

Patient Self-Collection Kit and Collection Process SOP - Telehealth

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



Instruction card

Spectrum SDNA-1000 Saliva Collection Device

Lab-Loc Specimen Bag for Biohazard

Alcohol Prep Pad

Overnight carrier overpack UN 3373 Biological Substance Category B

IVD Use; Rx Only; For use under an Emergency Use Authorization (EUA) only

Warnings:

This self-collection kit has:

- Not been FDA cleared or approved
- Been authorized by FDA under an EUA
- Been authorized only for the unsupervised self-collection and maintenance of nasal specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

This kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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, 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. 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



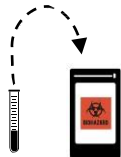
Login to HIPAA compliant telemedicine platform using [this link] to virtually meet with a trained healthcare provider who will guide the saliva self-collection.

5



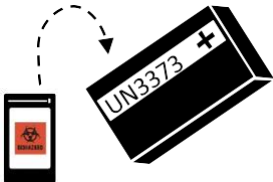
Provide government ID for verification. Open the package containing the SDNA-1000 saliva collection device. The healthcare provider will confirm the test ID and tracking number of the pre-paid return envelope*. Perform the supervised collection to the black line on the tube (2 ml). Remove funnel and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

6



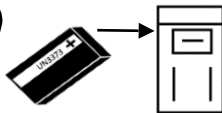
Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

7



Place the biohazard bag into the return package. 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 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 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

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1

Register for test



Register test with health care provider using 12-digit test ID located on the collection tube beneath the barcode.

2



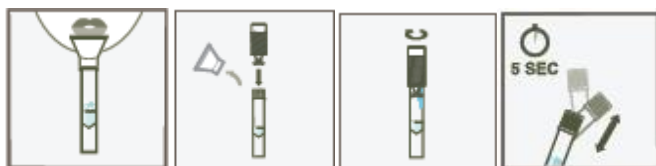
Before performing collection, confirm the nearest USPS, FedEx, or UPS drop off location and hours of operation. Ship the sample on the same day as collection before the last pick up.

3



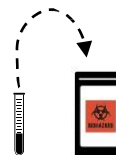
Wash hands before opening the test package. Do not eat, drink, smoke or chew gum within 30 minutes of the collection. Open test kit on a clean surface

4



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 [\[link here\]](#)

5



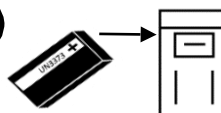
Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

6



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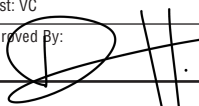


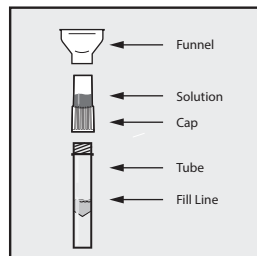
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8

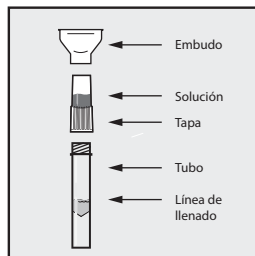


Lab inspects package and logs specimen serial number upon receipt of package. Test results are delivered to health care provider identified by kit serial number. Results are reported to patient by healthcare provider

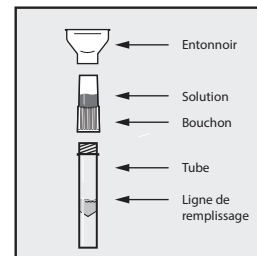
			1 BLACK
Customer SPECTRUM SOLUTIONS LLC			2 PMS 144
Part Number 2019077 V02.1		P1	3 PMS 185
FWO 103812	Size 10.5000 X 8.5000	Date 11/12/19	4
Artist: VC		Proof # 1	5
Approved By: 		Date 11/18/2019	6



Do NOT eat, drink, smoke, or chew gum for 30 minutes before giving your saliva sample.

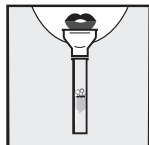


NO coma, beba, fume ni mastique chicle 30 minutos antes de dar su muestra de saliva.



ÉVITER de manger, boire, fumer ou mâcher du chewing-gum pendant 30 minutes avant de donner un échantillon de votre salive.

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.**

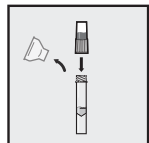
Llene el tubo con saliva hasta la línea negra ondulada.

Llene el tubo hasta que su saliva (sin considerar las burbujas) alcance o se encuentre justo sobre la línea ondulada. **NO LO LLENE EN EXCESO.**

Remplir le tube de votre salive jusqu'à la ligne ondulée noire.

Remplir le tube jusqu'à ce que votre salive (sans compter les bulles) atteigne au moins la ligne ondulée. **ÉVITER LES DÉBORDEMENTS.**

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.

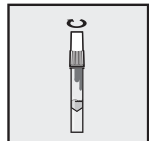
Reemplace el embudo por la tapa del líquido.

Extraiga el embudo del tubo. Enrosque **FUERTEMENTE** la tapa adherida para liberar la solución que estabilizará el DNA en su saliva.

Remplacer l'entonnoir par le bouchon.

Enlever l'entonnoir du tube. Visser **FERMEMENT** le bouchon fourni pour libérer la solution qui stabilisera l'ADN dans votre salive.

Step 3



Firmly screw cap down to release solution and seal tube.

You will know it works when the blue solution from the cap is released into the tube. Firmly tighten cap to assure the cap and tube is completely sealed.

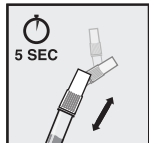
Enrosque con firmeza la tapa hacia abajo para liberar la solución y sellar el tubo.

Sabrás si funciona cuando la solución azul de la capa se libere en el tubo. Enrosque con firmeza la tapa para asegurarse de que la tapa y el tubo estén totalmente sellados.

Visser fermement le bouchon en poussant vers le bas pour libérer la solution et fermer le tube.

Vous saurez que cela aura fonctionné une fois que la solution bleue du bouchon aura été libérée dans le tube. Serrer fermement le bouchon pour assurer une fermeture bien étanche.

Step 4



Shake the tube for at least five seconds.

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

Agite el tubo al menos cinco segundos.

Esto garantizará que su muestra se mezcle bien con la solución estabilizante.

Secouer le tube pendant au moins cinq secondes.

Ceci permettra de bien mélanger votre échantillon avec la solution stabilisante.

Spectrum Solutions
12248 S Lone Peak Parkway, #106
Draper, UT 84020
www.Spectrum-DNA.com
Storage 15°C - 30°C
REF SDNA - 1000

Cap choking 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.

Riesgo de asfixia con la tapa. Mantenga fuera del alcance de los niños. Lávese con agua si la solución líquida entra en contacto con los ojos o la piel. **NO INGIERA EL LÍQUIDO.**

Este kit está diseñado para la recolección de muestras de saliva humana.

Hecho en EE. UU. Patente pendiente.

Solo para uso con fines investigativos. No debe utilizarse en procedimientos de diagnóstico.











Le bouchon peut présenter un risque d'étouffement. Garder hors de la portée des enfants. Laver avec de l'eau si la solution liquide entre en contact avec les yeux ou la peau. **NE PAS AVALER LE LIQUIDE.**

Ce kit est conçu pour la collecte d'échantillons de salive humaine.











Fabriqué aux États-Unis, Brevet déposé

Pour la recherche uniquement. Ne pas utiliser à des fins de diagnostic.











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
-  Temperature limit
-  Authorized representative
-  Manufacturer
-  Batch code

Leyenda de la etiqueta:

-  Consulte las instrucciones de uso
-  Fecha de vencimiento (junte la saliva antes de)
-  Dispositivo médico para diagnóstico in vitro
-  Número de catálogo
-  Distintivo CE
-  Precaución: consulte las instrucciones de uso
-  Límite de temperatura
-  Representante autorizado
-  Fabricante
-  Código del lote

Légende des étiquettes:

-  Lire les consignes d'utilisation
-  Date limite d'utilisation (Collecter la salive avant le)
-  Dispositif médical de diagnostic in vitro
-  Numéro de catalogue
-  Marquage CE
-  Attention, lire les consignes d'utilisation
-  Température limite
-  Représentant autorisé
-  Fabricant
-  Code de lot

