PRODUCT CATALOGUE

FertiPro

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.

bsi. ISO 13485 Medical Devices Quality Management

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.

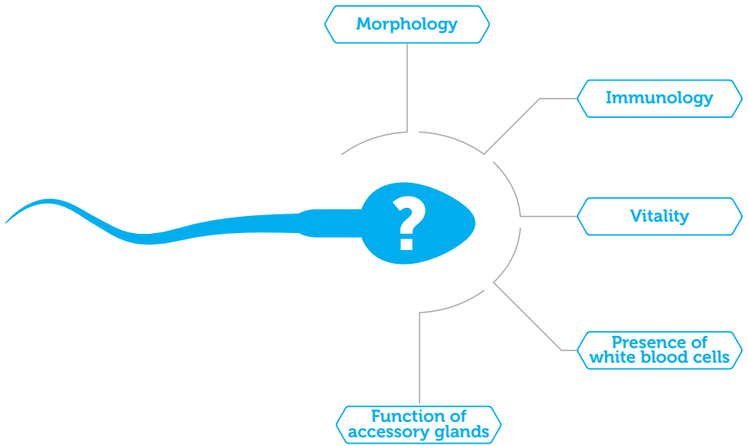
Certification & quality assurance

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.

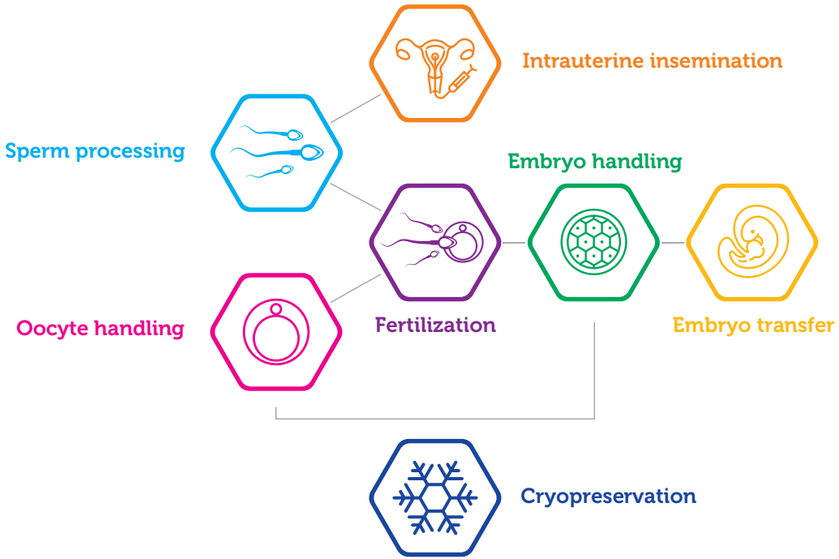
Contract manufacturing

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

Immunology

Vitality

Presence of white blood cells

Function of accessory glands

Spermac Stain

Sperm morphology stain

Regulatory

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

Storage

+25°C
+2°C
Store between 2-25°C

Stable until expiry date specified on the label (approximately 27 months)

Product order codes

SPS050	Spermac Stain	4x 50ml
SPS250	Spermac Stain	4x 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 fi xative 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).

Intended use

Spermac Stain is a qualitative, non-automated, diagnostic kit for professional use for the staining of human spermatozoa.

For professional use only

SpermMar Test IgA & IgG

Test for the detection of antisperm antibodies

General information

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. Antisperm 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.

Intended use

The SpermMar Test IgA and IgG are both semi-quantitative, 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).

For professional use only

Regulatory

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

Storage

+8°C
+2°C
Store between 2-8°C

SpermMar Test IgA: 12 months from date of manufacture
SpermMar Test IgG: 18 months from date of manufacture

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 glassware to perform the test.

VitalScreen

Sperm vitality test

Regulatory

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

Storage

+25°C
+2°C
Store between 2-25°C

24 months from date of manufacture

Product order codes

VITAL VitalScreen 200 tests

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

For professional use only

Hypo-osmotic Swelling Test

Sperm vitality test

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.

Intended use

The HOS Test is a semi-quantitative, 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).

For professional use only

Regulatory

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

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

Product order codes

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

Leucocyte staining method

Regulatory

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

Storage

+25°C
+2°C
Store between 2-25°C

12 months from date of manufacture

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.

For professional use only

Intended use

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

Fructose Test

Kit for the determination of fructose in seminal plasma/semen

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.

For professional use only

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).

Regulatory

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

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

Product order codes

FRUCTO	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/semen

Regulatory

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

Storage

+8°C
+2°C
Store between 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 alpha-glucosidase 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:

- 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).

Intended use

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

For professional use only

Assisted Reproductive Technologies: ART media

Sperm processing

Washing/swim-up

18 FertiCult Flushing medium
20 Sil-Select Plus Sperm Washing/ Insemination medium
28 GAIN medium

Density gradient separation

20 Sil-Select Plus
22 Sil-Select STOCK

Sperm processing for ICSI

23 10% PVP in FertiCult Flushing medium

Intrauterine insemination

18 FertiCult Flushing medium
20 Sil-Select Plus Sperm Washing/ Insemination medium
28 GAIN medium

Oocyte handling

Washing

18 FertiCult Flushing medium
24 FertiCult Aspiration medium

Pick-up

24 FertiCult Aspiration medium

Denudation

25 Hyaluronidase in FertiCult Flushing medium

Oocyte incubation

26 FertiCult IVF medium
28 GAIN medium

Fertilization

26 FertiCult IVF medium
28 GAIN medium
30 FertiCult Mineral Oil
31 FertiCult High Viscosity Oil

Embryo handling

Embryo washing

18 FertiCult Flushing medium

Embryo culture

28 GAIN medium

Culture overlay

29 FertiCult Mineral Oil
29 FertiCult High Viscosity Oil

Embryo transfer

18 FertiCult Flushing medium
28 GAIN medium

Cryopreservation media

Sperm cryopreservation

32 SpermFreeze
32 SpermFreeze SSP
33 SpermFreeze Box

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, intra-uterine 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).

For professional use only

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>): < 0.25EU/ml
- 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

+2°C +25°C — Store between 2-25°C

+2°C +8°C — Store between 2-8°C (for the gentamicin containing products)

18 months from date of manufacture

STERILE A — Sterilized using aseptic processing techniques

Keep away from (sun)light

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™ Flushing medium with phenol red and gentamicin	5x 20ml
FLUSH050PRG	FertiCult™ Flushing medium with phenol red and gentamicin	5x 50ml
FLUSH100PHR_G	FertiCult™ Flushing medium with phenol red and gentamicin	3x 100ml
FLUSH500PHR_G	FertiCult™ Flushing medium with phenol red and gentamicin	1x 500ml
WASH005	Sil-Select Plus™ Sperm Washing/ Insemination medium	25x 5 ml
WASH020	Sil-Select Plus™ Sperm Washing/ Insemination medium	5x 20 ml
WASH100G	Sil-Select Plus™ Sperm Washing/ Insemination medium with gentamicin	1x 100ml

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.

For professional use only

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)
  290-330 mOsm/kg (80%)
- Density: 1.0500-1.0700 (Upper layer)
  1.1050-1.1150 g/ml (Lower layer)
  1.097-1.107 g/ml (80%)
- 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): ≥ 80%
- Human sperm survival assay (% motility compared with control after 24 hours exposure to test medium): ≥ 75%
- 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 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 License – Brazil: Registered
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
SIP016	Sil-Select Plus™ Lower layer	2x 20ml
	Sil-Select Plus™ Upper layer	2x 20ml
	Sil-Select Plus™ Sperm Washing/Insemination medium	5x 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
SIP025LO	Sil-Select Plus™ Lower layer	25x 2.5ml
SIP025UP	Sil-Select Plus™ Upper layer	25x 2.5ml
SIP020LO	Sil-Select Plus™ Lower layer	5x 20ml
SIP020UP	Sil-Select Plus™ Upper layer	5x 20ml
SIP80_100	Sil-Select Plus™ 80%	1x 100ml

Single bottles can be ordered separately

Storage

18 months from date of manufacture

+8°C
+2°C
Store between 2-8°C

Keep away from (sun)light

STERILE A
Sterilized using aseptic processing techniques

Sil-Select STOCK

Sperm preparation media

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/ml
- 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): ≥ 80%
- Human sperm survival assay (% motility compared with control after 24 hours exposure to test medium): ≥ 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, Notified Body number 2797)
USA: US FDA Cleared
Canada: Health Canada License
Brazil: Registered
Other regions: Information available upon request

Storage

+8°C
+2°C
Store between 2-8°C

18 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

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).

For professional use only

10% PVP in FertiCult Flushing medium

Viscous medium for use in ICSI procedures

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.

For professional use only

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>: No growth
- One-cell mouse embryo assay (% blastocysts after 96 hours, after 10 minutes exposure time to test medium): ≥ 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
PVP1	10% PVP in FertiCult Flushing medium	1x 1ml

Regulatory

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

Storage

+8°C
+2°C
Store between 2-8°C

9 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

FertiCult Aspiration medium

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

Product specifications

- Chemical composition
- pH 7.30-7.90 (release criteria: 7.30-7.60)
- 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, after 1 hour exposure to test medium): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: CE-marked (MDD, Notified Body Number 0344)
Brazil: Registered
Other regions: Information available upon request

Storage

+25°C
+2°C
Store between 2-25°C

18 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

Product order codes

ASPI020	FertiCult Aspiration medium	5x 20ml
ASPI100	FertiCult Aspiration medium	5x 100ml

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 CO_2 incubation is required.

For professional use only

Hyaluronidase in FertiCult Flushing medium

Hyaluronidase solution

Intended use

Hyaluronidase in FertiCult Flushing medium contains bovine 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.

For professional use only

Product specifications

- Chemical composition
- pH: 7.30-7.90 (release criteria: 7.30-7.60)
- 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>): < 0.5 EU/ml
- One-cell mouse embryo assay (% blastocysts after 96 hours, after 30 minutes exposure to test medium): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: *CE-marked (MDR , Notified Body number 2797)*
Brazil: Registered
Other regions: Information available upon request

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

Product order codes

HYA001	Hyaluronidase in FertiCult Flushing medium	5x 1ml
HYA010	Hyaluronidase in FertiCult Flushing medium	1x 10ml

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% CO_2)
- 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 20ml
FECU050	FertiCult™ IVF medium	5x 50ml
FECU100	FertiCult™ IVF medium	3x 100ml
FECU020PHR	FertiCult™ IVF medium with phenol red	5x 20ml
FECU050PHR	FertiCult™ IVF medium with phenol red	5x 50ml
FECU100PHR	FertiCult™ IVF medium with phenol red	3x 100ml
FECU020PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	5x 20ml
FECU050PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	5x 50ml
FECU100PHR_G	FertiCult™ IVF medium with phenol red and gentamicin	3x 100ml

Regulatory

Europe: *CE-marked (MDR , Notified Body number 2797)*
Brazil: *registered*
Other regions: *information available upon request*

Storage

+25°C
+2°C
Store between 2-25°C

12 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

+8°C
+2°C
Store between 2-8°C (for the gentamicin containing products)

Keep away from (sun)light

GAIN medium

Cell culture media for use in human ART

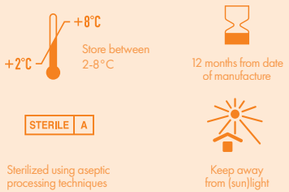
Product specifications

- Chemical composition
- pH: 7.20-7.45 (37 °C, 5% CO_2)
- 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 CO_2 incubation): ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

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

Storage



Product order codes

GAIN010	GAIN™ medium	5 x 10ml
GAIN020	GAIN™ medium	5 x 20ml

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).

For professional use only

VS

	FertiCult™ Mineral Oil	*FertiCult™ High Viscosity Oil*
Chemical composition:	✓	✓
Density:	*0.83-0.86g/ml*	*0.86-0.88g/ml*
Viscosity:	*< 60cP at 30 °C*	*95-140cP at 30 °C*
Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>):	*< 0.1 EU/ml*	*< 0.1 EU/ml*
Peroxide Value (POV):	*<0.1 mEq/kg (release criteria: <0.06 mEq/kg)*	*< 0.1 mEq/kg (release criteria: <0.06 mEq/kg)*
Sterility test by the current Ph. Eur. 2.6.1/ USP <71>:	*No growth*	*No growth*
One-cell Mouse embryo assay %:	*≥ 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)*
Use of pharmaceutical grade mineral (paraffin)oil:	✓	✓

FertiCult™ Mineral Oil and FertiCult™ High Viscosity Oil are pre-washed and ready-to-use mineral oils for use in human assisted reproductive techniques.

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.

Stricter release criteria

FertiPro is strongly committed to provide its customers the best possible quality products. In this regard, we have worked hard to validate an adapted method to measure peroxide values (POV) in FertiCult™ Mineral Oil and FertiCult™ High Viscosity Oil. The adapted method allows us to accurately detect peroxide values (POV) under the current (and commonly accepted in ART) specification of 0.1 mEq/kg. Starting from summer 2023, the release criteria for FertiCult™ Mineral Oil and FertiCult™ High Viscosity Oil will therefore be lowered to 0.06 mEq/kg.

FertiCult Mineral Oil - FertiCult High Viscosity Oil

Pre-washed mineral oils

Intended use

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.

For professional use only

Product specifications

	FertiCult Mineral Oil	*FertiCult High Viscosity Oil*
Chemical composition	✓	✓
Density:	0.83-0.86g/ml	0.86-0.88g/ml
Viscosity:	< 60cP at 30 °C	95-140cP at 30 °C
Endotoxin test by Limulus Amebocyte Lysate (LAL) methodology (USP <85>):	< 0.1EU/ml	< 0.1EU/ml
Peroxide Value (POV):	<0.1mEq/kg (release criteria: <0.06 mEq/kg)	< 0.1mEq/kg (release criteria: <0.06 mEq/kg)
Sterility test by the current Ph. Eur. 2.6.1 / USP <71>:	No growth	No growth
One-cell Mouse embryo assay %:	≥ 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)
Use of pharmaceutical grade mineral (paraffin)oil	✓	✓

Regulatory

Europe: *CE-marked* (MDR, Notified Body Number 2797)
USA: *US FDA Cleared*
Brazil: *registered*
Other regions: *information available upon request*

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

(PETG bottle)

MINOIL050P	FertiCult™ Mineral Oil	1 x 50ml
MINOIL100P	FertiCult™ Mineral Oil	1 x 100ml
MINOIL500P	FertiCult™ Mineral Oil	1 x 500ml

Product order codes

(glass bottle)

HVOIL050	FertiCult™ High Viscosity Oil	1 x 50ml
HVOIL100	FertiCult™ High Viscosity Oil	1 x 100ml
HVOIL500	FertiCult™ High Viscosity Oil	1 x 500ml

Storage

+15°C +25°C — Store between 15-25°C

18 months from date of manufacture

STERILE A — Sterilized using aseptic processing techniques

Keep away from (sun)light

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%
- 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

Product order codes

SpermFreeze

SPF05	SpermFreeze™	25 x 5ml
SPF	SpermFreeze™	5 x 20ml

SpermFreeze SSP

SSP001	SpermFreeze™ SSP	5 x 1ml

Storage

+2°C – +8°C Store between 2-8°C

18 months from date of manufacture

STERILE A Sterilized using aseptic processing techniques

Keep away from (sun)light

Product instruction video

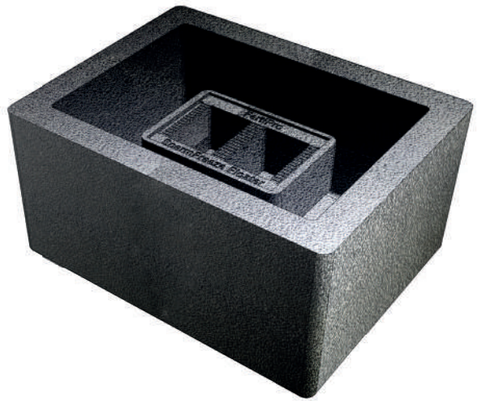
An instruction film on the use of SpermFreeze is available on our website.

Intended use

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

For professional use only

SpermFreeze Box



Intended use

The SpermFreeze Box is a box to optimize the sperm freezing procedure. It offers a standardized height of the sperm freezing straw in the liquid nitrogen vapour phase.

For professional use only

Product specifications

- Material: 100% expanded polypropylene
- Dimensions: 342 x 264 x 188 mm

Regulatory

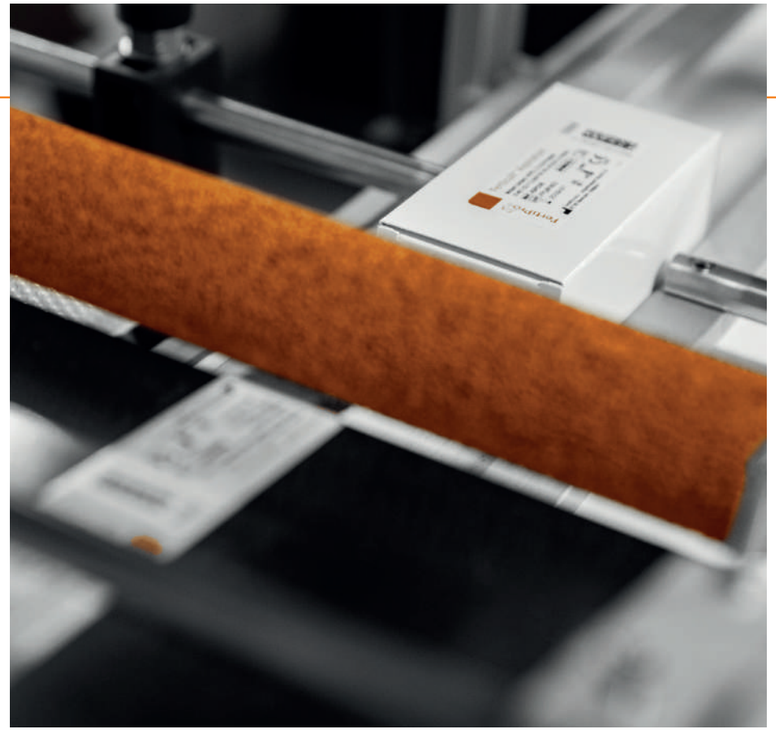
Europe: *CE-marked MDR (class I)*

Product order codes

SPF_BOX	SpermFreeze Box with SpermFreeze Floater (can hold 15 straws)

Storage

- Empty the SpermFreeze Box after each use
- The SpermFreeze Box can be used multiple times, is washable (dishwasher) and disinfectable (using disinfectants standardly used in an ART lab)



VitriFreeze – VitriThaw

Kits for vitrifying and warming of human blastocysts

Intended use

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

For professional use only

Product specifications

- 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) ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Product order codes

VF_KIT1 VitriFreeze™ kit
VT_KIT1 VitriThaw™ kit

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

Regulatory

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

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 cooling and warming media): ≥ 80%.
- Use of Ph Eur or USP grade products if applicable.

Product order codes

FVC_KIT FertiVit™ Cooling kit
FVW_KIT FertiVit™ Warming kit

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

Regulatory

Europe: *CE-marked (MDR, Notified Body number 2797)*
Brazil: *registered*
Other regions: *information available upon request*

Intended use

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

For professional use only

VitriFreeze ES – VitriThaw ES

Kits for vitrifying and warming of human embryos

Intended use

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

For professional use only

Product specifications

- Chemical composition
- pH: 7.20-7.40
- Osmolality (mOsm/kg):
  - VitriFreeze ES Pre-incubation medium: 270-295 (release criteria: 270-290)
  - VitriThaw ES Thawing medium 2: 805-865 (release criteria: 805-850)
  - VitriThaw ES Thawing medium 3: 535-565
  - VitriThaw ES Thawing medium 4: 405-435
  - VitriThaw ES Thawing medium 5: 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 (LAL) 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) ≥ 80%
- Use of Ph Eur or USP grade products if applicable

Regulatory

Europe: *CE-marked (MDR, Notified Body number 2797)*
Brazil: *registered*
Other regions: *information available upon request*

Product order codes

VF_KIT1_ES VitriFreeze ES™ kit
VT_KIT1_ES VitriThaw ES™ kit

Storage

+8°C
+2°C
Store between 2-8°C

12 months from date of manufacture

STERILE A
Sterilized using aseptic processing techniques

Keep away from (sun)light

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

Notes

Subscribe to our newsletter

- ISO 13485 certified
- MDSAP certified
- EU-MDR approved medical devices
- EU-IVDR conform diagnostics

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