FRASCO® profiles

CRL Rapid Response CLINICAL REFERENCE® LABORATORY

RAPID RESPONSE COVID-19 TEST

ABOUT THE TEST:

CRL Rapid Response is:

- A saliva-based molecular RNA test that detects the SARS-CoV-2 virus
- Authorized by the FDA under an Emergency Use Authorization

CONTACT US TO ORDER:

Test kits arrive in a case of 10. Shipping to your location is free. Individual test kits can also be shipped directly to the employee's home (shipping and handling fees apply).

TEST ADMINISTRATION:

Each test kit includes specimen collection instructions and a video tutorial is available at ***crlcorp.com/covid-19-testing/2***.

The employee must:

1. Register the kit online.
2. Take a brief health survey.
3. Complete the specimen (saliva) collection.
4. Return specimen using the provided pre-paid envelope.

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by Clinical Reference Laboratory, Inc. located in Lenexa, Kansas. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

BENEFITS:

Protect your workforce by ensuring a safe return to work

Positive employee experience:

- Minimally invasive
- No nasal swab required
- Saliva-based test collection
- Easy to self-administer at home without assistance

Results returned within 48 hours of specimen receipt:

- Text message to employee with link to results
- Results posted to employer through the Frasco web portal

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SALIVA-BASED COVID-19 TESTING:

CRL RAPID RESPONSE™ is a saliva-based molecular test, which is authorized by the FDA under an Emergency Use Authorization (EUA), that can be self-collected and shipped to our lab when determined to be appropriate by a healthcare provider. Results of the test can confirm if the virus is detected in the saliva of an individual. Since no nasal swab is required, collection is minimally invasive and can be self-administered without the assistance of a healthcare worker.

FLEXIBLE KIT DISTRIBUTION:

- Bulk distribution to specified site(s) for distribution to individuals
- Collection kits sent directly to individuals

REPORTING:

- Via the Frasco Profiles website
- To donor via text and digital portal

3 EASY COLLECTION STEPS:

1. REGISTER KIT

- Register collection kit at crlclear.com and complete a health screening questionnaire.

2. COMPLETE COLLECTION

- Spit into funnel until the amount of liquid (not bubbles) reaches the fill line.
- Close the funnel lid. The liquid in the lid will be released into the tube to mix with the sample.
- Unscrew the funnel from the tube, and use small cap to close tube tightly. Shake for five seconds.

3. RETURN SAMPLE

- Write first and last name on the barcode label and affix barcode label to the saliva collection device.
- Package the sample and return using the prepaid shipping label.

Emergency Use Authorization (EUA) request for distribution and/or use of the DNA Genotek OMNIgene® ORAL OM-505 saliva collection device for the collection and stabilization of saliva in buffer to transport viral SARS-CoV-2 RNA from patients suspected of COVID-19 by a healthcare provider. The specimen collection device is for use in conjunction with molecular diagnostic testing performed at a clinical laboratory using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that is authorized for use with the home collected kit.

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SALIVA-BASED COVID-19 TESTING:

Client provides supply order details. → CRL ships collection kits per client request. → Upon receipt, client distributes to donors. → Donors follow kit instructions.

TESTING PROCESS FOR DONORS:

Donor receives Rapid Response molecular saliva collection test kit. → Donor goes to CRL Clear website, activates test kit, and completes health screening questionnaire.* → Donor completes saliva sample collection and ships to lab.

POSSIBLE RESULTS OF MOLECULAR SALIVA TEST:

PCR (+)
Viral RNA detected

Follow CDC protocols. Retest with molecular prior to returning to work.

PCR (-)
Viral RNA not detected

Report not detected result. May be cleared to return to work.

*Survey questionnaire developed in accordance with applicable CDC COVID-19 guidelines.

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