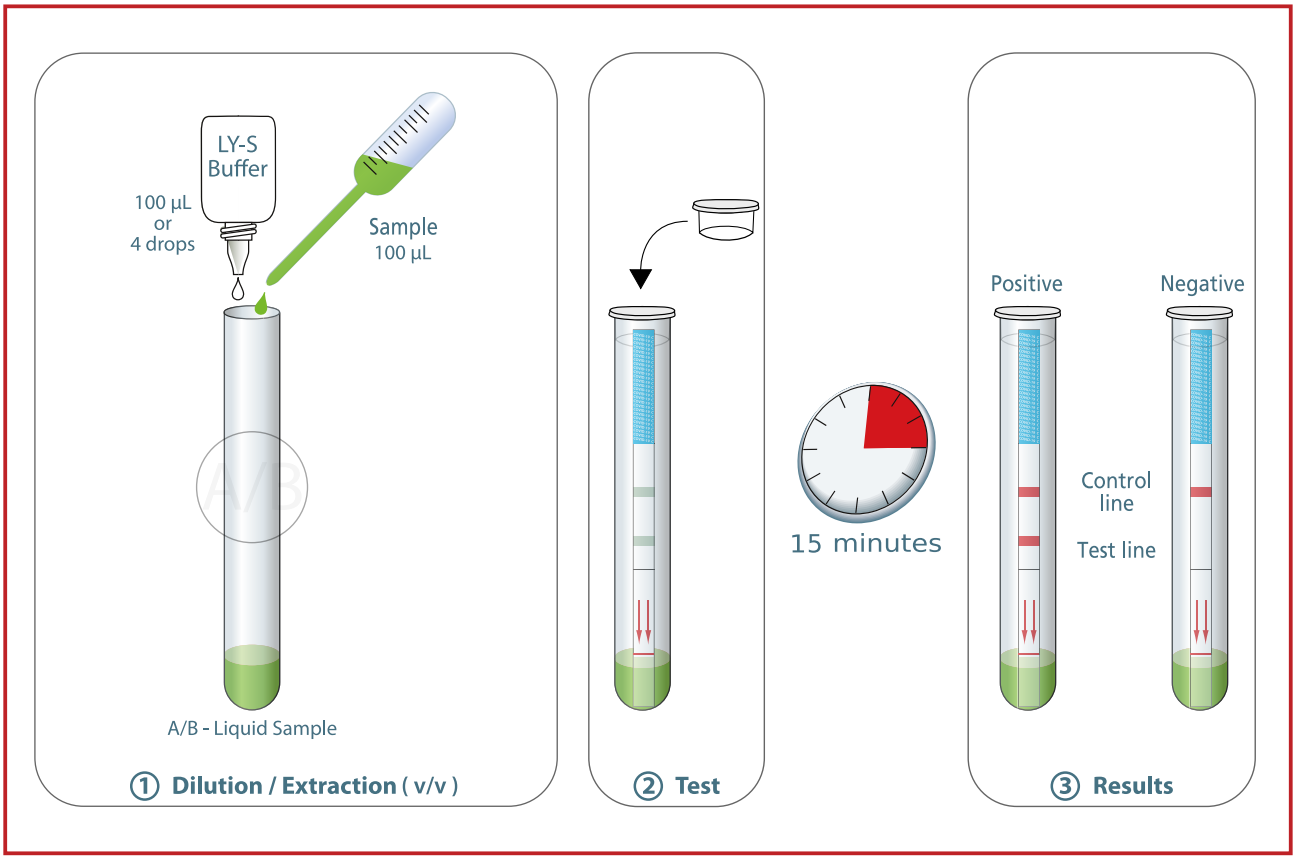
CORIS BioConcept

COVID-19 Ag Respi-Strip

Detection test of SARS-CoV-2

1. In the test tube, dilute 2 times the sample with the LYS buffer
2. The total volume must be between 100 et 500 µl
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 minutes on the test line, even a weak one, must be interpreted as positive (see strips attached to the prototypes : 1 = négative ; 2 = positive ; 3 = positive).

Performances:

The kit was validated (two Reference Hospitals) in comparison with RT-PCR on a total of 202 nasopharyngeal swab specimens. The following results were obtained:

Evaluation 1 (n=100)	95% confidence interval	
Sensitivity	60%	(40.8 to 76,8%)
Sensitivity threshold	85.71% on sampling with CT under 25	
Specificity	100%	(93.5 to 100%)
Positive predictive value	100%	(78.1 to 100%)
Negative predictive value	85.4%	(75.4 to 91.9%)
Agreement	88%	(88/100)

Evaluation 1 (n=102)	95% confidence interval	
Sensitivity	56.14%	(42.4 to 69.0%)
Sensitivity threshold	68.97% on sampling with CT under 25	
Specificity	100%	(90.2 to 100%)
Positive predictive value	100%	(86.7 to 100%)
Negative predictive value	64.3%	(51.9 to 75.1%)
Agreement	88%	(77/102)

Detectability:

- Viral detectability : 1,25 10e4 pfu/mL
- Recombinant protein detectability : 0,3 ng/mL

Reactivity and cross reactivity:

Viruses	Result
Influenza A	neg
Influenza B	neg
Respiratory Syncitial 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	pos
Coronavirus SARS-Cov-2	pos

Bacteria	Result
Staphylococcus aureus	light pos.
Legionella pneumophila	neg
Nocardia asteroides	neg
Streptococcus pneumoniae	neg
Moraxella catarrhalis	neg
Streptococcus pyogenes	neg
Haemophilus influenza	neg
Pseudomonas aeruginosa	neg
Acinetobacter baumanii	neg
Klebsiella pneumoniae	neg
Mycoplasma pneumoniae	neg

Fungus	Result
Aspergillus niger	neg

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