Indiana Department of Health

Indiana Family & Social Services Administration

BINAXNOW™ – AN INFORMATIONAL SESSION FOR CONGREGATE RESIDENTIAL AND SHELTER PROVIDERS

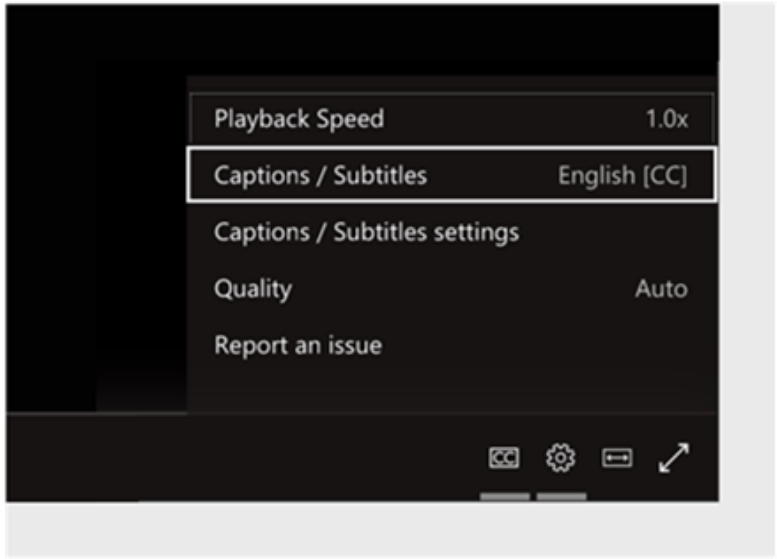
DECEMBER 17, 2020

Before We Get Started...

How to Use Live Captions

To turn on live captions and subtitles, select **Captions/Subtitles On** in your video controls.

To change the caption language, select **Settings** > **Captions / Subtitles**, and choose the language you want.



How to Ask a Question

1.) Select Q&A on the right side of the screen

2.) Type your question in the compose box, and then select Send.

3.) Your question will only be visible to the presenters

4.) Questions will be answered as time permits.

WELCOME AND TODAY'S AGENDA

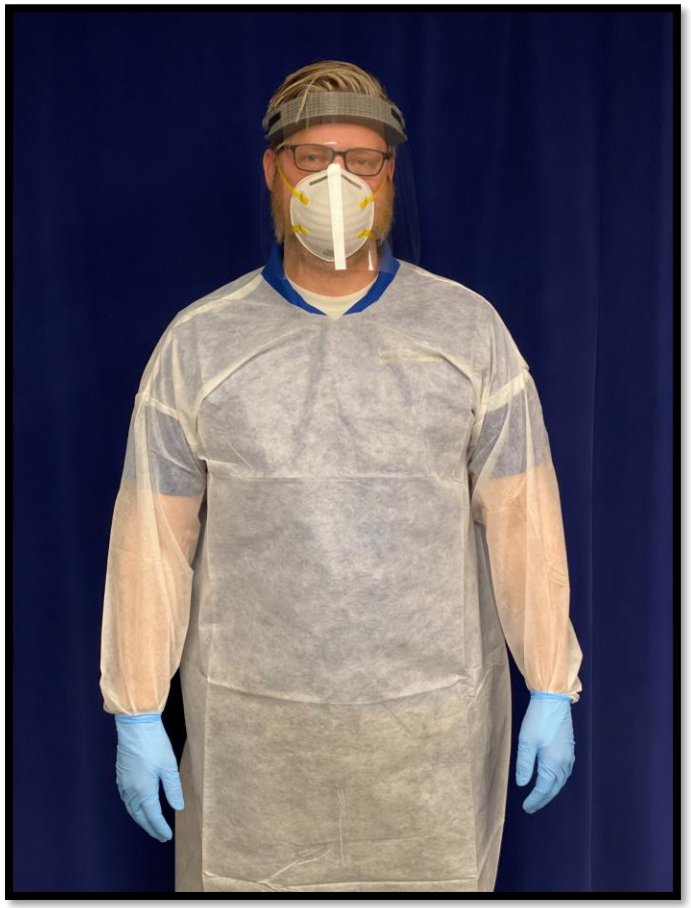
- Introduction
  - Rachel Lane, Chief Transformation Officer, Family and Social Services Administration
  - Kim Opsahl, Associate Director, Division of Disability and Rehabilitative Services
- Session Overview
  - Dr. Sara Blosser, PhD, D(ABMM), Program Manager, Indiana Department of Health COVID-19 Laboratory Testing Network
- Safety: Personal Protective Equipment (PPE); Patient Interaction: Requisition & Swabbing; Performing the BinaxNOW™ Test
  - Brandon Halleck, Linkage to Care Manager, Indiana Department of Health
  - Andrea Thurlow, Project Manager, Indiana Department of Health COVID-19 Laboratory Testing Network
- Reporting Requirements – Dr. Sara Blosser
- Applying for a CLIA Waiver – Dr. Sara Blosser
- Program Goals
  - Dr. Dan Rusyniak, MD, Chief Medical Officer, Family and Social Services Administration
- Wrap-Up and Q&A

SAFETY: PERSONAL PROTECTIVE EQUIPMENT (PPE)

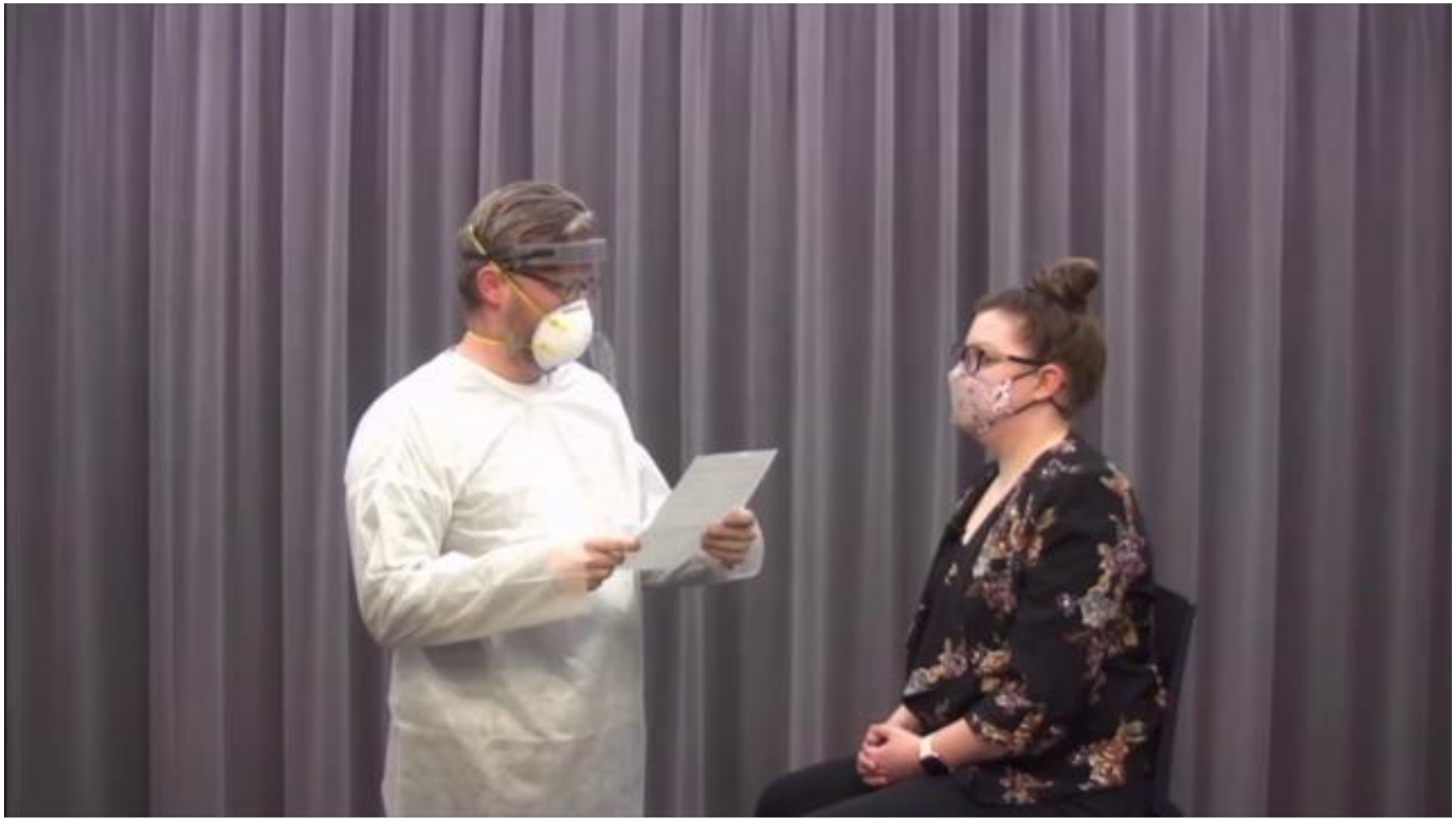
The following PPE is required for BinaxNOW specimen collection:

- Gown
- Mask
- Face shield or goggles
- Gloves

If the patient is self-swabbing, the tester only needs to wear gloves.



PATIENT INTERACTION: REQUISITION AND SWABBING



PATIENT INTERACTION: REQUISITION & SWABBING

Not Included in Kit:

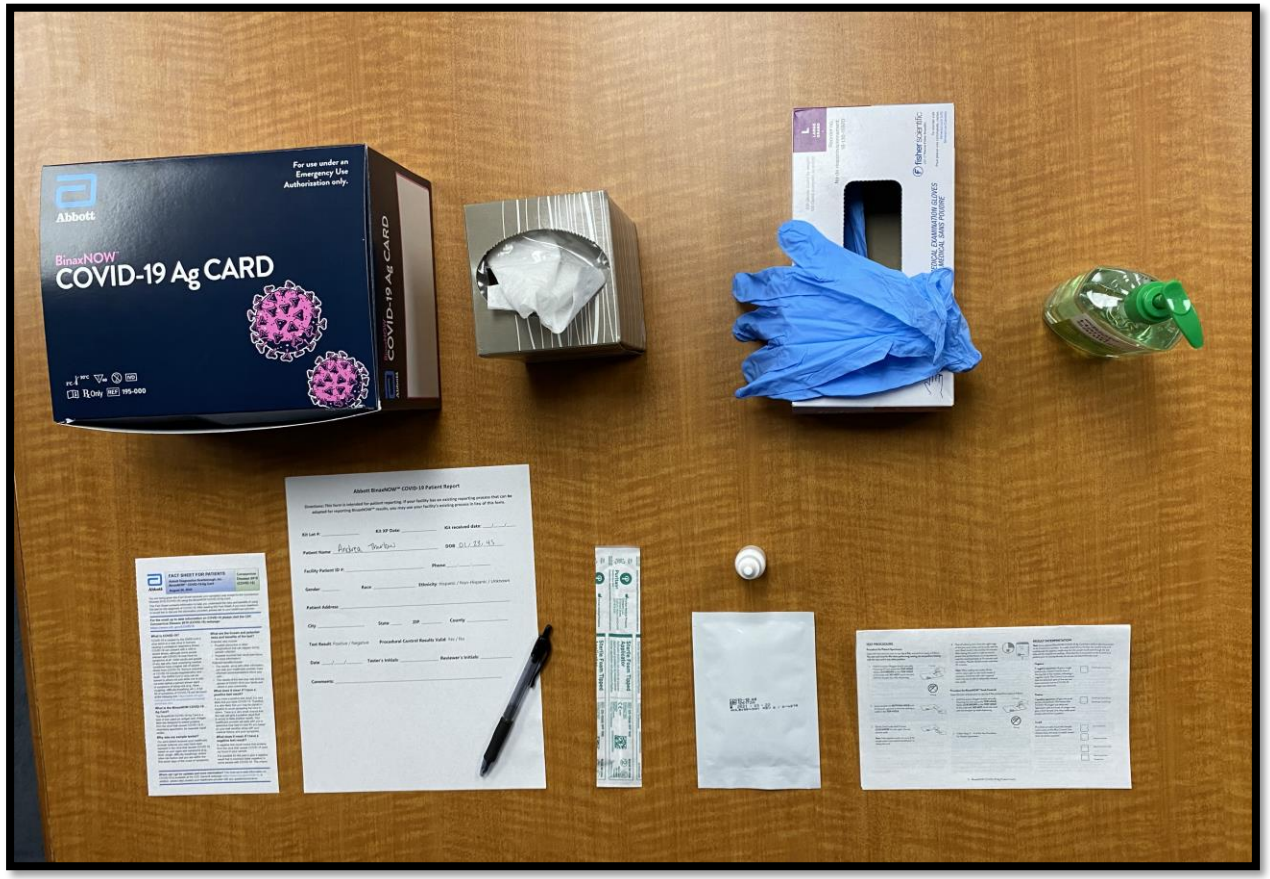
- Blank Patient Report
- QC Logs
- PPE for Testing Personnel
- Timer
- Tissues
- Access to hand washing stations AND hand sanitizer
- Disinfecting supplies
- Office supplies – pen, blank paper (for printing reports)
- Timer (DO NOT USE CELL PHONE)
- A flat surface to perform the testing – away from the nurse's station

Included in Kit:

- Patient Collection Nasal Swab
- Test Card
- Reagent
- Patient Fact Sheet
- Product Insert (Test Procedure)

PATIENT INTERACTION: REQUISITION & SWABBING

Specimen Collection Set-up



PATIENT INTERACTION: REQUISITION & SWABBING

Explain the procedure to the patient before swabbing

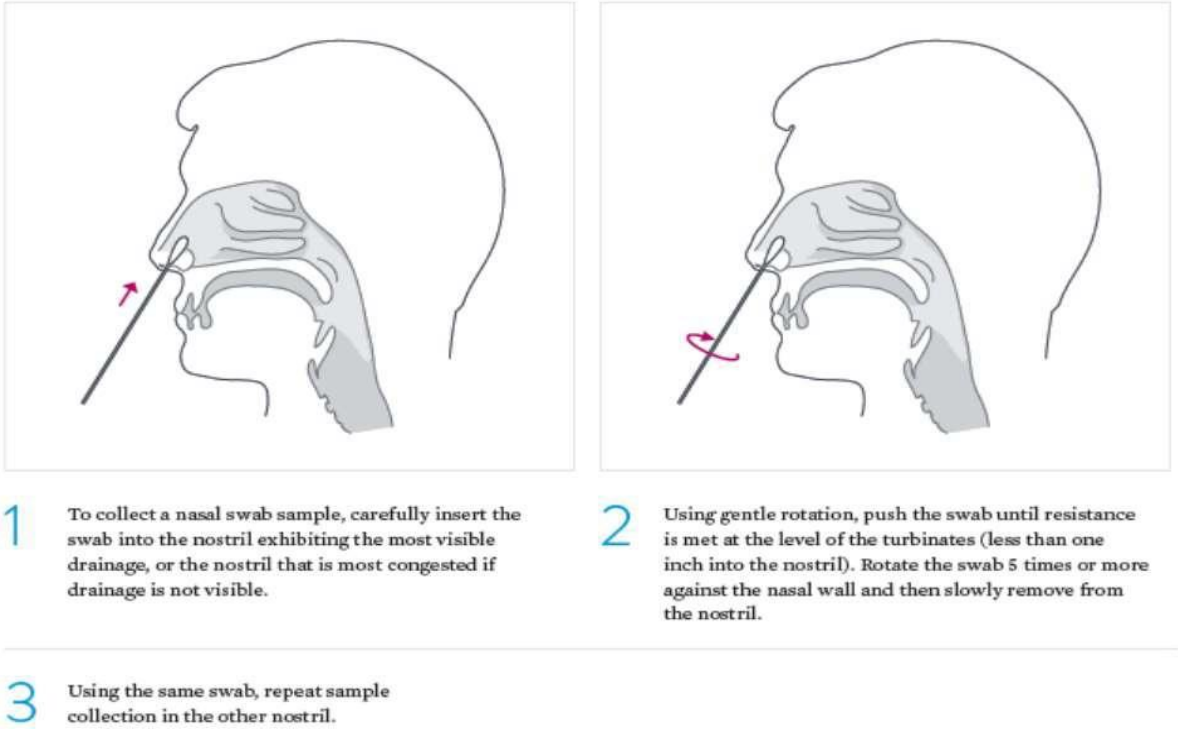
Key things to highlight:

- Swab will be inserted less then an inch into the nose and rotated 5 times. Same process will be repeated on the other side.
- The BinaxNOW test is a rapid COVID-19 test. Results will be available 15 minutes after starting the test.
- If the patient is experiencing nasal congestion, have them blow his/her nose before swabbing.
- Before swabbing, have the patient sit in a chair, back against a wall. If the patient is self-swabbing, standing may be more comfortable.

PATIENT INTERACTION: REQUISITION & SWABBING

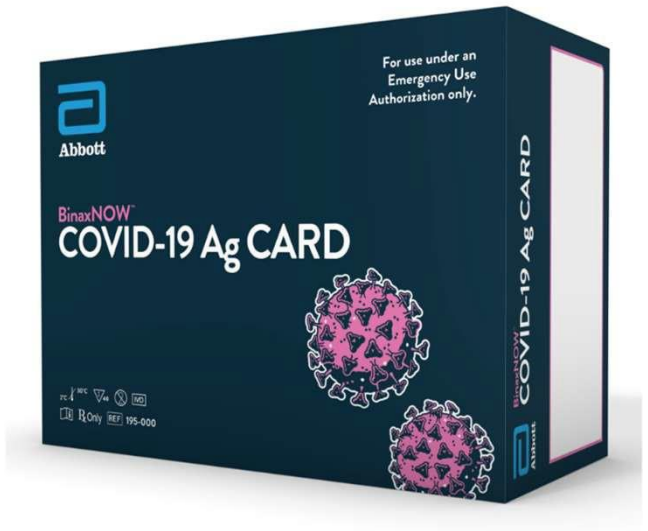
Swab the patient or have the patient to self-swab.

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
  - At the level of the nasal turbinates
  - Less than one inch into nostril
- Rotate the swab 5 times or more against the nasal wall
- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril



PERFORMING THE BINAXNOW™ TEST

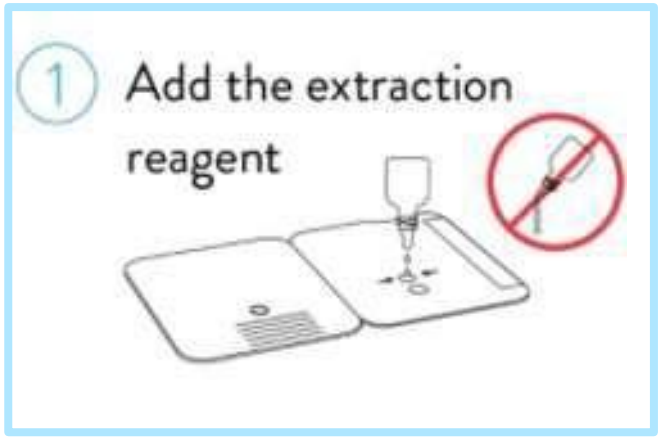
- **Prior to Beginning a Test Remember to:**
  - Ensure all components are at room temperature
  - Open test card <u>just prior</u> to use
  - Lay test card flat for use
  - Ensure Blue Control Line is present



PERFORMING THE BINAXNOW™ TEST

Step 1:

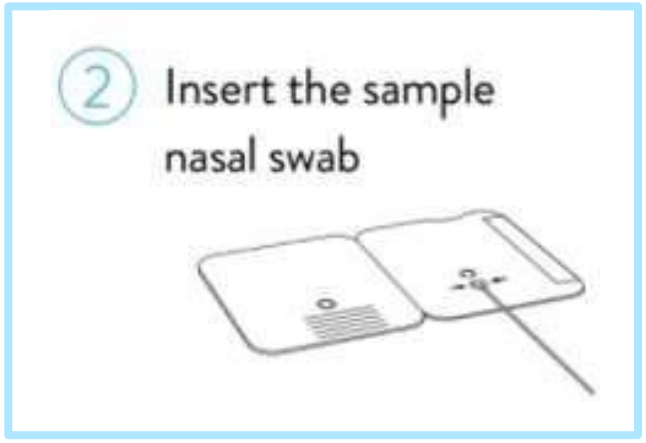
- Hold extraction reagent bottle **vertically** to ensure adequate volume
- Add 6 drops for a Patient test
- Add 8 drops for a Quality Control test



PERFORMING THE BINAXNOW™ TEST

Step 2:

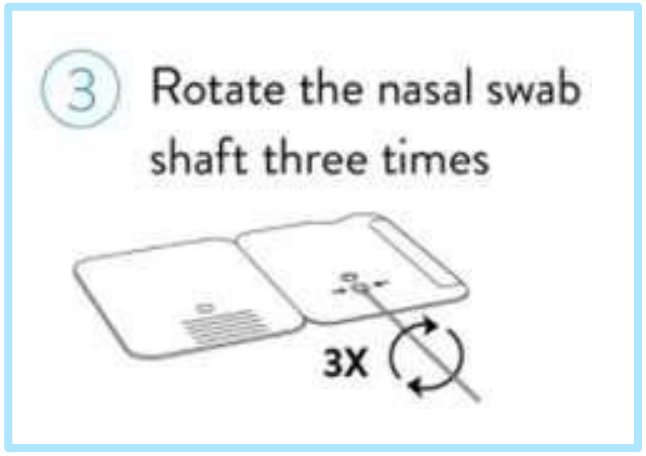
- Insert swab into the bottom hole of the test card
- Firmly push swab upwards until the swab tip is visible in the top hole



PERFORMING THE BINAXNOW™ TEST

Step 3:

- Rotate swab shaft **3 times** CLOCKWISE (to the right).
- False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card



PERFORMING THE BINAXNOW™ TEST

Step 4:

- Peel off adhesive liner from the right edge of the test card
- Close and securely seal the card
- To ensure proper test performance read results at **15 minutes** and not before
- Results should not be read after 30 minutes

PERFORMING THE BINAXNOW™ TEST – RESULTS INTERPRETATION

Negative

- **One pink/purple colored line** in the top half of the window, in the Control Line position
- Indicates a negative result & no antigen detected

Positive

- **Two pink/purple colored lines** in both the Control & Sample Line position
- Indicates COVID-19 antigen was detected
- Any visible pink/purple line is positive

PERFORMING THE BINAXNOW™ TEST – INVALID RESULTS

The assay is invalid & should be repeated if:

- Only the Sample Line is present
- No lines are present
- Blue Control Line remains blue

PERFORMING THE BINAXNOW TEST - DOCUMENTATION

Abbott BinaxNOW™ COVID-19 Patient Report

Directions: This form is intended for patient reporting. If your facility has an existing reporting process that can be adapted for reporting BinaxNOW™ results, you may use your facility's existing process in lieu of this form.

Kit Lot #: _____ **Kit XP Date:** _____ **Kit received date:** ____/_____/____

Patient Name: _____ **DOB:** _____/_____/_____

Facility Patient ID #: _____ **Phone:**_____-_____-_____

Gender: _____ **Race:** _____ **Ethnicity:** Hispanic / Non-Hispanic / Unknown

Patient Address: _____

City: _____ **State:** _____ **ZIP:** _____ **County:** _____

Test Result: Positive / Negative **Procedural Control Results Valid:** Yes / No

Date: _____/_____/_____ **Tester's Initials:** _____ **Reviewer's Initials:** _____

PERFORMING THE BINAXNOW TEST - DOCUMENTATION

Complete this form each time positive and negative controls are run.

BinaxNOW™ COVID-19 Ag Card External Quality Control Log

Abbott recommends that external positive and negative controls be run:

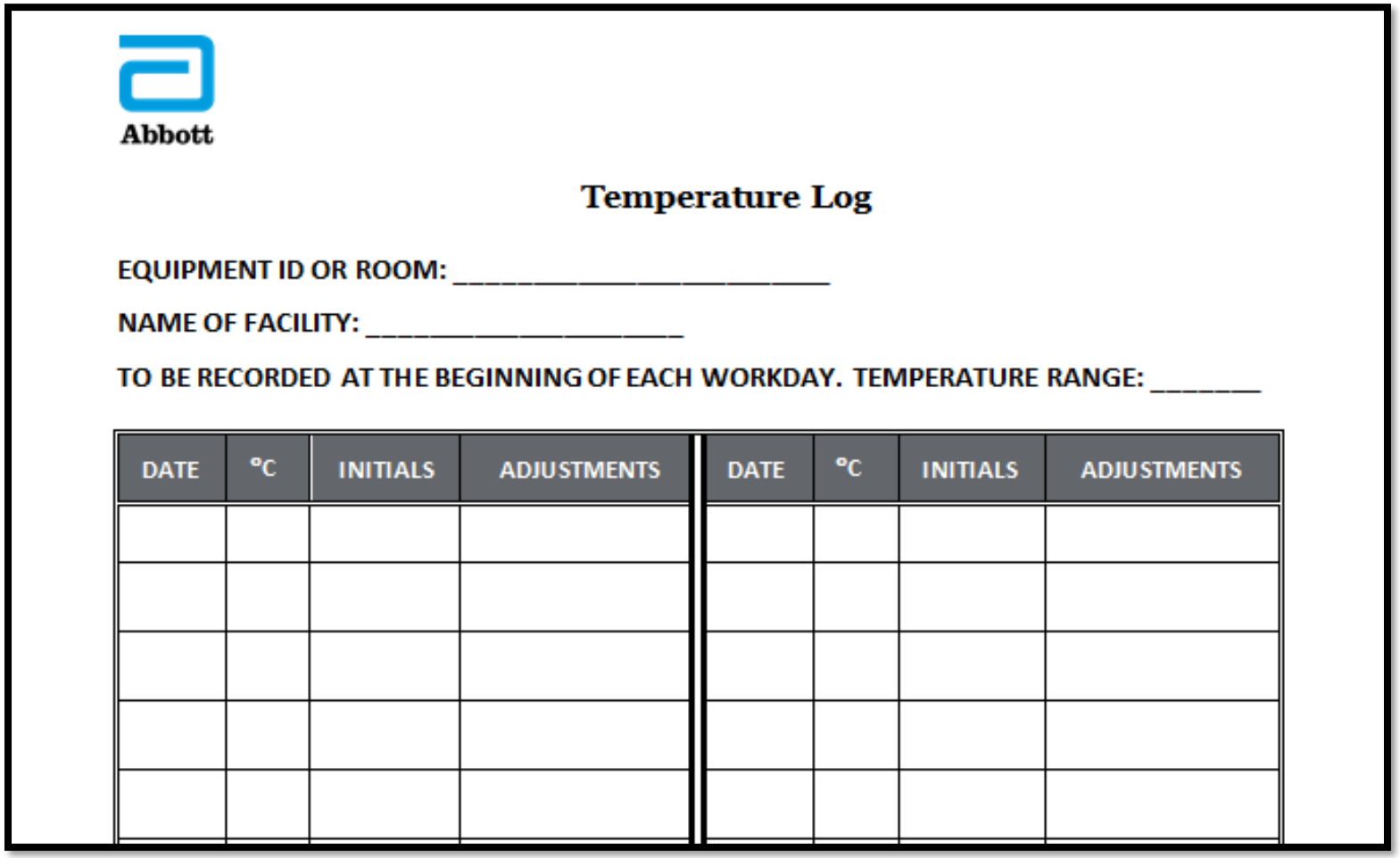
- Once with each new shipment received
- Once for each untrained operator
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

If the expected external control results are not obtained, do not report patient results. Contact Technical Service at 800-257-9525.

DATE	BinaxNOW™ COVID-19 Ag CARD KIT LOT/EXP	DATE SHIPMENT RECEIVED	POSITIVE CTRL LOT/EXP	NEGATIVE CTRL LOT/EXP	POSITIVE RESULT	NEGATIVE RESULT	CONTROL LINE PRESENT: Y/N	TESTER'S INITIALS	CORRECTIVE ACTION / COMMENTS

REVIEWED BY: _____ **DATE:** _____

PERFORMING THE BINAXNOW TEST - DOCUMENTATION



Abbott

Temperature Log

EQUIPMENT ID OR ROOM: _____

NAME OF FACILITY: _____

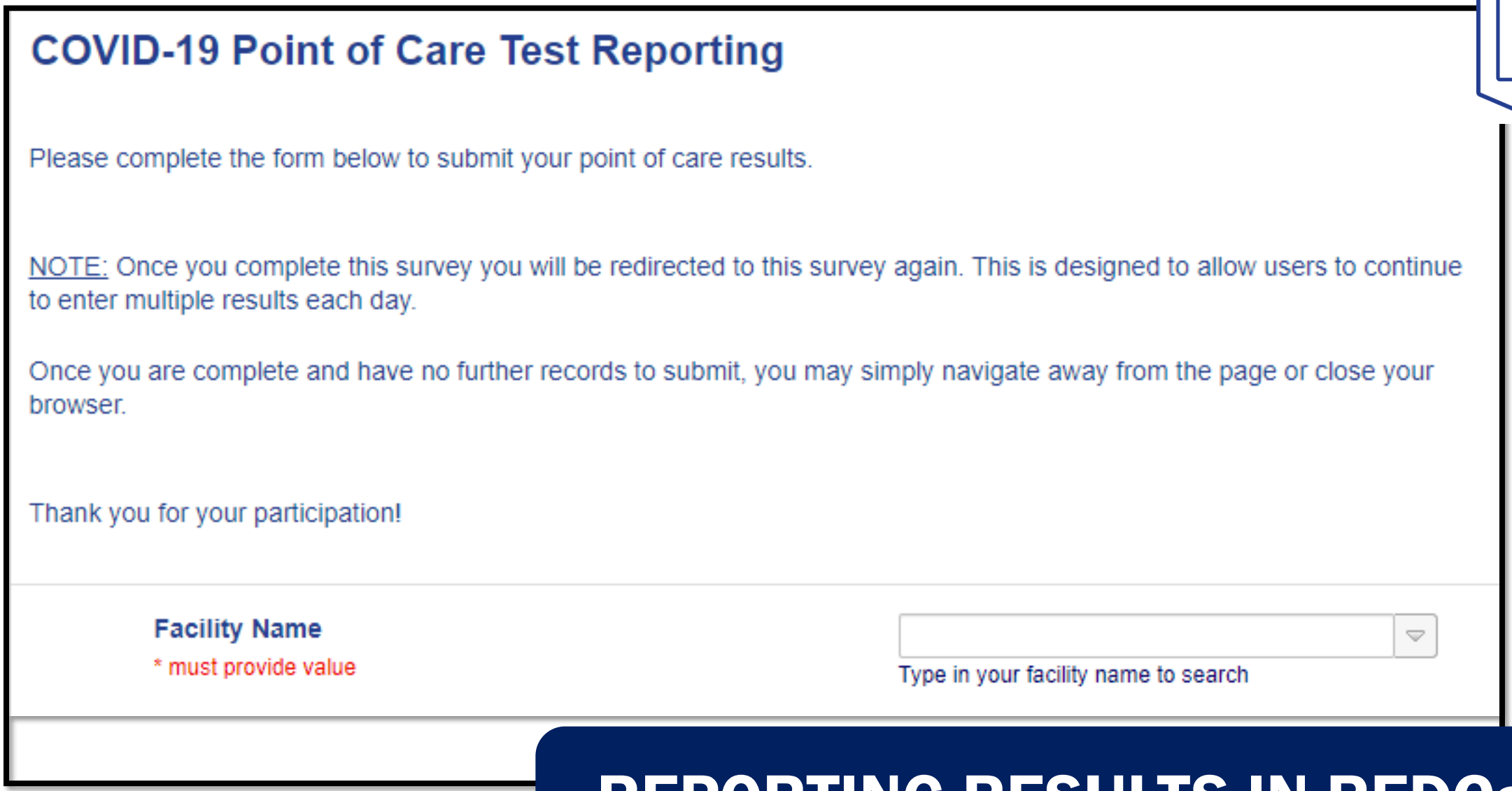
TO BE RECORDED AT THE BEGINNING OF EACH WORKDAY. TEMPERATURE RANGE: _____

DATE	°C	INITIALS	ADJUSTMENTS	DATE	°C	INITIALS	ADJUSTMENTS

REPORTING REQUIREMENTS

All COVID-19 tests are required to be submitted to the Indiana Department of Health, both negative and positive, within 24 hours of testing.

BinaxNOW™ can be easily reported to the state by using REDCap, a web-based reporting system.



Indiana Department of Health

REPORTING RESULTS IN REDCap

WHAT IS THE REDCap REPORTING FORM?

The REDCap COVID-19 Point of Care Test Reporting form is an online form developed by the Indiana Department of Health to allow point-of-care facilities to easily report COVID-19 test results. REDCap reporting is required for participating facilities. Use of the form ensures that Point of Care testing results are captured in the State's surveillance data. The REDCap form was developed with ease-of-use in mind. For a full example of the form and information on how to complete it, please see the following slides.

Click the link below to access the REDCap form:

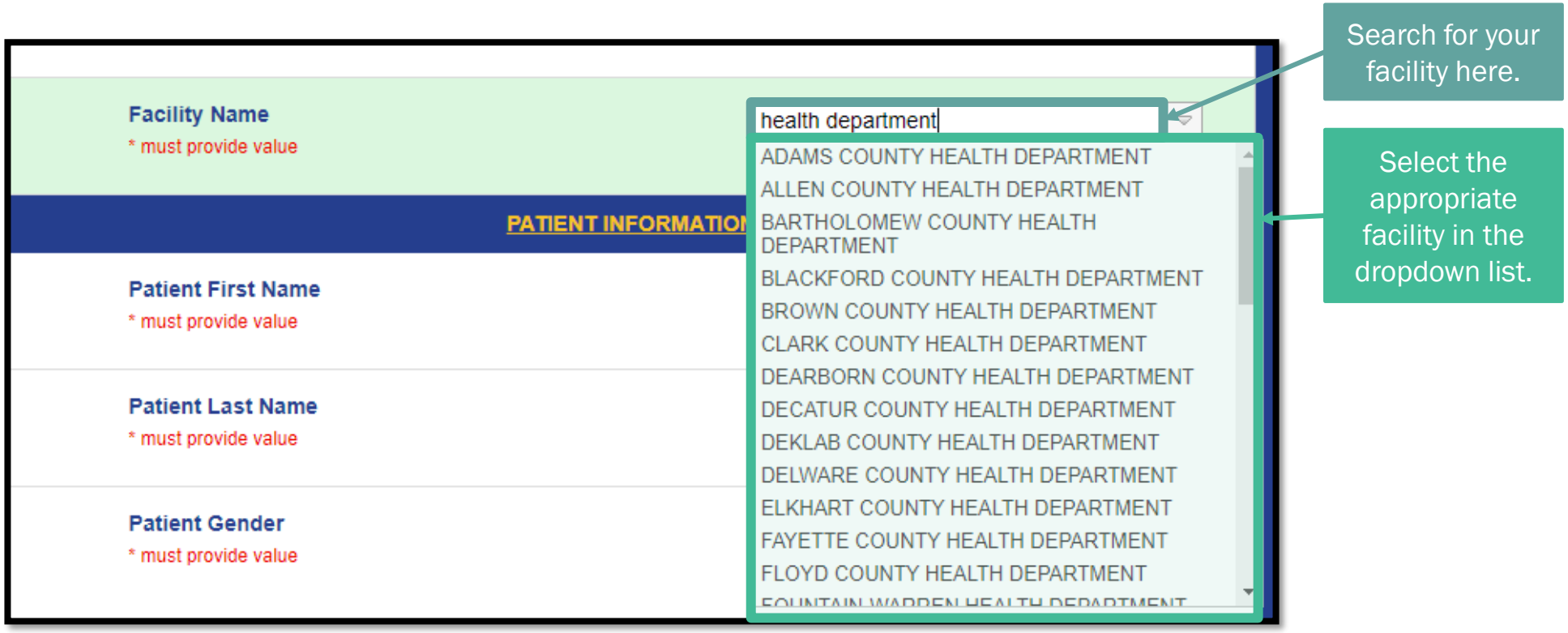
COVID-19 Point-of-Care Test Reporting - Indiana Department of Health REDCap

HOW DO I USE THE REDCap REPORTING FORM?

Use the link on the previous slide to access the form. You will see the following screen.

HOW DO I USE THE REDCap REPORTING FORM?

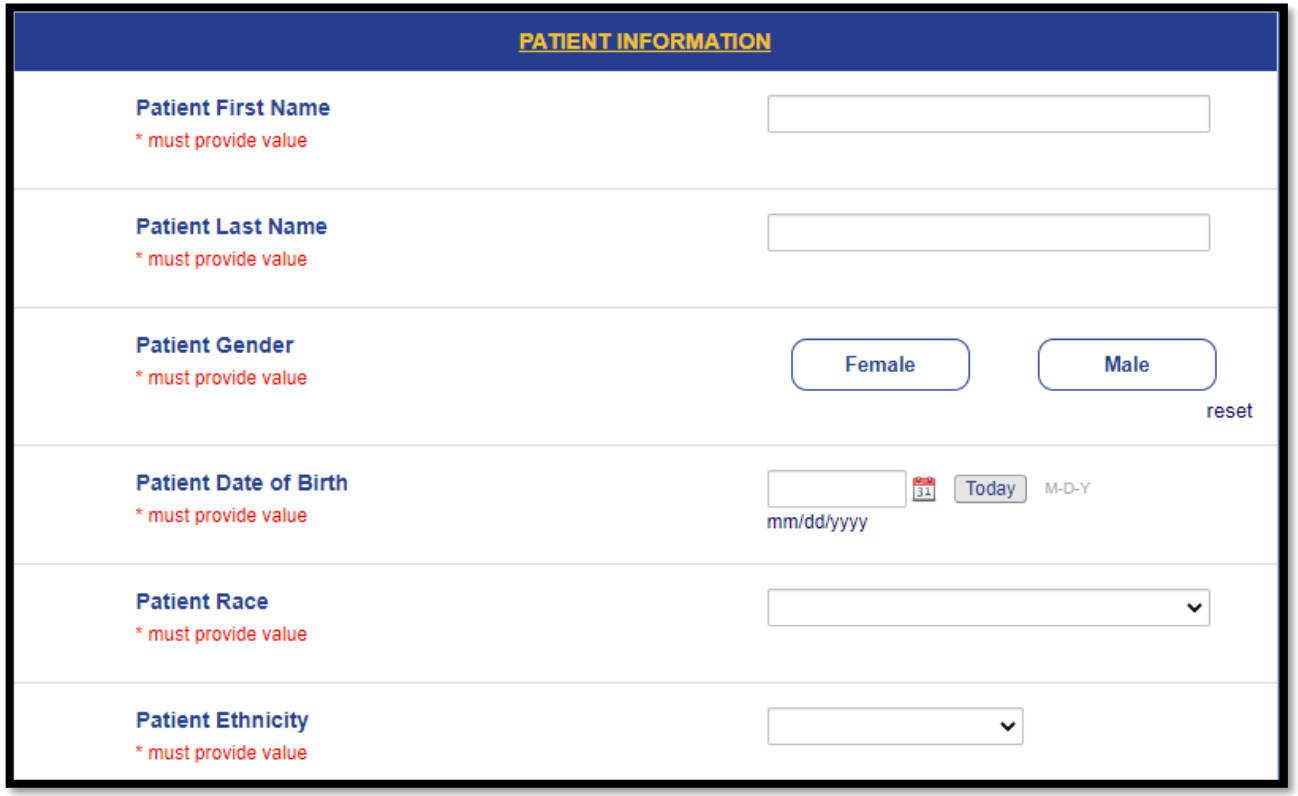
Search for your facility in the search box shown below and select the appropriate facility from the dropdown list.

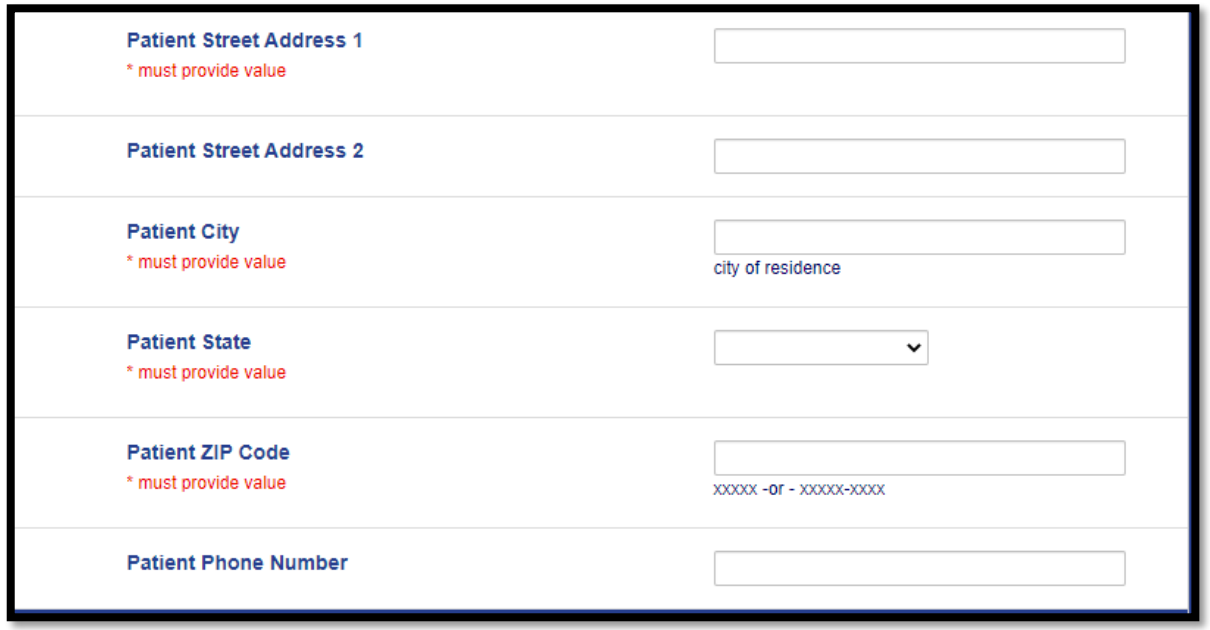


If your facility is not on the list, please email Kelly White at KeWhite@isdh.in.gov to be enrolled.

HOW DO I USE THE REDCap REPORTING FORM?

Enter the patient's first and last name, gender, date of birth, race, ethnicity, full address and phone number in the patient information section.





APPLYING FOR A CLIA WAIVER

Why do I need a CLIA Waiver?

A CLIA Certificate of Waiver is required for labs and point-of-care facilities that intend to perform tests that are categorized as waived tests according to the FDA. This includes the BinaxNOW™.

What is the purpose of a CLIA Waiver?

"Some waived tests have potential for serious health impacts if performed incorrectly….. To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed."

https://www.cdc.gov/labquality/waived-tests.html

Do you want to apply for a CLIA waiver?

Start by completing the attached testing requirement checklists:

1. CLIA-waived Testing Checklist
2. Abbott BinaxNOW Testing Checklist (if your site is to perform BinaxNOW testing)

General Checklist for CLIA-Waived Testing

Regulatory Requirements

Activity	Yes	No	N/A
Do you have a current CLIA Certificate of Waiver (CW)?			
Do you renew the Certificate of Waiver every 2 years?			
Do you perform only CLIA waived tests?			

Bold items require records.

Additional Checklists for CLIA-Waived Testing

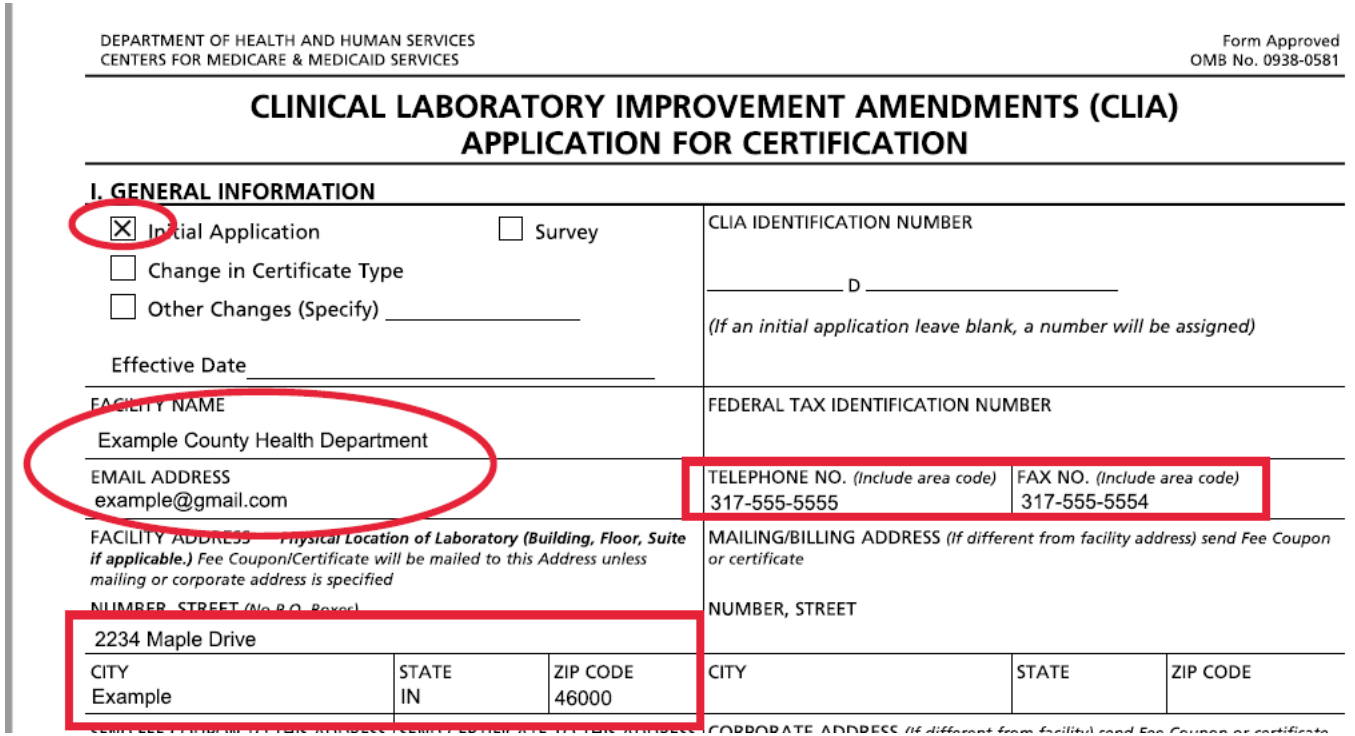
BinaxNOW

Activity	Yes	No	N/A
Do you store the BinaxNOW cards at 2-30°C?			
Do you ensure that the BinaxNOW cards are at room temperature before using them?			
Do you record the acceptability of procedural controls for each patient card?			
Do you record the positive QC swab result for each new shipment?			
Do you record the positive QC swab result for each new training?			
Do you record the negative QC swab result for each new shipment?			
Do you record the negative QC swab result for each new training?			

Checklists for each of these items are included in the training packet … or you can create your own!

1 **Click here to complete form CMS-116**

1. An example of the completed form is attached for your reference.
2. Please list the manufacturer name as well as the specific name of the COVID-19 test you will perform.
3. There may be a delay if we cannot determine the actual test. If you review the **FDA EUA website**, you can see there are many similar names for the COVID testing and several have very different authorizations depending on the manufacturer or methodology.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☒ Initial Application ☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____

Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME
Example County Health Department

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS
example@gmail.com

TELEPHONE NO. *(Include area code)*
317-555-5555

FAX NO. *(Include area code)*
317-555-5554

FACILITY ADDRESS ***(Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*
2234 Maple Drive

CITY	STATE	ZIP CODE
Example	IN	46000

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY	STATE	ZIP CODE

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

2 Complete Enclosure A (attached).

1. Please also provide the ownership documents listed on page 1 of Enclosure A: IRS Letter of Tax ID (e.g. Form W-9) and Secretary of State Certification.

NOTE: The Secretary of State Certification is only for Partnerships, Corporations, or Limited Liability Companies.

Indiana Department of Health Acute Care Division
CLIA Certification Program

ENCLOSURE A

DISCLOSURE OF OWNERSHIP REQUIRED INFORMATION

*Facility (Legal Business Name): _____

*DBA (Doing Business As name): _____

CLIA #: _____ (if assigned) Current EIN #: _____

I. Provide a copy of the IRS letter of assignment of your Employer Identification Number (EIN) or tax ID (TIN) showing the 9-digit number, e.g., 12-3456789.

II. Type of Entity:

For Profit	Non-Profit	Government
☐ Individual	☐ Church Related	☐ State
☐ Partnership*	☐ Individual	☐ County
☐ Corporation*	☐ Partnership*	☐ City
☐ Limited Liability	☐ Corporation*	☐ City/County
☐ Company*	☐ Limited Liability Company*	☐ Hospital District
☐ Other *(specify)*	☐ Other *(specify)*	☐ Federal
		☐ Other *(specify)*

3. **Submit both completed forms to the CMS Surveyor approximately 6 weeks prior to the desired testing start date. Forms may be submitted via email, fax or postal mail.**
    1. **Email:** lswitzer@isdh.in.gov or klara@isdh.in.gov
    2. **Fax:** 317-233-7157
    3. **Postal Mail:** Indiana Department of Health, Attn: CLIA Program
       2 North Meridian St, Rm 4A, Indianapolis, IN 46201
4. **Receive your facility's CLIA number from the CMS office by mail or email (1-6 weeks).**
5. **Your facility may now conduct the requested CLIA-waived testing per the following CMS Memorandum: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency.**

   NOTE: Each CLIA-waived facility will need to develop and operate under a record retention policy.
6. **Pay the CLIA certification application fee ($180).**

PROGRAM GOALS – HOMELESS SHELTERS

- Equip Homeless Shelters with access to BinaxNOW™ cards in order to rapidly identify positive cases to help with co-horting and contact tracing.
  - Testing materials are limited and should be used judiciously
  - Consider limiting use to symptomatic individuals and those that they have been in direct contact with
- Homeless Shelters will be able to access materials using the IDOH order form and sharing the following information:
  - their CLIA number and
  - the number of beds they have

PROGRAM GOALS – BDDS CONGREGATE RESIDENTIAL SETTINGS

- Equip BDDS Congregate Residential Settings with access to BinaxNOW™ cards in order to rapidly identify positive cases to help with co-horting and contact tracing.
  - Testing materials are limited and should be used judiciously
  - Use should be limited to helping to identify outbreaks by testing symptomatic individuals and those that they have been in direct contact within the setting
  - Tests are not being provided to conduct asymptomatic staff testing
- BDDS congregate residential providers will only receive one shipment of BinaxNOW™ cards, so they should only be used for the purposes identified above.