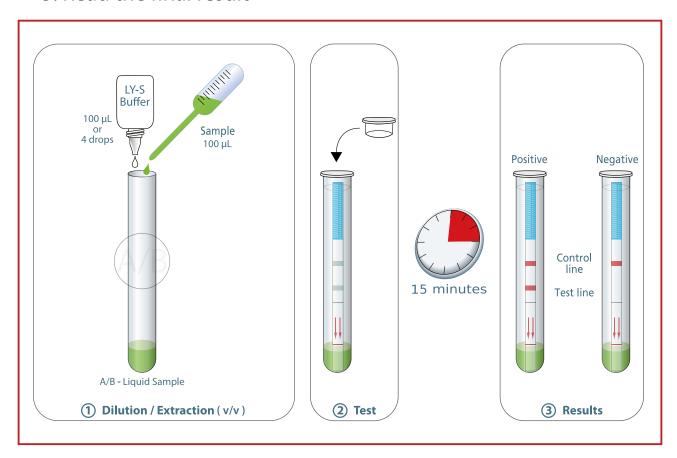


COVID-19 Ag Respi-Strip

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).

SARS-COVID-19

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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