STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D0668312	A. BUILDING _____ B. WING _____	05/19/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FAMILY PLANNING ASSOCIATES MED GRP INC	2500 H ST BAKERSFIELD, CA 93301

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS THE LABORATORY IS IN COMPLIANCE WITH THE REQUIREMENTS OF 42 CFR PART 493REQUIREMENTS FOR CLINICAL LABORATORY.	D 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

State of California — Health and Human Services Agency

California Department of Public Health

Karen L. Smith, MD, MPH
Director

Laboratory Field Services Branch Office:
320 West 4th Street, Suite 890
Los Angeles, California 90013
Telephone Number: (213) 620-6160; Fax Number: (213) 620-6565

EDMUND G. BROWN JR.
Governor

May 20, 2015

Family Planning Associates Med Grp Inc
2500 H St
Bakersfield, CA 93301-2818

CLIA #05D0668312 State I.D. # CNC 307327

RE: CERTIFICATION OF COMPLIANCE

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

California Department of Public Health, Laboratory Field Services conducted a recertification survey of your laboratory on May 19, 2015. The results of the survey showed that all CLIA Condition-level requirements were met during the time of the onsite survey. We are recommending to CMS that your laboratory be Recertification in the CLIA program.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every instance of non-compliance that may have occurred in the laboratory. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If you have questions regarding this letter, please contact me at 213-620-2138.

Sincerely,

Eul Hurley, Examiner I
Laboratory Field Services

Enclosure: CMS-2567

State of California — Health and Human Services Agency

California Department of Public Health

Karen L. Smith, MD, MPH
Director

Laboratory Field Services Branch Office
320 West 4th Street, Suite 890
Los Angeles, California 90013
Telephone Number: (213) 620-2138; Fax Number: (213) 620-6565

EDMUND G. BROWN JR.
Governor

May 1, 2015

Family Planning Associates Med Grp Inc
2500 H St
Bakersfield, CA 93301-2818

CLIA ID#: 05D0668312

Dear Laboratory Director:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42C.F.R.493).

This is to inform you that your laboratory facility has been scheduled for an onsite recertification survey of all non-waived testing **on May 19, 2015, at approximately 10:30am** Successful completion of this inspection process is a requirement for continued participation in the CLIA program. **If you have not done so already, please notify us immediately of any changes since your last inspection (e.g. Certificate type changes, accreditation status, or discontinuation of testing). Any changes in ownership, name, location or director need to be reported as well.**

In order to facilitate the survey process we request that you have the enclosed forms completed, signed, and available for the examiner at the time of survey: (NOTE: If you have any questions about filling out the paperwork, please call our office and ask to speak with an Examiner.)

1. Form 1513 Ownership Disclosure
2. CMS-209 Laboratory Personnel Report **(Allow two lines per name entered)**
3. State Laboratory Personnel Report (LAB 116)
4. Laboratory Testing Declaration Form (Estimated test volumes for 2014-2015; and names of equipment/kits)
5. Director's Attestation Form
6. CMS-116 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) Application for Certification
7. HCFA-668B Post Clinical Laboratory Survey Questionnaire **(Optional, to be filled out after onsite survey).**

As required under CLIA section 493.1773(c), all records and pertinent data must be readily accessible and retrievable within a reasonable time frame during the course of the inspection (since the last survey, if applicable, 2 years).

Please note that canceling this appointment will result in an unscheduled, unannounced survey of your facility at a later date and may compromise the continuation of your CLIA certification and reimbursement. We are giving you advanced notice of this inspection as a courtesy. This notification should afford you and your staff the opportunity to rearrange your schedules to facilitate and expedite the inspection process. You may notify our office if you have any questions about the upcoming survey, or requested paperwork. Thank you in advance for your cooperation.

Sincerely,

Eul Hurley, Examiner I

CLIA Program, Laboratory Field Services
cc: Enclosures

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

I. GENERAL INFORMATION

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

CLIA IDENTIFICATION NUMBER
05 D 0668312
(If an initial application leave blank, a number will be assigned)

FACILITY NAME
Family Planning Associates Medical Group, Inc

FEDERAL TAX IDENTIFICATION NUMBER
[redacted]

EMAIL ADDRESS
hrassist@allcare-med.com

TELEPHONE NO. *(Include area code)*
909-382-0201

FAX NO. *(Include area code)*
909-382-0210

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)*
2500 H Street

CITY: Bakersfield | STATE: CA | ZIP CODE: 93301

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

NUMBER, STREET
P.O. 10818

CITY: San Bernardino | STATE: CA | ZIP CODE: 92423-0818

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
164 W Hospitality Lane Suite 1A

CITY: San Bernardino | STATE: CA | ZIP CODE: 92408-5828

NAME OF DIRECTOR *(Last, First, Middle Initial)*
[redacted]

CREDENTIALS
Medical Doctor

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
☐ CAP ☐ COLA ☐ ASHI

5/21/15

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:	Varies	Varies	Varies	Varies	Varies	Varies	Varies
TO:	Varies	Varies	Varies	Varies	Varies	Varies	Varies

(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) Hemocue, Amoitek, EPT
HIV 1/2 Clearview, True Track (glucose)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed 3000

☐ 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)

285

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed 755

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		
☑ Bacteriology 110	285	755
☐ Mycobacteriology 115	"	
☑ Mycology 120	285	
☑ Parasitology 130	285	
☐ Virology 140		
DIAGNOSTIC IMMUNOLOGY		
☐ Syphilis Serology 210		
☐ General Immunology 220		
CHEMISTRY		
☐ Routine 310		
☐ Urinalysis 320	Waived	
☒ Endocrinology 330	3000	
☐ Toxicology 340		

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HEMATOLOGY 400		
☐ Hematology	~~1500~~	
IMMUNOHEMATOLOGY		
☐ ABO Group & Rh Group 510	1500	1500
☐ 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		2255

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
05D0668310	Family Planning Associates Medical Group, Inc
05D0668295	Family Planning Associates Medical Group, Inc

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.

[redacted] ORY *(Sign in ink)*	DATE 5/5/15

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

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.