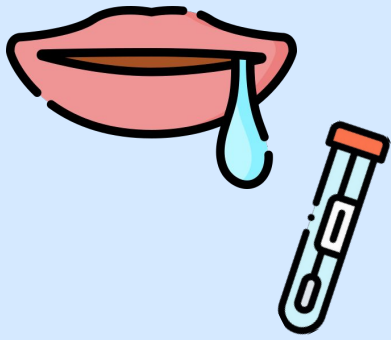




How Is Saliva Transforming The At-Home Testing Space?

PRESCOUTER



Saliva is a simple and non-invasive method of human specimen collection. It allows for easy storage and is low cost - when compared to blood. As a greater number of ailments become detectable through saliva, researchers are driving toward making at-home saliva collection devices as simple and seamless to use as possible.

The idea of using saliva as a diagnostic method has existed since 1975, when Dawes¹ emphasized the potential for developing saliva-based tests, because saliva carries a series of markers capable of revealing our state of health. However, it is only the more recent modernization of available techniques, along with the addition of chemical instrumentation devices, that have allowed for an increase in the use of saliva for medical and dental areas, for both basic and clinical purposes.

Through the coronavirus pandemic, saliva-based COVID-19 tests have been gaining ground as a more comfortable and easier-to-perform alternative to swab methods, generating interest in other testing that could be done using saliva.

In this Intelligence Brief, we highlight innovations in saliva-based diagnostic devices that are facilitating greater ease for saliva to be used for at-home testing.

1. [10.1113/jphysiol.1975.sp010811](https://doi.org/10.1113/jphysiol.1975.sp010811)

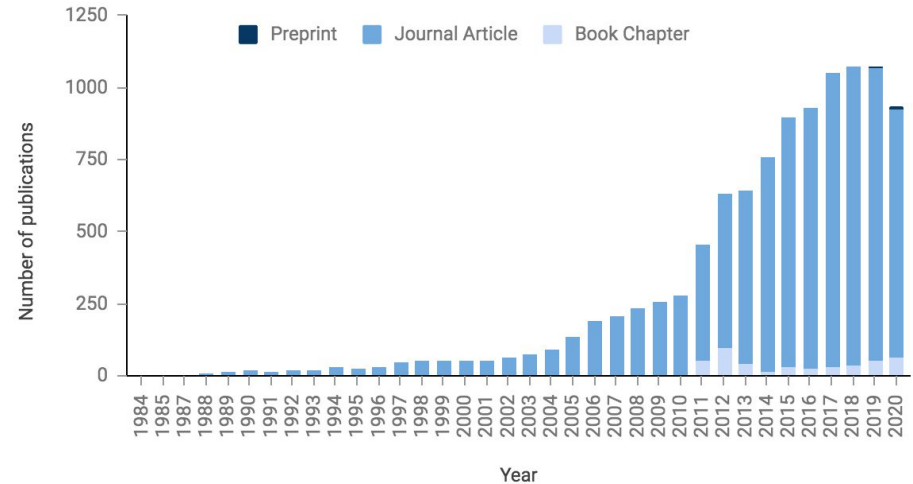
Saliva has been emerging as the sample type of choice for at-home testing.

Non-invasive collection methods are usually defined as methods that are painless and can allow self-collection, such that they can be used at home. Due to the COVID-19 pandemic, the interest in diagnostics testing for at-home use has increased, as people had to stay at home to prevent the virus from spreading while finding ways to test themselves for the COVID-19 virus.

Saliva is useful for new approaches to prognosis and diagnosis. It can help in the diagnosis of autoimmune disorders, cardiovascular diseases, infectious diseases, and cancer, as well as for drug monitoring. Saliva is easily collected and stored, and it is ideal for the early detection of diseases. Because of these characteristics, saliva has become recognized as an ideal non-invasive sample type, spurring development of methods to facilitate saliva collection and avoid contamination.

- [1]: [Saliva as a Diagnostic Fluid \(nih.gov\)](#)
[2]: [Saliva as a diagnostic fluid \(wiley.com\)](#)

Salivary biomarkers publications



There has been an exponential growth of salivary biomarkers publications over the years. From 2011 to 2019, the growth is even more pronounced, with a greater number of publications. These indicate a greater and greater number of ailments can be detected through saliva.

Source: [Salivary biomarkers detection: Analytical and immunological methods overview - ScienceDirect](#)



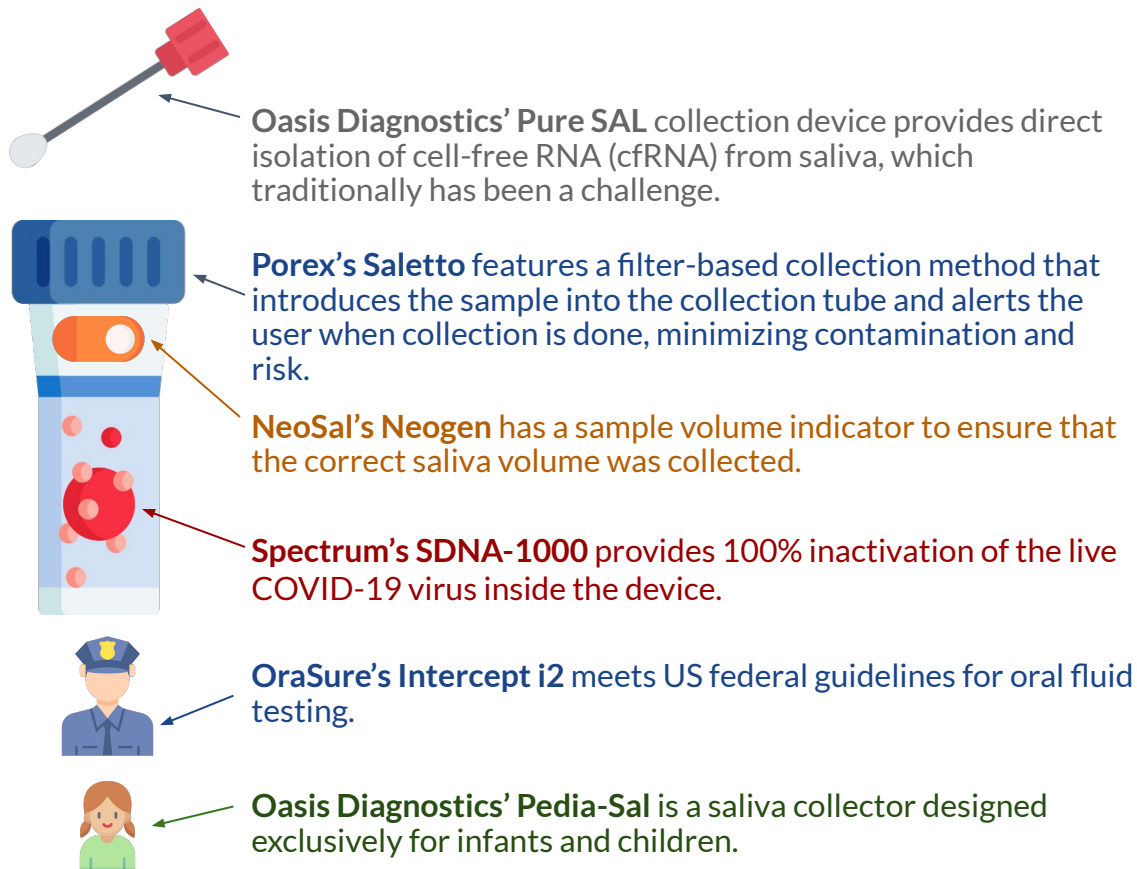
PRESCOUTER EXPERT NOTE:

“Saliva-based diagnostics hold the future of rapid, minimally invasive testing, compatible with all age groups.”

- Maikel Boot, Infectious Disease Expert, Technical Director

In every aspect of the saliva sample collection process, advances are being made to improve efficacy and ease of saliva-based sample collection.

In this report, we highlight six innovative saliva collection devices from OraSure, Oasis, Spectrum, NeoSal, and Porex.





Pure SAL allows the collection, purification, and stabilization of saliva samples for different downstream applications.

Direct isolation of cell-free RNA (cfRNA) from saliva has been a challenge due to existing cellular and molecular interfering factors. Pure SAL provides for a **proprietary system for the non-invasive, single-step, fast oral** collection of cfRNA, cfDNA, exosomes, and proteins.

Pure SAL by Oasis Diagnostics

Pure SAL uses an absorbent pad to collect saliva from the inside of the mouth next to the gum line, removing any mucinous materials. The device compression tube and a filtration medium remove interfering factors, giving a purified and stabilized sample for biomarker analysis.

Pure SAL provides for a cost-effective system for easy and fast saliva collection, thus allowing not only for point of care (POC) sample collection, but also for self-collection. This device also comes with an indicator for sample volume adequacy, allowing for the visual indication of the satisfactory volume of sample to be collected.

References:

1. Pure SAL saliva purification for liquid biopsy. Catalog number [PRsAL-401](#).
2. Khurshid et al (2017) Human salivary protein extraction from RNAPro-SAL, Pure-SAL, and passive drooling method. DOI: [10.4103/ejd.ejd_183_17](#).

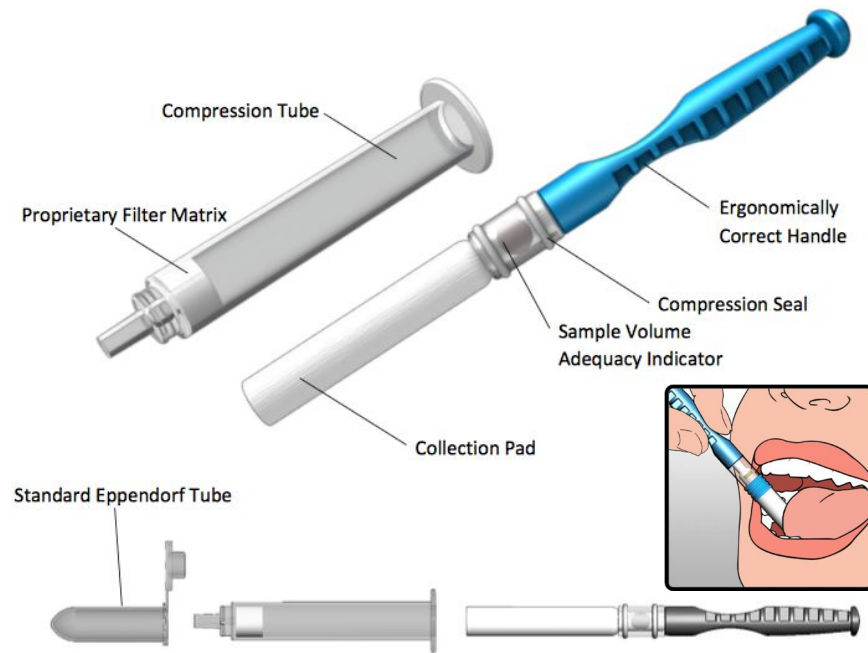


Figure: Product overview and demonstration of sample collection

Source: [Product Catalog](#)



Saletto Oral Fluid Collection Device, developed by Porex Life Sciences Institute, is **efficient, easy to use, and offers the patient safety and confidence to collect saliva**. It features an ergonomically designed cap that compresses the collection swab and forces the sample into the collection tube, minimizing contamination and risk. It also has a filtration system that eliminates debris and the need for centrifugation. To minimize collection errors, it features a color change indication technology that alerts the user that sufficient sample volume has been collected.

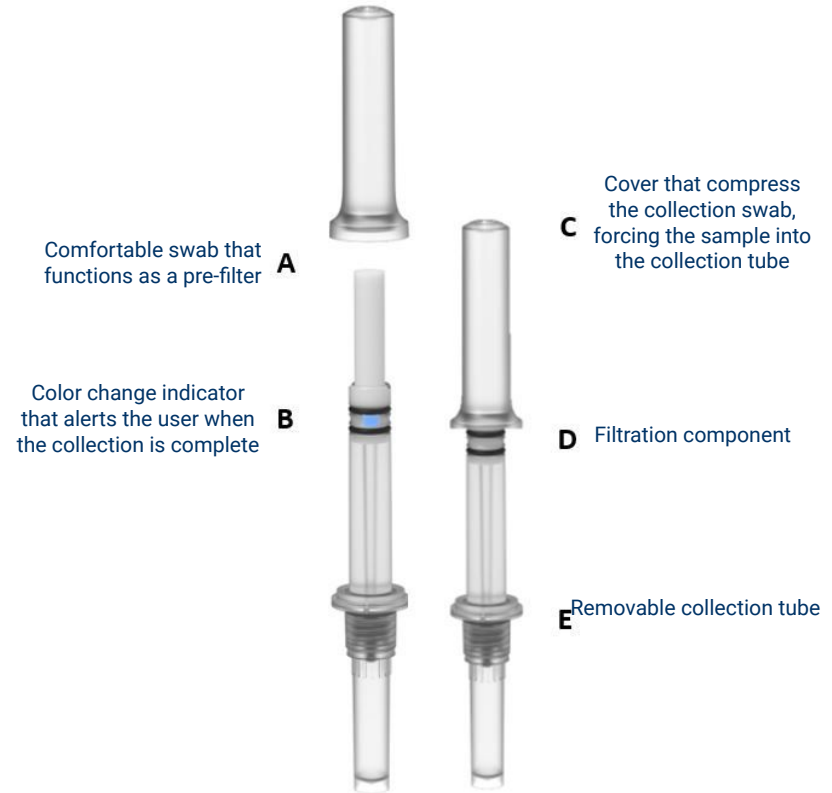
Saletto Oral Fluid Collection Device By Porex

The Saletto device from Porex is designed to be simple and easy to use. It is an integrated sample collection device that includes the swab attached to the storage location. It has a collection block connected to a handle with a sample sufficiency indicator, the storage tube, and a cover to protect the collection block once the sample is collected. The swab also functions as a pre-filter removing debris and is customized for the required volume of saliva. It has a color sensor to indicate to the patient that the collection is complete, eliminating common patient collection errors.

The Saletto device is under development and is currently only released for research purposes to validate its performance.

References:

1. <https://www.porexlifesciences.com/saletto-oral-fluid-collection-device/>



Source: [Saletto Oral Fluid Collection Device provides saliva-based diagnostics \(porexlifesciences.com\)](https://www.porexlifesciences.com/saletto-oral-fluid-collection-device/)



The **NeoSal Oral Fluid Collection System** by Neogen allows for easy and quick saliva collection without the use of any stimulator. This system has a **sample volume indicator** to ensure that the correct saliva volume was collected and uses a proprietary buffer to preserve the sample for drugs of abuse screening at room temperature.

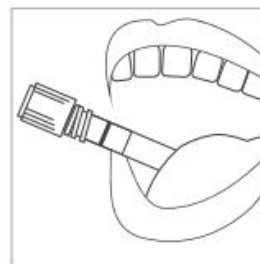
NeoSal by Neogen

The NeoSal system uses a handheld pad to collect saliva between the cheek and the gum, without the use of any stimulator, in up to 2 minutes. This system contains an indicator line that informs the user when the correct saliva sample volume was collected.

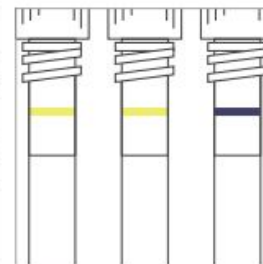
After saliva collection, the pad is placed in a proprietary buffer that ensures sample stability at room temperature. The NeoSal sample buffer is suitable for drugs of abuse screening by ELISA and analysis by liquid chromatography or mass spectrometry.

References:

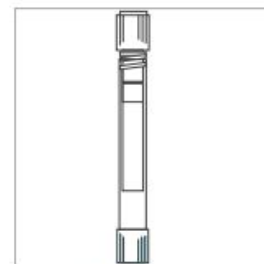
1. <https://www.neogen.com/categories/toxicology/neosal-oral-fluid-collection-system/#specifications>



Pool saliva in mouth. Insert collector pad in mouth between cheek and gum.



When a distinct blue line forms, remove collector from mouth. Typical collection time is 1–2 minutes.



Remove blue cap and snap into bottom of the tube. Insert saturated collector pad into tube.

Source:

<https://www.neogen.com/categories/toxicology/neosal-oral-fluid-collection-system/#specifications>



PRESCOUTER EXPERT NOTE:

“COVID-19 has revolutionized the way clinicians and consumers think about diagnostics. It has brought diagnostic devices closer to the homes of people.”

- Maikel Boot, Infectious Disease Expert, Technical Director

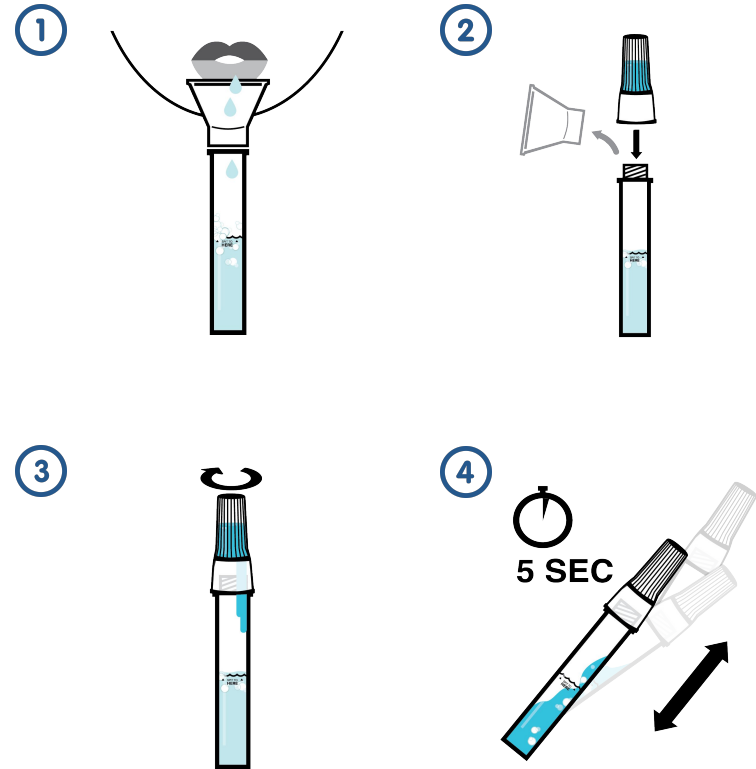
SDNA-1000 by Spectrum Solutions

The SDNA-1000 is a self-contained saliva collection system that provides sample consistency while suspending and neutralizing viral RNA transcripts post-collection for sensitive and specific analysis. A blue preservation chemistry (patented by Spectrum Solutions) contained in the cap of the SDNA-1000 is responsible for the suspension and stabilization of RNA transcripts.

This is a device designed to be easy to use, easy to carry, and safe. It provides 100% viral inactivation while preserving the DNA or RNA samples present in saliva for a long period of time, about 10 days. It is designed to collect, stabilize, and maintain during transport unprocessed saliva samples suspected of containing SARS-CoV-2 RNA.

References:

1. <https://spectrumsolution.com/spectrum-dna/clinical-products/sdna-whole-saliva-dna-collection-devices/#covid2>
2. <https://patentimages.storage.googleapis.com/f3/27/6d/1fcf0e2ffe985c/US20210052257A1.pdf>



Source: [SpectrumSolution.com](https://spectrumsolution.com)



OraSure Technologies



Intercept i2 is the latest advancement in oral fluid collection from OraSure. Its main feature is that **the device has been developed to meet US federal guidelines for oral fluid testing**. Adoption of oral fluid by the federal government eases the path to greater adoption in the commercial sector. It is also easy to use and has superior performance to comparable other devices.

Intercept i2 by OraSure

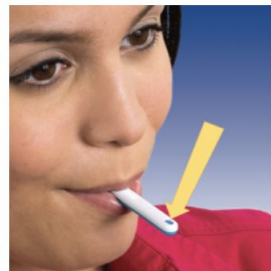
Intercept i2 from OraSure is a scientifically proven technology that allows non-invasive, easy, and convenient oral fluid collection within 3 minutes collection time. The device absorbs approximately 1.0 ml of fluid and may collect a mixture of gingival fluid and saliva rather than pure saliva, due to its positioning between cheek and gums. The retrieval of the matrix again appears via centrifugation. The intended use is for salivary drug testing, where it has shown good results. It enables accurate testing for drugs of abuse, including marijuana, cocaine, PCP, opiates, and amphetamines – including ecstasy – i.e., the standard DOT 5-panel. The Intercept i2 can also be used to screen for barbiturates, benzodiazepines and methadone.

References:

1. <https://www.future-science.com/doi/full/10.4155/bio-2017-0010>
2. <https://www.orasure.com/products-substance-abuse/i2.html>



Step 1 - Swab



Swab for 3 to 4 minutes
Maximum 15 minutes

Step 2 - Slide



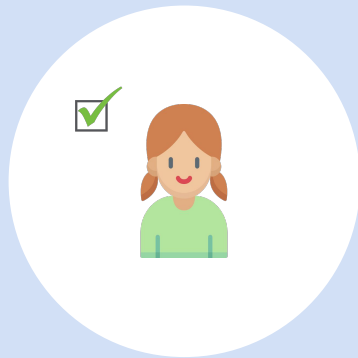
Slowly slide the
collection device into
the vial.

Step 3 - Seal



1. Screw cap onto vial
and apply seal.
2. Send to laboratory

Source: <https://www.orasure.com/products-substance-abuse/i2.html>



Oasis Diagnostics is a company focused on tools for non-invasive diagnosis and disease detection based on non-invasive samples.

Pedia-Sal is a **saliva collector designed exclusively for infants and children**. The device integrates a passive collection process with a pacifier design to not only collect fluid but also relax the infant.

PediaSAL by Oasis

Pedia-SAL, developed by Oasis Diagnostics, is a saliva collector for infants and children, including premature newborns. The device allows the analysis of DNA, RNA, proteins, and other components that may be of interest without causing any trauma to the child. The device integrates a passive collection process with a pacifier design to not only collect, but also relax the infant.

The pacifier in the device is placed in the child's mouth, where it passively passes the saliva onto a soft absorbent pad while the child sucks. After the absorbent pad is saturated, the healthcare provider is able to remove only the collection part, leaving the pacifier with the child. The saliva can be passed into a compression tube and then processed for analysis.

References:

1. <https://4saliva.com/products/pedia-sal/>



Figure: The Pedia-Sal integrates a perforated pacifier with a saliva sampling kit.

Source: <https://4saliva.com/products/pedia-sal/>



PRESCOUTER EXPERT NOTE:

“Next-generation saliva collection devices will have to focus on integrating sample preparation steps to make sample transfer into the diagnostic device as seamless as possible.”

- Maikel Boot, Infectious Disease Expert, Technical Director

Conclusion

Saliva-based collection devices are paving the way for non-invasive diagnostic tests that can be done closer to home, by inexperienced users.

- The Federal Testing Guidelines now list saliva as a valid sample for drugs of abuse testing. Devices such as the **Intercept i2 (OraSure)** are aimed at this new market.
- **Oasis Diagnostics** offers collection devices that are compatible with all ages groups, with **PediaSal** focusing on infant saliva collection.
- **Porex's Saletto** is a modular saliva collection device that can be integrated easily into existing assays or screening pipelines.
- Sample stabilization buffers are added to the collection tubes to preserve the sample during transport. **Spectrum** and **Neogen** both offer proprietary buffers added to their collection devices.

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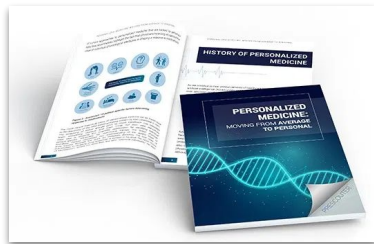
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