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Subject: MDx Receives FDA Clearance for IMDx VanR for Abbott m2000 assay

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Attachments: IMDx_VanR_for_Abbott_m2000_FDA_clearance_.pdf

I hope you are doing well and are having a great summer. I am pleased to announce that IMDx has achieved a pivotal milestone with the receipt of FDA clearance for its Vancomycin Resistance (VanR) test for the Abbott m2000 system. This test detects vancomycin-resistance genes that can be associated with vancomycin resistant enterococci (VRE.) VRE are bacteria which have become resistant to the antibiotic vancomycin, and are responsible for a variety of healthcare-associated infections, including surgical wound, urinary tract, and bloodstream infections.

My best,
Alice

IntelligentMDx Receives FDA Clearance for IMDx VanR for Abbott m2000 assay

Cambridge, MA, July 29, 2013 – IntelligentMDx (privately held) announced today that the U.S. Food and Drug Administration (FDA) has cleared its automated molecular diagnostic test that detects the presence of *vanA* and *vanB* genes that can be associated with vancomycin-resistant enterococci (VRE). This is one of the tests in IMDx's portfolio of infectious disease products to be cleared by the FDA for use on Abbott's fully automated m2000 platform.

VRE are bacteria which have become resistant to the antibiotic vancomycin, and are responsible for a variety of healthcare-associated infections, including surgical wound, urinary tract, and bloodstream infections. The IMDx VanR for Abbott m2000 assay is intended to be used as an aid to identify, prevent and control vancomycin-resistant colonization in healthcare settings.

The automated nature of the IMDx VanR for Abbott m2000 test allows laboratories to obtain results for up to 46 patient samples in less than 3 hours, and up to 94 patient samples in less than 4 hours. The assay is performed directly on human peri-rectal swabs, rectal swabs, or stool specimens from patients at risk for VRE colonization.

"We are proud to have received FDA clearance so that IMDx can offer a diagnostic solution to aid in the identification of vancomycin-resistant colonization in hospital settings in the U.S.," says Dr. Alice Jacobs Nesselrodt, Chairman and CEO of IMDx. "FDA clearance of the IMDx VanR for Abbott m2000 assay is a step toward the fulfillment of IMDx's mission to make clinically impactful molecular diagnostic testing solutions available as broadly as possible. We look forward to continuing to expand our menu of diagnostic tests in the U.S."

The IMDx VanR for Abbott m2000 assay is part of a broad real-time PCR test menu designed, developed, and manufactured for use on Abbott's RealTime m2000 system under a multi-year distribution agreement with Abbott.

About IMDx

Based in Cambridge, MA, IMDx (www.IntelligentMDx.com) is an innovator of unique proprietary molecular tests equipped with features and benefits to port onto nearly any molecular testing system. IMDx's competitive advantage lies in its extensive bioinformatics capabilities, enabling the production of rapid, low cost high quality products with top performance characteristics to empower clinicians to provide care with greater certainty. Current and future product lines include tests for Infectious Diseases (Healthcare Associated Infections, respiratory diseases, STDs, prenatal testing), oncology and other human genetic targets. The IMDx facilities are ISO 13485:2003 certified and all of the IMDx products are developed and manufactured within a regulatory compliant (FDA QSR, CE-IVDD and cGMP) environment.

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