


Instructions for the Use of **Paraffin Oil** for the Culture of Human Embryos

I. General Information

Intended Use:  **Paraffin Oil** is intended to be used as an oil overlay for droplets of medium for embryo culture or manipulation

Principle: An oil overlay is required to permit the use of microdrops for embryo culture and manipulation.

Composition: A pharmaceutical grade light paraffin oil, pre-washed with water.


Storage: Store at 15-25°C and protected from light.

Shelf Life: Eighteen months when stored at 15-25°C and protected from light.

Quality Control Specifications








	<u>Specification</u>	<u>Common Results</u>
Specific Gravity	≤0.86 g/ml	0.84-0.86
Viscosity (at 30°C)	<30 cP	18-24 cP
LAL Endotoxin	<0.5 EU/ml	<0.25 EU/ml
Sterility Test	Negative	Negative
1-cell Mouse Embryo Assay (% blastocysts at 96h of culture)	>80%	90–100%

II. Disclaimer

The procedures described below have been found to be effective for the preparation of  **Paraffin Oil** for the culture of human embryos and are offered only as examples. Every laboratory must define and optimize its own procedures.

III. Oil Preparation

Approximately 48 hours before preparing culture dishes for embryo culture:

1. Place 50 ml of  HTF (without HSA) into a 250 ml tissue culture flask and overlay with 200 ml of  **Paraffin Oil**.
2. Gas the  HTF slowly with 5:5:90 Blood Gas Mixture using a sterile serological pipette for 30 minutes. Allow the medium/oil to equilibrate for 24 hours at room temperature.
3. After 24 hours, remove the  HTF and replace with fresh  HTF.
4. Gas the  HTF slowly with 5:5:90 Blood Gas Mixture using a sterile serological pipette for 15 minutes.
5. Repeat the gassing process once per day until the  **Paraffin Oil** has been completely used.
6. Alternatively, the flask containing medium and oil can be equilibrated in an incubator. If this procedure is used, allow 72 hours of incubation to ensure that the oil warms up and become saturated with gas. Be sure not to tighten the cap of the flask on the culture medium because this will prevent gas exchange.

IV. Precautions and Warnings

1. Not to be used for injection
2. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
3. Do not use the product if:
 - the product packaging appears damaged or if the seal is broken
 - the expiry date has been exceeded
 - the product becomes discolored, cloudy, or shows evidence of particulate matter
4. Record on the label: Date Received and Date Opened
5. To avoid problems with contamination, practice aseptic techniques and discard minimal amounts of excess medium remaining in the bottle.
6. Once the bottle is opened, store the product tightly capped at 15-25°C and protected from light.