LIAISON® SARS-CoV-2 Antigen

A quantitative Antigen assay to achieve maximum impact in testing COVID-19 Symptomatic and Asymptomatic Individuals
The value of Diasorin’s LIAISON® SARS-CoV-2 Antigen

LIAISON® SARS-CoV-2 Ag assay is a unique quantitative solution to detect suspected COVID-19 individuals, do contact tracing and rapidly implement isolation procedures for those patients who have been infected and might be able to spread SARS-CoV-2. LIAISON® SARS-CoV-2 Ag assay could help to keep the COVID-19 pandemic at bay, because specimens can be tested out rapidly in a great numbers.

The assay is a solution when:
• NAATs is unavailable allowing to meet your testing needs
• Long TAT of molecular testing can preclude clinical utility of the test
• To offer a cost-effective solution alternative to RT-PCR
• Allow to process a high volume of samples and to improve traceability at time to result during outbreak
• To screen asymptomatic people and to identify the hidden sources of COVID-19 transmission (1)

According WHO guidelines (2), SARS-CoV-2 Ag assay that meets the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to a NAAT reference assay (3) can be used to diagnose SARS-CoV-2 infection in a range of settings where NAAT is unavailable or where prolonged turnaround time preclude clinical utility.

Referring to WHO recommendations LIAISON® SARS-CoV-2 Ag assay reports on NS collection a clinical sensitivity and a clinical specificity of 98.0% and 99.5% respectively on samples positive for Real time PCR within 10 days of the onset symptoms.

The LIAISON® SARS-CoV-2 Ag assay is in the selection of approved Ag assays by EU Commission for the release of the Green Pass Certificate (4).

The EU Member States mutually recognise the test results for public health measures.

The LIAISON® SARS-CoV-2 Ag assay is a chemiluminescence sandwich-immunoassay (CLIA) based technology for the quantitative determination of Nucleocapsid antigen protein from SARS-CoV-2 samples - in nasal swab (NS), nasopharyngeal swab (NPS) eluted in UTM/VTM directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of the onset of symptoms and in nasopharyngeal swab (NPS) in asymptomatic subjects.

Results from the LIAISON® SARS-CoV-2 Ag test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

The LIAISON® SARS-CoV-2 Antigen Ag delivers 136 tests per hour, early diagnosis combined with high throughput platform. The assay runs on the LIAISON® XL and LIAISON® platform.
Principle of the method

• The assay is a direct two-step sandwich chemiluminescence immunoassay (CLIA).
• Specific rabbit polyclonal antibodies to nucleocapsid antigen are used for coating magnetic particles (solid phase) and linked to an isoluminol derivative (isoluminol-antibody conjugate)
• During the first incubation, SARS-CoV-2 viral antigen present in calibrators, samples or controls binds to the conjugate (STEP.1)
• During the second incubation, the solid phase reacts with SARS-CoV-2 viral antigen already bound to the conjugate (STEP. 2)
• After second incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced (STEP. 3)

Technical Specification

<table>
<thead>
<tr>
<th>Name</th>
<th>LIAISON® SARS-CoV-2 Ag assay</th>
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</thead>
<tbody>
<tr>
<td>Intended Use CE</td>
<td>Quantitative determination of SARS-CoV-2 Nucleocapsid protein antigen in NS, NPS eluted in Viral Transport Media (UTM/VTM)</td>
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<tr>
<td>Assay Type</td>
<td>Sandwich-immunoassay 100 test/kit</td>
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<tr>
<td>Platforms</td>
<td>LIAISON® XL and LIAISON®</td>
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<tr>
<td>Time to first result</td>
<td>average 40 min*</td>
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<tr>
<td>Throughput</td>
<td>136 tests/h – approx. 700 test/working shift</td>
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<tr>
<td>Clinical Sensitivity (NS)</td>
<td>93.1% (95% CI: 86.4-96.6%) on samples positive for Real time PCR (within 10 days onset symptoms)</td>
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<tr>
<td>Clinical Specificity (NS)</td>
<td>100% (95% CI: 98.2-100%)</td>
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<tr>
<td>Clinical Sensitivity (NPS)</td>
<td>95.4% (95% CI: 89.7-98.0%) on samples positive for Real time PCR (within 10 days onset symptoms)</td>
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<tr>
<td>Clinical Specificity (NPS)</td>
<td>99.7% (95% CI: 98.1-99.9%)</td>
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<tr>
<td>Analytical Sensitivity</td>
<td>LOD = 22.0 TCID50/mL</td>
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*depending by the instrument setting and access mode
The SARS-CoV-2 nucleocapsid protein is an important structural protein for the coronaviruses. It is highly abundant in the viruses. Its function involves entering the host cell, binding to the viral RNA genome, and forms the ribonucleoprotein core.

**LEGEND**
- **Nucleocapside protein Ag**
- **Rabbit polyclonal antibodies to nucleocapsid antigen coating magnetic particles (solid phase)**
- **(isoluminol-antibody conjugate)**

**The selection of the antigen for the assay**

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Sample Workflow

**COLLECTION SITE**
NS, NPS in UTM

**LABORATORY BIOSAFETY CABINET**
Place and soak the swab into the pre-filled tube. Roll the swab at least 5 times.

**COLLECTION SITE**
Dry Nasal Swab (NS) flocked or wound fibers

**LABORATORY BIOSAFETY CABINET**
Virus Inactivation 30 min incubation RT

**LABORATORY BIOSAFETY CABINET**
Virus Inactivation 120 min incubation RT

**LABORATORY**
centrifugation

**LABORATORY**
RUN the assay

**Where does Ag test fit?**

Antigen tests can be used in a variety of testing strategies to respond to the coronavirus disease 2019 (COVID-19) pandemic.

**LIAISON® SARS-CoV-2 Ag**

**DIAGNOSTIC**
To identify current infections in Symptomatic or exposed persons

Symptomatic Contact tracing

NS UTM

**SCREENING**
To identify unknown infected person

Asymptomatic

NS UTM

**SURVEILLANCE**
To monitor a community or population level infection

Public Health surveillance testing

NS UTM
Ordering Information

<table>
<thead>
<tr>
<th>CE</th>
<th>Description</th>
<th>Configuration</th>
</tr>
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<tbody>
<tr>
<td>Ref. 311490</td>
<td>LIAISON® SARS-CoV-2 Ag</td>
<td>100 tests</td>
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<tr>
<td>Ref. 311491</td>
<td>LIAISON® Control SARS-CoV-2 Ag 2 vials SARS-CoV-2 Ag reactive controls 2 vials SARS-CoV-2 Ag controls</td>
<td>&gt;15 determinations</td>
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<td>Ref. 311492</td>
<td>LIAISON® SARS-CoV-2 Sample Inactivation Buffer</td>
<td>100 tubes/box</td>
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<tr>
<td></td>
<td>Swab provided upon request as accessories</td>
<td>100 swabs/box</td>
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</tbody>
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References:
4. EU health preparedness: A common list of COVID-19 rapid antigen tests; A common standardised set of data to be included in COVID-19 test result certificates; and A common list of COVID-19 laboratory based antigenic assays Agreed by the Health Security Committee

Please visit: www.diasorin.com/covid19CE
for more information and updates

LIAISON® is a registered trademark of DiaSorin
Available only on LIAISON®
Product availability subject to required regulatory approval

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