

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

LEPL "National Center for Disease Control and Public Health" / Richard Lugar Center for Public Health Research

0109, Alexeevka Settlement #3 Kakheti Highway 16 Tbilisi, Georgia

Fulfills the requirements of

ISO 15189:2012

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: 05 January 2026 Certificate Number: AM-2542

This medical laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012. 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 15189:2012

LEPL "National Center for Disease Control and Public Health" / Richard Lugar Center for Public Health Research

0109, Alexeevka Settlement #3 Kakheti Highway 16 Tbilisi, Georgia

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MEDICAL/CLINICAL TESTING

Valid to: January 5, 2026

Certificate Number: AM-2542

Clinical Microbiology

Sub-Specialty	Test-Analyte	Method	Matrix
Bacteriology	Staphylococcus, Streptococcus, Enterococcus, Neisseria, Haemophilus, Enterobacteriaceae, Non fermenting gr(-) bacteria, Corynebacteria, Listeria	Cultural, identification by biochemical tests – conventional method	Blood
Bacteriology	Salmonella spp., Shigella spp., Enteropathogenic E.coli; Enterobacteriaceae, Enterococcus, Yersinia spp, Listeria spp	Cultural, identification by biochemical tests – conventional method	Feces
Bacteriology	Antimicrobial Susceptibility Testing	Disk diffusion method in Mueller-Hinton agar MIC determination by E-test	Strain
Bacteriology	Staphylococcus, Streptococcus, Enterococcus, Neisseria, Enterobacteriaceae, Non fermenting gr(-) bacteria, Corynebacteria,	Cultural, identification by biochemical tests – conventional method	Urine



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Clinical Microbiology

Sub-Specialty	Test-Analyte	Method	Matrix
Bacteriology	Staphylococcus aureus, Streptococcus pneumoniae, Neisseria , Streptococcus lancefield group, Enterobacteriaceae, Non fermenting gr(-) bacteria, Corynebacteria diphtheriae, Listeria spp,	Cultural, identification by biochemical tests – conventional method	Sputum/Respiratory
Bacteriology	Staphylococcus aureus, Streptococcus, Enterococcus, Enterobacteriaceae, Non fermenting gr(-) bacteria,	Cultural, identification by biochemical tests – conventional method	Wound/Swab
Bacteriology	Neisseria meningitidis, Haemophilus influenzae, Streptococcus pneumoniae, other bacterial meningitis	Cultural, identification by biochemical tests – conventional method	CSF



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Serology

Sub-Specialty	Test-Analyte	Method	Matrix
Immuno-Serology	Anti-Measles Viruses NP ELISA (IgM)	Enzyme-Linked Immunosorbent Assay (ELISA)	Serum, Plasma, Dried Blood Spot
	Anti-Rubella Viruses Glycoprotein ELISA (IgM)	Enzyme-Linked Immunosorbent Assay (ELISA)	Serum, Plasma, Dried Blood Spot
Hepatitis	HBsAg confirmation	Enzyme Immunoassay (ELISA)	Serum, Plasma
	HBsAg One	Enzyme Immunoassay (ELISA)	Serum, Plasma
	ARCHITECT Anti-HBc II	chemiluminescent microparticle immunoassay (CMIA)	Serum, Plasma
	ARCHITECT HBs Ag Qualitative II	chemiluminescent microparticle immunoassay (CMIA)	Serum, Plasma
	HBs Ag Qualitative II confirmatory	chemiluminescent microparticle immunoassay (CMIA)	Serum, Plasma
	ARCHITECT Anti-HCV Ab	chemiluminescent microparticle immunoassay (CMIA)	Serum, Plasma
	ARCHITECT HCV Ag	chemiluminescent microparticle immunoassay (CMIA)	Serum, Plasma

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AM-2542.

Jason Stine, Vice President





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