



Accredited Laboratory

A2LA has accredited

EUROFINS DONOR & PRODUCT TESTING, LLC

Centennial, CO

for technical competence in the field of

Clinical

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



Presented this 8th day of August 2025.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council

Certificate Number 5912.01

Valid to August 31, 2027

Revised August 20, 2025

For the tests to which this accreditation applies, please refer to the laboratory's Clinical Scope of Accreditation.



SCOPE OF ACCREDITATION TO ISO 15189:2022

EUROFINS DONOR & PRODUCT TESTING, LLC
6933 S. Revere Parkway
Centennial, CO 80112
Ann Niedzinski Phone: 855-875-5227 ext. 803

CLINICAL

Valid To: August 31, 2027

Certificate Number: 5912.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of testing on human samples, including **Plasma (P)**, **Serum (S)**, **Sputum (SP)**, **Sterile Swab (SS)**, **Urine (U)**, **Wounds(W)**, **Whole blood (WB)** and **Lymphoid Tissue (LT)**:

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Chemistry				
	General Chemistry (Special Chemistry)			
		Hemoglobin A1C	Spectrophotometric	WB
Diagnostic Immunology				
	General Immunology			
		Cytomegalovirus IgG Antibody (CMV IgG)	EIA	P
		Cytomegalovirus IgM Antibody (CMV IgM)	EIA	P
		Cytomegalovirus Total Antibodies (CMV Total)	Solid Red Cell Adherence	P, S
		Epstein-Barr Virus- Viral Capsid Antigen IgG (EBV-VCA IgG)	ELISA	S
		Epstein-Barr Virus- Viral Capsid Antigen IgM (EBV-VCA IgM)	ELISA	S
		Hepatitis B Core Antigen (anti-HBc IgM)	EIA	P, S
		Hepatitis B Surface Antigen (HBsAg Neu)	Neutralization Confirmation, Qualitative EIA	P, S
		Hepatitis B Surface Antigen (HBsAg)	EIA, CMIA	P, S
		Hepatitis B Virus Core Total Antibody (HBc Total)	EIA, CMIA	P, S

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
General Immunology (cont.)				
		Hepatitis B Virus Surface Antibody (HBsAb)	EIA, CMIA	P, S
		Hepatitis C Virus Antibody (HCV)	ELISA, CMIA	P, S
		Herpes Simplex Virus IgG (HSV)	EIA	S
		Human Immunodeficiency Virus Antibody (HIV-1/2)	EIA, CMIA	P, S
		Human T-Lymphotropic Virus Type 1 and/or II Antibody (HTLV-I/II)	ELISA	P, S
		<i>Strongyloides</i> IgG	ELISA	S
		Syphilis Rapid Plasma Reagin (RPR)	Flocculation	P, S
		<i>Toxoplasma gondii</i> IgG Antibody (Toxo)	EIA	S
		<i>Trypanosoma cruzi</i> Antibody (<i>T. Cruzi</i>)	ELISA	P, S
Histocompatibility				
HLA Flow Cytometry				
		HLA B-Cell Crossmatching	Flow Cytometry	WB, LT
		HLA T-Cell Crossmatching	Flow Cytometry	WB, LT
HLA Molecular				
		ABO Genotyping	Real-Time PCR	WB
		HLA Class I and II	Real-Time PCR	WB, LT
		HLA Class I Typing, Generic	SSP/SSO	WB, LT
		HLA Class II Typing, Generic	SSP/SSO	WB, LT
HLA Solid Phase Assays				
		HLA Class I Antibody ID	Micro-bead Assay	WB, LT
		HLA Class I Antibody Screening	Micro-bead Assay	WB, LT
		HLA Class II Antibody ID	Micro-bead Assay	WB, LT
		HLA Class II Antibody Screening	Micro-bead Assay	WB, LT
Immunohematology				
ABO and Rh Group				
		ABO Blood Grouping	Gel & Solid Phase Techniques	WB
		Rh Type (includes Weak D)	Gel & Solid Phase Techniques	WB

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
Microbiology				
	Bacteriology			
		Antimicrobial Susceptibility	MIC (AST), Kirby Bauer Disc	HCT/Ps, Media, Swab
		Bacterial, Complete ID	Culture, MALDI-TOF, Biochemical, NH, VITEK-2, ANA	HCT/Ps, Media, Swab
		Bacterial Culture, Partial ID	Culture, MALDI-TOF, Biochemical, NH, VITEK-2, ANA	HCT/Ps, Media, Swab
		Bacterial Culture, Screen for Growth Only	Culture	HCT/Ps, Media, Swab
		Bioburden, Qualitative	Culture	HCT/Ps, Media, Swab
		Bioburden, Quantitative	Culture	HCT/Ps, Media, Swab
		Biological Indicator	Culture	Indicator Strip
		Cellular Therapies	Culture	HCT/Ps, Media, Swab
		Endotoxin	Turbidimetric, Chromogenic	Culture Media, Medical Devices, Regenerative Therapies
		Environmental Culture	Culture	Media, Swab
		Final Release Sterility	Culture, Direct Inoculation	HCT/Ps, Media, Swab
		Gram Stain	Manual	HCT/Ps, Media, Swab
		Media QC	Culture	Media
		Method Suitability	Culture	HCT/Ps, Media, Swab
		Mycoplasma	Real-Time PCR	Cell Culture Media, Buffers, Lysates
		Platelet Culture	Culture	Platelets
		Pre-Processing Cultures	Culture	HCT/Ps, Media, Swab, Media
		Process Validation	Various	Client-Specific
		Solid Organ Transplantation	Culture	U, Perfusate, WB, Sputum

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
	Bacteriology (cont.)			
		Sterility/ Aseptic Testing	Culture	HCT/Ps, Media, Swab
		VDMax Bioburden	Culture	HCT/Ps, Media, Swab
		VDMax Sterility	Culture	HCT/Ps, Media, Swab
		Water Culture	Culture	Water
	Mycology			
		Mycology Culture, Complete ID	Culture, Morphology, Lactophenol Blue	HCT/Ps, Media, Swab
		Mycology Culture, Partial ID	Culture, Morphology, Lactophenol Blue	HCT/Ps, Media, Swab
		Yeast ID	Culture, Vitek-2, MALDI-TOF	HCT/Ps, Media, Swab
	Virology			
		Hepatitis B Virus DNA (HBV DNA)	Nucleic Acid Amplification	P, S
		Hepatitis C Virus RNA (HCV RNA)	Nucleic Acid Amplification	P, S
		Human Immunodeficiency Virus RNA (HIV RNA), Donor Units	Nucleic Acid Amplification	P, S
		West Nile Virus RNA (WNV RNA)	Nucleic Acid Amplification	P, S