

# **Saliva Collection and Diagnostics Market - Global Industry Size, Share, Trends, Opportunity & Forecast, Segmented By Site of Collection (Parotid Gland Collection, Submandibular/Sublingual Gland Collection, Others), By Application Type (Disease Diagnostics, Forensic Applications, Research), By End User (Dentistry, Diagnostic Laboratories, Pharmaceutical & Biotechnology Companies, Research Institutes), By Region & Competition, 2021-2031F**

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## **Abstracts**

The Global Saliva Collection & Diagnostics Market is projected to expand from a valuation of USD 822.18 Million in 2025 to USD 1108.74 Million by 2031, registering a CAGR of 5.11%. This sector covers technologies dedicated to the non-invasive collection and analysis of oral biofluids to detect genetic markers, infectious agents, and general health indicators. A primary catalyst for this market is the growing patient preference for painless alternatives to venous blood draws and nasopharyngeal swabs, a shift that notably improves adherence among children and the elderly. Additionally, the push toward decentralized healthcare is promoting the use of stabilized saliva kits, which allow for safe ambient transport to support remote testing and molecular diagnostics.

Despite this potential, the industry encounters significant hurdles related to regulatory clearance and the validation of biomarkers against established blood standards. Manufacturers struggle to prove sample consistency and diagnostic equivalence

required for premarket approval. The severity of this challenge is highlighted by the American Dental Association, which noted that as of October 2024, there were no commercially available, FDA-approved salivary diagnostic tests for evaluating risks associated with periodontal disease, dental caries, or head and neck cancer, demonstrating the strict barriers to validation that currently exist.

## **Market Driver**

The proliferation of point-of-care (POC) and at-home testing sectors is a major force driving market expansion by decentralizing diagnostic availability and giving patients more control. This evolution enables individuals to conduct self-sampling for infectious diseases and general wellness without needing to visit clinical sites, effectively bypassing obstacles like logistical difficulties and the stigma often associated with testing. Regulatory authorities are increasingly endorsing these patient-focused models to extend public health coverage and facilitate early detection in vulnerable groups. For example, the U.S. Food and Drug Administration (FDA) approved a supplement for the OraQuick HIV Self-Test in December 2024, lowering the usage age to include adolescents aged 14 to 17, signaling a shift toward accessible over-the-counter tools that allow younger populations to manage their health proactively.

Simultaneously, technological progress in salivaomics and biomarker discovery is expanding the utility of oral fluids well beyond basic viral detection or drug screening. Researchers are actively validating new analytes for systemic diseases, prompting investments in multi-target platforms that achieve clinical-grade accuracy similar to blood tests. This scientific drive is bolstered by significant government support; the National Institute of Dental and Craniofacial Research (NIDCR) invested over \$3 million in salivary diagnostic research during fiscal year 2024 to accelerate the creation of rapid detection devices. Such funding is fueling innovation, as seen with Spectrum Solutions, which launched the SimplyPERIO saliva test in March 2024 to identify 16 specific oral targets from one sample, marking a shift toward high-throughput, molecular analysis for early intervention.

## **Market Challenge**

The Global Saliva Collection & Diagnostics Market faces substantial constraints due to strict regulatory mandates and the intricate clinical validation needed to prove equivalence with blood-based benchmarks. Manufacturers encounter high entry barriers, as they must demonstrate that biomarkers derived from saliva provide the same diagnostic precision and reliability as established plasma or serum tests. This

rigorous requirement for bioequivalence often prolongs development schedules and escalates expenses, compelling companies to fund extensive comparative studies prior to commercialization. Consequently, the uncertainty surrounding authorization pathways dampens investment enthusiasm and postpones the introduction of non-invasive testing innovations.

These regulatory obstacles directly reduce the variety of available tests and restrict patient access to advanced diagnostic instruments. Confronted with evolving compliance standards and higher evidentiary requirements, laboratories frequently choose to cut their test offerings rather than managing the expensive approval procedures. This trend of market shrinkage is reflected in recent industry findings; according to survey data from the Association for Diagnostics and Laboratory Medicine in 2024, over 50% of testing facilities intended to stop offering specific laboratory-developed tests because they could not meet new, more stringent regulatory criteria. This demonstrates how regulatory friction not only impedes new market entrants but also eliminates existing solutions, thereby retarding overall industry progress.

## **Market Trends**

The evolution of saliva-based liquid biopsy is reaching into the realm of preventative oncology, allowing for the non-invasive identification of systemic cancers that once necessitated invasive techniques. This approach leverages salivary microbiome and RNA data to detect specific tumor markers and precancerous indicators, significantly expanding the application of oral fluids beyond localized disease diagnosis. Validating this progression, News-Medical.Net reported in July 2025 that Viome Life Sciences formed a strategic alliance with Scripps Research to execute a clinical trial with 1,000 participants, aiming to create a saliva-based RNA test for early colorectal cancer prevention. This development confirms oral fluids as a feasible medium for evaluating gastrointestinal health, offering a potential reduction in the dependency on conventional colonoscopies for initial screenings.

In parallel, the growth of saliva testing within pharmacogenomics is transforming personalized medicine by enabling precise medication management through easier sample collection methods. Laboratories are increasingly adopting saliva-based genomic panels to examine how patients metabolize medications, helping to minimize adverse reactions in complex fields such as neurology and psychiatry. Highlighting this market shift, Quest Diagnostics introduced an advanced pharmacogenomic laboratory service in September 2025 capable of analyzing 17 genes and 4 HLA alleles to inform physician prescribing strategies. This advancement emphasizes the increasing

commercial practicality of utilizing saliva to integrate genetic insights into standard clinical practices, ensuring that treatments are customized to individual metabolic profiles.

### **Key Market Players**

DNA Genotek

Salimetrics

OraSure

Qiagen

Thermo Fisher

Abbott

Nipro

Zymo Research

LabCorp

BioDiagnostics Companies

### **Report Scope**

In this report, the Global Saliva Collection & Diagnostics Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Saliva Collection & Diagnostics Market, By Site of Collection

Parotid Gland Collection

Submandibular/Sublingual Gland Collection

Others

Saliva Collection & Diagnostics Market, By Application Type

Disease Diagnostics

Forensic Applications

Research

Saliva Collection & Diagnostics Market, By End User

Dentistry

Diagnostic Laboratories

Pharmaceutical & Biotechnology Companies

Research Institutes

Saliva Collection & Diagnostics Market, By Region

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

## **Competitive Landscape**

Company Profiles: Detailed analysis of the major companies present in the Global Saliva Collection & Diagnostics Market.

## **Available Customizations:**

Global Saliva Collection & Diagnostics Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

### **Company Information**

Detailed analysis and profiling of additional market players (up to five).

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