Participants randomly assigned into the intervention arms will receive comprehensive or brief interventional services from two trained interventionists. The interventions will be delivered in face-to-face encounters as well as over the telephone and the first dose of the intervention will be delivered on the day the participant is enrolled into study. During the first face-to-face encounter, an interventionist will administer a retention risk screener. This screener is a clinical tool that will help identify attitudes, barriers, and unmet needs that might prevent a patient from staying in care. The screener contains three sections: (1) Attitudes and beliefs about HIV care and treatment, (2) barriers to consistent clinic attendance (e.g., transportation, child care, housing instability, scheduling problems, and lack of social support), and (3) recent drug/alcohol use and mental health. The information obtained from the risk screener will be used to tailor the interventions to each individual patient's needs. Because a patient's situation or needs may change over time, the screener will be re-administered to intervention arm participants at a minimum every 3–4 months during a clinic visit or other arranged face-to-face meetings outside of the clinic. In addition, the study coordinator will obtain contact/locator information for all participants enrolled in the intervention arm. Contact information will be updated as necessary by the intervention staff.

The response burden for the six participating sites and patients enrolled in the study is estimated as:

ESTIMATED ANNUALIZED BURDEN HOURS

Type of form by phase	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden (in hours)
Phase 1					
Primary Care Provider Survey	150	4	600	0.167	100
Clinic Staff Survey	270	4	1,080	0.167	180
Patient Exit Survey	1,800	1	1,800	0.033	60
.....					
Electronic data abstraction	6	4	24	40.0	960
Phase 1 Burden	2,226	.....	3,504	.....	1,300
Phase 2					
Primary Care Provider Survey	150	2	300	0.167	50
Clinic Staff Survey	270	2	540	0.167	90
Patient Exit Survey	1,800	1	1,800	0.033	60
Patient Eligibility Screener*	3,000	1	3,000	0.083	249
Patient Baseline Survey*	1,800	1	1,800	0.50	900
Retention Risk Screener	1,200	4	4,800	0.25	1,200
Retention Specialist/Patient Navigator Encounter	12	300	3,600	0.017	61
Contact/locator information	1,200	4	4,800	0.083	398
Electronic data abstraction	6	4	24	40.0	960
Phase 2	8,238	.....	20,664	.....	3,968
Total Burden	11,664	.....	24,168	.....	5,268

*Only administered one time during the entire project period.

Written comments and recommendations concerning this proposed information collection should be sent within 30 days of this notice to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for HRSA.

Dated: July 27, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–18524 Filed 8–3–09; 8:45 am]

BILLING CODE 4165–15–P

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 two Emergency Use Authorizations (EUAs) (the Authorizations), one of which was amended, for certain in vitro diagnostic devices. FDA is issuing the Authorizations under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow the determination by the Acting Secretary of the 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 an explanation of the reasons for issuance, are reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain antiviral drug products and the issuance of an EUA for certain personal respiratory protection devices.

DATES: The authorization for the Swine Influenza Virus Real-time RT–PCR Detection Panel (rRT-PCR Swine Flu Panel) is effective as of April 27, 2009. The Authorization for the previously-cleared CDC Human Influenza Virus Real-time RT–PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA2) and Viral Culture is effective as of May 2, 2009.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. 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: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

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: ''(A) 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; (B) 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 (C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act 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) 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 CDC (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, approved or cleared under this Act, or licensed under Section 351 of the Public Health Service Act (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 (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, in the **Federal Register** of July 26, 2007 (72 FR 41083), FDA announced the availability of a guidance entitled ''Emergency Use Authorization of Medical Products.'' The guidance provides 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, 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. 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 virus), 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 is published elsewhere in this issue of the **Federal Register**.

On April 27, 2009, in response to a CDC request, FDA issued an EUA for the Swine Influenza Virus Real-time RT–PCR Detection Panel (rRT-PCR Swine Flu Panel) with certain written

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

information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. On May 2, 2009, in response to a CDC request to allow use of the rRT-PCR Swine Flu Panel for different sample types and different reagents, FDA amended the rRT-PCR Swine Flu Panel Authorization letter and reissued the Authorization letter in its entirety, with amended written information, including adequate directions for use. In addition, on May 2, 2009, in response to a CDC request, FDA issued an EUA with certain written information, including adequate directions for use, to allow the use of the FDA-cleared in vitro diagnostic device, CDC Human Influenza Virus Real-time RT–PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA2) and Viral Culture) (CDC rRT-PCR flu panel), for patient specimen types and reagents in addition to those of the cleared CDC rRT-PCR flu panel.

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.

The Authorization for the rRT-PCR Swine Flu Panel, as amended and reissued in its entirety on May 2, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road, MS C-12
Atlanta, GA 30333
Clifton, Bldg. 1, Room 6430

Dear Dr. Besser:

On April 27, 2009, FDA issued a letter authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) for the presumptive diagnosis of swine influenza A (H1N1), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by public health and other qualified laboratories. On May 1, 2009, CDC submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the rRT-PCR Swine Flu Panel is being reissued in its entirety with the amendments, as requested by CDC, 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, swine influenza A (H1N1).[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 the Department of Health and Human Services then declared an emergency justifying the authorization of the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) 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 Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel)[3] for the presumptive diagnosis of swine influenza A (H1N1) virus infection in human individuals who have been diagnosed with influenza A caused by a virus not subtypeable by currently available FDA-cleared devices, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection for human individuals who are diagnosed with influenza A caused by a virus that is not subtypeable by currently available FDA-cleared devices meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The recently isolated novel 2009 influenza A (H1N1), or swine flu, 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 rRT-PCR Swine Flu Panel may be effective in the presumptive diagnosis of swine influenza A (H1N1) virus infection, and that the known and potential benefits of the rRT-PCR Swine Flu Panel, when used in the presumptive diagnosis of swine influenza A (H1N1) virus infection, outweigh the known and potential risks of such products; and

(3) there is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection.[4]

Therefore, I have concluded that the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection in human individuals who are diagnosed with influenza A infections not subtypeable by currently available FDA-cleared devices meets the above criteria for issuance of an authorization.

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 rRT-PCR Swine Flu Panel for the presumptive diagnosis of 2009 H1N1 influenza A virus infection for individuals who are diagnosed with influenza A caused by a virus not subtypeable by currently available FDA-cleared devices.

The authorized rRT-PCR Swine Flu Panel is as follows:

The Swine Influenza Virus Real-time RT-PCR Detection Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis (Taqman®) probes for use in the real-time RT-PCR assay on the ABI 7500 Fast Dx Real-Time PCR instrument for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection and viral culture. The universal 2009 H1N1 influenza swInfA (NP gene) and swH1 (HA gene) primer and probe sets are designed for detection of 2009 A/H1N1 influenza viruses. In addition rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) authorized for emergency use utilizes the AgPath-ID™ One-Step RT-PCR Kit Human amplification reagents.

The rRT-PCR Swine Flu Panel includes the following primer and probe sets:

- **InfA** detects universal influenza A strains in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and virus culture.
- **swInfA** specifically detects swine influenza A strains (NP gene) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and virus culture.
- **swH1** is specific for swine influenza A, subtype H1 (HA gene) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and viral culture.

The **rRT-PCR** Swine Flu Panel also includes control materials:

- **RNase P (RP)** detects human RNase P and is used as a positive control with human clinical specimens to indicate that adequate isolation of nucleic acid resulted from the extraction of the clinical specimen.
- **Swine Influenza Panel Real-Time RT-PCR Positive Control (SIPC)** is a positive control designed to react with all the primer and probe sets including RNase P.

The above rRT-PCR Swine Flu Panel, when labeled consistent with the attached template is authorized to be distributed to public health and other qualified laboratories[5] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The following written information pertaining to the emergency use of the authorized rRT-PCR Swine Flu Panel is authorized to be made available to health care providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting Swine Influenza Rt-Pcr Detection Panel Test Results
- Fact Sheet For Patients: Understanding Swine Influenza Kit Test Results

See attached. As described in section IV below, CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel 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 rRT-PCR Swine Flu Panel in the specified population, when used in the presumptive diagnosis of swine influenza A (H1N1) virus infection, outweigh the known and potential risks of such 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 rRT-PCR Swine Flu Panel may be effective in the presumptive diagnosis of swine influenza A (H1N1) virus infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Swine Flu Panel, when used to presumptively diagnose swine influenza A (H1N1) 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 rRT-PCR Swine Flu Panel 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 rRT-PCR Swine Flu Panel described above is authorized to presumptively diagnose swine influenza A (H1N1) virus infection in human individuals who are diagnosed with influenza A caused by a virus not subtypeable by currently available FDA cleared devices.
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 rRT-PCR Swine Flu Panel 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 rRT-PCR Swine Flu Panel;
- registration and listing requirements under section 510 of the Act;
- 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);

- investigational device requirements, including requirements under 21 CFR Part 812; and
- reporting requirements that apply to cleared or approved devices, including requirements under 21 CFR Parts 803 and 806.

IV. Conditions of Authorization

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

CDC

A. CDC will distribute the rRT-PCR Swine Flu Panel labeled with the intended use statement, adequate directions for use, any appropriate limitations on the use of the device, and any available information regarding performance of the device only to qualified laboratories.

C. CDC will provide to the qualified state and/or local public health authority(ies) the authorized rRT-PCR Swine Flu Panel Fact Sheets for health care providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for patients.

D. CDC will make available on its website the authorized rRT-PCR Swine Flu Panel Fact Sheets for health care providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for patients.

E. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.

F. CDC will ensure qualified laboratories have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

G. CDC will track adverse events.

H. Through a process of inventory control, CDC will maintain records of device usage.

I. CDC will collect information on the performance of the assay, to include the incidence of false positive and negative results.

Public Health and Other Qualified Laboratories

J. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-time PCR instrument or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its laboratory performance (proficiency testing with the CDC sample panel not performed).

K. Qualified 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.

CDC and state and/or Local Public Health Authority(ies)

M. CDC and the appropriate state and/or local public health authority(ies) are authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only CDC may request changes to the authorized Fact Sheet for health care providers or the authorized rRT-PCR Swine Flu Panel Fact Sheet for patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. CDC and the appropriate state/and or local public health authority(ies) will ensure that 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 rRT-PCR Swine Flu Panel 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.

Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Acting Commissioner

[1] The amendments to the April 27, 2009 letter allow use of different sample types (throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens) and different reagents.

[2] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).

[3] FDA is authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) as described in the scope section of this letter (Section II). For ease of reference, this letter will use the term the ''rRT-PCR Swine Flu Panel.''

[4] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[5] All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See ''Conditions of Authorization'' below.

The Authorization for the cleared CDC rRT-PCR flu panel follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road, MS C-12
Atlanta, GA 30333
Clifton, Bldg. 1, Room 6430

Dear Dr. Besser:
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 CDC[1] Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**[2]) and Viral Culture (rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)) as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 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 public health and other qualified laboratories.

The CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel) was cleared by FDA on September 30, 2008 for use with nasopharyngeal and/or nasal swab specimens. Because of issues of availability and adequacy of the cleared test associated with the need for testing additional specimen types, this letter authorizes the emergency use of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** with specimen types and reagents in addition to those of the cleared test, as described below. The rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** is authorized as a first tier test for patient specimens with suspected 2009 H1N1 influenza virus and is an integral component of the testing algorithm for the rRT-PCR Swine Flu Panel authorized for use under an April 27, 2009 Emergency Use Authorization.

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.[3] 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 the Department of Health and Human Services then declared an emergency justifying the authorization of the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens **(NPS, NS, TS, NPS/TS, NA)** and Viral Culture 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 CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA)** and Viral Culture (rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**)[4] as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in individuals suspected of having a 2009 H1N1 influenza virus infection. The rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** is a first tier test because it should be used to test specimens from such individuals first. If the test result of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** is positive for influenza A and negative for H1 (seasonal) and H3 subtypes, then the laboratory should test the specimen with the rRT-PCR Swine Flu Panel.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The recently isolated novel 2009 influenza A (H1N1), or swine flu, 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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** may be effective as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection suspected of having a 2009 H1N1 influenza virus infection and/or from viral culture, and that the known and potential benefits of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**, when used as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3), outweigh the known and potential risks of such products; and

(3) there is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection and/or from viral culture specimens suspected of having a 2009 H1N1 influenza virus infection.[5]

Therefore, I have concluded that the emergency use of the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection meets the above criteria for issuance of an authorization.

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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection.

The authorized rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA):

CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens **(NPS, NS, TS, NPS/TS, NA)** and Viral Culture is a panel of oligonucleotide primers and dual-labeled hydrolysis probes for use in the real-time RT-PCR assay on the ABI 7500 Fast Dx Real-Time PCR instrument for the *in vitro* qualitative detection of human influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection and/or from viral culture.[6]

The rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** uses the same primer and probe sequences as the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel as the device cleared under K080570 except that the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** authorized for emergency use also utilizes the AgPath-ID™ One-Step RT-PCR Kit Human amplification reagents.

Assay principle

- The **rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)** is used in real-time RT-PCR assays on the ABI 7500 Fast instruments. The primer and probe sets are designed for detection and subtyping of influenza A viruses.

- One-step RT-PCR assays are one-tube assays that first reverse-transcribe specific Ribonucleic acid (RNA) templates into cDNA copies. The complementary deoxyribonucleic acid (cDNA) then undergoes a polymerase chain reaction (PCR) that utilizes a thermocyclic heating and cooling of the reaction to logarithmically amplify a specific region of DNA. The probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle.

- No template controls (NTCs) and positive template controls for all primer and probe sets are included in each run. An extraction control (HSC) provides a secondary negative control that validates the extraction procedure and reagent integrity. The RNase P assay serves as a control to ensure adequate RNA resulted from extraction of each clinical specimen and that no inhibitors were present in the specimen. RNA extracted from clinical samples contains human RNA. The RP primer and probe set targets the human ribonuclease P gene. Therefore, the level of the RNase P primer and probe set reaction reflects the relative amount of human RNA recovered from the specimen and its suitability for clinical testing.

The above rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**, when labeled consistent with the attached template, is authorized to be distributed to public health and other qualified laboratories[7] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The following written information pertaining to the emergency use of the authorized rRT-PCR Swine Flu Panel is authorized to be made available to health care providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA)** Test Results
- Fact Sheet For Patients: Understanding rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Kit Test Results

See attached. As described in section IV below, CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** 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 rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA)** in the specified population, when used as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such 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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** may be effective as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**, when used for qualitative detection of influenza virus types A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) from individuals suspected of having a 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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** 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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** described above is authorized as a first tier test to qualitatively detect influenza virus types A or B and subtype seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus 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 rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) during the duration of this emergency use authorization[8]:

- 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 rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**;
- registration and listing requirements under section 510 of the Act;
- 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);
- investigational device requirements, including requirements under 21 CFR Part 812; and
- reporting requirements that apply to cleared or approved devices, including requirements under 21 CFR Parts 803 and 806.

IV. Conditions of Authorization

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

CDC

A. CDC will distribute the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** labeled with the intended use statement, adequate directions for use, any appropriate limitations on the use of the device, and any available information regarding performance of the device only to qualified laboratories.

B. CDC will provide to the qualified state and/or local public health authority(ies) the authorized rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Fact Sheets for health care providers, and the authorized **rRT**-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Fact Sheets for patients.

C. CDC will make available on its website the authorized rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Fact Sheets for health care providers, and the authorized **rRT-PCR** Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Fact Sheets for patients.

D. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.

E. CDC will ensure qualified laboratories have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

F. CDC will track adverse events.

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

H. CDC will collect information on the performance of the assay, to include the incidence of false positive results.

Public Health and Other Qualified Laboratories

I. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-time PCR instrument or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its laboratory performance (proficiency testing with the CDC sample panel not performed).

J. Qualified 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.

CDC and State and/or Local Public Health Authority(ies)

K. CDC and the appropriate state and/or local public health authority(ies) are authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA)** that is consistent with, and does not exceed, the terms of this letter of authorization.

L. Only CDC may request changes to the authorized Fact Sheet for health care providers or the authorized rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** Fact Sheet for patients. Such requests will be made by contacting FDA concerning FDA review and approval.

M. CDC and the appropriate state/and or local public health authority(ies) will ensure that 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 rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA)** 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.

Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Acting Commissioner

[1] Centers for Disease Control and Prevention
[2] Nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, nasal aspirates.
[3] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[4] FDA is authorizing the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens **(NPS, NS, TS, NPS/TS, NA)** and Viral Culture (rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** as described in the scope section of this letter (Section II). For ease of reference, this letter will use the term the ''rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**.''
[5] The cleared test for in vitro qualitative detection of human influenza viral RNA (The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570) is not adequate because of the need to test additional types of samples during this emergency and it is not sufficiently available because of limited availability of certain reagents. No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[6] The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570 is indicated for the *in vitro* qualitative detection of human influenza viral RNA in nasopharyngeal swabs (NPS) and nasal swabs (NS) only.
[7] All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See ''Conditions of Authorization'' below.
[8] These requirements are waived only for the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** that is authorized for emergency use. These requirements, and all other applicable statutory and regulatory requirements, continue to apply to the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570.

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–18569 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0278]

Authorization of Emergency Use of Certain Personal Respiratory Protection Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization), as amended, for certain personal respiratory protection devices.[1] FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized personal respiratory protection devices. The Authorization follows the determination by the Acting Secretary of the 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 disposable National Institute for Occupational Safety and Health (NIOSH) certified N95 respirators, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorization, as amended, which includes an explanation of the reasons for its issuance, is reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate and the issuance of EUAs for certain in vitro diagnostic devices.

DATES: The Authorization is effective as of April 27, 2009.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

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: ''(A) 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; (B) a determination by the Secretary of Defense that there is a military

[1] The Authorization covers certain disposable respirators certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95 (certain disposable NIOSH certified N95 respirators).