CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☒ Initial Application

☐ Change in Certification Type

CLIA Identification Number

D

(If an initial application leave blank, a number will be assigned)

Facility Name

John Doe Community Outreach Center

Federal Tax Identification Number

57-37298

Telephone No. *(Include area code)* Fax No. *(Include area code)*

( )479-639-6643 ( ) 479-639-6602

Facility Address — *Physical Location of Laboratory (Building, Floor, Suite if applicable.)*

Building 4, Suite 302

Number, Street *(No P.O. Boxes)*

173 Frazier Drive

City State Zip Code

Atlanta GA 30062

Mailing/Billing Address *(If different from street address, include attention line and/or Building, Floor, Suite)*

Building 4, Suite 302

Number, Street

173 Frazier Drive

City State Zip Code

ATLANTA GA 30062

Name of Director

Last	*First*	*Middle initial*
MILLER	HAROLD	NMI

II. TYPE OF CERTIFICATE REQUESTED *(Check One)*

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

☐ Certificate for Provider Performed Microscopy Procedures (PPMP) *(Complete Sections I – X)*

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

☐ Certificate of Accreditation *(Complete Sections I through 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

☐ JCAHO ☐ AOA ☐ AABB

☐ CAP ☐ COLA ☐ ASHI

III. TYPE OF LABORATORY *(Check the **one** most descriptive of facility type)*

___ 01 Ambulatory Surgery Center
___ 02 Community Clinic
___ 03 Comp. Outpatient Rehab. Facility
___ 04 Ancillary Testing Site in Health Care Facility
___ 05 End Stage Renal Disease Dialysis Facility
___ 06 Health Fair
___ 07 Health Main. Organization
___ 08 Home Health Agency
___ 09 Hospice
___ 10 Hospital
___ 11 Independent
___ 12 Industrial
___ 13 Insurance
___ 14 Intermediate Care Fac. for Mentally Retarded
___ 15 Mobile Laboratory
___ 16 Pharmacy
___ 17 School/Student Health Service
___ 18 Skilled Nursing Facility/Nursing Facility
___ 19 Physician Office
___ 20 Other Practitioner *(Specify)* _____
___ 21 Tissue Bank/Repositories
___ 22 Blood Banks
___ 23 Rural Health Clinic
___ 24 Federally Qualified Health Center
___ 25 Ambulance
___ 26 Public Health Laboratories _____
X 27 Other Community-based organization (CBO)

Is this a Medicare/Medicaid certified facility? ☐ Yes ☒ No
If yes, indicate Medicare provider number_____
Medicaid number_____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM: AM		9		9		9	
PM							
TO: AM							
PM		5		5		5	

(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)*

Are you applying for the multiple site exception?

☒ No If **no**, go to section VI. ☐ Yes If **yes**, provide total number of sites under this certificate_____ and complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

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, list name, address and tests performed for each site below.

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, 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	Telephone No. ( )	
Name of laboratory or hospital department		
Address/location *(number, street, location if applicable)*		
City, State, ZIP	Telephone No. ( )	
Name of laboratory or hospital department		
Address/location *(number, street, location if applicable)*		
City, State, ZIP	Telephone No. ( )	

VI. WAIVED TESTING

Indicate the **estimated TOTAL ANNUAL TEST** volume for **all waived tests** performed. 3,000

VII. NONWAIVED TESTING *(Including PPMP testing)*

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 information included with the application package.)

If applying for certificate of accreditation, indicate the name of the accreditation organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (JCAHO, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
Histocompatibility		
☐ Transplant		
☐ Nontransplant		
Microbiology		
☐ Bacteriology		
☐ Mycobacteriology		
☐ Mycology		
☐ Parasitology		
☐ Virology		
Diagnostic Immunology		
☐ Syphilis Serology		
☐ General Immunology		
Chemistry		
☐ Routine		
☐ Urinalysis		
☐ Endocrinology		
☐ Toxicology		

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
☐ **Hematology**		
Immunohematology		
☐ ABO Group & Rh Group		
☐ Antibody Detection (transfusion)		
☐ Antibody Detection (nontransfusion)		
☐ Antibody Identification		
☐ Compatibility Testing		
Pathology		
☐ Histopathology		
☐ Oral Pathology		
☐ Cytology		
☐ **Radiobioassay**		
☐ **Clinical Cytogenetics**		

TOTAL ESTIMATED ANNUAL TEST VOLUME_____

VIII. TYPE OF CONTROL

Enter the appropriate two digit code from the list below 0 3 *(Enter only one code)*

Voluntary Nonprofit	For Profit	Government	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government _____ (Specify)
03 Other CBO (Specify)		07 State	

IX. 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:

NAME OF LABORATORY	ADDRESS	CLIA IDENTIFICATION NUMBER

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Indicate the total number of individuals involved in laboratory testing (directing, supervising, consulting or testing). Do not include individuals who only collect specimens or perform clerical duties. For nonwaived testing, only count an individual one time, at the **highest** laboratory position in which they function. (Example: Pathologist serves as director, technical supervisor and general supervisor. This individual would only be counted once (under director).)

A. WAIVED TESTING
Total No. of Individuals 10

B. NONWAIVED TESTING *(including PPMP)*

Total No. of Individuals _____
Director _____
Clinical consultant _____
Technical consultant _____
Cytotechnologist _____
Technical supervisor _____
General supervisor _____
Testing personnel _____

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
Harold Miller, EXECUTIVE DIRECTOR	12/15/03