

This National Children's Study (NCS) Child Saliva Collection Kit contains everything you will need to provide a sample of your child's saliva:

- 1 Oragene DISCOVER Saliva Collection kit, with pre-labeled outer plastic case
- 1 Clear re-sealable biohazard bag, with absorbent pad
- 1 Shipping box, with address label
- 1 Child Saliva Collection Instruction Sheet
- 1 Child Saliva Collection Self Administered Questionnaire (SAQ)

IMPORTANT NOTES

- ✓ DO NOT touch the tip of the sponge or the inside of the funnel or lid.
- ✓ Please be sure to complete the Child Saliva Collection SAQ.
- ✓ If the sample collection was **not** completed, please explain why on the Child Saliva Collection SAQ.

Instructions for collection:

- 1. Follow the directions on the Oragene DISCOVER package insert in the kit. These instructions are also provided on the back of this page.
- 2. The package insert refers to your child as 'donor'.
- 3. Once the saliva collection is completed and the tube is capped and mixed, place the closed collection tube back into the labeled plastic case.
- 4. Place the labeled plastic case into the resealable plastic bag with absorbent pad and seal the plastic bag. Throw away the rest of the supplies in the trash.
- Complete the Child Saliva Collection SAQ.
- 6. Place the sealed bag and the completed Child Saliva Collection SAQ into the shipping box.
- 7. Place the shipping airbill on the box.
- 8. Ship the box as soon as you are able, within one week of collection.

IF YOU HAVE ANY QUESTIONS PLEASE CALL THE LOCAL CONTACT NUMBER LOCATED ON THE LAST PAGE

THANK YOU FOR PROVIDING THIS SALIVA SAMPLE!

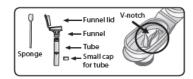
Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

Instructions:



For assisted collection of human DNA **ஊ** OGR-575

For Research Use Only Not for use in diagnostic procedures



Read all instructions prior to collection

This product is designed for the assisted collection of human DNA from saliva samples.

Contents: Kit contains stabilizing liquid.

Warnings and precautions:

- Choking hazards:

 - Small cap in collection kit.
 Plastic bag containing sponges.
 - Caution should be used when inserting sponge into donor's mouth.
- For supervised collections:
 - Do NOT leave donor unattended.
 - Do NOT allow donor to handle the sponge, small cap or packaging.
 - Wash with water if stabilizing liquid comes in contact with eyes or skin. Do not ingest. See MSDS at www.dnagenotek.com.

Storage: 15°C / 30°C

Summary and explanation of the kit:

Oragene DISCOVER is an assisted collection kit that provides the materials and instructions for collecting and stabilizing saliva specimens.

Collection precautions:

Do NOT remove the plastic film from the funnel lid.

Check sponge for damage each time before inserting into donor's mouth. Use second sponge if first sponge shows any signs of wear or tear.

Do NOT substitute with other sponges

Procedure:

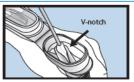
- Ensure donor does NOT eat, drink, smoke or chew gum for 30 minutes before collecting a saliva sample.
- Ensure donor is in an upright position during sample collection.
- It may take up to 15 minutes to collect a saliva sample following steps 1 to 7.

ENGLISH



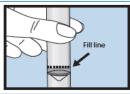
Place one sponge in cheek pouch. Gently move the sponge along the gums and inner cheeks for 30 seconds to soak up as much saliva as possible.





Once sponge is saturated with saliva, insert sponge in V-notch of funnel. Wring saliva out of sponge using a twisting and pushing motion against the inner wall of the V-notch. Saliva will flow into tube.





Repeat these steps (1 to 2) USING THE SAME SPONGE until the liquid saliva (not bubbles) reaches the fill line. Check sponge for damage each time before inserting into donor's mouth. Use second sponge if first sponge shows any signs of wear or tear.

Tap tube bottom against hard surface to reduce number of bubbles.



Hold the tube upright with one hand. Close the lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the saliva. Make sure the lid is closed tightly.





Hold the tube upright. Unscrew the funnel from the tube.



Use the small cap to close the tube tightly.



Shake the capped tube for 5 seconds. Discard or recycle the funnel. Discard sponges.

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PD-PR-001 58-ML Issue 5/2012-01

U.S. Patent No. 7,482,116; European Patent No. 1 513 952 and 1 956 969; Patent pending Canadian Design Nos. 1 27470; 132896; 132897 U.S. D631,554 S and D640,795 \$ Community Design Nos. 001095186-0001;-0002;-0003

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Label legend:

<u>□</u> Consult package insert Collect saliva by (Use by) REF Catalog number Industrial Design Patent 0

Caution, consult instructions for use 15°C 1/ 30°C Storage instructions

Insert local contact information label here.