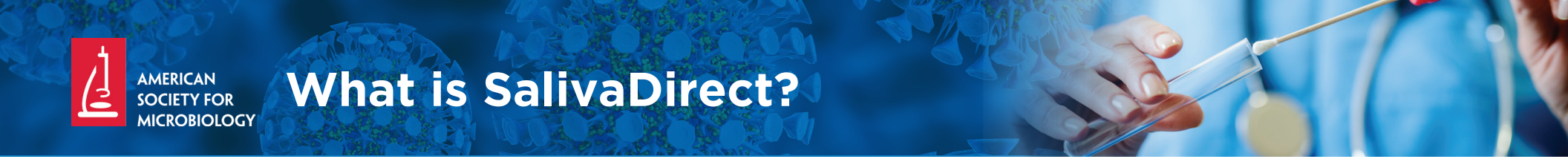


AMERICAN SOCIETY FOR MICROBIOLOGY

What is SalivaDirect?

What is the SalivaDirect test?

- This is a test for detecting nucleic acid from the SARS-CoV-2 virus that causes COVID-19. Like other COVID tests that look for the virus' nucleic acid (i.e. RNA), it still requires testing in a certified clinical lab. It is not a rapid test that can be done close to the patient; patients still need to wait for their results to come back from testing laboratory.

Why is this test receiving so much attention?

- **Easy-to-collect:** This test only requires collection of saliva in a sterile container, as opposed to deep nasal swab (i.e. the nasopharyngeal (NP) swab) which can be uncomfortable for the patient, and requires trained personnel wearing special personal protective equipment (PPE) to collect.
- **Fewer collection supplies required:** Saliva can be collected in sterile containers that are widely available, cheap and do not require special preservatives or containers. In these times during which supplies are scarce, this is very desirable.
- **Fewer steps in testing:** Testing for nucleic acids by molecular amplification (i.e., PCR) generally requires the viral RNA to be removed from the specimen and purified. This is called extraction and the reagents used for extraction have also been in short supply throughout this pandemic. The SalivaDirect test uses a simple procedure that does not require instrumentation to open the virus and remove the viral RNA. This RNA is then tested by molecular amplification.
- **Instrument accessibility:** Many current SARS-CoV-2 RNA tests are designed to be run on specific instruments, generally made by the manufacturer of the test. The SalivaDirect test can be performed on several types of instruments found in specialized clinical molecular laboratories, potentially allowing those laboratories to start testing without acquiring additional, expensive instruments.

What are the limitations of this test?

- **Skilled professionals:** Requires highly skilled lab personnel with experience in microbiology and molecular biology to run the test.
- **Expense:** While the test developers have stated the anticipated cost to be less than $5 per test, in actuality the cost will be more when taking into account costs of chemicals, instrumentation, highly skilled labor, test maintenance, and laboratory overhead. The true costs will be similar to current SARS-CoV-2 RNA tests, with any savings in reagents more than offset by increased labor.
- **Collection concerns:** Saliva can be hard to collect from some patients, may still pose an aerosol risk, and tends to contaminate the outside of the container. Care must be taken to avoid blood and sputum contamination, as these can interfere with molecular tests.
- **Hard to handle:** Saliva can be sticky and thick and hard for labs to handle safely and accurately. Automated sample handling machines have trouble with it.
- **Test sensitivity:** Saliva is 10-50x less sensitive as a sample type than a nasopharyngeal swab[1]. Patients with low viral loads may falsely test negative. Other research on saliva testing has shown similar loss of sensitivity.

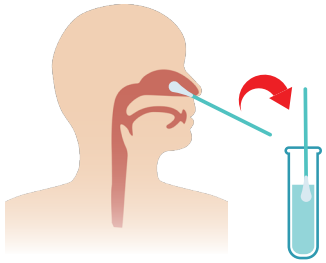
- **Test development and use:** Manual PCR tests like SalivaDirect requires significantly more skilled labor compared with other available tests. This test is also difficult to scale to high volumes, and still use many reagents and consumables.

Is this a rapid test that can be done where the samples are collected? Who can perform the test?

- No, this is not a point-of-care test that can be done in physician offices or near-patient, nor can it be used at home. Hence, it is not considered a rapid test. It's roughly as fast as existing lab-based tests.
- SalivaDirect requires a high complexity laboratory with experience in manual molecular testing with three physically separated areas for testing, one with biological safety cabinets. Most hospital laboratories cannot do this. Testing is performed by highly skilled laboratorians. Labs must ensure all regulatory requirements before providing testing.

Comparison of COVID-19 Molecular Tests using Nasopharyngeal (NP) specimen collection and SalivaDirect collection

Molecular Tests (Nucleic Acid Detection)



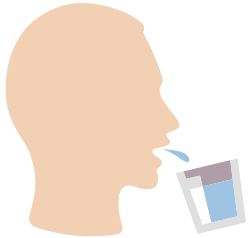
1. Obtain Specimen: NP swab

2. Extract RNA from specimen and convert to DNA.

3. Amplify by PCR with SARS-CoV-2 specific primers.

4. Interpret results: presence of viral RNA indicates active SARS-CoV-2 infection.

SalivaDirect Test



1. Obtain Specimen: SalivaDirect

2. RNA-extraction free process. Convert RNA from specimen to DNA and amplify by PCR with SARS-CoV-2 specific primers.

3. Interpret results: presence of viral RNA indicates active SARS-CoV-2 infection.

[1] https://www.medrxiv.org/content/10.1101/2020.06.16.20133041v1 and https://jcm.asm.org/content/early/2020/08/07/JCM.01824-20

Prepared by the American Society for Microbiology's Clinical and Public Health Microbiology Committee, Subcommittee on Laboratory Practices