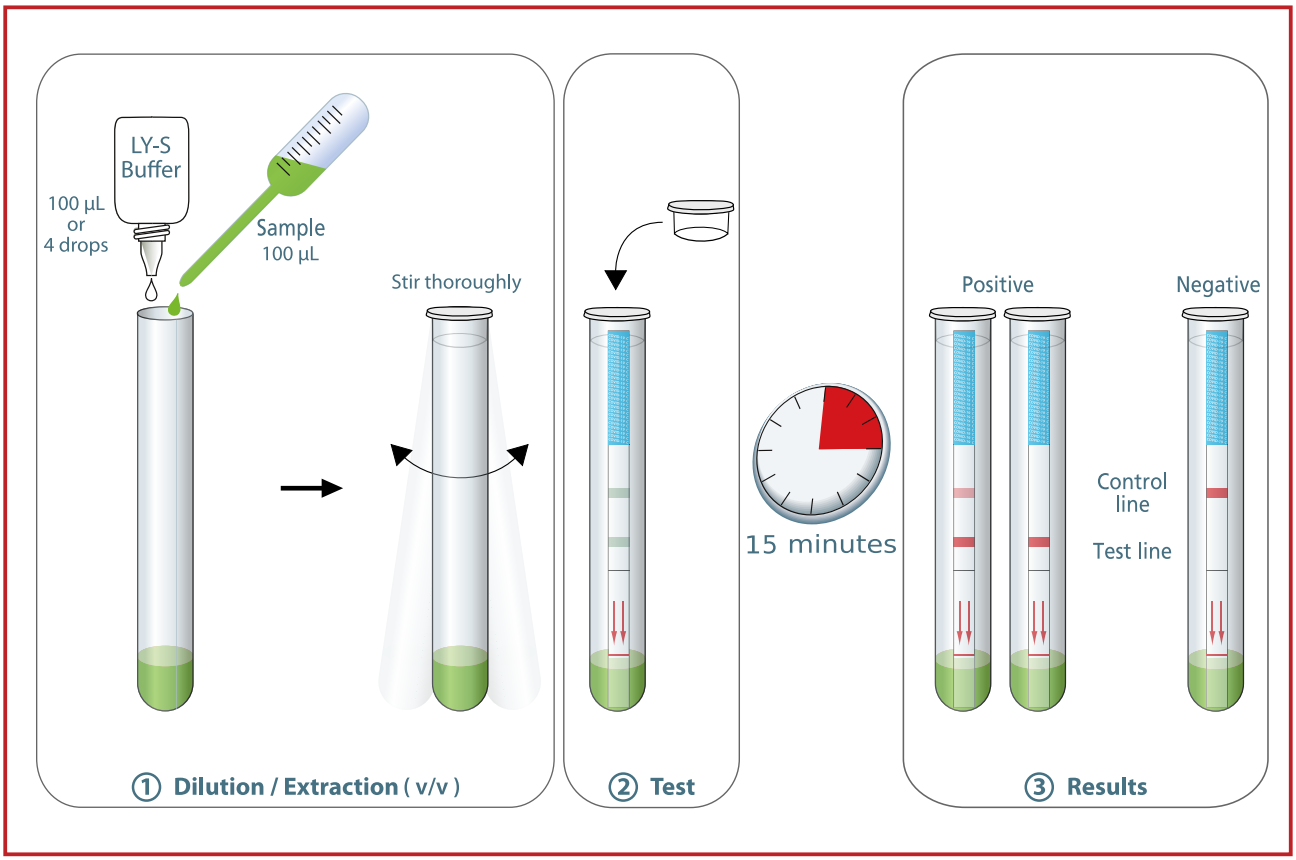
CORIS BioConcept

COVID-19 Ag Respi-Strip

Detection test of SARS-CoV-2

1. In the test tubethe sample is diluted 1:2 with the LY-S buffer
2. The total volume must be 200µl (buffer 100µl - sample100µl)
3. Dip the strip (the liquid must not exceed the red line under the red arrows)
4. Leave to react for 15 minutes
5. Read the final result



COVID-19 Respi-Strip Results

Any signal visible at 15 min on the test line, even a weak one, must be interpreted as positive

COVID-19 Ag Respi-Strip

Performances:

The kit was validated in comparison with RT-PCR on a total of 231 nasopharyngeal swab specimens in two Reference Hospitals: University Hospital Laboratory of Brussels (Evaluation 1) and the University Hospital Laboratory of Liège (Evaluation 2).
The following results were obtained:

Evaluation 1 (n=99)		(95% confidence interval)
Sensitivity	60%	(40.7 to 76,8%)
Sensitivity threshold	85.7% on sampling with CT under 25	(62.6 to 96.2%)
Specificity	100%	(93.4 to 100%)
Positive predictive value	100%	(78.1 to 100%)
Negative predictive value	85.2%	(75.2 to 91.8%)
Agreement	87.9%	(87/99)

Evaluation 2 (n=132)		(95% confidence interval)
Sensitivity	60.3%	(48.1 to 71.3%)
Sensitivity threshold	76.7% on sampling with CT under 25	(61 to 87.7%)
Specificity	98.3%	(89.7 to 99.9%)
Positive predictive value	97.8%	(86.8 to 99.9%)
Negative predictive value	66.7%	(55.7 to 76.2%)
Agreement	77.3%	(102/132)

Detectability:

- Viral detectability : 5x10exp3 pfu/mL
- Recombinant protein detectability : 0,25 ng/mL

Reactivity and cross reactivity:

Viruses	Result
Influenza A	neg
Influenza B	neg
Respiratory Syncytial Virus (RSV)	neg
Respiratory Adenovirus	neg
Parainfluenza	neg
Rhinovirus	neg
Metapneumovirus	neg
Enterovirus	neg
Coronavirus HKU1	neg
Coronavirus OC43	neg
Coronavirus 229E	neg
Coronavirus NL63	neg
Coronavirus SARS-CoV	pos
Coronavirus SARS-CoV-2	pos

Bacteria	Result
Staphylococcus aureus	neg*
Legionella pneumophila	neg
Nocardia asteroides	neg
Streptococcus pneumoniae	neg
Moraxella catarrhalis	neg
Streptococcus pyogenes	neg
Haemophilus influenzae	neg
Pseudomonas aeruginosa	neg
Acinetobacter baumannii	neg
Klebsiella pneumoniae	neg
Mycoplasma pneumoniae	neg

Fungus	Result
Aspergillus niger	neg

* Staphylococcus aureus was found positive at high bacteria concentrations (10e9 cfu/mL). No false-positive results were obtained when testing naso-pharyngeal sample from known S. aureus infected patients.

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
5032 Gembloux - Belgium
Ph: +32 (0)81 719 917
Fax: +32 (0)81 719 919
info@corisbio.com - sales@corisbio.com
www.corisbio.com

D-CUS-10-23-S/03
April 2020