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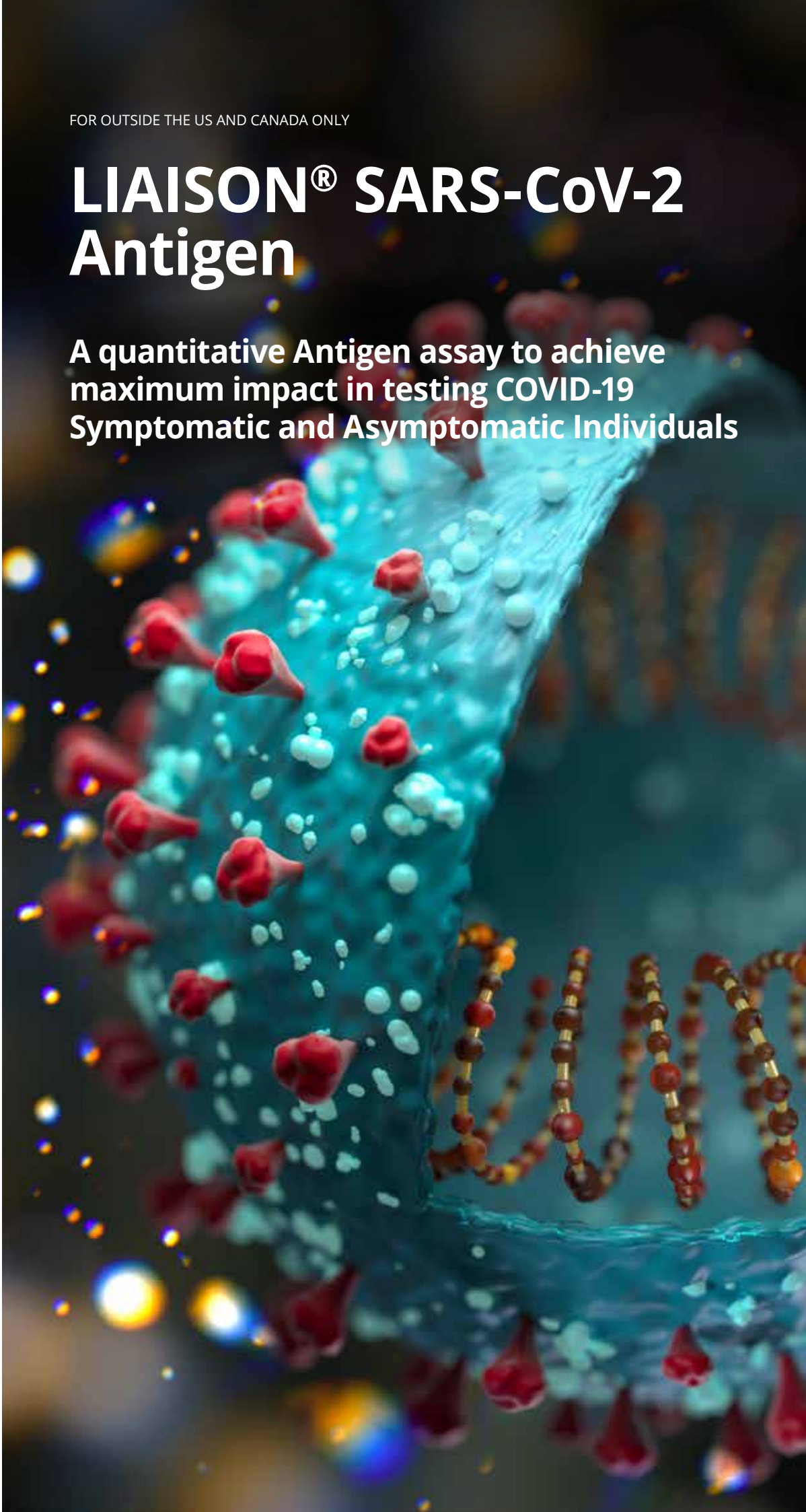
FOR OUTSIDE THE US AND CANADA ONLY

LIAISON® SARS-CoV-2 Antigen

A quantitative Antigen assay to achieve maximum impact in testing COVID-19 Symptomatic and Asymptomatic Individuals



INFECTIOUS DISEASES

DiaSorin

The Diagnostic Specialist

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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.

EU Digital COVID Certificate

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.**

Intended Use LIAISON® SARS-CoV-2 Ag assay

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

Name	**LIAISON® SARS-CoV-2 Ag assay**
Intended Use CE	**Quantitative determination of SARS-CoV-2 Nucleocapsid protein antigen in** NS, NPS eluted in Viral Transport Media (UTM/VTM)
Assay Type	Sandwich-immunoassay 100 test/kit
Platforms	LIAISON® XL and LIAISON®
Time to first result	average 40 min*
Throughput	136 tests/h – approx. 700 test/working shift
Clinical Sensitivity (NS)	93.1% (95% CI: 86.4-96.6%) on samples positive for Real time PCR (within 10 days onset symptoms)
Clinical Specificity (NS)	100% (95% CI: 98.2-100%)
Clinical Sensitivity (NPS)	95.4%, (95% CI: 89.7-98.0%) on samples positive for Real time PCR (within 10 days onset symptoms)
Clinical Specificity (NPS)	99.7% (95% CI: 98.1-99.9%)
Analytical Sensitivity	LOD = 22.0 TCID50/mL

*depending by the instrument setting and access mode

STEP. 1

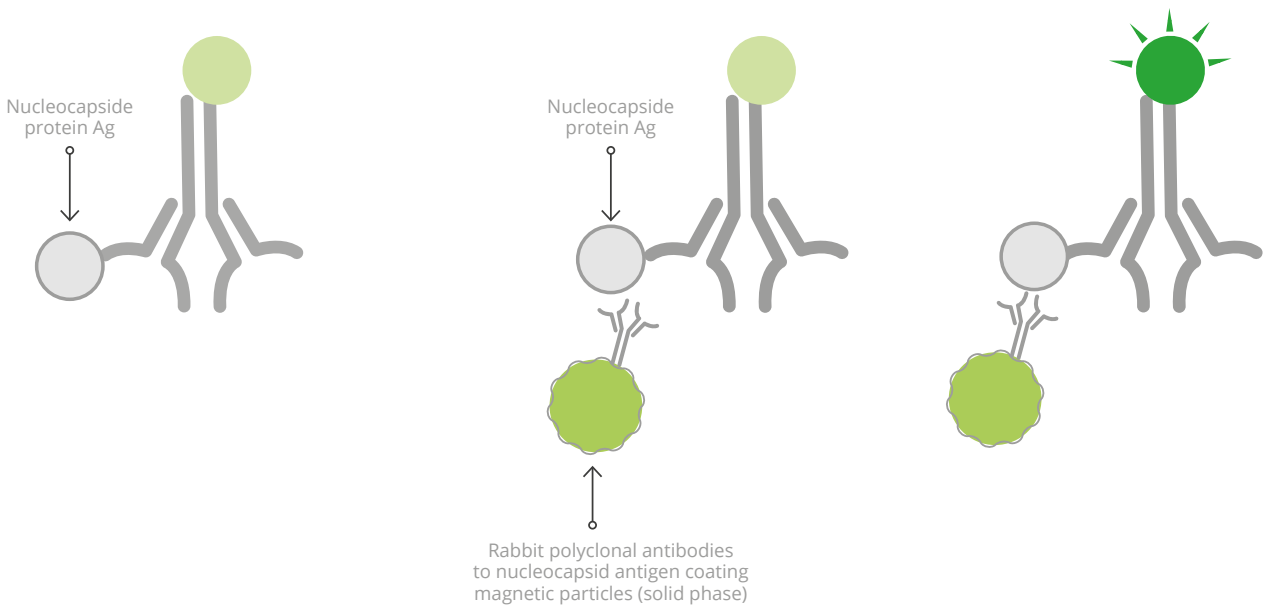
During the first incubation, SARS-CoV-2 viral antigen present in calibrators, samples or controls binds to the conjugate.

STEP. 2

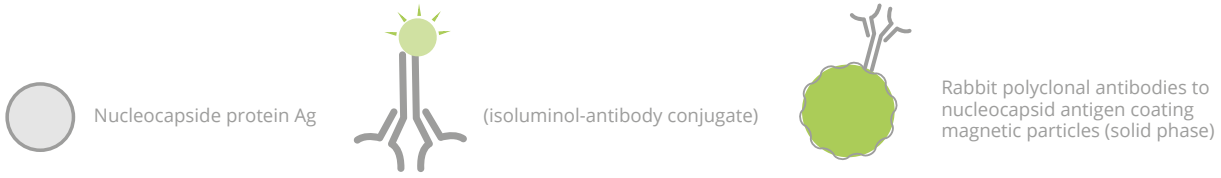
During the second incubation, the solid phase reacts with SARS-CoV-2 viral antigen already bound to the conjugate.

STEP. 3

The unbound material is removed by washing cycle and the starter reagents added to the reaction are able to develop a flash chemiluminescence.

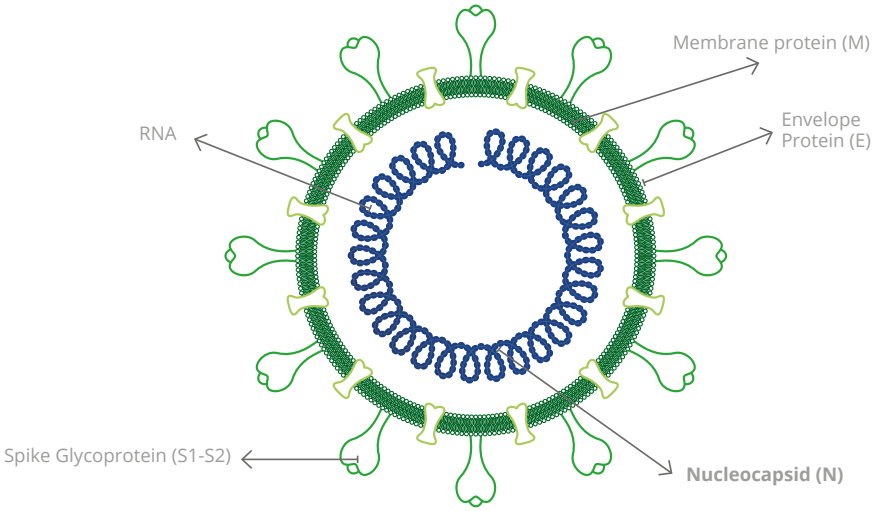


LEGEND

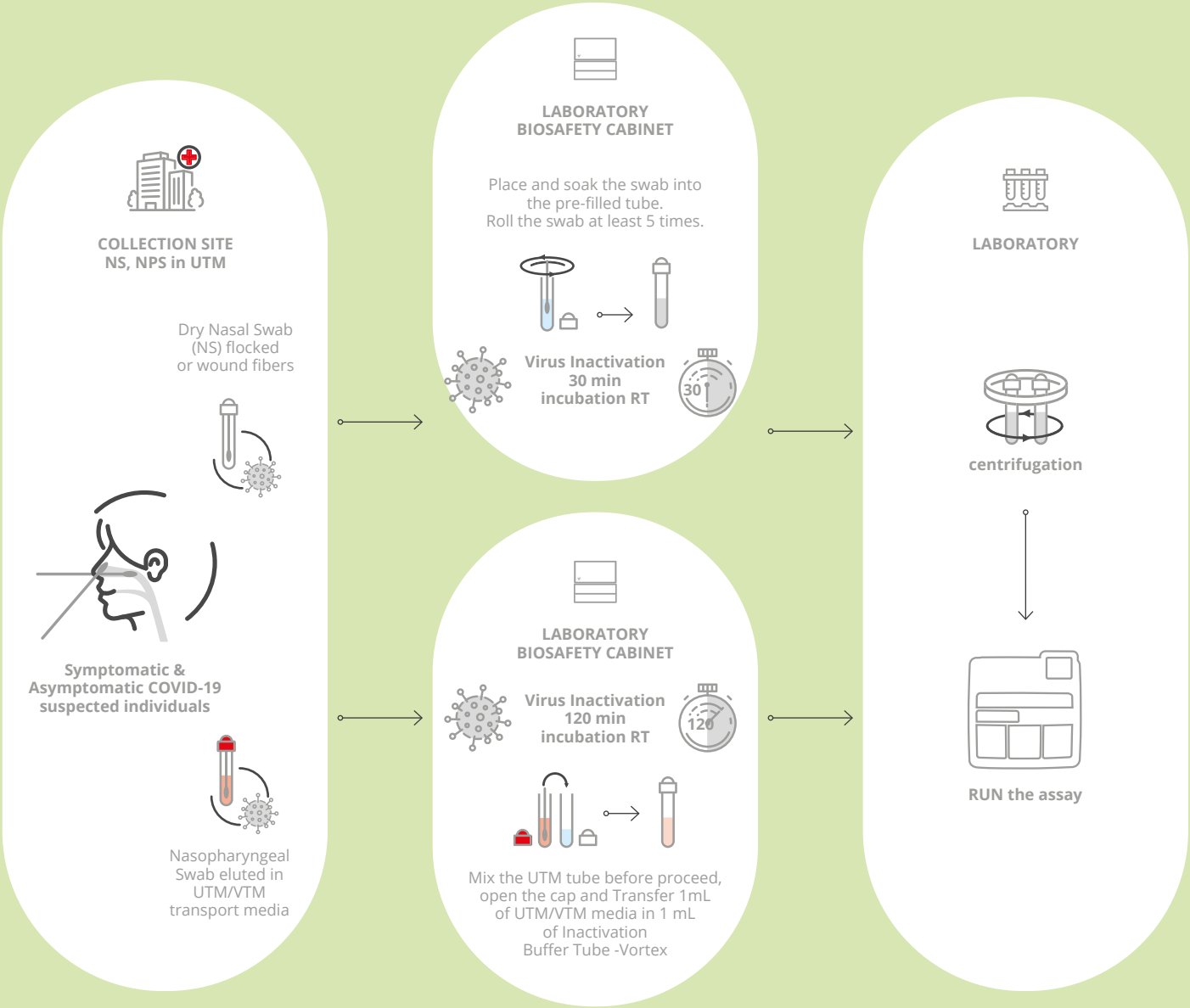


The selection of the antigen for the assay

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.

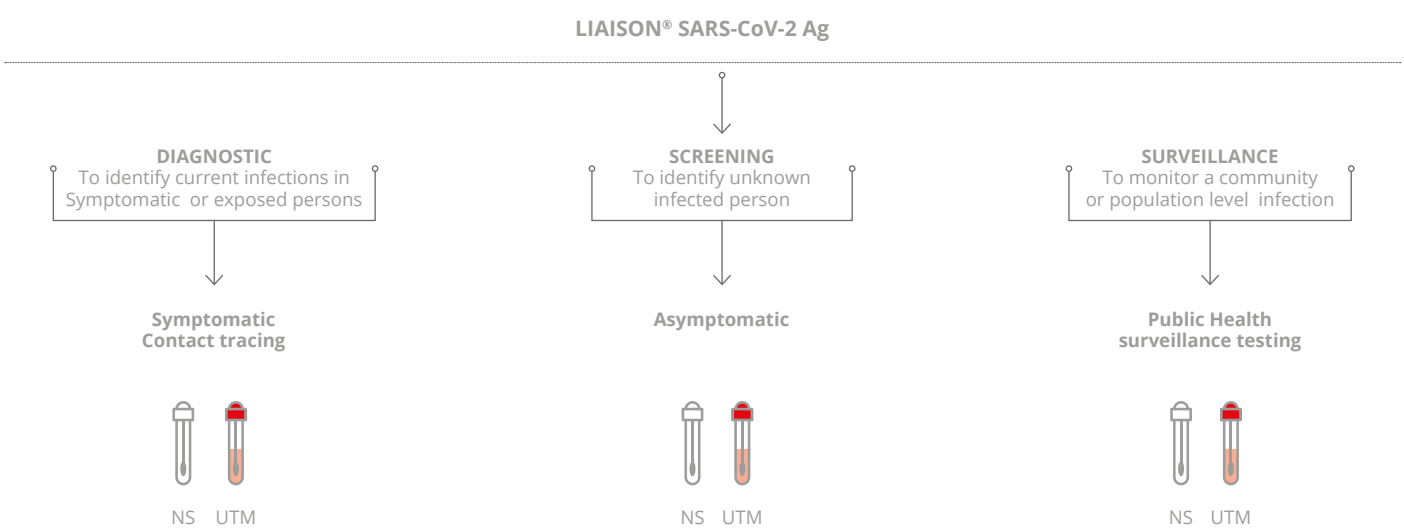


Sample Workflow



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.



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Ordering Information

CE	Description	Configuration
Ref. 311490	LIAISON® SARS-CoV-2 Ag	100 tests
Ref. 311491	LIAISON® Control SARS-CoV-2 Ag 2 vials SARS-CoV-2 Ag reactive controls 2 vials SARS-CoV-2 Ag controls	>15 determinations
Ref. 311492	LIAISON® SARS-CoV-2 Sample Inactivation Buffer	100 tubes/box
	Swab provided upon request as accessories	100 swabs/box

References:
1. Lee S, Kim T, Lee E, Lee C, Kim H, Rhee H, et al. Clinical Course and Molecular Viral Shedding Among Asymptomatic and Symptomatic Patients With SARS-CoV2 Infection in a Community Treatment Center in the Republic of Korea. JAMA Internal Medicine. 2020.
2. U.S. Food & Drug Administration. In Vitro Diagnostics EUAs 2020 [Available from: https://www.fda.gov/medicaldevices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/vitro-diagnostics-euas.
3. WHO Interim Guidance September 11th 2020 Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays.
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

Available only on LIAISON®

Product availability subject to required regulatory approval

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