

Care New England Health System
Department of Pathology & Laboratory Medicine
FAQ Regarding SARS-CoV-2 (COVID-19) RNA and Antibody Testing

June 8, 2020

Performance Characteristics of SARS-CoV-2 RNA testing at Care New England

* Due to supply constraint, providers will **NOT be able to specify** which RNA test to order. Please call the LAB so you may be provided with the proper collection kit.

**All SARS-CoV-2 RNA tests are performed under FDA Emergency Use Authorization (EUA) and therefore information on sensitivity and specificity is not available.

*Testing Platform	Claimed Limit of Detection (LoD)	TAT per test	**Sensitivity/Specificity
GenMark ePlex® (In-house)	500-1000 copies/mL	90 minutes	None provided
Abbott ID NOW™ (In-house)	125 copies/mL Reported 20,000 copies/mL	15 minutes	None provided
Cepheid Xpert® (In-house)	250 copies/mL	45 minutes	None provided
CDC (DOH) method	100-3,200 copies/mL depending on targets	24-48 hours	None provided
Mayo Reference Lab	~100 copies/mL	24-48 hours	None provided

Performance Characteristics of Abbott SARS-CoV-2 IgG antibody test at Care New England

Positive Agreement by Days Post-Symptom Onset

Days Post-Symptom Onset	n	Positive	Negative	PPA (95% CI)
< 3	4	0	4	0.00% (0.00, 60.24)
3 - 7	8	2	6	25.00% (3.19, 65.09)
8 - 13	22	19	3	86.36% (65.09, 97.09)
≥ 14	88 ^a	88	0	100.00% (95.89, 100.00)

Negative Agreement by Category

Category	n	Positive	Negative	NPA (95% CI)
Pre-COVID-19 Outbreak	997	4	993	99.60% (98.98, 99.89)
Other Respiratory Illness	73	0	73	100.00% (95.07, 100.00)
Total	1070	4	1066	99.63% (99.05, 99.90)

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Why are we using more than one kind of RNA test for COVID-19 infection?

There continues to be supply challenges with the RNA tests for COVID-19 infection. Being ready to do more than one kind of test allows us to have the supplies we need on any given day. Providers therefore will NOT be able to specify which test to order. Please call the LAB so you may be provided with the proper collection kit.

Each collection kit may contain different viral transport media depending on availability:

1. In-House (Blue) Kits for GenMark ePlex® or Cepheid Xpert® COVID testing

- a. Remel M6 media
- b. Remel M4 media
- c. Brown University media- orange caps (CDC VTM)
- d. BD Universal Transport Media (UTM)

2. In-House (Pink) Kits for Abbott ID NOW™ COVID testing

- a. Nasopharyngeal collection in dry transport system using Puritan REF 25-3317-H BT



3. (Red) Kits for DOH COVID testing

- a. Remel M6 media
- b. Remel M4 media
- c. BD UTM media

4. Quest (Green) Kits for Quest COVID testing

- a. Quest VCM media- green caps
- b. BD UTM media
- c. Remel M6 media
- d. Remel M4 media

If we are using different kinds of tests, how can I be sure I am doing the test the right way?

The specimen collection kit that you receive from the lab when you order a COVID-19 infection RNA test will come with instructions about how you are to collect the specimen and how to send the specimen to the lab. **PLEASE MAKE SURE THAT YOU READ THESE INSTRUCTIONS EACH TIME YOU COLLECT A SPECIMEN.** The **PUI FORM** included in each collection kit **MUST BE COMPLETED and RETURNED** with the specimen. The procedure for collecting and handling the specimen may vary depending on which test we have available at that time and day. The instructions released with the swab are the most accurate way to know how you should collect your specimen.

Regardless of the details of the specific RNA test being run, we are recommending that **ALL specimens testing for COVID-19 RNA test collected at Care New England should be done with a nasopharyngeal swab (a swab done of the back of the nose).**

 Care New England

How is a nasopharyngeal swab done?

To do a proper nasopharyngeal swab, insert the flexible swab through the nostril parallel to the roof of the mouth (NOT upwards) until resistance is encountered indicating contact with the nasopharynx (the back of the nose). The swab should reach a depth equal to the distance from nostrils to outer opening of the ear. Then gently rub and roll the swab. Leave the swab in place for several seconds to absorb secretions. Then slowly remove the swab while rotating it. The MOST important part of getting an accurate test for COVID-19 infection is following these instructions exactly.

(Here is a link to a video and description on the New England Journal of Medicine site on how to collect a nasopharyngeal swab: <https://www.nejm.org/doi/full/10.1056/NEJMvcm2010260>)

Are the COVID-19 RNA tests all done in our own lab?

Some of the tests are done in our own lab on different testing machines. Some are sent to the RI Department of Health Lab or outside private labs. The RNA tests we do in house tend to get us the fastest results (30-100 minutes depending on the machine) but they are also the ones with the most limited supply. Tests done outside the hospital are more available but results may take 1-4 days to return.

Who can order RNA testing for infection with COVID-19?

Any provider can order a COVID-19 infection RNA test. Typically they are only done for patients with symptoms of COVID-19. Most test centers try to give priority to hospitalized patients, people who live in communal living situations like nursing homes or group homes, and healthcare workers.

Do we plan to start testing more patients for infection with COVID-19?

Yes. Once we have a more steady supply of COVID-19 infection RNA tests in our own labs, we plan to do testing on more patients. Eventually we would like to be able to test every patient that gets admitted to our hospitals or care settings. The *COVID-19 Testing Group* has been assembled under the leadership of Erica Hardy, MD, to make sure that we can best prioritize our testing across Care New England until our testing capacity increases.

What about COVID-19 antibody testing?

COVID-19 infection RNA testing (done on a nasopharyngeal sample) tries to answer the question: Does this person HAVE a COVID-19 infection right now? COVID-19 antibody testing (done on a blood sample) tries to answer the question: Has this person (ever) HAD a COVID-19 infection?

The Care New England laboratory is able to do both the RNA and IgG tests. The *COVID-19 Testing Group* will help decide how to prioritize the use of the antibody tests and work with others to understand the role and reliability of each test in the weeks and months ahead.

Yours sincerely,

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