



## **COVID - 19 Testing Solutions**



## CRL Testing for COVID-19

#### Items

- 1) CRL Rapid Response Kit Components
- 6) Instructions and Web Video Link
- 7) Reporting and Results
  - WebOasis Administrators CRL Clear Individual Reporting
- 8) FAQ's



## CRL COVID - 19 Testing – Active Virus



Is an FDA EUA authorized saliva-based molecular test that is easily selfcollected and shipped to our Lab. Results of the test confirm if the COVID-19 virus is detected in the saliva of the individual. Since no nasal swab is required, collection is minimally invasive and can be reliably selfadministered without the assistance of a healthcare worker. Saliva is also more accurate for SARS-CoV-2 detection in COVID-19 patients than nasal swabs.



## Saliva Bulk Pack – 10 Kits per Cartons



Kits are self contained with all components

Bulk shipments include 10 kits per carton.





## Individual Saliva Collection Kit





## Saliva Kit – Easy Instructions

#### **3 EASY COLLECTION STEPS**

#### **1. REGISTER KIT**

Register your collection kit at criclear.com and complete a health screening questionnaire.

#### 2. COMPLETE COLLECTION

- Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.
- 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 the small cap to close the tube tightly. Shake for five seconds.

#### **3. RETURN SAMPLE**

- · Write your 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.













## Saliva Kit Instructions

FOR REUSE ONLY - FOR WOUSE ONLY MERCENCY USE AUTHORIZATION ONLY

123456123456

covid+9-se



- Collect sample by closing mouth and sucking. Spit into funnel until the amount of liquid (not
- bubbles) reaches the fill line shown in picture #1. DO NOT overfill tube
- Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix. with the sample. Make sure that the lid is closed tightly.
- Hold the tube upright. Unscrew the funnel from the tube
- Use the small cap located in the plastic clamshell to close the tube tightly.
- Shake the capped tube for five seconds. Discard or recycle the funnel.
- IMPORTANT: Wash your hands theroughly for 20 seconds again, then dry your hands after completing the col



#### LABEL YOUR COLLECTION DEVICE:

- Write your first and last name on the harcode label. The name on the barcode label must match the name on your online registration.
- Affix barcode label to the saliva collection device as shown, after completing collection.
- Label placement should start below the cap with barcode number running down the tube.
- Tip: Start at the arrow in front of the "F" in the ord FIS and run the label around the tube.
- Note: The label should not overlap. Testing may be delayed or not performed if tube is received unlabeled.



#### RETURN: STO Before returning sample, you MUST register your kit at CRUCLEAR.COM.

- DO NOT return the funnel with the sample. Prior to shipping, the tube should be sealed with the small cap. Funnel and the clamshell that the device arrived in can be discarded.
- Place the saliva collection tube into the small pouch of the plastic sip top bag with the absorbent pad and seal the bag.
- Unless you have been provided with alternative return instructions, place sealed plastic zip top bag containing the sample and the absorbent pad into the original kit box provided and dose the lid. Place the box that contains the sample inside the return shipping pouch and seal pouch. Place FedEx shipping label on exterior of shipping pouch.
- Shipment can be placed in any FedEx Drop Box or dropped at an approved FedEx location, Or, contact FedEx at 1-800-463-3339 to schedule a pickup, Specify you have a prepaid shipment for overnight delivery.

QUESTIONS: For additional information about COVID-19, visit

OE is a registered the described Object Reference Laboratory 1 Inc. ADV 061629



View the self-collection video for the CRL Rapid Response<sup>™</sup> Saliva Test.

https://www.crlcorp.com/covid-19testing/videos/

Keep the instructions to have a record of the sample barcode or take a picture of the barcode with your cell phone.

This is significant when tracking sample or addressing orphans and unregistered samples.



## Saliva Return Instructions

Place the saliva collection tube into the small pouch of the plastic zip top bag with the absorbent pad and seal the bag.





## **Return Specimen Bags**





# Saliva Sample Shipment Instructions



#### **Returning a sample:**

Unless you have been provided with alternative return Instructions, place the sealed zip top bag containing the Specimen and silica gel moisture absorbent packet into the Box provided with the UN 3373 marking and close the box. Place the box containing the specimen into the shipping Pouch and seal the pouch. Affix the included FedEx shipping Label on to the outside of the shipping pouch.

Shipment can be placed in any FedEx Drop Box or dropped at Any approved FedEx location. Or, contact FedEx at 1-800-463-3339 to schedule a pick-up (specify that you Have a prepaid shipment for overnight delivery).

Each person should keep their FedEx tracking number and sample barcode for easy tracing (write the information on paper instruction sheet and/or take a picture with the cell phone).





## **Testing and Reporting**

Turn Around Time (TAT) - The time it takes for a sample to reach CRL, be accessioned, processed and tested by the lab and, reported electronically to WebOasis (Administrator Portal to review results) and AccessMyLab (CRL's donor reporting portal)

#### Preliminarily identified as 2 days for Oral Fluid

**Oral Fluid Example:** sample arrives at CRL on Monday, is tested and reports by EOD Tuesday or Wednesday. Issues that can impact TAT may include:

- ✓ No registration of kit on CRL's Clear App (sample becomes an orphan and is researched by customer support)
- ✓ No barcode affixed to collection device the barcode is removed from the enclosed kit/typed instructions and affixed over the 55 barcode on the tube (the barcode connects the kit to your company/location – do not mix kits with other business locations)
- ✓ Incorrect or illegible labeling on the sample label (name and DOB must match the electronic order from crlclear.com)





### Web Oasis<sup>™</sup> Laboratory Reporting Internet Site User's Help Guide



## **Testing and Reporting**

Email Subject Line: COVID Testing WebOasis Access

Good morning XXXXXXX,

Thave set you up to receive COVID test results via our secure website.

This is the website you will access: <a href="https://oasis.crlcorp.com">https://oasis.crlcorp.com</a>

Your Log – In ID is: XXXXXX Your Username is: XXXXXX Your temporary password is XXXXXX

You will be prompted to setup a new password the first time you login.

You will receive an email each time new reports are ready (if you prefer for this feature to be turned off, just let me know). You can highlight and view or print the reports that you would like to access.

\*You can SKIP the registration page the first time that you log in.



## **Getting Started**

Go to the web address (URL) of https://oasis.crlcorp.com/ You can bookmark this address for quick access the next time you need to look up a result

#### Logging Into Web Oasis<sup>™</sup>

Web Oasis<sup>™</sup> requires each user to have a Login Id, User Name and Password. CRL provides your Login ID, User Name and a temporary Password. Your Login ID is a seven character code. If you do not have a Login ID or you encounter problems accessing Web Oasis<sup>™</sup>, please contact CRL COVID Testing Support at <u>ctsupport@crlcorp.com</u>

In **the Login ID field**, type in your login ID. Type in your user name in the **User Name field**. Type in your password in the **Password field**. As you enter your password, asterisks obscure the characters you type. This prevents unauthorized users from obtaining your password.

#### Welcome to *Oasis*™ Login ID Access and use of this web-site is restricted to authorized users (who have agreed to be bound by all the terms, requirements and conditions in CRL's OASIS™ Website Terms of Use). Unauthorized users should EXIT immediately to Username avoid possible civil or criminal liability. Unauthorized access to this facility or copying (or any other reproduction) of materials from this system is prohibited. Authorized Users may login with your Username Password and Password provided by your CRL authorized System Administrator. If you login to this web-site you are subject to the site's Terms of Use and you agree to be bound by these terms. Please read these terms carefully. If you do not wish to accept these terms, you must exit immediately. Loain

### Logging Into Web Oasis™

When you log in for the first time, you will be prompted to change your password. Type in your temporary password in the field marked as OLD PASSWORD. Tab down to the field marked NEW PASSWORD, and type in the password you wish to use. Tab again to the CONFIRM field, and retype the new password. After the fields are complete, press the **SUBMIT CHANGE** button to authenticate your changes.

You will be directed back to the log in page.

Password Neco	mmendations:			
Use a mix of numbers, Do not use a word from Do not use your user n Do not use word Dasis. Passwords may never t Your password must be	letters, and special cha na dictionary. ame, or any part of you er reused by a user. I between 4 and 48 chu	iractèrs. This password is ur name. aracters long.	not case sensitive.	
Change Password				
Change Password				
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**NOTE:** Passwords must be a minimum of 8 characters, containing at least one (1) character from four(4) of the following categories: uppercase letter, lowercase letter, numeric digit, and special character.

LINICAL REFERENCE

Greater Insights. Better Outcomes. 14

Once you are logged into Web Oasis<sup>™</sup>, you will see the Welcome screen. All unviewed reports will be listed.



Login ID
CRLWE81 🗸
Oasis v 9.3.2.0

Home CRL U

A message will appear if there are no new reports to view.

From here you can see all of the unviewed reports.

To generate a PDF of all reports, click ALL UNVIEWED LAB REORTS.

You may also download your reports by clicking the Download button. An Excel File will be downloaded for you to utilize.

To look at an individual donor's report, click on the check box located to the left of the name and click View. To look at more than one individual report, click on the check box located to the left of all names and click View.

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The lab summary page will be the first view seen after you have clicked on the View button from the Welcome Screen.

Under the *Results of Testing* section, You can review the donor's results directly.

To generate a PDF of the donor's report, click LAB Report.

When you have completed your review, click Next to show the subsequent report. The Previous button will show the report that you have already viewed.

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Once you have viewed a report, click on the button **MARK VIEWED**. You will then be returned to the unviewed reports screen, and that report will no longer show.

After viewing and/or printing all unviewed reports, you may click the button **Mark Selected as Viewed** 

You will see a confirmation box to confirm that you wish to mark all unviewed reports as viewed.

Are you sure you want to mark selected reports as viewed?



The reports will no longer show up when you are returned to the home screen.



## Imaged Documents

After you have been redirected to a new screen, click on the Clinical button under Specimen Images. If there are multiple images, more than one Clinical option may be available.



### Imaged Documents

If a donor's report has an associated imaged document, click the Document Images CRL button to view the information.

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Patient Demogra	aphics	Patient Notes						
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### Searching for Reports



Home CRL Order Supply Exit



Back Lab Manual New Search User Settings Summary Search Collection Site

To Locate a specific donor's report, click on NEW SEARCH.

Under Patient Demographics, enter the information you know about the donor's specimen. Often, entering a little information is better than entering a lot of information. For example, if the donor's last name was Public6, entering Pub in the Last Name field will return all persons whose last name starts with "Pub".





### Searching for Reports

When you have entered all of your search criteria, you can begin the search by clicking FIND.

If there are donors that match your search criteria, they will be listed one record per row in the Displaying Matches window. If you wish to view or print all records, then continue. Otherwise, select the donor you wish to examine by clicking on their name. To view the donor's laboratory report, click the VIEW button.



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## Searching for Reports

You can also search for a summary report by clicking the SUMMARY SEARCH button.

This will bring up the search screen allowing you to search by the following fields:

- Specimen Collected
- Specimen Received
- Report Updated
- Account
- Sample Type
- Reason for Testing
- Test Name
- Report Type

Clear Find		
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Reference Text Name	Any Work in Progress Reported to MRO Negative Non-Negative Processor	© yes

## **COVID** Support

COVID Testing Support: <a href="mailto:ctsupport@crlcorp.com">ctsupport@crlcorp.com</a>

Support for this product is available: Monday through Friday 7:30 AM to 5:30 PM Central time







## COVID - 19 Individual Results Reporting



### CRL Clear Reporting for Participants



Language English V

Welcome to the CRL Clear App. Clinical Reference Laboratory has developed self-collected tests for determining COVID-19 status: CRL Clear \*\* - a lab developed dried blood spot (DBS) finger stick test to determine the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19, and CRL Rapid Response \*\* - a lab developed saliva-based molecular test to determine the presence of the virus.

After registering your kit, you will be asked to complete a survey to determine eligibility for completing your CRL Clear<sup>TM</sup> dried blood spot test. After giving your consent, please follow the instructions on the next pages for how to obtain your sample and how to ship your sample back to the lab. Answers to FAQs can be found on each page.



### SMS Text to Participant to Review Results





This is displayed after clicking the URL in the text message (displayed on the previous slide).

This is the same phone number used when registering the kit (this pre-populates from the SMS text).

Input the correct date of birth (used when registering) and then accept the terms of use and click submit.



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### SMS Text Verification Code to Participant





Entering the verification code (shown on the previous slide) into the field and hit "submit".



Summary of results are displayed by test date.

Results Key: Not Detected = Negative Detected = Positive

Non-Negative (Defined on the next slide)

7/5/2020	PCR SARS-COV-2 VIRUS SALIVA	
Result:	NOT DETECTED	
7/22/2020	PCR SARS-COV-2 VIRUS SALIVA	
Result.	NOT DETECTED	
7/28/2020	PCR SARS-COV-2 VIRUS SALIVA	
Result	NOT DETECTED	
8/4/2020	PCR SARS-COV-2 VIRUS SALIVA	
Result.	NOT DETECTED	

#### Results Key: Not Detected = Negative Detected = Positive

#### **Non-Negative Result**

TNP (test not performed) – occurs if there is a miss-match between the tube and e-order or, if an order was not received for a sample.
SNS (sample not submitted) – received the e-order, but, did not receive a sample at the Lab.
NSA (not suitable for analysis) – no amplification of the sample / could be a collection issue or a repeat failure of the control.

CRLX CLINICAL REFERENCE"
Clear LABORATORY
Laboratory Report SID: 6059842564 Name Gender: Male Collected 8/4/2020 Reported Date 8/5/2020
Determination Your Result Expected Range
FOR ADDITIONAL INFORMATION/QUESTIONS REGARDING YOUR LABORATORY RESULTS. CONTACT YOUR PRIMARY CARE PHYSICIAN OR ORDERING PHYSICIAN NOTED ABOVE BEFORE GOING TO A HOSPITAL OR URGENT CARE FACILITY ALL TESTS PERFORMED ON BLOOD UNLESS OTHERWISE SPECIFIED THIS TEST WAS DEVELOPED AND ITS PERFORMANCE CHARACTERISTICS DETERMINED BY CLINICAL REFERENCE LABORATORY, INC. THIS TEST HAS NOT BEEN FDA CLEARED OR APPROVED THIS TEST HAS BEEN VALIDATED IN ACCORDANCE WITH THE FDA'S GUIDANCE DOCUMENT (POLICY FOR DIAGNOSTICS TESTING IN LABORATORIES CERTIFIED TO PERFORM HIGH COMPLEXITY TESTING UNDER CLIA PRIOR TO EMERGENCY USE AUTHORIZATION FOR CORONAVIRUS DISEASE-2019 DURING THE PUBLIC HEALTH EMERGENCY) ISSUED FEBRUARY 29TH, 2020 FDA INDEPENDENT REVIEW OF THIS VALIDATION IS PENDING.
TESTING PERFORMED AT CUNICAL REFERENCE LABORATORY 8433 QUIVIRA ROAD, LENEXA, KS 66215 (913)492-3652 DR ROBERT L. STOUT CLIA #17D0667123 CAP #3021101
Return

## FAQ's Specific to Testing Solutions

#### What is molecular PCR testing for and why is it being performed for COVID-19?

Molecular PCR tests are for individuals with COVID-19 symptoms (symptomatic), or who may be at risk due to a recent exposure. These tests are used to indicate presence of the virus or active COVID-19 infection. The molecular diagnostic test for COVID-19 detects the presence of the SARS-CoV-2 virus. To determine if a person has a current infection and to allow a health care provider to make recommendations regarding care. **What molecular PCR testing is not intended to do?** 

To make a diagnosis (that will be done by your health care provider), determine the severity of your infection, future clinical progression and recovery.

#### What are the symptoms of COVID-19?

Individuals with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Per the CDC, symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

- ✓ Cough, fever, chills, sore throat
- ✓ Shortness of breath or difficulty breathing, muscle pain, new loss of taste or smell
- Other less common symptoms have been reported, including gastrointestinal symptoms like nausea, vomiting, or diarrhea
- ✓ This is not a list of all possible symptoms

# FAQ's (continued)

#### How should specimens be collected?

Only specimens collected with **CRL RAPID RESPONSE™** kits are acceptable for testing with CRL laboratory procedures. Sample preparation, including pre-analytical conditions, are important for a successful self-collection. To help ensure success, each kit will have detailed instructions regarding preparation of collection space and a link to the CRL Clear™ App that will lead the collector/donor through a step-by-step process to complete the collection. Instructions for specimen collection, including illustrated guides, can also be found on our website at www.crlcorp.com/covid-19-testing/videos If I need additional assistance completing my collection, what should I do? Client Care specialists are available to assist and can be reached at

#### CTsupport@crlcorp.com

#### How can I check the STATUS of a result? <u>Status.crlcorp.com</u>

#### How should specimens be shipped?

All saliva specimens should be shipped at room temperature via overnight delivery service with the enclosed shipping materials from the kit.

#### What is the turnaround time (TAT) on results?

CRL Rapid Response (molecular) will report approximately 48 hours from sample receipt (in most cases).

## **Resources for COVID-19 Information**

For more information, see the FDA website:

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-updateserological-test-validation-and-education-efforts

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/euaauthorized-serology-test-performance

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqstesting-sars-cov-2

For the most current information regarding COVID-19 symptoms, please refer to the CDC Symptoms webpage: <u>https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</u>

For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) general webpage: <u>https://www.cdc.gov/COVID19</u>

## THANK YOU!