

RAPID COVID-19 ANTIGEN TEST RESULTS IN 15 MIN IN NASOPHARYGEAL SAMPLES

USE TO ASSIST IN RAPID DIAGNOSIS OR AS PART OF TESTING PROGRAMS ⁽¹⁾



- + Elution buffer inactivates the virus: reduce the risk of exposure to testing staff ⁽²⁾
- + Rapid: Results in 15 minutes
- + **Easy-to-use:** simple protocol ⁽³⁾ with no additional equipment required
- + **Ecological packaging:** tube racks supplied in recycled cardboard; cardboard strip format without any plastic
- + Slim swab improves patient comfort
- + Easy logistics: transport and store at room temperature
- + CE-IVD marked
- + Test developed, produced, and assembled in France



HIGH PERFORMANCE

- Sensitivity*: **90,8%** (IC_{95%} 82,9 – 95,3%), n=87
(**97,5%** (IC_{95%} 91,3 – 99,3%) for samples with Ct values ≤ 33**, n=81)
- Specificity*: **>99,9%** (IC_{95%} 97,8 – 100%) n=168
- Precision: **96,9%**

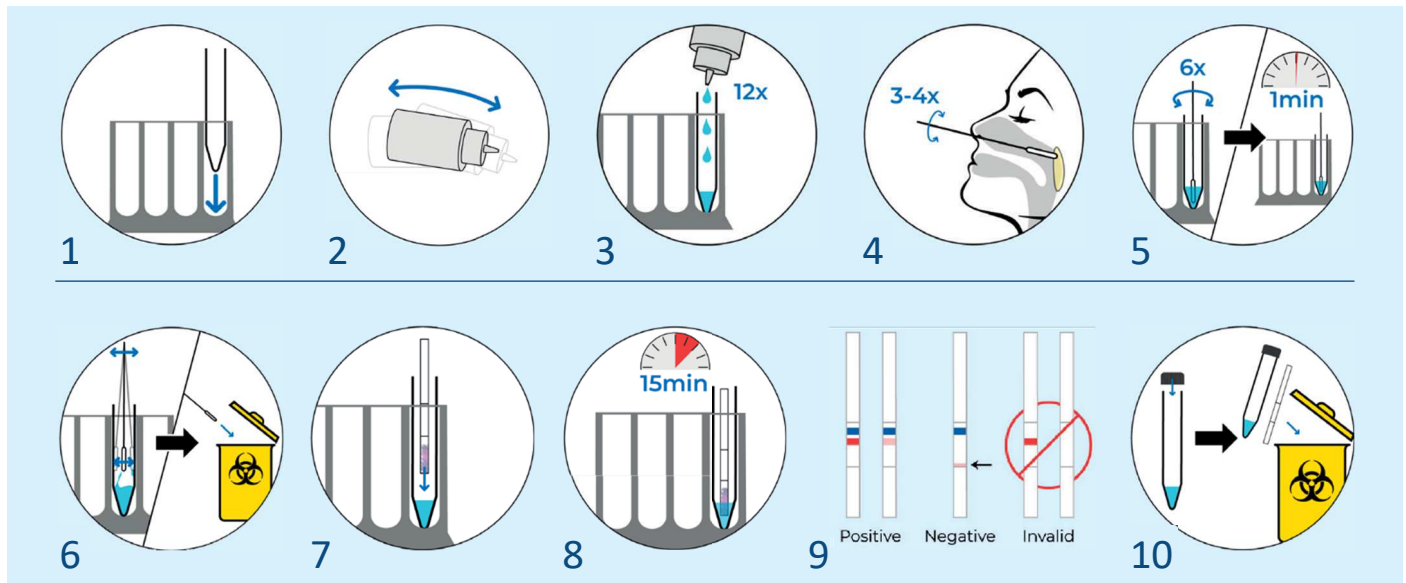
*Performance measured according to the recommendations of the French Health Agency - Haute Autorité de Santé (HAS) - opinion n°2020.0050/AC/SEAP of 24/09/2020. ** Equivalent RT-PCR IP4 CNR.

EFFICIENT SAMPLING FOR RELIABLE DIAGNOSIS



- + **Efficient and reliable sampling:** the swab efficiently collects sample and, in combination with the buffer in the kit, optimizes the release of secretions to allow for increased sensitivity
- + **Ensures patient comfort** thanks to the slim swab
- + **Safe:** the breaking point of the swab is at a safe distance from the flocked end

PROTOCOL



25 test kit includes:

- + 25 iD Rapid® COVID-19 Ag test strips packaged in an air-tight tube with a desiccant cap
- + 25 sterile, individually packaged flocked swabs (CE 0197)
- + Dropper bottle containing elution buffer which inactivates SARS-CoV-2
- + 1 cardboard tube rack
- + 25 elution tubes and associated tests and caps
- + 1 instructions for use
- + 1 rapid guide

Material required but not provided: personal protective equipment (ex. laboratory coat, face mask, face shield / eye goggles, gloves), timer, biohazard container

PRODUCT CODE	COVIDAGDIP
NUMBER OF TESTS PER KIT	25
CE-IVD MARKING	YES
FRENCH APPROVAL NUMBER	<i>underway</i>

- (1) Respect all recommendations provided by Health authorities and all regulations in vigour
- (2) The buffer composition inactivates the SARS-CoV-2 virus by lysis by detergents (NP40), and therefore allows also to reduce the exposure risk of testing staff. Inactivation has been shown in publications, after a 30-minute contact time (Welch SR, et al. 2020). Analysis of inactivation of SARS-CoV-2 by specimen transport media, nucleic acid extraction reagents, detergents, and fixatives. J Clin Microbiol 58:e01713-20). However, all samples must be considered as potentially infectious, and therefore individual personal protective equipment must be worn.
- (3) *In vitro* diagnostic medical device. Read the instructions for use carefully. All kits are designed for in vitro diagnostic use and may only be used by healthcare professions. The test is not designed for home use.