

# COVID-19 Testing Manual

*Procedures for K-12 Schools*



# Overview & Purpose

The objective of this program is to provide accurate, affordable, and efficient SARS-COV-2 testing services to organizations through saliva based testing. The following video may be helpful to share with your organization: [How to Swab on Vimeo](#).

Please contact [covid-support@quadrantbiosciences.com](mailto:covid-support@quadrantbiosciences.com) with further questions about the COVID-19 testing program.

## Performance Standards

1. This program utilizes the Clarifi COVID-19 Test Kit created by SUNY Upstate Medical University and Quadrant Biosciences. This test is authorized under an FDA Emergency Use Authorization (EUA).
2. The test is performed by Quadrant Laboratories, LLC, a CLIA/CLEP high-complexity accredited clinical laboratory.
3. Pooling results are delivered within 24 hours and reflex testing results are delivered 48 hours after samples are received on site at Quadrant Biosciences's laboratory.

## External References

[Clarifi COVID-19 Test Kit EUA Letter](#)

[Web App User Guide](#)

[Pooling Information](#)

[Patient Fact Sheet](#)

[Healthcare Provider Fact Sheet](#)

[UN3373 Stickers](#)

[Log Sheet](#)

# Prior to Testing

## Required Materials for Testing Using OR-100 Kit

Quadrant Biosciences will provide the following materials:

1. Barcoded saliva collection kits (one per person, as pictured on the right).
2. Labeled biohazard bag sufficient to hold 12 saliva collection kits.
3. Transportation containers for supplies.



Each organization is responsible for providing the following:

1. Personnel at each site. It is recommended each collection station will need **three** personnel:
  - a. One **Greeter** to screen test subjects as they arrive.
  - b. Two **Attendants** to distribute saliva collection kits, scan their barcodes, and receive completed collections.Each collection station is estimated to have a processing capacity of 100+ individuals per hour under ideal conditions.
2. One table for each collection station (for materials to distribute to individuals being tested)
3. Container of disinfecting lab wipes (one per station)
4. PPE, including disposable paper gowns with cuffed sleeves, plastic gloves, N95 or surgical fluid masks, and facial shield or goggles. Staff using these PPE should be properly trained on donning and doffing procedures.
5. Large trash receptacles (one per station) with bags and ties.
6. Social distancing reminder marks and signs.
7. Hand sanitizer stands.
8. Two barcode scanners for each station. These must be capable of reading 128C. We recommend the [Honeywell Genesis 7580g](#) or [Handheld Scanner](#).

## App Usage

These testing services utilize a web application for data collection. The app is located at:

[app.clarifi-covid-19.com](https://app.clarifi-covid-19.com)

(Note: The Web App [user guide](#) is provided in the top right corner of the app homepage.)

## Profile Creation

*For those being tested, and parents.*

Prior to testing, adults must create a profile for themselves through the app. Minors cannot create their own profiles; their parent/legal guardian must create one on their behalf. If a profile is not created, a person cannot be tested. Therefore, it is critical that anyone being tested is instructed to create a profile for themselves, and/or their children, prior to arriving at the testing site. We recommend that these profiles are created at least two days before testing.

### How to Create a Profile

**Below are step by step instructions that can be provided via email to the people being tested in your organization and/or their parents/guardians:**

1. For minors, one parent/guardian will need to use the provided URL ([app.clarifi-covid-19.com](https://app.clarifi-covid-19.com)), click "register," and complete the required fields to create a parent/guardian profile. For adults, they must self register. This information is needed for compliance with the NYS Department of Health and for insurance purposes.
2. The same parent/guardian should click "add a profile" within the parent/guardian profile for each minor they are responsible for, and/or for themselves if they are being tested.
3. Please be sure to click the correct organization when prompted to select an organization.
4. Individuals will not need to "Add a COVID-19 test" prior to testing. This will be completed for the child/student on site the day of testing.\*

*\* Unless your organization has been instructed by Quadrant Biosciences, test subjects or their parent/guardian do not "Add a COVID-19 test" themselves. This is **only** done once they are in possession of a test kit, and instructed to do so by a healthcare professional (HCP). Typically, the HCP does this on behalf of the individual.*

## Organization Manager Setup

*For organization administrators and health care professionals.*

Healthcare professionals (HCPs), organization administrators, or other authorized personnel can use the app to search profiles for their organization. This is helpful in order to view registrations that were completed by parents at home and compare against the organization/organization's roster.

In order to gain access, these individuals must:

1. First create an account at [app.clarifi-covid-19.com/register](https://app.clarifi-covid-19.com/register)
2. After creating an account, please have an administrative contact email [covid-support@quadrantbiosciences.com](mailto:covid-support@quadrantbiosciences.com) to specify (1) your organization and the (2) names and (3) email addresses that should have access as an organizational manager to facilitate testing and view results.

## Test Registration Manager Setup

*For personnel responsible for registering patient test samples. This user type does not allow users to view results.*

In order to assign this user type, Organization Managers must:

1. First create an account at [app.clarifi-covid-19.com/register](https://app.clarifi-covid-19.com/register).
2. After creating an account, please have an Organization Manager email [covid-support@quadrantbiosciences.com](mailto:covid-support@quadrantbiosciences.com) with the names and email addresses of the accounts which they would like to have the access to.

# Day of Testing

## Setup of the Test Area

### Option 1: Using a Designated Testing Area

1. Staff ensure they have proper PPE prior to testing. This includes N95 or surgical fluid masks, gloves, and close toed shoes.
2. Test subjects form a line with sufficient spacing to maintain social distancing. Staff not directly facilitating testing can be beneficial for this step.
3. When prompted, test subjects approach Greeter.
4. Greeter asks the test subject if they are currently experiencing any COVID-19 symptoms; if they are, the Greeter instructs the test subject to stop and report to the organization health office for separate evaluation. (Additional staff used to redirect symptomatic test subjects can be beneficial).
5. Non-symptomatic test subjects are asked to verify that they have not eaten, drank, brushed their teeth, or used other prohibited substances as instructed. If they cannot verify this, they are asked to exit and return in an hour.
6. Greeter will ask the test subject for their name and search for it in the app. If they don't exist, the test subject will be asked to leave the line and register prior to testing.
7. If the test subject passes this screening, they enter a line for collection points.
8. If the collection points have chairs, they must be sanitized between use.
9. Once prompted, test subjects sanitize their hands, and sit down in a collection seat.
10. An Attendant approaches the test subject with a test kit and can begin the Collection Procedures.

### Option 2: Mobile Room-to-Room Collection

*For this option, if test subjects are already seated in a classroom, or open office, and that space has them spaced at least six feet apart, testing staff can move from area to area testing subjects.*

1. Staff ensure they have proper PPE prior to testing. This includes N95 or surgical fluid masks, gloves, and close toed shoes.
2. Staff enter the testing area.
3. Prior to distributing the test kit, staff explain collection instructions to all the test subjects.
4. Staff ask anyone with COVID-19 symptoms to leave and report to the organization health office.
5. Non-symptomatic test subjects are asked to verify that they have not eaten, drank, brushed their teeth, or used other prohibited substances as instructed. If they cannot verify this, they are not given a test kit.

6. Staff check that each test subject is registered. If they are not, they are not given a test kit.
7. If test subjects are non-symptomatic, have not consumed prohibited substances, and are registered, the Attendant can now begin the collection procedures.

## Collection Procedures

1. Ensure the test subject understands the collection procedure prior to beginning collection.
2. The collection should be liquid saliva from the mouth, not phlegm from the throat, or nasal mucus. Avoid deep throat phlegm or mucus.
3. Unpack the collection tube enough so that the test subject can pick it up.
4. Have patients collect samples, by swabbing along the gumline and cheek or under their tongue.
5. Keeping the tube upright to ensure no liquid is spilled, have the test subject insert the swab into the collection tube and secure the sample by twisting the blue cap.
6. Once secured the test subject will then shake the tube for 10-15 times.
7. Instruct the test subject to hand back the collection tube, keeping it upright.
8. If collection is successful, using a finepoint lab marker, the Attendant writes the test subject's **legal full name and date of birth (DOB)** on the collection tube using caution not to write on the pre-printed barcode. [Labels](#) may be used and fixed to the tube (see below). Labels must NOT cover the barcode.

The name and DOB should follow the following syntax:

Last Name, First Name

MM/DD/YY

*Note: The **LEGAL** name **MUST** be used and **MUST** match the name listed within the registration app **EXACTLY** (e.g., subjects cannot register as Robert and write Rob on the tube). Any discrepancies will require follow-up with the organization manager and create delays in receiving test results.*

Please note that a **lab marker is preferred**, standard ballpoint pens will smear. (We recommend the [Thermo Scientific Fine Line Lab Pen](#), but if that cannot be acquired, a fine point permanent marker will suit).

9. After writing the test subject's information on the collection tube, the Attendant will scan the barcode on the collection tube into the app.
10. After scanning, the Attendant will **click "submit"** to complete test registration in the app. (**Note:** This is a critical step because if the "submit" button is not clicked successfully, the test registration will not be found by lab staff and sample results could be delayed)
11. At this point, the test subject should be instructed to exit the collection area.

**These collection devices cannot be pooled at your organization. Do not decant the contents into a pooled collection tube. The pooling will be performed by Quadrant Laboratories.**

## Ordering Supplies

Saliva collection kits can be ordered by contacting Heather Blair via email at [heather.blair@quadrantbiosciences.com](mailto:heather.blair@quadrantbiosciences.com). Supplies can be picked up or shipped to the organization. There are two warehouses to pick up supplies: 841 E Fayette St, Syracuse, NY 13210 and 6251 Fly Road, East Syracuse, NY 13057. The Fly Road location is approximately 10 minutes from the drop off site at Quadrant Biosciences. The pick up location will be confirmed by Heather Blair via email.



# Mailing Samples

Saliva samples are classified as UN3373 Biological Substance, Category B for shipping purposes. This means the sample must be in triple containment:

1. Primary leak proof packaging - saliva tube.
2. Secondary leak proof packaging - bag - this also requires a sufficient absorbent pad for the sample volume.
3. Outer packaging - shipment box.

In order to ship the saliva collection kits back to us, you will need to:

1. Complete the “[ELC Pooled Testing Manifest](#)” for every box of samples returned to the lab. It is critical that lab staff are able to easily identify the organization and number of samples being shipped from your organization.
2. Tighten the tops of the saliva collection kits to ensure spilling does not occur.
3. Add an absorbent pad to the biohazard bags.
4. Place 12 saliva collection kits into the biohazard bag. A pool will be created from the 12 samples you place in this bag. (However, if many bags are returned with less than 12 samples per bag, samples from your site will be combined to process pools of 12). You may provide 1-2 bags of less than 12 samples with each shipment. You can place up to 24 samples in a bag if you would like 2 pools to be created in a random fashion from the samples in the bag.
  - a. Your samples will NOT be combined with another site’s samples. Do not combine samples collected on different days into a bag to be pooled. Do not combine OR-100 and OM-505 saliva collection kits into one bag; these must be pooled separately within the lab.
  - b. If it is required that samples provided to the lab are not combined in a pool with other samples from your site (e.g., faculty vs. students) please write in permanent marker “Do not combine” on the bag.
5. Print a [UN3373 label](#) and fill in information for an emergency contact. Add the label to the box (a simple cardboard box is sufficient).
6. Contact Peter Rasmussen [peter.rasmussen@quadrantbiosciences.com](mailto:peter.rasmussen@quadrantbiosciences.com) if you were not assigned a laboratory to ship samples to.

# Dropping off Samples

## Syracuse Laboratory:

1. Complete the “[ELC Pooled Testing Manifest](#)” for every shipment.
2. Bring samples to Institute for Human Performance (IHP) located at 505 Irving Ave, Syracuse, NY 13210 between 8AM to 7PM Monday - Friday, and 8AM to 3PM on Saturday and Sunday.

- a. Samples dropped off on weekdays between 8AM - 3PM can expect a **next-day** delivery of results.
  - b. Samples dropped off on weekdays between 3PM - 7PM can expect a **two-day** delivery of results, with the potential for earlier delivery.
  - c. Samples dropped off after 6PM: please knock on the garage entrance door and the security guard will let you into the building.
3. When you arrive at IHP, park in the garage on Madison Ave side (see directions on page 13).
4. Enter IHP through the parking garage and ask the security guard at the front desk to unlock the pooling drop-off room on the first floor.
5. Place samples in the drop-off room and sign the log on the table which includes the date and time of the delivery, the organization, and initials of the person making the delivery.
6. If dropping off on Saturdays, please pull up to the front of the building. The building and garage are locked on the weekends. If a guard is not available to meet you, please call the lab phone at 315-464-7729 or Lab Manager Sarah Gentile at 315-575-3784 and a member of the lab staff will meet you to receive your samples.

#### **Buffalo Laboratory:**

1. Complete the "[ELC Pooled Testing Manifest](#)" for every shipment.
2. Deliver to Farber Hall 301 on the University at Buffalo South Campus (3435 Main Street, Buffalo NY) between 7AM and 8PM Monday - Friday and 8AM – 5PM Saturday and Sunday.
  - a. Samples dropped off on weekdays between 8AM - 3PM can expect a **next-day** delivery of results.
  - b. Samples dropped off on weekdays between 3PM - 7PM can expect a **two-day** delivery of results, with the potential for earlier delivery.
  - c. Samples dropped off after 6PM: Drop off in Room 224A.
3. Complete the log sheet which includes the date and time of the delivery, the organization and initials of the person making the delivery.
4. When the laboratory is closed, deliveries may be made to the Farber Hall mail room (Room 224A) on the second floor. The mail room is checked for deliveries daily.
5. Parking is available in the Farber Hall lot. (see map on page 14).
6. Any questions should be addressed to Lab Manager Mike Wendel at 716-335-5660.

**The Institute for Human Performance**  
**505 Irving Avenue**  
**Syracuse, NY 13210**



**From the North**

- (Syracuse Airport or Syracuse Transportation Center )
- Take Route 81 South to exit 18 (Adams St.)
- Exit down the ramp using the left lane
- Proceed underneath the expressway - keep to the far left lane
- Turn left on Adams St. and stay in left lane
- Travel three blocks to the top of the hill (Irving Ave.)
- Turn left on Irving Ave.
- Travel two blocks (IHP is on the right in second block), to Madison St. (4-way stop sign)
- Turn right on Madison
- Parking is off Madison on the right

**From the East**

- Take NYS Thruway to exit 34a (481)
- Take 481 south to 690 west to the Downtown/Townsend St exit 13
- Turn left off the ramp onto Townsend St.
- Turn left at sixth light (Adams St)
- Go under Route 81 overpass, crossing Almond St., stay in the left lane and go to the top of the hill (Irving Ave.)
- Turn left on Irving Ave
- Travel two blocks (IHP is on the right in second block), to Madison St. (4-way stop sign)
- Turn right on Madison
- Parking is off Madison on the right and behind the IHP

**From the West**

- Take NYS Thruway to exit 39
- Take Route 690 East to Route 81 South to exit 18 (Adams/Harrison Sts.)
- Exit down the ramp using the left lane
- Proceed underneath the expressway - keep to the far left lane
- Turn left on Adams St and stay in the left lane
- Travel three blocks to the top of the hill (Irving Ave.)
- Turn left on Irving Ave
- Travel two blocks (IHP is on the right in second block), to Madison St. (4-way stop sign)
- Turn right on Madison
- Parking is off Madison on the right and behind the IHP.

**From the South**

- Take Rt. 81 North to Exit 18 (Adams St.)
- Exit down the ramp using the right lane
- Turn right on Adams St
- Travel three blocks to the top of the hill -- keep to the far left lane
- Turn left on Irving Ave
- Travel two blocks (IHP is on the right in second block), to Madison St (4-way stop sign)
- Turn right on Madison
- Parking is off Madison on the right and behind the IHP



**\*Once you arrive in the parking garage, please go through the double doors and call the study staff to let us know you have arrived, and somebody will meet you in the lobby.**  
**(315)-385-9820**



**Quadrant Biosciences**

**3435 Main St.**

**Farber Hall Room 301**

**Buffalo, NY 14214**



### **Directions**

#### **From North/East**

- Travel west on I-90 (portions toll) to I-290 west (exit 50)
- proceed west on I-290 to Exit 7A, Main Street west (Route 5)
- travel about 3 miles to Bailey Ave (Route 62)
- turn left onto Bailey Ave and right onto Michael Road, into UB

#### **From South/West**

- Travel east on I-90 (portions toll) to I-290 west (exit 50)
- proceed west on I-290 to Exit 7A, Main Street west (Route 5)
- travel about 3 miles to Bailey Ave (Route 62)
- turn left onto Bailey Ave and right onto Michael Road, into UB

**Enter Here**

**Park Here**



# Sample Exceptions

There are several aspects of the test registration process and testing that must be completed accurately to avoid a sample being held out of processing as an exception. Results will be delayed for all samples marked as an exception. Necessary steps are legally required by the laboratory to correct for each invalid aspect of a sample before it can be processed.

For **each sample** marked as an exception, Quadrant Biosciences staff will contact your organization via email to correct one or more of the problems noted below and sign a specimen correct form as the responsible party making these changes.

- The person registered must choose their correct **organization** for organizational managers to successfully view results.
- **Name and Date of Birth** (DOB) on the sample must match the Name and DOB listed within the web app exactly (e.g., the person cannot be registered as Bob in the app and write Robert on the tube). It is strongly recommended that labels are printed prior to testing to write on and affix to the saliva collection kit or preprint with Name and DOB for each person being tested.
- The **barcode** on the tube must match the barcode typed or scanned into the web app (e.g., if the barcode is off by 1 number, the sample will be held out as an exception).
- If a test is being added to the web app on a phone or computer, the **submit button** must be clicked for the sample to be processed in the lab.
- The person being tested must have their accurate **permanent and legal address** entered in their profile on the web app. All results are now considered a diagnostic test and as such must be reported to NYSDOH.
- Unregistered samples will not be processed. All samples must be registered in the web app before they are returned to the lab.

# Results & Next Steps

Results can be accessed by organizational managers and the person tested through the web application: [app.clarifi-covid-19.com](http://app.clarifi-covid-19.com).

## Viewing results as an organization manager:

Once logged in, you will need to switch roles from “patient” (your personal dashboard) to “organization manager” by clicking “User Roles” in the top right corner.

Then, you will need to search for your organization from the dropdown menu on the left side of the dashboard (see below). (Note: You will not be able to view results or registrations from any organizations that you have not been provided “organization manager” access.) You can use the features listed on the left side of the dashboard to sort data (e.g., filter your organization's data by the date of testing).

## Profile Search View:

There are two search options available once the Organization Manager role has been assumed. You can select the “Profile Search” tab or the “Registration Search” tab and use the available fields as search filters applied to your organization's records. If you select Profile Search and enter your organization and select search all records in the organization will be displayed and can be exported to a CSV format by selecting the “Export”. You can inspect a single account by selecting “View Registrations” and inspect all test registrations for that user and view results using the same user interface the user is presented with upon their login.

Organization Manager

Profile Search

Registration Search

Daniel Giles Inc

First name

Last name

Date of birth

Search

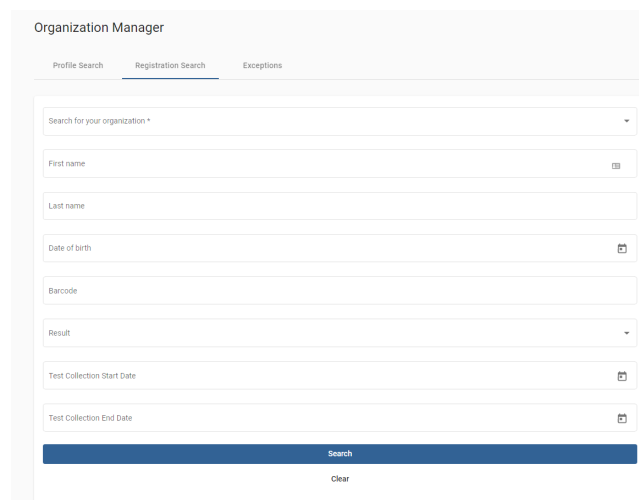
Clear

Registrations	First Name	Last Name	Date of birth	Address
<a href="#">View Registrations</a>	Kimberly	Perry	06/27/2004	Over there
<a href="#">View Registrations</a>	Jonathan	Navarro	09/09/1984	Over there
<a href="#">View Registrations</a>	dave	jadeski	01/01/2001	121 King St.
<a href="#">View Registrations</a>	Lauren	Rivera	03/06/1968	Over there
<a href="#">View Registrations</a>	Kelly	Vega	06/17/2012	Over there
<a href="#">View Registrations</a>	William	Haynes	05/18/2014	Over there
<a href="#">View Registrations</a>	Nicholas	Willis	11/13/2000	Over there
<a href="#">View Registrations</a>	Mark	Miller	03/30/1969	Over there

## Registration Search View:

In order to drill down, filter and export results from multiple tests select the “Registration Search” tab. You are presented with more search options as shown below:

- First Name and Last Name filters on a name or part of a name (i.e. Steph will return any Stephanie or any name beginning with Steph).
- Date of birth filters on the exact date of birth.
- Barcode filters on the exact barcode entered.
- Result allows filtering on test result status including:
  - In Transit: Sample has been collected has not arrived to lab
  - Exception: Sample arrived at lab. Organization Manager must review and correct exception.
  - Test in Progress: Sample arrived at lab and has begun testing process.
  - Pooled Positive: COVID has been detected in the pool. Reflex Testing required.
  - Pooled Negative: COVID has not been detected in the pool. Patients are Presumed Negative.
  - Reflex Positive: Patient sample has been tested individually and is COVID Positive.
  - Reflex Negative: Patient sample has been tested individually and is COVID Negative.
  - Test Canceled: Sample was rejected due to
    - a. Exception Status
    - b. Unstable due to time since collection
    - c. Canceled by Organization Manager
- Test Start and Test End Date allow filtering on a date range that is applied to the Test Collection date (not the date the test is processed).



Results are available directly on the “Registration Search” page and can be filtered by first name, last name, email, barcode and result. Once you are satisfied with “Registration Search” results, you are able to download **a csv text file** by selecting “Export Results” for any test results returned by the search (see below). CSV export is not required but remains an option to view results.

The resulting file contains the following information, which can be exported and used to manage your response to any results found in your organization:

SampleBarcode	LotBarcode	LabBarcode	HumanGene	SARSCOV	CollectionTime	LastName	FirstName
41001704580339	L00001	HHT-JYLR	PASS	POOL POSITIVE	2021-03-19T14:04:12.978Z	Davis	David

DOB	School	StudentId	Phone	Email	InstitutionCode
2013-12-28	Aaron King Inc	testStudentId-81012	2654696520	spencer.bragg+staging@quadrantbiosciences.com	HHT

# Contacts

Topic / Issue	Point of Contact Name	Contact Email Address	Contact Phone Number
<b>Logistics &amp; Training</b>	David Jadeski Michael Fletcher Peter Rasmussen	covid-support@quadrantbiosciences.com michael.fletcher@quadrantbiociences.com peter.rasmussen@quadrantbiosciences.com	Michael: 315-440-3434 Peter: 518-669-2733
<b>Billing:</b> <b>Collection Kits (SUNY)</b> <b>Collection Kits (Non-SUNY)</b> <b>Reflex Testing (All Clients)</b>		AR@quadrantbiosciences.com	
<b>Deliveries to Syracuse Lab</b>	Sarah Gentile	sarah.gentile@quadrantbiosciences.com	315-464-7729
<b>Deliveries to Buffalo Lab</b>	Michael Wendel	michael.wendel@quadrantbiosciences.com	716-335-5660
<b>New Client Inquiries</b>	Michael Fletcher	michael.fletcher@quadrantbiociences.com	315-440-3434
<b>Test Results</b>	Peter Rasmussen	peter.rasmussen@quadrantbiosciences.com	518-669-2733
<b>Testing Supply Orders</b>	Heather Blair	heather.blair@quadrantbiosciences.com	
<b>Web App/ Registration</b>	Dave Jadeski	covid-support@quadrantbiosciences.com	315-702-0302



# PROD-1244 (DOC-369) Ver. 0

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**Approved By:**

[\(CO-53\) CO-53 Implementation of PROD-1243 and PROD-1244](#)

**Description**

\*\*Update 08/19/21: Rerouting after minor revisions to both documents. Please review and approve by Friday (08/20) so these may be sent to Org Managers.\*\*  
Implementation of PROD-1243 Clarifi COVID-19 Testing Manual: Procedures for Organizations and PROD-1244 Clarifi COVID-19 Testing Manual: Procedures for K-12 Schools.

**Justification**

Standardization of procedures needed to ensure most up-to-date version of manual is published/sent to customers.

**Assigned To:**

Allison Iles

**Initiated By:**

Allison Iles

**Priority:**

High

**Impact:**

Major

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**Version History:**

Author	Effective Date	CO#	Ver.	Status
Allison Iles	August 19, 2021 2:24 PM EDT	<a href="#">CO-53</a>	0	Published