

Instructions For Use



Warnings:
For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use. For prescription use only.
For use by individuals age 18 years or older.

For questions, please contact us by phone at 781-391-7979 or e-mail: testing@nanobiosym.com

NANOBIOSYM

The Nano-Saliva Collection Kit to be used with The Nano Test for COVID-19

Please read these instructions carefully before you start to collect the sample.

WARNING

Do not clean with any substance containing bleach. Do not use if kit is expired. Cap is a 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.** Avoid contact with skin and eyes. If contact with body occurs, rinse with water. If irritation persists, seek medical advice. This kit is designed for the collection of human saliva samples.

Nanobiosym Precision Testing Services 245 First Street, Suite 175, Cambridge, MA 02142. Phone Number: (781)-391-7979
Nanobiosym. All Rights Reserved. Rx Only. For in vitro diagnostic use. For use under Emergency Use Authorization (EUA) only.

LABEL LEGEND

- | | | | |
|------------------------------|-------------------------------|--------------------|-----------------|
| Consult instructions for use | Catalog number | Temperature limits | Batch code |
| Use by date | Serial number | Manufacturer | Single use only |
| Do not use if damaged | Caution, consult instructions | | |

Do NOT eat, drink (even water), smoke, or chew gum for 30 minutes before collecting your saliva samples.

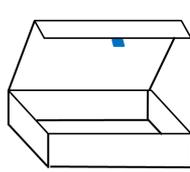
If you are having trouble collecting saliva in your mouth, try closing your mouth and wiggling your tongue, gently rubbing the outside of your cheeks, just behind your back teeth, and making chewing motions with your mouth. Wash your hands prior to and directly after collection.

Note: You must collect your sample on the same day that you can ship your sample and ensure delivery to our labs by 10:30am EST the following day. Verify shipping pickup & delivery times before collecting your sample. Do NOT register, collect, or ship your sample on a Saturday or Sunday. Nanobiosym Precision Testing Services will only accept your sample if it reaches the testing facility within 48 hours of being shipped and within 56 hours of being collected. Any samples received outside of this window will be rejected.

Open the kit and place all the contents on a clean, dry surface.

Inspect your test kit to ensure all components are included. Your Kit Includes Return Shipping Supplies! This includes a biohazard specimen bag (bio-bag) with absorbent material, a return shipping label, and a shipping bag. **Do NOT discard these items. They are required for return shipping!**

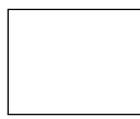
****Please discard SDNA-1000 paper instructions from blister-pack**



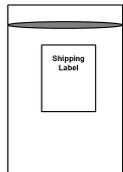
1. Test kit box



2. Welcome card



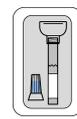
3. Instructions for use and shipping instructions



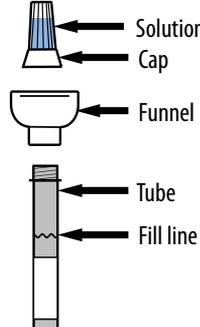
4. Shipping bag with prepaid return label*



5. Bio-bag with absorbent pad



6. Saliva collection SDNA-1000 blister-pack**



*Please take a picture of your prepaid return label for tracking purposes.

Step 1

Register online right before saliva collection.

A

Before collecting your sample, use your personal device to register at Nanobiosym-testing.com and select **register kit**.

or

Scan the QR code below with your camera app.



B

Log in to portal using your **Patient QR code** previously sent (via SMS/Email) when you ordered your kit. Fill out questionnaire. Create a **Patient QR code** (if you don't already have one).



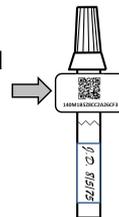
Copy and paste the **Patient QR code** in the link that was texted/emailed to you.

C

Register this Saliva Collection Kit to your patient record using this **test serial number** on the welcome card.



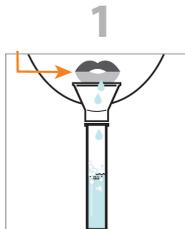
Peel and place this sticker on the enclosed saliva collection tube above the black wavy line. **Note: The sticker should not block the wavy line.**



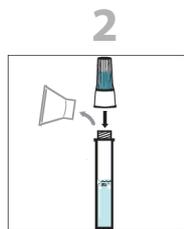
Step 2

Collect your sample.

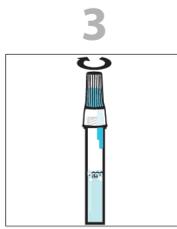
Collection Video Tutorial: Please visit <https://vimeo.com/694268545>



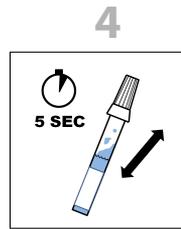
Fill the tube with saliva to the black wavy line. Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. **Do not overfill.**



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/RNA in your saliva.

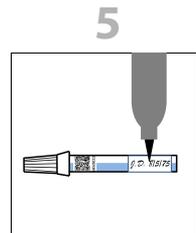


Firmly screw cap down to release solution and seal tube. You will know it works when the blue solution from the cap is released into the tube. Firmly tighten cap to assure the cap and tube is completely sealed.

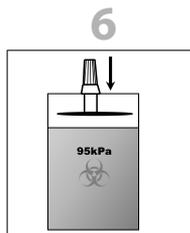


Shake the tube gently for at least five seconds. This will ensure your sample mixes thoroughly with the stabilizing solution.

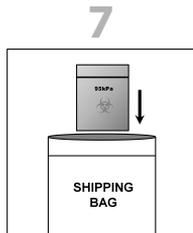
Label & package your sample



Write your initials and date of birth (mm/dd/yy) with a black marker on the white space on the tube.



Place the saliva tube inside bio-bag and seal bag closed. **Do not remove absorbent pad from the bag.**



Place sealed bio-bag into shipping bag with prepaid return label and seal closed.

Step 3

Return your sample to us. (See additional insert for return shipping instructions.)

Promptly ship your sample back via your local courier facility. Ship your sample before the last pickup of the day. Please ensure that it will arrive before 10:30am EST the following day. Note: Do not ship from 3rd party locations (eg. CVS, Walgreens, RiteAid, etc.)



Warning: This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. Saliva specimen will be collected at home or other collection sites outside of the healthcare setting from individuals suspected of COVID-19 by their healthcare provider. Federal Law restricts this device to sale by or on the order of a licensed practitioner. Only for 18+ use.

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



NANOBIOSYM
your health in your hands®

Warnings:
For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use. For prescription use only.
For use by individuals age 18 years or older.

Welcome to The Nano-Saliva Collection Kit to be used with The Nano Test for COVID-19

Note: You must collect your sample on the same day that you can ship your sample and ensure delivery to our labs by 10:30am EST the following day. Verify shipping pickup & delivery times before collecting your sample. Do not register, collect, or ship your sample on a Saturday or Sunday. Nanobiosym Precision Testing Services will only accept your sample if it reaches the testing facility within 48 hours of being shipped and within 56 hours of being collected. Any samples received outside of this window will be rejected.

Register online right before saliva collection.

A

Go to **nanobiosym-testing.com** and select "Register Kit".

or

Shortcut to website:



B

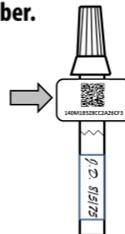
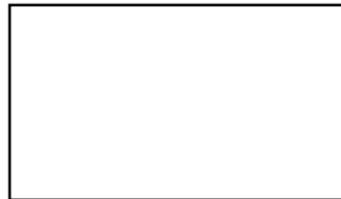
Log in to portal using your **Patient QR code** previously sent (via SMS/Email) when you ordered your kit. Fill out questionnaire. Create a **Patient QR code** (if you don't already have one).



Copy and paste the **Patient QR code** in the link that was texted/emailed to you.

C

Register this Saliva Collection Kit to your patient record using this **test serial number**.



Peel and place this sticker on the enclosed saliva collection tube above the black wavy line. **Note: The sticker should not block the wavy line.**

Warning: This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

Return The Nano-Saliva Collection Kit sample to us via FedEx

SHIPPING REMINDER: You must collect your sample on the same day that you can ship your sample and ensure delivery (via FedEx Priority Overnight) to our labs by 10:30am EST the following day. Please check with your local FedEx to ensure your sample ships same day. Please verify shipping pickup & delivery times before collecting your sample. Do NOT register, collect, or ship your sample on a Saturday or Sunday.

Nanobiosym Precision Testing Services will only accept your sample if it reaches the testing facility within 48 hours of being shipped and within 56 hours of being collected. Any samples received outside of this window will be rejected. Only samples that are shipped back and received Monday-Friday will be accepted. Samples received on weekends may be rejected.

You have 2 options for shipping the sample. Visit <https://bit.ly/fedexdropbox> to view FedEx drop box locations and pickup schedules.

FedEx Drop Box

It's important to bring your specimen to a drop box on the same day you collect it before the last Express pickup. Deliver your specimen to a drop box only after you have confirmed delivery (via FedEx Priority Overnight) to our labs by 10:30am EST the following day. Do not take it to a FedEx office. Do not place kit in drop box on Saturday or Sunday.

or

Schedule a FedEx Pickup

Schedule your FedEx pickup for a weekday and only after you have confirmed delivery to our labs by 10:30am EST the following day. Call FedEx at 800-463-3339 and answer some questions.

FedEx: "What are you calling about?" **You:** "FedEx Express® return pickup"

FedEx: "...a pickup request for a return. To arrange a pickup for today or tomorrow, depending on availability, say "pickup."
You: "Pickup"

FedEx: "Is the word "stamp" written anywhere on your return label?" **You:** "No"

FedEx: "What is the tracking number?" **You:** Provide the tracking number (TRK#) from the prepaid FedEx return label.

FedEx: "What kind of return are you calling about?" **You:** "FedEx Express"

Provide additional information as requested. You may be asked for the pickup location address, number of packages to be picked up, day and time window for the pickup, or if your shipment is currently ready. Note the confirmation pickup number provided. If you are asked for a credit card or account number, state that this is a FedEx Express prepaid return pickup and provide the tracking number (TRK#) from the return label.

NOTE: Please do not collect your specimen until you confirm pickup times of the drop box or have confirmed your scheduled pickup. It is important to bring your sample to a drop box on the same day you collect it before the last Express pickup.

Warning: This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner. For use under Emergency Use Authorization (EUA) only. For in vitro diagnostic use. For prescription use only. For use by individuals age 18 years or older.

Return The Nano-Saliva Collection Kit sample to us via

UPS

SHIPPING REMINDER: You must collect your sample on the same day that you can ship your sample and ensure delivery (via **Next Day Air**) to our labs by 10:30am EST the following day. Please check with your local UPS to ensure your sample ships same day. Please verify shipping pickup & delivery times before collecting your sample. Do **NOT** register, collect, or ship your sample on a Saturday or Sunday.

Nanobiosym Precision Testing Services will only accept your sample if it reaches the testing facility within 48 hours of being shipped and within 56 hours of being collected. Any samples received outside of this window will be rejected. Only samples that are shipped back and received Monday-Friday will be accepted. Samples received on weekends may be rejected.

You have 2 options for shipping the sample.

UPS Drop Box

Go to www.ups.com/dropoff to find an authorized UPS drop off location Monday through Friday. Be sure to drop off your completed kit before the latest 'Air' pickup on the same day you collect your sample.

Enter your ZIP code and check the box for "Find a drop off location". Click on "Location Type" to reveal a number of different options. Since this package must be guaranteed Next Day Air Delivery by 10:30 am EST the following day, you must select "The UPS Store" and "UPS Customer Center". Note: Do not ship from 3rd party locations (eg. CVS, Walgreens, RiteAid, etc.).

Click the "Find" button to list nearby authorized drop off locations. Scroll through the options to find the most convenient one for you. Operating hours and phone numbers are provided. Do not place kit in drop box on Saturday or Sunday.

Hand the sealed shipping package to the UPS representative and confirm that the package will be picked up today. Please confirm that your sample will be shipped to arrive at Nanobiosym Precision Testing Services by 10:30am EST the following day.

or

Schedule a UPS Pickup

Go to wwwapps.ups.com/pickup/schedule to schedule UPS to pick up this package at your address. Schedule your UPS pickup for a weekday and only after you have confirmed delivery to our labs by 10:30am EST the following day.

You can also call UPS at **800-742-5877** and answer some questions.

UPS: "How can I help you today?" **Your Answer:** "Schedule Pickup"

UPS: "How many packages are you shipping?" **You:** "1"

UPS: "What is the tracking number?" **Your Answer:** Say the Tracking # (begins with 1Z) from the pre-paid UPS return label.

UPS: "What kind of return are you calling about?" **You:** "UPS Next Day Air"

Provide additional information as requested. You may be asked for the pickup location address, number of packages to be picked up, day and time window for the pickup, or if your shipment is currently ready. Note the confirmation pickup number provided. If you are asked for a credit card or account number, state that this is a UPS return Next Day Air pickup and provide the Tracking # (begins with 1Z) from the prepaid UPS return label.

Please confirm that your sample will be delivered to Nanobiosym Precision Testing Labs by 10:30 am EST the following day. NOTE: Please do not collect your specimen until you confirm pickup times of the drop box or have confirmed your scheduled pickup. It is important to bring your sample to a drop box on the same day you collect it before the last UPS Next Day Air pickup.

Warning: This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner. For use under Emergency Use Authorization (EUA) only. For in vitro diagnostic use. For prescription use only. For use by individuals age 18 years or older.