

SAMPLE COLLECTION AND TRANSPORT KIT

INSTRUCTIONS FOR USE

The VERAgene non-invasive prenatal test sample collection and transport kit is intended for the collection, transportation and storage of samples for non-invasive prenatal testing.

PRECAUTIONS

- For In Vitro Diagnostic use.
- Blood collection tube and Buccal Swab collection device are for single use only.
- Store kits and gel packs at room temperature (15°C to 25°C). Properly stored kits are stable through the expiration date.
- Do not use expired kits.
- Do not freeze collected specimens.
- Take precautionary measures to ensure proper handling of glass tube to prevent breakage.
- Avoid potential biohazard exposure during blood collection following local and national regulations.

PRODUCT CONTENTS

This kit contains:



One (1) sterile Streck Cell-Free DNA BCT CE blood collection tube.
One (1) Buccal Swab collection device.



The following packaging materials:

- One (1) absorbent sleeve.
- Two (2) sealable biohazard specimen bags.
- One (1) gel pack.
- One (1) silver foil protective bubble wrap envelope.
- One (1) safety seal sticker.



The following documentation:

- One (1) barcode card (3 barcode labels).
- Sample Information Form (SIF).
- Informed Consent.

SAMPLE COLLECTION INSTRUCTIONS

1. Complete the SIF.
2. Write the patient's (pregnant woman) full name on 2 barcode labels (BCT, SIF) and affix to the blood collection tube (BCT) and on the SIF.
3. Write the biological father's name on the buccal swab (BS) barcode label and affix to the buccal swab device.
4. Collect the blood sample from the patient (pregnant woman).
 - a. Collect peripheral blood specimen by venipuncture avoiding backflow using the following precautions:
 - i. During the collection procedure, keep the patient's arm in a downward position.
 - ii. Hold the tube to ensure the stopper is in the uppermost position so that during sample collection the tube contents do not come into contact with the stopper or the end of the needle.
 - iii. Release the tourniquet within 2 minutes of application or once blood starts to flow.

- b. Collect 10 mL of peripheral blood in the tube.
- c. Mix the tube by inverting 180 degrees 10 times.
- d. Place the blood collection tube inside the absorbent sleeve.
- e. Place the sleeve inside the biohazard labeled bag and seal tightly.
5. Collect the buccal swab sample from the biological father.
 - a. Using gloves open the bag and remove the plastic tube.
 - b. To facilitate opening the tube cap, hold the swab by the plastic tube with one hand and with your thumb press the top of the white cap.
 - c. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface.
 - d. Holding the grip, insert the swab into the mouth onto the tongue and moisten it with saliva for ten seconds.
 - e. Move the swab to one side of the mouth (upper and lower) and forcefully rub it between the cheek and the gum for ten seconds. Using the other hand, exercise light pressure on the cheek during collection in order to increase the friction during rubbing.
 - f. Repeat step e on the opposite side of the mouth (upper and lower).
 - g. Once you have collected the sample, put the swab back into the plastic tube and securely close it.
 - h. Place the sample into the biohazard labeled bag and seal tightly.
6. Fold the gel pack over the biohazard specimen bags.
7. Place the contents (biohazard bags and gel pack) inside the silver protective bubble wrap envelope and seal tightly.
8. Place the silver protective envelope inside the transport box.
9. Seal the transport box with the provided safety seal sticker.

TRANSPORT

- Arrange for kit transport ensuring samples arrive at Medicover Genetics within 8 days.
- The kit can be sent at room temperature.
- Return to: 31 Neas Engomis Str, 2409 Engomi, Nicosia, Cyprus.

For more info contact Logistics department at logistics.cy@medicover.com.

IMPORTANT

- Buccal Swab sample must be collected immediately after opening the package.
- Do not force or excessively press or bend the swab when taking the sample from the patient, as this may result in accidental breakage of the shaft.
- The donor must not smoke, eat, drink (except water), brush their teeth, or chew gum **1 hour** before the sample is taken.
- Please follow these instructions for labeling, sample collection, and transport carefully.
- Verify that all patient identifiers are correct and fulfill requirements before packaging and transport.

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