



COUNTY OF HUMBOLDT

Legislation Details (With Text)

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Title: California Department of Public Health (CDPH) Abbott BinaxNOW Antigen Testing Supplies Acknowledgement and Acceptance of Responsibility State Standard Agreement
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Attachments: 1. Staff Report, 2. CDPH Abbott BinaxNOW Antigen Testing Acknowledgment & Acceptance State Std Agreement, 3. FDA Emergency Use Authorization Letter, Abbott BinaxNOW, 12.16.2020, 4. Humboldt County Public Health Clinic CLIA Certificate of Waiver

Date	Ver.	Action By	Action	Result
9/27/2022	1	Board of Supervisors	approved	Pass

To: Board of Supervisors
From: DHHS: Public Health
Agenda Section: Consent

SUBJECT:

California Department of Public Health (CDPH) Abbott BinaxNOW Antigen Testing Supplies Acknowledgement and Acceptance of Responsibility State Standard Agreement

RECOMMENDATION(S):

That the Board of Supervisors:

1. Approve the attached Acknowledgment and Acceptance of Responsibility state standard agreement with the CDPH to accept Abbott BinaxNOW COVID-19 antigen testing supplies and data use and disclosure regarding the Primary Diagnostics, Incorporated (Inc.) system;
2. Authorize the Director of Public Health, or a designee thereof, to sign the agreement; and
3. Authorize the Director of Public Health, or a designee thereof, to sign all future amendments and documents directly related to the agreement upon review and approval of County Counsel and Risk Management.

SOURCE OF FUNDING:

Public Health Funds (1175).

DISCUSSION:

The United States Food and Drug Administration (FDA) issued an Emergency Use Authorization

(EUA) on August 26, 2020 for BinaxNOW antigen tests, the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test was authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

On June 14, 2022, the ratification of a Memorandum of Understanding (MOU) and approval of amendment number 001 to the MOU with CDPH was approved by your Board (File #22-713). The amendment allowed Humboldt County Department of Health and Human Services - Public Health (DHHS - Public Health) to continue laboratory testing of samples for SARS- CoV-2 using the Abbott BinaxNOW antigen test under the state's CLIA Certificate of Waiver. The MOU's term was set to expire after thirty days of the lifting of the declaration of the COVID-19 state of emergency in California. The subsequent amendment extended the term through June 30, 2023 to allow for continued testing beyond the lifting of the emergency as needed.

CDPH sent a new state standard agreement to DHHS - Public Health on August 3, 2022 to replace the amended MOU. In the state's testing programs, organizations that have their own CLIA certification are no longer eligible to use the state's CLIA Certificate of Waiver. To continue participating in the state's antigen testing program and reorder tests, DHHS - Public Health is now required to perform antigen testing under their own CLIA Certificate of Waiver (05D0612837) and sign the attached Acknowledgment and Acceptance of Responsibility state standard agreement.

This state standard agreement also gives DHHS - Public Health access to the Primary Diagnostics, Inc. system. CDPH contracted with Primary Diagnostics, Inc. to provide patient registration services, as well as laboratory and medical records data collection, management, storage, and reporting services to organizations administering BinaxNOW antigen tests.

FINANCIAL IMPACT:

There are no direct costs associated with the attached agreement with CDPH regarding the County of Humboldt's acceptance of Abbott BinaxNOW antigen testing supplies, nor for the use of and data sharing through the Primary Diagnostics system. Therefore, approval of the attached agreement with the CDPH will not impact the Humboldt County General Fund.

STRATEGIC FRAMEWORK:

This action supports your Board's Strategic Framework by protecting vulnerable populations, creating opportunities for improved safety and health, and providing community-appropriate levels of service.

OTHER AGENCY INVOLVEMENT:

Primary Diagnostics, Inc.

ALTERNATIVES TO STAFF RECOMMENDATIONS:

The Board may choose not to approve the attached agreement with CDPH to continue to participate in

antigen testing, however, that is not recommended as it would limit DHHS - Public Health's ability to provide and perform antigen testing for COVID-19 in Humboldt County.

ATTACHMENTS:

1. CDPH Abbott BinaxNOW Antigen Testing Acknowledgment and Acceptance State Standard Agreement
2. FDA Emergency Use Authorization Letter, Abbott BinaxNOW, 12/16/2020
3. Humboldt County Public Health Clinic CLIA Certificate of Waiver

PREVIOUS ACTION/REFERRAL:

Board Order No.: D-19

Meeting of: 06/14/22

File No.: 22-713