



B.Next COVID-19 Test Database

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What the Database Is

[This database](#) is a tool for those who need to quickly obtain information about COVID-19 test kits and services for use in the United States. The database includes all molecular tests (as of the date stated below) that have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), whether they are kits that can be purchased by lab managers, or tests performed as a service by laboratories, whether sourced from manufacturers, or developed for their own use (so called "laboratory-developed tests", or LDTs).

Why We Built It

Our intention is to inform and simplify the task of buying and using the panoply of COVID-19 diagnostic test kits and services now on the market. The database was assembled to aid hospitals, health officials, employers and others in identifying and locating tests and test manufacturers that would be appropriate to their needs.

Public health officials, medical professionals and employers and others are seeking to purchase COVID-19 tests and test services. There are now many COVID-19 tests in the marketplace, some quite new. Some tests must be run on specific instruments or may be authorized to accept only specific types of biological samples (e.g., nasopharyngeal samples) which may require associated materials (e.g., nasopharyngeal swabs). Some tests require additional sample preparation "kits" and instruments, which must be obtained separately from the actual tests. Different tests have different performance characteristics, which include not only the accuracy of the test (specificity, sensitivity) but also the ease of use, speed and scale of throughput, and, of course, cost per test. Finally, it has been difficult for buyers to find test manufacturers' current and future capacity to deliver tests. This database does not include information on test availability, but it does provide users with information needed to contact test manufacturers and service laboratories.

In more conventional periods, the FDA licenses diagnostic tests only after an extensive and time-consuming review of their performance, typically based on the analysis of thousands of clinical samples. However, due to the speed of the COVID-19 outbreak and the initially slow pace of testing in the United States, the FDA began to issue Emergency Use Authorizations (EUAs) for both molecular tests and antibody tests, beginning in February 2020. To date, over 190 such tests have been authorized. These tests are listed on [a page at the FDA's website](#), but the information for each test is contained in separate files, making the critical data hard to extract, even for data scraping tools (we tried this!). We have manually opened and collected information from the EUA documents for molecular tests and antigen tests authorized between February 4 and September 3, 2020 and organized it into a searchable database.

How the Database Works

The database allows users to quickly search and sort FDA-authorized tests based on the following categories:

- Is the test a kit or a service?
 - **Test kits and antigen tests** will be of interest to lab managers who must acquire FDA-authorized materials to perform COVID-19 tests in their facilities. The information may also be of interest to those who are keeping track of the availability of testing resources, manufacturers, etc.
 - **Testing services** will be of interest to those who wish to obtain services for patients, employees, etc. The EUA Summary document (linked to in the database and available at the FDA website) will contain details on how samples are to be collected.
- What test instrument is required to perform the test?
 - Many instruments have multiple models. In some cases, we have grouped instruments under product lines (for example, ABI 7500 also includes ABI 7500 Fast Dx). Users will want to access the “Instructions For Users” (IFU) documents on each test for details on model and software versions. At least one (antigen) test requires no instrument.
- What types of biological samples will the test accommodate?
 - There are many labels for near-synonymous biological sample types. We have grouped them into seven categories:
 - nasopharyngeal swab
 - oropharyngeal swab (includes throat swab)
 - nasal swab (includes anterior nasal swab, mid-turbinate swab)
 - nasal wash (includes nasal aspirate, nasopharyngeal wash, nasopharyngeal aspirate specimens)
 - bronchoalveolar lavage (includes bronchial wash, tracheal aspirates, lower respiratory tract aspirate)
 - sputum
 - saliva
- Can a test be performed at the point of care?
 - Point-of-care tests are simple to perform and require minimal training, relative to laboratory-based tests. However, very few molecular tests that have FDA authorization meet this description. All four antigen tests that have received EUA can be used at the point of care.
- Is pre-sample processing (“sample prep”) integrated into the test?
 - A “N” answer indicates that samples must have the viral RNA extracted before analysis using the kit (this is true for most molecular tests). The IFU documents will often specify or recommend a sample prep method.
- How well does a COVID-19 test work?
 - Interpreting COVID-19 test data is more complex than reading a yes/no answer. To learn more about how to think about COVID-19 test performance, see our brief paper [here](#).
 - Then look to the rightmost link for each test entry, called “Performance”. This link will take you to our [web application](#) displaying the performance characteristics for the test selected (if data are available). For those tests, users can model the positive and negative predictive values given a user-adjustable level of disease prevalence. The performance of an influenza test is also shown as a reference.

- We have published a blog post discussing the performance app on IQT's blog [here](#); a copy of the post is also on the blog of portfolio company Plotly [here](#).

A user can also search the database for keywords or character strings. Once a user identifies tests of interest, they can:

- Click the link on a test's name to directly access the vendor's test webpage,
- Click the link marked "IFU/EUA" to directly access the IFU (for test kits) or the "EUA Summary" (for tests available as services) docs at the FDA webpage for COVID-19 *in vitro* diagnostics,
- Click on the highlighted line item for a popup box containing a summary of that test's information.

Where do the data come from? We obtained the data from EUA documents that are publicly accessible on the FDA's website. A complete list of COVID-19 tests that have received EUA from the FDA can be found [here](#).

What about serology tests? We have not included serology tests in this database, but may consider doing so in the future.

Are all of the tests available? What do they cost? We do not have availability or pricing data. Users will need to contact the individual vendors to determine pricing, availability, delivery timing, etc.

Contact us! We welcome and encourage feedback on the database: usefulness, desirable additions, corrections to mis-transcribed data, etc. We are also interested in exploring offers to help build, extend, and maintain it. You can reach us [here](#).

Help us build this resource! The code and a copy of the data can be found at the B.Next [GitHub repository](#).

Additional information on COVID-19 tests and testing:

- The U.S. Centers for Disease Control and Prevention (CDC) have drafted guidance for the use of COVID-19 tests and the collection of samples, which can be found [here](#).
- Carter *et al.* published [a very good paper](#) describing the features of molecular, antigen, and antibody tests in the journal *ACS Central Science*.
- Weissleder *et al.* further break down COVID-19 tests in [this recent paper published in Science](#).
- The University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP) provides [guidance on testing strategies](#) for using molecular and antibody tests to detect the virus in both symptomatic and asymptomatic people.
- There are other compilations of test data that readers may find useful, some of which include information on a large number of tests that have not received FDA Emergency Use Authorization (some of them may be applying):
 - **FIND Dx** is a non-profit organization based in Geneva, Switzerland that is promotes access to diagnostic technology, particularly in low- and middle-income countries. They have compiled data on molecular and serological tests for COVID-19 diagnostics [here](#).
 - **Massachusetts General Hospital** has compiled [a summary of COVID-19 diagnostics that can be downloaded](#).

- **Johns Hopkins University** has a COVID-19 testing [webpage](#) with a wealth of information. They maintain a list of serology tests [here](#).
- **Diagnostics news provider 360Dx** maintains an alphabetized list of molecular and serological tests from world-wide sources [here](#).
- **The Joint Research Centre of the European Union** has a compilation of COVID-19 test information [here](#).
- **Arizona State University** has prepared a large compendium of COVID-19 test data, the [COVID-19 Diagnostics Commons](#).

LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests. To facilitate the consistent reporting of COVID-19 test results, several organizations have **standardized the encoding of COVID-19 tests** and created a mapping tool to assist those who are collating and reporting test data. The project is described at [this CDC web page](#), which also contains a downloadable form of the spreadsheet in tests are mapped to their corresponding codes.

A shout-out to IQT portfolio companies [Plotly](#), [GitLab](#), and [Cockroach Labs](#), whose technologies we used to build the database and the performance analysis application!

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