Elecys® SARS-CoV-2 Antigen
Immunassay for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen

Summary
SARS-CoV-2, the causative agent of COVID-19, is an enveloped, single-stranded RNA Betacoronavirus.1-7 Conversions have been identified as agents of human infection, causing disease ranging from mild common cold to severe respiratory failure.8 Coronavirus shares the 4 structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N), the latter being the most abundant.9,10

SARS-CoV-2 is transmitted primarily from person-to-person through respiratory droplets and aerosols.11 The incubation period from infection to detectable viral load in the host commonly ranges from 2 to 14 days.12 Detection of viral load can be associated with the onset of clinical signs and symptoms, although a considerable proportion of individuals remains asymptomatic or mildly symptomatic.13 The interval during which an individual with COVID-19 is infectious has not yet been clearly established, however, transmission from symptomatic, asymptomatic, and pre-symptomatic individuals has been well described.14,15

An effective strategy for controlling the COVID-19 pandemic is to develop highly accurate methods for the identification of SARS-CoV-2 infected persons, including those who are asymptomatic.16 Antigen tests can also become part of regular testing regimens in the assessment of contacts of confirmed infected persons.17 Testing of mildly symptomatic or asymptomatic individuals can be considered in the assessment of contacts of confirmed infected persons.18 Antigen tests can also become part of regular testing regimens for identifying, isolating, and true tracking out currently infected persons, including those who are asymptomatic.19

The Elecsys® SARS-CoV-2 Antigen assay uses monoclonal antibodies directed against the SARS-CoV-2 N protein in a double-antibody sandwich enzyme format for the qualitative detection of SARS-CoV-2 in upper respiratory tract specimens.

Cobas, Cobas 6800/8800 Systems; Elecsys, Diagnostics; diagnostics.roche.com

References
6. World Health Organization (2020). Available at: https://www.who.int/newsroom/
**Relative sensitivity**

Relative sensitivity was evaluated using 232 nasopharyngeal and 158 oropharyngeal wash specimens, collected from individuals with signs and symptoms suggestive of COVID-19, with known or suspected exposure to SARS-CoV-2, and from individuals undergoing pre-admission screening before hospitalization for surgical intervention unrelated to an infectious disease. All subjects included in the analysis were tested positive in the **cobas** SARS-CoV-2 RT-PCR assay. RT-PCR-positive samples were further stratified using Target 2 (structural protein envelope E-gene/pan-Sarbecovirus detection) cycle threshold (Ct) values.

The figure below correlates the performance of the **Elecsys SARS-CoV-2 Ag** antigen assay in all RT-PCR-positive samples from symptomatic and asymptomatic individuals to the **cobas** SARS-CoV-2 C: value.

<table>
<thead>
<tr>
<th>Specimen type</th>
<th>Overall sensitivity [%]</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Nasopharyngeal swab</td>
<td>95.7 (90.8 – 99.4)</td>
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<tr>
<td>Oropharyngeal swab</td>
<td>92.5 (90.9 – 93.6)</td>
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**Relative specificity**

Relative specificity of the **Elecsys SARS-CoV-2 Ag** antigen assay was evaluated using 279 RT-PCR negative nasopharyngeal wash specimens, collected from individuals with signs and symptoms suggestive of COVID-19, with known or suspected exposure to SARS-CoV-2, and from individuals undergoing pre-admission screening before hospitalization for surgical intervention unrelated to an infectious disease.

**Estimated course of markers in SARS-CoV-2 infection**

The following table summarizes the relative sensitivity of the **Elecsys** SARS-CoV-2 Antigen assay in RT-PCR positive samples from symptomatic patients, stratified by days post symptom onset, and a **cobas** SARS-CoV-2 Target 2 C: value of 30.