From: Jeffrey Epstein <jeevacation@gmail.com>
To: Elizabeth Holland <[redacted]>
Cc: Alice Jacobs <[redacted]>
Subject: Re: IntelligentMDx (IMDx) Receives FDA Emergency Use Authorization (EUA) for First 2009 H1N1 Influenza Assay to be Authorized for Use on Multiple Instruments in Commercial Laboratories
Date: Wed, 24 Mar 2010 14:20:08 +0000

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it still says only good until april 2010,, i dont understand

On Wed, Mar 24, 2010 at 9:50 AM, Elizabeth Holland <[redacted]> wrote:

> **Corrected Date**
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> **IntelligentMDx (IMDx) Receives FDA Emergency Use Authorization (EUA) for First 2009 H1N1 Influenza Assay to be Authorized for Use on Multiple Instruments in Commercial Laboratories**
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> CAMBRIDGE, Mass., March 24/PRNewswire/ -- IMDx announced today that its IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay has been granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). The test, which is authorized for use on multiple instrument platforms (the Applied Biosystems 7500, the 7500 FAST Real-Time PCR Systems, and the 7500 Fast Dx Real-Time PCR Instrument) by CLIA High Complexity Laboratories to detect and differentiate 2009 Influenza A H1N1, uses a single test format and produces results in ninety minutes. "By receiving authorization for use on multiple instrument platforms, IMDx is able to provide a rapid assay solution that is flexible and adaptable to the wider needs of molecular diagnostics laboratory customers," said Alice Jacobs, M.D., IMDx, Chairman & CEO.
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> **About the FDA's Emergency Use Authorization**
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> The US Secretary of Health and Human Services has declared a public health emergency because of the outbreak of the pandemic flu virus. The FDA has issued emergency use authorizations to make important diagnostic and therapeutic tools available to public health and medical personnel in order to identify and respond to the 2009 H1N1 influenza virus under certain circumstances.
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> The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. The emergency use authorization authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products following a determination and declaration of emergency, provided certain criteria are met. The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay is authorized only for the duration of the emergency, unless the authorization is revoked sooner. The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.
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> **About IntelligentMDx (IMDx)**
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> IMDx utilizes a proprietary bioinformatics process to design molecular diagnostic assays. This process affords shorter design times, and results in more robust assays. IMDx is committed to development of new generations of influenza diagnostics. Influenza assays under development are multiplexed tests for the detection and differentiation of relevant Influenza A subtypes, Influenza B, and for detection of antiviral resistance mutations.

IMDx's mission is to commercialize test solutions under FDA quality system regulations for use in clinical reference laboratories. To guarantee quality for customers and partners, all IMDx assay solutions are designed, developed and manufactured to be compliant with FDA, ISO 13485 and IVDD regulations and guidances. IMDx tests are designed to be clinically impactful, competitively differentiated, and platform-agnostic test solutions.

Media Contact:

For more information on IntelligentMDx, visit www.intelligentmdx.com or contact Corporate Communications at cc@IntelligentMDx.com; 617-871-6400.

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