State of New Jersey
DEPARTMENT OF HEALTH
OFFICE OF EMERGENCY MEDICAL SERVICES
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Commissioner

To: School Superintendents, Charter School and Renaissance School Project Lead Persons, Administrators of Nonpublic Schools, School Nurses and School Safety Specialists

From: Kelly Anderson-Thomas, Director, COVID-19 Testing
New Jersey Department of Health

Date: May 4, 2021

The New Jersey Department of Health (NJDOH), local health departments, long-term care facilities, emergency medical services, K–12 schools, institutions of higher education, and others have been working in concert to coordinate and implement COVID-19 prevention and mitigation strategies as New Jersey continues to responsibly open facilities. The federal government provided New Jersey with Abbot BinaxNOWTM COVID-19 Rapid Antigen Card testing kits ("Binax"). The Binax tests are a point-of-care test that rapidly detects the presence of antigens from SARS-CoV-2 in individuals suspected of COVID-19 within the first seven (7) days of symptom onsets. Binax test results are available for review from health care providers in 15 minutes. Please note, the purpose of state-supplied Binax tests are to use as an early warning (screening) system to detect a potential outbreak of COVID-19. Binax testing is not meant to be used as a periodic or testing cadence nor as the sole testing technology.

NJDOH will provide Binax testing kits to Local Education Agencies (LEAs) in an effort to actualize continued full reopening of New Jersey's schools. NJDOH is conducting a survey to gauge interest from LEAs to integrate Binax testing as one part of the LEAs approach to mitigating and preventing the spread of COVID-19. LEAs that are interested in receiving Binax tests from the NJDOH are required to complete the above-mentioned survey including the submission of the LEAs testing plan, for NJDOH approval. This is step one (1) of the request to receive the Binax tests, while final approval will be based on the submission of the plan and current supply of Binax tests.

All survey responses are due by 12:00 pm on Friday, May 14, 2021.

Please access the COVID19 rapid antigen test request form survey at:
https://healthsurveys.nj.gov/NoviSurvey/TakeSurveyPage.aspx?s=b42718c0adc347d3b2c9ca3342ec17cc&tsid=1392e758faaa41f79dcc90311e2a6675&c=en-US

For more information regarding this effort, please refer to the Frequently Asked Questions document and Binax fact sheet. Questions regarding the completion of the survey should be directed to Statewide COVID19 Testing Team (STT) at: Covid19.TestMaterials@doh.nj.gov.

BinaxNOW COVID19 Rapid Antigen Test
Frequently Asked Questions

1. **What is a "CLIA Waiver" and does my facility need it to perform COVID19 tests?**

   - A Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver allows facilities, such as K–12 schools, Institutes of Higher Education, and so forth, perform waived COVID19 tests, such as the BinaxNOW COVID19 Rapid Antigen test.

   - Any facility that wishes to perform COVID19 tests must have a CLIA Certificate of Waiver.

2. **How do I apply for a CLIA Certificate of Waiver?**

   - If the facility does not have a CLIA Certificate of Waiver in place, they must complete and submit a CLIA application CMS-116 (See Resources Page), as well as a fee of $185. Submit mail or e-mail form to:

     New Jersey Department of Health
     Clinical Laboratory Improvement Service (CLIS)
     P.O. Box 361
     Trenton, NJ 08625-0361
     (609) 406-6824
     FAX: (609) 406-6827
     Email: CLIAlab@doh.nj.gov

   - A facility may also consider collaborating / partnering with CLIA-certified facilities (e.g., hospital, FQHC, urgent care) to administer BinaxNOW tests.

   - Please email COVID19.TestMaterials@doh.nj.gov if you need any assistance or further questions.

3. **How long is the turnaround time to process and receive a CLIA Certificate of Waiver?**

   - At this time, CLIA approval turnaround varies and is based on current request. Time averages anywhere from one (1) day to one (1) week. However, once approved, the facility will receive an e-mail confirmation that allows for testing to begin immediately while the facility's certificate is sent in the mail.

4. **Who can perform and analyze the BinaxNOW COVID19 Rapid Antigen test?**

   - Facilities with a CLIA Certificate of Waiver may perform BinaxNOW COVID19 Rapid Antigen tests.

   - Any healthcare professional, including, medical technicians or patient care technicians, can perform the test. However, analysis of results must always be done by, minimally, a registered nurse (RN).

5. **I have not yet received training materials for the BinaxNOW COVID19 Rapid Antigen test. Who will send that to me or when will I be trained?**

   - Abbott has created training modules and documents to make self-learning accessible and easy-to-follow. Please see the BinaxNOW COVID-19 Ag Card and NAVICA App training webpage for training videos and helpful documents: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html.

- In-person training is not necessarily required, however technical assistance can be offered by Abbott and/or NJDOH.
    - For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday or email ts.scr@abbott.com.
    - For NJDOH support, please contact the Statewide COVID19 Testing Team (STT) at: COVID19.TestMaterials@doh.nj.gov

6. **What kind of personal protective equipment (PPE) do we need to perform the test?**

- Testers are required to wear N95 masks if they are directly collecting the nasal specimen from a patient. N95 face masks are not required to perform the test itself or if the tester is observing self-collection from six (6) feet away. NJDOH will supply the testing technology and training.

7. **Is the used test considered "biohazard waste"? How do we dispose of it?**

- Yes, the test is considered biohazard waste and thus must be disposed of in red biohazard bag. The facility administering the test must plan for the disposal of its own biohazard waste.

8. **Do we have to report positive and negative results within 48 hours?**

- Any facility administering COVID19 test must report ***both*** positive and negative results back to the DOH via its designated reporting platform (i.e. CDRSS, COVID19 Point-of-Care (POC) Online Reporting Portal) within 48 hours.

9. **How will we report COVID19 results?**

- Facilities have the option of reporting results into one (1) of the following:

    A. Utilize NJDOH's COVID19 Point-of-Care (POC) Online Reporting Portal https://covidreporting.nj.gov/register

    B. Undergo CDRSS Quick-Start Training to have direct access into CDRSS. https://cdrs.doh.state.nj.us/cdrss/common/cdrssTrainingNotes

10. **Who will be responsible for the entering results into CDRSS?**

- A healthcare professional (i.e. RN) must be the one to analyze test results. However, organizations (i.e. K–12 schools) may assign a non-clinical staff member to log the results into the NJDOH COVID19 POC Online Reporting Portal. Any person assigned by the organization to enter results into the POC Online Reporting Portal must register their own account.

11. **Who will be responsible for training on data entry for these positive cases into the selected reporting vehicle?**

- Instructions on how to use the NJDOH COVID19 POC Online Reporting Portal will be given by NJDOH. Training for facilities approved to report through CDRSS can be found on the CDRSS Training Resources webpage: https://cdrs.doh.state.nj.us/cdrss/common/cdrssTrainingNotes (Also See Question #6).

12. **What is the NAVICA app for?**

    - The NAVICA app is meant to create a pass via a QR code, similar to an airline boarding pass. This allows organizations to verify negative test results for their employees. The app also allows for reporting and other data metrics.

13. **Does our organization need the NAVICA app to properly administer the test?**

    - No, the NAVICA app is ***not*** required to administer the BinaxNOW COVID19 Rapid Antigen test.

14. **What kind of technology is required to use the NAVICA app?**

    - The NAVICA Administrator app can use any tablet that has access to the App Store (Apple) or Google Play (Android/Google tablets). The NAVICA Administer app will only appear on tablets, not phones. When downloading to your facility's tablet, please choose the orange NAVICA app.

    - Patients must download the NAVICA app on their smartphones prior to the test administration. The patient-facing app is blue. This is also available at the App Store or Google Play. The patient's use of the app will allow for them to receive their results directly to their phone.

15. **How does our facility gain administrative access to the NAVICA Administrator app?**

    - Facilities must contact Abbott to gain administrative access to the NAVICA Administrator app. Abbott's sign-up form can be found on the BinaxNOW COVID-19 Ag card and NAVICA training webpage: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html.

16. **What happens when a parent challenges a positive BinaxNOW™ performed at school with a negative PCR test performed at another facility?**

    - Per CDS guidance, if an individual has a positive antigen test followed by a negative molecular test (collected within 48 hours of the collection of the antigen test), the antigen test ***may*** be considered false positive—this determination should be made in consultation with public health authorities.

17. **Are there recommendations on how/when to use the tests among the K–12 population?**

    - It is strongly recommended that K–12 institutions encourage parents not to send symptomatic students to school. Tests should be used for targeted functions (contact sports, plays, school dance/proms, etc.). NJDOH is providing the test to the school district to be used as an early warning system. Per the training, it should be used in cases of developed symptomatic cases throughout the day and high risk/close contact cases (to a symptomatic person). The NJDOH is not recommending that the tests be used for mass testing or outbreak settings.

COVID19 Testing Material inquiries can be sent to: COVID19.TestMaterials@doh.nj.gov

Instructions for submitting CLIA application for K–12 Schools: Form CMS-116

Note: The CLIA application for certification (PDF) is available online at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf.

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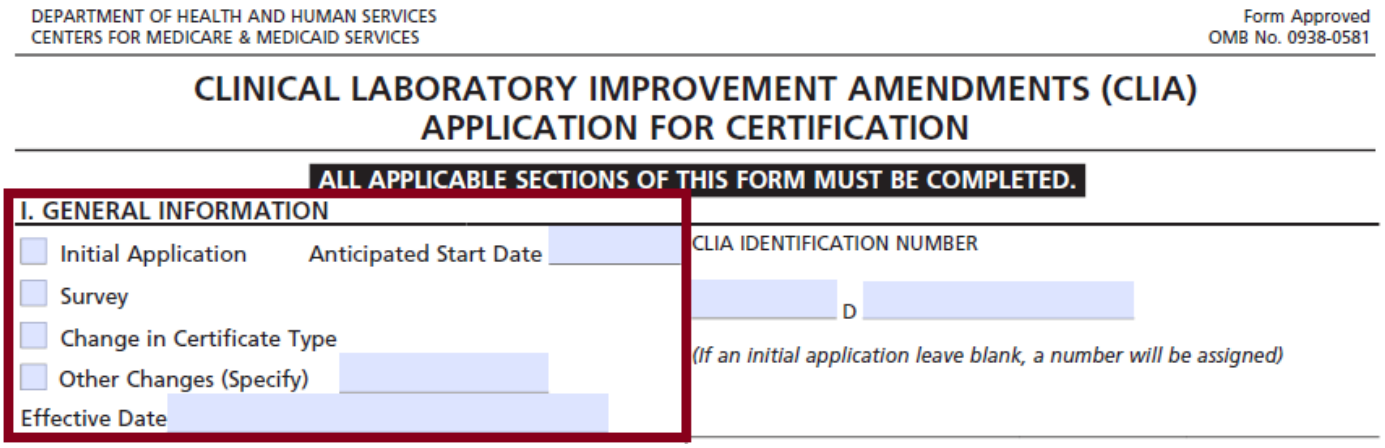
1. In the "I. General Information" section, select "Initial Application."



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

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

- ☐ Initial Application — Anticipated Start Date
- ☐ Survey
- ☐ Change in Certificate Type
- ☐ Other Changes (Specify)

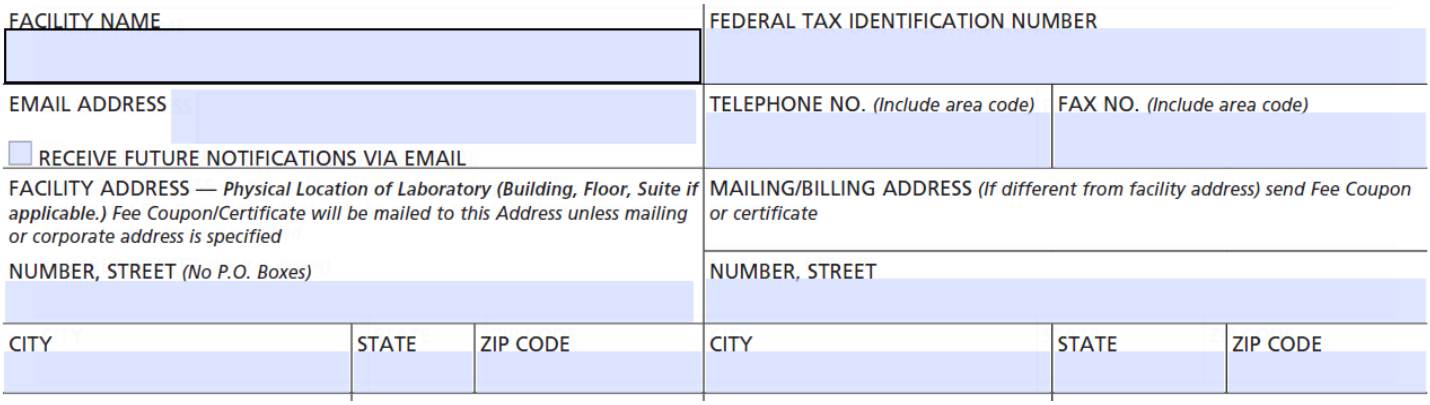
Effective Date

CLIA IDENTIFICATION NUMBER

D

(If an initial application leave blank, a number will be assigned)

2. Fill in the public school district's or private school's name, e-mail, tax ID, phone number, and address.



FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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)*

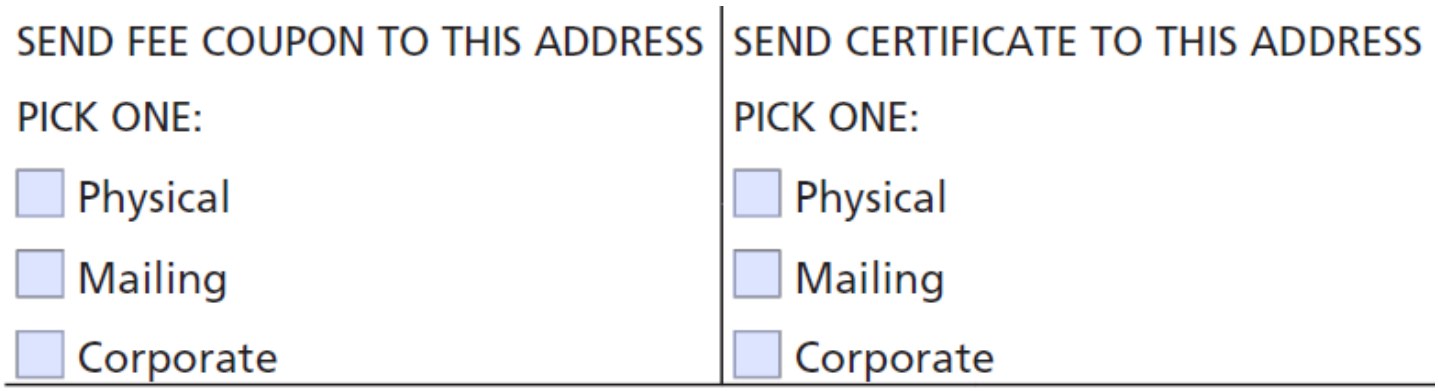
CITY | STATE | ZIP CODE

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

NUMBER, STREET

CITY | STATE | ZIP CODE

3. Select "Physical" for both "Fee coupon" and "Certificate" questions.



SEND FEE COUPON TO THIS ADDRESS	SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:	PICK ONE:
☐ Physical	☐ Physical
☐ Mailing	☐ Mailing
☐ Corporate	☐ Corporate

4. For name of director and credentials, fill with a name of school district superintendent or private school principal.

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*			MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*		
NUMBER, STREET *(No P.O. Boxes)*			NUMBER, STREET		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
SEND FEE COUPON TO THIS ADDRESS PICK ONE: ☐ Physical ☐ Mailing ☐ Corporate	SEND CERTIFICATE TO THIS ADDRESS PICK ONE: ☐ Physical ☐ Mailing ☐ Corporate		CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*	NUMBER, STREET	
			CITY	STATE	ZIP CODE
NAME OF DIRECTOR *(Last, First, Middle Initial)*			Laboratory Director's Phone Number		
CREDENTIALS			FOR OFFICE USE ONLY Date Received		

5. For "II. Type of Certificate Requested," select "Certificate of Waiver."

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☒ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-X)*

☐ Certificate of Compliance *(Complete Sections I – X)*

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ AAHHS/HFAP ☐ AABB ☐ A2LA

☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

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1. For "III. Type of Laboratory," select "26. School/Student Health Service."

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

☐ 01 Ambulance
☐ 02 Ambulatory Surgery Center
☐ 03 Ancillary Testing Site in Health Care Facility
☐ 04 Assisted Living Facility
☐ 05 Blood Bank
☐ 06 Community Clinic
☐ 07 Comp. Outpatient Rehab Facility
☐ 08 End Stage Renal Disease Dialysis Facility
☐ 09 Federally Qualified Health Center
☐ 10 Health Fair
☐ 11 Health Main. Organization
☐ 12 Home Health Agency
☐ 13 Hospice
☐ 14 Hospital
☐ 15 Independent
☐ 16 Industrial
☐ 17 Insurance
☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
☐ 19 Mobile Laboratory
☐ 20 Pharmacy
☐ 21 Physician Office
☐ 22 Practitioner Other *(Specify)*
☐ 23 Prison
☐ 24 Public Health Laboratories
☐ 25 Rural Health Clinic
☒ 26 School/Student Health Service
☐ 27 Skilled Nursing Facility/ Nursing Facility
☐ 28 Tissue Bank/Repositories
☐ 29 Other *(Specify)*

2. For "IV. Hours of Laboratory Testing," fill "7 am–5 pm" for Monday to Friday.

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

3. For "V. Multiple Sites," if the application will cover multiple locations (i.e., by public board of education), fill "Yes" and select:

- "No" for question #1 and #3
- "Yes" for question #2

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

   ☐ Yes ☐ No

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☐ No

   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

   ☐ Yes ☐ No

   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check h… the same format.

4. Provide names and addresses of schools (as multiple testing locations) on a separate sheet as an attachment.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

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1. In "VI. Waived Testing," fill “Abbott BinaxNOW COVID-19 Test” and estimate total annual test based on a proportion of total number of students and staff.

In the next three sections, indicate testing performed and estimated annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

2. Section VII does ***not*** need to be completed.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Pinworm examinations
- ☐ Fern tests
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Urine sediment examinations
- ☐ Nasal smears for granulocytes
- ☐ Fecal leukocyte examinations
- ☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

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1. Section VIII does ***not*** need to be completed.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.

Place a check (✔) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AAHHS/HFAP, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
			TIMATED ANNUAL TEST VOLUME:		

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1. For "IX. Type of Control," select appropriately.

IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)		
VOLUNTARY NONPROFIT	**FOR PROFIT**	**GOVERNMENT**
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
(Specify)		☐ 08 Federal
		☐ 09 Other Government
		(If 09 is selected, please specify the country or the province.)

2. Print, sign, and date application by public school district's superintendent or private school's principal.

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY	
PRINT NAME OF OWNER OF LABORATORY	
SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)*	DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf