

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 15189:2022

In the field of

MEDICAL AND CLINICAL LABORATORIES

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



Jason Stine, Vice President

Expiry Date: 03 November 2026 Certificate Number: AM-3146

This medical laboratory is accredited in accordance with the recognized International Standard ISO 15189:2022. This accreditation demonstrates technical competence for a defined scope and the operation of a medical laboratory quality management system (refer to joint IAF-ILAC-ISO Communiqué dated November 2021).



SCOPE OF ACCREDITATION TO ISO 15189: 2022

Laboratory Corporation of America Holdings

1440 York Court Burlington, NC 27215

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MEDICAL/CLINICAL TESTING

Valid to: November 3, 2026

Certificate Number: AM-3146

Compatibility Testing

Sub-Specialty	Tes <mark>t-Analy</mark> te	Method	Matrix
Histocompatibility	HLA Typing (Loci: A,B,C, DRB1/3/4/5, DPA1, DPB1, DQA1, DQB1)	Next Generation Sequencing (NGS) PacBio Platform	Blood, dried blood spot cards, buccal swabs, genomic DNA
Histocompatibility	HLA Typing (Loci: A,B,C, DRB1/3/4/5, DPB1, DPA1, DQB1, DQA1)	Next Generation Sequencing (NGS) Illumina Platform	Blood, dried blood spot cards, buccal swabs, genomic DNA
Histocompatibility	HLA-B27 Typing / Disease Association	SSOP / Next Generation Sequencing (NGS) Illumina Platform	Blood, buccal swabs
Histocompatibility	HLA-B57 Typing / Disease Association	SSOP / SBT (Sanger Sequencing)	Blood, buccal swabs
Histocompatibility	HLA-A*02:01	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-A29 Uveitis, Birdshot Retinopathy	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-B*15:02 Carbamazepine Sensitivity	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-B*15:02 and HLA- A*31:01 Carbamazepine Sensitivity	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-B51 Bechet's Syndrome	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs





Compatibility Testing

Sub-Specialty	Test-Analyte	Method	Matrix
Histocompatibility	HLA-B*58:01 Allopurinol	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-DR15 Immunosuppressive Response (MDS)	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	HLA-DR4 Rheumatoid Arthritis	Next Generation Sequencing (NGS) PacBio Platform	Blood, buccal swabs
Histocompatibility	Celiac Disease Association	Luminex SSO	Blood
Histocompatibility	Killer Immunoglobulin-like Receptors (KIR) presence/absence	Luminex SSO	Blood
Histocompatibility	HLA Antibody Identification	Luminex bead-based assay	Serum
Histocompatibility	ImmuKnow Cell Function Assay	ATP luciferase assay	Blood
Parentage Testing	Autosomal loci	STR	Blood, buccal swabs
Parentage Testing	X and Y chromosome loci	STR	Blood, buccal swabs
Parentage Testing	Engraftment Monitoring	STR	Blood, bone marrow
Parentage Testing	Cell Sorting (CD3, CD56, CD19, CD15, CD33/66B)	Positive Selection	Blood, bone marrow
Parentage Testing	Cell Line Authentication	STR	Cells
Parentage Testing	Mycoplasma	qPCR	Genomic DNA, cell pellet

Genetics

Sub-Specialty	Test-Analyte	Method	Matrix
Molecular Genetics	SNP	SNP Array testing	Saliva
Molecular Genetics	Apolipoprotein E (APOE)	SNP Array testing	Blood Saliva





Microbiology

Sub-Specialty	Test-Analyte	Method	Matrix
Molecular Microbiology	Microbiome	NGS (Illumina)	Fecal Swab

Primary Sample Collection

Type of Sample		Sampling Procedure
Blood		Phlebotomy
Buccal Swab		Swab
Fecal Swab		Swab
Cells		Phlebotomy
Bone Marrow		Aspirate
Saliva		Self-collect

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AM-3146.

Jason Stine, Vice President

www.anab.org