



RHEONIX LABORATORIES, LLC

RHEONIX LABORATORIES COVID-19 PCR TEST SALIVA HOME COLLECTION KIT

For use with the Rheonix COVID-19™ MDx Assay

R ONLY

INSTRUCTIONS FOR USE

Important! Completely review these instructions before collecting a saliva specimen.

For help with any step, call 1-607-252-6424, or visit Rheonixlabs.com

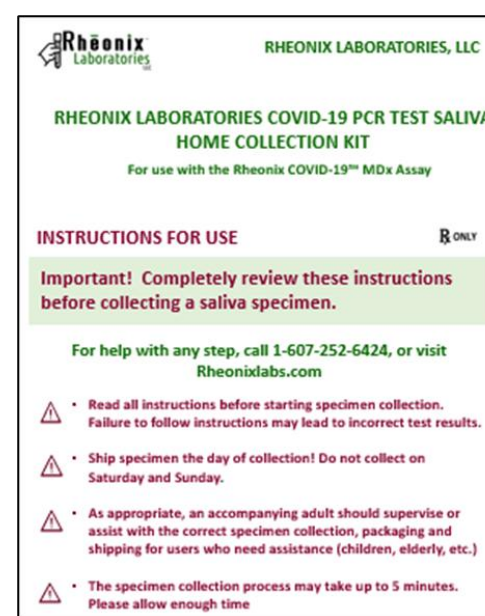
- ⚠️ • **DO NOT** eat, drink, smoke, or chew gum or tobacco for 30 minutes before collection of your saliva specimen.
- ⚠️ • As appropriate, an accompanying adult should supervise or assist with the correct specimen collection, packaging and shipping for users who need assistance (children, elderly, etc.)
- ⚠️ • Do not collect on Saturday and Sunday. Drop off at FedEx Location or FedEx drop box (open 24/7).
- ⚠️ • Ship specimen on the day of collection! Specimens not received at the lab within 48 hours will be rejected.
- ⚠️ • Specimen will be rejected if:
 - Not received within 48 hours from collection
 - It is not properly registered
 - It contains color or floating particles
 - Its volume is less than fill line
 - Patient information is missing or incorrect.
 - It leaks from the specimen collection tube

KIT CONTENTS

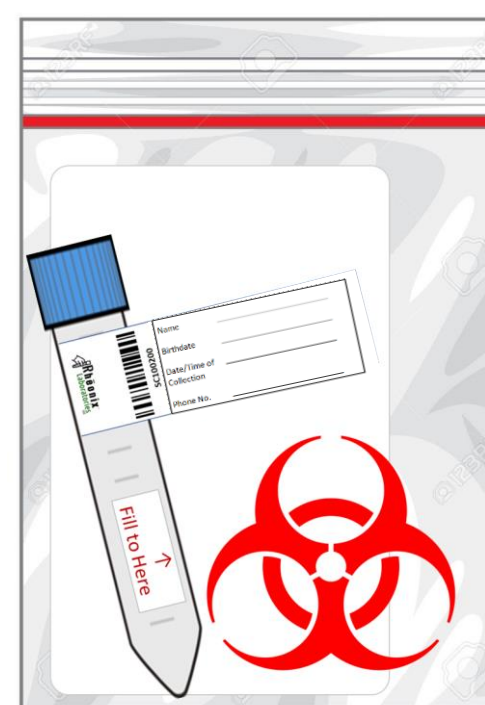
1. Instructions for Use
2. Labeled cardboard box to protect the specimen tube during transport to and from the testing laboratory
3. Specimen bag containing saliva tube and absorbent pad
4. Pre-paid, pre-addressed return shipping bag



Cardboard box containing collection kit



Instructions for use



Specimen bag with saliva collection tube and absorbent pad



Pre-paid, pre-addressed return shipping bag

STEP 1

Complete the Required Patient Information on Your Specimen Tube

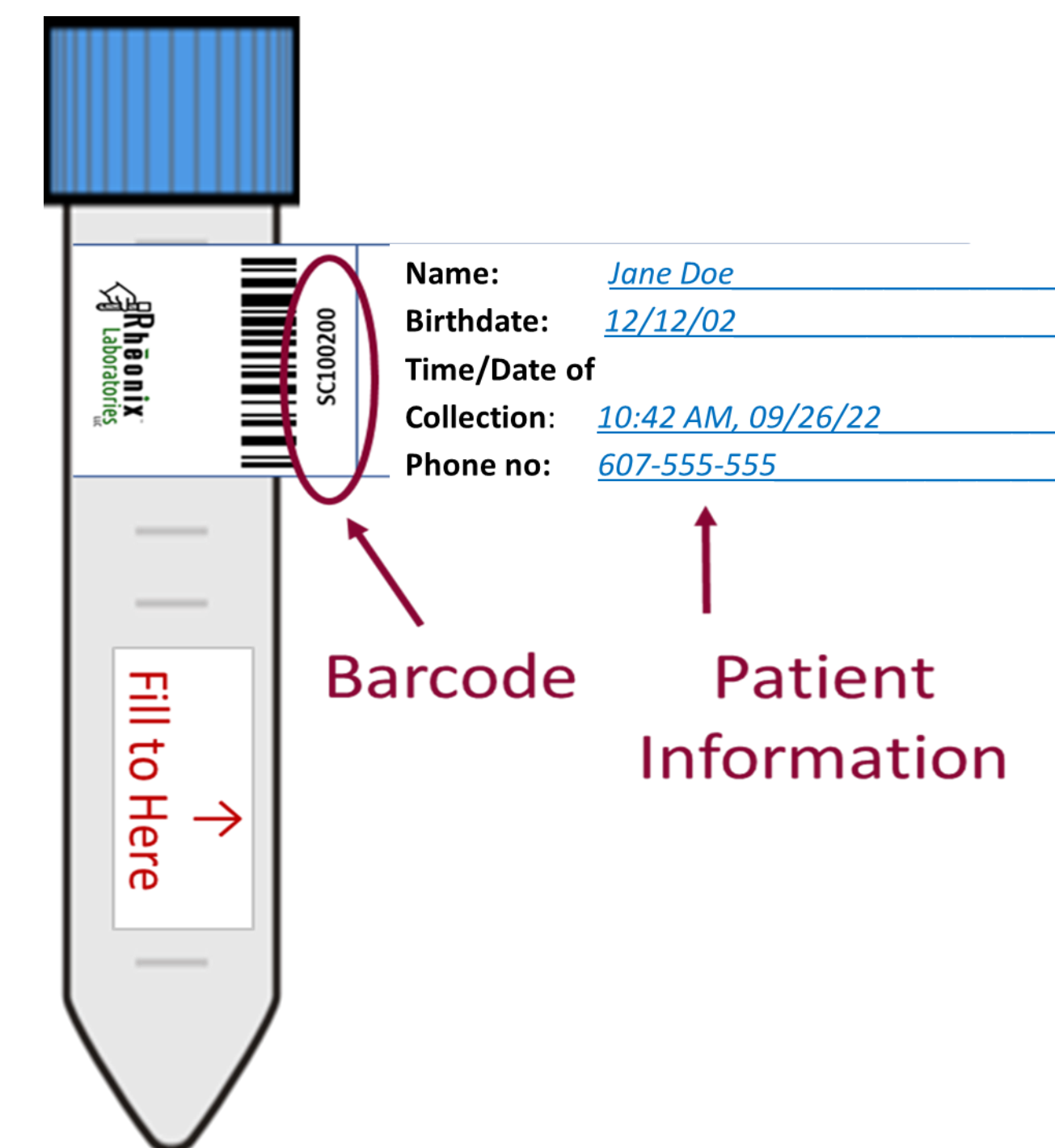
Testing cannot occur if patient information on specimen tube is missing or incorrect!

1. Have your registration confirmation available.
2. Clean your hands (soap & water or sanitizer).
3. Open kit and take out saliva collection tube.
4. Fill out your **Patient Information: Name, Birthdate, Time and Date of specimen collection, and Telephone Number** on the label attached to the collection tube.

Patient information (example)

Saliva Specimen Tube	Rheonix Laboratories LLC	00200125	Name: <u>Jane Doe</u>
			Birthdate: <u>12/12/02</u>
			Time/Date of Collection: <u>10:42 AM, 09/26/22</u>
			Phone no: <u>607-555-555</u>

5. Verify that the **barcode number** on the saliva collection tube matches the number on your registration confirmation.

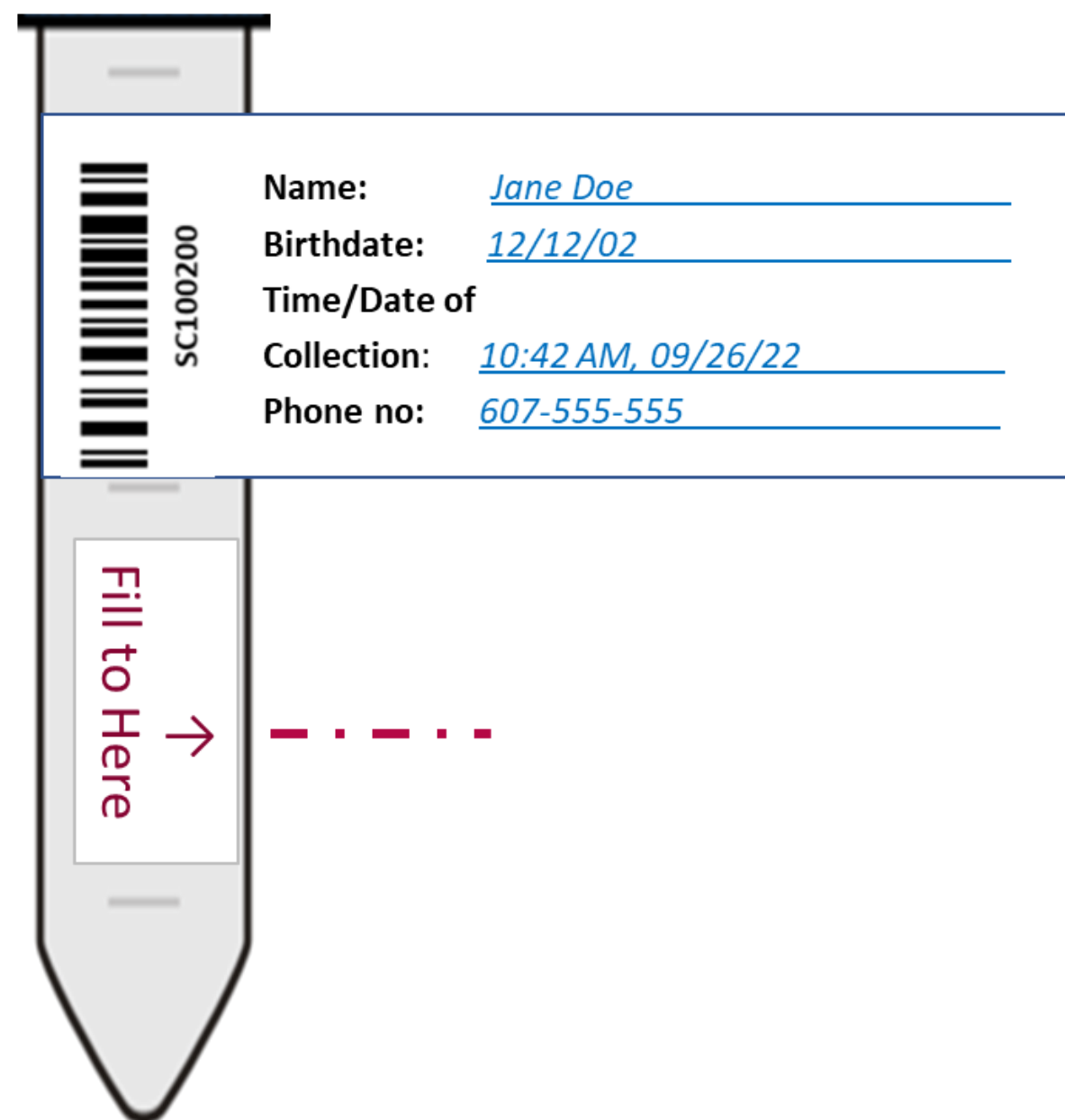


Testing cannot occur if patient information on specimen tube is missing or incorrect!

STEP 2

Collect Saliva Specimen

1. Remove the cap and place it face down on a clean flat surface.
2. Before drooling into the tube, relax and rub your cheeks gently for 30 seconds to increase saliva production.



Fill to Here →

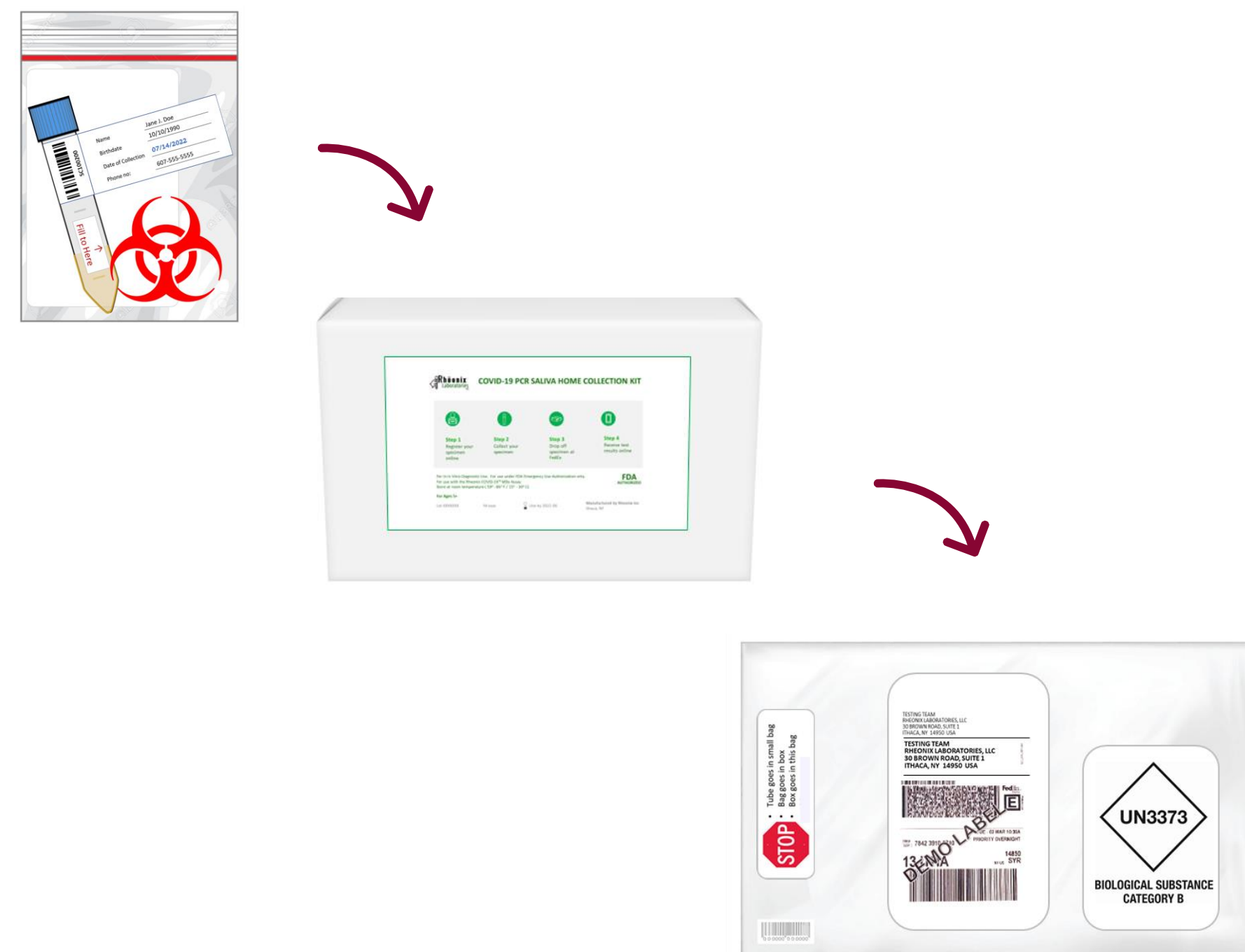
3. Drool saliva into the collection tube up to the “Fill to here” line (3 mL).
4. Any bubbles should be above the marked line. Drooling may take up to 5 minutes or more.
5. Cap tube and **ensure cap is tightly sealed.**
⚠ If the sample leaks, it will not be accepted for testing.
6. Place capped tube containing saliva back in the specimen bag with absorbent pad. Seal the zip lock specimen bag.
7. Clean your hands (soap & water or sanitizer).

STEP 3

Ship Specimen to the Lab

- ⚠ **Specimens MUST be shipped via FedEx on the day of collection.**
- ⚠ **Specimens not received at the lab within 48 hours will be rejected**

1. Place the sealed specimen bag containing saliva tube and absorbent pad in the cardboard box and close.
2. Place the box in the pre-paid pre-addressed return shipping bag and seal the bag.
3. Store your specimen at room temperature until shipped.
4. Record your tracking number (TRK# on the pre-paid shipping label) if you wish to track delivery of your sample at fedex.com.
5. Drop off at a FedEx Location or drop box (open 24/7); visit fedex.com for locations.
6. **To check the status of your returned sample, log onto your account at TestDirectly.com**



Call 1-607-252-6424 or visit Rheonixlabs.com if you need assistance with shipping your sample.

STEP 4

Obtain Your Results

RESULTS

1. Notification of available results will be sent via text or by secure email to the mobile phone or email address provided by the patient.
2. Results will be available by logging into **TestDirectly.com**



For help with any step, call 1-607-252-6424, or visit Rheonixlabs.com

Manufactured by Rheonix, Inc.

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1-607-252-6424

- For use under Emergency Use Authorization Only.
- For Prescription Use Only.
- For *In Vitro* Diagnostic Use .
- For use by individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision) or 5 years and older (collected with adult assistance).
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-Co-2, not for any other viruses or pathogens.
- The emergency use of this product 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.