

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



## Online Application

## CMS 116 form (Page 1)



For a new laboratory license online application, refer to the user manual for “Single Site” “New License” at

[cdph.ca.gov/OnlineAppHelp](http://cdph.ca.gov/OnlineAppHelp)

Find the matching number on the right.

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

2. “Mailing Address” must match.



# Online Application

# CMS 116 form (Page 1)



Enter the Testing Site or facility information.

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

### Site Details

Type of Site \*

Business Hours and Days \*  Requesting Exemption?

Oversight Type \*  Federal Certificate Type \*

### 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 \*

County \*  Country \*

3. "Testing Site Name" must match with the "Facility Name."
4. Leave the CLIA ID blank if you don't have one.
5. "Oversight Type" must match with Section II.
6. Email and phone must match. Secondary Phone could be the Fax No.
7. "Physical Location" and "Facility Address" must match.

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

Facility Name

Email Address

RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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

Number, Street (No P.O. Boxes)

City  State  Zip Code

SEND FEE COUPON TO THIS ADDRESS    SEND CERTIFICATE TO THIS ADDRESS

PICK ONE:  Physical     Physical

Mailing     Mailing

Corporate     Corporate

Corporate Address (If different from facility) send Fee Coupon or certificate

City  State  Zip Code

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 of 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](mailto:LabExcellence@cms.hhs.gov).

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

### Site Information

Testing Site Name \* | Doing Business As | Federal CLIA ID

### Site Details

**8** Type of Site \*  
Select

**9** Business Hours and Days \* | Requesting Exemption? No

Oversight Type \* | Federal Certificate Type \*

### Site Contact

First Name \* | Middle Initial | Last Name \*  
Email \* | Primary Phone \* | Secondary Phone

### Physical Location

Address Line 1 \* | Address Line 2  
City \* | State \* (California) | Zip Code \*  
County \* | Country \* (United States) | Validate | Cancel

**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"/> 03 Ancillary Testing Site in Health Care Facility	<input type="checkbox"/> 13 Hospice	
<input type="checkbox"/> 04 Assisted Living Facility	<input type="checkbox"/> 14 Hospital	<input type="checkbox"/> 23 Prison
<input type="checkbox"/> 05 Blood Bank	<input type="checkbox"/> 15 Independent	<input type="checkbox"/> 24 Public Health Laboratories
<input type="checkbox"/> 06 Community Clinic	<input type="checkbox"/> 16 Industrial	<input type="checkbox"/> 25 Rural Health Clinic
<input type="checkbox"/> 07 Comp. Outpatient Rehab Facility	<input type="checkbox"/> 17 Insurance	<input type="checkbox"/> 26 School/Student Health Service
<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"/> 27 Skilled Nursing Facility/ Nursing Facility
<input type="checkbox"/> 09 Federally Qualified Health Center	<input type="checkbox"/> 19 Mobile Laboratory	<input type="checkbox"/> 28 Tissue Bank/Repositories
<input type="checkbox"/> 10 Health System	<input type="checkbox"/> 20 Pharmacy	<input type="checkbox"/> 29 Other (Specify)
<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.



# 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:

Expiration Date:

Board Certified:

License Number:

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Survey

Change in Certificate Type

Other Changes (Specify)

Effective Date:

FACILITY NAME:

EMAIL ADDRESS:

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

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

CITY:  STATE:  ZIP CODE:

SEND FEE COUPON TO THIS ADDRESS:  Physical  Mailing  Corporate

SEND CERTIFICATE TO THIS ADDRESS:  Physical  Mailing  Corporate

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

CITY:  STATE:  ZIP CODE:

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

CREDENTIALS:

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

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**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.**

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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

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Form CMS-116 (12/21)

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](https://cdph.ca.gov/OnlineAppHelp)