

CAREFULLY READ THE INSTRUCTIONS BEFORE ATTEMPTING TO USE THE DEVICE

### INTENDED PURPOSE

The **EMBRYO BIOPSY KIT** (ref. FL1026; FL1054) in combination with the **EMBRYO BIOPSY WASH BUFFER** (ref. RE1361) 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 (PGT). 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 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 KIT** (ref. FL1026; FL1054) 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.
- Proper sealing mechanisms to prevent leaks and ensure that the samples are securely contained during transport.
- Allow for accurate sample tracking and traceability.
- Ensure compatibility with common laboratory equipment.
- Packaging durable enough to withstand the rigors of transportation, protecting the samples from physical damage or environmental factors.

### TEST PRINCIPLE

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

### PRODUCT DESCRIPTION

The **EMBRYO BIOPSY KIT** (ref. FL1026; FL1054) consists of polypropylene PCR tubes. These tubes are autoclavable, certified RNase, DNase, endotoxin free, DNA and PCR Inhibitor free. They are prepared to minimize fluid loss through evaporation. They are commonly used in PCR applications and are designed to securely contain reaction mixtures.

The **EMBRYO BIOPSY KIT** (ref. FL1026; FL1054) is composed of 10 tubes of 0,2 ml each (ref. FL1026) or 100 tubes of 0,2 ml each (ref. FL1054) in plastic bags and sealed under aseptic conditions.

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 WASH BUFFER** (ref. RE1361, 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 at room temperature (15-25 °C) prior to use.  
Avoid exposure to direct sunlight

### SAFETY INFORMATION AND WARNINGS

1. Wear gloves and avoid contamination of PCR tubes at all times.
2. Do not use **EMBRYO BIOPSY KIT** (ref. FL1026; FL1054) after the indicated expiry date.
3. Check each individual tube for damage before use and do not use if packaging is damaged.
4. Biological specimens must be handled in compliance with the applicable hygiene and safety regulations.
5. Check that data written with markers is not easily erased when handling the tube.
6. The PCR vessels are intended for single use. After use, the vessels must be disposed of in accordance with applicable regulations. There is a risk of contamination if reused.

#### Other requirements:

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

### RECOMMENDATIONS FOR USE

In order to avoid any contamination of the sample by exogenous DNA, follow these recommendations.

- a) Do not handle the tubes without wearing laboratory gloves.
- b) Do not leave the tubes on properly sanitized and disinfected surfaces.
- c) In the case of using any object or equipment for opening or closing, ensure that they are adequately sanitized and disinfected.
- d) Once the sample has been introduced into the tube, close it immediately using the cap included in the tube.

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### PROCEDURE

1. Open the kit containing the PCR vessels in the **EMBRYO BIOPSY KIT** (ref. FL1026; 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  $\mu$ L 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; 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; FL1054).
7. In case the collected sample is not going to be shipped immediately preserve the samples inside the **EMBRYO BIOPSY KIT** (ref. FL1026; 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; FL1054) box 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



Single Use



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.