



PUBLIC HEALTH LABORATORY

"Providing quality laboratory services to protect community health and prevent the spread of disease."





San Diego County's Public Health Laboratory provides a wide variety of diagnostic tests that:

- **Support disease control efforts**
- **Provide patient diagnostic information**
- **Characterize the types of disease agents in our jurisdiction**
- **Look for antibiotic resistance**
- **Detect environmental threats**

TODAY'S REQUEST



LIVE WELL
SAN DIEGO

Authorizes the Health and Human Services Agency (HHSA) to accept future State and federal revenue for Public Health emergency preparedness and response activities. This funding not only supports laboratory response (recent examples include H1N1, Ebola, and now Zika) but also ongoing Public Health emergency preparedness and hospital preparedness activities.

TODAY'S REQUEST



Authorizes HHSA to enter into contracts with local hospitals, the Council of Community Clinics (dba Health Center Partners), and First Watch for emergency preparedness planning/training and disease surveillance as well as authorizing potential agreements with other counties and Mexico for coordinated Zika testing.



LIVE WELL
SAN DIEGO

Tests for human diagnostics must be approved by the Food and Drug Administration

- Test manufacturers must demonstrate by clinical evaluation that the test is effective and reliable.



LIVE WELL
SAN DIEGO

EMERGENCY USE AUTHORIZATION (EUA)

Under section 564 of the Federal Food, Drug, and Cosmetic Act the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.



EMERGENCY USE AUTHORIZATION (EUA)

Before FDA may issue an EUA, the HHS Secretary must declare that circumstances exist justifying the authorization . This declaration is referred to in as an “EUA declaration”

EUA DECLARATIONS



Before FDA may issue an EUA, the HHS Secretary must declare that circumstances exist justifying the authorization (section 564(b)(1)). This declaration (referred to in this guidance as an “EUA declaration”) must be based on one of the following actions:

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 CBRN agent(s);
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 CBRN agent(s);



This guidance explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical [and] include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents,

including emerging infectious disease threats such as pandemic influenza.

H1N1- INFLUENZA APRIL 2009



TEST AVAILABLE IN COUNTY LAB

CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel with additional specimens and reagents –May 2, 2009

First National case was a patient in San Diego

TEST AVAILABLE IN COMMERCIAL/ HOSPITAL LAB

Roche RealTime ready Influenza A/H1N1 Test	11/13/09
Prodesse ProFlu-ST Influenza A assay for the diagnosis of 2009 H1N1 Influenza virus infection	10/27/09
Diatherix 2009 H1N1 Test	10/9/09

2013 AVIAN INFLUENZA EMERGENCY USE AUTHORIZATION



On April 19, 2013 Secretary Kathleen Sebelius determined that avian influenza A(H7N9) poses a significant potential for a public health emergency

2013 H7N9 INFLUENZA EMERGENCY USE AUTHORIZATION



[CDC Human Influenza Virus Real-Time RT-PCR Diagnostic](#)

[Panel-Influenza A/H7 \(Eurasian Lineage\) Assay \(CDC\) - April](#)

[22, 2013](#)

This device will be distributed by CDC to public health and other qualified laboratories.

EBOLA 2014



TEST AVAILABLE FOR COUNTY LAB

**DoD EZ1 Real-time RT-PCR Assay
(Ebola)**

8/5/14

TEST AVAILABLE FOR COMMERCIAL/
HOSPITAL LABS

**BioFire Defense LLC FilmArray
NGDS BT-E Assay**

10/25/14

2015 ENTEROVIRUS D68 (EV-D68) EMERGENCY USE AUTHORIZATION



On February 6, 2015, ..the Secretary of Health and Human Services (HHS), Sylvia Burwell, 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 EV-D68.

[EV-D68 2014 rRT-PCR Assay \(CDC\) - May 12, 2015](#)

No commercial test has been developed

ZIKA VIRUS DETECTION



TEST AVAILABLE IN COUNTY LAB

Emergency Use Authorization (EUA) to use the Centers for Disease Control and Prevention's (CDC) Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) for the qualitative detection and differentiation of RNA from Zika virus

March 17, 2016,

TEST AVAILABLE IN COMMERCIAL/ HOSPITAL LAB

Emergency Use Authorization (EUA) to Focus Diagnostics, Inc.'s, Zika Virus RNA Qualitative Real-Time RT-PCR test for the qualitative detection of RNA from Zika virus

**April 28,
2016**



ZIKA (EUA)

The assay is intended for use.... by
qualified laboratories designated by CDC.

- This was initially State and local Public Health Laboratories

IMPLEMENTATION BARRIERS



EXCERPT FROM AUTHORIZATION

Equipment:

- the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument

BARRIER TO LOCAL TESTING

None

- SD PHL was already using this equipment for Influenza testing

IMPLEMENTATION BARRIERS



EXCERPT FROM AUTHORIZATION

Equipment:

- the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument

Reagents

- SuperScript™ III RT/Platinum® One-Step qRT-PCR Kit
- Quanta qScript™ One-Step qRT-PCR Kit, Low Rox™

BARRIER TO LOCAL TESTING

None

- SD PHL was already using this equipment for Influenza testing

None

- SD PHL was already using this equipment for Influenza testing

IMPLEMENTATION BARRIERS



EXCERPT FROM AUTHORIZATION

Equipment

- the MagNA Pure LC Total Nucleic Acid

Isolation Kit

- Used on the MagNA Pure 96 automated instrument

BARRIER TO LOCAL TESTING

\$50,000 purchase acquisition

- The lab had to use a manual method to prepare samples while we went through the 3 month purchase process.

TODAY'S REQUEST



In the event that the Food and Drug Administration grants Emergency Use authorization or the Secretary of Health and Human Services (has) determined that there is a significant potential for a public health emergency



...the Public Health Laboratory may accept funding passed down through Federal and State agencies and acquire Authorized equipment and supplies to protect the health of the people and to respond to the significant potential for a public health emergency.

TODAY'S REQUEST



Authorizes HHSA to enter into contracts with local hospitals, the Council of Community Clinics (dba Health Center Partners), and First Watch for emergency preparedness planning/training and disease surveillance as well as authorizing potential agreements with other counties and Mexico for coordinated Zika testing.



 **LIVE WELL
SAN DIEGO**

THANK YOU

For More Information

Brett.Austin@sdcounty.ca.gov

619-692-8500

COUNTY OF SAN DIEGO



HHSA

HEALTH AND HUMAN SERVICES AGENCY

