

# **Instructions For Use (IFU)**

B Buccal swab sample collection for genetic testing



# SAMPLE COLLECTION AND TRANSPORT KIT

# **INSTRUCTIONS FOR USE**

The sample collection and transport kits are intended for the collection, transportation and storage of samples for genetic testing as indicated by the selected test.

#### **PRECAUTIONS**

- For In Vitro Diagnostic use.
- Buccal swab collection devices are per person 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.
- Do not freeze collected specimens.

#### TRANSPORT

- The kits can be shipped 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 patient must not smoke, eat, drink (except water), brush their teeth, or chew gum within 30 minutes of sample collection.
- 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.

# **INSTRUCTIONS FOR USE PER PRODUCT**

- Evartia
- Family Analysis
- PreSENTIA
- Ventrilia
- Adventia
- Buccal Swab Collection Kit (generic kit)
- Oreana
- Rodinia

#### • Postnatal Whole Exome Sequencing (WES)

• Postnatal Whole Genome Sequencing (WGS)

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# THE FOLLOWING SECTION IS APPLICABLE FOR THESE PRODUCTS:

- Evartia
- Family Analysis
- PreSENTIA
- Ventrilia

### **PRODUCT CONTENTS**



#### **COLLECTION DEVICE**

i. One (1) buccal swab collection device.





#### DOCUMENTATION

- i. One (1) barcode card with two (2) barcode labels.
- ii. Sample Information Form (SIF) available via QR code on bubble envelope.
- iii. Informed Consent available on the SIF.

# SAMPLE COLLECTION INSTRUCTIONS

- 1. Complete the SIF. A signed, paper copy of the completed SIF should always be sent along with the sample.
- 2. Write the patient's full name on the barcode label ending in BS and affix it on the buccal swab collection device. Add the other barcode label on the SIF.
- 3. Using gloves, open the bag and remove the buccal swab collection device.
- 4. 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.
- 5. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface.
- 6. Holding the grip, insert the swab into the mouth onto the tongue and moisten it with saliva for ten seconds.
- 7. 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.
- 8. Repeat step 7 on the opposite side of the mouth (upper and lower).
- 9. Once you have taken the sample, put the swab back into the plastic tube and close it securely.
- 10. Place the sample into the sealable biohazard specimen bag and seal it tightly.
- 11. Place the sealed bag inside the bubble envelope.
- 12. Remove the protective cover from the adhesive strip and seal the bubble envelope.

## THE FOLLOWING SECTION IS APPLICABLE FOR THESE PRODUCTS:

- Adventia
- Buccal Swab Collection Kit (generic kit)
- Oreana
- Rodinia

### **PRODUCT CONTENTS**



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i. Two (2) buccal swab collection devices.

<b>PACKAGING MATERIALS</b>				
i.	One (1) sealable biohazard			
	specimen bag.			

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#### DOCUMENTATION

- i. One (1) barcode card with three (3) barcode labels.
- ii. Sample Information Form (SIF) available via QR code on bubble envelope.
- iii. Informed Consent available on the SIF.

### SAMPLE COLLECTION INSTRUCTIONS

- 1. Complete the SIF. A signed, paper copy of the completed SIF should always be sent along with the sample.
- 2. Write the patient's full name on the barcode labels ending in BS1 and BS2 and affix them on the buccal swab collection devices. Add the other barcode label on the SIF.
- 3. Using gloves, open the bag and remove one buccal swab collection device.
- 4. 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.
- 5. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface.
- 6. Holding the grip, insert the swab into the mouth onto the tongue and moisten it with saliva for ten seconds.
- 7. 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.
- 8. Repeat step 7 on the opposite side of the mouth (upper and lower).
- 9. Once you have taken the sample, put the swab back into the plastic tube and close it securely.
- 10. Place the sample into the sealable biohazard specimen bag. Repeat the procedure with the second buccal swab collection device and seal the specimen bag tightly.
- 11. Place the sealed bag inside the bubble envelope.
- 12. Remove the protective cover from the adhesive strip and seal the bubble envelope.

# THE FOLLOWING SECTION IS APPLICABLE FOR THESE PRODUCTS:

- Postnatal Whole Exome Sequencing (WES)
- Postnatal Whole Genome Sequencing (WGS)

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#### **COLLECTION DEVICE**

**PRODUCT CONTENTS** 

Single Analysis:

i. One (1) buccal swab collection device.

#### Duo Analysis:

i. Two (2) buccal swab collection devices.

#### Trio Analysis:

i. Three (3) buccal swab collection devices.



#### **PACKAGING MATERIALS**

Single Analysis: i. One (1) sealable biohazard specimen bag.

Duo Analysis:

- i. Two (2) sealable biohazard specimen bags.
- Trio Analysis: i. Three (3) sealable biohazard specimen bags.



#### DOCUMENTATION

Single Analysis:

- i. One (1) barcode card with two (2) barcode labels.
- ii. Sample Information Form (SIF) available via QR code on bubble envelope.
- iii. Informed Consent available on the SIF.

#### Duo Analysis:

- i. One (1) barcode card with three (3) barcode labels.
- ii. Sample Information Form (SIF) available via QR code on bubble envelope.
- iii. Informed Consent available on the SIF.

#### Trio Analysis:

- i. One (1) barcode card with four (4) barcode labels.
- ii. Sample Information Form (SIF) available via QR code on bubble envelope.
- iii. Informed Consent available on the SIF.

# SAMPLE COLLECTION INSTRUCTIONS

- 1. Complete the Sample Information Form (SIF). A signed, paper copy of the completed SIF should always be sent along with the sample.
- 2. Write the patient's full name on the barcode label ending in BS1, and affix that on one buccal swab collection device. Add the SIF barcode label on the SIF.
- 3. Using gloves, open the bag and remove the plastic tube.
- 4. 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.
- 5. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface.
- 6. Holding the grip, insert the swab into the mouth onto the tongue and moisten it with saliva for ten seconds.
- 7. 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.
- 8. Repeat step 7 on the opposite side of the mouth (upper and lower).
- 9. Once you have taken the sample, put the swab back into the plastic tube and close it securely.
- 10. For duo and trio analysis, perform the same sample collection procedure for the family members providing their sample. If you have chosen 'single analysis', skip step 10 and proceed with step 11.
  - For duo analysis: Perform sample collection of the family member as described in steps 5-9. After sample collection, add the barcode label ending in BS2 on the second buccal swab collection device, and fill in the details of 'family member 1' on page 3 of the SIF. Proceed with step 11.
  - For trio analysis: Perform sample collection of the family members as described in steps 5-9. After sample collection, add the barcode label ending in BS2 on the second buccal swab collection device, and fill in the corresponding details of 'family member 1' on page 3 of the SIF. Add the barcode label ending in BS3 on the third buccal swab collection device, and fill in the corresponding details of 'family member 2' on page 3 of the SIF. Proceed with step 11.
- 11. Place each sample into different sealable biohazard specimen bags and seal tightly.
- 12. Place the sealed bags inside the bubble envelope.
- 13. Remove the protective cover from the adhesive strip and seal the bubble envelope.



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