPro N.V., In

8730 Beemem, Belg

REF HOST

Intended use

The HOS Test is a semi-auantitative. non-automated diagnostic test to evaluate the vitality (membrane function) of spermatozoa in a semen sample. The HOS Test should not be used for the selection of sperm in ART procedures such as intra-cytoplasmatic sperm injection (ICSI).

Hypo-osmotic Swelling Test Sperm vitality test

Regulatory

Europe: CE-marked (IVDD) – Canada: Health Canada License Brazil: registered – Australia: registered – USA: registered Other regions: information available upon request

Storage



HOST Hypo-osmotic Swelling Test 5x 20ml

Product instruction video



An instruction film on the use of the Hypo-osmotic Swelling Test is available on YouTube.

LeucoScreen Plus

Improved leucocyte staining method

Kit for the determination of fructose in seminal plasma

Regulatory

Europe: CE-marked (IVDD) – USA: registered Australia: registered – Brazil: registered – Canada: registered Other regions: information available upon request

Storage



Product order codes

LEUCO_PLUS LeucoScreen Plus 40 days of analysis

Product instruction video



An instruction film on the use of LeucoScreen Plus is available on YouTube. Training form can be downloaded from www.fertipro.com



General information

Most human ejaculates contain leucocytes and the predominant form of leucocytes in human semen are peroxidase-positive granulocytes. Excessive presence of these cells (leucocytospermia) may indicate the existence of reproductive tract infection. Leucocytospermia may also be associated with defects in the semen profile (reduction in sperm motility and DNA integrity, raise of sperm viscosity as well as loss of sperm function as a result of oxidative stress, and/or secretion of cytotoxic cytokines by these white blood cells). Although leucocytospermia is not an absolute indication of infertility, this condition is observed on average in 10 to 20% of all infertile men.

Intended use

LeucoScreen Plus is a semiguantitative, non-automated, histochemical and diagnostic kit for the determination of peroxidase-positive white blood cells in human semen.

Fructose Test Respent 1 - TCA solution REF FRUCTO_1 2020-12 Company Avenue Provide Avenue Fructose Test REF FRUCTO_2 LOT FP19FR06 uctose Test Fructose Test gent 4 - NaOH uctose REF FRUCTO_ST FRUCTO 4 REF FRUCTO LOT FP19FR06 2020-12 2020 12 2020-12 2020-12

General information

The secretion of the seminal vesicles constitutes the main fraction of the ejaculate. Seminal fructose concentration can be used as a marker of the seminal vesicular function. Low fructose in semen is characteristic for partial or complete ejaculatory duct obstruction, bilateral congenital absence of the vas deference, partial retrograde ejaculation and androgen deficiency.

Intended use

The Fructose Test is a quantitative, non-automated, photometric and diagnostic kit for the measurement of fructose in human semen or seminal plasma (fresh or frozen).

Fructose Test



Regulatory

Europe: CE-marked (IVDD) – Australia: registered Other regions: information available upon request

Storage

Product order codes

FRUCTOSE Fructose Test 96 tests

Product instruction video



An instruction film on the use of the Fructose Test is available on YouTube

EpiScreen Plus

Kit for the determination of neutral alpha-glucosidase in seminal plasma

Regulatory

Europe: CE-marked (IVDD) – Australia: registered Other regions: information available upon request

Storage

+2°C -+8°C Store bu 2-8°C 24 months from date of manufacture

Product order codes

EPI_PLUS EpiScreen Plus – 25 tests

Product instruction video



An instruction film on the use of EpiScreen Plus is available on YouTube.



General information

EpiScreen Plus can be used to determine the neutral alphaglucosidase activity in semen (plasma), an enzyme which is mainly secreted by the epididymis. The activity of this enzyme is a reliable marker for epididymis function in patients with (very) low sperm concentration or azoospermic patients, having a normal androgen blood level:

EpiScreen Plus is a quantitative, non-automated, photometric and diagnostic kit for detecting neutral alphaglucosidase in human semen or seminal plasma.

- very low activity indicates a bilateral obstruction between the epididymis and the ejaculatory duct.
- low activity may reflect partial obstruction of the epididymis.
- normal enzyme activity is expected when there is an obstruction above the area in which the enzyme is secreted or in cases of non-obstructive azoospermia (testicular disfunction).







Assisted Reproductive Technologies: ART media



Washing/swim-up

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- 18 FertiCult Flushing medium
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- 28 GAIN medium

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Pick-up

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Oocyte incubation

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– Embryo handling

Embryo washing

18 FertiCult Flushing medium

Embryo culture

28 GAIN medium

Culture overlay

- 29 FertiCult Mineral Oil
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- 18 FertiCult Flushing medium
- 28 GAIN medium



Sperm cryopreservation

- 32 SpermFreeze
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Oocyte cryopreservation

34 FertiVit Cooling / FertiVit Warming

Embryo cryopreservation

- 35 VitriFreeze / VitriThaw
- 36 FertiVit Cooling / FertiVit Warming
- 37 VitriFreeze ES / VitriThaw ES

FertiCult Flushing medium HEPES buffered cell culture medium for use in human ART

Intended use

FertiCult Flushing medium is intended for in vitro procedures involving human gametes (sperm and oocytes), including washing of gametes, sperm swim-up procedures, intrauterine insemination (IUI) of the spermatozoa and sperm injection during intracytoplasmic sperm injection (ICSI). FertiCult Flushing medium can also be used for human embryo washing and holding, and for embryo transfer (ET).



Product specifications

- Chemical composition
- pH: 7.30-7.90 (release criteria: 7.30-7.60)
- Osmolality: 270-290 mOsm/kg
- Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>):
- Sterility test by the current Ph. Eur. 2.6.1 / USP <71>: No growth
- One-cell mouse embryo assay (% blastocysts after 96 hours, after 60 minutes exposure to test medium:): ≥ 80%
- Human sperm survival assay (% motility compared with control after 24 hours exposure to test medium): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: CE marked (MDR, Notified Body number 2797) Canada: Health Canada Licence – Brazil: registered Other regions: information available upon request

Storage





Product order codes

FLUSH020	FertiCult™ Flushing medium	5x 20ml
FLUSH050	FertiCult™ Flushing medium	5x 50ml
FLUSH100	FertiCult™ Flushing medium	3x 100ml
FLUSH020PHR	FertiCult [™] Flushing medium with phenol red	5x 20ml
FLUSH050PHR	FertiCult [™] Flushing medium with phenol red	5x 50ml
FLUSH100PHR	FertiCult [™] Flushing medium with phenol red	3x 100ml
FLUSH500PHR	FertiCult [™] Flushing medium with phenol red	1x 500ml
FLUSH020PRG	FertiCult TM Flushing medium with phenol red and gentamicin	5x 20ml
FLUSH050PRG	FertiCult TM Flushing medium with phenol red and gentamicin	5x 50ml
FLUSH100PRG_G	FertiCult TM Flushing medium with phenol red and gentamicin	3x 100ml
FLUSH500PRG_G	FertiCult TM Flushing medium with phenol red and gentamicin	1x 500ml
WASH005 WASH020	Sil-Select Plus™ Sperm Washing/ Insemination medium Sil-Select Plus™ Sperm Washing/ Insemination medium	25x 5 ml 5x 20 ml
WASH100G	Sil-Select Plus™ Sperm Washing/ Insemination medium with gentamicin	1x 100ml



Sterilized using aseptic processing techniques



Sil-Select Plus Sperm preparation media



Intended use

Sil-Select Plus is a ready-to-use gradient system for semen preparation.

The following gradients are available:

- Sil-Select Plus Upper layer (45%)
- Sil-Select Plus 80%
- Sil-Select Plus Lower layer (90%)

The Sil-Select Plus system can be used for semen preparation for Intra Uterine Insemination (IUI), In Vitro Fertilization (IVF) and IntraCytoplasmatic Sperm Injection (ICSI).

Sil-Select Plus Sperm Washing/Insemination medium is intended for use in Assisted Reproductive Technologies, more specifically for sperm washing/holding and for the production of density gradients. The medium can be used for IUI.



Product instruction video



An instruction film on the use of Sil-Silect Plus is available on our Sil-Silect Plus is available on our website.

Product specifications

Sil-Select Plus Upper layer/Lower layer/80% media:

- Chemical composition
- pH criteria: 7.20-7.90 (release criteria: 7.20-7.60)
- Osmolality: 280-310 mOsm/kg (Upper layer) 290-330 mOsm/kg (Lower layer)
- Density: 1.0500-1.0700 (Upper layer)
- Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>):< 0.5EU/m
- Sterility test according to the current Ph. Eur. 2.6.1/USP <71>: No growth
- Human sperm survival assay (% motility compared with control after 4 hours exposure to test
- Human sperm survival assay (% motility compared with control after 24 hours exposure to tes
- Not MEA tested
- Use of Ph Eur or USP grade products if applicable

Sil-Select Plus Sperm Washing/Insemination medium:

- Chemical composition
- pH criteria: 7.30-7.90 (release criteria: 7.30-7.60,)
- Osmolality: 270-290 mOsm/kg
- Sterility test according to the current Ph. Eur. 2.6.1/USP<71>: No growth
- Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>): < 0.25EU/ml
- One-cell Mouse Embryo Assay (blastocysts after 96 hours, after 60 minutes exposure to
- Human Sperm Survival Assay (% motility compared with control after 24 hours exposure to test medium): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: CE-marked (MDR, Notified Body number 2797) USA: US FDA-cleared – Other regions: Information available upon request

Product order codes

	SIP008	Sil-Select Plus™ Lower layer	8x 2.5ml
		Sil-Select Plus™ Upper layer	8x 2.5ml
		Sil-Select Plus™ Sperm Washing/Insemination medium	8x 5ml
nl	SIP016	Sil-Select Plus™ Lower layer	2x 20ml
		Sil-Select Plus™ Upper layer	2x 20ml
4		Sil-Select Plus™ Sperm Washing/Insemination medium	5x 20ml
st	SIP020LO	Sil-Select Plus™ Lower layer	1x 20ml
	SIPO20UP	Sil-Select Plus™ Upper layer	1x 20ml
	SIP050	Sil-Select Plus™ Lower layer	1x 50ml
		Sil-Select Plus™ Upper layer	1x 50ml
	SIP100	Sil-Select Plus™ Lower layer	1x 100ml
		Sil-Select Plus™ Upper layer	1x 100ml
	SIP80_100	Sil-Select Plus™ 80%	1x 100ml

Storage ____



Sil-Select STOCK Sperm preparation media



10% PVP in FertiCult Flushing medium Viscous medium for use in ICSI procedures

Product specifications

- Chemical composition
- pH criteria: 7.20-7.90 (Release criteria: 7.20-7.60)
- Osmolality: 300-330 mOsm/kg
- Density: 1.1150-1.1250 g/m
- Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>): < 0.5EU/ml
- Sterility test according to the current Ph. Eur. 2.6.1/USP <71>: No growth
- Human sperm survival assay (% motility compared with control after 4 hours exposure to test medium): $\geq 80\%$
- Human sperm survival assay (% motility compared with control after 24 hours exposure to test medium): $\geq 75\%$
- Not MEA tested
- Use of Ph Eur or USP grade products if applicable

Product order codes

SIS100	Sil-Select Stock™	1x 100ml
SIS500	Sil-Select Stock™	1x 500ml
SIS100_32G	Sil-Select Stock™ with gentamicin	1x 100ml

Regulatory

Europe: CE-marked (MDR, Canada: Health Canada License Brazil: Reaistered available upon request

Storage

∩**~+8°C** +2°C -/

18 months from date

Sterilized using aseptic processing techniques STERILE A





Intended use

Sil-Select Stock is a stock solution for semen preparation. It is an isotonic gradient for semen preparation with a density of approximately 1.12 g/ml. Sil-Select Stock can be used for semen preparation for Intra Uterine Insemination (IUI), In Vitro Fertilization (IVF) and IntraCytoplasmatic Sperm Injection (ICSI).

10% PVP Flushing REF PVP1 LOT FP22 -m 2022 2 2022

Intended use

10% PVP in FertiCult Flushing medium is a viscous medium containing polyvinylpyrrolidone (PVP) used for sperm preparation for Intracytoplasmic Sperm Injection (ICSI). These procedures require the capture of individual sperm cells in a glass pipette for injection into the oocyte and this is facilitated by first immobilizing the sperm by placing them in a viscous medium like 10% PVP in FertiCult Flushing medium prior to nicking the tail to immobilize sperm completely.

- No arowth

PVP1

Product specifications

 Chemical composition • pH: 7.20-7.90 (release criteria: 7.20-7.60) • Osmolality: 280-340 mOsm/kg (release criteria: 280-320 mOsm/kg) • Viscosity: >170 cP at 25 °C Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>): <0.5EU/ml • Sterility test by the current Ph. Eur. 2.6.1 / USP <71>: One-cell mouse embryo assay (% blastocysts after 96 hours,

after 10 minutes exposure time to test medium): $\geq 80\%$ • Human sperm survival assay (% motility compared with control, after 60 minutes exposure time to test medium): ≥ 80% • Use of Ph Eur or USP grade products if applicable

Product order codes

PVP0.2S 10% PVP in FertiCult Flushing medium (screw cap) 5x 0.2ml Flushing medium

Regulatory

(MDR, Notified Body number 2797) Canada: Health Canada License Brazil: Reaistered available upon request

Storage





9 months from date of manufacture

STERILE A Sterilized using aseptic processing techniques



FertiCult Aspiration medium

HEPES buffered cell culture medium for human oocyte pick-up and follicular flushing



Hyaluronidase in FertiCult Flushing medium Hyaluronidase solution

Product specifications

7.30-7.90 (release criteria: 7.30-7.60) No growth Mouse embryo assay^{*} \geq 80% blastocysts formed after 96h incubation Use of Ph Eur or USP grade products if applicable

Regulatory

Brazil: registered Other regions: information available upon request

Product order codes

ASPI020 ASPI100 Storage ∩<u>~+25°C</u> +2°C -/

18 months from date of manufacture Keep away from (sun)light

* 1-cell MEA



Intended use

FertiCult Aspiration medium is a ready to use formulation for oocyte pick-up and follicular flushing. FertiCult Aspiration medium contains heparin (pharmaceutical grade) and HEPES to stabilize the pH under air, no CO2 incubation is required. Product is sterilized using aseptic processing techniques.



Hyaluronidase in FertiCult Flushing medium contains derived 80 IU/ml hyaluronidase in FertiCult Flushing medium. The solution is used in the oocyte denudation process. Hyaluronidase digests the hyaluronic acid between the cumulus cells, which makes it easier to remove the cumulus mechanically. Product is sterilized using aseptic processing techniques.

Regulatory

Brazil: registered

Product specifications

7.30-7.90 (release criteria: 7.30-7.60) 270-290 mOsm/kg No growth Mouse embryo assay^{*} ≥ 80% blastocysts formed after 96h incubation Use of Ph Eur or USP grade products if applicable

Europe: CE-marked (Notified Body 0344) Other regions: information available upon request

Product order codes

Hyaluronidase in FertiCult Flushing medium 5x 1 ml Hyaluronidase in FertiCult Flushing medium 1x 10ml Storage





12 months from date of manufacture



FertiCult IVF medium

Fertilization medium

Intended use

FertiCult IVF medium is intended for washing and holding of human oocytes, performing fertilization by In Vitro Fertilization (IVF) or IntraCytoplasmatic Sperm Injection (ICSI) (until 2PN).

For professional use only



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 products if applicable

Product order codes

FECU020	FertiCult™ IVF medium	5x 20r
FECU050	FertiCult™ IVF medium	5x 50r
FECU100	FertiCult™ IVF medium	3x 100
FECU020PHR	FertiCult™ IVF medium with phenol red	5x 20r
FECU050PHR	FertiCult™ IVF medium with phenol red	5x 50r
FECU100PHR	FertiCult™ IVF medium with phenol red	3x 100
FECU020PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	5x 20r
FECU050PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	5x 50r
FECU100PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	3x 100



Regulatory Europe: CE-marked MDR (Notified Body number 2797) Brazil: registered Other regions: information available upon request Storage 12 months from date of manufacture +2°C -/ STERILE A Sterilized using aseptic processing techniques ∬**∠** +8°C Keep away from (sun)light +2°C - Store between 2-8°C (for the gentamicin

GAIN medium Cell culture media for use in human ART



Product specifications

- Chemical composition
- pH: 7.20-7.45 (37 °C, 5% 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
- One-cell mouse embryo assay (% blastocysts after 96 hours culture in test medium): ≥ 80%
- Human sperm survival assay (% motility compared with control, after 24 hours exposure to test medium at room temperature, no CO₂ incubation): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Storage

Europe: CE-marked (MDR. Notified Body Number 2797) Brazil: Reaistered Other regions: Information available upon request

Product order codes

5 x 20ml

STERILE A

Sterilized using aseptic processing techniques

∩~+8°C

Keep away from (sun)light

 \Box

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Intended use

GAIN medium is a single-step cell culture medium for use with human embryos and gametes. GAIN medium can additionally be used in all the procedures indicated below:

- For semen washing and Intra Uterine Insemination (IUI)
- For oocytes handling/incubation in preparation of, or during fertilization by In Vitro Fertilization (IVF)/ Intra Cytoplasmatic Sperm Injection (ICSI).
- For embryo culture from day 1 to expanded blastocyst stage.
- For embryo transfer (ET).

Ferticult[™] High Visa

NEW

High viscosity paraffin oil - Ready-for-use-R Density: < 0.88 a/ml MEA (1-cell to expanded blastocyst in 12 Endotoxin: < 0.1 EU/ml Peroxide Value <0.1 mEg/kg STERILE MD A symbol glossary is provided in the instruction for use

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FertiCult High Viscosity Oil

- Experience the comfort of using FertiCult High Viscosity Oil with significant higher viscosity compared to FertiCult Mineral Oil!
- Make it simple. Preparing and handling dishes will never have been that easy
- Feel more relaxed. Sometimes, manipulations outside the incubator need more time. The viscous oil layer guarantees a perfectly stable pH for at least 30 minutes!
- FertiCult Mineral Oil and FertiCult High Viscosity Oil are produced and tested according to the highest quality standards and CE marked according to the EU-MDR.

FertiCult Mineral Oil - FertiCult High Viscosity Oil

Pre-washed mineral oils



NEW

Ferticult[™] High Vi High viscosity paraffin oil - Ready-forus Density: < 0.88 g/ml MEA (1-cell to expanded blastocyst Endotoxin: < 0.1 EU/ml Peroxide Value <0.1 mEg/kg





FertiCult Mineral Oil and FertiCult High Viscosity Oil are ready to use, pre-washed mineral oils for use in In Vitro Fertilization (IVF), Intracytoplasmatic Sperm Injection (ICSI) and related Assisted Reproductive Technologies (ART).

FertiCult High Viscosity Oil is more viscous and has higher density values compared to FertiCult Mineral Oil. The difference in viscosity (and density) is reflected in the practical use of the product and is dependent on the procedures used by a certain laboratory. In this way, laboratories can choose between both types of oil in order to guarantee the most optimal culture system according to their procedures.

Product specifications

FertiCult Mineral Oil	FertiCult High Viscosity Oil	
✓	 ✓ 	
0.83-0.86g/ml	0.86-0.88g/ml	
< 60cP at 30 °C	95-140cP at 30 °C	
< 0.1EU/ml < 0.1EU/ml		
<0.1mEq/kg	< 0.1 mEq/kg	
No growth	No growth	
≥ 80% (blastocysts after 120 hours in standard mouse IVF medium covered with test item)	≥ 80% (blastocysts after 120 hours in standard mouse IVF medium covered with test item)	
×	×	
Product order codes	Product order codes	
(glass bottle) MINOIL050 FertiCult™ Mineral Oil 1 x 50ml MINOIL100 FertiCult™ Mineral Oil 1 x 100ml MINOIL500 FertiCult™ Mineral Oil 1 x 500ml	(glass bottle) HVOIL050 FertiCult™ High Viscosity Oil 1 x 50m HVOIL100 FertiCult™ High Viscosity Oil 1 x 100r HVOIL500 FertiCult™ High Viscosity Oil 1 x 500r	
	✓ O.83-0.86g/ml <60cP at 30 °C <0.1EU/ml <0.1mEq/kg No growth ≥80% (blastocysts after 120 hours in standard mouse IVF medium covered with test item) ✓ Product order codes [glass bottle) MINOIL050 FertiCult™ Mineral Oil 1 x 50ml MINOIL100 FertiCult™ Mineral Oil 1 x 100ml	

Other regions: information available upon request

Storage







MINOIL100P FertiCult™ Mineral Oil 1 x 100ml

MINOIL500P FertiCult[™] Mineral Oil 1 x 500ml

(glass bottle)			(glass bottle)	
MINOIL050	FertiCult™ Mineral Oil	1 x 50ml	HVOIL050	FertiCult™ High Vis
MINOIL100	FertiCult [™] Mineral Oil	1 x 100ml	HVOIL100	FertiCult™ High Vis
MINOIL500	FertiCult™ Mineral Oil	1 x 500ml	HVOIL500	FertiCult™ High Vis
(PETG bottle)				
MINOIL050P	FertiCult™ Mineral Oil	1 x 50ml		

SpermFreeze / SpermFreeze SSP

Medium for freezing human spermatozoa

¥ ¥ *****

Product specifications

- Chemical composition
- pH 7.20 7.90 (Release criteria: 7.20 7.60)
- Sterility test by the current Ph. Eur. 2.6.1 / USP <71>: No growth
- Endotoxins (USP <85>): < 0.25EU/ml
- Human sperm survival assay (% motility compared with control after 4 hours exposure to test medium): ≥ 80%

Product order codes

SPF SpermFreeze™

SSPOO1 SpermFreeze™ SSP 5 x 1 ml

SpermFreeze SSP

5 x 20ml

SpermFreeze

- Not MEA tested
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: CE-marked (MDR, Notified Body number 2797) USA: US FDA Cleared Canada: Health Canada License (only SpermFreeze) Brazil: Registered Other regions: Information available upon request

Storage





Intended use

SpermFreeze and SpermFreeze SSP are media for cryopreservation of human sperm for further use in Assisted Reproductive Technologies.

For professional use only



Protocol

NEW

- Fill the box with 1 liter of liquid nitrogen
- Place your sealed straws on the floater
- Opposit the floater on the liquid nitrogen
- Close the box with the lid

Product order code: SPF_BOX SpermFreeze Box (342 x 264 x 188mm)

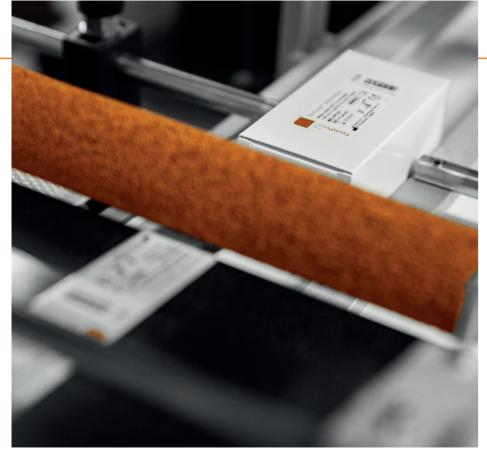
SpermFreeze Box

- Freezing tool to standardize your sperm freezing protocols
- Ideal height above liquid nitrogen level guaranteed thanks to the SpermFreeze Floater
- Robust Freezing Box with a thick wall to work safe with liquid nitrogen
- Manufactured from EPP (Expanded Poly Propylene)
- Multiple use, washable (dish washer) and sterilisable

Wait for at least 15 minutes

O Plunge the straws in the liquid nitrogen

 Store them in your nitrogen storage container for long term preservation







Intended use

VitriFreeze and VitriThaw are a set of media for vitrification and thawing of human embryos (morula till expanded blastocyst stage).

- Chemical composition • pH: 7.20-7.40 • Osmolality (mOsm/kg): - VitriFreeze Pre-incubation: 270-295 (release criteria: 270-290) - VitriThaw Thawing 1: 805-865 (release criteria: 805-850) - VitriThaw Thawing 2: 535-565 - VitriThaw Thawing 3: 405-435 - VitriThaw Thawing 4: 270-295 (release criteria: 270-290) • Sterility test by the current Ph. Eur. 2.6.1. / USP <71>: no growth • Endotoxins test by Limulus Lysate methodology (USP <85>): < 0.25 EU/ml • One-Cell Mouse embryo assay (% blastocysts stage after 96 hours following a sequential exposure to the cooling and warming media) \geq 80%

VF_KIT1 VitriFreeze™ kit VT KIT1 VitriThaw™ kit

Regulatory

VitriFreeze – VitriThaw

Kits for vitrifying and warming of human blastocysts

Product specifications

• Use of Ph Eur or USP grade products if applicable

Product order codes





FertiVit Cooling – FertiVit Warming

Kits for vitrification and warming of human oocytes and embryos up till blastocyst stage





Product specifications

- Chemical composition.
- pH: 7,20-7,50 (release criteria: 7,20-7,40).
- Osmolality (mOsm/kg):
- Pre-incubation / Warming 6: 270-295 (release criteria: 270-290)
- Warming 3: 805-865 (release criteria: 805-850)
- Warming 4: 535-565
- Warming 5: 405-435
- Sterility test by the current Ph. Eur. 2.6.1. / USP <71>: No growth
- Endotoxins test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>): < 0,25 EU/ml.
- One-Cell Mouse Embryo Assay (% blastocyst stage after 96 hours following a sequential exposure to the
- Use of Ph Eur or USP grade products if applicable.

Product order codes

FVC_KIT FertiVit[™] Cooling kit FVW KIT FertiVit[™] Warming kit

Regulatory

Brazil: registered Other regions: information available upon request



 \sum 12 months from date of manufacture 鯊 STERILE A

Keep away from (sun)light

Sterilized using aseptic processing techniques



FertiVit Cooling and FertiVit Warming are a set of media for vitrification and warming of human oocytes and embryos (zygote till blastocyst).



Intended use

VitriFreeze ES and VitriThaw ES are a set of media for vitrification and thawing of human embryos (zygote till expanded blastocyst stage).

- Chemical composition
- pH: 7.20-7.40

- VitriThaw ES Thawing medium 2: 805-865

- <71>: no growth

- applicable

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VitriFreeze ES – VitriThaw ES

Kits for vitrifying and warming of human embryos

Product specifications

- Osmolality (mOsm/kg):
- VitriThaw ES Thawing medium 4: 405-435
- VitriThaw ES Thawing medium 5: 270-295
- Sterility test by the current Ph. Eur. 2.6.1. / USP
- Endotoxins test by Limulus Lysate (LAL)
- One-cell Mouse Embryo Assay (% blastocysts
- stage after 96 hours following a sequential
- exposure to the cooling and warming media)

• Use of Ph Eur or USP grade products if

Regulatory

Europe: CE-marked (Notified Body 0344) Brazil: registered Other regions: information available

Product order codes

VF_KIT1_ES	VitriFreeze ES™ kit
VT_KIT1_ES	VitriThaw ES™ kit

Storage



Sterilized using aseptic processing techniques

12 months from date



Quality is at the basis of everything we do

Quality is a philosophy

In order to be able to live up to our and your quality standards, we have literally designed our company from the ground up around one goal: providing the best possible quality every time, all the time.

This is reflected in everything that we do:

- the concept, design and implementation of the production sites in Beernem
- the people we employ
- training, validation and evaluation of our staff
- maintenance of our production facilities
- calibration and validation of the production and testing methods
- selection and storage of raw materials used in production
- packaging materials and methods
- in-production and end product testing
- labeling and technical information
- traceability of raw materials, intermediate and finished products
- storage and handling
- shipping and delivery
- pricing policy















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