C4Diagnostics Announces CE Marking of C4Covid-19 Human™: a Covid-19 Saliva-Based Rapid Diagnostic Test

April 16, 2021, Marseille, FRANCE - C4Diagnostics, a French biotech developing innovative *In vitro* diagnostic tests for infectious diseases, announced today the CE marking and commercialization of C4Covid-19 Human™ for the rapid diagnostic of Covid-19 from a saliva sample. The performance of the test was calculated upon a largescale clinical trial of 1320 participants, carried out in collaboration with Synlab Provence Laboratories. Sensitivity is 86% and specificity is 97.5%.

C4Covid-19 Human™ is an in vitro diagnostic test (IVD) designed to address the growing need for saliva-based screening, combining high performance while being deployable outside the clinical laboratory. Based on RT-LAMP technology, which is close to RT-PCR, it requires minimal equipment, namely a portable reader-analyzer, and the result is delivered in less than 30 minutes.
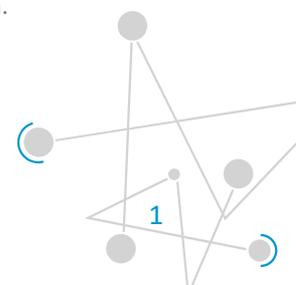
*"The CE marking of our **C4Covid-19 Human™** test is great news as it offers new perspectives to control the disease spread with painless immediate diagnosis. It is also a significant milestone for C4Diagnostics as C4Covid-19 Human™ is our first in vitro diagnostic product to be CE marked and on the market for a medical use. We have overcome the usual limitations of LAMP technology and of saliva samples to offer a kit with performances close to those of RT-PCR analysis on nasopharyngeal swabs"*, stated **Younes Lazrak, CEO of C4Diagnostics**.

*"**C4Covid-19 Human™** is the result of our team's hard work and dedication, but also of extensive collaborations with our partners. Already adopted by our first target customers, the C4Covid-19 Human™ test is being marketed with a gradual and controlled increase in production to rapidly meet the need in France, Europe, as well as in the Middle East and North Africa"*, commented **Thomas Tran, Managing Director at C4Diagnostics**.

*"Synlab Provence is perfectly equipped to handle large batches of samples in its laboratories and since the beginning of the pandemic we have tested over 500,000 samples for Covid-19. The **C4Covid-19 Human™** test completes our testing capabilities as we also need saliva-based rapid tests to extend Covid-19 screening to specific populations. The **C4Covid-19 Human™** test allows us to offer on the field a quality of analysis comparable to that of the laboratory"*, declared **Dr Farid Mersali, medical biologist, principal investigator of the clinical trial and general manager of Synlab Provence Laboratories**.

About C4Covid-19 Human™ IVD test

The diagnostic test C4Covid-19 Human™ is based on RT-LAMP technology. The distinct advantages of the RT-LAMP technology are its speed, ease of use and robustness. In accordance with the WHO recommendations, the C4Covid-19 Human™ test includes two viral targets (T and E genes). The patented primers used in the test were invented by the Institut Pasteur's Urgent Response to Biological Threats (CIBU) team, led by Dr. Manuguerra, and licensed to C4Diagnostics. This diagnostic test detects the native form of the virus ("wild-type") as well as its known variants, notably English, South African and Brazilian.

The clinical trial was conducted in Marseille (FRANCE) at the Covid-19 screening centers of Synlab Provence laboratories. A double sampling, nasopharyngeal and salivary, was performed on the participants, in order to compare the saliva-based test RT-LAMP C4Covid-19 Human™ to the gold-standard nasopharyngeal RT-PCR test.

The performances, analyzed on these 1320 subjects, showed a sensitivity of 86% and a specificity of 97.5%.

The clinical study is ongoing to further refine the performance of the C4Covid-19 Human™ test in comparison to a saliva-based RT-PCR test, and to analyze more specifically the performance of the test in contact cases.

About C4Diagnostics

C4Diagnostics is a French-based biotech specialized in the development of in vitro diagnostic (IVD) tests for human infectious diseases

C4Diagnostics' strategy for the better management of Human infectious diseases, is to develop game changing IVD tests which are significantly faster than standard methods whilst maintaining comparable or better performance.

Its pipeline of products currently focuses on the diagnosis of Covid-19 (C4Covid-19 Human™), Legionnaires' Disease (C4Legio-LFA), urinary tract infections (C4UTI) and the development of antimicrobial susceptibility tests (C4AST).

C4Diagnostics also has a business unit dedicated to environmental diagnostics, called C4Services. It provides services for the detection of SARS-CoV-2 in the environment (wastewater, air, surface) and has contributed to several Covid-19 surveillance and prevention campaigns since the beginning of the pandemic.

With its rapid and highly sensitive IVD tests, C4Diagnostics ambitions to become one of the main actors in the diagnosis of human infectious diseases field, by giving medical labs and healthcare professionals sensible and reliable diagnostic information in a timely manner.

The game changing diagnostic solutions developed by C4Diagnostics are a leverage to fight against antibiotic resistance and curb infectious disease epidemics.

www.C4Diagnostics.com

Contacts

Ophelie Philipot
Strategy and Communication Manager
+33 (0)6 70 07 87 47
Ophelie.Philipot@C4Diagnostics.com