

Guide to Match Information on CMS 116 CLIA Form with the California Laboratory Online Licensing System

Online Application

For a renewal of laboratory license online application, refer to the user manual for “Single Site” “Renew License” at

cdph.ca.gov/OnlineAppHelp

Follow this guide only if you are renewing with changes. Describe the changes on Section I, and enter the “Effective Date.”

Find the matching number on the right.

1. “Tax ID” online must match the CMS 116 form, page 1.

2. “Mailing Address” must match.

CMS 116 form (Page 1)



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

Change in Certificate Type Effective Date _____
 Other Changes (Specify) _____

FACILITY NAME _____ FEDERAL TAX IDENTIFICATION NUMBER _____

EMAIL ADDRESS _____ TELEPHONE NO. (Include area code) _____ FAX NO. (Include area code) _____

RECEIVE FUTURE NOTIFICATIONS VIA EMAIL MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon (if applicable) Fee Coupon certificate will be mailed to this Address unless you specify a different address. If specified or corporate address is specified _____
 NUMBER, STREET (No P.O. Boxes) _____ NUMBER, STREET _____

CITY _____ STATE _____ ZIP CODE _____ CITY _____ STATE _____ ZIP CODE _____

SEND FEE COUPON TO THIS ADDRESS SEND CERTIFICATE TO THIS ADDRESS CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate NUMBER, STREET _____

PICK ONE: PICK ONE: CITY _____ STATE _____ ZIP CODE _____
 Physical Physical
 Mailing Mailing
 Corporate Corporate

NAME OF DIRECTOR (Last, First, Middle Initial) _____ Laboratory Director's Phone Number _____

CREDENTIALS _____ FOR OFFICE USE ONLY
 Date Received _____

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 ACHC 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.

PRA Disclosure Statement
 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 03/31/2024. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

Form CMS-116 (12/21) 1



Online Application

CMS 116 form (Page 1)



Edit the Testing Site or facility information. Update with new information.

Update Site

1 Site Information 2 Tests Performed 3 Laboratory Personnel

Site Information

3 Testing Site Name * HEALTH CARE TEST Doing Business As Federal CLIA ID 05D1234567 4 State ID CLP-00333333

Site Details

Type of Site * Hospital

Business Hours and Days * 24 HOURS, 7 DAYS/WEEK Requesting Exemption? No

5 Oversight Type * State Federal Certificate Type * Certificate for Provider Performed Microscopy Procedures

Site Contact

6 Email * Testing@cdph.ca Confirm Email * Testing@cdph.ca Primary Phone * (916) 444-4444 Secondary Phone * (###) ###-####

7 **Physical Location**

Address Line 1 1500 Howe Avenue Address Line 2 City Sacramento State California Zip Code 95825 Country LOS ANGELES United States Edit

3. "Testing Site Name" must match with the "Facility Name."
4. CLIA ID cannot be edited online. This must match on CMS116. Do not leave blank.
5. "Oversight Type" must match with Section II.
6. Email and phone must match.
7. "Physical Location" and "Facility Address" must match.

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

4 CLIA IDENTIFICATION NUMBER

3 Effective Date

6 FACILITY NAME

7 EMAIL ADDRESS

6 TELEPHONE NO. (Include area code) FAX NO. (Include area code)

RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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

7 MAILING/BILLING ADDRESS (if different from facility address) send Fee Coupon or certificate

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

CITY STATE ZIP CODE

NUMBER OF DIRECTOR (Last, First, Middle Initial) Laboratory Director's Phone Number

CREDENTIALS FOR OFFICE USE ONLY Date Received

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

Section II

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

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Form CMS-116 (12/21)



- 8. "Type of Site" must match with Section III.
- 9. "Business Hours and Days" must match Section IV.

Application ID	Application Status	Application Created On	Business Name	Testing Site Name
APL-4773	New	11/17/22 4:24 PM	TENDER CARE	---

Site Information

Testing Site Name * Doing Business As Federal CLIA ID

_____ _____ ##0#####

Site Details

8 Type of Site *
Select

9 Business Hours and Days * Requesting Exemption?
_____ No

Oversight Type * Federal Certificate Type *
Select Select

Site Contact

First Name * Middle Initial Last Name *
_____ _____ _____

Email * Primary Phone * Secondary Phone
_____ (###) ###-#### (###) ###-####

Physical Location

Address Line 1 * Address Line 2
_____ _____

City * State * Zip Code *
_____ California _____

County * Country * Validate Cancel
_____ United States

Section III

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

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

Section IV

9 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.)

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.

- 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.
- 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.
- 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 here and attach the additional information using the same format.

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)



Online Application

CMS 116 form (Pages 3 & 4)



10. "Annual Test Volume of California Specimens" and "Total Estimated Annual Test Volume" must match, if the application is for moderate/high complexity.

For Waived certificate type, complete Section VI.
For PPMP, complete Section VII.

The screenshot shows the 'Tests Performed' section of the application. A callout box with the number '10' and a hand icon points to the 'Annual Test Volume of California Specimens' dropdown menu, which is currently set to 'Between 1,000,001 - 1,500,000'. Other visible fields include 'License Type' (High), 'Federal Certificate Type' (Certificate of Compliance), and an 'Add tests to be performed at this site' dropdown menu.

This image shows sections VI and VII of the CMS 116 form. Section VI, 'WAIVED TESTING', includes a table with columns for 'ANALYTE / TEST', 'TEST NAME', and 'MANUFACTURER'. Below the table are instructions to indicate the 'ESTIMATED TOTAL ANNUAL TEST volume' for all waived tests performed. Section VII, 'PPM TESTING', includes a list of tests with checkboxes and instructions to indicate the 'ESTIMATED TOTAL ANNUAL TEST volume' for all PPM tests performed.

certificate of Accreditation) Complete
 as possible. This includes each
 for high complexity.
 MANUFACTURER M or H
 corporation M
 format.
 low. If applying for one certificate
 format." Include text box similar to
 rms testing. Enter the
 waived tests, or tests run for quality
 additional guidance on counting
 n beside the applicable specialty/
 AABB, AZLA, CAP, COLA or ASHI)

ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME

This image shows the bottom portion of the CMS 116 form, listing various test categories such as Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Diagnostic Immunology, Chemistry, and Radioimmunoassay. A callout box with the number '10' points to the 'TOTAL ESTIMATED ANNUAL TEST VOLUME' field at the bottom right of the list.



Online Application



CMS 116 form (Page 1)

The Laboratory Director (#11) and License Number (#12) must match "Name of Director" and "Credentials" on page 1 of the CMS 116 form.

Laboratory Personnel

A CLIA laboratory director must be added.

First Name	Middle Name	Last Name	Role	Edit	Remove
JANE		DOE	Laboratory Director		

[Add New Laboratory Director](#)

License Information

Provide most relevant license/certification details relating to the role above.

[Add License](#)

License Type:

Granting Agency:

Issued in California: Yes No

Expiration Date:

Board Certified:

License Number:

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Survey

Change in Certificate Type

Other Changes (Specify):

Effective Date:

FACILITY NAME:

EMAIL ADDRESS:

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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

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

NAME OF DIRECTOR (Last, First, Middle Initial):

CREDENTIALS:

CLIA IDENTIFICATION NUMBER:

FEDERAL TAX IDENTIFICATION NUMBER:

TELEPHONE NO. (include area code): FAX NO. (include area code):

NUMBER, STREET (No P.O. Boxes):

NUMBER, STREET:

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

NUMBER, STREET:

CITY: STATE: ZIP CODE:

CITY: STATE: ZIP CODE:

Laboratory Director's Phone Number:

FOR OFFICE USE ONLY

Date Received:

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

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Please note: All other fields on the CMS 116 form must be completed if applicable. For more details visit the CMS website.

For questions, visit our Help page: cdph.ca.gov/OnlineAppHelp