



C4Diagnostics, Bertin Technologies, and Enalees announce the launch of their clinical trial of *BEC-SARS-CoV-2 for humans*, a rapid point-of-care Covid-19 diagnostic test

- The French Ethics Committee¹ has given its approval for a prospective clinical trial;
- This prospective clinical trial has been launched in several clinical centres in France;
- The CE-IVD marking is expected by the end of September 2020

September 16, 2020, Paris and Marseille - C4Diagnostics, Bertin Technologies, and Enalees announce the launch of their clinical trial of *BEC-SARS-CoV-2 for humans*, a diagnostic test for Covid-19, developed jointly with Pasteur Institute. The *BEC-SARS-CoV-2 for humans* test has been submitted to the authorities in accordance with French regulations, the detection process has been validated and a clinical trial has been launched by the consortium in order to obtain CE-IVD marking by the end of September. In the meantime, the test is available as RUO². This sensitive, rapid, and portable diagnostic test relies on two innovative technologies for the extraction of viral RNA and its rapid detection using RT-LAMP. Due to its portable format, it can detect SARS-CoV-2 in human on site within 25 minutes (from collection to result) from a nasal or nasopharyngeal swab, with an endogenous control and two different target genes (in line with the World Health Organization and the French Health Authority (HAS) recommendations).

Laurent Thiery, CEO and Co-founder of Enalees, states:

"The *BEC-SARS-CoV-2 for humans* test kit is based on the Enalees test concept that we have been using for 2 years to detect and curtail the transmission of respiratory diseases, on site, in domestic animals such as horses. In particular, our **rapid viral RNA extraction technique** validated previously on test kits for animal diseases is at the core of this new test kit. In addition, this test also uses a **rapid molecular diagnostic technology based on RT-LAMP**, used in all Enalees test kits and during previous health crises such as Ebola or Zika by Pasteur Institute. We have adapted our standardised and optimised sample preparation and analysis procedures for human SARS-CoV-2 diagnostic test in time to help manage the current health crisis. *BEC-SARS-CoV-2 for humans* therefore provides a proven solution both in terms of performance and ease of use. This integrated approach highlights the benefits of the One Health approach, combining the best of human, animal, and environmental health. "

Younes Lazrak, CEO of C4Diagnostics, continues:

" While waiting for an effective vaccine against Covid-19, we must expand and facilitate population screening. To cope with the current health crisis, a diagnostic test kit such as *BEC-SARS-CoV-2 for humans* is particularly suitable for scenarios where access to a diagnostic laboratory is difficult or even impossible (at sea, for instance), and/or where test results must be determined immediately for on-site testing of asymptomatic individuals who may be potential Covid-19 carriers (for example, before using public transport such as planes, trains, etc.). The ability to carry out **field testing of people in a rapid, easy, and robust way is a major step forward for Covid-19 rapid screening campaigns**. The results we have obtained are currently being tested in a prospective clinical trial led by Pasteur Institute in several clinical centres. The clinical data will confirm the sensitivity and specificity of our

¹ Comité de Protection des Personnes (CPP)

² RUO: Research Use Only

diagnostic test and we expect that **BEC-SARS-CoV-2 for humans** will receive its CE-IVD marking by the end of September".

Bruno Vallayer, CEO of Bertin Technologies, concludes:

*"Like the vast majority of products developed by Bertin Technologies, this **test, developed and produced in France**, meets our esteemed quality standards. The **BEC-SARS-CoV-2 for humans** test kit complements the one we developed and marketed jointly in May 2020 for the detection of the SARS-CoV-2 in the environment. Used in conjunction with our Coriolis air sampler, the **BEC-SARS-CoV-2 for the environment** test kit provides a comprehensive solution for analysing environmental contamination. Combined, the two **BEC-SARS-CoV-2** tests allow the detection of Covid-19 in a contaminated person's social group and in their environment. This **dual approach is key to stopping all new outbreaks of SARS-CoV-2 in a controlled and localised way**".*

ABOUT THE **BEC-SARS-CoV-2 for humans TEST KIT**

This field diagnostic test kit uses RT-LAMP technology which has an equivalent sensitivity to RT-PCR for the detection of SARS-CoV-2. RT-LAMP is an amplification method which, unlike traditional RT-PCR, does not require temperature cycles for the amplification of RNA. The advantages of this technique are highlighted in its speed, ease of use, and robustness. Amongst the various existing isothermal amplification methods, LAMP has gained particular popularity over the last few years. As an example, the WHO recommended its use for the diagnosis of tuberculosis.

In terms of robustness and performance, this test satisfies the requirements of the French National Health Authority (HAS). It has two viral target genes for better sensitivity and specificity, and an endogenous positive control to ensure both the quality of the sampling technique and the correct functioning of the test and equipment, thus limiting the number of false negatives.



ABOUT C4Diagnostics

Based in Marseille, France, **C4Diagnostics** designs, develops, and markets innovative in-vitro diagnostic tests for infectious diseases. Recipient of numerous awards, C4Diagnostics tests are based on a cutting-edge technology that detects pathogenic microorganisms rapidly through their own metabolism. C4Diagnostics aims to become one of the main players in the area of infectious disease diagnosis and lead the global market on in vitro diagnostics (IVD) of infectious diseases by providing the relevant information to physicians and patients in a faster and more sensitive way. C4Diagnostics tackles major public health problems such as infection control and antibiotic resistance.

Since April 2020, C4Diagnostics has been operating the COMETE (COvid-19 Marseille Environmental TESting) platform for the French Navy firefighters battalion in Marseille and has launched C4Services, its dedicated business unit for detecting SARS-CoV-2 in people and in the environment. C4Diagnostics is the only company currently offering a full range of tests for detecting SARS-CoV-2. More than 3,000 samples have been analysed by C4Diagnostics since the start of the Covid-19 pandemic.

www.c4diagnostics.com



ABOUT BERTIN TECHNOLOGIES

BERTIN TECHNOLOGIES, subsidiary of **CNIM** Group, relies on its long history of innovation to develop, produce, and market innovative systems and equipment worldwide. The company is active at a global level. Its instrumentation activities are conducted through the brand **BERTIN INSTRUMENTS**. Its innovative measurement and sampling solutions are aimed at markets with strict regulations:

- Life sciences (biological air samplers, biological sample preparation, bioanalysis kits, digital microscopes),
- Nuclear and radiation protection (portable radiation protection equipment, environmental radiation monitoring, radiation portal monitors, professional radon monitoring),
- Defence, security, and safety: Site, force, and critical infrastructure protection (detection of CBRN* threats, optronic surveillance modules and sensor networks set up in conjunction with its subsidiary Exensor).

www.bertin-instruments.com



ABOUT ENALEES

Enalees is a French company founded in 2015 at the site of Genopole biopark in Evry, Greater Paris. Enalees is the leader in rapid molecular diagnostic tests for infectious diseases in domestic animals (horses, dogs, and cats), namely equine influenza, leptospirosis, and Lyme disease. These innovative tests are simple and rapid, and can be carried out on site by veterinarians during consultations. They allow sick animals to be treated and quarantined immediately and assist actively in the containment of certain epidemics. tests for equine infectious diseases were first launched in 2019 and are already being used by more than a third of equine clinics in France. Enalees also began manufacturing tests for dogs and cats recently, including one for COVID-19 in cats, expanding its catalogue to include more than 15 tests, available throughout Europe and shortly in North America.

www.enalees.com

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