

## Can we trust self-screening tests facing SARS-CoV-2 variants?

Press Release of the French National Academy of Medicine

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The emergence of new variants of SARS-CoV-2, and their rapid spread since the beginning of 2021 have upset the epidemiological situation of Covid-19 in the world. Carrying numerous mutations, including the N501Y mutation which confers a better transmissibility, the variants of interest have a selective advantage, especially the so-called "British" variant, which has become the most common in France in all regions and is contributing to the current epidemic resurgence [1].

Faced with this situation, the intensification of screening operations has become essential to curb the epidemic rebound. In addition to the deployment of free mobile screening units, recommended more than 6 months ago by the French National Academy of Medicine [2], the strategy of mass screening has been applied in the most affected geographical areas before extending it to the school environment.

However, the capacity of the tests to detect the infection, whether symptomatic or not, could be altered by the genomic or antigenic modifications of the circulating variants of the three main lineages: B.1.1.7 (British), B.1.351 (South African) and P1 (Brazilian). This is why the French regulation stipulates that RT-PCR tests should include two amplification targets in order to identify mutants in case of discordance. Likewise, the antigenic tests approved in France target the N protein (viral nucleocapsid), which is less prone to mutations than the S protein (spike).

Furthermore, some variants such as B.1.616 (20C/655Y), that emerged in Brittany in January 2021, may give weak or even negative RT-PCR results despite a clinical context suggestive of Covid-19, as their identification requires the complete sequencing of the viral genome by one of the four French EMER-GEN platforms [3].

The sale of self-tests in pharmacies, recently authorized by ministerial decree, can contribute to the early detection of contaminators and the reduction of new outbreaks of infection. These are antigenic tests that can be performed after nasal self-sampling in asymptomatic people aged 15 years or over. They could strengthen the screening strategy in the family, but also in business, high schools and universities, provided they are used correctly and their limitations are known. The main disadvantage of self-tests is their low sensitivity in asymptomatic people, to whom they are intended, aggravated by the possibility of insufficient sampling, faulty handling and misinterpretation. A result considered as negative by the user may lead to a false security and an inappropriate relaxation of preventive measures.

Furthermore, particular attention must be paid to all antigenic tests, as their intensive use in "real life" has shown a higher frequency of false positives for certain batches of reagents than

that observed during the assessments. This finding confirms the need to control all positive results by RT-PCR, which remains the most sensitive and specific reference technique to date.

In order not to compromise the effectiveness of screening for variants, the French National Academy of Medicine recommends

- to assess regularly the performance of the available tests against the new circulating SARS-CoV-2 lineages, "*variants of interest*" and "*variants to follow*" and to reinforce the monitoring of batches for their withdrawal in the event of lack of sensitivity and/or specificity;

- to restrict the sale and distribution of self-tests to pharmacies in order to inform each user:

- o on good sampling, handling and reading practices

- o on the obligation, in the event of a negative result, to maintain the barrier gestures;

- o on the obligation, in case of a positive result, to isolate oneself and alert one's contacts;

- to insist on the need to confirm by RT-PCR any positive antigenic test, whether carried out by a health professional or by self-testing, in order to characterize a possible variant and to enter this result in the national SI-DEP database allowing the monitoring of the epidemic.

1. Press release of the French National Academy of Medicine "Monitoring SARS-CoV-2 variants: how and why", March 16, 2021

2. Press release of the French National Academy of Medicine "Covid-19: Screening more, screening better", August 3, 2020

3. DGS-urgent "What to do with a variant to be monitored (derived from clade 20c) detected for the first time in Brittany", March 30, 2021