

FDA Clears QIAGEN's *artus C. difficile* QS-RGQ MDx Kit, developed in partnership with IMDx; IMDx and QIAGEN Continue to Expand Pipeline for QIASymphony SP/AS and Rotor-Gene Q Instruments

Waltham, MA – In April 2014, the FDA cleared the QIAGEN *artus C. difficile* QS-RGQ MDx Kit, developed and manufactured by IMDx, for use on the QIAGEN QIASymphony RGQ MDx System, for use in the United States. The *artus C. difficile* QS-RGQ MDx Kit, which is used as an aid in diagnosis of *Clostridium difficile* (*C. difficile*) infection, was CE-marked in December 2013. The QIASymphony RGQ MDx System was simultaneously cleared by the FDA, and provides an integrated automated sample preparation and assay setup for a full sample to result workflow solution.

The *artus* VanR QS-RGQ Kit, another product in the healthcare-acquired infection test menu designed, developed and manufactured by IMDx for use on the QIAGEN QIASymphony RGQ MDx System, was CE-marked in March 2014. The *artus* VanR QS-RGQ Kit is intended as an aid to identify, prevent, and control vancomycin-resistant colonization in patients at risk for vancomycin-resistant enterococci infection. A Premarket Notification 510(k) submission for the test is being submitted shortly to FDA for review.

"The global burden of HAIs is significant, with approximately 1 in 14 hospitalized patients acquiring an infection during their stay," says Dr. Alice Nesselrodt, Chairman & CEO of IMDx. "We are pleased to aid QIAGEN in offering users of the QIASymphony RGQ MDx System the *artus C. difficile* and VanR QS-RGQ Kits in order to assist in making timely, informed decisions about patient treatment to help control the spread of HAIs."

Under a multi-year development and license agreement with QIAGEN, IMDx will continue to aid in expanding the QIAGEN test menu through the design, development and manufacture of kits for use on the QIASymphony RGQ MDx System. Additional tests in the 2014 pipeline include a test for the detection of Herpes Simplex Viruses 1 and 2 in male and female genital and oral lesions and a test for the detection of Group B Streptococcus from enriched cultures taken from pregnant women.

The artus VanR, HSV-1/2, and GBS QS-RGQ Kits are not available for sale in the United States or Canada.

About IMDx

Based in Waltham, MA, IMDx () designs, develops and manufactures platform-agnostic, regulatory-cleared molecular diagnostic tests that enable partners to more rapidly and efficiently expand test menus. Beyond growing its portfolio of assays for infectious disease, IMDx is pursuing new targets in companion diagnostics, oncology and human genetics, as well as next generation instrument systems. IMDx facilities are ISO 13485:2003 certified and all products are developed and manufactured within a regulatory compliant (FDA QSR, CE-IVDD and cGMP) environment.

