



## FDA Clears the Quest Diagnostics Simplexa® *C. difficile* Molecular Test

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### Test eliminates nucleic-acid sample extraction, for faster results

MADISON, N.J. and CYPRESS, Calif., April 11, 2012 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to its Simplexa *C. difficile* Universal Direct Test on the 3M™ Integrated Cycler.

The test, from the company's Focus Diagnostics business, is intended to aid in the diagnosis of *Clostridium difficile*-associated disease, one of the most common and dangerous acquired infections in healthcare settings. It uses a proprietary technique to eliminate the time consuming nucleic-acid sample extraction process required by many other molecular tests, for potentially faster results reporting for hospitals and clinical laboratories.

Simplexa tests, running on the 3M™ Integrated Cycler, employ real-time polymerase chain reaction (RT-PCR) to qualitatively detect viruses, bacteria and other analytes. The Simplexa *C. difficile* Universal Direct test is performed on liquid or unformed human stool samples and detects the toxin B gene (*tcdB*) of *C. difficile*, including NAP1. The test uses a proprietary chemistry that eliminates the need for nucleic-acid extraction. Using the Simplexa test, hospital and other labs may complete the entire testing process in about an hour.

*C. difficile*-associated disease is a common and sometimes fatal healthcare-associated infection that causes diarrhea and other intestinal problems. As many as 14,000 people die of *C. difficile*-associated disease in the United States each year, according to the U.S. Centers for Disease Control and Prevention.

"Detecting and containing *C. difficile* associated disease is one of the greatest clinical challenges in today's healthcare environment," said Jay M. Lieberman, M.D., medical director, infectious disease, for Quest Diagnostics and Focus Diagnostics. "Fast, reliable PCR tests that are highly specific and sensitive in the detection of the *tcdB* gene, a toxin-B producing gene of *C. difficile*, are essential for identifying and treating this infection as well as containing its spread."

With the FDA clearance, the Simplexa *C. difficile* Universal Direct Test on the 3M Integrated Cycler is immediately available in the United States. Focus Diagnostics launched the test in Europe during the second quarter of 2011.

#### About Simplexa®

Focus Diagnostics, a wholly-owned business of Quest Diagnostics, develops and manufactures the Simplexa line of molecular test products operating on the 3M™ Integrated Cycler, a compact, portable testing platform, as part of an exclusive global collaboration with 3M™. Simplexa was the first test kit to be FDA cleared for aiding in the detection and differentiation of the 2009 H1N1 influenza virus, in May 2010. Additional FDA-cleared Simplexa tests aid the detection of influenza A and B and respiratory syncytial virus. Several other Simplexa-branded tests, including for *Clostridium difficile*, Epstein Barr and BK viruses, are CE marked and distributed in Europe. In 2011, the Simplexa/3M technology won a gold Medical Design Excellence Award in the *in vitro* diagnostics category and an Edison Award for new science and medical diagnostic product.

To learn more about or to order Simplexa and other Focus Diagnostics tests, please contact Focus Diagnostics at 800-445-0185 (U.S.) or +49-6026-9499540 (Europe), or visit SimplexDx.com or FocusDx.com.

#### About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at [QuestDiagnostics.com](http://QuestDiagnostics.com). Follow us at Facebook.com/QuestDiagnostics and Twitter.com/QuestDX.

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#### Contacts:

Wendy Bost (Media): 973-520-2800

Kathleen Valentine (Investors): 973-520-2900

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