



SCOPE OF ACCREDITATION TO ISO 15189:2012

EUROFINS DONOR & PRODUCT TESTING, INC.  
6933 S. Revere Parkway  
Centennial, CO 80112  
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CLINICAL

Valid To: August 31, 2025

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)
<b>Chemistry</b>				
	<b>General Chemistry (Special Chemistry)</b>			
		Hemoglobin A1C	Spectrophotometric	WB
		Hemoglobin S Solubility (Hgb S)	ELISA	WB
		Hepatitis B Core Antigen (anti-HBc IgM)	EIA	P, S
		Hepatitis B Surface Antigen (HBsAg)	EIA	P, S
		Hepatitis B Surface Antigen (HBsAg Neu)	Neutralization Confirmation, Qualitative EIA	P, S
		Hepatitis B Virus Core Total Antibody (HBc Total)	EIA	P, S
		Hepatitis B Virus Surface Antibody (HBsAb)	EIA	P, S
		Hepatitis C Virus Antibody (HCV)	ELISA	P, S
		Human Immunodeficiency Virus Antibody (HIV-1/2)	EIA	P, S
		Human T-Lymphotropic Virus Type 1 and/or II Antibody (HTLV-I/II)	ELISA	P, S
		<i>Trypanosoma cruzi</i> Antibody ( <i>T. Cruzi</i> )	ELISA	P, S
		Zika IgM Ab	ELISA	P, S

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
<b>Hematology</b>				
	<b>Hematology / Flow Cytometry</b>			
		CD 34+ Enumeration	Flow Cytometry	WB, LT
<b>Histocompatibility</b>				
	<b>HLA Flow Cytometry</b>			
		HLA B-Cell Crossmatching	Flow Cytometry	WB, LT
		HLA T-Cell Crossmatching	Flow Cytometry	WB, LT
	<b>HLA Molecular</b>			
		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
	<b>HLA Solid Phase Assays</b>			
		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
<b>Diagnostic Immunology</b>				
	<b>General Immunology</b>			
		ABO Blood Grouping	Gel & Solid Phase Techniques	WB
		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 IgM (EBV-VCA IgM)	ELISA	S
		Epstein-Barr Virus- Viral Capsid Antigen IgG (EBV-VCA IgG)	ELISA	S
		Herpes Simplex Virus IgG (HSV)	EIA	S

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
<b>Diagnostic Immunology</b>				
	<b>General Immunology (cont.)</b>			
		Rh Type (includes Weak D)	Gel & Solid Phase Techniques	WB
		Syphilis Rapid Plasma Reagin (RPR)	Flocculation	P, S
		<i>Toxoplasma gondii</i> IgG Antibody (Toxo)	EIA	S
<b>Microbiology</b>				
	<b>Bacteriology</b>			
		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

Specialty	Sub Specialty	Test/Analyte	Method(s)	Matrix(ces)
<b>Microbiology</b>				
	<b>Bacteriology (cont.)</b>			
		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
		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
	<b>Mycology</b>			
		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
	<b>Virology</b>			
		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
		Zika RNA	Nucleic Acid Amplification	P, S



## Accredited Laboratory

A2LA has accredited

# EUROFINS DONOR & PRODUCT TESTING, INC

*Centennial, CO*

for technical competence in the field of

## Clinical

This laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012 *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 27<sup>th</sup> day of September 2023.

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, 2025

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