BIOLYTICAL LABORATORIES INC. RECEIVES CE MARK FOR THE WORLD'S FIRST ONE MINUTE HEPATITIS C (HCV) ANTIBODY RAPID TEST

bioLytical announced today that its INSTI® HCV Antibody Test has received approval for immediate market entry into the European Union by its Notified Body

RICHMOND, BRITISH COLUMBIA, CANADA, July 12, 2021 /EINPresswire.com/ -- •bioLytical's INSTI® HCV Antibody Test is the world's first one minute test
•bioLytical has received CE Mark and approval to sell across Europe
•The test is portable, does not require any additional equipment, and can be performed in a multitude of settings with easy-to-interpret results in real-time
•Test performance in clinical studies demonstrated high accuracy of over 99%
•bioLytical's quality system is MDSAP certified

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>
> *Robert Mackie, CEO*

bioLytical Laboratories Inc. ("bioLytical"), a global leader in rapid in vitro medical diagnostics, announced it received CE Mark for the world's first one minute HCV Antibody Test, allowing it to sell its kits across Europe. The innovative rapid through-flow technology allows INSTI® to provide accurate test results in real-time, offering medical professionals the ability to test patients easily and flexibly in different locations.

Affecting an estimated 71 million globally, Hepatitis C ("HCV") is a growing international health concern. It can remain asymptomatic and thus undiagnosed, and if left untreated, can cause serious health problems, including liver damage, cirrhosis, liver cancer and even death.

With both taking the test and receiving results in real-time, bioLytical's INSTI® HCV Antibody Test will help connect more people to care. Treatment can cure more than 95% of people with

Hepatitis C, but access to diagnosis is still too low. Ending an epidemic starts with testing. That's why we've developed an all-new, one minute solution for HCV antibody testing.

“By using our proven INSTI® platform, we were able to take advantage of our rapid test technology to develop a fast and easy-to-use test with over 99% accuracy,” said Robert Mackie, CEO for bioLytical. “Ending HCV in Europe begins with testing. By providing access to the world’s first one minute HCV test, we are excited to play a role in reducing transmission in Europe to help diagnose and connect individuals to care.”

Leveraging bioLytical’s proven INSTI® technology, the INSTI® HCV Antibody Test was designed to identify HCV antibodies, paving the way for reliable and fast screening using a simple fingerstick method to receive results that are more than 99 percent accurate in only one minute. bioLytical will manufacture the INSTI® HCV Antibody Tests in its facility in Richmond, British Columbia, to sell and distribute across Europe.

Proven Testing Technology Now Broadly Available

The INSTI® HCV Antibody Test uses the same proven and innovative technology as the existing INSTI® platform, joining the INSTI® line-up of infectious through-flow rapid tests that have been available for sale in Europe since 2015, including the HIV-1/HIV-2 Antibody Test, the HIV Self Test, the Multiplex HIV Syphilis Ab Test, and the COVID-19 Antibody Test.

About bioLytical

bioLytical Laboratories Inc. is a privately-owned Canadian company focused on the research, development and commercialization of rapid in vitro medical diagnostics using its proprietary INSTI® technology platform. bioLytical has won several local and industry awards, including B.C. Exporter of the Year in 2019. We have been named Lifesciences B.C.’s Growth Stage Med Tech Company of the Year and have been featured on B.C.’s Fastest Growing Companies four years in a row, including the Globe and Mail’s Fastest Growing Companies list in 2020. bioLytical moved to a significantly larger, state-of-the-art facility in Richmond, B.C. in 2020 to accommodate the extraordinary growth achieved through our team. Providing accurate results in one minute or less, the INSTI® range includes the INSTI HIV-1/HIV-2 Antibody Test, INSTI® Multiplex HIV Syphilis Ab Test, INSTI® HIV Self Test, INSTI® Covid-19 Antibody Test, and now the INSTI® HCV Antibody Test. bioLytical sells its products in Europe, North America, South America, Africa, and Asia.

By delivering accurate results in real-time, INSTI® generates meaningful outcomes for medical professionals, patients, and public health organizations worldwide and is a key partner in tackling some of the world's most severe healthcare challenges. Please visit www.insti.com and www.bioLytical.com for more information.

References

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