

ACKNOWLEDGMENT AND ACCEPTANCE OF RESPONSIBILITY

I. Antigen Test Kits

In consideration of the California Department of Public Health's ("CDPH") distribution of test kits for the "Abbott BinaxNOW Covid-19 Ag Card Point-of-Care SARS-CoV-2 Diagnostic Test" ("antigen test kits"), I acknowledge and agree as follows:

I accept the supply of antigen test kits in the condition known to both my organization and CDPH at the time of delivery of the antigen test kits.

I understand that it is my responsibility to abide by all the applicable state and federal requirements relating to the administration and use of the Abbott BinaxNOW antigen test kits, which include, but are not limited to, all of the following:

- Applicable state and federal clinical laboratory registration and certification requirements.
- Compliance with the terms and conditions, including those applicable to "authorized laboratories," of the federal Food and Drug Administration's Emergency Use Authorization, dated December 16, 2020. (See <https://www.fda.gov/media/141567/download>)

II. Primary Diagnostics, Inc. Services

CDPH, through CDPH Agreement 20-10982, Amendment 2, has contracted with Primary Diagnostics, Inc. to provide patient registration services and laboratory and medical records data collection, management, storage, and reporting services to organizations that meet the following criteria:

- The organization performs tests using the CDPH-provided rapid antigen test kits described in Paragraph 1.
- The organization performs these tests under their own state and federal clinical laboratory registration and certification.
- The organization will grant CDPH access, via Primary Diagnostics, Inc., to aggregate and de-identified data for purposes of evaluating testing utilization and positivity rates.

In consideration of the services provided by Primary Diagnostics, Inc., I acknowledge and agree as follows:

- My organization meets the criterion established above.
- I understand that it is my responsibility to abide by applicable state and federal disease reporting requirements.
- I acknowledge that CDPH does not own or have responsibility over the data obtained and stored by my organization or by Primary Diagnostics, Inc.
- I understand that it is my responsibility to abide by applicable state or federal health

information privacy laws and laboratory records retention laws regarding any data obtained and stored by my organization or by Primary Diagnostics, Inc.

Signature

Organization

Print Name

Organization Address

Date

In Process