

PVP Medium & PVP Clinical Grade

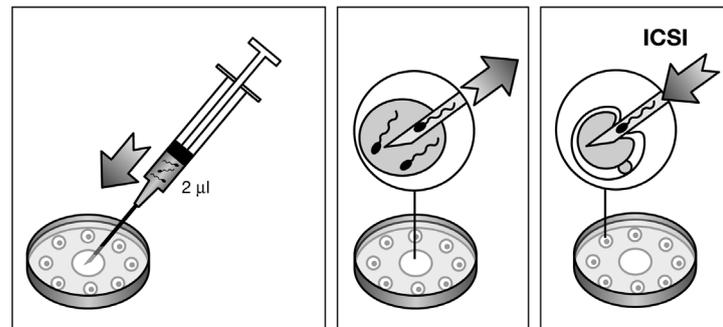
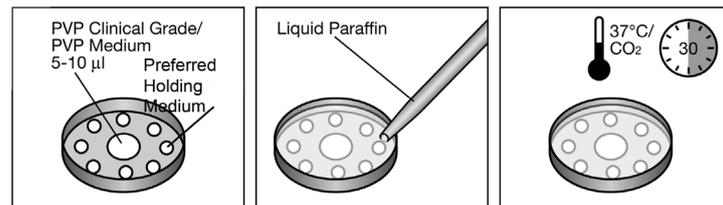
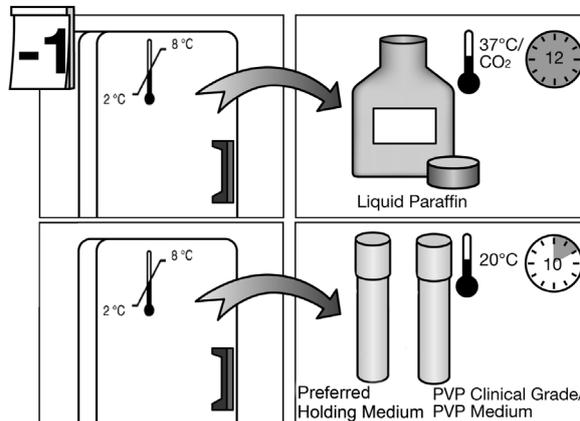
Product No.:

1089
1090

Customer Service:

E-mail: customerservice.medicult@origio.com
Tel: +45 46 79 02 02 • Fax: +45 46 79 03 02

ORIGIO a/s
Knardrupvej 2, DK-2760 Måløv, Denmark
www.origio.com
Tel: +45 46 79 02 00 • Fax: +45 46 79 03 00



PVP Medium & PVP Clinical Grade

Intended use

PVP Medium and PVP Clinical Grade are used for slowing down the movement of spermatozoa for ICSI

Composition

Pharmaceutical grade polyvinylpyrrolidone
+ Sperm Preparation Medium
Synthetic Serum Replacement (SSR®)*
(USA: ART Supplement)
* Contains Recombinant Human Insulin
Human serum albumin (HSA)
HEPES
Phenol Red (except product 1090)

Quality control testing

Sterility tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.2 EU/mL (Ph.Eur., USP)
Not Mouse Embryo Assay (MEA) tested
Sperm Survival tested
Sperm immobilization tested

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

Storage instructions and stability

Store in original container at 2-8°C, protected from light.
Do not freeze.
'Discard excess (unused) media following warming
The product is to be used within 7 days after opening.
When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

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: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Notes:

Due to the native physical characteristics of PVP, small variations in viscosity may occur between batches.
The presence of human serum albumin (HSA) may occasionally cause a small amount of precipitation in the medium.

Instructions for use

1. Remove PVP and preferred holding medium from storage at 2-8°C and leave at room temperature for 10 minutes.
2. Depending on the number of oocytes for injection, pipette a corresponding number of 10 μ L droplets of preferred holding medium onto the bottom of the ICSI dish.
3. In the middle of the same dish place a 5-10 μ L droplet of PVP Clinical Grade or PVP Medium.
4. Cover with pre-equilibrated Liquid Paraffin and place the dish in a CO₂ environment at 37°C for 30 minutes prior to use.
5. Introduce 2 μ L of prepared and washed sperm to the droplet of PVP Clinical Grade or PVP Medium. The PVP will reduce the motility of the sperm and facilitate the capture and loading of a single spermatozoon in the injection pipette.