

The SalivaDirect straw collection kit.

WARNING AND PRECAUTIONS BEFORE BEGINNING

Before providing your sample, first carefully read through the instructions below about how to provide a good saliva sample. **Not following the instructions could lead to an incorrect result.**

It is very important that you do not force yourself to produce a saliva sample. Please do not cough anything up from your chest. Please do not sniff anything back from your nose into your mouth.

Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.

If you have any questions, please reach out to the support email on the activation card.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA; This product has been authorized only for the collection and maintenance of saliva specimens as an aid in 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 medical devices under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



IVD
For Use Under Emergency Use Authorization (EUA) Only
For use by individuals age 18 years or older (self-collected),
14 years and older (self-collected under adult supervision),
or 2 years and older (collected with adult assistance).

PRE-COLLECTION

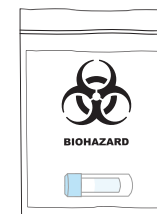
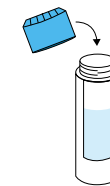
This test is designed to test saliva that naturally collects in your mouth (for example when you think about a delicious meal).

WARNING: Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.

- ① Visit the FedEx website at fedex.com/labreturns to view drop box locations and pick up schedules.
 - Your sample should be shipped the same day that you collect it. Make sure you can get to your drop box before the last pickup time on the same day you collect your sample.
 - Do not deliver your sample to a drop box on the weekend.
- ② Identify your sample transport tube.
 - Using a permanent pen, write your date of birth (MM-DD-YY) on the patient identifier sticker.
 - Remove the adhesive backing from the patient identifier sticker and affix it to the sample transport tube.
 - Do not write on or cover up the printed barcode or ID number on the tube.
- ③ Activate your kit using the link on the registration card.
 - Follow the instructions on the page to fill in your information.

COLLECTING YOUR SAMPLE

- ④ Wash your hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.
- ⑤ Remove everything from the collection kit and place it in front of you. Set the bag aside. **Avoid touching the inside of the collection device.**
- ⑥ Unscrew the collection tube cap and insert the rigid end of the saliva straw into the collection tube. Swallow once to clear your mouth.
- ⑦ Imagine eating your favorite food, think about an upcoming meal or even a sour lemon and allow saliva to collect in your mouth. Be patient and it will start to collect! Remember to avoid coughing or sniffing.
- ⑧ Pool saliva in mouth and push saliva into the straw until the collection tube is at least half full (1mL) and no more than $\frac{3}{4}$ full.
- ⑨ Remove and discard straw and securely cap the collection tube.
- ⑩ Use the alcohol wipe to wipe your hands and the sample tube. DO NOT wipe the printed part of the label.
- ⑪ Place the closed sample tube into the biospecimen bag.
- ⑫ Discard the alcohol wipe and wash your hands thoroughly with soap and water or clean them with an alcohol-based sanitizer.



RETURNING YOUR SAMPLE

- ⑬ Place the biospecimen bag into the SalivaDirect-labeled box it came in. Place the SalivaDirect-labeled box into the FedEx UN 3373 Pak.
- ⑭ Remove the adhesive liner of the FedEx UN 3373 Pak and press down firmly to seal Pak tightly.
- ⑮ Please drop off your sample on the same day you collect it and before the last pickup time. Do not deliver your sample to a drop box on the weekend.



Welcome to the SalivaDirect™ DTC Saliva Collection Kit

Please read through this entire document and collection kit instructions. If you have any questions, please reach out to the support email on the activation card.



1. ACTIVATE YOUR KIT

Before collecting your sample, activate your kit online using the link on the activation card. Follow the instructions on the page to fill in the necessary contact information to tie your sample to your results.



2. COLLECT YOUR SAMPLE

Collect your sample following the full instructions.

Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.



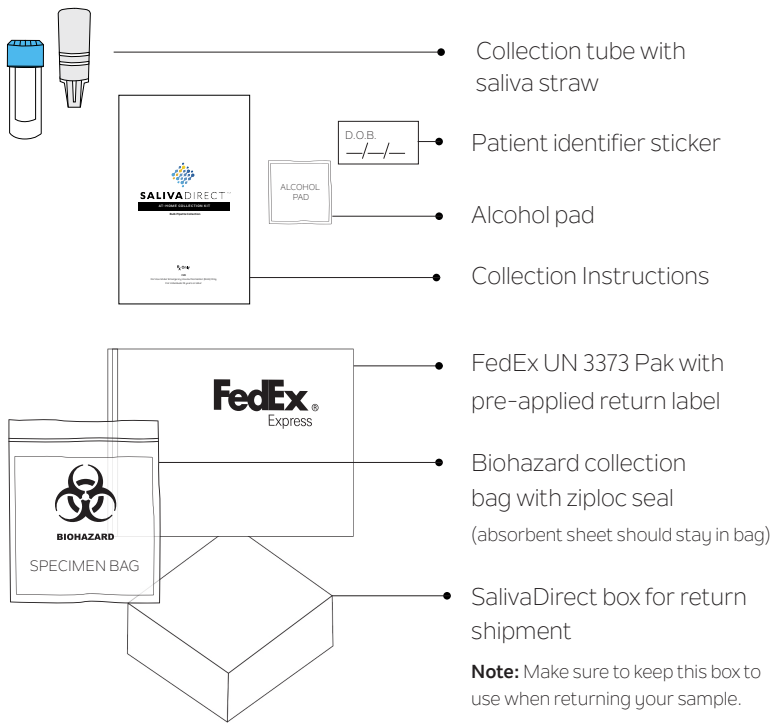
3. SHIP BACK YOUR SAMPLE SAME DAY

Your sample should be shipped the same day it is collected. See the collection brochure for more information.



SALIVADIRECT™

COMPONENTS



REMINDERS & TIPS

Make sure you are able to drop off your box before the last pickup time on the same day you collect your sample. Do not deliver your sample to a drop box on the weekend.

Use a permanent pen or marker when labeling your collection tube.

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The SalivaDirect funnel collection kit.

WARNING AND PRECAUTIONS BEFORE BEGINNING

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It is very important that you do not force yourself to produce a saliva sample. Please do not cough anything up from your chest. Please do not sniff anything back from your nose into your mouth.

Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.

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PRE-COLLECTION

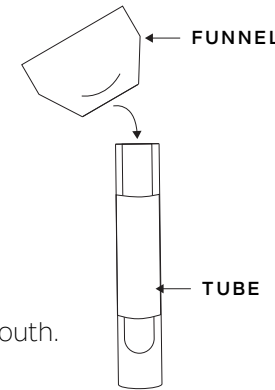
This test is designed to test saliva that naturally collects in your mouth (for example when you think about a delicious meal).

WARNING: Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.

- ① Visit the FedEx website at fedex.com/labreturns to view drop box locations and pick up schedules.
 - Your sample should be shipped the same day that you collect it. Make sure you can get to your drop box before the last pickup time on the same day you collect your sample.
 - Do not deliver your sample to a drop box on the weekend.
- ② Identify your sample transport tube.
 - Using a permanent pen, write your date of birth (MM-DD-YY) on the patient identifier sticker.
 - Remove the adhesive backing from the patient identifier sticker and affix it to the sample transport tube.
 - Do not write on or cover up the printed barcode or ID number on the tube.
- ③ Activate your kit using the link on the registration card.
 - Follow the instructions on the page to fill in your information.

COLLECTING YOUR SAMPLE

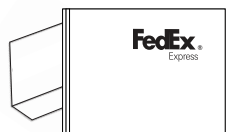
- ④ Wash your hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.
- ⑤ Remove everything from the collection kit and place it in front of you. Set the bag aside. **Avoid touching the inside of the funnel.**
- ⑥ Pick up the funnel and the sample tube. Position the funnel into the collection tube as shown.
- ⑦ Swallow once to clear your mouth.
- ⑧ Imagine eating your favorite food, think about an upcoming meal or even a sour lemon and allow saliva to collect in your mouth. Be patient and it will start to collect!
 - Remember to avoid coughing or sniffing.
- ⑨ Hold the funnel up so that it surrounds your mouth. Then gently release the saliva that has pooled in your mouth into the funnel.
 - Please avoid 'spitting' into the tube. Saliva should instead be gently released from your mouth.
- ⑩ Collect enough saliva so the tube is half-filled. Any bubbles in the tube do not count towards the final volume.
 - You may have to repeat this process a couple of times until the tube is half-full.
 - Be patient and don't force it. Just keep thinking about food and you'll get there!



- ⑪ Once you have collected enough saliva, remove the funnel from the sample tube and tightly screw the cap back onto the tube.
 - Make sure the cap is secure before proceeding to the next step.
- ⑫ Use the alcohol wipe to wipe your hands and the sample tube. DO NOT wipe the printed part of the label.
- ⑬ Place the closed sample tube into the biospecimen bag.
- ⑭ Discard the alcohol wipe and used funnel.
- ⑮ Wash your hands thoroughly with soap and water or clean them with alcohol-based sanitizer.

RETURNING YOUR SAMPLE

- ⑯ Place the biospecimen bag into the SalivaDirect-labeled box it came in. Place the SalivaDirect-labeled box into the FedEx UN 3373 Pak.
 - Remove the adhesive liner of the FedEx UN 3373 Pak and press down firmly to seal Pak tightly.
 - Please drop off your sample on the same day you collect it and before the last pickup time. Do not deliver your sample to a drop box on the weekend.



Welcome to the SalivaDirect™ DTC Saliva Collection Kit

Please read through this entire document and collection kit instructions. If you have any questions, please reach out to the support email on the activation card.



1. ACTIVATE YOUR KIT

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2. COLLECT YOUR SAMPLE

Collect your sample following the full instructions.

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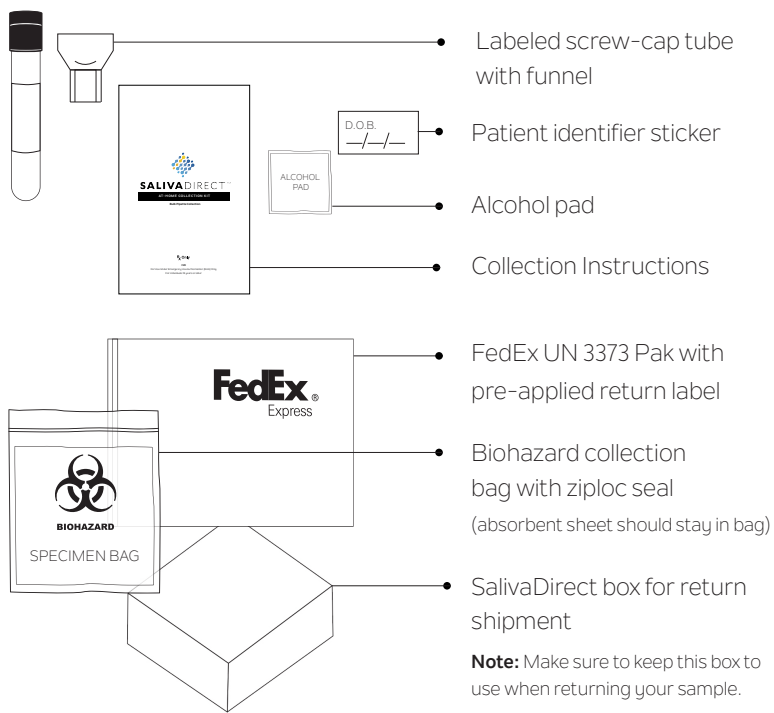
3. SHIP BACK YOUR SAMPLE SAME DAY

Your sample should be shipped the same day it is collected. See the collection brochure for more information.



SALIVADIRECT™

COMPONENTS



REMINDERS & TIPS

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Use a permanent pen or marker when labeling your collection tube.

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The SalivaDirect

bulb pipette collection kit.

WARNING AND PRECAUTIONS BEFORE BEGINNING

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IVD
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For individuals 18 years or older

PRE-COLLECTION

This test is designed to test saliva that naturally collects in your mouth (for example when you think about a delicious meal).

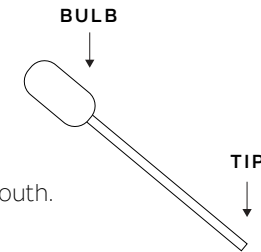
WARNING: Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.

- ① Visit the FedEx website at fedex.com/labreturns to view drop box locations and pick up schedules.
 - Your sample should be shipped the same day that you collect it. Make sure you can get to your drop box before the last pickup time on the same day you collect your sample.
 - Do not deliver your sample to a drop box on the weekend.
- ② Identify your sample transport tube.
 - Using a permanent pen, write your date of birth (MM-DD-YY) on the patient identifier sticker.
 - Remove the adhesive backing from the patient identifier sticker and affix it to the sample tube.
 - Do not write on or cover up the printed barcode or ID number on the tube.
- ③ Activate your kit using the link on the registration card.

Follow the instructions on the page to fill in your information.
- ④ Wash your hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.
- ⑤ Remove everything from the collection kit, place in front of you, and set the bag aside.

COLLECTING YOUR SAMPLE

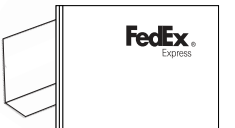
- ⑥ Unscrew the cap from the labelled collection tube.
- ⑦ Place the open tube in front of you so that it is standing upright. You may place the cap to the side for now.
- ⑧ Open the bulb pipette packaging **starting at the end with the bulb** (see illustration).
- ⑨ Swallow once to clear your mouth.
- ⑩ Imagine eating your favorite food, think about an upcoming meal or even a sour lemon and allow saliva to collect in your mouth. Be patient and it will start to collect!
 - Remember to avoid coughing or sniffing.
- ⑪ Pick up the bulb pipette and press the bulb end between your index finger and thumb to push out all of the air.
- ⑫ Keeping your lips mostly closed, gently insert the tip into your mouth where saliva is collecting.
- ⑬ Gently release your finger and thumb to allow the bulb pipette to fill with saliva.
 - Please avoid 'spitting'. Saliva should instead be gently released from the mouth.
- ⑭ Remove the bulb pipette from your mouth and pick up the sample tube with your other hand.
- ⑮ Carefully insert the tip of the bulb pipette into the sample tube. Then gently push down on the bulb to slowly empty the saliva into the tube.



- ⑯ Repeat steps 10-15 until the sample tube is about half filled. Any bubbles in the tube do not count towards the final volume.
 - You may have to repeat this process a couple of times until the tube is half-full.
 - Be patient and don't force it. Just keep thinking about food and you'll get there!
- ⑰ Once you have collected enough saliva, tightly screw the cap back onto the sample tube.
 - Make sure the cap is secure before proceeding to the next step.
- ⑱ Use the alcohol wipe to wipe your hands and the sample tube. DO NOT wipe the printed part of the label.
- ⑲ Place the closed sample tube into the biospecimen bag.
- ⑳ Discard the alcohol wipe and used bulb pipette.
- ㉑ Wash your hands thoroughly with soap and water or clean them with alcohol-based sanitizer.

RETURNING YOUR SAMPLE

- ㉒ Place the biospecimen bag into the SalivaDirect-labeled box it came in. Place the SalivaDirect-labeled box into the FedEx UN 3373 Pak.
 - Remove the adhesive liner of the FedEx UN 3373 Pak and press down firmly to seal Pak tightly.
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Welcome to the SalivaDirect™ DTC Saliva Collection Kit

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1. ACTIVATE YOUR KIT

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2. COLLECT YOUR SAMPLE

Collect your sample following the full instructions.

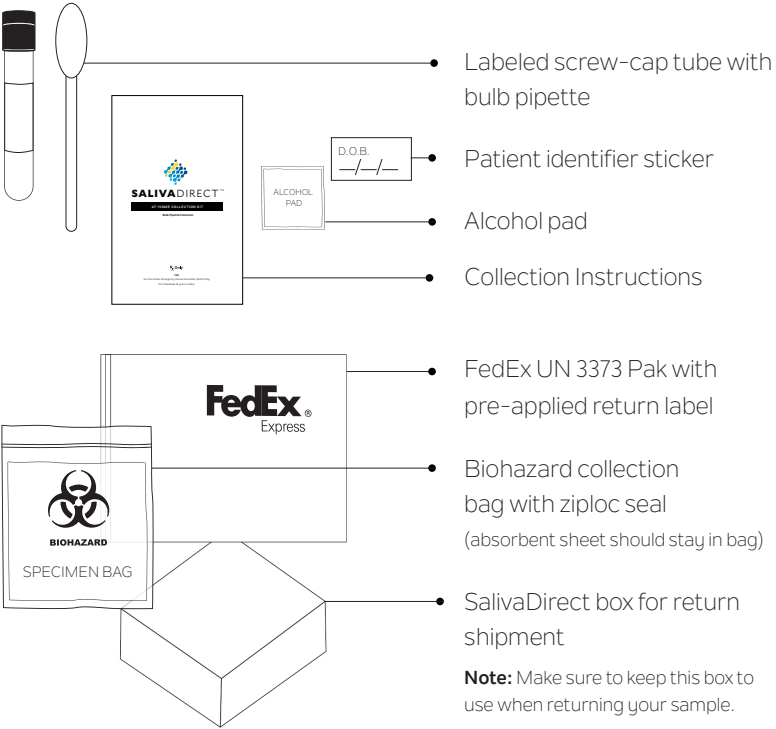
Do not eat, drink, smoke, clean your teeth, chew gum, or use nasal sprays for 30 minutes before collecting your saliva sample.



3. SHIP BACK YOUR SAMPLE SAME DAY

Your sample should be shipped the same day it is collected. See the collection brochure for more information.

COMPONENTS



REMINDERS & TIPS

Make sure you are able to drop off your box before the last pickup time on the same day you collect your sample. Do not deliver your sample to a drop box on the weekend.

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IVD | For Use Under Emergency Use Authorization (EUA) Only
For individuals 18 years or older

DTC SALIVA COLLECTION KIT

SALIVADIRECT™



Complete your text in 4 easy steps!

- 1** Order your kit
- 2** Collect your sample
- 3** Send back your SalivaDirect™ kit
- 4** Get results

- 1 Order your kit
- 2 Collect your sample
- 3 Send back your SalivaDirect™ kit
- 4 Get results

Emergency Use Authorization (EUA) Only | For In Vitro Diagnostic Use

The SelectDx™ CTC Selectable Cell Isolation System (SCIS) is a laboratory diagnostic device that is used to isolate and analyze circulating tumor cells (CTCs) from blood samples. The SCIS is designed to be used in a laboratory setting and is not intended for use in a clinical setting. The SCIS is a laboratory diagnostic device that is used to isolate and analyze CTCs from blood samples. The SCIS is designed to be used in a laboratory setting and is not intended for use in a clinical setting.

Administration's Emergency Use Authorization

UN 3373

PHOTOLOGICAL SUBSTANCE,
CATEGORY B

This kit includes:

- SalivDirect™ box
- Activation Card & Collection instructions
- Return Pak with the pre-applied return label
- Biohazard bag

This product is offered with an FDA Emergency Use Authorization. This means:
 This product has not been FDA-approved for use under the EUA, and this product has not been authorized for use under the EUA under an EUA.
 This product has been authorized only for the collection and maintenance of saliva specimens as an aid in 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 medical devices under Section 564(b)(1) of the Federal Food and Cosmetic Act, 21 U.S.C. § 360(b)(1)-(3)(vii), unless the declaration is terminated or authorization is revoked sooner.