

Intended use: 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 (59°F-86°F)

Summary and explanation of the kit:

ORAgene-Dx 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 or swabs.

Label legend:

	Catalog number
	In vitro diagnostic medical device
	CE marking
	UKCA marking
	Manufacturer
	Medical device
	Do not re-use
	Consult instructions for use
	Collect saliva by (Use by)
	Lot number
	Authorized Representative
	Caution

User instructions

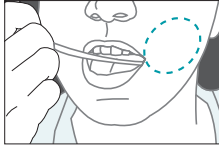
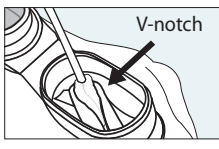
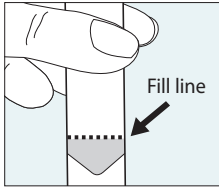
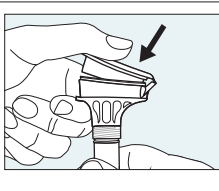
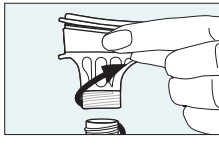
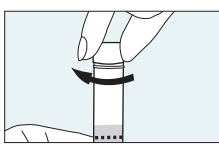
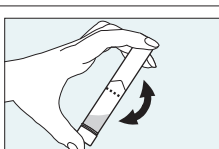
Read all instructions prior to collection.

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.

	<p>1 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.</p>
	<p>2 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.</p>
	<p>3 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.</p> <p>Tap tube bottom against hard surface to reduce number of bubbles.</p>
	<p>4 Hold the tube upright with one hand. Close the lid with the other hand 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.</p>
	<p>5 Hold the tube upright. Unscrew the funnel from the tube.</p>
	<p>6 Use the small cap to close the tube tightly.</p>
	<p>7 Shake the capped tube for 5 seconds. Discard the funnel and sponges.</p>

See additional instructions for use PD-HB-00001 at www.dnagenotek.com

For In Vitro Diagnostic Use    
 For Prescription and Direct-to-Consumer Use

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Patent (www.dnagenotek.com/legal/notices)
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