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COVID-19: clinical trial launched for a rapid saliva-based screening test

A French consortium consisting of scientists from the CNRS laboratory Sys2Diag, the SkillCell biotechnology company and Montpellier University Hospital (CHU de Montpellier) have announced the launch of a clinical trial to evaluate the performance of the new EasyCov screening test beginning on 11 April 2020. In parallel, the development, production, and distribution chain is organizing for the rapid and mass deployment of the test to medical personnel in May.

The consortium's goal is to bring to market a saliva-based diagnostic test for the SARS-CoV-2 virus, one that is easy to use and does not require cumbersome equipment. The EasyCov (patent EP20166524) saliva-based test was developed for this purpose. It has already been tested and validated by the viral RNA isolated at the Sys2Diag (CNRS/Alcen) laboratory, as well as with the active virus at the Institut de recherche en infectiologie de Montpellier (CNRS/Université de Montpellier). The clinical trial led by teams from Sys2Diag and CHU de Montpellier can confirm or disprove its performance in real conditions.

To this end, 180 people were recruited by the COVID teams of the CHU de Montpellier beginning on 11 April. This double-blind clinical trial will be conducted with patients who tested positive for COVID-19, as well as presumably negative medical staff from the hospital. The analyses that detect the presence of the viral RNA specific to SARS-CoV-2 will simultaneously be conducted using a conventional method. The sensitivity and specificity of EasyCov could be optimized based on the trial results, which are expected in late April.

The EasyCov test is easy to administer, and does not require a laboratory. All that is needed is a sample of saliva—one of the primary vectors for the virus—which is then placed with the reagents at a temperature of 65°C for 30 minutes. Medical personnel can read the results with the naked eye, as opposed to the standard test method, which requires multiple hours of processing in the laboratory, as well as considerable equipment and reagents.

If the results of the clinical trial are conclusive, the rapid implementation of an effective and reliable production chain will be indispensable to mass availability of the EasyCov test in France. SkillCell, a subsidiary of the French industrial group Alcen, will identify and secure reagent suppliers, as well as French partners who possess substantial production and distribution capacity. This effort will be facilitated by the very small amounts of reagents required by EasyCov. This chain could be ready for deployment with medical staff in May.

Finally, the consortium is seeking to develop a version of Easycov for the general public. In the event that the test would still require incubation at 65°C, the development and industrialization of a mobile heating device is underway. The French company Vogo, an expert in high value-added audio and video communication systems, is in charge of developing and launching the technological tool that will automate results analysis via colorimetric reading of the EasyCov test, which would be required for the massive screening of the population.

Visual from the EasyCov saliva-based diagnostic test for SARS-CoV-2. It includes a sealed 0.5 mL tube containing the reagents needed for colorimetric detection of the virus.
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