

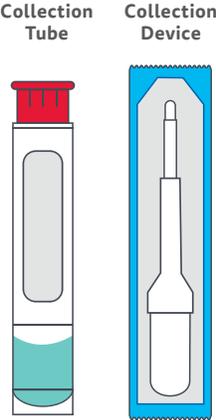
# SARS-CoV-2 Testing using Saliva for Symptomatic Patients Ages 4 to 18

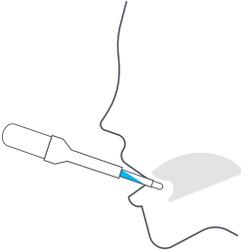
We have performed an internal study looking at the performance of our typical collection sample, nasopharyngeal (NP) swab, compared to saliva using a saliva collection device (SCD) for detection of SARS-CoV-2. Our results showed that the SCD samples were comparable in sensitivity compared to NP swab samples in symptomatic patients. For asymptomatic patients, sensitivity of SCD samples was much lower (30 to 60%) compared to NP swab samples.

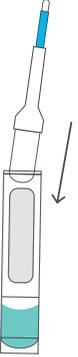
It is highly recommended that the individual does not eat or drink at least 10 minutes prior to saliva collection.

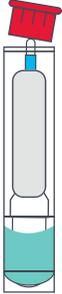
## Saliva Collection Instructions

1. Peel open the package containing the saliva collection device (SCD) and remove the collection device. As this action is occurring, the individual can move their tongue from side to side to accumulate saliva in the mouth prior to collection.


2. Place the SCD under the individual's tongue. The individual's head should be tilted down to allow gravity to assist with saliva collection. The collection device cannot be chewed or sucked on.


3. Allow the device to collect saliva (about 2 to 5 minutes) until the indicator on the SCD turns blue.
4. Hold the transport tube in an upright position and uncap the transport collection tube.
5. Remove the SCD from the individual's mouth and place the SCD into the tube, with the collection pad facing down into the transport tube.


6. Snap the transport tube's cap firmly.


7. Make sure that the patient's name and DOB is legible on the label of the tube and then place parafilm around the cap to secure and reduce leaking.



# Frequently Asked Questions about Saliva Samples for SARS-CoV-2 Testing

## What is the difference between NP swab and saliva samples?

An NP swab is the best method for detection of SARS-CoV-2, the virus that causes COVID-19 disease. An NP swab sample is a small swab that is inserted in the nostril and reaches the nasopharynx, which is the upper part of the throat (pharynx) that lies behind the nose. Once in the nasopharynx, the NP swab is rotated for sufficient sample collection, and then removed and placed into sterile transport medium (saline). When the sample is received in the laboratory, the swab is removed, and the transport medium is tested for detection of virus.

For the saliva sample, the collection device is held under the tongue, with the patient's head tilted forward. The collection device will wick up the saliva and when enough saliva is collected (takes ~2 to 5 minutes), a blue indicator line will appear on the device. This device is then placed in a transport medium and sent to the lab. Upon arrival, the device is removed, and the transport medium is tested for detection of virus.

## What type of PPE do I need for collecting saliva?

Collection of saliva is much less invasive than other sample source collections for SARS-CoV-2. We recommend using disposable gloves, lab coat and a surgical mask. Follow traditional PPE guidelines.

## Which sample is more accurate?

The NP swab sample is the gold standard sample type for SARS-CoV-2 testing, in that it is the most sensitive sample type in detecting the SARS-CoV-2 virus. When comparing the performance of NP swab samples to saliva samples that are collected by a saliva collection device, our study results showed that the SCD was comparable in sensitivity compared to NP swab samples in symptomatic pediatric patients. For asymptomatic pediatric patients, sensitivity of the saliva sample was much lower (30 to 60%) compared to NP swab samples.

## Why is saliva for SARS-CoV-2 testing limited to individuals aged 4 to 18 years?

Saliva samples for SARS-CoV-2 testing is limited to patients aged 4 to 18 years. Even though the study included a single 2-year-old patient, the device can fall apart if a young patient chews on the device. Therefore, our group decided that patients aged 4 years and older can follow the directions for the saliva collection device and not chew on the device when it is inserted in their mouths. The current upper age cutoff is 18 years since our study included patients aged 4 to 18. We do not have clinical data to support saliva testing in patients 19 years or older.

## Is there a turnaround time difference between saliva and NP swab samples?

There is no turnaround time difference between NP swab and saliva samples for SARS-CoV-2 testing.

## How is the test ordering done?

Test ordering will follow the same process for all other testing. When placing the order electronically or with a paper order, the ordering provider will need to specify 'saliva' as the specimen collection source. If the saliva source is not clearly indicated on the order (electronic or paper), then it may be missed. Please note: In scenarios where there are challenges collecting the saliva specimen, our team may need to switch to the NP swab collection method.

## Is there a price difference for SARS-CoV-2 testing between NP swab and saliva samples?

There is no cost difference between NP swab and saliva samples for SARS-CoV-2 testing.

## Can we perform other testing using the saliva sample?

Unfortunately, saliva samples are acceptable only for SARS-CoV-2 testing. If other respiratory tests are requested (influenza and/or respiratory pathogen panel), an NP swab sample will be needed.

