DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

I. Identifying Information

Name of entity	D/B/A			
Shasta County Public Health Laboratory				
Address (number, street)		**City**	**State**	**ZIP code**
2650 Breslauer Way		Redding	CA	96001
CLIA number	**Taxpayer ID number (EIN)**	**Telephone number**		
05D0644240	94-6000535	(530) 225-5072		

II. Answer the following questions by checking "Yes" or "No." If any of the questions are answered "Yes," list names and addresses of individuals or corporations under "Remarks" on page 2. Identify each item number to be continued.

		YES	NO
A.	Are there any individuals or organizations having a direct or indirect ownership or control interest of five percent or more in the institution, organizations, or agency that have been convicted of a criminal offense related to the involvement of such persons or organizations in any of the programs established by Titles XVIII, XIX, or XX?	☐	☑
B.	Are there any directors, officers, agents, or managing employees of the institution, agency, or organization who have ever been convicted of a criminal offense related to their involvement in such programs established by Titles XVIII, XIX, or XX?	☐	☑
C.	Are there any individuals currently employed by the institution, agency, or organization in a managerial, accounting, auditing, or similar capacity who were employed by the institution's, organization's, or agency's fiscal intermediary or carrier within the previous 12 months? (Title XVIII providers only)	☐	☑

III. A. List names, addresses for individuals, or the EIN for organizations having direct or indirect ownership or a controlling interest in the entity. (See instructions for definition of ownership and controlling interest.) List any additional names and addresses under "Remarks" on page 2. If more than one individual is reported and any of these persons are related to each other, this must be reported under "Remarks."

NAME	ADDRESS	EIN
County of Shasta	1450 Court Street, Ste 308A Redding, CA 96001-1680	94-6000535

B. Type of entity: ☐ Sole proprietorship ☐ Partnership ☐ Corporation ☐ Unincorporated Associations ☒ Other (specify) Local Government

C. If the disclosing entity is a corporation, list names, addresses of the directors, and EINs for corporations under "Remarks."

D. Are any owners of the disclosing entity also owners of other Medicare/Medicaid facilities? (Example: sole proprietor, partnership, or members of Board of Directors) If yes, list names, addresses of individuals, and provider numbers. ☐ ☐

NAME	ADDRESS	PROVIDER NUMBER

CDPH CCIA #05D0644240

RISK MANAGEMENT APPROVAL

BY: 03/26/18

James Johnson
Risk Management Analyst

APPROVED AS TO FORM
SHASTA COUNTY COUNSEL

3/26/18

Alan B. Cox
Deputy County Counsel

		YES	NO
IV. A.	Has there been a change in ownership or control within the last year? ..... If yes, give date. _____	☐	☑
B.	Do you anticipate any change of ownership or control within the year? ..... If yes, when? _____	☐	☑
C.	Do you anticipate filing for bankruptcy within the year? ..... If yes, when? _____	☐	☑
V.	Is the facility operated by a management company or leased in whole or part by another organization? ..... If yes, give date of change in operations. _____	☐	☑
VI.	Has there been a change in Administrator, Director of Nursing, or Medical Director within the last year?	☐	☑
VII. A.	Is this facility chain affiliated? ..... (If yes, list name, address of corporation, and EIN.)	☐	☑

Name		EIN	
Address (number, name)	City	State	ZIP code

B. If the answer to question VII.A. is NO, was the facility ever affiliated with a chain? (If yes, list name, address of corporation, and EIN.)

Name		EIN	
Address (number, name)	City	State	ZIP code

Whoever knowingly and willfully makes or causes to be made a false statement or representation of this statement, may be prosecuted under applicable federal or state laws. In addition, knowingly and willfully failing to fully and accurately disclose the information requested may result in denial of a request to participate or where the entity already participates, a termination of its agreement or contract with the state agency or the secretary, as appropriate.

Name of authorized representative (typed)	Title
Les Baugh	Chairman, Board of Supervisors
Signature	Date

Remarks

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0151

LABORATORY PERSONNEL REPORT (CLIA)

(For moderate and high complexity testing)

1. LABORATORY NAME: Shasta County Public Health Laboratory

2. CLIA IDENTIFICATION NUMBER: 05D0644240

3. LABORATORY ADDRESS *(NUMBER AND STREET)*: 2650 Breslauer Way

CITY: Redding

STATE: CA

ZIP CODE: 96001

5. TELEPHONE *(INCLUDE AREA CODE)*

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)
QUALIFIES ACCORDING TO SUBPART M

DATE OF SURVEY

4. Instructions:
a. List below all technical personnel, by name, who are employed by the laboratory. Check (✓) the appropriate column for each position held. For TC and TS follow instructions on reverse.
b. Indicate whether shift worked is (1) day, (2) evening or (3) night.
c. Indicate highest level of testing for which personnel are qualified: Use (M) for moderate and (H) for high complexity.
d. Indicate whether position held is full (F) or part-time (P).

Positions:
D-Director
CC - Clinical Consultant
TC - Technical Consultant
TS - Technical Supervisor
GS - General Supervisor
TP- Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

EMPLOYEE NAMES			a. POSITION HELD							b. SHIFT	c. M OR H	d. F OR P
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT			
Gonzalez	Anthony	H	✓								1	H	P
Deckert	Andrew	W		✓							1		F
Cole	Kenneth	J			1	1		✓			1	H	F
					2	2					1	H	F
					5	5					1	H	F
					6	6					1	H	F
Hood	Heather	E						✓			1	H	F
Mello	Brandi	M									1		F
Stockton	Pepper	D			1	1	✓	✓			1	H	F
					2	2					1	H	F
					5	5					1	H	F
					6	6					1	H	F

❑ Check (✓) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

6. SIGNATURE OF LABORATORY DIRECTOR: Anthony H. Gonzalez

7. DATE: 2/5/2018

FORM CMS-209 (09/92)

IF CONTINUATION SHEET PAGE ___ OF ___

State of California—Health and Human Services Agency

California Department of Public Health
Laboratory Field Services
850 Marina Bay Parkway,
Bldg. P, 1st Floor
Richmond, CA 94804-6403

LABORATORY PERSONNEL REPORT

Laboratory name	State ID number	CLIA number
Shasta County Public Health Laboratory	CPH 1318	05D0644240

Laboratory address (number, street)	City	State	ZIP code
2650 Breslauer Way	Redding	CA	96001

Contact person	Telephone number
	(530) 225-5072

EMPLOYEE NAMES			POSITION(S) HELD			TESTING IN THE FOLLOWING:									
Last Name	First Name	M.I.	Director	Testing Personnel	License or Certificate Number	MICRO	IMMUN	CHEM	HEM	IMMUNHEM	CYTO	PATH	ORALPATH	HISTCOMP	CYTOGEN
Cole	Kenneth	J		✓	1922	✓	✓								
Gonzalez	Anthony	H	✓		2011										
Hood	Heather	E		✓	2211	✓	✓								
Stockton	Pepper	D		✓	2191	✓	✓								
Deckert	Andrew	W													

I certify that all of the individuals listed above meet the requirements of California Business and Professions Code, Section 1206.5.

Signature of laboratory director	Date
Anthony H. Gonzales	2/5/18

THIS FORM MAY BE PHOTOCOPIED

LAB 116 (7/07)

Laboratory name or ID number

Shasta County Public Health Laboratory

INSTRUCTIONS: List all personnel (e.g., laboratory assistant, phlebotomist, etc.) who are engaged in collecting and preparing specimens but who are not responsible for test results as "testing personnel."

EMPLOYEE NAMES			HOURS		DAYS							FUNCTION
Last Name	First Name	M.I.	From	To	M	T	W	TH	F	SA	SU	
Mello	Brandi	M	0800	1700	✓	✓	✓	✓	✓			Lab Assistant

THIS FORM MAY BE PHOTOCOPIED

State of California—Health and Human Services Agency

LABORATORY TESTING DECLARATION

Calif. Dept. of Public Health
Laboratory Field Services
850 Marina Bay Parkway,
Bldg. P, 1st Floor
Richmond, CA 94804-6403

Name of laboratory (as listed on CLIA certificate)	Laboratory location	CLIA number
Shasta County Public Health Laboratory	2650 Breslauer Way, Redding, CA 96001	05D0644240

Check and name all tests (by manufacturer and equipment) which are performed in your laboratory and indicate the annual volume of tests performed by subspecialty. Attach separate page if additional space is needed.

☐ Waived tests only

☐ Physician performed microscopy procedures only

010 Histocompatibility _____

Annual Volume _____

110 Bacteriology
- ☑ Gram stain Hardy
- ☑ Direct antigen Difco, BD, Denka Seiken, Remel
- ☐ Limited identification _____
  - ☐ Throat _____
  - ☐ Urine _____
  - ☐ G.C. _____
- ☑ ID genus and species Api, Hardy, Remel
- ☐ Susceptibility testing _____
- ☐ C. difficile Ag _____
- ☑ Molecular diagnostics CT/GC-GenProbe, Pertussis-Roche, Flu

Annual Volume 1710

115 Mycobacteriology
- ☑ Acid fast stain Hardy
- ☑ ID acid fast Hardy
- ☐ ID and/or susceptibility for M.T.B. _____
- ☐ ID and susceptibility for all acid fast _____
- ☐ Molecular diagnostics _____

Annual Volume 360

120 Mycology
- ☐ ID yeast and/or dermatophytes _____
- ☐ ID genus _____
- ☐ ID genus and species _____

Annual Volume _____

130 Parasitology
- ☐ Wet mounts and/or pinworms preparation _____
- ☐ ID conc. and/or stain _____

Annual Volume _____

140 Virology
- ☑ Direct antigen HSV, VZV-Light Diagnostics
- ☐ ID _____
- ☑ Molecular diagnostics Flu-ABI/Invitrogen, Norovirus-Roche

Annual Volume 700

210 Syphilis serology
- ☐ FTA–ABS _____
- ☑ RPR BD Macroview
- ☐ RST _____
- ☐ VDRL _____
- ☐ MHA–TP _____

Annual Volume 15

220 General immunology
- ☐ Alpha–1 antitrypsin _____
- ☐ Alpha–fetoprotein _____
- ☐ Antihuman immunodeficiency virus (HIV) _____
- ☐ Antinuclear antibody _____
- ☐ Antistreptolysin O _____
- ☐ Complement C3 _____
- ☐ Complement C4 _____
- ☐ CRP _____
- ☐ Hepatitis A antibody _____
- ☐ Hepatitis B core Ab _____
- ☐ HBsAb _____
- ☐ HBsAg _____
- ☐ HBeAg _____
- ☐ Hepatitis C Ab _____
- ☐ H. pylori Ab _____
- ☐ IgA _____
- ☐ IgE _____
- ☐ IgG _____
- ☐ IgM _____
- ☐ Infectious mononucleosis _____
- ☐ Rheumatoid factor _____
- ☐ Rubella _____

Annual Volume _____

310 Routine chemistry
- ☐ Alanine aminotransferase (ALT/SGPT) _____
- ☐ Albumin _____
- ☐ Alkaline phosphatase _____
- ☐ Ammonia _____
- ☐ Amylase _____
- ☐ Aspartate aminotransferase (AST/SGOT) _____
- ☐ Bilirubin, total _____
- ☐ Blood gases: ☐ pH ☐ pCO2 ☐ pO2 _____
- ☐ Calcium _____
- ☐ CEA _____
- ☐ Chloride _____
- ☐ Cholesterol, high density lipoprotein (HDL) _____
- ☐ Cholesterol, total _____
- ☐ CO2 _____
- ☐ Creatine kinase _____
- ☐ Creatine kinase, iso and CKMB _____
- ☐ Creatinine _____
- ☐ Cryoglobulin _____
- ☐ Ferritin _____
- ☐ Folate _____
- ☐ Gamma GT _____
- ☐ Glucose, serum _____
- ☐ Glucose, whole blood _____
- ☐ Iron, total _____
- ☐ TIBC _____
- ☐ Lactate dehydrogenase (LDH) _____
- ☐ LDH isoenzymes _____
- ☐ Lactic acid _____
- ☐ Magnesium _____
- ☐ Osmolality _____
- ☐ Phosphorus _____
- ☐ Potassium _____
- ☐ PSA _____
- ☐ Sodium _____
- ☐ Total protein _____
- ☐ Triglycerides _____
- ☐ Troponin—1 _____
- ☐ Urea nitrogen _____
- ☐ Uric acid _____
- ☐ Vitamin B-12 _____

Annual Volume _____

320 Urinalysis
- ☐ Dipsticks _____
- ☐ Microscopy _____

Annual Volume _____

330 Endocrinology
- ☐ Cortisol _____
- ☐ Estradiol _____
- ☐ Estriol _____
- ☐ Free thyroxine (free T–4) _____
- ☐ FSH _____
- ☐ Human chorionic gonadotrophin, serum (HCG) _____
- ☐ Human chorionic gonadotrophin, urine (HCG) _____
- ☐ LH _____
- ☐ Progesterone _____
- ☐ Prolactin _____
- ☐ Testosterone _____
- ☐ Thyroid–stimulating hormone (TSH) _____
- ☐ Thyroxine (T–4) _____
- ☐ Triiodothyronine (T–3) _____
- ☐ T–3 uptake _____

Annual Volume _____

DIRECTOR'S ATTESTATION

I attest that effective 10/01/2017 (date), I am the laboratory director, or a co-director of:

Shasta County Public Health Laboratory (name of laboratory) clinical laboratory, located at

2650 Breslauer Way, Redding CA 96001 (street address)

CLIA number: 05D0644240 **State ID number (if known):** CPH 1318

As the director or co-director, I assume all directorship responsibilities for CLIA and State of California purposes. I understand that as a director of this laboratory, I am responsible for the accuracy and reliability of all testing performed by the laboratory and for ensuring that the laboratory meets all applicable CLIA and state requirements as stipulated in both federal and California laws (Code of Federal Regulations [CFR], Title 42, Sections 493.1407, 493.1445; California Business and Professions Code [BPC], Section 1209).

I understand that I will be held jointly and severally responsible with the laboratory owner(s) for any violations of law by this clinical laboratory (BPC Section 1265(b)). If deficient or unlawful practices are found that occurred while I was serving as laboratory director or co-director, which the laboratory fails or is unable to correct, and which results in the revocation of the laboratory's CLIA certificate or state license or registration, I understand that pursuant to Title 42 of the United States Code (USC), Section 263(a)(i)(3), 42 CFR 493.1840(a)(8), and BPC Section 1324, I would be prohibited from owning, operating, or directing another clinical laboratory for a period of at least two years from the date of revocation. Such action may also be grounds for referral to the Medical Board of California or other licensing board for appropriate action.

I understand that any false statement or representation of material fact in obtaining or retaining CLIA certification or state licensure or registration may be grounds for revocation of the laboratory's CLIA certificate under 42 CFR 493.1840(a)(1), and state license or registration under BPC Section 1320(f).

I understand that I will be responsible, along with the laboratory owner(s), to notify the Department of Public Health in writing of any changes in the laboratory ownership, directorship, name or location within **thirty days** of the change, and that failure to provide such notification will result in automatic revocation of the state license or registration (BPC Section 1265(g)), and sanctions against the CLIA certificate (42 CFR 493.39(b), 493.45(b)(2), 493.51(a), 493.53(a), 493.57(a)(2), and 493.63(a)).

I understand that I will continue to be held responsible as a laboratory director of this laboratory until the day that the California Department of Public Health **receives** a signed statement from me notifying the Department of my resignation or termination.

I affirm under penalty of perjury, that all information I have given in this document is true.

Anthony H. Gonzalez
Director's signature

2/5/2018
Date

Anthony H Gonzalez, PhD, HCLD(ABB), Laboratory Director
Print or type director's name and title

CLIA Director: ☑ Yes ☐ No

4033 Quarter Dome Circle, Rancho Cordova, CA 95742
Director's address (as recorded on personal professional license)

(916) 874-9231
Director's direct contact telephone number

Or

California Board license number:

California Director license number: HCLD (ABB) 2060019

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☒ Survey
☐ Change in Certificate Type
☐ Closure/Other Changes (Specify) _____

Effective Date 1/02/2018

CLIA IDENTIFICATION NUMBER
05 D 0644240
(If an initial application leave blank, a number will be assigned)

FACILITY NAME	FEDERAL TAX IDENTIFICATION NUMBER
Shasta County Public Health Lab	94-6000535

EMAIL ADDRESS	TELEPHONE NO. *(Include area code)*	FAX NO. *(Include area code)*
pstockton@co.shasta.ca.us	(530) 225-5072	(530) 225-5061

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)*
2650 Breslauer Way

CITY	STATE	ZIP CODE
Redding	CA	96001

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

CITY	STATE	ZIP CODE

SEND CERTIFICATE TO THIS ADDRESS	SEND FEE COUPON TO THIS ADDRESS
☒ Physical	☒ Physical
☐ Mailing	☐ Mailing
☐ Corporate	☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*
NUMBER, STREET

NAME OF DIRECTOR *(Last, First, Middle Initial)*	CITY	STATE	ZIP CODE
Gonzalez, Anthony H			

CREDENTIALS	FOR OFFICE USE ONLY
PhD, HCLD(ABB)	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)*
☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I – 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 ☐ AOA ☐ 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.

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.

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

  Is this a shared lab?

  ☐ Yes ☐ No
- ☐ 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)*

  _____

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:		0800	0800	0800	0800	0800	
TO:		1700	1700	1700	1700	1700	

(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.

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 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)*	

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

VI. WAIVED TESTING

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

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

☒ Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

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

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.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation)*

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.

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, AOA, AABB, 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		2050	☐ 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		115	☐ 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:**		2165

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
		_____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
05D0644185	Sacramento County Public Health Laboratory

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.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE
Anthony M. Cagaly	2/5/2018

NOTE: Completed 116 applications must be sent to your local State Agency.

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

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 of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition 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 which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check **"initial application"**. For an initial survey or for a recertification, check **"survey"**. For a request to change the type of certificate, check **"change in certificate type"** and provide the effective date of the change. For all other changes, including change in location, director, lab closure, etc., check **"closure/other changes"** and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a: **Certificate of Waiver** can only perform tests categorized as waived;*

- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.**

III. TYPE OF LABORATORY

Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting 'physician office' (code 21), also answer a related question regarding 'shared labs'.

A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund one laboratory's operations. The definition of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory's operation.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3) Hospice and HHA could qualify for an exception.

VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at: **http:www.cms.gov/CLIA/downloads/waivetbl.pdf**

VII. PPM TESTING

Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: **http://www.cms.gov/clia/downloads/ppmp.list.pdf**

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*

The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type of ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate 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 verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES

HISTOCOMPATIBILITY (010)
HLA Typing (disease associated antigens)

MICROBIOLOGY

Bacteriology (110)
Gram Stain
Culture
Susceptibility
Strep screen
Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology (115)
Acid Fast Smear
Mycobacterial culture
Mycobacterial susceptibility

Mycology (120)
Fungal Culture
DTM
KOH Preps

Parasitology (130)
Direct Preps
Ova and Parasite Preps
Wet Preps

Virology (140)
RSV (Not including waived kits)
HPV assay
Cell culture

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology (210)
RPR
FTA, MHATP

General Immunology (220)
Allergen testing
ANA
Antistreptolysin O
Antigen/Antibody (hepatitis, herpes, rubella, etc.)
Complement (C3, C4)
Immunoglobulin
HIV
Mononucleosis assay
Rheumatoid factor
Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

*Tumor markers can alternatively be listed under Routine Chemistry instead of General Immunology.

HEMATOLOGY (400)
Complete Blood Count (CBC)
WBC count
RBC count
Hemoglobin
Hematocrit (Not including spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time (Not including waived instruments)
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

IMMUNOHEMATOLOGY
ABO group (510)
Rh(D) type (510)
Antibody screening
Antibody identification (540)
Compatibility testing (550)

PATHOLOGY
Dermatopathology
Oral Pathology (620)
PAP smear interpretations (630)
Other Cytology tests (630)
Histopathology (610)

RADIOBIOASSAY (800)
Red cell volume
Schilling test

CLINICAL CYTOGENETICS (900)
Fragile X
Buccal smear
Prader-Willi syndrome
FISH studies for: neoplastic disorders, congenital disorders or solid tumors.

CHEMISTRY

Routine Chemistry (310)
Albumin
Ammonia
Alk Phos
ALT/SGPT
AST/SGOT
Amylase
Bilirubin
Blood gas (pH, pO2, pCO2)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO2
Creatinine
Ferritin
Folate
GGT
Glucose (Not fingerstick)
Iron
LDH/LDH isoenzymes
Magnesium
Potassium
Protein, electrophoresis
Protein, total
PSA
Sodium
Triglycerides
Troponin
Uric acid
Vitamin B12

Endocrinology (330)
Cortisol
HCG (serum pregnancy test)
T3
T3 Uptake
T4
T4, free
TSH

Toxicology (340)
Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis (320)**
Automated Urinalysis (Not including waived instruments)
Microscopic Urinalysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfosalicylic acid

** Dipstick urinalysis is counted in Section VI. WAIVED TESTING

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf** and **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf.** You may also call your State agency for further information. State agency contact information can be found at: **http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf.**

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopia examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialities**, do not count calculations (e.g., A/G ratior, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.

340 Toxicology
- [ ] Acetaminophen
- [ ] Alcohol, blood
- [ ] Amikacin
- [ ] Blood lead
- [ ] Carbamazepine
- [ ] Digoxin
- [ ] Drug screen
- [ ] Drug confirmation
- [ ] Ethosuximide
- [ ] Gentamicin
- [ ] Lidocaine
- [ ] Lithium
- [ ] Phenobarbital
- [ ] Phenytoin
- [ ] Primidone
- [ ] Procainamide (and metabolite)
- [ ] Quinidine
- [ ] Salicylates
- [ ] Theophylline
- [ ] Tobramycin
- [ ] Valproic acid

Annual Volume

400 Hematology
- [ ] Erythrocyte count (RBC)
- [ ] Hematocrit
- [ ] Hemoglobin
- [ ] Leukocyte count (WBC)
- [ ] Platelet count
- [ ] Eosinophil count
- [ ] Automated WBC differential
- [ ] Manual WBC differential
- [ ] Retic count
- [ ] Sickle cell
- [ ] ACT/bleeding time
- [ ] Factor assay
- [ ] Fibrinogen
- [ ] FDP
- [ ] Partial thromboplastin time (PTT)
- [ ] Prothrombin time
- [ ] Thrombin time
- [ ] Sedimentation rate
- [ ] Semen analysis
- [ ] CSF/body fluid counts

Annual Volume

510 ABO and Rh type
- [ ] ABO group
- [ ] D(Rho) type

Annual Volume

520 Ab detection transfusion
- [ ] Unexpected antibody detection

Annual Volume

530 Ab detection nontransfusion
- [ ] Unexpected antibody detection

Annual Volume

540 Antibody ID
- [ ] Antibody identification

Annual Volume

550 Compatibility testing

Annual Volume

610 Histopathology

Annual Volume

620 Oral pathology

Annual Volume

630 Cytology

Annual Volume

800 Radiobioassay
- [ ] Schilling test
- [ ] Blood volume

Annual Volume

900 Clinical cytogenetics
- [ ] Cytogenetics
- [ ] Molecular diagnostics

Annual Volume

List all other tests performed and annual test volume.

QuantiFERON In-tube Gold - 100

This statement to be signed by owner or person legally authorized to bind the owner and the laboratory director.
I declare under penalty of perjury that foregoing statements are true and correct.

Director signature	Name (typed)	Date
Anthony R. Gonzales	Anthony Gonzalez	2/5/2018
Owner signature	Name (typed)	Date
	Les Baugh Chairman Board of Supervisors	