CLINICAL LABORATORY PERMIT

pennsylvania
DEPARTMENT OF HEALTH

Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 38091

Name and Director of Laboratory:

HMS SCHOOL FOR CHILDREN WITH CEREBRAL PALSY
LAURA L. OWENS, M.D.
4400 BALTIMORE AVE.
PHILADELPHIA, PA 19104

Owner:

TOM QUINN, PRESIDENT

ISSUE DATE: January 05, 2021

DATE EXPIRES: August 15, 2021

AUTHORIZED CATEGORIES/TESTS:

VIROLOGY

COVID-19 (Waived by EUA)

Rachel L. Levine, MD
Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY

This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.

HMS SCHOOL FOR CHILDREN WITH CEREBRAL PALSY
LAURA L. OWENS, M.D.
4400 BALTIMORE AVE.
PHILADELPHIA, PA 19104

pennsylvania
DEPARTMENT OF HEALTH
Phone: (610) 280-3464
Fax: (610) 450-1932

January 05, 2021

38091
LAURA L. OWENS, M.D.
HMS SCHOOL FOR CHILDREN WITH CEREBRAL PALSY
4400 BALTIMORE AVE.
PHILADELPHIA, PA 19104

Dear Dr. Owens:

Your application for a Clinical Laboratory Permit under the Clinical Laboratory Act of Pennsylvania has been received in this office.

[ ] The Department must be notified in writing which proficiency testing program your lab is enrolled with. Proof of enrollment would be an invoice, order confirmation from the PT provider or a copy of your grades. (A list of approved agencies is enclosed)

[ ] Prelicensure testing samples must be evaluated and results returned to our office. (To be sent in a separate mailing)

[X] Approved for COVID -19 testing Waived by EUA. Facility must report all COVID-19/SARS-CoV-2 results, positive and negative, to Pennsylvania's reportable disease surveillance system on a daily basis. To set up an account with the system, email PA-NEDSS@PA.GOV as soon as possible."

Remember, no patient testing may be performed until a permit has been granted.

We encourage your laboratory to maintain compliance with all CLIA and State regulations. The director shall be responsible for the proper performance of all tests in the laboratory and the continuous application of quality control procedures to the work in accordance with recommendations and directives of the Department (Title 28 Chapter 5).

Should you have any questions concerning the prelicensure requirements, please do not hesitate to contact this office.

Sincerely,

Pamela Groff, Administrative Assistant
Division of Laboratory Improvement
(484) 870-6425
pgroff@pa.gov

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Point of Care Testing for COVID-19

Overview

Testing at the point-of-care (POC) for COVID-19 adds a distinct advantage—rapid availability of results upon which to make treatment and infection prevention and control decisions. The clinical performance of POC tests depend on the circumstances in which they are used and how carefully the test is performed. They need to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed. In addition, the clinical status (e.g., symptomatic, exposed) of individuals being tested also needs to be considered when performing and interpreting the results of these tests. Reporting of results to Pennsylvania's electronic disease surveillance system, PA-NEDSS is mandated by law and becomes the responsibility of the facility conducting the testing.

Types of Tests

At present, the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for POC testing for COVID-19 via two types of tests: molecular detection and antigen detection.

Molecular detection tests use nucleic acid amplification technology (NAAT) for the qualitative detection of viral nucleic acids found in the RNA of the target virus. This is the same technology used by most clinical laboratories to detect SARS-CoV-2, the virus that causes COVID-19. This type of test has high sensitivity and specificity, but test performance varies by manufacturer and depends on proper specimen collection.

Antigen detection tests will react to the detection of nucleocapsid antigens. These antigens are generally detectable in the respiratory system during the acute stage of infection. Antigen tests are very specific but not as sensitive as molecular detection tests. This means that a positive antigen test is highly accurate, but there is a greater chance of false-negative results (i.e. a person who is infected will still test negative) with this test type.

POC testing can be used for diagnostic purposes or for screening. Testing is considered diagnostic when used to identify current infection in a person who has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2. Testing is considered screening when used for persons who are asymptomatic and do not have known or suspected exposure to SARS-CoV-2.

The performance of these tests is dependent on pretest probability. Pre-test probability is the chance that the patient has the disease, estimated before the test result is known. Pretest probability should be informed by using a rolling average of the positivity rate over the previous 7-10 days along with clinical context. Pretest probability needs to be considered when interpreting the results of these tests.

Specimen Collection and Testing

Each POC test uses a different method of specimen collection and storage. Carefully follow the Instructions for Use (IFU) for the instrument. Don all required personal protective equipment per PA-HAN-524 including a respirator or a facemask (if respirator is not available), eye protection, clean gown and clean gloves prior to specimen collection. Remove gloves, perform hand hygiene, and don clean gloves between collection or handling of each specimen.

All testing for SARS-CoV-2, including rapid antigen testing, is directly impacted by the integrity of the specimen, which depends on specimen collection and handling. Improper specimen collection may cause some swabs to have limited amounts of viral genetic or antigenic material for detection. Inadequate quality assurance procedures could result in cross contamination of the specimen, which could cause inaccurate test results. Delays from sample collection to testing should be minimized.

Plan and prepare a method for specimen collection and handling that minimizes the potential for specimen contamination, which can occur from specimen-to-specimen or from the provider performing specimen collection or running the test. IFUs should be carefully followed with attention to hand hygiene, glove use, and environmental cleanliness.

Measures should be taken to reduce the risk of result reporting errors by choosing an appropriate patient ID to key enter into the POC instrument and label the collected specimen. The best practice is to use the patient's MRN number or a combination of the full name and date of birth to ensure the results are matched correctly to individual being tested.

Interpreting Results

Clinical presentation and pretest probability should be carefully considered in evaluating results from POC testing platforms. When pre-test probability is low (e.g., absence of compatible symptoms, limited COVID circulation in the community, patient was not exposed to COVID, no outbreaks in the community), there is an increased likelihood of false positives and an increased likelihood of true negatives. When the pre-test probability is high (e.g., presence of compatible symptoms, COVID circulation in the community is high, patient exposed to COVID, outbreaks in the community), there is an increase likelihood of true positives and an increased likelihood of false negatives. These factors must be considered along with proper laboratory techniques when interpreting the results of antigen tests.

Per the FDA EUA, positive results must be used in conjunction with clinical presentation and patient history. Negative results should be treated as presumptive and do not rule out COVID-19. If there is still concern that a person has COVID-19 after a negative POC test, that person should be tested again using a different authorized molecular test. For testing in long-term care facilities, see guidance provided in PA-HAN-526.

CLIA Certification

Facilities utilizing POC tests for COVID-19 must have a Pennsylvania laboratory permit and a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov to assure laboratory compliance.

Training

Facilities must carefully review the Instructions for Use (IFU) and must train staff on the collection of specimens and performance of the test according to the IFU. Use online training videos provided by the company or the package insert instructions. Document staff training and competency.

The Centers for Disease Control and Prevention (CDC) Booklet Ready, Set, Test is a good resource for ensuring that staff has the basic training necessary to safely and accurately

perform POC laboratory testing. An online training which conveys information in this booklet is also available and offers educational credits for a number of different professions. Familiarity with good laboratory techniques will improve the accuracy of results from these POC tests.

Reporting Results to PA-NEDSS

All positive, negative and inconclusive/indeterminate results must be reported within 24 hours to Pennsylvania's electronic surveillance system, PA-NEDSS. Do not report "invalid" results; repeat testing as per the IFU. To request a PA-NEDSS account, complete the PA-NEDSS Prime Contact Information Form and send it to PA-NEDSS@pa.gov. The facility will then receive registration instructions and training materials.

A "prime contact" for the facility will need to be named; the prime contact can then add people who are designated to report on behalf of the facility. Training information will be sent with the registration information. The attached Disease Reporter Guide also provides instructions. The following fields are required:

- Patient name
- Patient date of birth
- Patient address (use the address of the facility for residents; employees must have their residential address reported)
- Patient race and ethnicity
- Patient phone number (can use facility phone number for residents)
- Patient gender
- Test name
    - For molecular detection tests, choose "2019 novel coronavirus nucleic acid detection (rRT-PCR, probe)"
    - For antigen detection tests, choose "2019 novel coronavirus ANTIGEN detection"
- Test information
    - Specimen collection date
    - Test completed date (for point-of-care testing these dates are likely to be the same)

Key training resources for PA-NEDSS include the New User Guide, Disease Reporter Guide, and Technical Bulletin which provides basic technical information for PA-NEDSS.

Additional Requirements

Follow manufacturer's instructions for performance of the test.

Additional Resources

CMS guidance for how to receive a CLIA Certificate of Waiver
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

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Table of Point-of-Care Tests for COVID-19

	Test Type	Authorized Use Under the EUA	Specimen Source	Specimen Type	Detects	FDA EUA Approval Letter*	Instructions for Use*	Healthcare Provider Fact Sheet*	Patient Handout*
Quidel SARS 2 Antigen TIA	Antigen	Persons suspected of having COVID-19[1] within the first five days of the onset of symptoms	Naso-pharyngeal and nasal swab[2]	Direct or in viral transport media (VTM)	SARS-CoV nucleocapsid antigen[3] and SARS-CoV-2 nucleocapsid antigen	May 8, 2020	IFU	Fact Sheet	Patient Handout
BD Veritor System	Antigen	Persons suspected of having COVID-19[1] within the first five days of the onset of symptoms	Nasal swab (dual nares collection method)[2]	Direct specimen only	SARS-CoV-2 nucleocapsid antigen	July 2, 2020	IFU	Fact Sheet	Patient Handout
Abbott ID Now	Molecular	Persons suspected of having COVID-19[1]	Naso-pharyngeal, nasal, or throat swab[2]	Direct specimen only	SARS-CoV-2 viral RNA	June 1, 2020	IFU	Fact Sheet	Patient Handout
Abbott BinaxNOW COVID-19 Ag CARD	Antigen	Persons suspected of having COVID-19[1] within the first seven days of the onset of symptoms	Nasal swab[2]	Direct specimen only	SARS-CoV nucleocapsid antigen[3] and SARS-CoV-2 nucleocapsid antigen	August 26, 2020	IFU	Fact Sheet	Patient Handout

*These resources were obtained from the Food & Drug Administration (FDA) website and are subject to change. This table contains information for select devices. Additional devices are listed on the FDA website. If the links provided no longer function, or you need additional information, we advise going to the FDA COVID-19 Emergency Use Authorization (EUA) website, under the section for COVID Invitro Diagnostic Products. From there, type the name of the test into the search box or browse the list provided.

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Footnotes

1. Individuals suspected of COVID-19 infection or exposure can be symptomatic, pre-symptomatic, or asymptomatic. Diagnostic tests authorized for use on individuals suspected having of COVID-19 by their healthcare provider may be performed on specimens from *certain* asymptomatic individuals (e.g., those who have likely been exposed to an infected individual).
2. Follow the collection procedure outlined in the instructions for use (IFU).
3. The Department of Health has sufficient evidence to conclude that detection of SARS-CoV, the virus that causes SARS, will not be a significant contributor to the detection of antigen using this test based on the current absence of SARS-CoV in the Commonwealth at this time.

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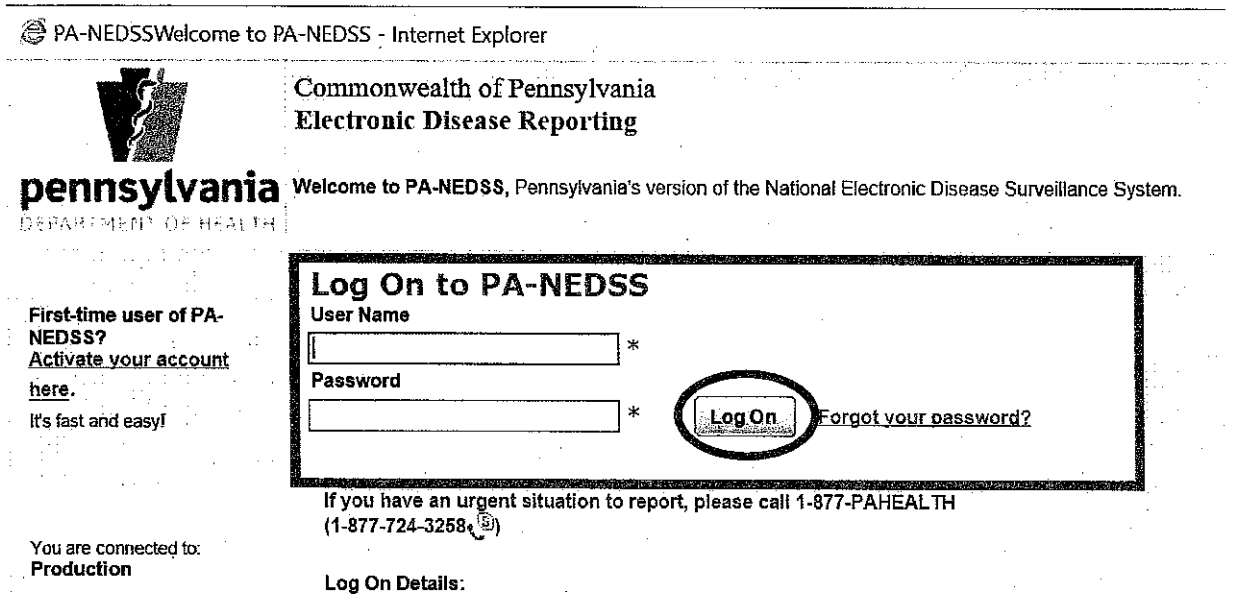
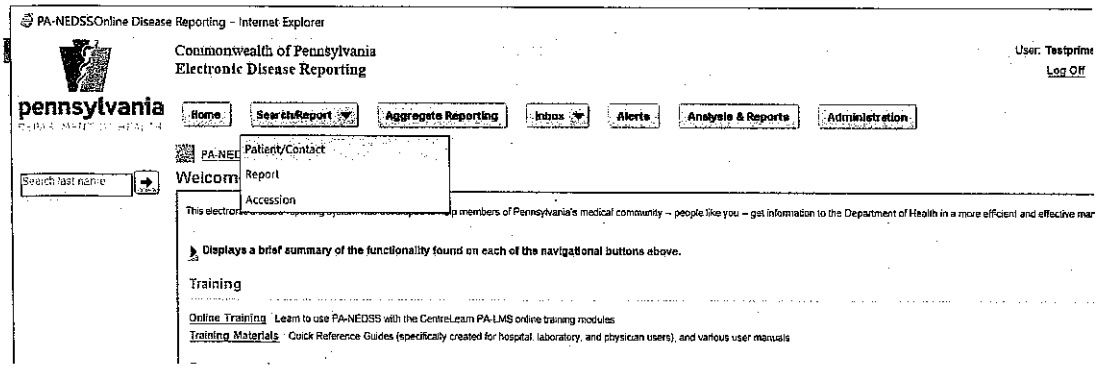
PA-NEDSS Manual Test Reporting Instructions for Point of Care (POC) Tests

Navigate to PA-NEDSS home page at https://www.nedss.state.pa.us/nedss/ NOTE: PA-NEDSS can only be accessed through Internet Explorer. Enter your username and password. Click the Log On button.



Click the Search/Report down arrow. Click the Patient/Contact option.



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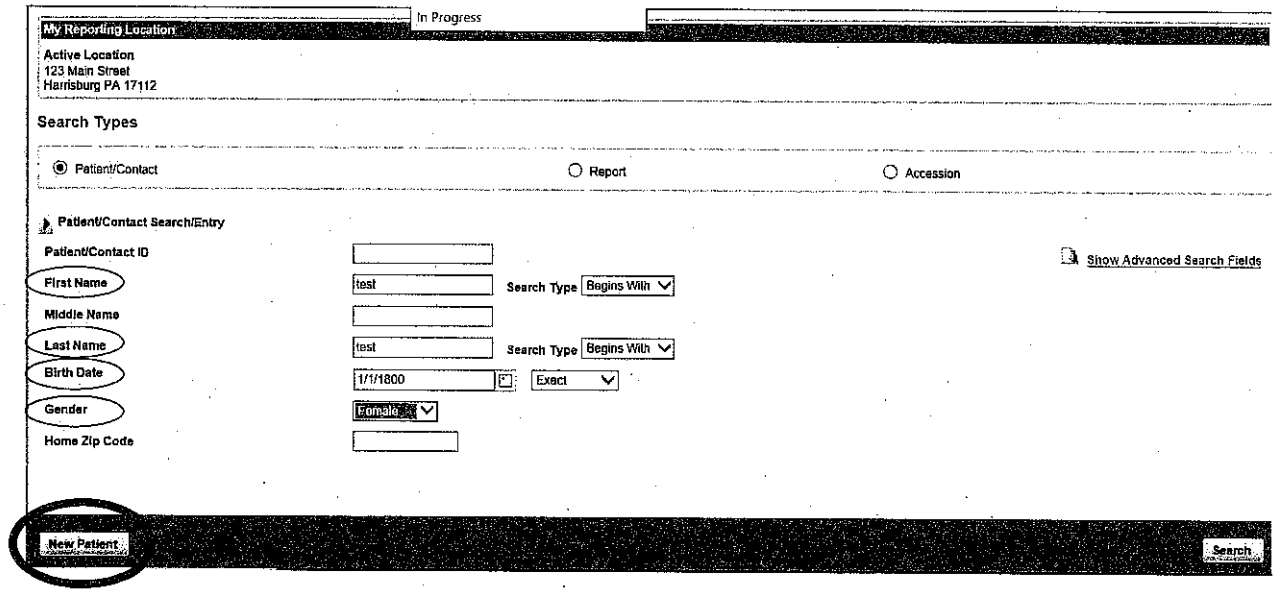
On the next screen fill out the following fields:

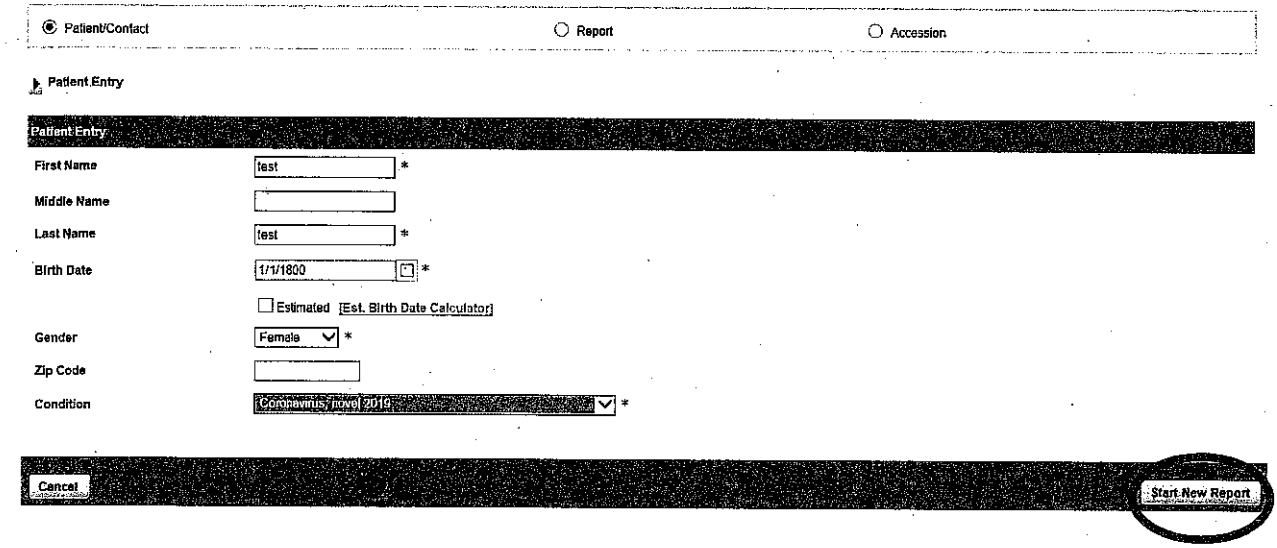
- First name
- Last name
- Birthdate. Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.
- Gender

Click New Patient (bottom left)



Choose condition ***Coronavirus, novel 2019***. Click Start New Report (bottom right).

NOTE: Even if the test is negative, please DO select *coronavirus, novel 2019* as the condition. That just indicates that the report pertains to COVID, it does not mean that the test indicates that the patient has COVID.



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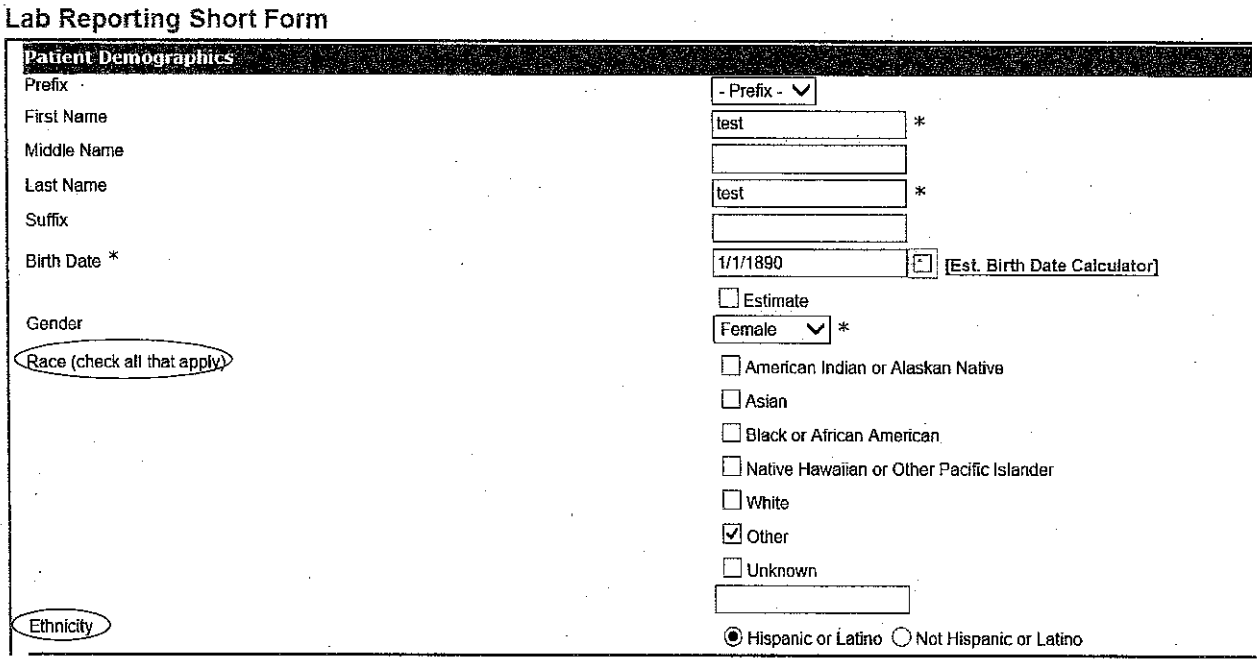
Complete the Patient Demographics section. Name, birthdate, and gender will prepopulate from the initial entry screen. ***Race and ethnicity*** are high priority fields for COVID reporting and should be entered whenever possible. If race is unknown, choose "unknown." If ethnicity is unknown, leave both fields unchecked.

PATIENT DEMOGRAPHICS

Fields on the patient demographics page with red asterisks are required by PA-NEDSS and a report will not be created if these fields are blank.



LOCATION (PRIMARY RESIDENCE)

Complete the ***Location (primary residence) section***. This should be the residential address for the patient. If address unknown, use the zip code of the provider that ordered the test. **Zip code is a required field.**

Examples:

- Long-term care facility resident - facility address
- Long-term care facility staff - staff home address NOT the facility address
- University/college student - college associated address (either on campus or off campus)
- University/college staff-staff - home address

Complete the ***home phone number***. This should be the phone number at which the patient is most likely to be reached.

Examples:

- Long-term care facility resident - facility phone number
- Long-term care facility staff - staff home or mobile number
- University/college student or staff - home or mobile number NOT the university main number

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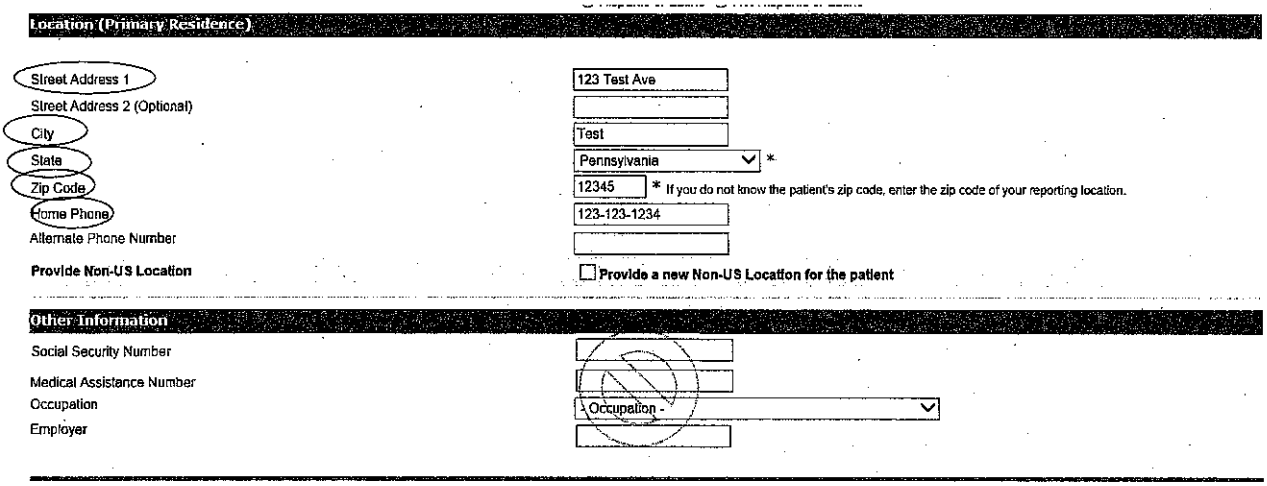
OTHER INFORMATION

The Other Information section can be left blank. We DO NOT need social security number, etc.



CLINICAL INFORMATION

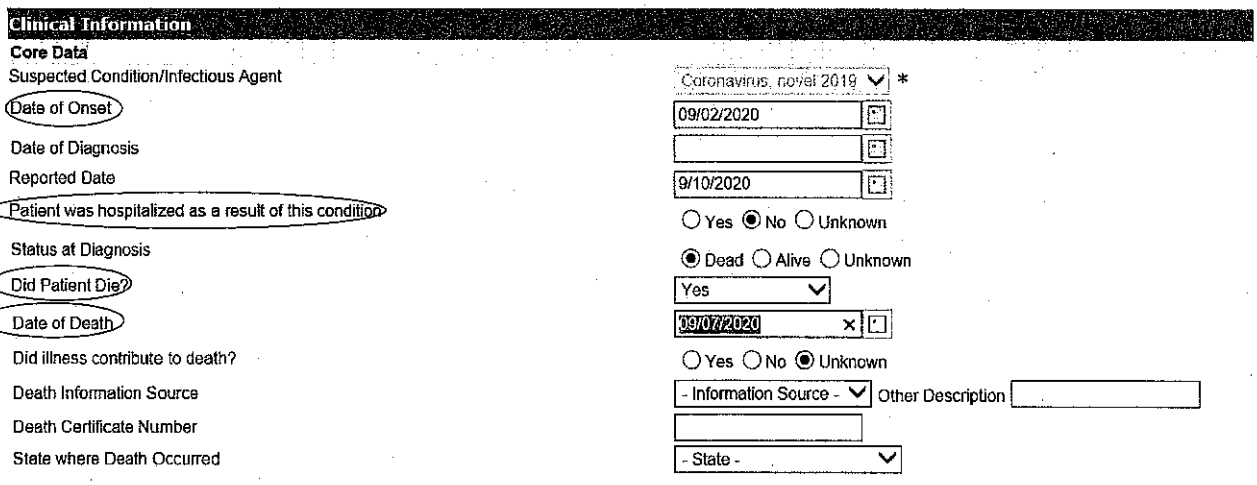
Complete the following fields in Clinical Information section, if information is available.

Date of onset- please complete, if known, and if the person had symptoms. Leave this blank for asymptomatic patients. Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.

Reported date- will be automatically generated

Hospitalization- if known

Death and date of death- if known. Other death information is not needed



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SPECIMEN INFORMATION

THIS SECTION IS VERY IMPORTANT. PLEASE COMPLETE ALL CIRCLED SECTIONS.

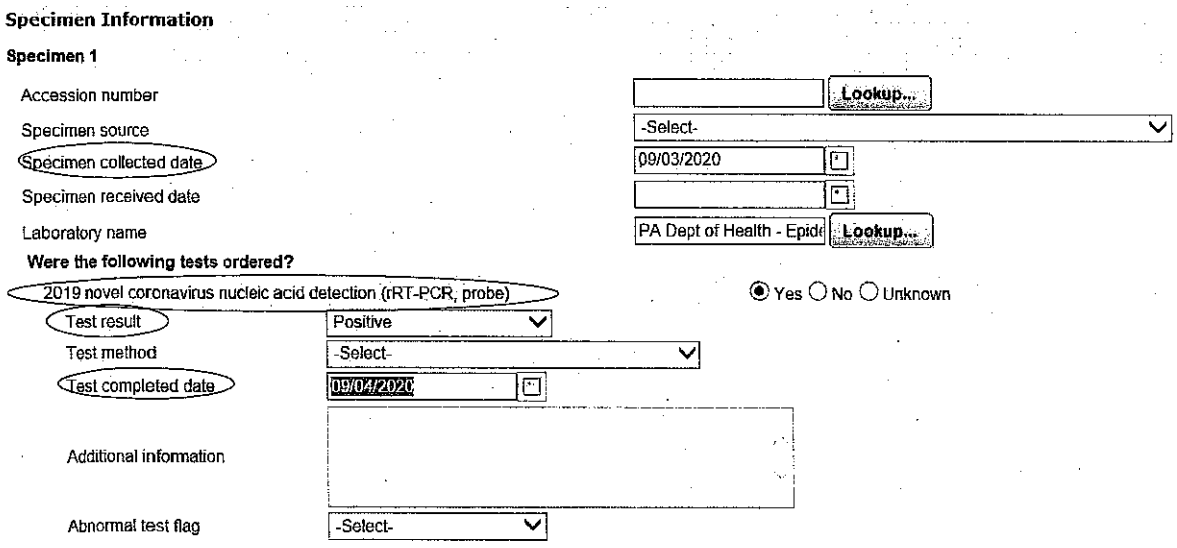
If you have the **Abbott ID NOW** POC machine, the test is a nucleic acid detection test (PCR). You must fill out the following Specimen Information sections:

Specimen collection date- Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.

2019 novel coronavirus nucleic acid detection (rRT-PCR, probe) = yes

Test result - positive, negative, inconclusive, indeterminate. This should be whatever result the machine displays. Options are available by choosing the down arrow. DO NOT report patients if the result is listed as INVALID.

Test completed date- Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.



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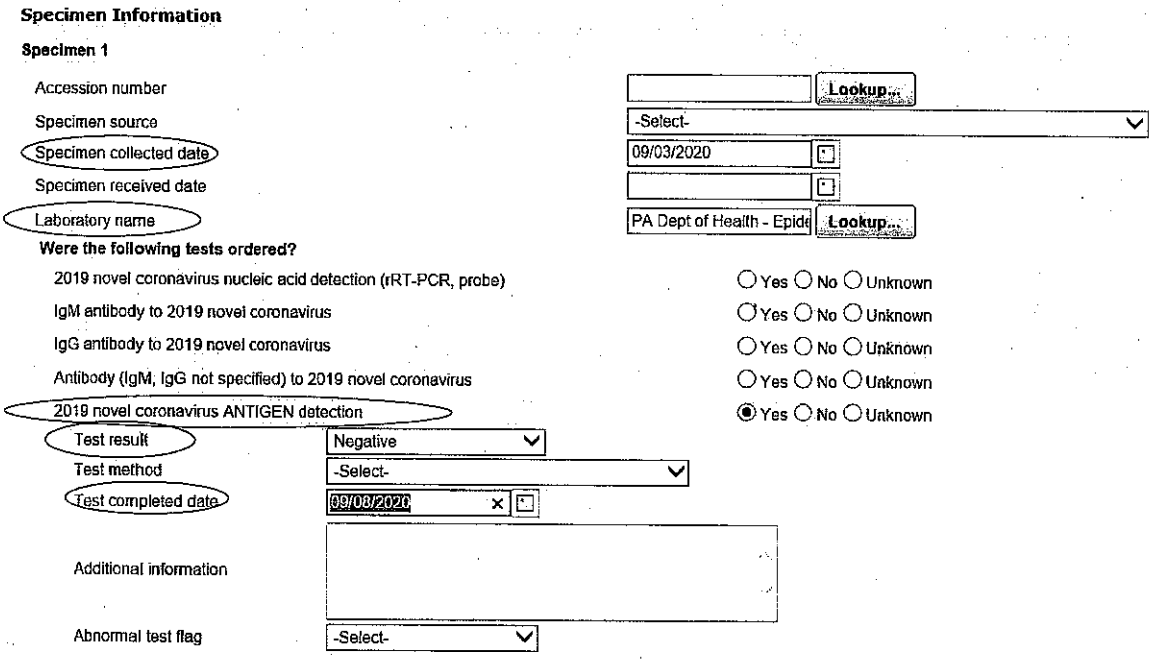
If you have the **BD Veritor, Quidel Sofia 2, LumiraDX, or BinaxNOW** POC machine, the test is an ANTIGEN test. You must fill out the following Specimen Information sections:

Specimen collection date- Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.

2019 novel coronavirus ANTIGEN = yes

Test result - positive, negative, inconclusive, indeterminate. This should be whatever result the machine displays. Options are available by choosing the down arrow. DO NOT report patients if the result is listed as INVALID.

Test completed date-Format is MM DD YYYY (i.e., for July it has to be 07 not 7) if you prefer key entry rather than use of calendar.



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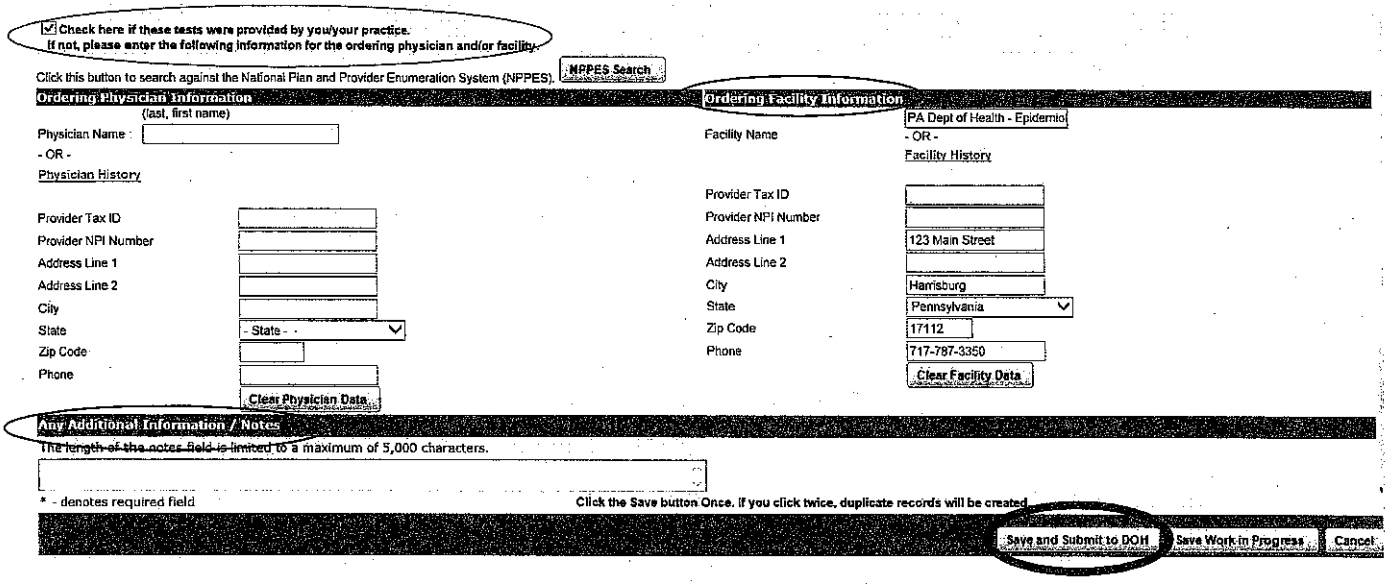
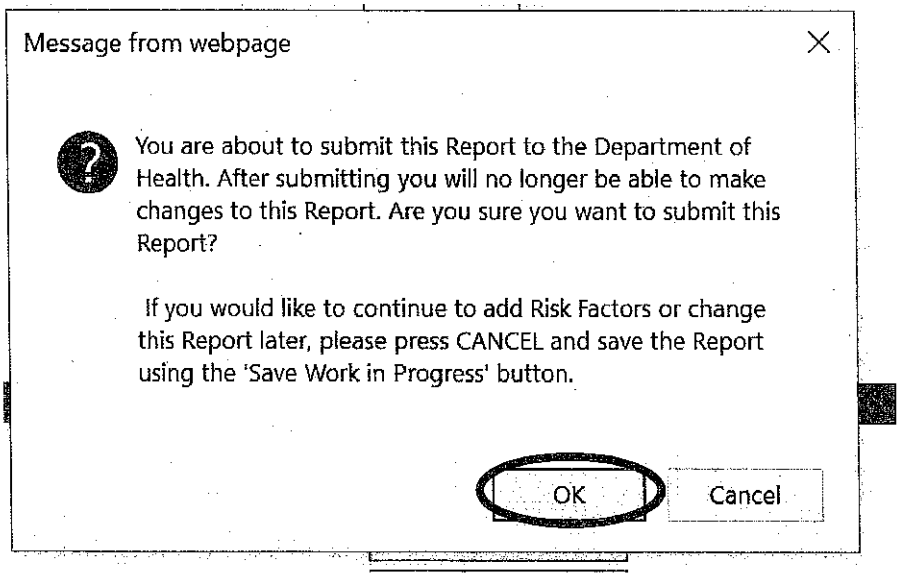
ORDERING PHYSICIAN INFORMATION

Check the box that says "Check here if these tests were provided by you/your practice." This will populate the Ordering Facility Information. Type any additional information or relevant notes into the Additional Information/Notes text box. This is not required and is only necessary if you have information you would like to share with DOH.

Click Save and Submit to DOH. You must click this button or the report will not be submitted and information will be lost.



You will receive the message below. Click OK when you are ready to submit.



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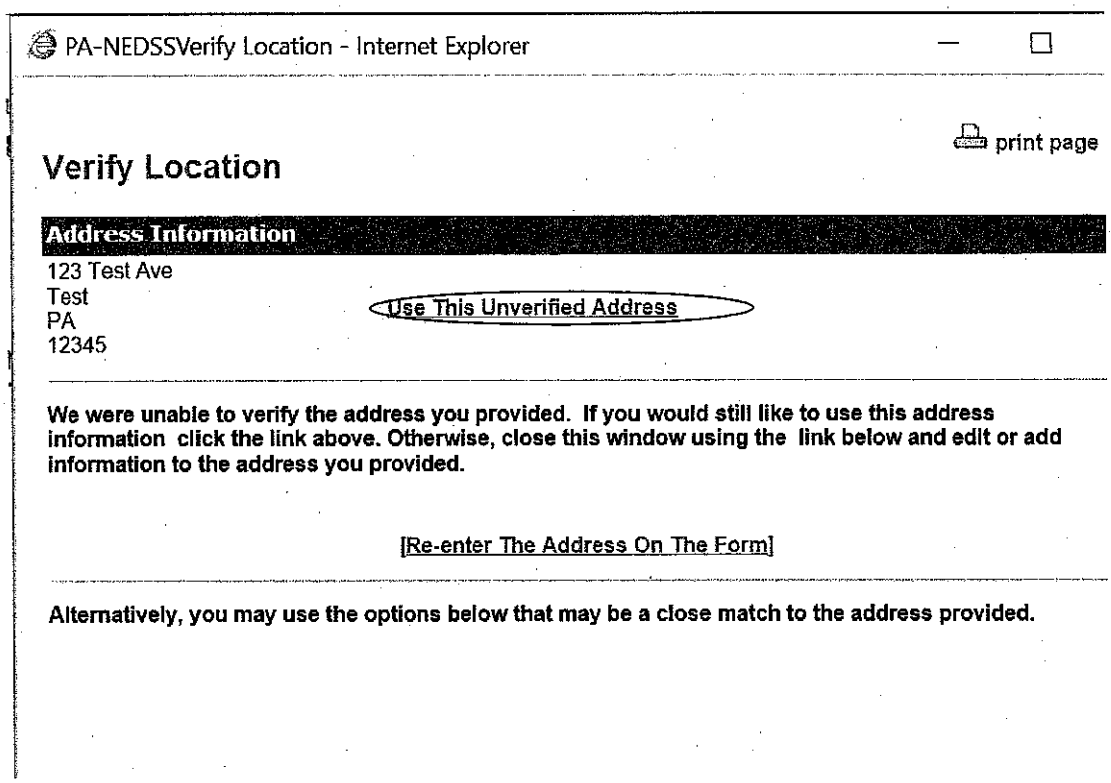
If the address information is not verified in the PA-NEDSS system you will receive the pop-up below. Click Use this unverified address. The report will then be submitted into PA-NEDSS. If the address doesn't verify but is close, NEDSS will present the unverified version and the verified version and will ask the user to choose. If the verified version looks reasonable, choose the verified version.



PENNSYLVANIA DEPARTMENT OF HEALTH
2020 – PAHAN – 495 – 4-14 - ALT
ALERT: Providing demographic variables as part of laboratory submission forms

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DATE:	4/14/2020
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	**ALERT: Providing demographic variables as part of laboratory submission forms**
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Alert": conveys the highest level of importance; warrants immediate action or attention.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- Key demographic variables including patient date of birth, phone number, address, race, and ethnicity are frequently missing from laboratory submission forms and patient test results
- These variables are essential for a complete and timely public health response to patients with COVID-19 and other reportable diseases
- Providers are reminded that patient date of birth, address, telephone number, race, and ethnicity data fields should be included on all laboratory submission forms
- Clinical laboratories are mandated to report the name, age, address, telephone number, and other information requested by the Department regarding the person from whom the specimen was obtained. See (PA Code, Title 28, Chapter 27: § 27.22 "Reporting of cases by clinical laboratories")
- Laboratories are unable to report this information unless they receive it with submitted specimens

The Pennsylvania Department of Health (Department) has identified a large number of laboratory test results submitted without key variables including patient date of birth, address, and telephone number. These demographic fields are essential for correct jurisdiction assignment and for the timely initiation of case investigations, particularly related to COVID-19 exposures.

In addition, race and ethnicity data are missing from more than 60% of reports submitted to the Department. This information is necessary to understand public health disparities across the Commonwealth and to guide resource needs and allocation.

Providers should always include patient name, date of birth, address, telephone number, and race and ethnicity information when completing the laboratory submission/requisition form for patients being

referred for testing of a reportable condition, including COVID-19. If this information is not included on the laboratory submission/requisition form, the ordering facility should enter these demographic elements into PA-NEDSS as mandated under PA Code, Title 28, Chapter 27.

Clinical laboratories are required to report the name, age, address, and telephone number from whom the specimen was obtained under PA Code, Title 28, Chapter 27: § 27.22 "Reporting of cases by clinical laboratories." (http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/028/chapter27/s27.22.html&d=reduce). However, they are unable to do this if they do not receive the information from the providers submitting specimens. In addition, clinical laboratories reporting via ELR should report race data in PID-10 and ethnicity data in PID-22 as per Health Level Seven (HL7) version 2.5.1 guidelines. Clinical laboratories using manual entry into PA-NEDSS should include this information in the appropriate short form sections.

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of April 13, 2020 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.

CLIA ID Number: 39D2208120
HMS SCHOOL FOR CHILDREN WITH CEREBRAL
4400 BALITMORE AVENUE
PHILADELPHIA, PA 19104

STATE AGENCY ADDRESS AND PHONE NUMBER:

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
110 PICKERING WAY
EXTON, PA 19341
(610)280-3464

LABORATORY MAILING ADDRESS:

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS	CLIA ID NUMBER
HMS SCHOOL FOR CHILDREN WITH CEREBRAL 4400 BALITMORE AVENUE PHILADELPHIA, PA 19104	39D2208120
	EFFECTIVE DATE
	01/05/2021
LABORATORY DIRECTOR	EXPIRATION DATE
LAURA L OWENS M.D.	01/04/2023

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Amy M. Zale, Acting Director
Division of Clinical Laboratory Improvement & Quality
Quality, Safety & Oversight Group
Center for Clinical Standards and Quality

370 Certs1_011921

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.