

0606-07

Sperm Preparation Medium

Product No.:

1069

1070

Customer Service:
Sales@coopersurgical.com



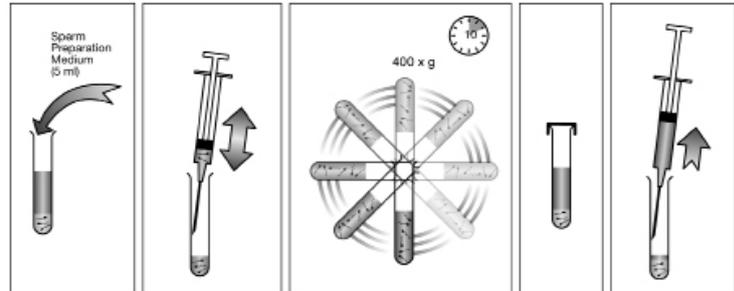
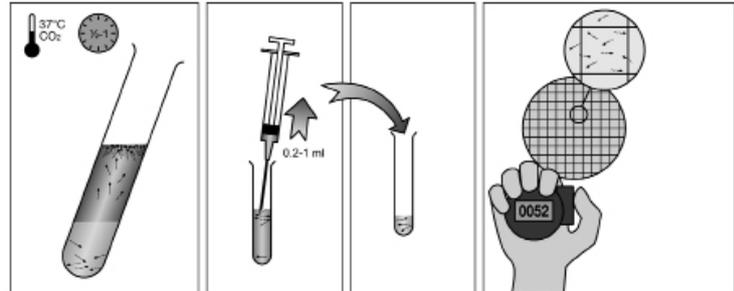
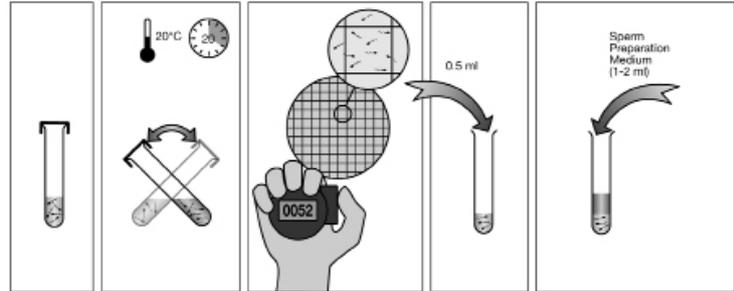
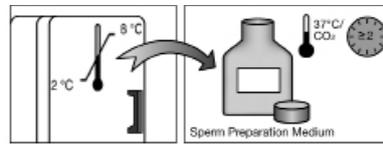
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Explanation of Symbols (in random order)

	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Discard excess (unused) media following warming.
	Indicates the medical device manufacturer
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates a medical device that has been manufactured using accepted aseptic techniques.
	Indicates a medical device that should not be used if the package has been damaged or opened.
	Indicates a medical device that needs protection from light sources.
	Indicates the need for the user to consult the instructions for use.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Indicates the temperature limits to which the medical device can be safely exposed.



Sperm Preparation Medium

Intended use

Sperm Preparation Medium is for sperm washing and isolation of motile viable spermatozoa either by the swim-up method or by the SupraSperm® density gradient method (REF 1091/1092/1097)

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

Composition

Synthetic Serum Replacement (SSR®)
Contains Recombinant Human Insulin
Human serum albumin (HSA)
Physiological salts
Glucose
Sodium pyruvate
Sodium bicarbonate
HEPES
Gentamicin sulphate 10 µg/ml
Phenol Red (not product No. 1069)

Quality control testing

Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)
Sperm Survival Test ≥ 80%

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

The products are aseptically processed and supplied sterile.

Store in original container at 2-8°C, protected from light.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Do not freeze.

The product is provided in vials intended for single use.

Excess (unused) media should be discarded.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

Instructions for use

1. Note! During the aspiration Equilibrate for a minimum of 2 hours in 5-6% CO₂ at prior to use.
2. Soon after collection the semen sample is thoroughly mixed (i.e. repeated tilting for 20 minutes at room temperature). If the sample does not liquefy, you may need to pass it through a narrow pipette and/or mix it with a small amount of Sperm Preparation Medium.
3. After the mixing process is completed, sperm concentration and motility should be assessed under the microscope to confirm the method of washing.
4. Carefully layer 0.5-1 ml of the liquefied semen in each tube underneath 1-2 ml pre-equilibrated Sperm Preparation Medium.
5. If possible, place the tubs at an angle to increase the interface between the semen sample and the Sperm Preparation Medium. This is done in order to increase recovery of the most motile spermatozoa as they migrate into the medium. Place the rack in a CO₂ environment at 37°C for 30-60 minutes depending on the semen quality. The swim-up can also be performed at room temperature, in which case the caps of the tubes are tightened to keep the pH of the medium stable.
6. After swim-up the upper 0.2-1 ml is

aspirated and assessed for sperm concentration and motility. If the sperm count is too low, the next 0.5 ml is included as well. Pool the aspirates together.

Care should be taken not to disturb the interface between the semen sample and the media.

7. If further concentration of the aspirated sperm medium is needed, add 5 ml of Sperm Preparation Medium, mix and centrifuge at 400 g for 10 minutes.
8. Aspirate the supernatant and re-suspend the remaining pellet in a suitable volume of pre-equilibrated Sperm Preparation Medium.

When the caps of the tubes are tightened the prepared semen can be kept at room temperature (20-25°C) for up to one hour prior to fertilization. It is recommended that the sperm sample be wrapped in Aluminium foil. Alternatively the unwrapped sperm sample can be stored in a 5-6% CO₂ environment at 37°C.