Vitrification Freeze / Vitrification Thaw
Slow Freezing / Thaw Media / CBS - HSV /
SYMS III / Sperm Cryopreservation Media

Cryo Bio System
Groupe I.M.V. Technologies

www.cryobiosystem.com

IrvineScientific
Grow With Us™

Vit Kit® - Freeze and Vit Kit® - Thaw

Irvine Scientific's Vit Kit® - Freeze and Vit Kit® - Thaw consist of solutions optimized for vitrification and recovery of oocytes (MII stage) and embryos (zygote to blastocyst stage).

Media Composition

The composition of these solutions is based upon published methods utilizing a combination of ethylene glycol (EG) and dimethylsulfoxide (DMSO) as the permeating cryoprotectants. The basal medium for these solutions consists of Modified M199 (containing 21mM HEPES buffer) supplemented with 20% DSS (HSA and Dextran, containing 10 mg/mL protein) and 35 µg/mL gentamicin as the antibiotic.

Solution	DMSO (v/v)	EG (v/v)	Sucrose
Equilibration Solution (ES)	7.5%	7.5%	0
Vitrification Solution (VS)	15%	15%	0.5M
Thawing Solution (TS)	0%	0%	1.0M
Dilution Solution (DS)	0%	0%	0.5M
Washing Solution (WS)	0%	0%	0

Vit Kit® - Freeze Configurations

90133 - Starter

ES, 1 x 1 mL
VS, 2 x 1 mL
10 CryoTips

Vit Kit® - Thaw Configurations

90137 - SO

TS, 4 x 1 mL
DS, 1 x 1 mL
WS, 1 x 2 mL

Advantages of Irvine Scientific's Vitrification system

- Proven formulation that can be used for oocytes and all stages of embryos.
- Kits provide multiple applications and can be used on more than one patient.
- 8 weeks shelf-life after opening.
- The solutions are HEPES buffered to maintain pH during procedures performed at room temperature.
- Simple, straight forward protocols.
- Convenient configurations available with the CryoTip®, HSV straw, or with just the solutions.
- CryoTip® is an FDA approved closed freezing device.

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ASSISTED REPRODUCTIVE TECHNOLOGY

Each lot of Vit Kit Freeze and Vit Kit Thaw Kit receives a complete laboratory evaluation including mouse embryo testing, endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

Irvine Scientific's commitment to excellence is demonstrated by our products' performance and adherence to the industry's highest quality standards. We were one of the first companies in the USA to receive ISO 13485:2003 quality systems certification, the new rigorous international quality assurance standard designed specifically for Medical Devices.

Always refer to product insert for complete instructions for use.

For more information on all of our Reproductive Products,
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infocbs@imvindia.com

Embryo Freeze & Embryo Thaw Media

Embryo Freeze and Thaw Media kits consist of convenient, ready-to-use solutions designed for the cryopreservation and recovery of cleavage-stage embryos (zygote to 8-cell).

The composition of these solutions is based upon published standard propanediol and sucrose freezing (2 step) and thawing (3 step) protocols, which have proven to be the most clinically successful methods for cryopreservation and recovery of zygote to early cleavage stage human embryos, achieving similar implantation and pregnancy rates to that for transfers of fresh embryos.

Irvine Scientific has performed extensive efficacy testing on our Embryo Freeze and Thaw Media using mouse embryos and two different bioassay methods. Since standard MEA (exposure only) does not specifically emulate the intended application of these products; and as part of our ongoing efforts to enhance the sensitivity of our QC test methods, a specific Embryo Recovery Assay was developed and used to emulate the intended use of these products (Figure 1).

These solutions were also evaluated using the standard one-cell mouse embryo assay (Figure 2), typically employed as the accepted QC test method for commercially available formulas.

Results from 4 independent IVF laboratories showed that the recovery of one-cell cryopreserved mouse embryos from Irvine Scientific's Embryo Freeze and Thaw Media was equivalent to, or better than that achieved for their control cryopreservation media (in house prepared media using either propanediol / sucrose or DMSO methods) currently used in clinical practice for cryopreservation of human embryos.

Use of the Embryo Recovery Assay (with one-cell mouse embryos) is a highly sensitive performance test for the intended use of Irvine Scientific's Embryo Freeze and Thaw Media. High blastocyst development rates were obtained using the standard mouse embryo assay, which confirms the lack of toxicity of these solutions. The use of these media can achieve up to 100% recovery of cryopreserved cleavage-stage embryos.

Embryo Freeze Media Kit

Embryo Freeze Medium - F1, 2 x 10 mL
Embryo Freeze Medium - F2, 4 x 10 mL

Embryo Thaw Media Kit

Embryo Thaw Medium - T1, 2 x 10 mL
Embryo Thaw Medium - T2, 2 x 10 mL
Embryo Thaw Medium - T2, 2 x 10 mL

Features and Benefits

- Convenient ready-to-use kits consisting of two media for cryopreservation and three media for the thawing of embryos.
- Rapid protocol with just two steps to freeze and three steps to thaw.
- Each solution contains HTF medium buffered with HEPES to maintain proper pH during cryopreservation and thawing procedures at ambient temperature and atmosphere.
- Gentamicin sulfate is included in each medium as an antibiotic.
- Store at 2 - 8° C.
- Shelf life of 6 months.

Media Composition

Kit	Embryo Freeze Media		Embryo Thaw Media		
Kit Part	90116		90124		
Basal Medium and Protein	Modified HTF (containing 21mM HEPES buffer) supplemented with 12mg/mL HSA and 10µg/mL gentamicin sulfate				
Propanediol	1.5 M	1.5 M	1.0 M	0.5 M	0
Sucrose	0	0.1 M	0.2 M	0.2 M	0.2 M

Table 1. The basal medium for these solutions consist of modified HTF (with 21mM HEPES buffer to maintain pH) supplemented with 12 mg/mL human serum albumin (HSA) and gentamicin sulfate (10 µg/mL).

Mouse Embryo Recovery

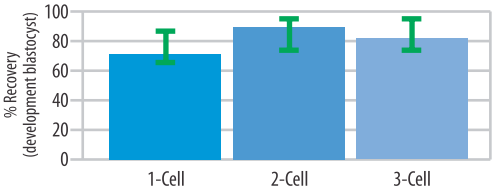

Figure 1. Fresh 1-cell, 2-cell and 8-cell mouse embryos were cryopreserved, thawed and then cultured to the blastocyst stage. The % recovery (growth to blastocyst) for each cryopreserved stage is shown. Each bar represents the average of three experiments (n=93 embryos total). A control (for the growth phase only) using fresh embryos was evaluated and shown to be 100% (data not shown).

Mouse Embryo Assay (one-cell)

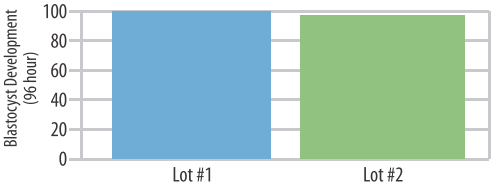

Figure 2. A standard mouse embryo assay was performed on two lots of Embryo Freeze and Thaw Media. Fresh 1-cell mouse embryos (31 for each lot) were exposed to each solution of Embryo Freeze and Thaw Media in sequence, washed and then cultured to blastocyst in HTF + BSA for 96 hours. The % blastocyst development is shown. (Development for growth medium alone was 100%).

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ASSISTED REPRODUCTIVE TECHNOLOGY

Each lot of Embryo Freeze & Embryo Thaw Media receives a complete laboratory evaluation including mouse embryo testing, endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

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Embryo Freeze Media:
90116 - 6x10 mL

Embryo Thaw Media:
90124 - 6x10 mL

Sperm Cryopreservation Media

Media containing TEST-yolk buffer (TYB) has been shown to be effective in preserving sperm when refrigerated for short intervals of time, and for long term frozen storage with the addition of glycerol.

Sperm Maintenance Medium with glycerol, but without TEST-yolk buffer, is also designed for procedures involving the cryopreservation and storage of human sperm used for IUI, IVF and other assisted reproductive procedures.

Features and Benefits

- Formulated with Irvine Scientific's WFI Grade Water.
- Chemicals used in Irvine Scientific's reproductive products meet USP and ACS standards, where available.
- All are membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3}.

Refrigeration Medium - TYB with Gentamicin
for short term storage of human sperm at 2° to 5°C.

- 20% egg yolk - from USDA certified SPF (Virus Free) laying flocks, heat inactivated at 56°C for 30 minutes.
- 10 µg/mL Gentamicin Sulfate.
- Available in 20 x 5 mL configuration.
- Store below -10°C.
- Shelf life: 2 years from date of manufacture.

Freezing Medium - TYB with Glycerol & Gentamicin
for cryoprotection when freezing human sperm.

- 20% egg yolk - from USDA certified SPF (Virus Free) laying flocks, heat inactivated at 56°C for 30 minutes.
- 12% v/v Glycerol.
- 10 µg/mL Gentamicin Sulfate.
- Available in 20 x 5 mL and 100 mL configurations.
- Store below -10°C.
- Shelf life: 2 years from date of manufacture.

Sperm Maintenance Medium
for cryoprotection when freezing human sperm.

- 28% v/v Glycerol without egg yolk.
- Available in 100 mL configuration.
- without antibiotics.
- Store below -10°C.
- 20 mg/ml (2%) Human Serum Albumin.
- Shelf life: 2 years from date of manufacture.

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ASSISTED REPRODUCTIVE TECHNOLOGY

Each lot of Sperm Cryopreservation Media receives a complete laboratory evaluation including mouse embryo testing, endotoxin level, pH, osmolality and sterility testing. All results are provided in a lot-specific Certificate of Analysis.

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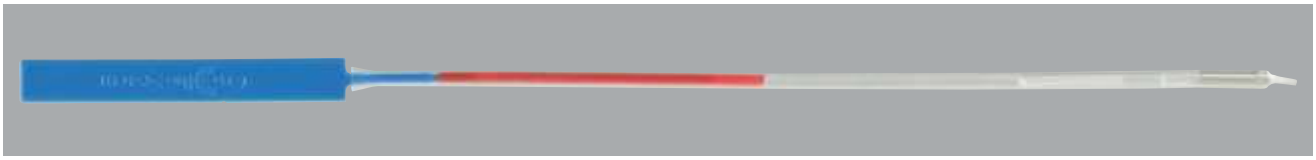
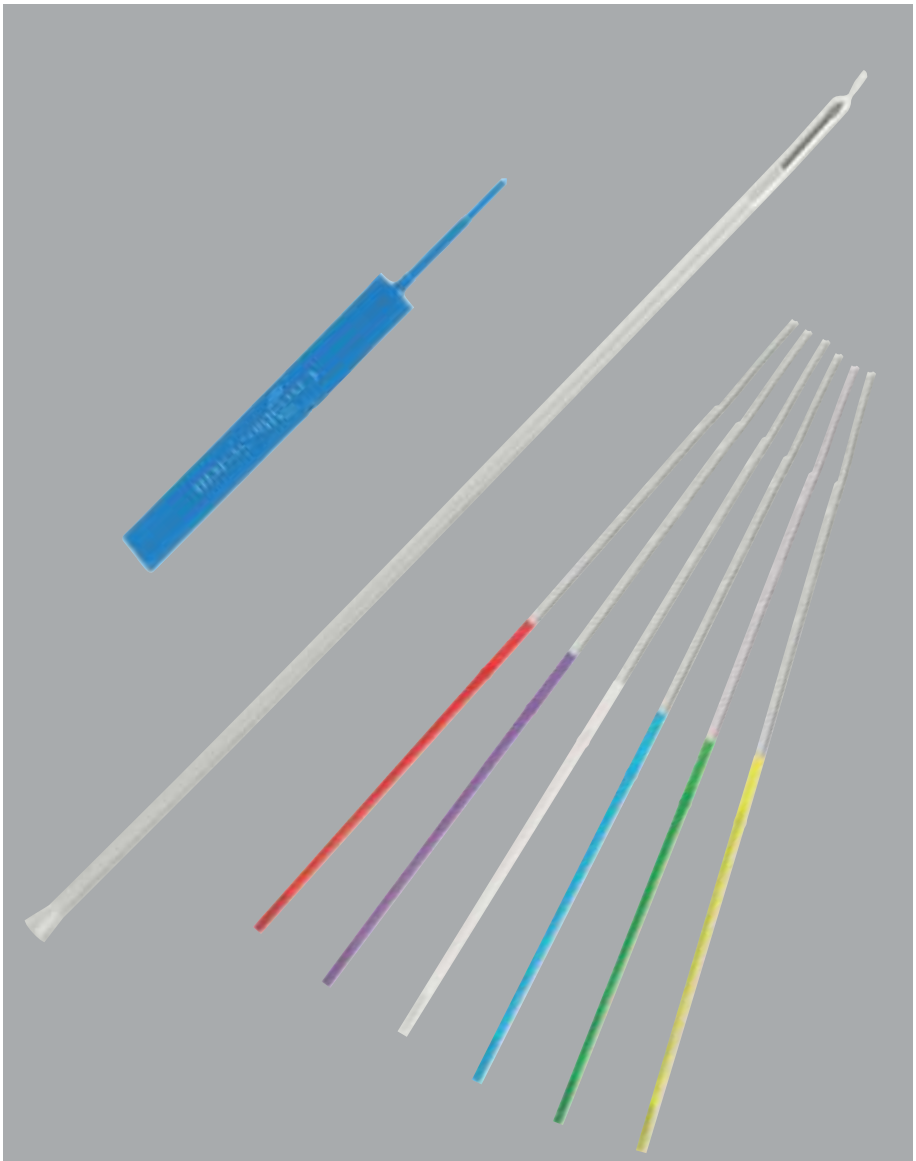
90128 - Freezing Media TYB with Glycerol & Gentamicin
90129 - Refrigeration Media TYB with Gentamicin
99176 - Sperm Maintenance Media

Vitrification

HSV High Security Vitrification Kit





Pack of 4 sterile HSV High Security Vitrification kits					
019916	red	**019917**	white	**019918**	yellow
019919	purple	**019920**	blue	**019921**	green
022406	Opening device for HSV kit				

DESCRIPTION / USE

Vitrification of oocytes and embryos.

The HSV High Security Vitrification kit is comprised of 3 parts:

- a High Security ionomeric resin straw;
- a capillary tube with a pre-formed gutter attached to a colored handling rod; and
- a blue plastic insertion device.

Sterilized by irradiation.

Packaged in a peel off blister pack (4 kits).

IDENTIFICATION

The HSV kit can be labeled using LN2 resistant labels.

FILLING AND SEALING

- Prepare the identification label (liquid nitrogen resistant) for the HSV straw and apply it approximately 20 mm (0.8 inch) from the flared end of the straw;
- Connect the end of the blue plastic insertion device to the colored end of the handling rod;
- Prepare the sample for vitrification according to laboratory protocol;
- Using a micro-pipette, carefully deposit the sample into the gutter one millimeter from the end. The drop holding the sample must be under 0.5 µL. Maximum of 2 oocytes or embryos. In this case, use a droplet by sample;
- Immediately place the pre-formed gutter with handling rod in the flared end of the straw. Push until the rectangular portion of the blue handler comes into contact with the flared end of the straw;
- Slightly pinch the straw between your thumb and finger and remove the insertion device;
- While still holding the straw in place, seal the open end using a SYMS sealer;
- Hold the straw using tweezers in the area of the handling rod;
- Quickly plunge the entire straw into liquid nitrogen vertically;
- Gently stir the straw in liquid nitrogen for a few seconds so as to avoid formation of an isolating air bubble layer around the straw.

Vitrification

STORAGE IN LIQUID NITROGEN

Cryo Bio System carries a line of accessories for storage and management of HSV kits in liquid nitrogen.

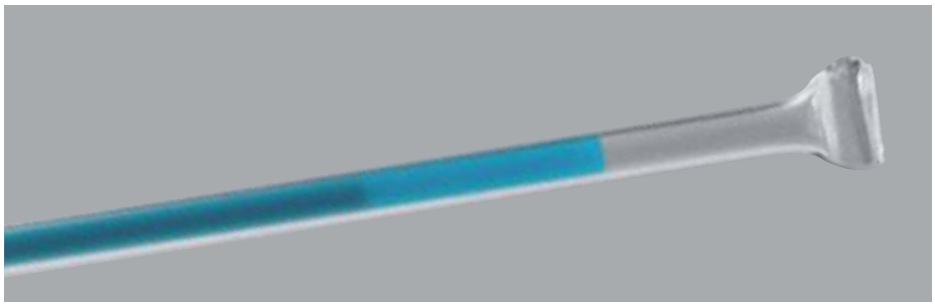
THAWING

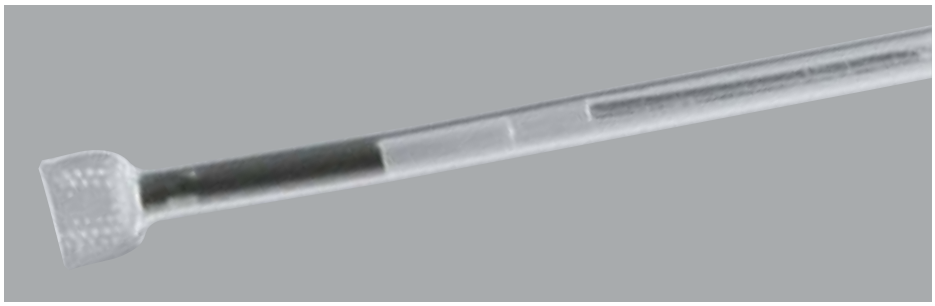
Thawing of the specimen should be done in a controlled environment, such as a laminar flow hood.

- Prepare the thawing / dilution media;
- Identify the HSV straw;
- Transfer the straw from the storage container to a transport dewar filled with liquid nitrogen;
- Lift the straw enough to expose the colored handling rod. Make sure the end with the sample remains immersed in the liquid nitrogen;
- While holding the straw, use the opening device for HSV kit to section the straw;
- Immediately (within 2 seconds), plunge the gutter into the first dilution media.

SHELF-LIFE

Three years from date of manufacture.





Opening device for HSV kit

SYMS III Unique Sealer for CBS High Security Straws & Tubes

The SYMS III sealer is a bench top unit that can be used under laminar flow hood and is using the "thermal" procedure to weld CBS High Security 0.3 mL, 0.5 mL and 2 mL straws, CBS High Security tubes as well as the HSV High Security vitrification straw.

022319 **SYMS III sealing system for CBS High Security straws and tubes**
022847 Spare Teflon strip

KEY FEATURES

- Available in 3 languages (French, English or Spanish)
- Glove compatible touch screen interface
- Easy-to-use touch screen advises user of the machines actions: heating up, ready, welding process, etc.
- Pre-set specific combination of seal temperature, time and jaw position for each CBS device
- Two sealing modes: fully automatic straw detection system or touch screen operator control
- Error management: alarm message on touch screen and audible signal
- Electronic touch screen monitors and advises on the maintenance needs of the machine
- Easy to clean and maintain

INSTRUCTIONS FOR USE

- Place the CBS High Security straw or the CBS High Security tube holder;
- Place the straw or tube on the holder and gently push forward;
- Automatic mode: As soon as the sensor detects the straw or tube in the sealing position, the sealing process starts automatically;
- Manual mode: the straw or tube is sealed when the operator presses the 'WELD' button on touch screen.

TECHNICAL SPECIFICATIONS

Setup, maintenance and downtime time are approximately 5 minutes per day.
Potentially contaminated parts of the system can be cleaned with ethanol or non-corrosive decontamination fluids.
L x W x H: 363x 276x 152mm Weight: 6 kg Power supply: 110 or 220 V / 60 or 50 Hz

CBS™ High Security Tube

A revolutionary High Security 1.2 mL sterile container for long term storage of sperm and ovarian tissue in liquid nitrogen. Safe sealed as CBS™ High Security straws.

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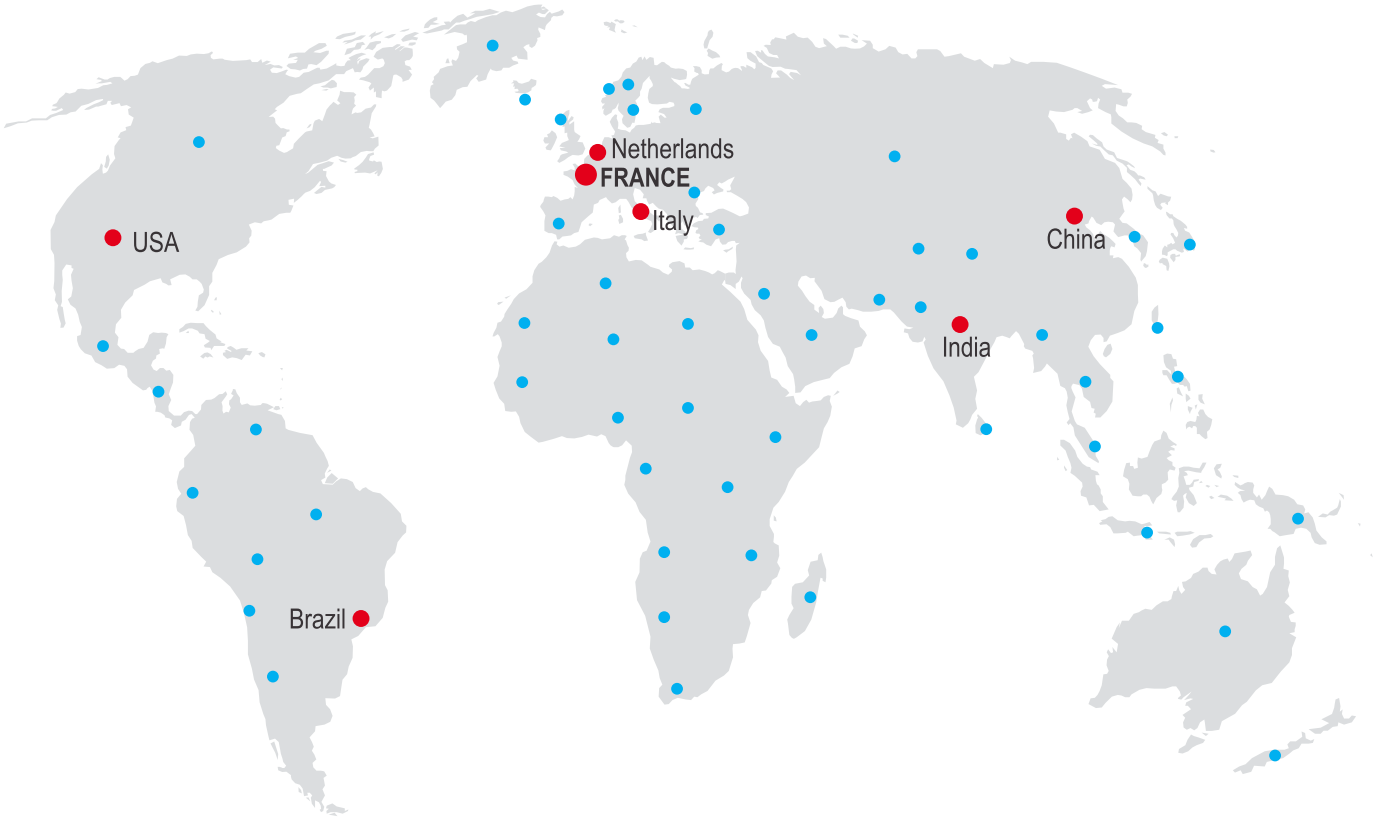

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