BD Veritor Plus Analyzer

Rapid Antigen Testing for COVID-19

Toronto Regional IPAC Team

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Objectives

- Purpose and eligibility of rapid antigen screening
- Frequency and results of rapid antigen screening
- How to order and store the BD Veritor COVID-19 Rapid Test Supplies
- Steps to set up a Rapid Test Area
- How to use the BD Veritor Plus Analyzer
  - Test preparation, sample collection, test procedure, results interpretation, and quality control
- How to report and document results
- Limitations of BD Veritor rapid testing

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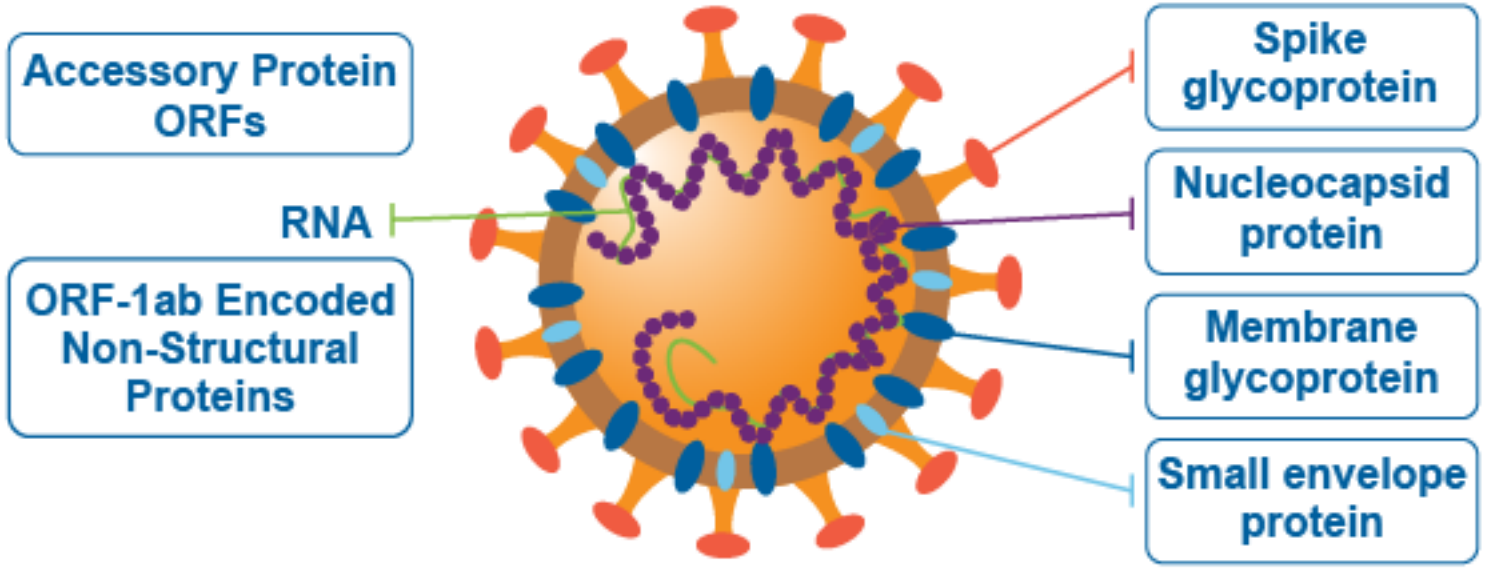
This presentation was adapted for Safehaven using BD Veritor Education

What the test is detecting

- In vitro diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)
- Detects nucleocapsid protein inside the SARS-CoV-2 virus



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Purpose

- To screen for potentially contagious individuals within 15 minutes
- Should only be used on individuals who are asymptomatic
- Should only be used to enhance screening processes already in place
- Should NOT be used to diagnosis COVID-19 infection
  - Test in preliminary only
- Individuals who are symptomatic require PCR testing from a healthcare provider, an assessment centre, or participating community lab.

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Eligibility

- Asymptomatic individuals who have passed entry screening
  - Staff, visitors, volunteers, students, contractors, agency staff, AND clients
- Can only be used in areas which are not deemed in outbreak
- Individuals who have previously been infected with and recovered from COVID-19 should NOT undergo repeat testing/antigen screening – these individuals get an exemption from routine rapid testing

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Frequency

- Monthly testing of all Safehaven clients
- Used as surveillance to support external partners on their staff and clients are subject to testing on the day we are requested on site.

Results

- A **positive result** on a rapid antigen test is considered a “preliminary positive”
  - **Every preliminary positive must be followed up with a confirmatory PCR test.**
  - **Public health unit must be notified.**
  - **Individual must be sent home to self-isolate and instructed to seek confirmatory testing**

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Results

- A **negative result** on a rapid antigen test is only applicable if the individual who has been tested is asymptomatic with no known exposures to COVID-19
  - **Individuals must be counselled that the result is negative and a false negative is possible.**
  - **Individuals should be instructed to continue following public health guidelines and infection prevention and control measures.**

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Ordering

- TBD – Will be online portal through MCCSS
- Instructions to come from Ministry

Storage

- 30 tests come with each kit
- Stored between 2-30^{o}C – DO NOT FREEZE!
- 12 month shelf life
- Testing time: 15 minutes – no longer than 16 minutes

- In winter months kits may be shipped with heat packs.

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BD Veritor Kit Contents

- 30 test devices
- 30 pre-filled reagent tubes
- 30 sterilized nasopharyngeal (NP) swabs for specimen collection
- 1 Positive control swab
- 1 Negative control swab
- 1 tube rack
- 1 Quick reference guide
- 1 Instructions for use
- Nasal sample quick reference instructions

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Who can perform the test?

- Regulated and unregulated health professionals can conduct testing
  - A physician, nurse practitioner, registered nurse, registered practical nurse, dentist, pharmacist, paramedic or community paramedicine practitioner; Audiology and Speech-Language Pathology; Chiropody and Podiatry; Chiropractic; Dental Hygiene; Dental Technology; Dentistry; Denturism; Dietetics; Homeopathy; Kinesiology; Massage Therapy; Medical Laboratory Technology; Medical Radiation Technology; Medicine; Midwifery; Naturopathy; Occupational Therapy; Opticianry; Optometry; Pharmacy; Physiotherapy; Psychology; Psychotherapy; Respiratory Therapy; Traditional Chinese Medicine and Acupuncture
  - Personal support workers, Physician assistants, Physiotherapy assistants, Speech language therapists, Osteopaths, etc.

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Setting up for Rapid Testing

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Conducting Quality Control Before Testing

- Quality control swabs should be tested by staff who will be operating the testing station.
- Quality control swabs should be tested:
  - with each new shipment of kit
  - with any new kit lot number
  - by all newly trained operators before they begin testing individuals
  - for sites using **>1 box of tests/day**, perform quality control swabs at the beginning of the day before testing begins
  - for sites performing less than **<1 box of tests/day**, perform quality control swabs each time a new kit box is opened or at least weekly, whichever is more frequent
- It is important to time the control test for the full 15 minutes.

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Test Preparation

- Prepare kits in advance
  - Pre-filled extraction reagent tube
  - Test cartridge
  - Swab
  - Timer
  - Bin
  - Results certificate
- Pre-label test tubes and cartridges with participant information (i.e.. Name or initials and DOB)
  - Two labels are ideal. One for extraction tube, one for test cartridge/device
- Record the name of person being tested and store the record in a secure location (P drive)

Detailed steps

- Read instructions of the rapid test kit
- Ensure full PPE is worn
- Collect all the supplies for running the test
- Allow all components to come to room temperature (15-30^{o}C) prior to use
- Check expiry date on the back of the test device/cartridge and assure the pouch has not been damaged or tampered with.
- Remove test device from the pouch just before testing
- Place test device on a flat surface and write or affix label with 2 identifiers

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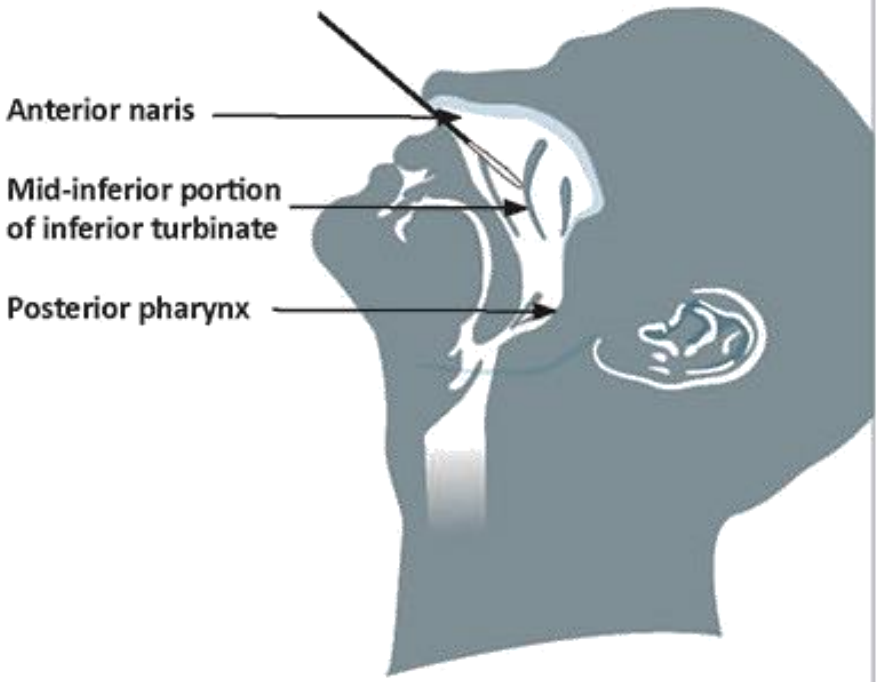
Deep Nasal Sample Collection

Deep Nasal Specimen Collection Instructions

Public Health Ontario | Santé publique Ontario

1. Tilt patient's head back 70°.
2. While gently rotating swab, insert swab about 2.5 cm (>1 in.)* straight back (not up) into nostril until the collar/safety stopping point touches the outside of the nose.
3. Rotate swab several times against the wall.
4. Leave swab in place for several seconds to absorb secretions.
5. Repeat for both nostrils using same swab.
6. Immediately place in sterile tube containing transport medium.

**Pediatrics: swab insertion distance will differ for pediatric patients.*



In a seated position, tilt the head back at a 70° angle as illustrated in the picture

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Administering the Test

BD Veritor™ System for Rapid Detection of SARS-CoV-2
Workflow Overview

Detection of SARS-CoV-2 antigens in samples processed from nasal swabs

Assay time of 15 minutes, with 1 minute of hands on-time*

STEP 1
Collect patient sample (mid-nasal)

STEP 2
Remove cap & insert swab into tube

STEP 3
Mix sample for 15 sec with reagent, then remove swab

STEP 4
Close dispensing cap, then dispense sample into test device

STEP 5
Insert test device into the analyzer
For Walk Away mode, insert immediately
For Analyze Now mode, insert after timing the assay development

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* Source: www.bd.com/bd-Veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing Simple Use Section 20/08/2020

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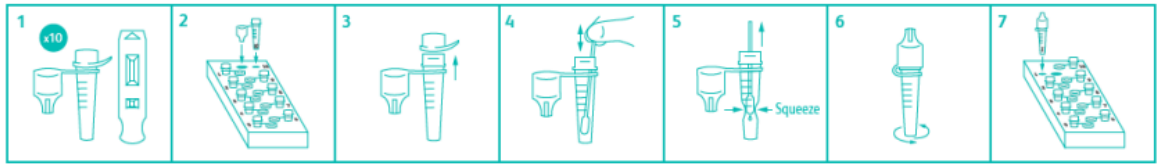
Batch testing workflow

Batch sample collection (10 tests)



- **Gather 10 sets of test materials.**
- Label each set with patient ID.
- Label the tube tray with patient ID.
- **Set each tube in the tray** with matching patient ID.
- Select extraction reagent tube and **remove cap**.
- **Insert patient sample swab** and vigorously plunge the swab up and down for 15 seconds taking care not to splash contents out of the tube.
- **Remove swab** while squeezing to extract liquid.
- Properly dispose of swab.
- Press dispensing tip on the tube firmly.
- **Mix the sample** by swirling the bottom of the tube.
- **Place tube back in tray** with matching patient ID.
- Repeat steps 3-7 until all remaining tubes have been prepared.
- Specimen processed in the reagent vial must be **run within 30 minutes** on the test device.

Batch preparation and analysis (10 tests)

- Select the extracted sample and the matching test device for each specimen.
- **Add 3 drops of the processed sample** to the test device sample well.
- Activate a 15 minute timer.
- **Each test device must incubate for 15 minutes***** before it can be analyzed.
- Repeat steps 8-9 until **all remaining test devices have been prepared and are incubating,** each with their timers running.
- When first test is ready, **power on the Analyzer** by pressing the blue start button once.
- Analyzer may remain on until all testing is completed.
- When prompted, **insert the test device to read.**
- If using the **BD Veritor™ InfoScan module,** follow the screen prompts to scan operator ID, specimen ID and kit lot number to start the test analysis.
- After required scans are completed, the Analyzer displays a countdown timer and test analysis begins.
- **Result will appear on screen,** and will be stored in the Analyzer.
- Test results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).
- Record result.
- Remove test device and properly dispose.
- Continue with the next test device once it has incubated for 15 minutes.

Interpretation of results

Display	Interpretation
CoV2: +	Positive Test for SARS-CoV-2 (antigen present)
CoV2: –	Presumptive Negative Test for SARS-CoV-2 (no antigen)
CONTROL INVALID	Test Invalid. Repeat the test.

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Interpreting the results

Interpretation of results

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Communicating Preliminary Positive Results

- Positive results must be communicated in a confidential manner.
- Staff must take steps to maintain confidentiality of the results.
- Leadership must be notified of a preliminary positive result.
- Staff must obtain a PCR test at a rapid assessment center on same day.
- Staff must be sent home to self-isolate and await instructions for Public Health.

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Results

- Positive Results
  - Rapid antigen testing is considered preliminary. Each positive rapid antigen test must be followed up with a confirmatory PCR laboratory test.
- Negative Results
  - Is only applicable if the individual being tested has no symptoms and no known exposures to COVID-19
  - Individuals should be counselled that the result is negative, and a false negative is possible.
  - Individuals should be directed to continue to follow infection prevention and control measures.

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Noteworthy

- Testing station should be cleaned and sectioned off prior to beginning testing
- DO NOT move the test device until the test is complete
- Clean up any spillage with a disinfectant wipe
- Change gloves after handling each extraction tube
- Frequent squeezing of the extraction tube can cause strain (sore fingers), take turns with other staff to reduce strain if possible.

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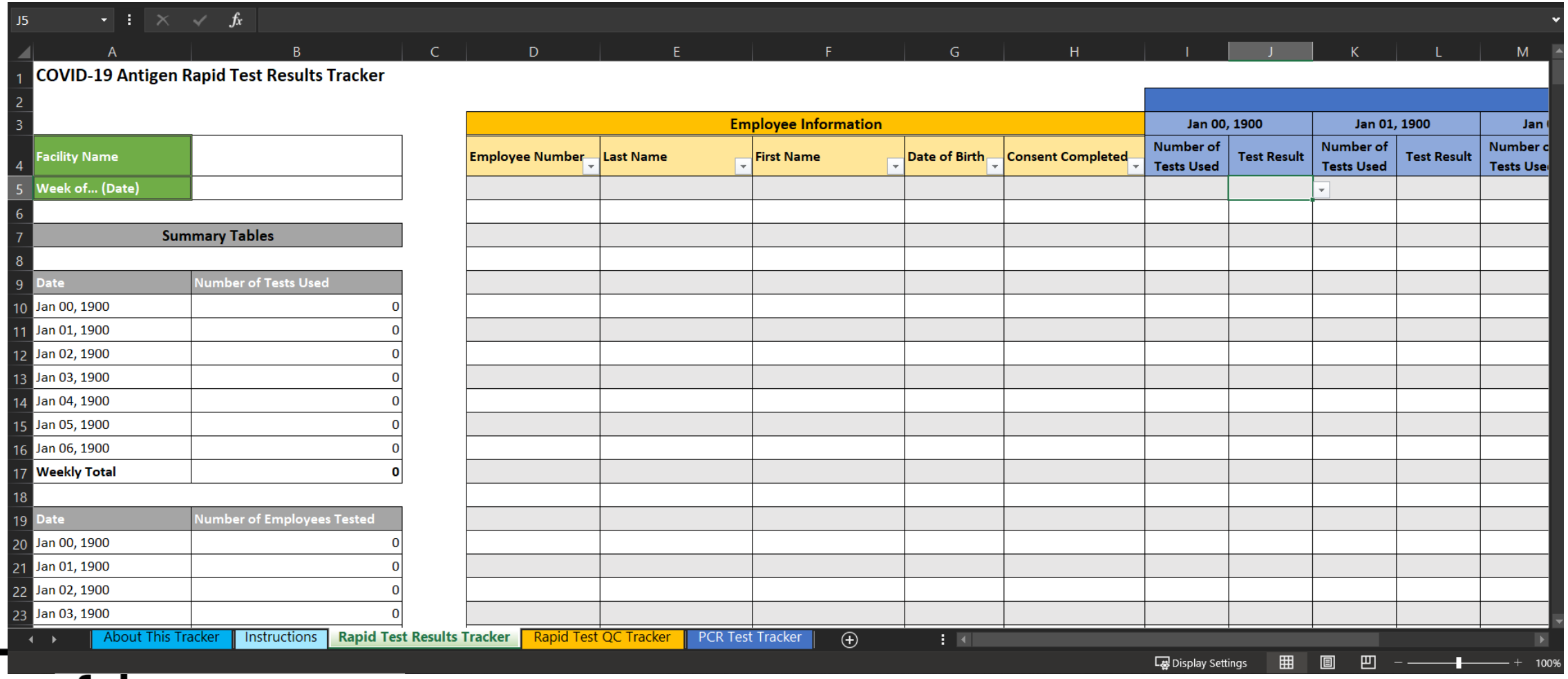
Documentation



COVID-19 Antigen Rapid Test Results Tracker

Facility Name	
Week of... (Date)	

Summary Tables

Date	Number of Tests Used
Jan 00, 1900	0
Jan 01, 1900	0
Jan 02, 1900	0
Jan 03, 1900	0
Jan 04, 1900	0
Jan 05, 1900	0
Jan 06, 1900	0
Weekly Total	**0**

Date	Number of Employees Tested
Jan 00, 1900	0
Jan 01, 1900	0
Jan 02, 1900	0
Jan 03, 1900	0

Employee Information					Jan 00, 1900		Jan 01, 1900		Jan
Employee Number	Last Name	First Name	Date of Birth	Consent Completed	Number of Tests Used	Test Result	Number of Tests Used	Test Result	Number c Tests Use

About This Tracker | Instructions | Rapid Test Results Tracker | Rapid Test QC Tracker | PCR Test Tracker

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Remember

- Prepare all test components before specimen collection
- Always wear PPE including gloves when handling specimens
- Ensure the correct amount of buffer is added to the extraction tube
- Test devices are single use only
- Treat all specimens as **potentially infectious samples**
- Discard all items into appropriate biohazard containers
- Do not mix components of the test kits

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Lastly…

- Rapid antigen testing is used for **screening purposes only** and should NOT be used for diagnosis of acute COVID-19 infection
- Testing does not prevent someone from getting COVID-19
- Rapid antigen testing can be thought of as an additional screening tool
- Rapid antigen screening does not replace public health measures such as symptom screening, physical distancing, masking and hand hygiene

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Thanks for listening!

Questions?

Email us at:

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