



## General Information for State Policymakers – Roche Antibody Test

### **Background**

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) on May 2, 2020, for the Roche Elecsys® Anti-SARS-CoV-2 antibody test. The test is designed to help determine if a person has been exposed to the SARS-CoV-2 virus and if the person has developed antibodies against the virus. Roche will manufacture and ship millions of these tests beginning immediately, ramping up to global production of high double-digit millions of tests per month by the end of June. The test runs on Roche instruments already used across the U.S. in numerous large reference labs and hospital labs.

### **What is an “antibody test” and a “serology test”? What type of sample is required?**

An antibody test detects antibodies that an individual produces after exposure to a pathogen such as the novel coronavirus. A serology test is a diagnostic test involving blood serum—the part of a person’s blood that contains proteins other than those involved in blood clotting. Roche’s new test is both an antibody test and a serology test in that it uses blood serum to determine the presence of antibodies associated with exposure to the SARS-CoV-2 virus. From patients, blood samples drawn by health-care professionals are required, similar in size to samples drawn for common blood tests.

### **Why are such tests important in dealing with the COVID-19 epidemic?**

Antibody tests such as Roche’s can assess if a person was exposed to the SARS-CoV-2 virus. The test may be used in epidemiological research to better understand the spread of the disease, and together with molecular tests to aid in the diagnosis of suspected COVID-19 patients. If further studies confirm that antibodies confer immunity to SARS-CoV-2, and how long this immunity lasts, then this could help determine if individuals can go back into the workforce without risk of being infected and infecting others.

### **Are specific instruments needed to run the Roche antibody test? Are they the same instruments used with the cobas® SARS-CoV-2 Test?**

Roche’s antibody test must be performed on a **cobas e** analyzer—**cobas e 411**, **cobas e 601/602**, or **cobas e 801**—which has the appropriate signal-detection technology. These analyzers use specific consumables (plastics) to run the assays, built for the Roche instruments to assure proper performance. The **cobas e** analyzers required for the antibody test are not the same as the cobas 6800/8800 platforms used with Roche’s molecular test for SARS-CoV-2. The technology of serology testing is different. In practice, this will increase flexibility within labs to continue both kinds of testing at the same time.

### **How many tests can be carried out on the cobas e analyzers, in what period of time?**

Individual test results take about 18 minutes to obtain. Theoretical throughput is somewhat higher but under typical conditions the **cobas e** series analyzers can process tests at rates ranging from about 45 tests per hour up to 220 tests per hour depending on the analyzer model.

### **Where are the tests, the cobas e analyzers, and the needed consumables made?**

The Roche antibody test is being developed in Penzberg, Germany, and produced in Penzberg and Mannheim, Germany. The analyzers on which this test will run are produced in Japan. Other components, such as system consumables and reagents, originate throughout our global supply chain network.

### **What is the installed base of cobas e analyzers in the U.S.?**

More than 3,000 **cobas e** analyzers of the four models are installed in the U.S.



**How many tests will be going into my lab/location/state?**

Based on the availability of **cobas e** analyzers, the tests will go in particular to large reference labs and the labs of major hospital networks in the U.S. We expect demand to outpace supply in the ongoing pandemic but we will make every effort to meet the needs of our customers.

**Are you coordinating allocation of these tests with the White House or the CDC?**

We remain in constant dialogue with the White House coronavirus task force and government agencies with regard to the allocation of tests and other issues related to the pandemic.

**Will you keep producing your COVID-19 diagnostic test and support the Research Use Only (RUO) solution you announced in February?**

Yes. Initially we shipped about 400,000 **cobas**® SARS-CoV-2 Tests per week in the U.S., after it received EUA on March 12, 2020. Since then, we have ramped up production and distribution significantly and will continue to supply that test at high levels. We also continue to support labs carrying out SARS-CoV-2 testing on our LightCycler® and **cobas z** 480 Analyzers to run the TIB Molbiol LightMix® assays.

**Is the Roche test the only option for SARS-CoV-2 antibody testing?**

No. Other diagnostics manufacturers are developing antibody tests—including other manufacturers of mid- to high-volume tests such as the Roche test. It is vital that total capacities of the diagnostics industry and laboratory facilities are considered when assessing allocation and supply of SARS-CoV-2 testing.

**Is Roche's antibody test an IgG, IgM or IgG/IgM assay?**

Roche designed a total antibody test that detects SARS-CoV-2 antibodies (independent of subtype) using what scientists call “a high-affinity double antigen sandwich assay” (or “double antigen bridge assay”) designed to target mature antibodies. It is designed as a soluble nucleocapsid protein to which mature SARS-CoV-2 Immunoglobulin antibodies bind. Since two antigens are needed to form the bridge, two high affinity binding sites are needed in the antibody molecule, so false positives are avoided.

**How accurate is the Roche antibody test?**

Based on the measurement of more than 5,000 samples, the Roche test has 99.81% specificity and shows no cross-reactivity with the common cold coronaviruses. This means it can lower the chance of false positives. The test also exhibited 100% clinical sensitivity for samples collected at least 14 days after confirmation of the virus in a person, which means it also can avoid false negatives.

**What is the price of the Roche antibody test and how does it compare with similar tests?**

This test is priced responsibly and affordably. In pandemic situations such as this, cost should not be a barrier to accessing diagnostics. We do not discuss specific prices, since the ultimate price of tests to consumers depends on laboratory pricing policies and insurance decisions.

**Are there enough reagents and consumables for the test to be made and used in large numbers?**

We are confident in our ability to manufacture the antibody test in large and growing numbers in the weeks ahead. When planning the ramp up of our test, we have taken a holistic view on all the different consumables and general purpose reagents that are needed to run the test. We are in close contact with the suppliers of the system consumables and ramping up production to ensure the assumed increased demand coming from anti-SARS-CoV-2 testing can be fulfilled.

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