CMS-116 CLIA Application: Introduction to the New Version

FORM EFFECTIVE DATE

April 2026

IMPLEMENTATION DATE

November 4, 2026

https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf

CMS-116 Application Updates

Summary of Changes

Simplified Instructions
Streamlined and relocated to the first page.

Restructured User-Friendly Layout
Reorganized form sections for intuitive navigation.

Expanded Email Support
Supports up to 3 email addresses, plus an optional 4th reserved for invoices only.

Required Contact Info
Name & phone number now mandatory for Lab Director and Owner.

Mandatory CCN Linking
Must link other assigned facility CCNs to the CLIA certificate.

General Information

Initial Application Submissions

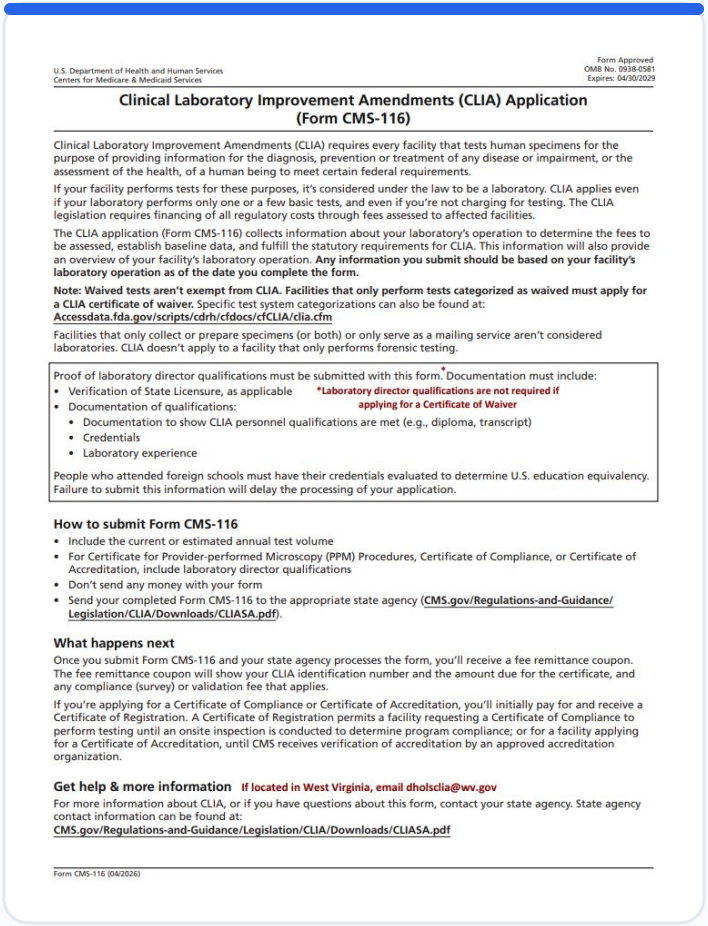
State CLIA offices will upload initial applications directly into the new CLIA data system.

An integrated **AI scanner** will extrapolate responses and automatically parse data into the new laboratory record.

Submission Guidelines & Formatting

While the AI scanner will attempt to read handwriting, typed answers are strongly requested.

Please type all responses to guarantee data accuracy.



U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0581
Expires: 04/30/2029

Clinical Laboratory Improvement Amendments (CLIA) Application
(Form CMS-116)

Clinical Laboratory Improvement Amendments (CLIA) requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment, or the assessment of the health, of a human being to meet certain federal requirements.

If your facility performs tests for these purposes, it's considered under the law to be a laboratory. CLIA applies even if your laboratory performs only one or a few basic tests, and even if you're not charging for testing. The CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation to determine the fees to be assessed, establish baseline data, and fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. **Any information you submit should be based on your facility's laboratory operation as of the date you complete the form.**

Note: Waived tests aren't exempt from CLIA. Facilities that only perform tests categorized as waived must apply for a CLIA certificate of waiver. Specific test system categorizations can also be found at:
Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm

Facilities that only collect or prepare specimens (or both) or only serve as a mailing service aren't considered laboratories. CLIA doesn't apply to a facility that only performs forensic testing.

Proof of laboratory director qualifications must be submitted with this form.* Documentation must include:
- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Documentation to show CLIA personnel qualifications are met (e.g., diploma, transcript)
  - Credentials
  - Laboratory experience

*Laboratory director qualifications are not required if applying for a Certificate of Waiver

People who attended foreign schools must have their credentials evaluated to determine U.S. education equivalency. Failure to submit this information will delay the processing of your application.

How to submit Form CMS-116
- Include the current or estimated annual test volume
- For Certificate for Provider-performed Microscopy (PPM) Procedures, Certificate of Compliance, or Certificate of Accreditation, include laboratory director qualifications
- Don't send any money with your form
- Send your completed Form CMS-116 to the appropriate state agency (CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf).

What happens next

Once you submit Form CMS-116 and your state agency processes the form, you'll receive a fee remittance coupon. The fee remittance coupon will show your CLIA identification number and the amount due for the certificate, and any compliance (survey) or validation fee that applies.

If you're applying for a Certificate of Compliance or Certificate of Accreditation, you'll initially pay for and receive a Certificate of Registration. A Certificate of Registration permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until CMS receives verification of accreditation by an approved accreditation organization.

Get help & more information If located in West Virginia, email dholsclia@wv.gov

For more information about CLIA, or if you have questions about this form, contact your state agency. State agency contact information can be found at:
CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Form CMS-116 (04/2026)

FORM CMS-116

Introduction Page: Simplified Instructions

Certificate of Waiver Exemption

Laboratory Director qualification documents are **not required** if applying for a Certificate of Waiver.

Online Payments Mandatory

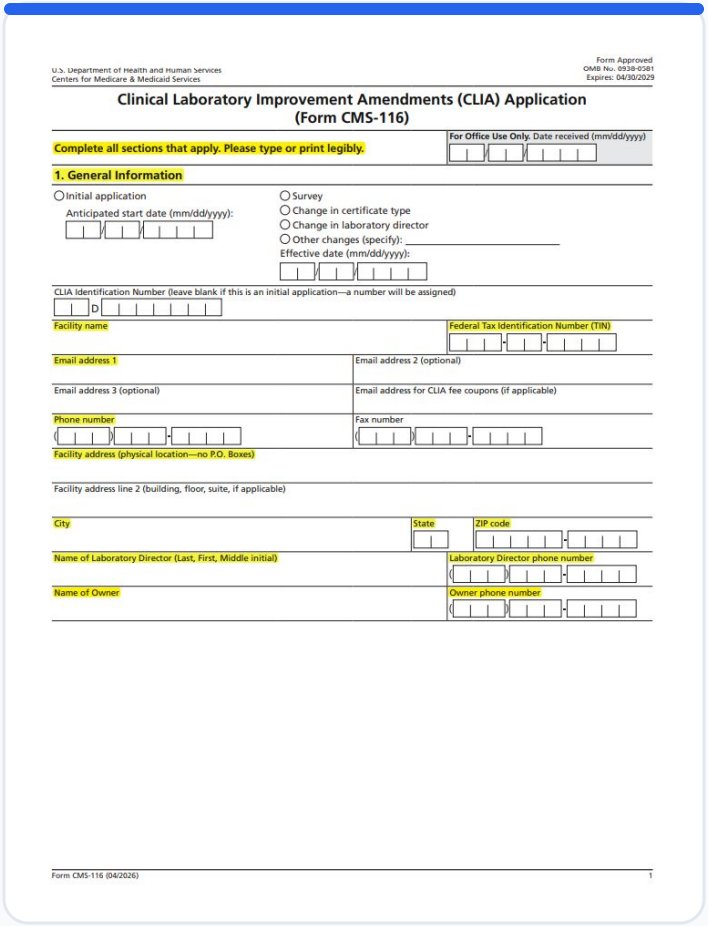
Do not send checks to our office. All payments must be made online at pay.gov form 55598674.

West Virginia Laboratory Submissions

Submit questions and completed applications to the WV CLIA program at dholsclia@wv.gov.

Out-of-State Laboratories

Refer to the CLIA state agency contact list linked at the bottom of the application.



U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0581
Expires: 04/30/2029

Clinical Laboratory Improvement Amendments (CLIA) Application
(Form CMS-116)

Complete all sections that apply. Please type or print legibly.

For Office Use Only. Date received (mm/dd/yyyy)

1. General Information

- ○ Initial application
  - Anticipated start date (mm/dd/yyyy):
- ○ Survey
- ○ Change in certificate type
- ○ Change in laboratory director
- ○ Other changes (specify): _____
  - Effective date (mm/dd/yyyy):

CLIA Identification Number (leave blank if this is an initial application—a number will be assigned)

Facility name

Federal Tax Identification Number (TIN)

Email address 1

Email address 2 (optional)

Email address 3 (optional)

Email address for CLIA fee coupons (if applicable)

Phone number

Fax number

Facility address (physical location—no P.O. Boxes)

Facility address line 2 (building, floor, suite, if applicable)

City

State

ZIP code

Name of Laboratory Director (Last, First, Middle initial)

Laboratory Director phone number

Name of Owner

Owner phone number

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Page 1: General Information

Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

Application Type & Dates

Initial Application: Enter anticipated start date.

Existing/Changes: Select change type, effective date, and enter existing CLIA #.

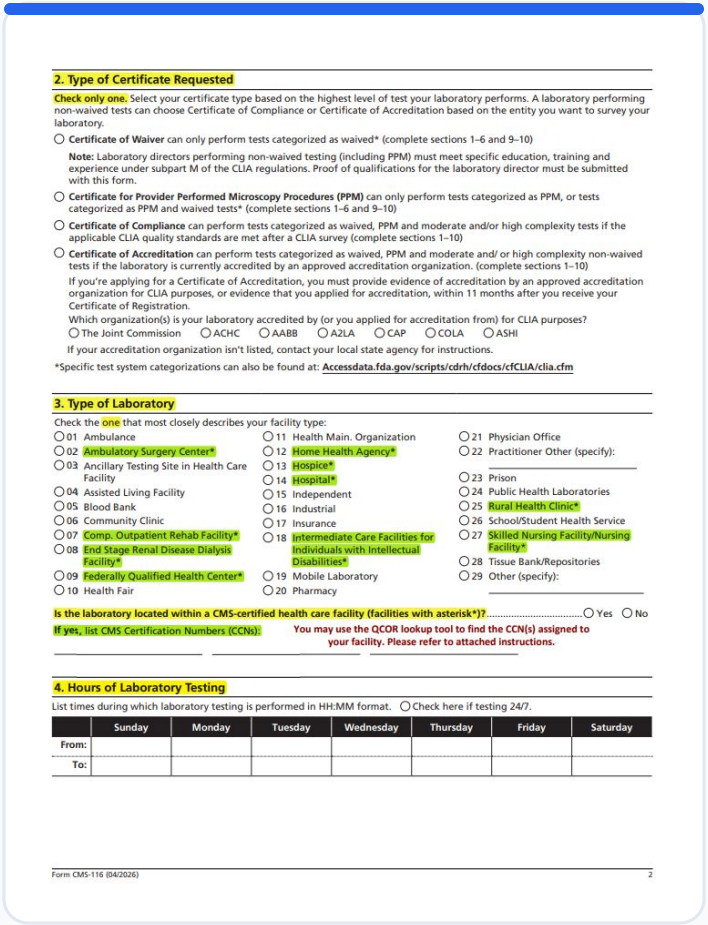
Note: Only one radio button permitted. Use "other changes" line for multiple updates.

Email Address Guidelines

1 email required; you may enter up to 3 for general communications and a 4th exclusively for fee invoices.

Laboratory Director & Owner

If the laboratory director and owner are the same individual, list their information on both designated lines.



2. Type of Certificate Requested

Check only one. Select your certificate type based on the highest level of test your laboratory performs. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the entity you want to survey your laboratory.

- ○ **Certificate of Waiver** can only perform tests categorized as waived* (complete sections 1–6 and 9–10)

  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 qualifications for the laboratory director must be submitted with this form.
- ○ **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests* (complete sections 1–6 and 9–10)
- ○ **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests if the applicable CLIA quality standards are met after a CLIA survey (complete sections 1–10)
- ○ **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests if the laboratory is currently accredited by an approved accreditation organization. (complete sections 1–10)

  If you're applying for a Certificate of Accreditation, you must provide evidence of accreditation by an approved accreditation organization for CLIA purposes, or evidence that you applied for accreditation, within 11 months after you receive your Certificate of Registration.

  Which organization(s) is your laboratory accredited by (or you applied for accreditation from) for CLIA purposes?
  ○ The Joint Commission ○ ACHC ○ AABB ○ A2LA ○ CAP ○ COLA ○ ASHI

  If your accreditation organization isn't listed, contact your local state agency for instructions.

*Specific test system categorizations can also be found at: Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm

3. Type of Laboratory

Check the one that most closely describes your facility type:

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

Is the laboratory located within a CMS-certified health care facility (facilities with asterisk*)? ○ Yes ○ No

If yes, list CMS Certification Numbers (CCNs): You may use the QCOR lookup tool to find the CCN(s) assigned to your facility. Please refer to attached instructions.

4. Hours of Laboratory Testing

List times during which laboratory testing is performed in HH:MM format. ○ Check here if testing 24/7.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							

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Page 2: Certificates & Facility Types

Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

Section 2: Type of Certificate Requested

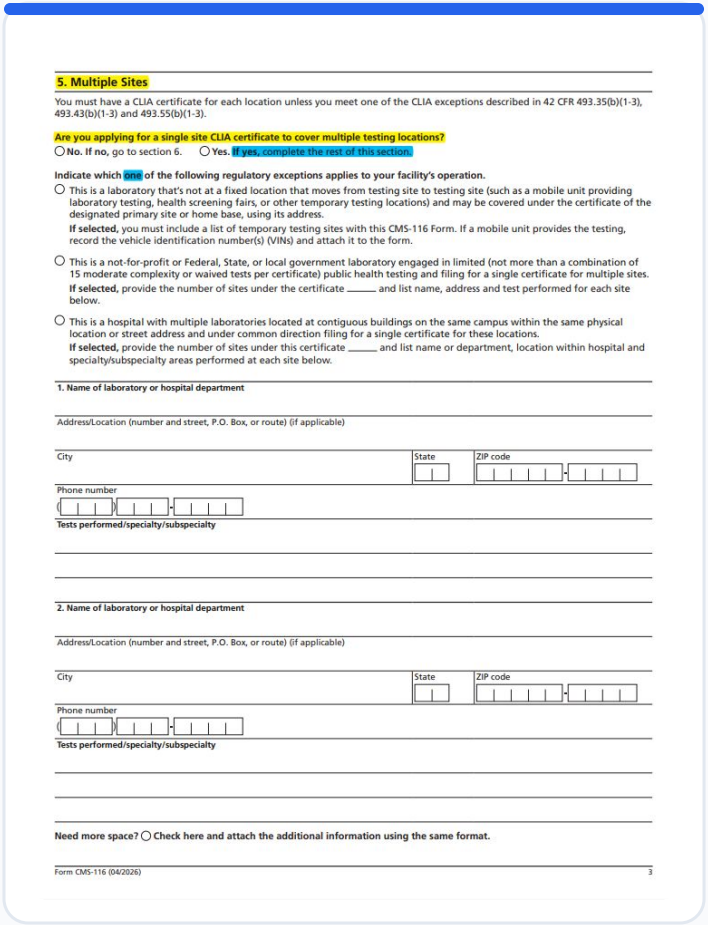
Select the type of CLIA certificate being requested in Section 2.

Accreditation Note: The form currently allows selecting only one accrediting organization. If your lab seeks accreditation with multiple organizations, manually mark the others in ink or using software.

Section 3: Type of Laboratory

Select ONE type of laboratory that most closely describes your facility.

CMS Facility Types (Green): If located inside a green-highlighted CMS facility type, you must provide associated CMS Certification Number(s) (CCNs). Refer to the instructions for locating CCNs.



5. Multiple Sites

You must have a CLIA certificate for each location unless you meet one of the CLIA exceptions described in 42 CFR 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).

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

○ **No. If no,** go to section 6. ○ **Yes. If yes,** complete the rest of this section.

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

○ This is a laboratory that's not at a fixed location that moves from testing site to testing site (such as a 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.
If selected, you must include a list of temporary testing sites with this CMS-116 Form. If a mobile unit provides the testing, record the vehicle identification number(s) (VINs) and attach it to the form.

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

○ This is a hospital with multiple laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction filing for a single certificate for these locations.
If selected, 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.

1. Name of laboratory or hospital department

Address/Location (number and street, P.O. Box, or route) (if applicable)

City | State | ZIP code

Phone number

Tests performed/specialty/subspecialty

2. Name of laboratory or hospital department

Address/Location (number and street, P.O. Box, or route) (if applicable)

City | State | ZIP code

Phone number

Tests performed/specialty/subspecialty

Need more space? ○ **Check here and attach the additional information using the same format.**

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Page 3: Multiple Sites & Exceptions

Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

Multiple Site Exception (MSE) Eligibility

Select the option that applies. If none apply, your laboratory is **not eligible** for an MSE and each location must have a separate CLIA certificate.

Instructions by Exception Type

Exception 1: Temporary Testing

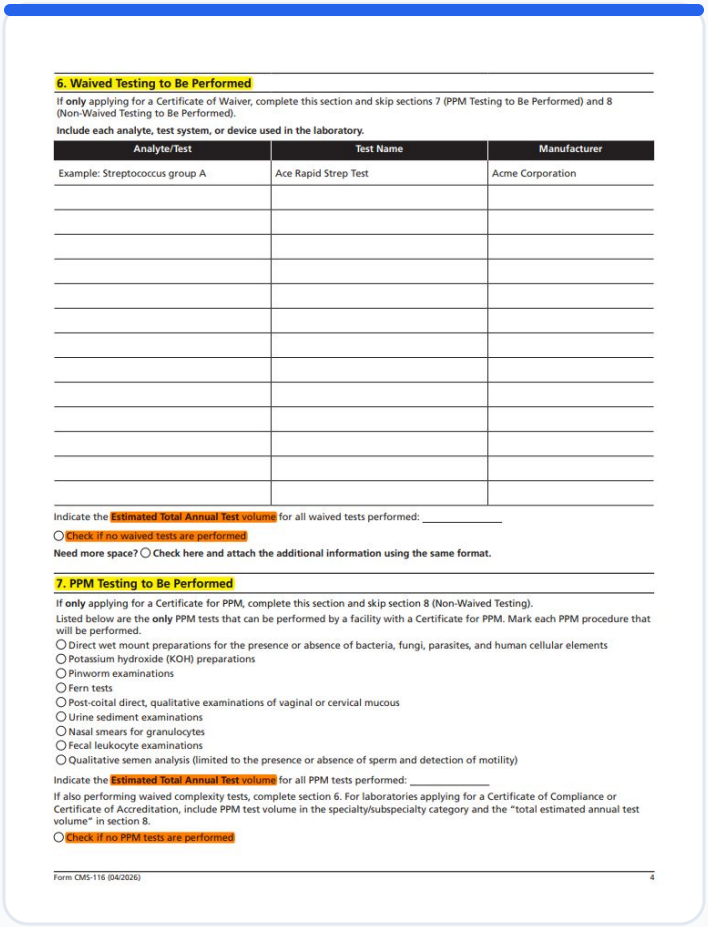
- Mobile unit testing (e.g. ambulance): Provide list of VINs for each unit.
- Non-mobile unit testing: Do not provide VINs.

Exception 2: Limited Public Health Testing

- Non-profit or government labs: List number of sites and add details at the bottom of the page.

Exception 3: Campus Hospital Labs

- Multiple labs on same campus under same director: List number of sites and add details at the bottom.



6. Waived Testing to Be Performed

If **only** applying for a Certificate of Waiver, complete this section and skip sections 7 (PPM Testing to Be Performed) and 8 (Non-Waived Testing to Be Performed).

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

Need more space? ○ **Check here and attach the additional information using the same format.**

7. PPM Testing to Be Performed

If **only** applying for a Certificate for PPM, complete this section and skip section 8 (Non-Waived Testing).

Listed below are the **only** PPM tests that can be performed by a facility with a Certificate for PPM. Mark each PPM procedure that will 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 6. For laboratories applying for a Certificate of Compliance or Certificate of Accreditation, include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section 8.

○ Check if no PPM tests are performed

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Page 4: Waived & PPM Testing

Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

Section 6: Waived Testing

Provide a list of all waived tests to be performed and the estimated annual test volume (your best estimate is sufficient).

No waived testing? Leave the chart and volume blank, and mark the circle stating no waived tests are performed.

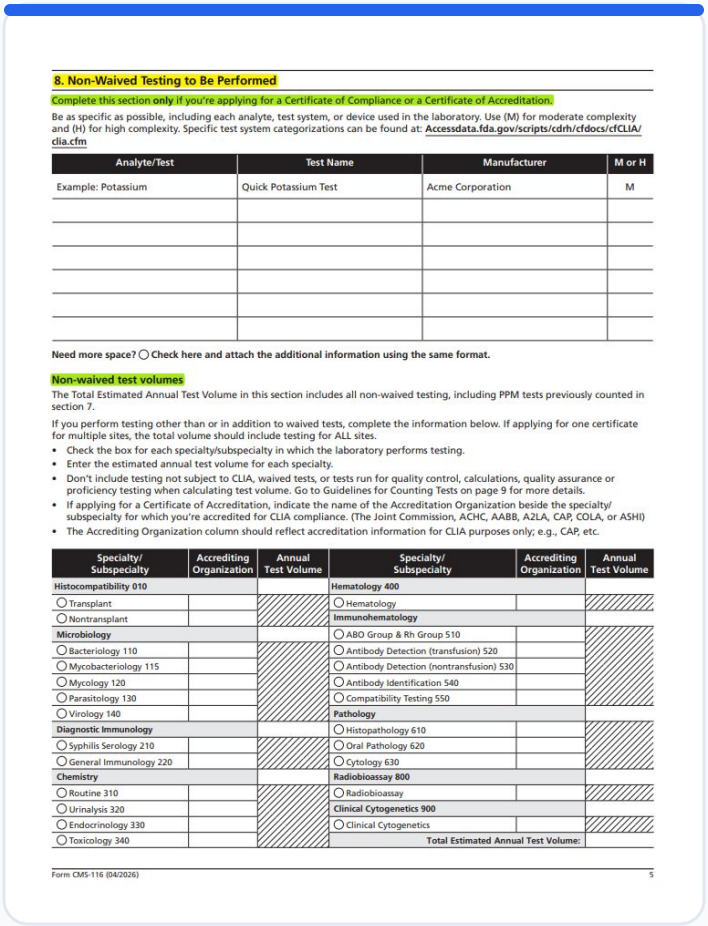
Section 7: PPM Testing

Applying for PPM Certificate: Mark all PPM tests to be performed and provide estimated annual volume.

Not obtaining PPM Certificate: Mark the circle stating no PPM tests are performed.

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Page 5: Non-Waived Testing



8. Non-Waived Testing to Be Performed

Complete this section **only** if you're applying for a Certificate of Compliance or a Certificate of Accreditation.

Be as specific as possible, including each analyte, test system, or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity. Specific test system categorizations can be found at: **Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**

Analyte/Test	Test Name	Manufacturer	M or H
Example: Potassium	Quick Potassium Test	Acme Corporation	M

Need more space? ◯ **Check here and attach the additional information using the same format.**

Non-waived test volumes

The Total Estimated Annual Test Volume in this section includes all non-waived testing, including PPM tests previously counted in section 7.

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.

- Check the box for each specialty/subspecialty in which the laboratory performs testing.
- Enter the estimated annual test volume for each specialty.
- Don't include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. Go to Guidelines for Counting Tests on page 9 for more details.
- If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the specialty/subspecialty for which you're accredited for CLIA compliance. (The Joint Commission, ACHC, AABB, A2LA, CAP, COLA, or ASHI)
- The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.

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		
◯ Toxicology 340			**Total Estimated Annual Test Volume:**		

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Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

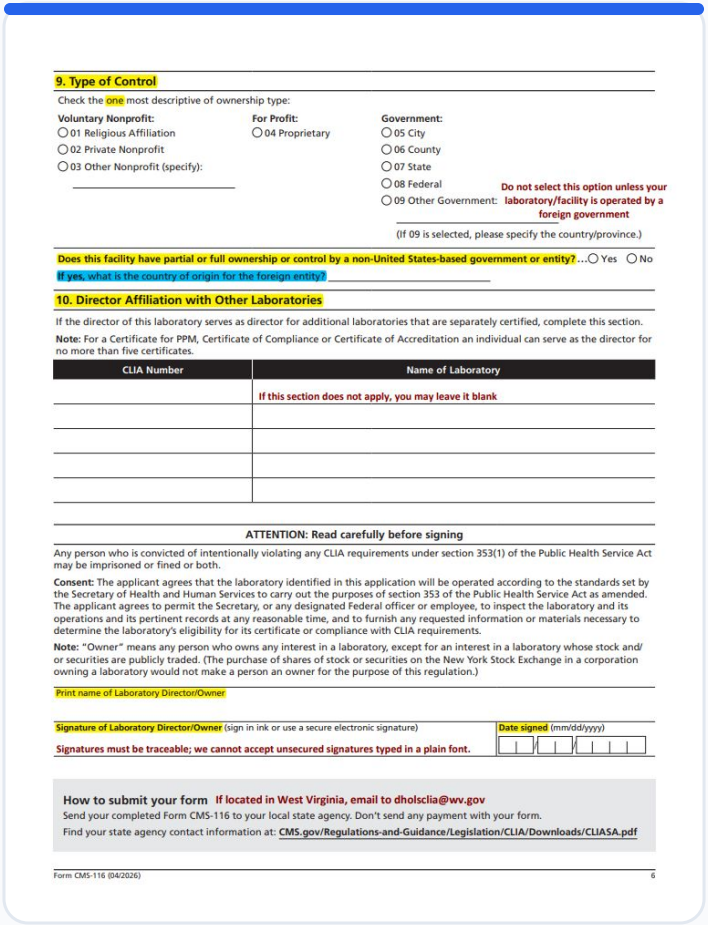
Section 8: Nonwaived testing

Waiver or PPM Certificate: Skip this entire page.

CoC or CoA Certificate: Enter nonwaived tests to be performed (or refer to an attached document listing all tests).

Completing the Volume Chart

- Mark each subspecialty in which testing will be performed
- Indicate your test volume per specialty
- Calculate the total estimated annual test volume
- **If applying for CoA:** Add the accrediting organization to each line where testing is performed



9. Type of Control

Check the one most descriptive of ownership type:

Voluntary Nonprofit:
- ○ 01 Religious Affiliation
- ○ 02 Private Nonprofit
- ○ 03 Other Nonprofit (specify): _____

For Profit:
- ○ 04 Proprietary

Government:
- ○ 05 City
- ○ 06 County
- ○ 07 State
- ○ 08 Federal
- ○ 09 Other Government: _____ (If 09 is selected, please specify the country/province.)

Do not select this option unless your laboratory/facility is operated by a foreign government

Does this facility have partial or full ownership or control by a non-United States-based government or entity? ... ○ Yes ○ No

If yes, what is the country of origin for the foreign entity? _____

10. Director Affiliation with Other Laboratories

If the director of this laboratory serves as director for additional laboratories that are separately certified, complete this section.

Note: For a Certificate for PPM, Certificate of Compliance or Certificate of Accreditation an individual can serve as the director for no more than five certificates.

CLIA Number	Name of Laboratory
	If this section does not apply, you may leave it blank

ATTENTION: Read carefully before signing

Any person who is convicted of intentionally violating any CLIA requirements under section 353(1) of the Public Health Service Act may be imprisoned or fined or both.

Consent: The applicant agrees that the laboratory identified in this application will be operated according to the standards set 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 agrees to permit the Secretary, or any designated Federal officer or employee, 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 for its certificate or compliance with CLIA requirements.

Note: "Owner" means any person who owns any interest in a laboratory, except for an interest in a laboratory whose stock and/or securities are publicly traded. (The purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Print name of Laboratory Director/Owner

Signature of Laboratory Director/Owner (sign in ink or use a secure electronic signature)	Date signed (mm/dd/yyyy)
Signatures must be traceable; we cannot accept unsecured signatures typed in a plain font.	

How to submit your form If located in West Virginia, email to dholsclia@wv.gov

Send your completed Form CMS-116 to your local state agency. Don't send any payment with your form.

Find your state agency contact information at: CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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Page 6: Control, Affiliations & Signatures

Required Fields Highlighted

All fields highlighted in yellow are mandatory and must be completed.

Section 9: Type of Control

- Select **one** control option.
- If selecting 03 "Other Nonprofit," specify type.
- Do not select 09 "Other Government" unless foreign government operated (list country).

Section 10: Director Affiliations

Nonwaived labs (PPM, CoC, CoA): Add CLIA numbers and names for all affiliated labs nationwide.

Waived labs: Affiliation info is optional (may be left blank).

Signature & Attestation

The laboratory director or owner must print name, sign, and date.

Important Signature Requirement:
Must be hand-drawn (ink/electronic) or secure (with timestamp). Plain typed fonts are not accepted.

How to locate a CCN

Step 1: visit https://qcor.cms.gov/main.jsp





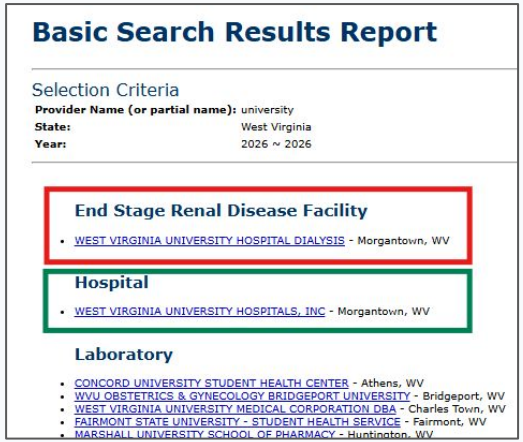
Step 2: select “Basic Search”

Step 3: add information to search fields

- You can enter any combination of data.
- We recommend broad searches, such as city and state, to ensure each facility is identified and listed as required.

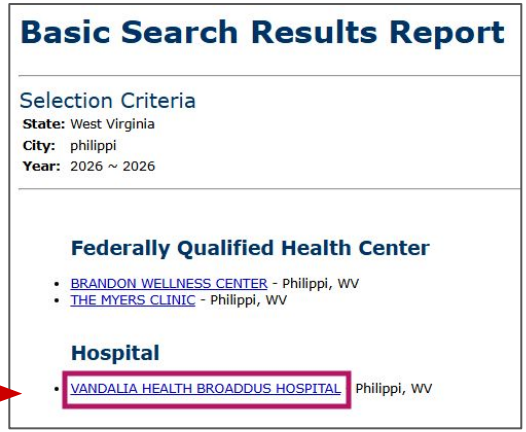


Search examples
1: provider name and state
2: city and state





Step 4: click the link to the applicable facility to open the details window



Step 5: locate the CCN

