Dated: June 15, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0277]

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of seven Emergency Use Authorizations (EUAs) (the Authorizations), two of which were amended after initial issuance, for certain in vitro diagnostic devices. FDA is issuing the Authorizations and amendments thereto under the Federal Food, Drug, and Cosmetic Act (the act). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow the determination by the then Acting Secretary of the U.S. Department of Health and Human Services Charles E. Johnson (the Acting Secretary) that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorizations, which include explanations of the reasons for their issuance or reissuance, are reprinted in this document.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for effective dates of the Authorizations.

ADDRESSES: Submit written requests for single copies of the Emergency Use Authorization(s) to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4140, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4140, Silver Spring, MD 20993, 301–796–8510.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. § 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds:

(1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) A determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) A determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e, respectively) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and the Center for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency), FDA[1] concludes:

(1) that an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that:

(A) the product may be effective in diagnosing, treating, or preventing—

(1) such disease or condition; or

(2) a serious or life-threatening disease or condition caused by a product authorized under section 564 of the act, approved or cleared under the act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and

[1] The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, FDA published guidance in July 2007 entitled "Emergency Use Authorization of Medical Products" to provide more information for stakeholders and the public about the EUA authority and the agency's process for the consideration of EUA requests.

II. EUA Request for Certain In Vitro Diagnostic Products

On April 26, 2009, under section 564(b)(1)(C) of the act (21 U.S.C. 360bbb-3(b)(1)(C)), the Acting Secretary determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. The determination has been renewed. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of certain in vitro diagnostics for detection of Swine Influenza A (2009 H1N1 flu), accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). Notice of the determination and the declaration of the Acting Secretary was published in the **Federal Register** on August 4, 2009 (74 FR 38628).

(1) On January 21, 2010, in response to a request from ViraCor Laboratories, FDA issued an EUA for the ViraCor 2009 H1N1 Influenza A Real-time RT–PCR test with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(2) On November 13, 2009, in response to a request from Epoch BioSciences, FDA issued an EUA for the ELITech Molecular Diagnostics 2009–H1N1 Influenza A virus Real-Time RT–PCR test for distribution to Associated Regional and University Pathologists (ARUP) Laboratories, with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. On April 19, 2010, notice of the initial Authorization was published in the **Federal Register** (75 FR 20441). On February 1, 2010, in response to a request from Epoch BioSciences, FDA amended the Authorization letter to authorize use of additional upper respiratory tract samples and lower respiratory tract specimens, and for other reasons, and reissued the Authorization letter in its entirety. The Authorization letter, as amended and reissued on February 1, 2009, which includes an explanation for its reissuance, is reprinted in this document. The original August 2009 Authorization letter is not reprinted in this document.

(3) On February 16, 2010, in response to a request from Longhorn Vaccines and Diagnostics, FDA issued an EUA for the Longhorn Influenza A/H1N1–09 Prime RRT–PCR Assay with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. On March 23, 2010, in response to a request from Longhorn Vaccines and Diagnostics, FDA amended the Authorization letter to authorize use of additional upper respiratory tract samples and for other reasons, and reissued the Authorization letter in its entirety. The Authorization letter, as amended and reissued on March 23, 2010, which includes an explanation for its original issuance and its reissuance, is reprinted in this document. The original February 16, 2010 Authorization letter is not reprinted in this document.

(4) On February 16, 2010, in response to a request from Diagnostic Hybrids, Inc., FDA issued an EUA for the Diagnostic Hybrids, Inc. D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(5) On March 11, 2010, in response to a request from Qiagen, FDA issued an EUA for the *artus*® Inf. A H1N1 2009 LC RT–PCR Kit with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(6) On March 22, 2010, in response to a request from IntelligentMDX, FDA issued an EUA for the IMDx 2009 Influenza A H1N1 Real-Time RT–PCR Assay with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(7) On May 4, 2010, in response to a request from IQuum, Inc., FDA issued an EUA for the Liat Influenza A/2009 H1N1 Assay with certain written information, including fact sheets for healthcare providers and patients, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov*.

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations, one as amended, under section 564(c) of the act are met, FDA has authorized the emergency use of certain in vitro diagnostic devices.

(1) The Authorization for ViraCor 2009 H1N1 Influenza A Real-time RT–PCR test issued on January 21, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Renée Forsberg, ASQ CQA
Director, Regulatory Affairs and Quality Assurance
ViraCor Laboratories
1001 NW Technology Drive
Lee's Summit, MO 64086

Dear Ms. Forsberg:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test by ViraCor Laboratories for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). ViraCor Laboratories is certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests (a CLIA High Complexity Laboratory).

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to ViraCor Laboratories' use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test:

The ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)), and lower respiratory tract specimens (such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue) from patients with signs and symptoms of respiratory infection. The testing procedure consists of nucleic acid extraction on the NucliSENS® easyMAG® system (bioMérieux, Inc.) followed by rRT-PCR on the Applied Biosystems 7500 Real-Time PCR System.

The ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test includes the following primer and probe sets:
- **INFA:** detects a conserved region of the matrix (M) gene that is present in both seasonal and 2009 H1N1 influenza A viruses.
- **2009 H1N1**: detects a region of the hemagglutinin (H) gene found in the 2009 H1N1 influenza virus. This primer/probe set may react with other swine origin influenza A strains.
- **IC (Internal Control)**: detects an RNA sequence in whole bacteriophage MS2 that is noncompetitive with the INFA and 2009 H1N1 2009 targets.

The ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test also includes the following control materials:
- **Bacteriophage MS2 Internal Control (IC)** is added to every patient sample and is carried through all steps of the procedure from nucleic acid isolation and purification through amplification to ensure that effective nucleic acid extraction is achieved and to monitor for inhibition of rRT-PCR.
- **Negative Control** consists of a known negative sample and is taken through both nucleic acid extraction and rRT-PCR processes to demonstrate that all extraction and amplification reagents are free of target RNA and amplicons and to ensure that detection of target genes is not due to false positive results.
- **Positive Controls** consist of separate in vitro transcribed RNAs containing targets recognized by the INFA and 2009 H1N1 detection systems and are included in each rRT-PCR run to demonstrate that these detection systems are operating at the required level of sensitivity.

The ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test requires the following hardware with corresponding software:
- Applied Biosystems 7500 Real-Time PCR System with ABI Software: SDS software version 1.4.
- bioMérieux NucliSENS® easyMAG® extraction system with software version 2.0

The ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test requires the use of the following additional reagents/materials:
- SuperScript™ III Platinum® One-Step qRT-PCR kit (Invitrogen Cat. No. 11732-088)
- Extraction Reagents for NucliSENS® easyMAG® system (bioMérieux Cat. Nos. 280130, 280131, 280132, 280133, 280134).

The above described ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test, when labeled consistently with the labeling authorized by FDA, entitled ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Package Insert (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be used by ViraCor Laboratories,[3] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpreting ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Test Results
- Fact Sheet for Patients: Understanding ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Test Results

As described in section IV below, ViraCor Laboratories is also authorized to make available additional information relating to the emergency use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ViraCor Laboratories

A. ViraCor Laboratories, Inc., will not sell or distribute the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test to other laboratories.

B. ViraCor Laboratories will include with reports of the results of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Healthcare Providers and the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Patients.

C. ViraCor Laboratories will make available on its Web site the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Healthcare Providers and the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Patients.

D. ViraCor Laboratories will clearly and conspicuously state on reports of the results of the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other virus or pathogen.

E. ViraCor Laboratories will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

G. All advertising and promotional descriptive printed matter relating to the use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

H. No advertising or promotional descriptive printed matter relating to the use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

I. ViraCor Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

J. ViraCor Laboratories will track adverse events and report to FDA as required under 21 CFR part 803.

K. Through a process of inventory control, ViraCor Laboratories will maintain records of device usage.

L. ViraCor Laboratories will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which ViraCor Laboratories becomes aware.

M. ViraCor Laboratories is authorized to make available additional information relating to the emergency use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only ViraCor Laboratories may request changes to the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Healthcare Providers or the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. ViraCor Laboratories will perform the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test on the bioMérieux NucliSENS® easyMAG® extraction system with software version 2.0 and Applied Biosystems 7500 Real-Time PCR System with SDS software version 1.4.

P. ViraCor Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[3] This EUA does not authorize the ViraCor 2009 H1N1 Influenza A Real-time RT-PCR test to be sold or distributed to or used by other laboratories.

(2) The Authorization for the ELITech Molecular Diagnostics 2009–H1N1 Influenza A virus Real-Time RT–PCR test issued on November 13, 2009, as amended and reissued in its entirety on February 1, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Dr. Walt Mahoney
VP R&D and Operations
Managing Director
Epoch BioSciences
21720 23rd Drive S.E. Suite 150
Bothell, WA 98021

Dear Dr. Mahoney:

On November 13, 2009 FDA issued a letter authorizing the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests (CLIA High Complexity Laboratories). On December 22, 2009, Epoch Biosciences submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test is being reissued in its entirety with the amendments incorporated.[1]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[2] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test:

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test is a real-time reverse-transcription PCR for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)), and lower respiratory tract specimens (such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue) from patients with signs and symptoms of respiratory infection. Amplification and detection are accomplished using PCR primers and Pleiades hybridization probes manufactured by Epoch BioSciences, a Division of Wescor, Inc. The testing procedure consists of nucleic acid extraction on the Qiagen BioRobot 9604 instrument followed by real-time reverse-transcription PCR on the Applied Biosystems 7900HT Real-Time PCR System.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test includes the following primer and probe sets:

- **2009H1:** detects the presence of the hemagglutinin (HA) gene specifically found in the 2009 H1N1 influenza A virus.
- **M1:** detects a conserved region of the Matrix Protein 1 (M1) gene that is present in seasonal and 2009-H1N1 influenza A viruses.
- **Bacteriophage MS2 Internal Control:** detects RNA sequence in whole bacteriophage MS2 that is noncompetitive with the 2009-H1N1 and M1 targets.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test also includes the following control materials:

- **Bacteriophage MS2 Internal Control (IC)** is added to every patient sample and is carried through all steps of the procedure from nucleic acid isolation and purification through amplification to monitor for inhibitors present in the specimen or reaction tube. The IC also serves as a general process control ensuring that each step of the procedure was performed correctly, assay and instrument parameters were set correctly, and that general reagents were working.

- **Negative Control** consists of IC diluted with water and is taken through both nucleic acid extraction and PCR processes to demonstrate that no carryover contamination has occurred during the test process (rule out false positives caused by contamination). The Negative Control is incorporated into each batch of patient specimen processing.

- **Positive Controls** consist of separate RNA templates containing targets recognized by the 2009H1 and M1 detection systems. Each Positive Control is taken through both nucleic acid extraction and PCR processes to demonstrate that nucleic acid extraction and PCR are effective (rule out false negatives caused by test failure). The Positive Controls are incorporated into each batch of patient specimen processing.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test requires the following hardware with corresponding software:

- Applied Biosystems 7900HT Real-Time PCR System with ABI Software: SDS 7900HT, v2.2.2 or v2.3.

- Qiagen BioRobot 9604 with QIAsoft 3.0 PLUS software.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test requires the use of the following additional reagents/materials:

- Qiagen QuantiTect Probe RT-PCR Master mix (Qiagen Cat. No 204443)

- Consumables for Qiagen BioRobot 9604

- QIAamp Virus BioRobot 9604 Kit (Qiagen Cat. No 965662)

- RNase Inhibitor (Applied Biosystems Cat. No N8080119)

- Heat-labile Uracil N-Glycosylase (Roche Cat No 11775367001)

- MasterAmp 10X PCR Enhancer (Epicentre Cat No ME81210)

The above described ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when labeled consistently with the labeling authorized by FDA, entitled ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Package Insert (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by ARUP Laboratories,[4] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpretation of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test Results

- Fact Sheet for Patients: Understanding the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test Results

As described in section IV below, Epoch Biosciences, is also authorized to make available additional information relating to the emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Epoch Biosciences

A. Epoch Biosciences will distribute the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test with the authorized labeling, as may be revised with written permission of FDA, only to ARUP Laboratories.

B. Epoch Biosciences will provide to ARUP Laboratories the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Patients.

C. Epoch Biosciences will make available on its website the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Patients.

D. Epoch Biosciences will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. Epoch Biosciences will ensure ARUP Laboratories has a process in place for reporting test results to health care providers and federal, state, and/or local public health authorities, as appropriate.

F. Epoch Biosciences will track adverse events and report to FDA as required under 21 CFR part 803.

G. Through a process of inventory control, Epoch Biosciences will maintain records of device usage.

H. Epoch Biosciences will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Epoch Biosciences becomes aware.

I. Epoch Biosciences is authorized to make available additional information relating to the emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only Epoch Biosciences may request changes to the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Healthcare Providers or the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

ARUP Laboratories

K. ARUP Laboratories will include with reports of the results of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

L. ARUP Laboratories will clearly and conspicuously state on reports of the results of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, respiratory syncytial virus (RSV) or any other pathogen.

M. ARUP Laboratories will use the Qiagen BioRobot 9604 for nucleic acid extraction and perform the assay on the Applied Biosystems 7900HT Real-time PCR instrument.

N. ARUP Laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

O. ARUP Laboratories will collect information on the performance of the assay, and report to Epoch Biosciences any suspected occurrence of false positive or false negative results of which ARUP Laboratories becomes aware.

Epoch Biosciences and ARUP Laboratories

P. Epoch Biosciences and ARUP Laboratories will make available on their Web sites the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

Q. Epoch Biosciences and ARUP Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

R. All advertising and promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

S. All advertising and promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

T. No advertising or promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

The emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] The amendments to the October 16, 2009 letter authorize use of a) additional upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and lower respiratory tract specimens, such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue and b) ABI Software SDS 7900HT v2.3 on the Applied Biosystems 7900HT real-Time PCR System. There are also minor wording changes made to be consistent with more recently issued Emergency Use Authorizations for in vitro diagnostic devices.
[2] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[4] This EUA does not authorize the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test to be sold or distributed to or used by other laboratories.

(3) The Authorization for the Longhorn Influenza A/H1N1–09 Prime RRT–PCR Assay issued on February 16, 2010, as amended and reissued in its entirety on March 23, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Gerald W. Fischer, M.D.
Executive Director and Chief Medical Officer
Longhorn Vaccines and Diagnostics
3 Bethesda Metro Center, Suite 375
Bethesda, MD 20814

Dear Dr. Fischer:

On February 16, 2010 FDA issued a letter authorizing the emergency use of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay™ for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests (CLIA High Complexity Laboratories). On February 26, 2010, Longhorn Vaccines and Diagnostics submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay is being reissued in its entirety with the amendments incorporated.[1]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[2] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets in conjunction with clinical and epidemiological risk factors the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection[3].

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay:

The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay is a real-time reverse transcriptase PCR (RRT-PCR) for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS) from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The testing procedure consists of nucleic acid extraction on the RNAqueous system (Ambion, Inc.) or QIAamp Viral RNA Minikit (Qiagen) followed by RRT-PCR on the Applied Biosystems 7500 Real-Time PCR System.

The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay includes the following primer and probe sets:
- **FluA:** detects a conserved region of the matrix (M) gene that is present in pan A, seasonal and 2009 H1N1 influenza A viruses.
- **H1-09:** detects a region of the hemagglutinin (HA) gene found in the 2009 H1N1 influenza virus.
- **IPC (Internal Positive Control):** detects a nonsense RNA sequence contained in the PrimeStore reagent.

The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay also includes the following control materials:
- **Internal Positive Control (IPC)** is contained in the PrimeStore reagent that is added to every patient sample before beginning nucleic acid isolation and purification, and is present through amplification to ensure that effective nucleic acid preservation and recovery is achieved and to monitor for inhibition of RRT-PCR.
- **Negative Control** consists of PrimeStore reagent and is taken through both nucleic acid extraction and RRT-PCR processes to demonstrate that all extraction and amplification reagents are free of target RNA and amplicons and to ensure that detection of target genes is not due to false positive results.
- **Positive Controls** consist of separate RNA templates containing targets recognized by the FluA and H1-09 detection systems and are included in each RRT-PCR run to demonstrate that these detection systems are operating at the required level of sensitivity.

The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay requires the following hardware with corresponding software:
- Applied Biosystems 7500 Real-Time PCR System with SDS v1.4 software

The Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay requires the use of the following additional reagents/materials:

- Nucleic acid isolation kit, RNAqueous® Micro Kit or QIAamp Viral RNA Minikit

The above described Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay, when labeled consistently with the labeling authorized by FDA, entitled Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Package Insert (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories, under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Results**
- **Fact Sheet for Patients: Understanding Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Results**

As described in section IV below, Longhorn Vaccines and Diagnostics is also authorized to make available additional information relating to the emergency use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Longhorn Vaccines and Diagnostics

A. Longhorn Vaccines and Diagnostics will distribute the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Longhorn Vaccines and Diagnostics will provide to the CLIA High Complexity Laboratories the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Healthcare Providers and the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Patients.

C. Longhorn Vaccines and Diagnostics will make available on its website the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Healthcare Providers and the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Patients.

D. Longhorn Vaccines and Diagnostics will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- FDA has not determined that this test may be performed in settings with certificates of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the diagnosis of 2009 H1N1 influenza virus and not for the diagnosis of any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is revoked sooner; and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. Longhorn Vaccines and Diagnostics will ensure that CLIA High Complexity Laboratories using the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Longhorn Vaccines and Diagnostics will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Longhorn Vaccines and Diagnostics will maintain records of device usage.

K. Longhorn Vaccines and Diagnostics will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which Longhorn Vaccines and Diagnostics becomes aware.

L. Longhorn Vaccines and Diagnostics is authorized to make available additional information relating to the emergency use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only Longhorn Vaccines and Diagnostics may request changes to the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Healthcare Providers or the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity Laboratories

N. CLIA High Complexity Laboratories will include with reports of the results of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA High Complexity Laboratories will perform the assay on the Applied Biosystems 7500 Real-Time PCR System with SDS v1.4 software

P. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Longhorn Vaccines and Diagnostics any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

R. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

Longhorn Vaccines and Diagnostics and CLIA High Complexity Laboratories

S. Longhorn Vaccines and Diagnostics and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Longhorn Influenza A/H1N1-09 Prime RRT-PCR Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] The amendments to the February 16, 2010 letter authorize use of additional upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and use of QIAamp viral RNA minikit for extraction.
[2] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(4) The Authorization for the Diagnostic Hybrids, Inc. D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit issued on February 16, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Ronald H. Lollar
Senior Director Product Realization
Management and Marketing
Diagnostic Hybrids, Inc.
1055 East State Street
Suite 100
Athens, OH 45701

Dear Mr. Lollar:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Diagnostic Hybrids, Inc. D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit for the detection of 2009 H1N1 influenza A viral antigens present in infected cells directly from nasal and nasopharyngeal swabs and aspirates/washes specimens or cell culture from individuals with signs and symptoms of respiratory infection who have previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by CLIA high complexity laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Diagnostic Hybrids D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit (as described in the scope section of this letter (Section II)) for the detection of 2009 H1N1 influenza A viral antigens present in infected cells directly from nasal and nasopharyngeal swabs and aspirates/washes specimens or cell culture from individuals with signs and symptoms of respiratory infection who have previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Diagnostic Hybrids D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit for the detection of 2009 H1N1 influenza A viral antigens present in infected cells directly from nasal and nasopharyngeal swabs and aspirates/washes specimens or cell culture from individuals with signs and symptoms of respiratory infection who have previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Diagnostic Hybrids D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Diagnostic Hybrids D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Diagnostic Hybrids D[3] Ultra 2009 H1N1 Influenza A Virus ID Kit for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit for detection of 2009 H1N1 influenza A viral antigens present in infected cells directly from nasal and nasopharyngeal swabs and aspirates/washes specimens or cell culture from individuals with signs and symptoms of respiratory infection who have previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device

The Authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit:

The Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit uses a blend of 2009 H1 influenza antigen-specific murine monoclonal antibodies that when combined with a fluorescein-labeled conjugate is intended for the detection of 2009 H1N1 Influenza A Virus antigens present in infected cells directly from nasal and nasopharyngeal swabs and aspirates/washes specimens or cell culture from individuals with signs and symptoms of respiratory infection who have previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device.

Components of the Test:

The Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit includes the following components:

- D^3 Ultra 2009 Flu-A ID Reagent, 5.0-mL. One dropper bottle containing a mixture of murine monoclonal antibodies directed against 2009 H1 influenza A virus antigen. The buffered, stabilized, aqueous solution contains 0.1% sodium azide as preservative.
- D^3 Flu-A ID Conjugate, 5.0-mL. An aqueous, stabilized, buffered solution containing fluorescein-labeled, affinity purified goat-anti-mouse IgG antibody and Evans Blue with sodium azide as preservative.
- 40X PBS Concentrate, 25-mL. One bottle of 40X PBS concentrate containing 4% sodium azide (0.1% sodium azide after dilution to 1X using de-mineralized water).
- Mounting Fluid, 7-mL. One dropper bottle containing an aqueous, buffer-stabilized solution of glycerol with 0.1% sodium azide.

The Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit also includes the following control materials:

- D^3 Ultra 2009 H1N1 Influenza A Virus ID Antigen Control Slides, 5-slides. Five (5) individually packaged control slides containing 2 wells with cell culture-derived positive and negative control cells.
- The positive well contains cells infected with 2009 H1N1 influenza A virus.
- The negative wells contain non-infected cells. Each slide is intended to be stained only one time.

The above described Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit, when labeled consistently with the labeling authorized by FDA, entitled D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Package Insert, (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting the D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Test Results
- Fact Sheet For Patients: Understanding the D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Test Results

As described in section IV below, Diagnostic Hybrids, Inc. is also authorized to make available additional information relating to the emergency use of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection who previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Diagnostic Hybrids, Inc.

A. Diagnostic Hybrids, Inc. will distribute the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Diagnostic Hybrids, Inc. will provide to the CLIA High Complexity Laboratories the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Fact Sheet for Healthcare Providers and the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Fact Sheet for Patients.

C. Diagnostic Hybrids, Inc. will make available on its website the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Fact Sheet for Healthcare Providers and the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit Fact Sheet for Patients.

D. Diagnostic Hybrids, Inc. will clearly and conspicuously state on reports of the results of the D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other virus or pathogen

E. Diagnostic Hybrids, Inc. will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

G. All advertising and promotional descriptive printed matter relating to the use of the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.

H. No advertising or promotional descriptive printed matter relating to the use of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

I. Diagnostic Hybrids, Inc. will ensure that CLIA High Complexity Laboratories using the authorized D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

J. Diagnostic Hybrids, Inc. will track adverse events and report to FDA as required under 21 CFR part 803.

K. Through a process of inventory control, Diagnostic Hybrids, Inc. will maintain records of device usage.

L. Diagnostic Hybrids, Inc. will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which Diagnostic Hybrids, Inc. becomes aware.

M. Diagnostic Hybrids, Inc. is authorized to make available additional information relating to the emergency use of the authorized D^3 H1N1 Influenza A Virus ID Kit that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only Diagnostic Hybrids, Inc. may request changes to the authorized D^3 2009 H1N1 Influenza A Virus ID Kit Fact Sheet for Healthcare Providers or the authorized D^3 2009 H1N1 Influenza A Virus ID Kit for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. Diagnostic Hybrids, Inc. will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

CLIA High Complexity Laboratories

P. CLIA High Complexity Laboratories will test a patient sample using the Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit only when the patient sample has already tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence antibody influenza A device.

Q. CLIA High Complexity Laboratories will include with reports of the results of the Diagnostic Hybrids D^3 2009 H1N1 Influenza A Virus ID Kit the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

R. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

S. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Diagnostic Hybrids, Inc. any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

T. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Diagnostic Hybrids D^3 2009 H1N1 Influenza A Virus ID Kit that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

U. Diagnostic Hybrids, Inc. and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Diagnostic Hybrids D^3 Ultra 2009 H1N1 Influenza A Virus ID Kit as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Dr. Margaret A. Hamburg,
Commissioner of Food and Drugs Administration

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(5) The Authorization for the *artus* Inf. A H1N1 2009 LC RT–PCR Kit issued on March 11, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Kim Davis
Manager - Regulatory and Clinical Sciences North America
QIAGEN
1201 Clopper Road
Gaithersburg, MD 20878

Dear Ms. Davis:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the *artus* Inf. A H1N1 2009 LC RT-PCR Kit (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the *artus* Inf. A H1N1 2009 LC RT-PCR Kit for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the *artus* Inf. A H1N1 2009 LC RT-PCR Kit may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the *artus* Inf. A H1N1 2009 LC RT-PCR Kit, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the *artus* Inf. A H1N1 2009 LC RT-PCR Kit for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized *artus* Inf. A H1N1 2009 LC RT-PCR Kit for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized *artus* Inf. A H1N1 2009 LC RT-PCR Kit Test:

The *artus* Inf. A H1N1 2009 LC RT-PCR Kit test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the *in vitro* qualitative detection and differentiation of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS) from patients with signs and symptoms of respiratory infection. The *artus* Inf. A H1N1 2009 LC RT-PCR Kit is to be used in combination with the LightCycler® 2.0 Real Time PCR system and the EZ1 DSP Virus System. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step reverse transcription and PCR amplification using fluorogenic probes for detection.

The *artus* Inf. A H1N1 2009 LC RT-PCR Kit includes the following primer and probe sets:

- **H1F and H1C:** two primer-probe sets designed to detect the presence of two regions of the hemagglutinin (HA) gene specifically found in the 2009 H1N1 influenza virus. Probes specific to each amplicon are labeled with the same fluorophore for the direct detection in fluorescence channel 530.
- **InfA:** a one-primer pair-three-probes set designed to detect the presence of a well conserved region of the matrix (M) gene found in influenza A virus. The inclusion of three probes provides increased assurance that the assay will still detect influenza A in the event of a mutation occurring in the targeted region. Detection of InfA also occurs through fluorescence channel 530.
- **Internal Control (IC):** a primer-probe set designed to detect an artificial sequence with no homologies to influenza sequences. The IC serves as extraction control and is detected in fluorescence channel 610.

The *artus* Inf. A H1N1 2009 LC RT-PCR Kit also includes the following control materials:

- **Influenza A Matrix Positive Control** and **2009 H1N1 Positive Control.**

A Positive Control for the influenza A matrix gene is included in the Influenza A Master and a positive control for the 2009 H1N1 HA gene is included in the Influenza H1N1 Master to ensure that the assay reagents and instruments are functioning as intended for the detection of influenza A virus and 2009 H1N1 influenza virus. Both controls must generate a positive response in order for the run to be considered valid.
- **Negative (no template) Control.**
  A Negative Control ("no template") is needed to control for sample-to-sample carryover or contamination of reagents with target sequences. Nuclease-free PCR grade water is provided with the *artus* kit as a negative (no-template) control.

The *artus* Inf. A H1N1 2009 LC RT-PCR Kit requires the following hardware with corresponding software:

- **EZ1 Advanced Instrument** (QIAGEN, cat. no. 9001410) with the EZ1 DSP Virus Card v. 2.0 (QIAGEN, cat. no. 9018306).
- **LightCycler® 2.0** instrument with software v. 4.1 (Roche Diagnostics).

The *artus* Inf. A H1N1 2009 LC RT-PCR Kit requires the use of the following additional reagents/materials:

- **EZ1 DSP Virus Kit** (QIAGEN, cat. no. 62724).
- **LightCycler® Multicolor Demo Set** (Roche Applied Science, cat. no. 03 624 854 001).
- **LightCycler® Capillaries**, 20 µl (Roche Applied Science, cat. no. 04 929 292 001).
- **LightCycler® Cooling Block** and centrifuge adaptors (Roche Applied Science, cat. no. 11 909 312 001).
- **LightCycler® Capping Tool** (Roche Applied Science, cat. no. 03 357 317 001)

The above described *artus* Inf. A H1N1 2009 LC RT-PCR Kit, when labeled consistently with the labeling authorized by FDA, entitled *artus*® Inf. A H1N1 2009 LC RT PCR Kit Protocol, (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described *artus* Inf. A H1N1 2009 LC RT-PCR Kit is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Test Results**

- **Fact Sheet for Patients: Understanding the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Test Results**

As described in section IV below, QIAGEN is also authorized to make available additional information relating to the emergency use of the authorized *artus* Inf. A H1N1 2009 LC RT-PCR Kit that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the *artus* Inf. A H1N1 2009 LC RT-PCR Kit.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

QIAGEN

A. QIAGEN will distribute the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. QIAGEN will provide to the CLIA High Complexity Laboratories the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Healthcare Providers and the authorized *artus* Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Patients.

C. QIAGEN will make available on its website the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Healthcare Providers and the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Patients.

D. QIAGEN will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- FDA has not determined that this test may be performed in settings with certificates of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the diagnosis of 2009 H1N1 influenza virus and not for diagnosis of any other viruses or pathogens;

- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is revoked sooner, and

- The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. QIAGEN will ensure that CLIA High Complexity Laboratories using the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. QIAGEN will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, QIAGEN will maintain records of device usage.

K. QIAGEN will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which QIAGEN becomes aware.

L. QIAGEN is authorized to make available additional information relating to the emergency use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only QIAGEN may request changes to the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Healthcare Providers or the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity Laboratories

N. CLIA High Complexity Laboratories will include with reports of the results of the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA High Complexity Laboratories will use the QIAGEN EZ1 Advanced Instrument for nucleic acid extraction and perform the assay on the LightCycler® 2.0 Real Time PCR system.

P. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to QIAGEN any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

R. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the *artus*® Inf. A H1N1 2009 LC RT-PCR Kit that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other virus or pathogen.

QIAGEN and CLIA High Complexity Laboratories

S. QIAGEN and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized *artus*® Inf. A H1N1 2009 LC RT-PCR Kit as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(6) The Authorization for the IMDx 2009 Influenza A H1N1 Real-Time RT–PCR Assay issued on March 22, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Dr. Phillip T. Moen, Jr.
Director, Product Development
IntelligentMDx
19 Blackstone Street
Cambridge, MA 02139

Dear Dr. Moen:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay:

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection and differentiation of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)) from patients with signs and symptoms of respiratory infection. The testing procedure consists of nucleic acid extraction with the Qiagen QIAamp Viral RNA Mini Kit followed by rRT-PCR on the Applied Biosystems 7500 Real-Time PCR System, 7500 Fast Real-Time PCR System, or the 7500 Fast Dx Real-Time PCR Instrument.

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay includes the following primer and probe sets:
- **INF A:** detects a conserved region of the matrix (M) gene that is present in both seasonal and 2009 H1N1 influenza A viruses.
- **2009 H1N1:** detects a region of the hemagglutinin (HA) gene found in the 2009 H1N1 influenza virus.
- **Extraction/Process Control:** detects an RNA sequence in whole bacteriophage MS2 that is noncompetitive with the INFA and 2009 H1N1 2009 targets.

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay also includes the following control materials:
- **Bacteriophage MS2 Extraction/Process Control** is added to every patient sample and is carried through all steps of the procedure from nucleic acid isolation and purification through amplification to ensure that effective nucleic acid extraction is achieved and to monitor for inhibition of RT-PCR.
- **Negative Control** consists of viral transport media containing MS2 bacteriophage and is taken through both nucleic acid extraction and RT-PCR processes to demonstrate that all extraction and amplification reagents are free of target influenza RNA and amplicons and to ensure that detection of target genes is not due to false positive results.
- **No Template Control** consists of nuclease free water and is included in each RT-PCR run to demonstrate that amplification reagents are free of target influenza and MS2 RNA and amplicons.
- **Positive Controls** consist of separate in vitro transcribed RNAs containing targets recognized by the INF A and 2009 H1N1 detection systems and are included in each RT-PCR run to demonstrate that these detection systems are operating at the required level of sensitivity.

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay requires the following Applied Biosystems hardware with corresponding software:
- 7500 Real-Time PCR System (SDS v1.4 Software or 7500 Software v2.01), or

- 7500 Fast Real-Time PCR System (SDS v1.4 Software or 7500 Software v2.01), or
- 7500 Fast Dx Real-Time PCR Instrument (SDS v1.4 Software)

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay requires the use of the following additional reagents/materials:
- Qiagen QIAamp Viral RNA Mini Kit

The above described IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay, when labeled consistently with the labeling authorized by FDA, entitled IntelligentMDx IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Package Insert (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Results**

- **Fact Sheet for Patients: Understanding IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Results**

As described in section IV below, IntelligentMDX is also authorized to make available additional information relating to the emergency use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

IntelligentMDx

A. IntelligentMDx will distribute the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. IntelligentMDx will provide to the CLIA High Complexity Laboratories the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Healthcare Providers and the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Patients.

C. IntelligentMDx will make available on its website the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Healthcare Providers and the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Patients.

D. IntelligentMDx will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- FDA has not determined that this test may be performed in settings with certificates of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the diagnosis of 2009 H1N1 influenza virus and not for the diagnosis of any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is revoked sooner; and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.

G.No advertising or promotional descriptive printed matter relating to the use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. IntelligentMDx will ensure that CLIA High Complexity Laboratories using the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. IntelligentMDx will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, IntelligentMDx will maintain records of device usage.

K. IntelligentMDx will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which IntelligentMDx becomes aware.

L. IntelligentMDx is authorized to make available additional information relating to the emergency use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only IntelligentMDx may request changes to the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Healthcare Providers or the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity Laboratories

N. CLIA High Complexity Laboratories will include with reports of the results of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA High Complexity Laboratories will perform the assay on an Applied Biosystems 7500 Real-Time PCR System, 7500 Fast Real-Time PCR System, or the 7500 Fast Dx Real-Time PCR Instrument with the appropriate software.

P. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to IntelligentMDx any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

R. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other virus or pathogen.

IntelligentMDx and CLIA High Complexity Laboratories

S. IntelligentMDx and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(7) The Authorization for the Liat Influenza A/2009 H1N1 Assay issued on May 4, 2010, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Shuqi Chen, PhD
CEO
IQuum, Inc.
700 Nickerson Road
Marlborough, MA 01752

Dear Dr. Chen:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Liat™ Influenza A/2009 H1N1 Assay for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate complexity tests and by laboratories certified under CLIA to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Liat Influenza A/2009 H1N1 Assay (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Liat Influenza A/2009 H1N1 Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Liat Influenza A/2009 H1N1 Assay may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Liat Influenza A/2009 H1N1 Assay, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Liat Influenza A/2009 H1N1 Assay for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Liat Influenza A/2009 H1N1 Assay for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Liat Influenza A/2009 H1N1 Assay:

The Liat Influenza A/2009 H1N1 Assay is a rapid, automated multiplex real-time RT-PCR assay intended for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate complexity tests and in laboratories certified under CLIA to perform high complexity tests using the Liat Analyzer for the *in vitro* qualitative detection of influenza A virus and differentiation of 2009 H1N1 influenza viral RNA. The Liat Influenza A/2009 H1N1 Assay uses nasopharyngeal swab (NPS) specimens collected from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The assay targets a conserved region of the matrix gene of Influenza A viral RNA (Inf A target) and the hemagglutinin gene of 2009 H1N1 Influenza viral RNA (2009 H1N1 target). An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target viruses and to monitor the presence of inhibitors in the RT-PCR reactions.

The Liat Influenza A/2009 H1N1 Assay is performed on the lab-in-a-tube technology platform. The system consists of a disposable Liat Influenza A/H1N1Assay Tube and the Liat Analyzer. The Liat Tube uses a flexible tube as a sample vessel. It contains all required unit dose reagents pre-packed in tube segments, separated by peelable seals, in the order of reagent use. The Liat Analyzer performs all assay steps from raw sample and report assay result automatically. During the testing process, multiple processing actuators of the analyzer compress the Liat Tube to selectively release reagents from tube segments, move the sample from one segment to another, and control reaction volume, temperature and time to conduct sample preparation, nucleic acid extraction, target enrichment, inhibitor removal, nucleic acid elution and real-time RT-PCR. An embedded microprocessor controls and coordinates the actions of these sample processors to perform all required assay processes within the closed Liat Tube.

The Liat Influenza A/2009 H1N1 Assay includes the following primer and probe sets:

- **InfA:** A single primer pair and probe were designed to recognize a conserved region of the matrix gene of Influenza A viral RNA. The specific probe for InfA is detected at 525 nm.
- **2009 H1N1:** Three primer pairs and two probes were designed to specifically detect a region of the hemagglutinin gene of 2009 H1N1 Influenza viral RNA but not react with other Influenza A strains of swine origin. Each of the probes for 2009 H1N1 are labeled with the same reporter dye allowing for detection at 630 nm.
- **IPC (Internal Process Control):** MS2 bacteriophage is pre-packed in each Liat tube. When conducting an assay, it is first mixed with sample and then goes through all the test process to monitor both the sample extraction process and RT-PCR reaction performance. The sample tube contains a primer pair and probe specifically designed for detection of a region of MS2 bacteriophage genome. The reporter probe for the IPC is labeled with a reporter dye that allows for detection at 710 nm.

The Liat Influenza A/2009 H1N1 Assay RNA also uses the following control materials:

- Liat Influenza A/2009 H1N1 Assay External Positive/Negative Control Kit (Cat # 20-03628, IQuum) and Liat Influenza Assay Quality Control Kit (Cat# 20-03643)
  - **External Negative Control** consists of Liat Swab Dilution Buffer. The negative control is run during the "add lot" process and is used to assess Liat sample tube validity and performance. Additional runs of the negative control can be run to determine if there is contamination resulting in false positive results.
  - **External Positive Control** of the assay is provided by the Liat Influenza A/2009 H1N1 Positive Control Tube. This sample is also run during the "add-lot' process and is used to assess Liat sample tube validity and performance. This control also ensures that the instrument is functioning as intended.

The Liat Influenza A/2009 H1N1 Assay requires the following hardware:

- Liat Analyzer

The Liat Influenza A/2009 H1N1 Assay requires the use of the following additional reagents/materials:

- Liat Influenza A/2009 H1N1 Assay Tube (Cat # 20-03701, IQuum)
- Liat NP Swab Collection Kit (Liat Dilution Buffer) (Cat # 20-03641, IQuum)
- Liat NP Swab Collection Kit (UTM) (Cat # 20-03642, IQuum)

The above described Liat Influenza A/2009 H1N1 Assay, when labeled consistently with the labeling authorized by FDA, entitled Liat Influenza A/2009 H1N1 Assay Package Insert (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity and Moderate Complexity Laboratories, under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Liat Influenza A/2009 H1N1 Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting the Liat Influenza A/2009 H1N1 Assay Results**
- **Fact Sheet for Patients: Understanding the Liat Influenza A/2009 H1N1 Assay Results**

As described in section IV below, IQuum is also authorized to make available additional information relating to the emergency use of the authorized Liat Influenza A/2009 H1N1 Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Liat Influenza A/2009 H1N1 Assay in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Liat Influenza A/2009 H1N1 Assay may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Liat Influenza A/2009 H1N1 Assay, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Liat Influenza A/2009 H1N1 Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Liat Influenza A/2009 H1N1 Assay described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Liat Influenza A/2009 H1N1 Assay during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Liat Influenza A/2009 H1N1 Assay.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

IQuum

A. IQuum will distribute the authorized Liat Influenza A/2009 H1N1 Assay with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity or Moderate Complexity Laboratories.

B. IQuum will provide to the CLIA High Complexity and Moderate Complexity Laboratories the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Healthcare Providers and the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Patients.

C. IQuum will make available on its website the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Healthcare Providers and the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Patients.

D. IQuum will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Liat Influenza A/2009 H1N1 Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized Liat Influenza A/2009 H1N1 Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- FDA has not determined that this test may be performed in settings with certificates of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the diagnosis of 2009 H1N1 influenza virus and not for the diagnosis of any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is revoked sooner; and
- The declaration of emergency will expire on June 23, 2010, unless it is terminated sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Liat Influenza A/2009 H1N1 Assay may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. IQuum will ensure that CLIA High Complexity and Moderate Complexity Laboratories using the authorized Liat Influenza A/2009 H1N1 Assay have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. IQuum will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, IQuum will maintain records of device usage.

K. IQuum will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which IQuum becomes aware.

L. IQuum is authorized to make available additional information relating to the emergency use of the authorized Liat Influenza A/2009 H1N1 Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only IQuum may request changes to the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Healthcare Providers or the authorized Liat Influenza A/2009 H1N1 Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity and Moderate Complexity Laboratories

N. CLIA High Complexity and Moderate Complexity Laboratories will include with reports of the results of the Liat Influenza A/2009 H1N1 Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA High Complexity and Moderate Complexity Laboratories will perform the assay on the Liat system.

P. CLIA High Complexity and Moderate Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA High Complexity and Moderate Complexity Laboratories will collect information on the performance of the assay, and report to IQuum any suspected occurrence of false positive or false negative results of which CLIA High Complexity and Moderate Complexity Laboratories become aware.

R. CLIA High Complexity and Moderate Complexity Laboratories will clearly and conspicuously state on reports of the results of the Liat Influenza A/2009 H1N1 Assay that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

IQuum and CLIA High Complexity and Moderate Complexity Laboratories

S. IQuum and CLIA High Complexity and Moderate Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Liat Influenza A/2009 H1N1 Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

Dated: June 15, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–14881 Filed 6–18–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

American Indians Into Medicine; Notice of Competitive Grant Applications for American Indians Into Medicine Program

Announcement Type: New.

Funding Opportunity Number: HHS–2010–IHS–INMED–0001.

CFDA Number: 93.970.

Key Dates

Application Deadline: July 21, 2010.

Review Date: July 29, 2010.

Earliest Anticipated Start Date: September 1, 2010.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive grant applications for the American Indians into Medicine Program. This program is authorized under the authority of 25 U.S.C. 1616g (a), Indian Health Care Improvement Act, Public Law 94–437, as amended by Public Law 111–148.

Purpose

The purpose of the Indians into Medicine Program (INMED) is to augment the number of Indian health professionals serving Indians by encouraging Indians to enter the health professions and removing the multiple barriers to their entrance into the IHS and private practice among Indians.

This program is described at 93.970 in the Catalog of Federal Domestic Assistance. Costs will be determined in accordance with applicable Office of Management and Budget Circulars. The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Educational and Community-based programs. Potential applicants may obtain a copy of Healthy People 2010, summary report in print, Stock No. 017–001–00547–9, or via CD–ROM, Stock No. 107–001–00549–5, through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250–7945, (202) 512–1800. You may access this information via the Internet at the