

CAREFULLY READ THE INSTRUCTIONS BEFORE ATTEMPTING TO USE THE DEVICE

INTENDED PURPOSE

The **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) in combination with the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054) is an in vitro diagnostic medical device intended for the collection, preservation, and transport of embryonic biopsy samples (trophectoderm cells) from patients being investigated for suspected embryonic genetic conditions. The collected biopsy samples are meant for subsequent analysis using Preimplantation Genetic Testing. This device is intended to be used as part of a diagnostic workflow with the PGT processes, aiding in identifying viable embryos for implantation.

The trophectoderm samples obtained can be used for automatic or manual specimen processing. The product is intended for use by IVF laboratory professionals.

The main performance characteristics of the **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) are:

- Maintain the integrity of the collected samples.
- Maintain the required conditions for sample preservation during transport.
- Facilitate aseptic handling to prevent contamination of the embryonic biopsy samples during collection, preservation and transport.

TEST PRINCIPLE

When used in conjunction with the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054), the **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) serves as both a homeostatic medium and a system of physical support, carefully preserving the integrity of embryo biopsy specimens during transit. In the face of outside disturbances.

PRODUCT DESCRIPTION

The **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) is composed of 6 units of 1,5 ml tubes filled with 0,5 ml of washing buffer each.

Any serious incident occurs in relation to the device shall be reported to Juno Genetics España S.L. and/or the competent authority of the Member State in which the user is established

MATERIALS REQUIRED BUT NOT PROVIDED

- **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054, Juno Genetics España S.L.).
- Micropipettes for washing biopsied cells.
- Sterile petri dishes (recommended to open a new pack).
- Permanent marker pen (preferably black).
- Portable Fridge and pack coolers for sample shipping.
- Lab Gloves.

STORAGE

Store the kit in a refrigerator (4-8°C). Avoid exposure to direct sunlight.

SAFETY INFORMATION AND WARNINGS

1. Wear gloves and avoid contamination of tubes at all times.
2. Do not use **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361), after the indicated expiry date.
3. Check each individual tube for damage before use and do not use if packaging is damaged or leakage is detected.
4. Biological specimens must be handled in compliance with the applicable hygiene and safety regulations.
5. Read the material safety data sheet for more information.

Other requirements:

- Controlled laboratory environment.
- Embryologist trained in handling biopsy specimens' in vitro fertilization (IVF) clinics.

PREPARATORY HANDLING OF THE DEVICE BEFORE ITS USE

Shake vigorously, or vortex, the vials with the washing medium before use. If precipitates are observed after this operation, discard the washing medium.

RECOMMENDATIONS FOR USE

- Discard leftover medium in pipette tips when changing embryos.
- Do not mix different batches of washing media within the group of the biopsied embryos that belong to the same case.
- Leftover amounts of **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) in a vial can be reused on other embryos/cases and different days. Always check that remaining washing buffer is properly stored (4-8°C) until next use, no contamination with external biological material is ensured.
- Do no refill vials with the leftover from other vials, even when they are from the same batch.

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PROCEDURE

1. Open the kit containing the PCR vessels in the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054).
2. Place the PCR vessels in an appropriate stand for 0,2 mL tubes.
3. Place the trophectoderm cell sample, with the provided **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) into the PCR vessel. Make sure that the vessel is not filled above the nominal volume (2 µL or quantity required by the performed method).
4. Close the PCR tube and add a unique ID to the tube that allows uniquely link the sample with the case.
5. Centrifuge the tubes to collect the drop of buffer containing the biopsy at the bottom of the tube and return them to the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054), gently inserting them into the foam holder holes provided in the kit case.
6. Identify the samples to which the case belongs by inserting the identification card on the top flap of the outside of the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054).
7. In case the collected sample is not going to be shipped immediately preserve the samples inside the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054) refrigerated (4-8 °C). For longer periods the samples can be stored in a freezer (-20°C).
8. For shipping, put the **EMBRYO BIOPSY KIT** (ref. FL1026; ref. FL1054) within a portable fridge along with coolers.

KEY FOR SYMBOLS AND LABELS



Manufacturer



Batch code



Use by-date



Catalogue number



Do not use if package is damaged and consult instructions for use



Keep away from sunlight



Indicates the total number of tests that can be performed with the medical device



Consult instructions for use



In vitro diagnostic device



CE mark

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BASIC MANUFACTURER CONTACT DETAILS

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Thank you
for choosing Juno Genetics.