Quest Diagnostics receives US FDA nod for Simplexa Influenza A H1N1 (2009) test

I-Micronews

The Simplexa Influenza A H1N1 (2009) test runs on the 3M Integrated Cycler under an exclusive global distribution agreement between Focus Diagnostics and 3M. The test employs real-time reverse transcription (RT) polymerase chain reaction (PCR) to qualitatively detect RNA of the 2009 H1N1 flu virus (2009 H1N1) in a patient's nasal or nasopharyngeal specimens. It reports if a specimen is positive or negative for the presence of 2009 H1N1 or influenza A virus. By comparison, some flu tests, including rapid point-of-care influenza tests, can detect the presence of influenza A, but not differentiate the presence of 2009 H1N1. In addition to 2009 H1N1, influenza A viruses include some seasonal flu subtypes.

"*Thankfully, H1N1 is not currently a widespread public health problem, but reliable detection continues to be important to help manage high-risk patients, such as expectant mothers who have flu-like symptoms,*" said **Jay M Lieberman**, medical director, infectious diseases, Quest Diagnostics and Focus Diagnostics. "*Influenza viruses are unpredictable, and reliable tests will be needed, particularly if, as expected, 2009 H1N1 activity again increases later this year.*"

"*Innovation often emerges in response to crisis, and the 2009 H1N1 is no exception,*" said **John G Hurrell**, vice president and general manager, Focus Diagnostics. "*When 2009 H1N1 surfaced about a year ago, limitations in traditional flu tests made them unsuitable for dealing with a virus infecting large swaths of the population. These limitations included the sensitivity of rapid tests and the need to ship samples to reference labs with reliable PCR methods. We designed our Simplexa 2009 H1N1 test to overcome these problems by bridging highly reliable PCR with testing technologies that many hospital labs can perform in-house.*"

"*Moreover, US FDA clearance of our Simplexa test means hospital and other labs can use our test with confidence since it meets regulatory requirements long term, unlike flu tests authorized for 2009 H1N1 emergency use testing until late June,*" added **Hurrell**.

Focus Diagnostics has led the diagnostics industry in the development of new 2009 H1N1 influenza testing technologies. It was the first company to receive emergency use authorization from the US FDA for a commercial H1N1 2009 test and the first company to launch a commercial test kit for qualitatively detecting RNA of the H1N1 2009 virus by RT-PCR.

The Focus Diagnostics Simplexa Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cycler as part of the Microfluidic Molecular System for the in vitro qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and

nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.

Focus Diagnostics is an infectious disease diagnostics company, providing infectious disease reference laboratory services to hospitals and laboratories nationwide, and manufacturing and distributing diagnostic products worldwide.

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions.

SOURCE [1]

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