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**Subject:** IMDx Introduces CE-marked Assay for VanR for European Market and ROW

**Date:** Wed, 28 Sep 2011 16:45:04 +0000

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I hope that this message finds you well. I am pleased to announce that IMDx has launched its second CE-marked product in two months for commercialization and distribution in Europe and ROW by Abbott for detecting deadly health care infections, the IMDx™ VanR for Abbott m2000™ test (see below). This test detects vancomycin-resistance genes associated with vancomycin resistant enterococci (VRE.)

Enterococci are normally found in the GI/GU tracts and can cause infections of the urinary tract, blood stream, or in wounds from surgery or catheter insertions.

My best,

Alice

### **IntelligentMDx (IMDx) Introduces a CE-Marked Automated Molecular Test for the Detection of Vancomycin Resistance Genes vanA and vanB Most Commonly Found in Vancomycin-Resistant Enterococci**

**Cambridge, MA, September 21, 2011** – IntelligentMDx (IMDx) announced today that it has received CE-Mark for its second automated molecular test for the Abbott FDA cleared m2000 instrument. The IMDx™ VanR for Abbott m2000™ test accurately detects and distinguishes the vanA and vanB genes most commonly found in vancomycin-resistant enterococci (VRE) in specimens from patients at risk for colonization or infection. Detection of both the vanA and vanB genes allows for identification of a higher number of at-risk patients than existing tests that only target the vanA gene. Like the recently introduced CE-marked IMDx C. difficile for Abbott m2000 test, the IMDx VanR for Abbott m2000 test offers a high-throughput solution for early detection of pathogens associated with common healthcare-associated infections.

VRE are bacteria which have become resistant to the antibiotic vancomycin, and are responsible for a variety of healthcare-associated infections, including those of surgical wounds, urinary tract, and bloodstream. VRE are transmitted through contact and are most often seen in hospitals due to the high prevalence of contaminated surfaces and hand to hand contact.

The automated nature of the IMDx VanR for Abbott m2000 test allows laboratories to obtain results for up to 48 patient samples in less than 3 hours, and up to 94 patient samples in less than 4 hours. The IMDx VanR for Abbott m2000 test exhibits high sensitivity and specificity when compared to traditional chromogenic agar methods, with values of 96.4% and 98.0%, respectively.

"At IMDx, we have developed unique proprietary software analytic tools, enabling us to produce tests that are sensitive, cost-effective, and rapid alternatives to existing culture-based screening methods for vancomycin-resistant infections. We are proud to offer physicians the ability to make timely, informed decisions about patient care in order to aid in preventing the spread of healthcare-associated infections." says Alice Jacobs, MD, Chairman & CEO of IMDx.

#### **About IMDx**

Based in Cambridge, MA, IMDx ([REDACTED]) is an innovative company that designs, develops and manufactures molecular diagnostic products. IMDx has developed molecular solutions that are clinically impactful and competitively differentiated for a range of disease areas for current and next generation systems, including targets in infectious diseases, oncology and genetics. IMDx's expertise spans evolutionary biology, bioinformatics, microbiology, chemistry and molecular biology. These capabilities are harnessed by IMDx's proprietary bioinformatics and product

development processes allowing for the rapid design and development of tests to meet clinical needs.

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