

Laboratory Corporation of America Holdings - Burlington

having been assessed by AAB, has been found to meet the requirements of applicable Standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

Relationship Testing Activities

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AAB Corporate Seal to be affixed.

Effective Dates

July 01, 2021 - June 30, 2023



President, AAB



Chair, Accreditation Program Committee

BB Accreditation

LabCorp - Burlington

having been assessed by AABB, has been found to meet the requirements of applicable Standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

Relationship Testing Activities

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AABB Corporate Seal to be affixed.

Effective Dates

July 01, 2019 – June 30, 2021



A handwritten signature in dark ink, appearing to read "D. J. Tripp MD".

President, AABB

A handwritten signature in dark ink, appearing to read "D. J. Tripp MD".

Chair, Accreditation Program Committee

New York State Department of Health

PFI: 8399 Clinical Laboratory Permit

CLIA: 34D0954530

Laboratory Corporation of America

1440 York Court

Burlington NC 27215-3361

Director:
George C. Maha, Ph.D.

Owner:
Laboratory Corporation of America Holdings

is hereby authorized to perform laboratory procedures at the above location in the following categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This permit shall become void upon a change in the director, owner or location of the laboratory, and an application for a new permit shall be made to the Department.

Genetic Testing
Molecular
(limited to SNP analyses)

Histocompatibility
STATE OF
OPPORTUNITY
Department
of Health

Parentage/Identity Testing
Transplant Monitoring

Renewal

Effective Date: July 1, 2022

Expiration Date: June 30, 2023

Subject to Revocation
Permit Not Transferable

POST CONSPICUOUSLY

Serial: LAP 159095

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

LABORATORY CORPORATION OF AMERICA HOLD
1440 YORK COURT
BURLINGTON, NC 27215

CLIA ID NUMBER

34D0954530

EFFECTIVE DATE

04/28/2021

EXPIRATION DATE

04/27/2023

LABORATORY DIRECTOR

GEORGE C MAHA PHD, JD, MT (AS

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Monique Spruill

Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

72 Certs2_033021

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOCOMPATIBILITY (010)	01/09/2003

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
---------------------------------	-----------------------



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



COLLEGE of AMERICAN
PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

**Laboratory Corporation of America Holdings
DNA Identity Testing Division
Burlington, North Carolina
George C. Maha, PhD, JD, A(ACH), AB**

CAP Number: 1396905

AU-ID: 1365207

CLIA Number: 34D0954530

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **February 14, 2025** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

K/Beavis, M)

Kathleen G. Beavis, MD, Accreditation Committee Chair

Emily Volk, MD, FCAP, President, College of American Pathologists



Laboratory Corporation of America Holdings
DNA Identity Testing Division

LAP Number: 1396905

AU ID: 1365207

The above Laboratory is accredited by the College of American Pathologists Laboratory Accreditation Program for the following services:

All Common

Clinical Transplantation Support

Director Assessment

HLA Cellular Functional Tests

HLA Flow Cytometry

HLA Molecular

HLA Solid Phase Assays

Laboratory General

Molecular Microbiology

Molecular Pathology

This accreditation is valid for the period ending February 14, 2025.

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Laboratory Corporation of America Holdings
1440 York Court
Burlington, NC 27215

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to read 'R.D.L.', with a long, sweeping horizontal stroke extending to the right.

R. Douglas Leonard Jr., VP, PILR SBU
Expiry Date: 24 September 2023
Certificate Number: AT-1688



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Laboratory Corporation of America Holdings

1440 York Court
Burlington, NC 27215
Dr. George Maha 336-436-7307
mahag@labcorp.com

TESTING

Valid to: **September 24, 2023**

Certificate Number: **AT-1688**

Biological

Category	Subcategory	Analytical Technique
HLA Typing by Molecular Methods IDHLA400 Histocompatibility	Sample Preparation	Robotic extraction, amplification, and set-up
		Manual extraction, amplification, and set-up
		Automated liquid handler
	Genetic Analysis	Human Leukocyte Antigen (HLA)
		HLA Antibody Identification
		Data analysis
		ATP luciferase assay
	Detection Methodology	Capillary Electrophoresis
		Gel Electrophoresis
		Bead Assay
		SSOP
		SSP
		Sanger Sequencing
		Massively Parallel Sequencing (NGS)
		SNP
		Polymerase Chain Reaction (PCR)
		Luminometer
	General Laboratory Procedures	-

Category	Subcategory	Analytical Technique
Post Transplant Engraftment Monitoring by PCR Engraftment monitoring IDENG 751	Sample Preparation	Manual extraction, amplification, and set-up
		Automated liquid handler
		Cell Sorting
	Genetic Analysis	Autosomal STR
		Data analysis
	Detection Methodology	Capillary Electrophoresis
		Polymerase Chain Reaction (PCR)
	General Laboratory Procedures	-
PCR Analysis Relationship testing Cell Line Authentication IDPAT651	Sample Preparation	Robotic extraction, amplification, and set-up
		Manual extraction, amplification, and set-up
		Automated liquid handler
	Genetic Analysis	Autosomal STR
		X and Y-STR
		Human Leukocyte Antigen (HLA)
	Detection Methodology	Capillary Electrophoresis
		Gel Electrophoresis
		Polymerase Chain Reaction (PCR)
	General Laboratory Procedures	-
Single Nucleotide Polymorphism Testing Using Illumina's Infinium Assay Genomics LC-BN-DNA-GNM-011	Sample Preparation	Robotic extraction, amplification, and set-up
		Automated liquid handler
	Detection Methodology	SNP
		Whole Genome Amplification (WGA)
	General Laboratory Procedures	-

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1688.



R. Douglas Leonard Jr., VP, PILR SBU