

Kaiser Permanente High Throughput SARS-CoV-2 Assay

- Date [EUA](#) Issued/Last Updated: 9/22/2021
- Entity: Southern California Permanente Medical Group
- Attributes: Real-Time RT-PCR, Saliva, Home Collection
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [EUA Summary](#), [IFU](#)
- Test is intended for qualitative detection of nucleic acid from SARS-CoV-2 in saliva that is self-collected unsupervised at home using the Kaiser Permanente Saliva Home Collection Kit by individuals 18 years or older suspected of COVID-19.
- **Testing is limited to the Southern California Permanente Medical Group** - Regional Reference Laboratory (SCPMG-RRL) located at 13000 Peyton Dr., Chino Hills, CA 91709.

SalivaDirect for use with DTC Kits

- Date [EUA](#) Issued/Last Updated: 8/27/2021
- Entity: Yale School of Public Health, Department of Epidemiology of Microbial Diseases
- Attributes: Direct to Consumer (DTC), Real-time RT-PCR, Saliva, Home Collection, Screening
- [Fact Sheet for HCP](#), [Fact Sheet for Individuals](#), [EUA Summary](#), [IFU](#)
- SalivaDirect for use with DTC Kits is a direct to consumer product for testing saliva specimens selfcollected at home (which includes in a community-based setting) using the SalivaDirect DTC Saliva Collection Kit.
- Testing is limited to laboratories **designated by the Yale School of Public Health**, Department of Epidemiology of Microbial Diseases, that includes the Clinical Molecular Diagnostics Laboratory, Department of Pathology, Yale School of Medicine, located at 310 Cedar St., New Haven, CT 06510, **that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests.**

covidSHIELD

- Date [EUA](#) Issued/Last Updated: 8/26/2021
- Entity: University of Illinois Office of the Vice President for Economic Development and Innovation
- Attributes: Real-time RT-PCR, Saliva, Serial Screening, Home Collection
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [EUA Summary](#), [IFU \(Home Collection\)](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected without preservatives in a sterile collection tube or into a sterile collection tube with a straw, in the presence of a trained observer (adult trained on how to collect saliva samples).
- This test is also for use with saliva specimens that are collected at home or in a community-based setting by individuals age 16 years and older (self-collected) or 6 years and older (collected with adult assistance) using the SHIELD Saliva Collection Kit.
- Testing is limited to laboratories **designated by the University of Illinois Office of the Vice President for Economic Development and Innovation**, that includes the University of Illinois Veterinary Diagnostic Laboratory, University of Illinois Urbana Champaign School of Veterinary Medicine, located at 2001 S. Lincoln Ave., Urbana, IL 61802, **that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.**

BioFire COVID-19 Test

- Date [EUA](#) Issued/Last Updated: 8/25/2021
- Entity: BioFire Defense, LLC
- Attributes: RT, Nested multiplex PCR, Pooling, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- The BioFire COVID-19 Test can be used to test saliva specimens collected without preservatives in a sterile container in a healthcare setting under the supervision of a healthcare provider.
- Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests and similarly qualified U.S. Department of Defense (DoD) and non-U.S. laboratories.

SDNA-1000 Saliva Collection Device

- Date [EUA](#) Issued/Last Updated: 8/4/2021
- Entity: Spectrum Solutions LLC
- Attributes: Saliva Collection Device
- [EUA Summary](#), [IFU](#)
- Intended for use by individuals to collect, stabilize and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA). The device may be used for unsupervised specimen self-collection by a layperson 18 years and older or for specimen collection by a healthcare worker from individuals of any age.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263 using an FDA authorized in vitro diagnostic (IVD) test for the detection of SARS CoV-2 that is indicated for use with the SDNA-1000 Saliva Collection Device.

TaqPath COVID-19 Fast PCR Combo Kit 2.0

- Date [EUA](#) Issued/Last Updated: 7/30/2021
- Entity: Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.)
- Attributes: Real-time RT-PCR, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva collected without preservatives in a sterile container under the supervision of a healthcare provider in a healthcare setting from individuals suspected of COVID-19.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

PerkinElmer New Coronavirus Nucleic Acid Detection Kit

- Date [EUA](#) Issued/Last Updated: 7/15/2021
- Entity: PerkinElmer, Inc.
- Attributes: Real-time RT-PCR, Pooling, Screening, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected using the SalivaSecure Saliva Collection Kit either by a HCP or self-collected under the supervision of a HCP in a healthcare setting from individuals suspected of COVID-19.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Rheonix COVID-19 MDx Assay

- Date [EUA](#) Issued/Last Updated: 7/1/2021
- Entity: Rheonix, Inc.
- Attributes: RT-PCR, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected without preservatives in a sterile tube in a healthcare setting from individuals who are suspected of COVID19 by their healthcare provider.
- Authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

TRUPCR SARS-CoV-2 Kit

- Date [EUA](#) Issued/Last Updated: 6/24/2021
- Entity: 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd
- Attributes: Real-time RT-PCR, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected with the assistance of a HCP in a healthcare setting using the OMNIgene·ORAL OM-505/OME-505 saliva collection device.
- Authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

WREN Laboratories COVID-19 PCR Test

- Date [EUA](#) Issued/Last Updated: 6/17/2021
- Entity: WREN Laboratories LLC
- Attributes: Real-time RT-PCR, Home Collection, Saliva, Screening
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [EUA Summary](#), [IFU \(Home Collect\)](#)
- Saliva specimens that are collected at home or in a healthcare setting using the WREN Laboratories COVID-19 Saliva Test Collection Kit by any individuals 18 years and older (selfcollected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance).
- Testing is limited to laboratories **designated by WREN Laboratories LLC that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high-complexity tests.**

Phosphorus COVID-19 RT-qPCR Test

- Date [EUA](#) Issued/Last Updated: 5/17/2021
- Entity: Phosphorus Diagnostics LLC
- Attributes: Real-time RT-PCR, Home Collection, Saliva, Screening
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [EUA Summary](#), [IFU \(Home Collect\)](#), [IFU \(Clinic\)](#)
- Saliva specimens that are self-collected at home or in a healthcare setting using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit by any individuals 18 years or older.
- Testing is limited to laboratories **designated by Phosphorus Diagnostics LLC that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high-complexity tests.**

Clarifi COVID-19 Test Kit

- Date [EUA](#) Issued/Last Updated: 5/6/2021
- Entity: Quadrant Biosciences Inc.
- Attributes: Real-time RT-PCR, Saliva, Pooling
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#)
- Qualitative detection of RNA from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the ORAcollect•RNA (OR-100/ORE-100) or the OMNIgene•ORAL (OM-505/OME-505) collection device.
- Qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to twelve (12) individually collected saliva specimens.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

P23 Labs TaqPath SARS-CoV-2 Assay

- Date [EUA](#) Issued/Last Updated: 4/1/2021
- Entity: P23 Labs, LLC
- Attributes: Real-time RT-PCR, Home Collection, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#), [EUA Summary](#)
- Qualitative detection of nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) including saliva specimens that are self-collected at home or in a healthcare setting with or without the supervision and/or assistance of an HCP, by individuals using the P23 At-Home COVID-19 Test Collection Kit.
- Testing is limited to laboratories **designated by P23 Labs, LLC (P23), that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.**

Advanta Dx SARS-CoV-2 RT-PCR Assay

- Date [EUA](#) Issued/Last Updated: 2/26/2021
- Entity: Fluidigm Corporation
- Attributes: Real-time RT-PCR, Saliva, Home Collection
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#), [IFU \(Home Collect\)](#)
- Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected without preservatives in a sterile container from individuals suspected of COVID-19 by their healthcare provider.
- This test is also for use with saliva specimens that are selfcollected at home with or without the supervision of a healthcare provider (HCP) with the AZOVA COVID-19 Test Collection Kit.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

NeuMoDx SARS-CoV-2 Assay

- Date [EUA](#) Issued/Last Updated: 1/22/2021
- Entity: NeuMoDx Molecular, Inc.
- Attributes: RT-PCR, Collection Kit, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [IFU](#), [IFU \(Collect\)](#)
- Qualitative detection of SARS-CoV-2 RNA from saliva specimens that are collected in a healthcare setting under the supervision of a HCP using the NeuMoDx Saliva Collection Kit.

- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Express Gene 2019-nCoV RT-PCR Diagnostic Panel

- Date [EUA](#) Issued/Last Updated: 1/22/2021
- Entity: Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory
- Attributes: Real-time RT-PCR, Collection Kit, Saliva
- [Fact Sheet for HCP](#), [Fact Sheet for Patients](#), [EUA Summary](#), [IFU](#)
- For use with saliva specimens that are collected with the assistance of a HCP in a healthcare setting, by individuals suspected of COVID-19 using the mLIFE True Oral Fluid/Viral Collection Kit.
- Testing is limited to laboratories **designated by Express Gene LLC**, DBA: Express Gene Molecular Diagnostics Laboratory which are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, **and meet the requirements to perform high complexity tests.**

For additional tests, please consult FDA's EUA website [here](#).