## Patient Self-Collection Kit and Collection Process SOP - Telehealth

**Test package dispatched and sent via express carrier or USPS including:**

<table>
<thead>
<tr>
<th>Instruction card</th>
<th>Spectrum SDNA-1000 Saliva Collection Device</th>
<th>Lab-Loc Specimen Bag for Biohazard</th>
<th>Alcohol Prep Pad</th>
<th>Overnight carrier overpack UN 3373 Biological Substance Category B</th>
</tr>
</thead>
</table>

### 1. Register for test

Register the test online at [link here] and type in the 12-digit test ID located on the collection tube beneath the barcode.

### 2. Before performing collection

Before performing collection, confirm the nearest USPS, FedEx, or UPS drop off location and hours of operation. Ship the sample on the same day as collection before the last pick up.

### 3. Wash hands before opening the test package

Wash hands before opening the test package. Do not eat, drink, smoke or chew gum within 30 minutes of the collection. Do not open the Spectrum SDNA-1000 saliva collection kit until you are advised during your medically supervised telehealth visit.

### 4. Login to HIPAA compliant telemedicine platform

Login to HIPAA compliant telemedicine platform using [this link] to virtually meet with a trained healthcare provider who will guide the saliva self-collection.

### 5. Provide government ID for verification

Provide government ID for verification. Open the package containing the SDNA-1000 saliva collection device. The healthcare provider will confirm the test ID and tracking number of the pre-paid return envelope*. Perform the supervised collection to the black line on the tube (2 ml). Remove funnel and screw on cap to release blue preservation agent into the tube. Shake the specimen for 5 seconds to mix preservative with sample.

### 6. Wash hands thoroughly again

Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

### 7. Place the biohazard bag into the return package

Place the biohazard bag into the return package. Remove the adhesive cover strip and seal the package closed. Wipe the package with the provided alcohol wipe.

### 8. Immediately deliver package to a USPS, FedEx or UPS drop box

Immediately deliver package to a USPS, FedEx or UPS drop box using the prepaid, pre-addressed return package. Ship the sample on the same day as collection before the last pick up.

### 9. Lab inspects package and logs specimen serial number

Lab inspects package and logs specimen serial number upon receipt of package. Test results are delivered to health care provider identified by kit serial number. Results are reported to patient by healthcare provider.
Register test with health care provider using 12-digit test ID located on the collection tube beneath the barcode.

Before performing collection, confirm the nearest USPS, FedEx, or UPS drop off location and hours of operation. Ship the sample on the same day as collection before the last pick up.

Wash hands before opening the test package. Do not eat, drink, smoke or chew gum within 30 minutes of the collection. Open test kit on a clean surface.

Open the package containing the SDNA-1000 saliva collection device. Perform the collection as per the instructions for use card and spit into the funnel until your saliva reaches the black line on the tube (2 ml). Remove funnel and screw on cap to release blue preservation agent into the tube. Shake the specimen for 5 seconds to mix preservative with sample. If needed a video that illustrates sample collection can be found at [link here]

Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

Place the biohazard bag into the return package. Remove the adhesive cover strip and seal the package closed. Wipe the package with the provided alcohol wipe.

Immediately deliver package to a USPS, FedEx or UPS drop box using the prepaid, pre-addressed return package. Ship the sample on the same day as collection before the last pick up.

Lab inspects package and logs specimen serial number upon receipt of package. Test results are delivered to health care provider identified by kit serial number. Results are reported to patient by healthcare provider.
**Step 1**

Fill the tube with saliva to the black wavy line.

- Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. **DO NOT OVERFILL.**
- Cap chewing hazard. Keep out of reach of children. Wash with water if liquid solution comes in contact with eyes or skin. **DO NOT INGEST LIQUID.**
- This kit is designed for the collection of human saliva samples. Made in USA, Patent Pending. For research use only. Not for use in diagnostic procedures.

**Step 2**

Replace the funnel with the fluid cap.

- Remove the funnel from the tube. Screw on the enclosed cap **TIGHTLY** to release the solution that will stabilize the DNA in your saliva.

**Step 3**

Firmly screw cap down to release solution and seal tube.

- You will know it works when the blue solution that will stabilize the DNA in your saliva.

**Step 4**

Shake the tube for at least five seconds.

- This will ensure your sample mixes thoroughly with the stabilizing solution.

**Label Legend:**
- Consult instructions for use
- Use by date (Collect saliva by)
- In vitro diagnostic medical device
- Catalog number
- CE Marking
- Caution, consult instructions for use
- Authorized representative
- Manufacturer
- Batch code

**Legend of the label:**
- Consult the instructions of use
- In vitro diagnostic medical device
- Distinctive CE
- Precaution: consult the instructions of use
- Temperature limit
- Manufacturer
- Code of lot

**Légend des étiquettes:**
- Lire les consignes d'utilisation
- Date limite d'utilisation (Collecter la salive avant le)
- Dispositif médical de diagnostic in vitro
- Marquage CE
- Attention, lire les consignes d'utilisation
- Température limite
- Fabricant
- Code de lot