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



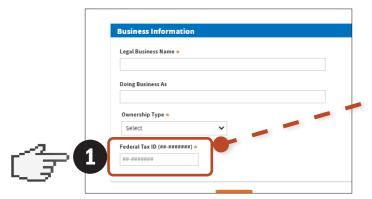


Online Application

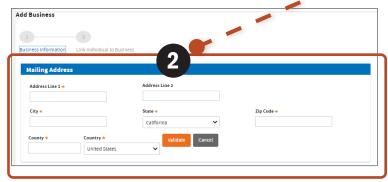
For a new laboratory license online application, refer to the user manual for "Single Site" "New License" at cdph.ca.gov/OnlineAppHelp

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.



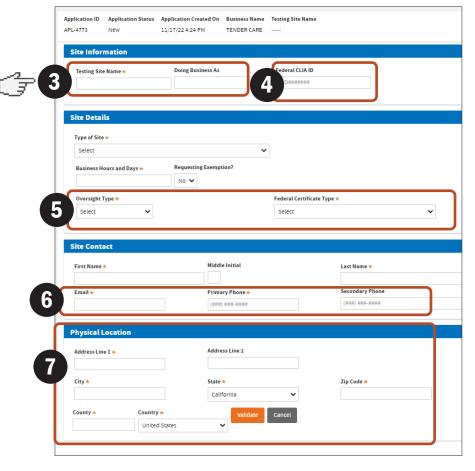
CMS 116 form (Page 1)



CLINIC			OVEMENT AMENDM OR CERTIFICATION	ENTS (CLI	A)	
I. GENERAL INFORMATION		ABLE SECTIONS OF	THIS FORM MUST BE COMPL	ETED.		
Initial Application Anticipated Start Date			CLIA IDENTIFICATION NUMBER			
Survey			D			
Change in Certificate T	ype		(If an initial application leave blank, a number will be assigned)			
Other Changes (Specify)			(II an Initial application leave biar	ik, a number will	be assigned)	
Effective Date			\			
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER			
EMAIL ADDRESS			TELEPHONE NO. (Include area code)	FAX NO. (Includ	de area code)	
FACILITY ADDRESS — Physical L		ory (Building, Flo	MAILING/BILLING ADDRESS (If diffe	rent from facility a	ddress) send Fee Co	
applicable.) Fee Coupon/Certificate or corporate address is specified	will be mailed to t	his Address un	r certificate			
NUMBER, STREET (No P.O. Boxes	5)		UMBER, STREET			
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE	
SEND FEE COUPON TO THIS ADD	SEND CERTIF	ICATE TO THIS ADDRES	S CORPORATE ADDRESS (If different	NUMBER, STRE	FT	
PICK ONE:	PICK ONE:		from facility) send Fee Coupon or certificate			
Physical	Physical					
Mailing	Mailing		CITY	STATE	ZIP CODE	
Corporate	Corpora	te				
NAME OF DIRECTOR (Last, First,	Middle Initial)		Laboratory Director's Phone Numi	oer		
CREDENTIALS			FOR OFFICE USE ONLY			
			Date Received			
II. TYPE OF CERTIFICATE certificate testing requirem		(Check only one) Ple	ease refer to the accompanying i	nstructions for	inspection and	
Certificate of Waiver	(Complete Se	ections I – VI and I	X – X)			
NOTE: Laboratory directors pe subpart M of the CLIA regulati	rforming non-wa ons. Proof of the	ived testing (including se qualifications for th	PPM) must meet specific education, le laboratory director must be submi dures (PPM) (Complete Sectio	tted with this ap	plication.	
Certificate of Compli						
Certificate of Accredi	tation (Compl	ete Sections I – X)	and indicate which of the foll which you have applied for ac			
The Joint Commission ACHC		AABB A2LA				
CAP	[COLA	ASHI			
	isted above for C		e evidence of accreditation for your nce of application for such accreditat			
The valid OMB control number for estimated to average one hour per review the information collection. I CMS, 7500 Security Boulevard, Attn	this information col response, including f you have commen : PRA Reports Clear i, medical records or	lection is 0938-0581. Expi the time to review instru ts concerning the accurace ance Officer, Mail Stop C4 any documents containin	espond to a collection of information unitration Date: 03/31/2024. The time required ctions, search existing data resources, gat y of the time estimate(s) or suggestions fe-26-05, Baltimore, Maryland 21244-1850. Ig sensitive information to the PRA Repor	to complete this in ther the data neede or improving this fo *****CMS Disclaim ts Clearance Office.	formation collection d, and complete an orm, please write to er*****Please do n Please note that a	



Enter the Testing Site or facility information.



- 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.

CMS 116 form (Page 1)

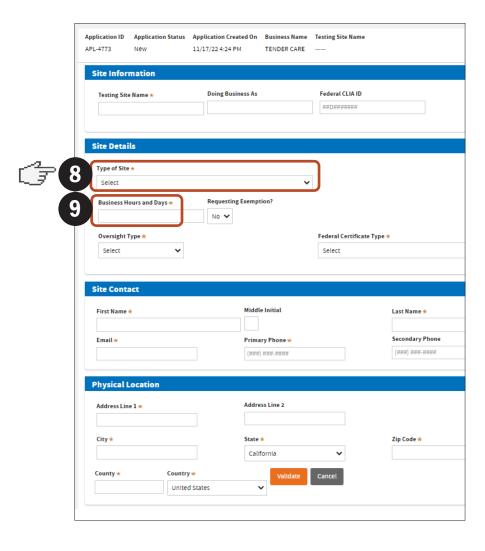
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Other Changes (Specify)					
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FACILITY NAME		FEDERAL TAX IDENTIFICATION NO	INIBER		
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FACILITY ADDRESS — Physical Location	on of Laboratory (Building, Floor, Su		erent from facility address) send Fe		
applicable.) Fee Coupon/Certificate will to or corporate address is specified	e mailed to this Address unless mai	iling or certificate			
NUMBER, STREET (No P.O. Boxes)		NUMBER, STREET	NUMBER, STREET		
CITY	STATE ZIP CODE	CITY	STATE ZIP CODE		
SEND FEE COUPON TO THIS ADDRESS	SEND CERTIFICATE TO THIS ADDR		NUMBER, STREET		
PICK ONE:	PICK ONE:	from facility) send Fee Coupon or certificate			
Physical	Physical				
Mailing	Mailing	CITY	STATE ZIP CODE		
Corporate	Corporate				
NAME OF DIRECTOR (Last, First, Midd	le Initial)	Laboratory Director's Phone Num	ber		
CREDENTIALS		FOR OFFICE USE ONLY			
		Date Received			
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CMS 116 form (Page 2)



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



	ABORATORY (heck the one mo	st descriptive of fa	cility type)			
03 Ancillary Health Ca 04 Assisted L 05 Blood Bar 06 Communi	ry Surgery Center Festing Site in re Facility iving Facility ik ty Clinic tpatient Rehab Far Renal Disease icility		1 Health Main. (12 Home Health / 13 Hospica 14 Hospica 15 Independent 16 Industrial 17 Insurance 18 Intermediate (1 Individuals with Disabilities 19 Mobile Labora 19 Friedrick 19 Friedrick 19 Friedrick 19 Hospical 19 Friedrick 19 Hospical 19	Agency Care Facilities for h Intellectual	23 24 25 26 27	Practitioner Other Prison Public Health Labo Rural Health Clinic School/Student He Skilled Nursing Fa Nursing Facility Tissue Bank/Repos Other (Specify)	oratories c ealth Service cility/
Secti	on IV		21 Physician Offic	e			
IV. HOURS OF	LABORATORY	TESTING (List til	mes during which lai	poratory testing is pe	erformed in HH:MM	format) If testing	24/7 Check
	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATUR
FROM:							
TO:							
(For multiple sites	, attach the addition	onal information	using the same fo	mat.)			
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No. If no, go				inder of this sec			
	of the following oratory that is no	-					
Yes Nes If yes and a application. If this a not	mobile unit is pr -for-profit or Fec omplexity or wai	roviding the laboral, State or lo	oratory testing,	record the vehicl	e identification	not more than a	a combinat
Yes I		of sites under the	e certificate	and list	name address	and test perforn	med for ea
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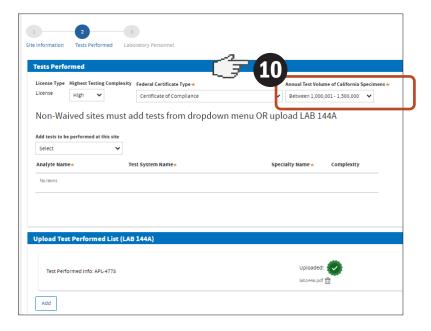


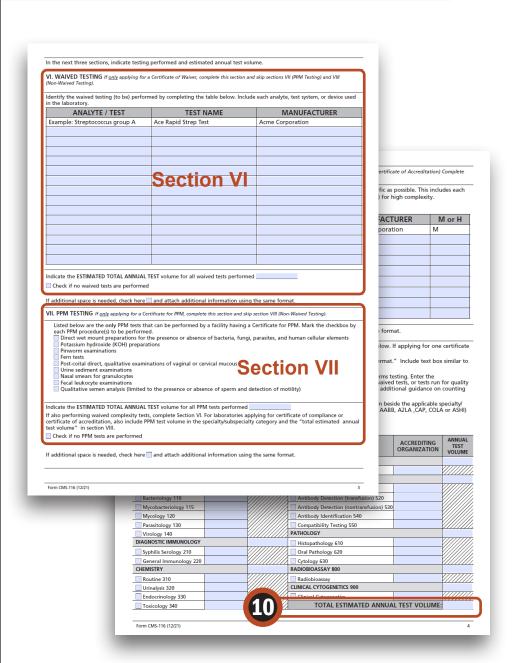
CMS 116 form (Pages 3 & 4)



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

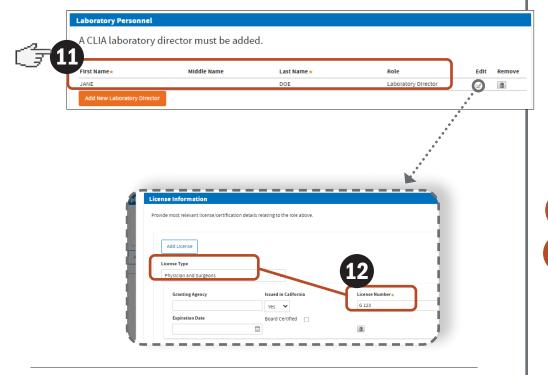
For Waived certificate type, complete Section VI. For PPMP, complete Section VII.







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



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

CMS 116 form (Page 1)

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CLINICAL			OVEMENT AMENDN OR CERTIFICATION	IENTS (CLIA	A)
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Mailing	Mailing		CITY	STATE	ZIP CODE
Corporate	Corpora	te			
NAME OF DIRECTOR (Last, First, Midd	lle Initial)		Laboratory Director's Phone Num	ber	
CREDENTIALS			FOR OFFICE USE ONLY		
		J	Date Received		
II. TYPE OF CERTIFICATE REc		(Check only one) Ple		instructions for i	nspection ar
Certificate of Waiver (Co	mnlete Se	ections I – VI and IX	(– X)		
NOTE: Laboratory directors perform				, training and expe	erience under
subpart M of the CLIA regulations.	Proof of the	se qualifications for the		itted with this app	lication.
Certificate of Compliance	e (Comple	ete Sections I – X)			
Certificate of Accreditation laboratory is accredited by			and indicate which of the fol thich you have applied for ac		
The Joint Commiss	sion	ACHC	AABB A2LA		
CAP		COLA	ASHI		
If you are applying for a Certificate accreditation organization as listed your Certificate of Registration.					
PRA Disclosure Statement According to the Pagerwork Reduction A The valid OMB control number for this in estimated to average one hour per respo review the information collection. If you CMS, 7500 Security Boulevard, Attr. PRA send applications, claims, payments, med correspondence not pertaining to the infi florwarded, or retained. If you have ques	nformation col onse, including have commen Reports Clear lical records or formation colle	llection is 0938-0581. Expira the time to review instruc- its concerning the accuracy ance Officer, Mail Stop C4- r any documents containing ection burden approved ur	tion Date: 03/31/2024. The time required tions, search existing data resources, ga of the time estimate(s) or suggestions i 26-05, Baltimore, Maryland 21244-1850. g sensitive information to the PRA Repo der the associated OMB control numbe	to complete this info ther the data needed, for improving this for *****CMS Disclaimer rts Clearance Office. P r listed on this form w	rmation collecti , and complete ; n, please write : ******Please do 'lease note that vill not be reviev