COVID-19 and HAI Updates and Q&A Webinars for Long-Term Care and Congregate Residential Settings

September 30th, 2022

Housekeeping

- All attendees in listen-only mode
- Submit questions via Q&A pod to **All Panelists**
- Slides and recording will be made available later

IDPH
Illinois Department of Public Health

Agenda

- Upcoming Webinars
- CDC Updates Infection Prevention and Control Guidance for U.S. Healthcare Settings
- Point of Care Testing Changes
- Open Q & A

Slides and recording will be made available after the session.

IDPH
Illinois Department of Public Health

Upcoming COVID-19 and Infection Prevention and Control Updates

1:00 pm - 2:00 pm

Date	Infection Control Topic	Registration Link
Friday, October 14th	Environment of Care	https://illinois.webex.com/illinois/onstage/g.php?MTID=e28e6b8e9fe0ca77cc79b9b7d6abcc426
Friday, October 28th	MDROs: Lab Results, Interpretation, and Response	https://illinois.webex.com/illinois/onstage/g.php?MTID=e17814ed8fc09addc0adfdc28defb874b

Previously recorded webinars can be viewed on the IDPH Portal

Continued Education will be offered. It will only be for the live presentation. Please ensure when registering that your name and email are correctly spelled. To receive the continued education, you must complete a training survey, which will be provided with the link to the recording.

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Upcoming Telligen QI Connect™ Events

Monkeypox Clinical Presentation & Pain Management

Wednesday, October 5 | 1 – 2 p.m. CT

» REGISTER NOW

Disaster Management Overview

Wednesday, October 19 | 12 – 1 p.m. CT

» REGISTER NOW

View Telligen's complete event calendar here.

Telligen QI Connect™
Partnering to improve health outcomes through relationships and data

CDC Updates Infection Prevention and Control Guidance for U.S. Healthcare Settings

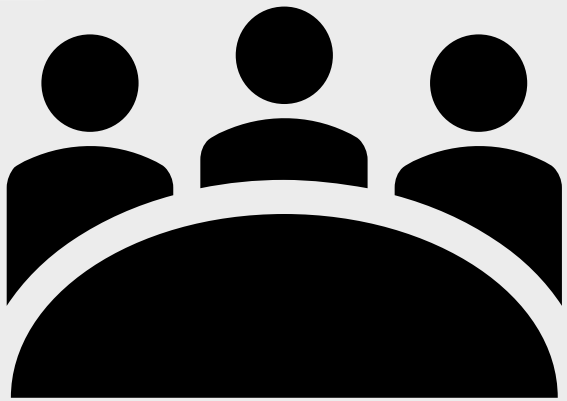
- **Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic**
  - Updated Sept. 23, 2022
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
- **Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2**
  - Updated Sept. 23, 2022
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html
- **Strategies to Mitigate Healthcare Personnel Staffing Shortages**
  - Updated Sept. 23, 2022
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html

CMS Updated Rules Sept 23, 2023

- QSO-20-38-NH Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements
  - https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf
- QSO-20-39-NH Nursing Home Visitation - COVID-19 (REVISED)
  - https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf
- QSO-22-25-CLIA CMS Rescinds December 7, 2020, Enforcement Discretion for the Use of SARS-CoV-2 Tests on Asymptomatic Individuals Outside of the Test's Instructions for Use
  - https://www.cms.gov/files/document/qso-22-25-clia.pdf

Suggestions

- Keep doing what you are doing for the time being
- All of IDPH/Hektoen are working hard to make changes
- Need to consider Executive Orders and Emergency Rules
- Infection Preventionist Work with your Interdisciplinary Team
- Start to compare your existing policies and procedures with new CDC guidance and CMS rules



We Even Have Some Blue!
Still 14,000 cases
141 hospitalizations
68 deaths in Illinois
7 day moving average
Not over yet…
But getting better

https://covid.cdc.gov/covid-data-tracker/#county-view?list_select_state=Illinois&data-type=Risk

Illinois

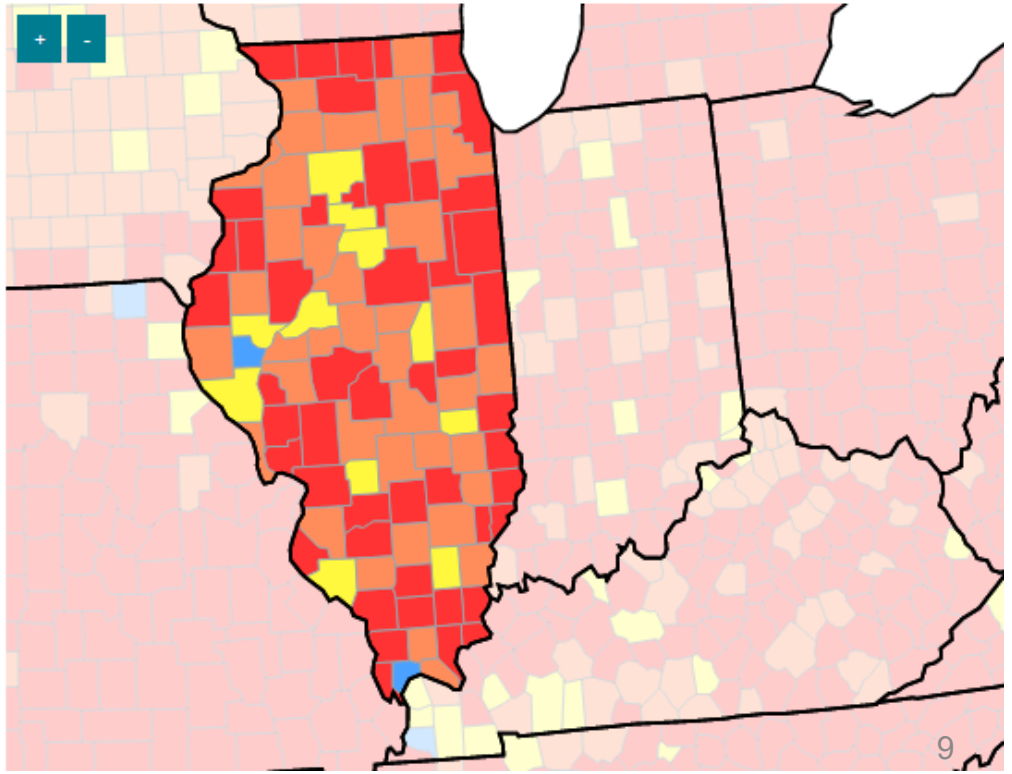
State Health Department

7-day Metrics

Cases	14,504
% Positivity	5-7.9 %
Deaths	68
% of Population ≥ 5 Years of Age Fully Vaccinated	74.2%
New Hospital Admissions (7-Day Moving Avg)	141.29

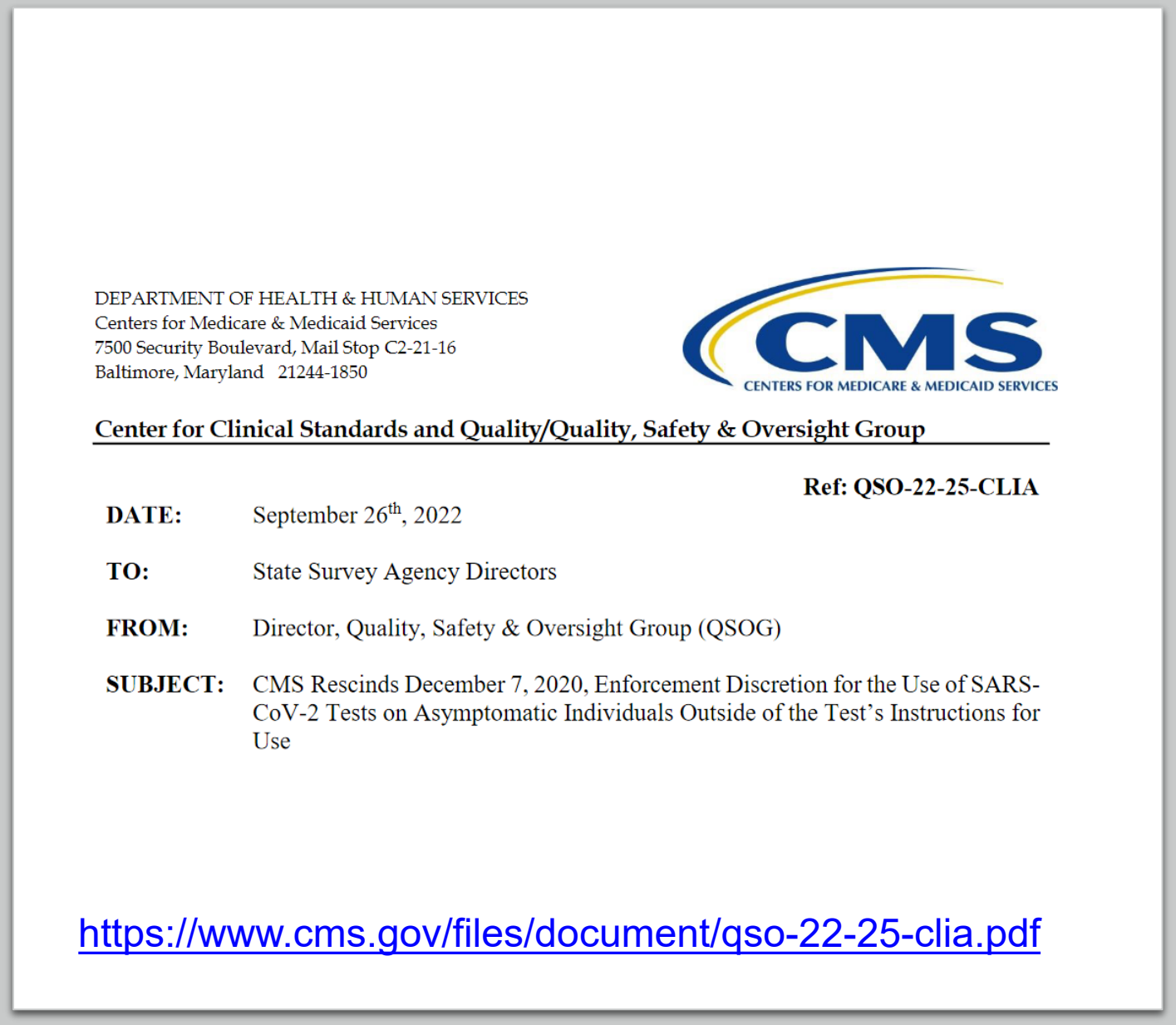
Data Type: Community Transmission

Map Metric: Community Transmission



Point of Care Testing Changes

- Applies to both NAAT (PCR) and antigen testing
- Any facilities entering lab results into NHSN and Simple Reports have been acting as laboratories with CLIA waivers
- Using SARS-CoV-2 tests outside the test instructions for use (IFU): No longer allowed
- **30 days from September 26th, 2022 (the date of the memorandum) to come into compliance**



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-25-CLIA

DATE: September 26th, 2022

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: CMS Rescinds December 7, 2020, Enforcement Discretion for the Use of SARS-CoV-2 Tests on Asymptomatic Individuals Outside of the Test's Instructions for Use

https://www.cms.gov/files/document/qso-22-25-clia.pdf

Question: We have Antigen Tests. How do I Know These Tests can be Used on Asymptomatic Persons?

- Instructions for Use (IFU) for the “Rapid SARS-CoC-2 Antigen Test Card”, you will find instructions that state:

- If the certificate of waiver lab (or nursing home) has an **antigen test that is only authorized for use in symptomatic patients,** they would be expected to follow those instructions and use that test under the proper circumstance.

What Does This Mean?

- Instructions for Use (IFU) must be followed
- CMS will cite if tests are not used exactly according to instructions for use (IFU)
- You have 30 days from September 26, 2022 to get into compliance
- YES, there are some common tests that can be used on **both** asymptomatic and symptomatic persons
- Antigen tests that are authorized for asymptomatic use can be found on the FDA's website
- Refer to Excel file provided courtesy of Dr. Geltz IDPH (separate attachment)

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

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Click on Link to Find FDA Authorization on How Test Can be Used (from IDPH Excel file)

A	B	C	D	E	F	G	H
Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)1	Authorization Documents2	Asymptomatic Testing	Symptomatic Testing
5/4/2022	Oceanit Foundry LLC	ASSURE-100 Rapid COVID-19 Test	Lateral Flow, Visual Read, Single Target	H, M, W	HCP, Patients, IFU	No	Yes
2/4/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card	Lateral Flow, Visual Read, Single Target	H, M, W	HCP, Patients, IFU	No	Yes
10/27/2021	Princeton BioMeditech		Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU		

Click Hyperlink to get to FDA Letter

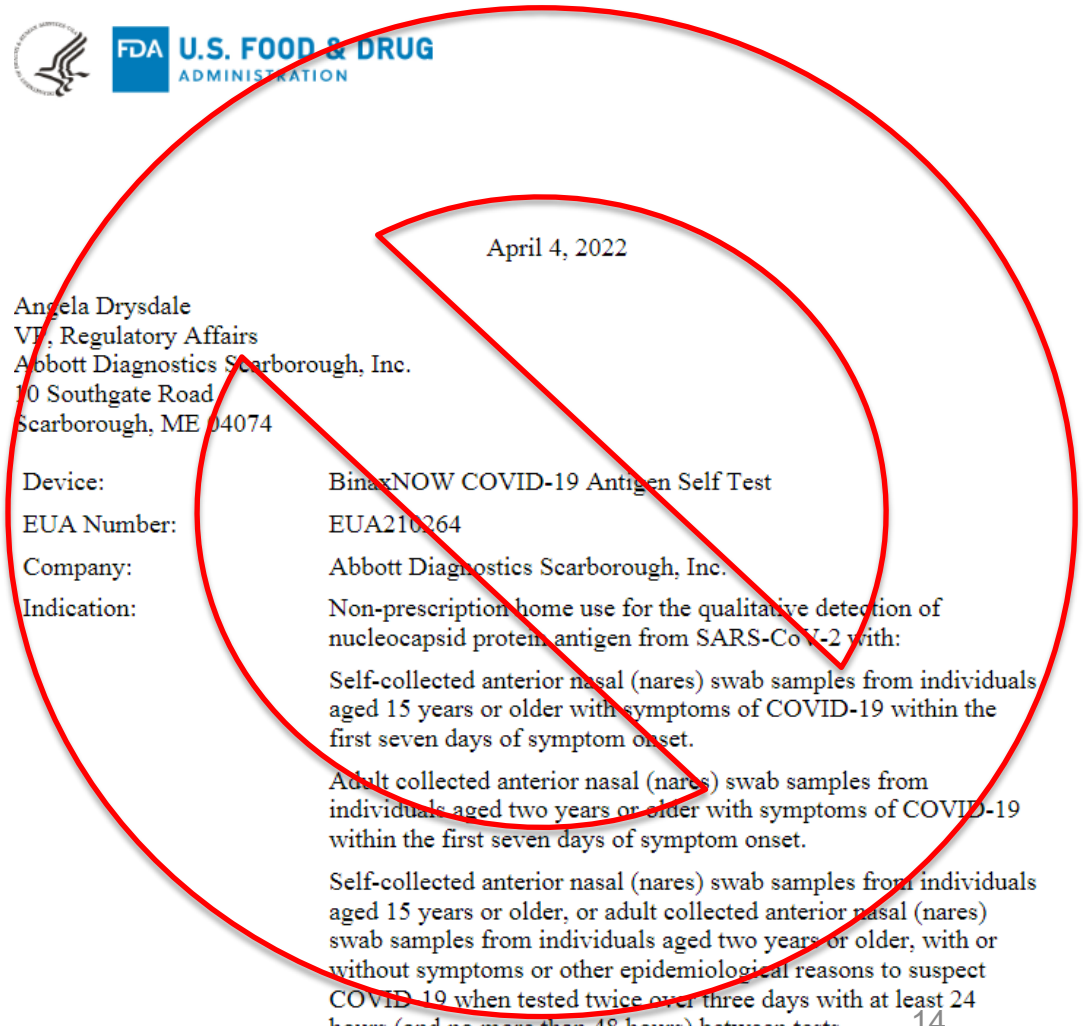
BinaxNOW RX vs. BinaxNOW Non-Prescription

FDA U.S. FOOD & DRUG ADMINISTRATION

December 16, 2020

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Device:	BinaxNOW COVID-19 Ag Card
Company:	Abbott Diagnostics Scarborough, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	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 is 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.



FDA U.S. FOOD & DRUG ADMINISTRATION

April 4, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Device:	BinaxNOW COVID-19 Antigen Self Test
EUA Number:	EUA210264
Company:	Abbott Diagnostics Scarborough, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven days of symptom onset. Adult collected anterior nasal (nares) swab samples from individuals aged two years or older with symptoms of COVID-19 within the first seven days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged two years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

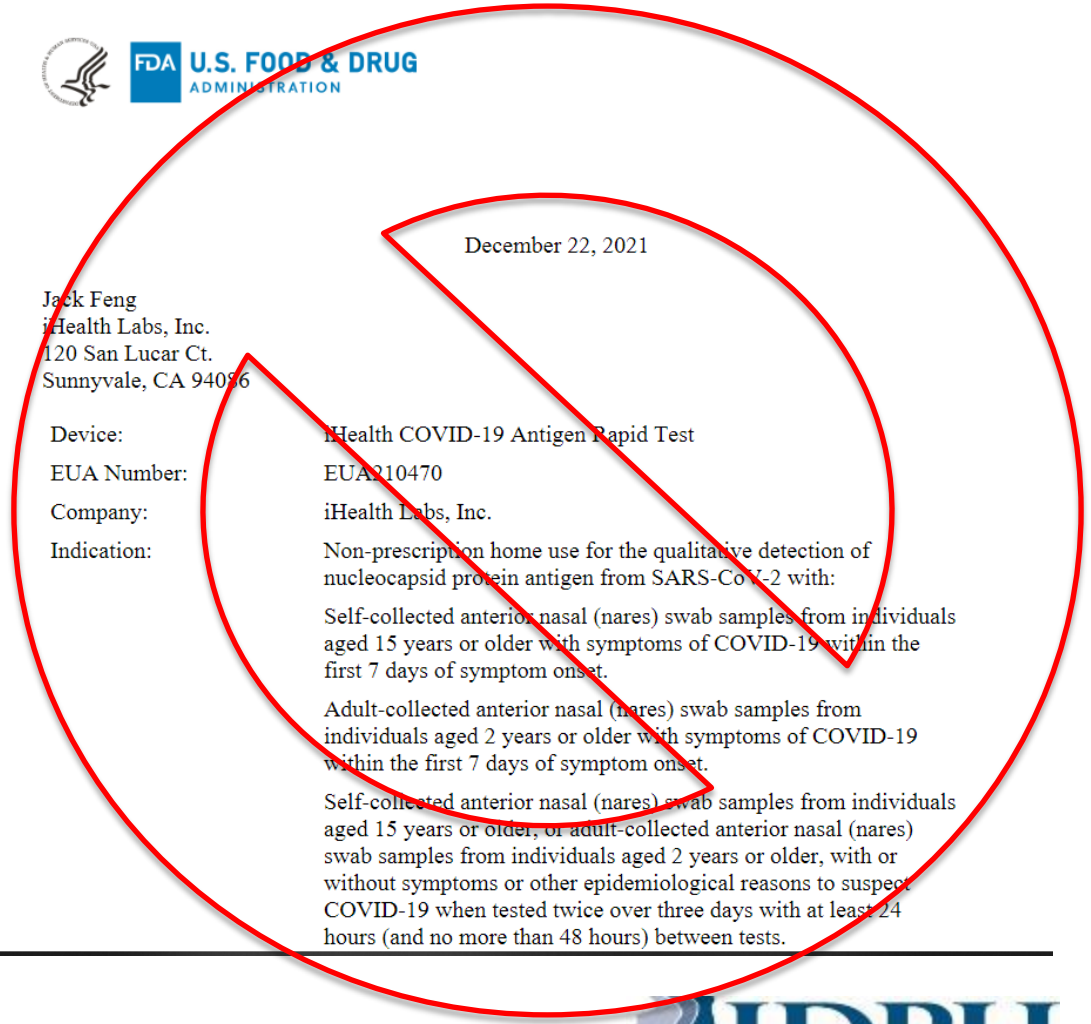
iHealth RX vs. iHealth Non-prescription

U.S. FOOD & DRUG ADMINISTRATION

January 14, 2022

Jack Feng
iHealth Labs, Inc.
120 San Lucar Ct.
Sunnyvale, CA 94086

Device:	iHealth COVID-19 Antigen Rapid Test Pro
EUA Number:	EUA210536
Company:	iHealth Labs, Inc.
Indication:	Qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct anterior nasal swab samples from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	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 product is 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.



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Tips to Make Sure Tests Can Be Used in Healthcare and Congregate Care From FDA Letter and IFU

YES

- *Emergency use of this test is limited to authorized laboratories*
- *Authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver*
- *Swab specimen is collected from the patient,*

NO

- *Non-prescription home use*
- *Self Test*

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Tips To Determine How Tests Can be Used in Healthcare and Congregate Care from FDA Letter and IFU

ASYMPTOMATIC AND SYMPTOMATIC

- *Individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset* ***or from individuals without symptoms or other epidemiological reasons to suspect COVID-19***

ONLY SYMPTOMATIC

- *Individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.*

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Open Q&A

Submit questions via Q&A pod to **All Panelists**

Please do not resubmit a single question multiple times

Slides and recording will be made available after the session.

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Reminders

- SIREN Registration
  - To receive situational awareness from IDPH, please use this link to guide you to the correct registration instructions for your public health related classification: http://www.dph.illinois.gov/siren

- NHSN Assistance:
  - Contact Telligen: **nursinghome@telligen.com**