

# product catalogue









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## **FertiPro**

Your partner in semen analysis and Assisted Reproductive Technologies

#### FERTIPRO

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, citric acid, 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, light paraffin oil, a ready-to-use hyaluronidase solution, PVP solution, density gradients for sperm selection and media for cryopreservation (slow freezing and vitrification) 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.

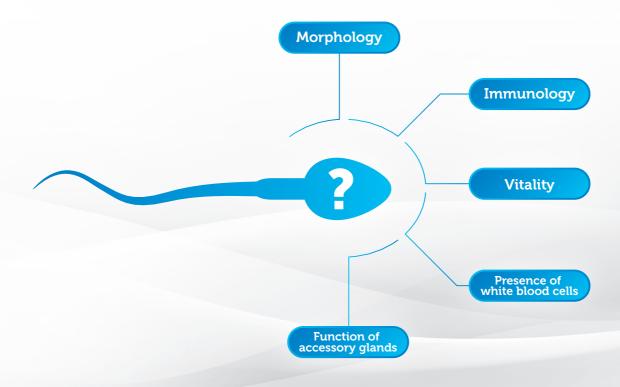
#### **CERTIFICATION & QUALITY ASSURANCE**

FertiPro is an ISO9001 and ISO13485 certified company, that participates in the MDSAP program. We have product registrations in Europe, Canada, United States of America and in increasingly more countries worldwide. A complete list can be found on our website. All of our diagnostic kits and most of our media products 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

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# **Spermac Stain**

Sperm morphology stain



#### PRODUCT

Assessment of sperm morphology is a standard procedure in semen analysis.

The Spermac Stain method is simple yet perfectly adequate for the detailed investigation of morphology of all parts of the spermatozoa. The stained smears are assessed under direct bright light and oil immersion (1000x).

#### **PRODUCT INSTRUCTION VIDEO**

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



#### STORAGE





#### REGULATORY

Europe: CE-marked – USA: registered – Canada: registered

Brazil: registered – Australia: registered

Other regions: information available upon request

#### PRODUCT ORDER CODES

SPS050 Spermac Stain – 4x 50ml SPS250 Spermac Stain – 4x 250ml

# SpermMar Test IgA & IgG

Test for the detection of anti-sperm antibodies

#### **PRODUCT**

SpermMar Test IgA and SpermMar Test IgG are rapid, easy-to-use, microscopic tests for the detection of anti-sperm antibodies in semen and serum. Anti-sperm antibodies (ASA) are produced when the blood-testis barrier is disrupted by obstruction, infection or traumatism. Immunoglobulines of the IgG class are usually present in both serum and semen, and the IgG antibodies attach to the spermatozoa. ASA of the IgA class are secreted by the accessory sex glands and are found in semen only. ASA of the IgG class may be detected in seminal plasma, but there is usually no free IgA in seminal plasma. Anti-sperm antibodies of the IgA class almost never occur without IgG antibodies. In case more than 40% of motile spermatozoa present ASA of the IgG class, complementary testing for IgA antibodies is advisable. The immunological factor reduces the probability of natural conception, and this is particularly true when ASA of the IgA class are also present.

#### PRODUCT INSTRUCTION VIDEO

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









#### STORAGE





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

#### REGULATORY

Europe: CE-marked – USA: registered – Canada: Health Canada License Brazil: registered – Australia: registered
Other regions: information available upon reguest

#### 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 \* The complete kit contains pipettes and glassware to perform the test.

SPMG\_P SpermMar Test IgG Positive Control – 50 tests SPMG\_N SpermMar Test IgG Negative Control – 50 tests

С

## **VitalScreen**

Sperm vitality test



This eosin-nigrosin staining technique is based on the principle that dead cells will take up the eosin and as a result stain red. The nigrosin provides a dark background which makes it easier to assess the slides

#### **PRODUCT INSTRUCTION VIDEO**

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





#### STORAGE





#### REGULATORY

Europe: CE-marked – USA: registered – Canada: registered

Brazil: registered – Australia: registered

Other regions: information available upon request

#### PRODUCT ORDER CODES

VITAL VitalScreen – 200 tests

# **Hypo-osmotic Swelling Test**Sperm vitality test



#### PRODUCT

The Hypo-osmotic Swelling Test is based on the principle that live spermatozoa swell due to the absorption of a hypo-osmotic solution.

The Hypo-osmotic Swelling Test is based on the test procedures described in the WHO laboratory manual for the examination and processing of human semen (2010).

#### PRODUCT INSTRUCTION VIDEO

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



#### STORAGE





#### REGULATORY

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

#### PRODUCT ORDER CODES

HOST Hypo-osmotic Swelling Test – 5x 20ml

#### LeucoScreen

Leucocyte staining method

#### PRODUCT

Almost every semen sample contains cells other than spermatozoa. These may be polygonal cells from the genital tract, but mostly they are nucleated round cells. Round cells are either spermatogenetic precursor cells (spermatids, spermatocytes, sometimes spermatogonia) or white blood cells. Amongst the latter, lymphocytes are rather uncommon, and the majority are polymorphonuclear granulocytes, characterized by granules containing the enzyme peroxidase.

LeucoScreen differentiates round cells on the basis of their peroxidase content.

The number of tests that can be performed with the LeucoScreen kit is not specified, instead, the kit has been designed for 20 days of analysis.

#### **PRODUCT INSTRUCTION VIDEO**

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





#### STORAGE





#### REGULATORY

Europe: CE-marked – USA: registered – Canada: registered

Brazil: registered – Australia: registered

Other regions: information available upon request

#### PRODUCT ORDER CODE

LEUCO LeucoScreen – 20ml

# **EpiScreen Plus**

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

#### **PRODUCT**

Semen contains neutral alpha-glucosidase secreted by the epididymis.

EpiScreen Plus is a reliable and useful kit which aids in determining the cause of azoospermia in patients with normal androgen levels in peripheral blood. Patients with a bilateral obstruction located between the epididymis and ejaculatory duct have very low alphaglucosidase activity in their seminal plasma. In contrast, patients in whom azoospermia is due to an arrest of sperm maturation, obstruction between epididymis - rete testis, or in the rete testis itself, have normal alphaglucosidase activity in seminal plasma.

An Excel sheet for the calculation of test results obtained with the EpiScreen Plus kit can be downloaded from our website.

#### **PRODUCT INSTRUCTION VIDEO**

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





#### STORAGE





24 months from date of manufacture

#### REGULATORY

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

#### PRODUCT ORDER CODE

EPI\_PLUS EpiScreen Plus – 25 tests

#### **Fructose Test**

Kit for the determination of fructose in seminal plasma

#### **PRODUCT**

The major part of the ejaculate volume, which contains fructose, is secreted by the seminal vesicles. Deficient secretion of the seminal vesicles occurs in cases of hypo-androgenism or after infection of the seminal vesicles. In these cases the ejaculate volume is lower than normal and fructose concentration is decreased. In congenital agenesis of the seminal vesicles, which is commonly associated with congenital bilateral absence of the deferential ducts (CBAVD), the patient presents with azoospermia, low ejaculate volume, acidic semen pH, and there is no fructose in the seminal plasma.

An Excel sheet for the calculation of test results obtained with the Fructose Test can be downloaded from our website.

#### PRODUCT INSTRUCTION VIDEO

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





#### STORAGE





12 months from date of manufacture

#### REGULATORY

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

#### PRODUCT ORDER CODE

FRUCTO Fructose Test - 96 tests

#### **Citric Acid Test**

Kit for the determination of citric acid in seminal plasma



Citric acid is secreted by the prostate and contributes to the acidic pH of prostatic fluid. Deficient secretion of citric acid occurs in case of infection of the prostate (prostatitis) which is usually accompanied by infection of the other accessory sex glands (epididymo-vesiculitis). The total output of citric acid per ejaculate was found to be the best marker of prostate function. It is recommended to measure citric acid concentration in all semen samples, particularly if history taking, clinical investigation, or an increased number of white blood cells in urine or semen suggest male accessory gland infection.

#### PRODUCT INSTRUCTION VIDEO

An instruction film on the use of the Citric Acid Test is available on YouTube.





#### STORAGE





12 months from date of manufacture

#### REGULATORY

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

#### PRODUCT ORDER CODE

CITRIC Citric Acid Test – 96 tests

# Assisted Reproductive Technologies: ART media



# **Sperm processing**

#### Washing/swim-up

- p. 18 FertiCult Flushing medium
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#### Density gradient separation

- p. 20 Sil-Select Plus
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#### Sperm processing for ICSI

p. 23 10% PVP in FertiCult Flushing medium



# Intrauterine insemination

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# **Oocyte handling**

#### Pick-up

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## **Embryo handling**

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#### Culture overlay

p. 30 FertiCult Mineral Oil

#### Embryo washing

p. 18 FertiCult Flushing medium



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# Cryopreservation

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#### Oocyte cryopreservation

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# FertiCult Flushing medium

HEPES buffered cell culture medium for use in human ART











#### PRODUCT

FertiCult Flushing medium is a chemically balanced salt solution (HEPES buffered) with 4 g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved), used for oocyte washing, embryo replacement, sperm injection in ICSI, sperm washing, density gradient preparation and swim-up techniques in human IVF.

FertiCult Flushing medium is available with or without phenol red and/or gentamicin.



PRODUCT SPECIFICATIONS

\* 1-cell MEA

pH (ambient air) 7.30 - 7.90 (release criteria: 7.30 - 7.60)

Osmolality 270 - 290 mOsm/kg

Sterility SAL  $10^{-3}$  Endotoxin < 0.25 EU/ml

Mouse embryo assay\* > 80% blastocysts formed after 96h incubation

Water All FertiPro media are manufactured using ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw materials are used

In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained

and the products are stored at 2-8°C

#### STORAGE







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18 months from date of manufacture

#### REGULATORY

Europe: CE-marked - Canada: Health Canada License - Other regions: information available upon request

#### PRODUCT ORDER CODES

FertiCult Flushing medium	FLUSH020 – 5x 20ml FLUSH050 – 5x 50ml FLUSH100 – 3x 100ml	FertiCult Flushing medium with phenol red and gentamicin	FLUSH020PRG – 5x 20ml FLUSH050PRG – 5x 50ml FLUSH100PHR_G – 3x 100ml
FertiCult Flushing medium with phenol red	FLUSH020PHR – 5x 20ml FLUSH050PHR – 5x 50ml FLUSH100PHR – 3x 100ml	Sil-Select Plus Sperm Washing/ Insemination medium Sil-Select Plus Sperm Washing/ Insemination medium with genta	WASH020 – 1x 20 ml  WASH100G – 1x 100 ml amicin



## Sil-Select Plus

Sperm preparation media



#### PRODUCT

Sil-Select Plus is FertiPro's in-house developed gradient system for semen preparation.
Sil-Select Plus is a solution of silane-coated silica particles in Earle's Balanced Salts Solution (EBSS) with HEPES (pH buffer) and supplemented with a small amount of HSA. Extensive tests during the design phase have shown that the product is non-cytotoxic and non-irritant with a non-significant allergenic potential. Sil-Select Plus is manufactured from raw colloidal silica, with full control over each step in the production process. Sil-Select Plus are ready-to-use dilutions of Sil-Select Stock.



#### PRODUCT SPECIFICATIONS

pH (ambient air)  7.20-7.90 7.20-7.90 7.20-7.60)  (release criteria: 7.20-7.60)  Osmolality  280-310 mOsm/kg 290-330 mOsm/kg 290-330 mOsm/kg  SAL 10-3  SAL 10-3  SAL 10-3  SAL 10-3  Endotoxin  Oensity  - 1.105-1.115 g/ml  1.097-1.107 g/ml  Sperm Survival Test  280% motility recovery after 4h exposure of spermatozoa to the test medium;  275% motility recovery after 24h exposure of spermatozoa to the test medium  Water  All FertiPro media are manufactured using ultra purified water (Ph Eur)  Ingredients  Where applicable Ph Eur or USP grade raw materials are used  Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C		SIL-SELECT PLUS UPPER LAYER	SIL-SELECT PLUS LOWER LAYER	SIL-SELECT PLUS 80%	
Osmolality 280 - 310 mOsm/kg 290 - 330 mOsm/kg 290 - 330 mOsm/kg  Sterility SAL 10 <sup>-3</sup> SAL 10 <sup>-3</sup> SAL 10 <sup>-3</sup> Endotoxin < 0.5 EU/ml < 0.5 EU/ml < 0.5 EU/ml  Density - 1.105 - 1.115 g/ml 1.097 - 1.107 g/ml  Sperm Survival Test > 80% motility recovery after 4h exposure of spermatozoa to the test medium; > 75% motility recovery after 24h exposure of spermatozoa to the test medium  Water All FertiPro media are manufactured using ultra purified water (Ph Eur)  Ingredients Where applicable Ph Eur or USP grade raw materials are used  In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	pH (ambient air)				
Sterility SAL 10 <sup>-3</sup> Endotoxin <ul> <li>&lt; 0.5 EU/ml</li> <li>&lt; 0.5 EU/ml</li> <li>&lt; 0.5 EU/ml</li> <li>&lt; 0.5 EU/ml</li> </ul> <li>Density              <ul> <li>−</li> <li>1.105-1.115 g/ml</li> <li>1.097-1.107 g/ml</li> <li>≥ 80% motility recovery after 4h exposure of spermatozoa to the test medium; ≥ 75% motility recovery after 24h exposure of spermatozoa to the test medium</li> <li>Water</li> <li>All FertiPro media are manufactured using ultra purified water (Ph Eur)</li> <li>Ingredients</li> <li>Where applicable Ph Eur or USP grade raw materials are used</li> <li>Can be used safely up to 7 days after opening, when sterile conditions are maintained</li> </ul> </li>			,		
Endotoxin < 0.5 EU/ml < 0.5 EU/ml < 0.5 EU/ml	Osmolality	280-310 mOsm/kg	290 - 330 mOsm/kg	290-330 mOsm/kg	
Density − 1.105 -1.115 g/ml 1.097 -1.107 g/ml  Sperm Survival Test ≥ 80% motility recovery after 4h exposure of spermatozoa to the test medium; ≥ 75% motility recovery after 24h exposure of spermatozoa to the test medium  Water All FertiPro media are manufactured using ultra purified water (Ph Eur)  Ingredients Where applicable Ph Eur or USP grade raw materials are used  In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	Sterility	SAL 10 <sup>-3</sup>	SAL 10 <sup>-3</sup>	SAL 10 <sup>-3</sup>	
Sperm Survival Test  ≥ 80% motility recovery after 4h exposure of spermatozoa to the test medium;  ≥ 75% motility recovery after 24h exposure of spermatozoa to the test medium  Water  All FertiPro media are manufactured using ultra purified water (Ph Eur)  Ingredients  Where applicable Ph Eur or USP grade raw materials are used  In-use stability  Can be used safely up to 7 days after opening, when sterile conditions are maintained	Endotoxin	< 0.5 EU/ml	< 0.5 EU/ml	< 0.5 EU/ml	
≥ 75% motility recovery after 24h exposure of spermatozoa to the test medium  Water All FertiPro media are manufactured using ultra purified water (Ph Eur)  Ingredients Where applicable Ph Eur or USP grade raw materials are used  In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	Density	_	1.105 - 1.115 g/ml	1.097 - 1.107 g/ml	
Water All FertiPro media are manufactured using ultra purified water (Ph Eur) Ingredients Where applicable Ph Eur or USP grade raw materials are used In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	Sperm Survival Test	> 80% motility recovery after 4h exposure of spermatozoa to the test medium;			
Ingredients Where applicable Ph Eur or USP grade raw materials are used In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained		> 75% motility recovery after 24h exposure of spermatozoa to the test medium			
In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)			
In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained	Ingredients	Where applicable Ph Eur or USP grade raw materials are used			
	In-use stability				

#### STORAGE





Keep away from (sun)light

18 months from date of manufacture

#### REGULATORY

Europe: CE-marked - Canada: Health Canada License - Other regions: information available upon request

#### PRODUCT ORDER CODES

SIP008 SIP016	Sil-Select Plus – 8 preparations* Sil-Select Plus – 16 preparations*		l-Select Plus – 2x 100ml l-Select Plus 80% – 100ml	* include bottles Sil-Select Plus Sperm Washing/Insemination medium
SIP020	Sil-Select Plus – 2x 20ml			
SIP050	Sil-Select Plus – 2x 50ml	Single bottles o	an be ordered separately.	



## Sil-Select STOCK

Sperm preparation media

#### PRODUCT

Sil-Select STOCK is an isotonic gradient for semen preparation with a density of approximately 1.12g/ml. It consists of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution). Extensive tests during the design phase have shown that the product is non-cytotoxic and non-irritant with no significant allergenic potential. Sil-Select STOCK medium is an isotonic solution that is used to prepare density gradients of varying densities (e.g. 40-80% or 45-90% dual gradient).



#### PRODUCT SPECIFICATIONS

pH (ambient air) 7.20 - 7.90 (release criteria: 7.20 - 7.60)

Osmolality 300 – 330 mOsm/kg

 Sterility
 SAL 10-3

 Endotoxin
 < 0.5EU/ml</td>

 Density
 1.115-1.125 g/ml

Sperm Survival Test > 80% motility recovery after 4h exposure of

spermatozoa to the test medium;

≥ 75% motility recovery after 24h exposure of

spermatozoa to the test medium

Water All FertiPro media are manufactured using

ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



18 months from date

#### REGULATORY

Europe: CE-marked - USA: US FDA Cleared

Canada: Health Canada License

Other regions: information available upon request

#### PRODUCT ORDER CODES

SIS100 Sil-Select STOCK – 100ml SIS500 Sil-Select STOCK – 500ml

SIS100G Sil-Select STOCK with gentamicin – 100ml



# 10% PVP in FertiCult Flushing medium

Viscous medium for use in ICSI procedures

#### **PRODUCT**

10% PVP in FertiCult Flushing medium is used in human ICSI procedures. The viscosity of the product is such that optimal slowing of the spermatozoa is obtained for easy pickup of individual cells. The PVP that is used as the source material for the product is of pharmaceutical grade (Ph Eur).



#### PRODUCT SPECIFICATIONS

\* 1-cell MEA

pH (ambient air) 7.20 - 7.90 (release criteria: 7.20 - 7.60)

Osmolality 280-340 mOsm/kg

(release criteria: 280 - 320 mOsm/kg)

Sterility SAL 10<sup>-3</sup>

Viscosity > 170cP @ 25°C Endotoxin < 1.00 EU/ml

Mouse embryo assay\* > 8

Water

 $\geq 80\%$  blastocysts formed after 96h incubation

All FertiPro media are manufactured using

ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



9 months from date of manufacture

#### REGULATORY

Europe: CE-marked – Canada: Health Canada License

Brazil: registered – Other regions: information available upon request

#### 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



# FertiCult Aspiration medium

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

#### PRODUCT

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<sub>2</sub> incubation is required.



#### PRODUCT SPECIFICATIONS

\* 1-cell MEA

pH (ambient air) 7.30 - 7.90 (release criteria: 7.30 - 7.60)

Osmolality 270 - 290 mOsm/kg

Sterility SAL 10<sup>-3</sup>
Endotoxin < 0.25 EU/ml

Mouse embryo assay\*

Water

≥ 80% blastocysts formed after 96h incubation All FertiPro media are manufactured using

ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



l8 months rom date of manufacture

#### REGULATORY

Europe: CE-marked - Brazil: registered

Other regions: information available upon request

#### PRODUCT ORDER CODES

ASPI020 FertiCult Aspiration medium – 5x 20ml ASPI050 FertiCult Aspiration medium – 5x 50ml ASPI100 FertiCult Aspiration medium – 5x 100ml



## Hyaluronidase in FertiCult Flushing medium

Hyaluronidase solution

#### **PRODUCT**

Hyaluronidase in FertiCult Flushing medium contains 80 IU/ml pharmaceutical grade 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 SPECIFICATIONS

\* 1-cell MFA

pH (ambient air) 7.30 - 7.90 (release criteria: 7.30 - 7.60)

Osmolality 270 - 290 mOsm/kg

Sterility SAL 10<sup>-3</sup> Endotoxin < 1.00 EU/ml

Mouse embryo assay\*

Water

All FertiPro media are manufactured using ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

> 80% blastocysts formed after 96h incubation

the products are stored at 2-8°C

#### STORAGE







of manufacture

#### REGULATORY

Europe: CE-marked – Other regions: information available upon request

#### PRODUCT ORDER CODES

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



## FertiCult IVF medium

Fertilization medium



#### PRODUCT

FertiCult IVF medium is a bicarbonate buffered cell culture medium for fertilization by IVF or ICSI. The composition of this medium fulfills the needs of gametes in preparation of, and during fertilization. FertiCult IVF medium contains 4g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved) and 50 IU/Liter insulin.



#### **PRODUCT SPECIFICATIONS**

\* mouse IVF performed in FertiCult IVF medium

pH (@ 37°C in 6% CO<sub>2</sub>) 720-750

Osmolality 270 - 290 mOsm/kg

Sterility SAL 10<sup>-3</sup> Endotoxin  $< 0.25 \, EU/ml$ 

Mouse embryo assay\* > 80% blastocysts formed after 96h incubation

All FertiPro media are manufactured using ultra purified water (Ph Eur) Water

Ingredients Where applicable Ph Eur or USP grade raw materials are used

Can be used safely up to 7 days after opening, when sterile conditions are maintained In-use stability

and the products are stored at 2-8°C

#### STORAGE









#### PRODUCT ORDER CODES

FertiCult IVF medium FECU020 - 5x 20ml

FECU050 - 5x 50ml FECU100 - 3x 100ml

FertiCult IVF medium FECU020PHR - 5x 20ml with phenol red

FECU050PHR - 5x 50ml FECU100PHR - 3x 100ml

with phenol red and gentamicin

FertiCult IVF medium FECU020PHR\_G - 5x 20ml FECU050PHR\_G - 5x 50ml FECU100PHR G - 3x 100ml



# GAIN medium Early Stage GAIN medium Blastocyst



Cell culture media for use in human ART





#### PRODUCT

GAIN media have historically been presented and CE-certified as a set of 2 ready to use bicarbonate buffered cell culture media for use in human ART procedures:

- GAIN medium Early Stage (ES) for gamete washing and incubation, fertilization and embryo culture till 4-cell stage;
- GAIN medium Blastocyst (BL) for culture as from 2PN or 4-cell stage till blastocyst, and for embryo transfer.

GAIN ES medium and GAIN BL medium have **exactly** the same composition and the differences are limited to the color of the flip-off cap and the product label.

GAIN medium has originally been developed as a single step medium for human embryos. FertiPro's initial marketing strategy to distinguish between ES and BL medium, has been revised because of the increasing demand for single step media and feedback from ART labs worldwide. In the near future, it is our intention to rename both media to "GAIN medium" which is suitable for gamete and embryo culture till blastocyst stage. This change will be implemented after approval by Notified Body 0344.

The media contain 3.5 g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved), gentamicin and a low concentration of phenol red.

#### PRODUCT SPECIFICATIONS

\* single step culture of mouse zygotes to blastocyst stage

pH (@37°C - 5% CO<sub>2</sub>) 7.20 - 7.45

Osmolality 270 - 290 mOsm/kg

Sterility SAL 10<sup>-3</sup> Endotoxin < 0.25EU/ml

Mouse embryo assay\* ≥ 80% blastocysts formed after 96h incubation

Water All FertiPro media are manufactured using ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw materials are used

In-use stability Can be used safely up to 7 days after opening, when sterile conditions are maintained

and the products are stored at 2-8°C

#### STORAGE







#### REGULATORY

Europe: CE-marked – Brazil: registered – Other regions: information available upon request

#### **PRODUCT ORDER CODES**

GAIN010ES GAIN medium Early Stage – 1x 10ml GAIN010BL GAIN medium Blastocyst – 1x 10ml



### FertiCult Mineral Oil

Pre-washed, light mineral oil



#### **PRODUCT**

FertiCult Mineral Oil is pre-washed, pharmaceutical grade, light paraffin oil. The oil is washed twice with ultra purified water (Ph Eur) and filtered over a 0.2 µm filter for sterilisation. FertiCult Mineral Oil is used as a culture overlay. The product functions as a temperature/gas exchange buffer, and avoids evaporation culture medium.



#### PRODUCT SPECIFICATIONS

Sterility SAL 10<sup>-3</sup>

 Density
 0.83 - 0.86 g/ml

 Viscosity
 < 30cP @ 30°C</td>

 Endotoxin
 < 0.1 EU/ml</td>

 Peroxide value
 < 0.1 mEq/kg</td>

Mouse embryo assay\*  $\geq$  80% blastocysts formed after 120h incubation

with FertiCult Mineral Oil

Water FertiCult Mineral Oil is washed with ultra purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 28 days after opening,

when sterile conditions are maintained and the products are stored at at room temperature.

#### STORAGE





Keep away from (sun)light



18 months from date

\* 1-cell MEA

#### REGULATORY

Europe: CE-marked – USA: US FDA Cleared – Brazil: registered

Other regions: information available upon request

#### PRODUCT ORDER CODES

MINOIL050 FertiCult Mineral Oil – 1x 50ml MINOIL100 FertiCult Mineral Oil – 1x 100ml MINOIL500 FertiCult Mineral Oil – 1x 500ml



## **SpermFreeze**

Medium for freezing human spermatozoa

#### PRODUCT

SpermFreeze is a single step freezing medium for use with human sperm cells. The medium is clear (does not contain any milk, egg yolk,...) and ready to use.



#### PRODUCT SPECIFICATIONS

pH (ambient air) 7.20 - 7.90 (release criteria: 7.20 - 7.60)

Sterility SAL 10<sup>-3</sup> Endotoxin < 0.25 EU/ml

Sperm survival test ≥ 80% motility recovery after 4h exposure

Water All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



18 months from date of manufacture

#### REGULATORY

Europe: CE-marked - USA: US FDA Cleared

Canada: Health Canada License

Other regions: information available upon request

#### **PRODUCT ORDER CODES**

SPF SpermFreeze – 25x 5ml SPF SpermFreeze – 5x 20ml



## SpermFreeze SSP

Medium for freezing human spermatozoa

#### **PRODUCT**

SpermFreeze SSP has a higher glycerol concentration which allows the semen to be stored in fewer freezing straws compared to the standard SpermFreeze. Importantly, the end concentration of glycerol in the sperm straws is not higher when the instructions for use are strictly followed.



#### PRODUCT SPECIFICATIONS

pH (ambient air) 7.20 - 7.90 (release criteria: 7.20 - 7.60)

Sterility SAL  $10^{-3}$  Endotoxin < 0.25 EU/ml

Sperm survival test  $\geq$  80% motility recovery after 4h exposure

Water All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



18 months from date of manufacture

#### REGULATORY

Europe: CE-marked – Other regions: information available upon request

#### PRODUCT ORDER CODE

SSP001 SpermFreeze SSP - 5x 1ml



# FertiVit Cooling FertiVit Warming

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

#### **PRODUCT**

FertiVit Cooling and FertiVit Warming kits are sets of cell culture media designed for the vitrification and warming of human oocytes and embryos from 2PN up till blastocyst stage (different protocols are described in the instructions for use). The media are optimized and validated for use with closed vitrification systems (e.g. High Security Vitrification straws from CBS). Both kits consist of 6 media, but not all media are needed for embryo vitrification.



#### PRODUCT SPECIFICATIONS

\* exposure to all media in sequence at zygote stage (1-cell MEA)

pH (ambient air) 7.20 - 7.50 (release criteria: 7.20 - 7.40)

Sterility SA1. 10<sup>-3</sup> Endotoxin < 0.25 EU/ml

Mouse embryo assay\* Water

> 80% blastocysts formed after 96h incubation All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE







#### REGULATORY

Europe: CE-marked – Other regions: information available upon request

#### **PRODUCT ORDER CODES**

FVC\_KIT FertiVit Cooling – 4 procedures FVW\_KIT FertiVit Warming - 4 procedures



## VitriFreeze ES VitriThaw ES

Kits for vitrifying and warming of human embryos

#### **PRODUCT**

VitriFreeze ES / VitriThaw ES kits are sets of cell culture media designed for the vitrification and warming of 2PN up till blastocyst stage, human embryos. The media are optimized to work with both aseptic (closed) and non-aseptic (open) vitrification devices (separate protocols). The vitrification kit consists of 4 media and the warming kit contains 5 media.



#### **PRODUCT SPECIFICATIONS**

\* exposure to all media in seguence at zygote stage (1-cell MEA)

pH (ambient air) 7.20 - 7.40SA1. 10<sup>-3</sup> Sterility Endotoxin < 0.25 EU/ml

Mouse embryo assay\*

> 80% blastocysts formed after 96h incubation All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE

Water







#### REGULATORY

Europe: CE-marked - Brazil: registered

Other regions: information available upon request

#### **PRODUCT ORDER CODES**

VF\_KIT1\_ES VitriFreeze ES – 4 procedures VT KIT1 ES VitriThaw ES – 4 procedures



# VitriFreeze VitriThaw

Kits for vitrifying and warming of human blastocysts

#### **PRODUCT**

VitriFreeze and VitriThaw kits are sets of cell culture media designed for the vitrification and warming of human blastocysts. The media are suitable for use with non-aseptic (open) vitrification devices.

The vitrification kit consists of 3 media and the warming kit contains 4 media.



#### **PRODUCT SPECIFICATIONS**

\* exposure to all media in sequence at zygote stage (1-cell MEA)

pH (ambient air) 7.20-7.40Sterility  $SAL\ 10^{-3}$ Endotoxin  $< 0.25\ EU/ml$ 

Mouse embryo assay\* Water  $\geq$  80% blastocysts formed after 96h incubation All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



12 months from date of manufacture

#### REGULATORY

Europe: CE-marked – USA: US FDA Cleared Other regions: information available upon request

#### **PRODUCT ORDER CODES**

VF\_KIT1 VitriFreeze – 4 procedures VT\_KIT1 VitriThaw – 4 procedures



# EmbryoFreeze EmbryoThaw

Medium for freezing and thawing of human embryos

#### **PRODUCT**

EmbryoFreeze and EmbryoThaw media are PBS/propanediol based cell culture media for (slow) freezing and thawing of human embryos. These media can be used with 2PN up till 4-cell stage human embryos.

The kit has been designed with a 1-step freezing and 3-step thawing protocol.



#### **PRODUCT SPECIFICATIONS**

\* exposure to all media in sequence at zygote stage (1-cell MEA)

pH (ambient air) 7.20-7.40Sterility  $SAL\ 10^{-3}$ Endotoxin  $< 0.25\ EU/ml$ 

Mouse embryo assay\*

Water

≥ 80% blastocysts formed after 96h incubation All FertiPro media are manufactured using ultra

purified water (Ph Eur)

Ingredients Where applicable Ph Eur or USP grade raw

materials are used

In-use stability Can be used safely up to 7 days after opening,

when sterile conditions are maintained and

the products are stored at 2-8°C

#### STORAGE





Keep away from (sun)light



18 months from date

#### REGULATORY

Europe: CE-marked – Other regions: information available upon request

#### PRODUCT ORDER CODES

EMF30\_P EmbryoFreeze/Thaw - 30 procedures EMF40\_T\_P EmbryoThaw - 40 procedures EMF120 F P EmbryoFreeze - 12 vials

# **Notes**

# **Notes**







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