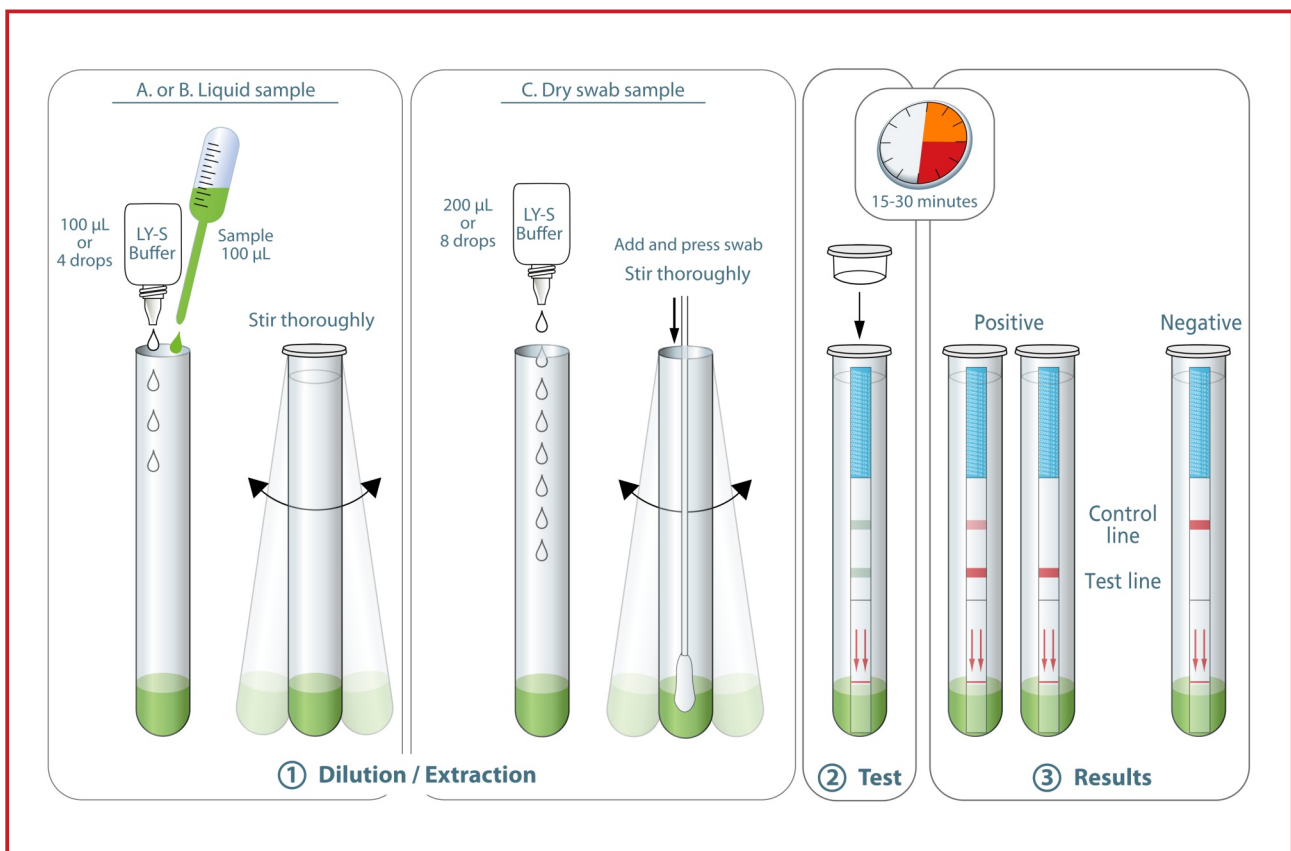


COVID-19 Ag Respi-Strip

Detection test of SARS-CoV-2

- Can be used in hospital settings and POCT -

1. Liquid sample : dilute 1:2 with the LY-S buffer
 Flocked swab : dip the swab in 200µl of LY-S buffer
 The total volume must be 200µl !
2. Dip the strip (the liquid must not exceed the red line under the red arrows)
 Leave to react for 15-30 minutes
5. Read the final result



COVID-19 Respi-Strip Results

Any signal visible at 30 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 189 nasopharyngeal swab specimens in GP clinic settings (USA) and on 231 nasopharyngeal swab specimens with UTM in two Reference Hospitals: University Hospital Laboratory of Brussels and the University Hospital Laboratory of Liège.

The following results were observed:

Evaluation on dry swabs: n=189 (95% confidence interval)

Sensitivity (14.9 < Ct < 34)	91.2%	(75.2 to 97.7%)
Specificity	99.4%	(96 to 100%)
Positive predictive value	96.9%	(82 to 99.8%)
Negative predictive value	98.1%	(94 to 99.5%)
Agreement	97.9%	(185/189)

Evaluation on UTM: n=231 (95% confidence interval)

Sensitivity	60.1%	(48.1 to 71.3%)
Sensitivity threshold	80% on sampling with Ct under 25 (67 to 88%)	
Specificity	99%	(95 to 100%)
Positive predictive value	98%	(90 to 100%)
Negative predictive value	76%	(68 to 82%)
Agreement	82%	(189/321)

Detectability:

- Viral detectability : 3×10^4 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
<i>Staphylococcus aureus</i>	neg*
<i>Legionella pneumophila</i>	neg
<i>Nocardia asteroides</i>	neg
<i>Streptococcus pneumoniae</i>	neg
<i>Moraxella catarrhalis</i>	neg
<i>Streptococcus pyogenes</i>	neg
<i>Haemophilus influenzae</i>	neg
<i>Pseudomonas aeruginosa</i>	neg
<i>Acinetobacter baumannii</i>	neg
<i>Klebsiella pneumoniae</i>	neg
<i>Mycoplasma pneumoniae</i>	neg

Fungus	Result
<i>Aspergillus niger</i>	neg

* *Staphylococcus aureus* was found positive at high bacteria concentrations (10^9 cfu/mL). No false-positive results were obtained when testing naso-pharyngeal sample from known *S. aureus* infected patients.

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