

ENGLISH

FOR THE EXAMINATION OF SPECIMEN

INDICATIONS FOR USE

IVF Labware is intended for the examination of specimen, e.g. sperm, oocytes and tissue, derived from the human body.


- **V-CENTERWELL:** For preparing, examining the cells and observing the growth of the cells under the same conditions.
- **V-CULTUREDISH:** For the cultivation of cells, searching for Cumulus-oocyte-complexes in follicular fluid and observation of cell growth under the microscope.
- **V-ICSIDISH:** For examining the quality of a sample under the microscope, e.g. sperm, enables a better image under the microscope at a higher magnification.
- **V4WELLDISH:** For the handling of gametes and observation of the cell growth.

PRODUCT DESCRIPTION

IVF Labware are ready-to-use plastic disposables.

PRODUCT SPECIFICATIONS

- Material:
 - V-CENTERWELL: Polystyrene.
 - V-CULTUREDISH: Polystyrene.
 - V-ICSIDISH: Polystyrene.
 - V4WELLDISH: Polystyrene.
- Sterility: sterile (SAL 10⁴)
- Endotoxins: < 20 EU/device
- MEA 1-Cell to expanded blastocyst in 96h: ≥80%
- Human Sperm Survival Assay (HSSA): ≥ 70 %
- A certificate of analysis and MSDS are available upon request.

 Sterilized using irradiation.

CONTRAINDICATION

No known contraindication.

WARNINGS

- Only for intended use.
- Do not use after expiry date.
- Do not use if package is damaged.
- Not sterile after opening.
- Do not re-sterilize.
- Do not reuse.
- Multiple use may lead to in cross-contamination.

PRECAUTIONS

- **R** Only Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- VITROMED recommends handling under aseptic conditions.
- The products may only be disposed of in accordance with the applicable regulations for waste products.

INSTRUCTIONS FOR USE

IVF Labware should only be used for its intended purpose by staff trained with the procedure.

V-CENTERWELL

1. Fill the center well and the outer chamber with equilibrated media according to your protocol. For the center well compartment, the recommended volume is 1 mL when used with oil, otherwise 2 mL. For the outer well compartment, the recommended volume is 2 mL when used with oil, otherwise 4 mL.
2. Dispose after use by appropriate measures.

V-CULTUREDISH:

1. For small volume cell culturing use V-CULTUREDISH-35, for large volume cell culturing V-CULTUREDISH-90, in case of droplet culture place small droplets (20-50 µL) on the bottom of the dish.
2. Overlay the drops with oil.
3. VITROMED recommends preincubating the medium and Oil when working with CO₂ dependent media.
4. Place the cells into the culture medium.
5. Incubate the cells according to your protocol
6. Dispose after use by appropriate measures.

V-ICSIDISH:

1. Place small droplets on the bottom of the dish. Recommended volume per drop is 5 – 50 µL depending on the intended use.
2. Overlay the drops with oil. The recommended volume is 5 mL.
3. Place the cells to examine into the droplet and examine them e.g. with a microscope.
4. Dispose after use by appropriate measures.

V4WELLDISH:

1. To culture the cells, fill the wells with medium and place the dish in the incubator or heating unit before use.
2. The recommended volume of medium per well is 0.5 mL in combination with oil, otherwise 1.2 mL. VITROMED recommends the use of oil.
3. Dispose after use by appropriate measures.















STORAGE INSTRUCTIONS AND STABILITY

- Store at room temperature.
- Keep away from sunlight and heat.
- Keep dry.

FEEDBACK AND OBLIGATION TO INFORM


Thank you for purchasing our product. If you have any suggestions for us to improve our products, please send them to qc@vitromed.com. Report any serious incidents that have occurred with the product immediately by email to qc@vitromed.com.

SYMBOL GLOSSARY (ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements)

Symbol (reference number)	Title of symbol
 (5.1.1)	Manufacturer
 (5.1.4)	Use-by date
 (5.1.5)	Batch code
 (5.1.6)	Catalog number
 (5.2.4)	Sterilized using irradiation
 (5.2.6)	Do not re-sterilize
 (5.2.8)	Do not use if package is damaged
 (5.2.11)	Single sterile barrier system
 (5.2.14)	Single sterile barrier system with protective packaging outside
 (5.3.1)	Fragile, handle with care
 (5.3.2)	Keep away from sunlight
 (5.4.2)	Do not reuse
 (5.4.3)	Consult instructions for use
 (5.5.1)	In Vitro Diagnostic Medical Device



Directive 98/79/EC on *in vitro* diagnostic medical devices

VITLabware	
Piece per unit	
V-CENTERWELL, 300 x 1	V-CWD-60
V-CULTUREDISH-60, 300 x 1	V-CTD-60
V-CULTUREDISH-90, 300 x 1	V-CTD-90
V-CULTUREDISH-35, 300 x 1	V-CTD-35
V-ICSIDISH-50, 300 x 1	V-ICD-50
V-4WELLDISH, 200 x 1	V-4WD



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