DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

February 14, 2014

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Quidel Corporation
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San Diego, CA 92121

Dear Dr. Tamerius:

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 Lyra™ Influenza A Subtype H7N9 Assay for the presumptive detection of novel influenza A (H7N9) virus (detected in China in 2013) in patients with signs and symptoms of respiratory infection who have positive specimens for influenza A viral RNA that are determined to be un-subtypable, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On April 19, 2013, 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 significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such an agent or agents - in this case, novel influenza A (H7N9) virus.[1] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for the detection of A (H7N9) influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a). [2]

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 Lyra™ Influenza A Subtype H7N9 Assay by Clinical Laboratory Improvement Amendments (CLIA) High Complexity Laboratories[3] or foreign laboratories on certain instruments for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in certain patients (as described in the scope section of this letter (Section II)), subject to the terms of this authorization.

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[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[2] Memorandum, Determination of a Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (April 19, 2013).

[3] These are laboratories certified under the CLIA of 1988, 42 U.S.C. § 263a, to perform high complexity tests.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Lyra™ Influenza A Subtype H7N9 Assay on the specified instruments for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The influenza A (H7N9) virus (detected in China in 2013) can cause influenza, a serious or life threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Lyra™ Influenza A Subtype H7N9 Assay used on the specified instruments may be effective in diagnosing influenza A (H7N9) virus (detected in China in 2013) in the specified population, and that the known and potential benefits of the Lyra™ Influenza A Subtype H7N9 Assay, when used on the specified instruments for diagnosing influenza A (H7N9) virus (detected in China in 2013) infection in the specified population, 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 Lyra™ Influenza A Subtype H7N9 Assay for diagnosing influenza A (H7N9) virus (detected in China in 2013).[4]

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 Lyra™ Influenza A Subtype H7N9 Assay in conjunction with the bioMerieux NucliSENS® easyMAG® system, followed by rRT-PCR on the Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument, for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in patients with signs and symptoms of respiratory infection who have positive specimens for influenza A viral RNA that were determined to be "un-subtypable."

The Authorized Lyra™ Influenza A Subtype H7N9 Assay:

The Lyra™ Influenza A Subtype H7N9 Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection and differentiation of influenza A (H7N9) virus (detected in China in 2013) viral RNA in nasal swabs (NS) and nasopharyngeal swabs (NPS) from patients with signs and symptoms of respiratory infection. It is only authorized for use after a nasal or nasopharyngeal swab specimen has tested positive for influenza A viral RNA by using a FDA-cleared influenza A device, and has been determined to be "un-subtypable" by using FDA-cleared influenza device(s) with subtyping capabilities for all currently circulating influenza A viruses in the United States (i.e., seasonal A/H3 and A/H1 pandemic). The authorized testing consists of nucleic acid extraction on the FDA-cleared bioMerieux NucliSENS® easyMAG® system, followed by rRT-PCR on the FDA-cleared Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument.

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

The Lyra™ Influenza A Subtype H7N9 Assay includes the following reagents:

- **Rehydration Solution**
- **Lyra™ Influenza A Subtype H7N9 Assay Master Mix**

The Lyra™ Influenza A Subtype H7N9 Assay also includes the following control materials:

- **Process Control (PRC)**
- **Avian Influenza A (H7N9) Synthetic DNA Positive Control**

The above described Lyra™ Influenza A Subtype H7N9 Assay, when labeled consistently with the labeling authorized by FDA, entitled "Lyra™ Influenza A Subtype H7N9 Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised with written permission of FDA, is authorized to be distributed to and used by public health and other qualified laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay Test Results**

- **Fact Sheet for Patients: Understanding Results from the Lyra™ Influenza A Subtype H7N9 Assay**

As described in section IV below, Quidel Corporation is also authorized to make available additional information relating to the emergency use of the authorized Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay in the specified population, when used on the specified instruments for presumptive detection of influenza A (H7N9) virus (detected in China in 2013), 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 Lyra™ Influenza A Subtype H7N9 Assay used on the specified instruments may be effective in the diagnosis of influenza A (H7N9) virus (detected in China in 2013) infection in the specified population 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 Lyra™ Influenza A Subtype H7N9 Assay, when used to diagnose influenza A (H7N9) virus (detected in China in 2013) 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 Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay described above is authorized to diagnose influenza A (H7N9) virus (detected in China in 2013) infection on the specified instruments in the specified population.

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 Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 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:

Quidel Corporation

A. Quidel Corporation will distribute the authorized Lyra™ Influenza A Subtype H7N9 Assay with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories or foreign laboratories.

B. Quidel Corporation will provide to the CLIA High Complexity Laboratories the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers and the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients.

C. Quidel Corporation will make available on its website the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers and the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients.

D. Quidel Corporation 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 Lyra™ Influenza A Subtype H7N9 Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized for use only by CLIA High Complexity Laboratories or foreign laboratories;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of influenza A (H7N9) virus (detected in China in 2013) and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the HHS declaration of emergency that justifies this authorization, unless the authorization is revoked sooner.

F. No advertising or promotional descriptive printed matter relating to the use of the authorized Lyra™ Influenza A Subtype H7N9 Assay may represent or suggest that this test has been found to be safe or effective for the diagnosis of influenza A (H7N9) virus (detected in China in 2013).

G. Quidel Corporation will ensure that CLIA High Complexity laboratories using the authorized Lyra™ Influenza A Subtype H7N9 Assay have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate.

H. Quidel Corporation will track adverse events and report to FDA as required under 21 CFR Part 803.

I. Through a process of inventory control, Quidel Corporation will maintain records of device usage.

J. Quidel Corporation 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 Quidel Corporation becomes aware.

K. Quidel Corporation is authorized to make available additional information relating to the emergency use of the authorized Lyra™ Influenza A Subtype H7N9 Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

L. Only Quidel Corporation may request changes to the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers or the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity Laboratories

M. CLIA High Complexity Laboratories will include with reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

N. CLIA High Complexity Laboratories will perform the assay on a bioMerieux NucliSENS® easyMAG® Nucleic Acid Extraction System and an Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with the appropriate software, respectively.

O. 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.

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

Q. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay that this test is only authorized for the diagnosis of influenza A (H7N9) virus (detected in China in 2013) and not for seasonal influenza A, B, or any other pathogen.

Quidel Corporation and CLIA High Complexity Laboratories

R. Quidel Corporation 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 Lyra™ Influenza A Subtype H7N9 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.

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

Enclosures