cobas®

PRODUCT INF... RELATED PRO...

Elecsys® Anti-SARS-CoV-2

Immunoassay for the qualitative detection of antibodies (incl. IgG) against SARS-CoV-2

Immunoassay to qualitatively detect antibodies (including IgG) against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

Elecsys® Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to SARS-CoV-2 in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analysers. The assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2.

Elecsys® Anti-SARS-CoV-2 Factsheet

Elecsys® Anti-SARS-CoV-2 Factsheet

SARS-CoV-2: An overview of virus structure, transmission and detection

SARS-CoV-2 is an enveloped, single-stranded RNA virus of the family Coronaviridae. Coronaviruses share structural similarities and are composed of 16 nonstructural proteins and 4 structural proteins: spike, envelope, membrane, and nucleocapsid. Coronaviruses cause diseases with symptoms ranging from those of a mild common cold to more severe ones such as Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.[1,2]

SARS-CoV-2 is transmitted from person-to-person primarily via respiratory droplets, while indirect transmission through contaminated surfaces is also possible.[3–6] The virus accesses host cells via the angiotensin-converting enzyme 2 (ACE2), which is most abundant in the lungs.[7–9]

The incubation period for COVID-19 ranges from 2 – 14 days following exposure, with most cases showing symptoms approximately 4 – 5 days after exposure.[3,10] The spectrum of symptomatic infection ranges from mild (fever, cough, fatigue, loss of smell, shortness of breath) to critical.[11,12] While most symptomatic cases are not severe, severe illness occurs predominantly in adults with advanced age or underlying medical comorbidities and requires intensive care. Acute respiratory distress syndrome (ARDS) is a major complication in patients with severe disease. Critical cases are characterised, for example, by respiratory failure, shock and/or multiple organ dysfunction, or failure.[11,13,14]

Definitive COVID-19 diagnosis entails direct SARS-CoV-2 detection by nucleic acid amplification technology (NAAT).[15-17] Serological assays can contribute to the identification of individuals exposed to the virus and assess the extent of exposure of a population, and might thereby help to decide on application, enforcement or relaxation of containment measures.[18]

CONTACT US

Related Instruments

cobas e 601 module

cobas e 602 module

cobas e 411 analyzer

cobas e 801 module

Related information

Roche's response to the COVID-19 pandemic

Roche develops new serology test to detect COVID-19 antibodies

Roche's cobas SARS-CoV-2 Test to detect novel coronavirus

cobas® SARS-CoV-2 Test

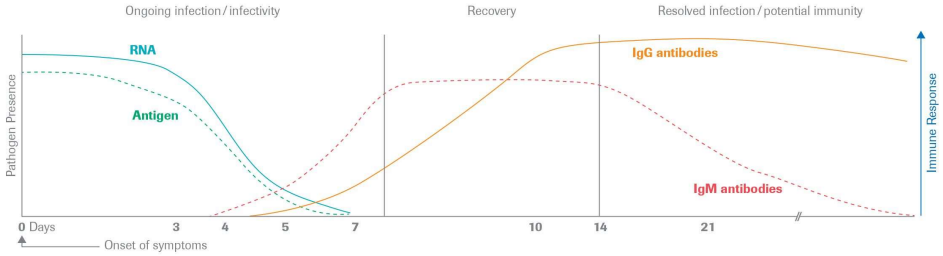
cobas® 6800 System

cobas® 8800 System

Structure of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

- Nucleocapsid protein (N)
- Envelope protein (E)
- Spike protein (S)
- Membrane glycoprotein (M)
- RNA

Illustrative course of markers in SARS-CoV-2 infection[19-27]



Elecsys® Anti-SARS-CoV-2

- Systems

  cobas e 411 analyzer, **cobas e** 601 / **cobas e** 602 modules, **cobas e** 801 module

Testing time	18 minutes

Calibration	○ 2-point
Interpretation	○ COI* < 1.0 = non-reactive COI ≥ 1.0 = reactive

- Sample material

Serum collected using standard sampling tubes. Li-heparin, K2-EDTA and K3-EDTA plasma.

- Sample volume

20 µL **cobas e** 411 analyzer, **cobas e** 601 / **cobas e** 602 modules
12 µL **cobas e** 801 module

Onboard stability	○ 72 hours

* COI: cutoff index

CLINICAL SPECIFICITY[28]

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CLINICAL SENSITIVITY[28]

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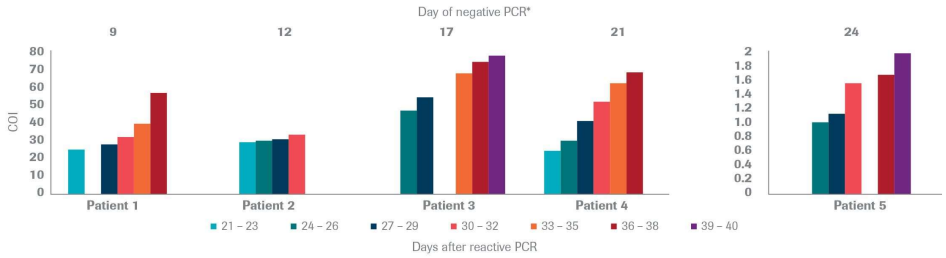
Seroconversion sensitivity[28]

Seroconversion sensitivity

After recovery from infection, confirmed by a negative PCR result, 26 consecutive samples from 5 individuals were tested with the Elecsys® Anti-SARS-CoV-2 assay.



* Day 0 represents initial positive PCR

Roche’s response to the COVID-19 pandemic

Our commitment to support India's COVID-19 testing need.

See more

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Last Updated: 12.06.2020