STATE OF CALIFORNIA **CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**

Memorandum

Date: 04/03/17

To: SHASTA COUNTY HEALTH DEPARTMENT
ATTENTION: LABORATORY DIRECTOR
2650 BRESLAUER WAY
REDDING, CA 96001

From: CDPH-Laboratory Field Services
850 Marina Bay Parkway Bldg. P, 1st FL.
Richmond, CA. 94804
ATTENTION: Rona Aquino

CLA☐CLM ☐ CLF☒# CPH 1318
CLIA # 05D0644240

E-mail:

SUBJ: INCOMPLETE PACKAGE FOR CHANGE OF DIRECTOR/OWNERSHIP

Department records indicate that the renewal packet you submitted is incomplete. A complete application packet must include ALL forms. The items marked with an "X" below are missing. PLEASE COMPLETE THE REQUIRED FORMS AND RETURN TO THE ABOVE ADDRESS IMMEDIATELY. ***COPIED OR FAXED APPLICATIONS ARE NOT ACCEPTABLE.***

☒ Application for Clinical Laboratory License (**LAB144**) complete & sign
☐ Form B Application for additional Clinical Laboratory Testing Site (**LAB 144B**)
☒ Laboratory Personnel Report (**LAB116**) Make sure to fill out the **license number column** complete & sign
☒ Annual Test Volume of Test Performed (**LAB 167**) complete & sign
☐ Director's Attestation (**LAB183**)
☐ Disclosure of Ownership & Control Interest Statement (**LAB 1513**)
☒ CLIA Application for Certification (**CMS 116**) complete & sign
☒ CLIA Laboratory Personnel Report (**CMS 209**) complete & sign
☒ **Original signatures** must be on all forms where signatures are required. **No faxes or copies.**
☒ Continuing Education (***20 units of Continuing Education** is required if director was not board certified **on or before 2/28/1992** **OR** if director is not board certified as a Dermatologist or Pathologist* if performing histopathology testing.) See Link below http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CME_Courses_for_Laboratory_Directors_of_Moderate_Complexity_Laboratories.html
☐ Fee $_____ (***Payable to: CDPH Laboratory Field Services,** not refundable*)
☐ **Evidence** from accrediting organization (JHACO,CAP,Etc.)stating the facility applied for accreditation.
☒ **Resignation letter** from the previous director(*if previous director is not available have the new director write a letter with the name and the effective day of previous director's resignation*)
☐ Business Status-Articles of Incorporation, Bill of Sale, Merger, Partnership Agreement.
☒ Others
Please complete & sign all forms. Please include a copy of Dr.Dondero's resignation letter.
Please send all requested documents to the highlighted address. Thank you!

Return this letter with the completed renewal packet

Note: State law requires that you notify the department WITHIN 30 DAYS of any change in ownership, laboratory director, name and location. IF YOU DO NOT COMPLY, YOUR LICENSE ALSO WILL BE AUTOMATICALLY REVOKED 30 DAYS AFTER A MAJOR OWNER AND/OR DIRECTOR CHANGE OCCURS. If your license is revoked, you must submit a new application/fee within 30 days if you wish to continue performing clinical laboratory tests.

State LAB forms can be downloaded from *http://www.cdph.ca.gov/pubsforms/forms/Pages/RegulatedLaboratories.aspx*

APPLICATION FOR INITIAL CLINICAL LABORATORY LICENSE

Refer to California Business and Professions Code, Division 2, Chapter 3

Instructions: Complete both pages of this application and return with the required information and fee to:

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

CPH 1318

1. Please choose one of the following options:
   X I choose to register for state oversight.
   ☐ I choose deemed status with the following accrediting organization approved by the California Department of Public Health:

   ☐ CAP ☐ COLA ☐ The Joint Commission (JC)

   Note: If you choose deemed status, please provide a copy of your current certificate of accreditation, or a letter of acknowledgement from the accrediting organization that you have applied.

2. Name of Laboratory			Tax ID Number	
Shasta County Public Health Laboratory			94-6000535	
Address (number, street, suite/apt)	City	County	State	Zip Code
2650 Breslauer Way	Redding	Shasta	CA	96001
Telephone Number	Fax Number	Email Address		
(530) 225-5072	(530) 225-5061	mcastagnoli@co.shasta.ca.us		

3. CLIA provider number 05D 0644240

4. State the number of testing sites for this CLIA number 1. If there is more than one, complete form B.

5. Legal name of corporation, district, or association owning laboratory (Fictitious name permit must be on file; provide name of locality where permit is filed)
   County of Shasta

6. Select type of ownership. Check (✓) and complete the name and address (Section 1211 of Business Professions Code).

   ☐ Individual
   ☐ Partnership (general or limited). List name(s) and address(s) of all members of the partnership. Use supplementary sheet if necessary.
   ☐ Corporation. List names of officers, directors, shareholders holding a 5% interest in the corporation, and any person, partnership, or corporation who or which has the responsibility to manage or conduct the day-to-day operation of the laboratory. (Use supplementary sheet if necessary.)
   ☐ Unincorporated Association
   ☒ District, City, County, or State
   ☐ Other (specify) (if nonprofit, submit proof of nonprofit status):_____

Name	Address	City	State	Zip Code
County of Shasta	2650 Breslauer Way	Redding	CA	96001
Name	Address	City	State	Zip Code
Name	Address	City	State	Zip Code
Name	Address	City	State	Zip Code
Name	Address	City	State	Zip Code
Name	Address	City	State	Zip Code

7. Laboratory Director(s) (M.D., D.O.)

Name	Address (number, street)	City	State	Zip Code	Hour Per Week On Site
Mark Castagnoli	661 San Gabriel Street	Redding	CA	96003	40
Name	Address (number, street)	City	State	Zip Code	
Name	Address (number, street)	City	State	Zip Code	
Name	Address (number, street)	City	State	Zip Code	
Name	Address (number, street)	City	State	Zip Code	
Name	Address (number, street)	City	State	Zip Code	

This statement must be signed by the owner or a person legally authorized to bind the owner, and the laboratory director.
I declare that the foregoing statements are true and correct to the best of my knowledge and belief.

Laboratory Director Signature	Type or Print Name	Title	Date
Mark Castagnoli	Mark Castagnoli	Chief Public Health Microbiologist	5/3/2017
Owner Signature	Type or Print Name	Title	Date
	David A. Kehoe	Chairman Board of Supervisors County of Shasta	

For application questions, email: lfsnewfaclic@cdph.ca.gov
NOTE: State registration fees schedule: http://www.cdph.ca.gov/programs/lfs/Documents/A-License-FeeSchedules.pdf
Make checks payable to: California Department of Public Health

APPROVED AS TO FORM
SHASTA COUNTY COUNSEL
6/9/17
Alan B. Cox
Deputy County Counsel

RISK MANAGEMENT APPROVAL
BY: 06/12/17
James Johnson
Risk Management Analyst

State of California—Health and Human Services Agency

California Department of Public Health

DIRECTOR'S ATTESTATION

I attest that effective 2/1/2017 (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):** 94-6000535

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.

Mark Castagnoli

Director's signature

5/3/2017

Date

Mark Castagnoli Chief Public Health Microbiologist

Print or type director's name and title

CLIA Director: [X] Yes [ ] No

661 San Gabriel Street, Redding, CA 96003

Director's address (as recorded on personal professional license)

(530) 245-6859

Director's direct contact telephone number

Or California Board license number: _____

California Director license number: _____

LAB 183 (7/07)

State of California
Department of Health Services

Date Issued
October 27, 1982

Certificate Number
1522

MARK R. CASTAGNOLI

having fulfilled the legal requirements for certification as

Public Health Microbiologist

and having successfully passed an examination in bacteriology, serology, parasitology, mycology, and virology is entitled to engage in any of the activities of laboratories approved by the Department of Health in accordance with Title 17 of the California Administrative Code.

LAB-100 (9/73)

8024-034

State of California
Department of Public Health

CLINICAL LABORATORY SCIENTIST

THIS LICENSE IS ISSUED PURSUANT TO DIVISION 2, CHAPTER 3 OF THE CALIFORNIA BUSINESS AND PROFESSIONS CODE, TO AUTHORIZE

MARK R CASTAGNOLI

TO ENGAGE IN CLINICAL LABORATORY PRACTICE IN ACCORDANCE WITH THE CLINICAL LABORATORY TECHNOLOGY LAWS AND REGULATIONS OF DIVISION 2, CHAPTER 3, OF THE CALIFORNIA BUSINESS AND PROFESSIONS CODE.

LICENSE NUMBER: MTA00028265
RENEWAL VALID THROUGH: 08/07/2018

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

State of California—Health and Human Services Agency

California Department of Public Hea
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	94-6000535	05D0644240

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

Contact person	Telephone number
Mark Castagnoli	(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
Castagnoli	Mark	R	X	X	1522	X	X								
Cole	Kenneth	J		X	1922	X	X								
Stockton	Pepper	D		X	2191	X	X								

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: Mark Castagnoli

Date: 5/3/2017

LABORATORY PERSONNEL REPORT (Continued)

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		0800	1700	X	X	X	X	X			Lab Assistant

THIS FORM MAY BE PHOTOCOPIED

State of California — Health and Human Services Agency

California Department of Public Health
Laboratory Field Services

ANNUAL TEST VOLUME OF TEST PERFORMED

Indicate the annual volume of tests performed by specialties or subspecialty.

Shasta County Public Health Laboratory	94-6000535		05D0644240
Name of Laboratory	State ID Number		CLIA
2650 Breslauer Way	Redding	CA	96001
Address (number, street)	City	State	ZIP

SPECIALTY/SUBSPECIALTY	ANNUAL TEST VOLUME	SPECIALTY/SUBSPECIALTY	ANNUAL TEST VOLUME
110 Bacteriology	1348	010 Histocompatibility	0
115 Mycobacteriology	340	400 Hematology	0
120 Mycology	0	510 ABO and Rh Type	0
130 Parasitology	0	520 Antibody Detection Transfusion	0
140 Virology	631	530 Antibody Detection Non-transfusion	0
210 Syphilis Serology	15	540 Antibody Identification	0
220 General Immunology	249	550 Compatibility Testing	0
310 Routine Chemistry	0	610 Histopathology	0
320 Urinalysis	0	620 Oral Pathology	0
330 Endocrinology	0	630 Cytology	0
340 Toxicology	0	900 Clinical Cytogenetics	0

Sub-Total: 2,583

List all other tests performed and annual test volume (Use additional sheets if necessary)

Sub-Total: _____

Total Volume: _____

Authorized Signature: Mark Castagnoli Printed Name: Mark Castagnoli Date: 5/3/2017

LAB 167 (4/12)

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

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

5. TELEPHONE *(INCLUDE AREA CODE)*: (530) 225-5072

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

DATE OF SURVEY _____

EMPLOYEE NAMES			a. POSITION HELD								b. SHIFT 1 2 3	c. M OR H	d. F OR P	
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT				
Castagnoli	Mark	R	X		1	1	X	X			1	H	F	
					2	2					1	H	F	
					5	5					1	H	F	
					6	6					1	H	F	
Cole	Kenneth	J			1	1	X	X			1	H	F	
					2	2					1	H	F	
					5	5					1	H	F	
					6	6					1	H	F	
Stockton	Pepper	D						X			1	H	F	
Mello	Brandi	M									1		F	
Deckert	Andrew	W		X							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

Mark Castagnoli

7. DATE

5/3/2017

INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

Instructions for 4(a) TC/TS:
When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a line for each specialty/subspecialty.

GRID:

1. Bacteriology
2. Mycobacteriology
3. Mycology
4. Parasitology
5. Virology
6. Diagnostic Immunology
7. Chemistry
8. Hematology
9. Immunohematology
10. Clinical Cytogenetics
11. Histocompatibility
12. Radiobioassay
13. Histopathology
14. Oral Pathology
15. Cytology
16. Dermatopathology
17. Ophthalmic Pathology

EXAMPLE

EMPLOYEE NAMES			a. POSITION HELD								b. SHIFT 1 2 3	c. M OR H	d. F OR P
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT			
Smith	John				1						1	M	F
						4						H	
						6						H	

FOR OFFICIAL USE ONLY

Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology supervisor, and those testing personnel and cytotechnologist sampled during the survey process.

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

CPH 1318

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) Director Change
Effective Date 2/1/2017

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

FACILITY NAME
Shasta County Public Health Laboratory

FEDERAL TAX IDENTIFICATION NUMBER
94-6000535

EMAIL ADDRESS
mcastagnoli@co.shasta.ca.us

TELEPHONE NO. *(Include area code)*
(530) 225-5072

FAX NO. *(Include area code)*
(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

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

CITY	STATE	ZIP CODE
Redding	CA	96001

CITY	STATE	ZIP CODE

SEND CERTIFICATE TO THIS ADDRESS
☒ Physical
☐ Mailing
☐ Corporate

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

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

NAME OF DIRECTOR *(Last, First, Middle Initial)*
Castagnoli Mark R.

CITY	STATE	ZIP CODE

CREDENTIALS PHM Certificate # 1522
10/27/1982

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)*
☐ 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
HISTOCOMPATIBILITY 010		
☐ Transplant		
☐ Nontransplant		
MICROBIOLOGY		2,300
☒ Bacteriology 110		
☒ Mycobacteriology 115		
☐ Mycology 120		
☐ Parasitology 130		
☒ Virology 140		
DIAGNOSTIC IMMUNOLOGY		264
☒ Syphilis Serology 210		
☒ General Immunology 220		
CHEMISTRY		
☐ Routine 310		
☐ Urinalysis 320		
☐ Endocrinology 330		
☐ Toxicology 340		

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HEMATOLOGY 400		
☐ Hematology		
IMMUNOHEMATOLOGY		
☐ ABO Group & Rh Group 510		
☐ Antibody Detection (transfusion) 520		
☐ Antibody Detection (nontransfusion) 530		
☐ Antibody Identification 540		
☐ Compatibility Testing 550		
PATHOLOGY		
☐ Histopathology 610		
☐ Oral Pathology 620		
☐ Cytology 630		
RADIOBIOASSAY 800		
☐ Radiobioassay		
CLINICAL CYTOGENETICS 900		
☐ Clinical Cytogenetics		
TOTAL ESTIMATED ANNUAL TEST VOLUME:		2564

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
N/A	

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
Mark Contogeri	5/3/2017

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

Dale Dondero
Public Health Laboratory Director
Shasta County Health and Human Services
Public Health Branch
2650 Breslauer Way
Redding CA 96001-4246

February 1, 2017

Brandy Isola
Deputy Branch Director
Health and Human Services Agency
Public Health Branch

Dear Brandy,

This is to inform you that effective February 28, I will no longer be serving as the Director for the Shasta County Public Health Laboratory located at the above address.

Thank you,

Dale Dondero
Public Health Laboratory Director