County of San Bernardino
DELEGATED AUTHORITY – DOCUMENT REVIEW FORM

This form is for use by any department or other entity that has been authorized by Board of Supervisors/Directors action to execute grant applications, awards, amendments or other agreements on their behalf. All documents to be executed under such delegated authority must be routed for County Counsel and County Administrative Office review prior to signature by designee.

Note: This process should NOT be used to execute documents under a master agreement or template, or for construction contract change orders. Contact your County Counsel for instructions related to review of these documents.

Complete and submit this form, along with required documents proposed for signature, via email to the department's County Counsel representative and Finance Analyst. If the documents proposed for signature are within the delegated authority, the department will submit the requisite hard copies for signature to the County Counsel representative. Once County Counsel has signed, the department will submit the signed documents in hard copy, as well as by email, to CAO Special Projects Team for review. If approved, the department will be provided routing instructions as well as direction to submit one set of the executed documents to the Clerk of the Board within 30 days.

For detailed instructions on submission requirements, reference Section 7.3 of the Board Agenda Item Guidelines as the Delegation of Authority does not eliminate the document submission requirements.

Department/Agency/Entity: Behavioral Health

Contact Name: Rebecca Lombard Telephone: (909) 383-3978

Agreement No.: _____ Amendment No.: _____ Date of Board Item 07/26/2022 Board Item No.: 18

Name of Contract Entity/Project Name: CLIA Waiver Authorization: DBH-Phoenix Community Counseling Center

Explanation of request/Special Instructions:

Behavioral Health is requesting the Chief Executive Officer's signature on "Clinical Laboratory Improvement Amendments Application for Certification" and the "Owners Attestation" as approved by the Board on July 26, 2022, Item No. 18, Recommendation No. 2

This application and attestation are required by the California Department of Health Care Services for an initial application of Clinical and Public Health Laboratory License through the California Department of Public Health.

Insert check mark that the following required documents are attached to this request:

☑ **Documents proposed for signature (Note: For contracts, include a signed non-standard contract coversheet for contracts not submitted on a standard contract form).**

☑ **Board Agenda item that delegated the authority**

Department Routed to County Counsel	County Counsel Name: Dawn Martin	Date Sent: 03/16/2023
Reviewing County Counsel Use Only	Review Date 3/16/23 Signature	**Determination:** __X__ Within Scope of Delegated Authority ____ Outside Scope of Delegated Authority
CAO-Special Projects Use Only	Review Date 3/31/23 Signature	**Disposition:** __✓__ Route for signature to: ___ Chair __✓__ CEO ___ Department ___ Return to Department for preparation of agenda item

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 04/03/2023
☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

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

FACILITY NAME Phoenix Community Counseling Center	FEDERAL TAX IDENTIFICATION NUMBER 95-6002748
EMAIL ADDRESS DBHMedicalServices@dbh.sbcounty.gov ☒ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL	TELEPHONE NO. *(Include area code)* (909) 601-4220 FAX NO. *(Include area code)* (909) 387-7717
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)* 820 E. Gilbert St. Suite #151	MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate* NUMBER, STREET
CITY San Bernardino / STATE CA / ZIP CODE 92415	CITY / STATE / ZIP CODE
SEND FEE COUPON TO THIS ADDRESS PICK ONE: ☐ Physical ☒ Mailing ☐ Corporate	SEND CERTIFICATE TO THIS ADDRESS PICK ONE: ☐ Physical ☒ Mailing ☐ Corporate
	CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate* NUMBER, STREET CITY / STATE / ZIP CODE
NAME OF DIRECTOR *(Last, First, Middle Initial)* Avalos, Jonathan, D.	Laboratory Director's Phone Number (909) 601-4220
CREDENTIALS MD, Addiction Medicine Physician	**FOR OFFICE USE ONLY** Date Received

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

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

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-X)*

☐ Certificate of Compliance *(Complete Sections I – X)*

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ ACHC ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

PRA Disclosure Statement

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

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
- ☐ 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)* Community Outpatient Clinic

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:		08:00	08:00	08:00	08:00	08:00	
TO:		05:00	05:00	05:00	05:00	05:00	

(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 estimated annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation
Neotrophil percentage (NEUT %)	Athelas Home	Athelas INC
Urine pregnancy test	Clear Choice Pregnancy Test	Phamatech
Finger-stick Glucose	Free Style Precision Neo H System	Abbott Diabetes Care, Inc.
White blood cell (WBC)	Athelas Home	Athelas INC
Alcohol, Saliva	Alco-Screen Saliva Alcohol Test	Chematics
HIV-1 and HIV-2 Antibodies	OraQuick Advance Rapid HIV 1/2 Test	OraSure Technologies
Drugs of use testing	Quick Screen Pro Multi Drug Screening	Phamatech, INC
Hemoglobin	Sysmex XW-100	Sysmex America, Inc
Platelet count	Sysmex XW-100	Sysmex America, Inc
Hematocrit	Sysmex XW-100	Sysmex America, Inc
Red blood cell count	Sysmex XW-100	Sysmex America, Inc
White blood cell count (WBC)	Sysmex XW-100	Sysmex America, Inc
White blood cell differential (WBC diff)	Sysmex XW-100	Sysmex America, Inc
Triglyceride	Sysmex XW-100	Sysmex America, Inc

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed 55,438

☐ Check if no waived tests are performed

If additional space is needed, check here ☒ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
☐ Potassium hydroxide (KOH) preparations
☐ Pinworm examinations
☐ Fern tests
☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
☐ Urine sediment examinations
☐ Nasal smears for granulocytes
☐ Fecal leukocyte examinations
☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

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

If also performing waived complexity tests, complete Section VI. 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.

Continuation of Waived testing

Facility name	Phoenix Community Counseling Center
Federal Tax Identification Number	95-6002748

ANALYTE / TEST	TEST NAME	MANUFACTURER
HDL cholesterol	O2 Lifecare CURO L5 Lipid Profile	O2 Lifecare, Inc.
Cholesterol	O2 Lifecare CURO L5 Lipid Profile	O2 Lifecare, Inc.
Glucose	O2 Lifecare CURO L5 Lipid Profile	O2 Lifecare, Inc.
Protein, total	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
albumin	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Alanine aminotransferase (ALT) (SGPT)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Calcium, total	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Aspartate aminotransferase (AST) (SGOT)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
glucose	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Sodium	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Potassium	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Creatinine	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Alkaline phosphatase (ALP)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Urea (BUN)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Bilirubin, total	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Chloride	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Carbon dioxide, total (CO2)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Amylase	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Cholesterol	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Creatine kinase (CK)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Gamma glutamyl transferase (GGT)	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
HDL cholesterol	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Phosphorus	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Triglyceride	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Uric acid	Abaxis Piccolo Blood Chemistry Analyzer	Abaxis, Inc.
Glycated hemoglobin, total	Metrika INViEW multi-test A1c monitor	Metrika, Inc.
Thyroid stimulating hormone (TSH)	Thyrotest Whool blood TSH Test	Thyrotec, LLC
Urine dipstick	Mission Urinalysis Reagent Strips	Acon Lab. Co.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

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.

If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.

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, ACHC, AABB, A2LA ,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			☐ 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			☐ 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:**		

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
		_____ (If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐ Yes ☒ No

If Yes, what is the country of origin for the foreign entity? _____

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
05D2191939	Barstow Counseling and Behavioral Health Center
05D2188395	Supervised Treatment After Release Program
05D2188393	Mariposa Community Counseling
05D2230661	Rialto Behavioral Addiction Treatment Services

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.

PRINT NAME OF DIRECTOR OF LABORATORY

Jonathan Avalos, MD

PRINT NAME OF OWNER OF LABORATORY

Leonard X. Hernandez

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)*

Leonard X. Hernandez

DATE 3/31/2023

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://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. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. 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 **"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.

Email Address: A valid Email Address will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address.

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 '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.

VII. PPM TESTING
Indicate the estimated total annual test volume for all PPM tests performed.

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.

Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency **(https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf).**

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. State agency contact information can be found at:
https://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 **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf** and **https://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: **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf**.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **chemistry**, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).
- 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. NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.
- For manual gynecologic and nongynecologic **cytology**, each slide (not case) is counted as one test.
- For **flow cytometry**, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- **Genetics tests** should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.
- 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 **histocompatibility**, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- 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 **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification 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 test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For **urinalysis**, microscopic and macroscopic 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 ratio, 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.

OWNER'S ATTESTATION

I attest that effective March 8, 2023 (date), I am the laboratory owner, or a co-owner of:

Phoenix Community Counseling Center (name of laboratory) clinical laboratory, located at

820 E. Gilbert St. Suite #151, San Bernardino, CA 92415 (street address)

CLIA ID number: New Application **State ID number (if known):** _____

As the owner or co-owner, I understand I am legally responsible for the operation of the laboratory under both CLIA and State law. I understand that as an owner of this laboratory, I, along with the director, must ensure the accuracy and reliability of all testing performed and that the laboratory meets all applicable CLIA and state requirements.

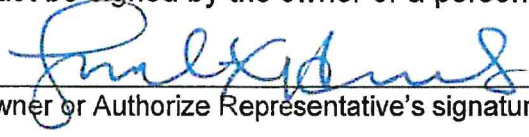
I understand that I will be held jointly and severally responsible with the laboratory director(s) for the maintenance and conduct of the laboratory and all employees therein or for any violations of law by this clinical laboratory (Business and Professions Code (BPC) section 1265(b)). If deficient or unlawful practices are found that occurred while I was serving as laboratory owner or co-owner, 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 reasons listed in BPC section 1320, including any false statement or representation of 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 and may subject me to criminal or civil sanctions.

I understand that I will be responsible, along with the laboratory director(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 owner 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. This statement must be signed by the owner or a person legally authorized by the owner.



Owner or Authorize Representative's signature

3/3/2023

Date

Leonard X. Hernandez, Chief Executive Officer

Print or type name and title

(909) 387-5418

Owner's contact telephone number

385 N. Arrowhead Avenue, San Bernardino, CA 92415-0103

Owner's address

DIRECTOR'S ATTESTATION

I attest that effective March 8, 2023 (date), I am the laboratory director, or a co-director of:

Phoenix Community Counseling Center (name of laboratory) clinical laboratory, located at

820 E. Gilbert St. Suite #151, San Bernardino, CA 92415 (street address)

CLIA number: New Application **State ID number (if known):**

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.

DocuSigned by:
Jonathan Avalos, MD
Director's signature 5871BD04F0...

4/3/2023
Date

Dr. Jonathan Avalos
Print or type director's name and title

CLIA Director: ☑ Yes ☐ No

303 E. Vanderbilt Way, San Bernardino CA 92415-0001
Director's address (as recorded on personal professional license)

(909) 601-4220
Director's direct contact telephone number

Or

California Board license number: A139612

California Director license number: