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Subject: IMDx receives 3rd FDA clearance and relocates HQ to Waltham

Date: Tue, 12 Nov 2013 21:14:41 +0000

Attachments: IMDx_Cdiff_Press_Release_12NOV2013.pdf

I hope you are doing well and having a great fall. On the heels of a successful move into our new corporate headquarters in Waltham, MA, IMDx today announced its third FDA clearance for its *C. difficile* assay for Abbott m2000 assay.

My best,
Alice

IntelligentMDx Receives FDA Clearance for IMDx *C. difficile* for Abbott m2000 Assay, Completes Move of Corporate Headquarters to Waltham

WALTHAM, MA, November 12, 2013 -- IntelligentMDx announced today that it has received FDA clearance for the IMDx *C. difficile* for Abbott m2000 assay which detects nucleic acids encoding the toxin A gene and toxin B gene sequences of toxigenic strains of *Clostridium difficile* in human liquid or soft stool specimens collected from patients suspected of having *Clostridium difficile* associated disease. This is the third test from IMDx to receive FDA clearance within three months for use on Abbott's fully-automated m2000 system and follows clearances of the IMDx VanR for Abbott m2000 and IMDx Flu A/B and RSV for Abbott m2000 assays.

C. difficile is the leading cause of hospital-acquired diarrhea and may cause more severe intestinal conditions such as pseudomembranous colitis. According to the CDC, *C. difficile* infection is linked to approximately 14,000 deaths in the United States annually.* Effective molecular diagnostic tests for early detection of *C. difficile* remain critical to help control the spread of infection and the threat of more serious complications.

Analytical reactivity studies demonstrated that the IMDx *C. difficile* for Abbott m2000 assay is capable of detecting the 31 different toxigenic *C. difficile* strains that were tested. These strains represent the global diversity of *C. difficile* strains, including NAP1, and *tcdB*-variant strains, such as 1470.

"FDA clearance of the IMDx *C. difficile* for Abbott m2000 assay comes at a pivotal time when incidence of *C. difficile* infection and severity in both hospital and community settings is increasing," says Dr. Alice Jacobs Nesselrodt, Chairman & CEO of IMDx. "Detection of a wide variety of *C. difficile* strains, including hypervirulent strains, by the IMDx *C. difficile* for Abbott m2000 assay will help ensure that a high number of cases of *C. difficile* are detected in a timely manner, regardless of the source of infection."

The IMDx *C. difficile* 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.

IMDx also recently completed the move of its corporate headquarters, manufacturing and R&D operations to its new facility in Waltham, Massachusetts. The design-built facility features BL-2 laboratory space and GMP manufacturing in compliance with FDA and ISO 13485 standards.

*MMWR Weekly Report "Vital Signs: Preventing *Clostridium difficile* Infections" March 9, 2012 / 61(09); 157-162

About IMDx

Based in Waltham, MA, IMDx (www.IntelligentMDx.com) 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.

Alice Jacobs Nesselrodt, M.D.
Chairman & CEO

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WE'VE MOVED – Effective October 10, 2013, please send all correspondence and/or shipments to our new Corporate Headquarters located at : **285 Bear Hill Road, Waltham, MA 02451.**

Please note our telephone, fax numbers and email addresses will all remain the same.

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