MEDICOVER GENETICS

Amfira® PGT

SAMPLE COLLECTION AND TRANSPORT KIT

INSTRUCTIONS FOR USE

The Amfira sample collection and transport kit is intended for the collection, transportation and storage of samples for preimplantation genetic testing.

PRECAUTIONS

- For In Vitro Diagnostic use.
- Rack containing 16 biopsy tubes is per patient and for single use only.
- Store kits at room temperature (15°C to 25°C). Properly stored kits are stable through the expiration date.
- Do not use expired kits.
- The biopsy samples collected must be stored at -20°C until dispatch.

PRODUCT CONTENTS

THIS SHIPMENT CONTAINS:

This kit contains:



One (1) rack with 16 biopsy tubes
One (1) vial of DPBS buffer



The following packaging materials:

i. One (1) sealable biohazard specimen bag
ii. Two (2) sealable bags, one for the DPBS buffer and one for the rack and relevant documentation specified below.
iii. One (1) safety seal sticker



The following documentation:

i. One (1) barcode card (35 barcode labels)
ii. Sample Information Form (SIF)
iii. Patient Informed Consent
iv. Worksheet
v. One (1) Labeling Instructions Diagram

+ INTERNATIONAL SHIPPING BOX CONTAINS:



The following packaging and documentation for international samples only:

i. One (1) polystyrene box
ii. One (1) packaging label (UN3373)
iii. Eight (8) ice packs that should be placed in the freezer (at -20°C) upon receipt of the box, for a minimum of 24 hours before ready for use.

Please see the instructions for international shipments on the 'Important' section below

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SAMPLE COLLECTION INSTRUCTIONS

1. Complete the SIF.
2. Write the patient's full name on the barcode labels and affix on the rack, worksheet and SIF (see Labeling Instructions' document).
3. Add 2.5µL of DPBS buffer to all tubes that will be used for the biopsy.
4. Proceed with the embryo biopsy and tubing. If you are using a blank, add 1-2 µL of the wash buffer used for the biopsy to the blank tube.
5. Each tube must be labeled either with a sample label (eg S1) or with a blank label (eg. B).
6. Close the rack containing the collected samples and secure the rack with the provided safety seal sticker. Place the rack in the biohazard bag and seal tightly.
7. Fill in the worksheet and affix the Worksheet Label (WRK) on the upper right corner. Add the labels corresponding to each sample on the table e.g. For the row that the information of Embryo 1 biopsy (labeled S1) is written, add the barcode W1).
8. Documents must be placed in a separate sealable bag.
9. Store rack containing the biopsies at -20°C until dispatch.
10. Follow the domestic or international shipping instructions which are specified on the next section. Please contact logistics.cy@medicover.com for shipping instructions and support.
11. Return to: 31 Neas Engomis Str, 2409 Engomi, Nicosia, Cyprus.

IMPORTANT

- Please follow these instructions for labeling, blood collection, and transport carefully.
- Verify that all patient identifiers are correct and fulfill requirements before packaging and transport.
- Each biopsy rack must be accompanied with its documentations.
- For **domestic shipments**, please follow the instructions on this document and when the biopsy is ready for pickup, contact us at +(357) 22 266 888.
- For **international shipments**, please follow the instructions on this document as well as the following:
  1. Open the shipping box and remove the icepacks. Freeze the icepacks until ready for use.
  2. When the biopsy samples are ready to be sent, place one frozen icepack at the bottom of the shipping box. Place the rack with the biopsy samples above the icepack, and add another icepack on top of the rack. Place the sealable bag containing the patient's documentation in the box.
  3. Securely close the shipping box. Affix the packaging label (UN3373) on the outside of the shipping box, along with the transport information label. For questions or support, please contact info.genetics@medicover.com.

SUPPORT AND ORDERING INFORMATION

For assistance or to order additional kits, please call +(357) 222 66 888 or email info.genetics@medicover.com.
Additional information is available online at www.medicover-genetics.com.