Hellenic Accreditation System

Annex G1/4 to the Certificate No. **1207**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

NEOLAB

Private Diagnostic Laboratory, Medical S.A.

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Chemical Tests		
1. Dried blood spots on Guthrie cards	1. Quantitative determination of aminoacids Ala, Arg, Cit, Gly, Leu, Met, Phe, Tyr, Val & acylocarnitines (C0,C2,C3,C3DC,C4,C4OH, C5, C5:1, C5DC, C6,C6DC,C8,C8:1,C10,C10:1, C10:2, C12,C12:1, C14, C14:1, C14:2, C14OH, C16, C16:1, C16OH, C16:1OH, C18, C18:1, C18:2, C18OH, C18:1OH in dried blood spot Samples	*In-house method* EMA-1 Newborn screening of Metabolic Diseases by Tandem Mass Spectrometry technique (LC MS-MS) Quattro Micro API Mass Spectrometer, Waters QAA1308 (MS Detector 1) Quattro Micro API Mass Spectrometer, Waters QAA525 (MS detector2) based on literature 1. Technological Developments of Tandem MS FOR Neonatal Screening Birmingham Children's Hospital 1999, 2. Newborn Screening by Tandem Mass Spectrometry; Proposed Guideline CLSI I/LA32-P Vol 29 No 25
	2. Determination of biotinidase enzyme activity	Optical chromatometric technique EMA-2 based on literature Heard, G, Secor McVoy, J, & Wolf, B (1984) A screening method for biotinidase deficiency in newborns. Clin Chem 30: 125-127
Immunochemical Tests		
1. Dried blood spots on Guthrie cards	1. Determination of immunoreactive trypsinogen (IRT)	Immunoenzyme Elisa method EMA-3 Microtiter Plate Fluorometer (Labsystems Diagnostics NS Reader)

		based on literature Manual Labsystems Diagnostics
	2. Determination of 17- hydroxy progesterone	Immunoenzyme method EMA-4 Kinetic Microplate Reader (Molecular Devices) based on literature Accubind (product code 5525-300)

Site of assessment: **Permanent Laboratory Facilities, Berbainon 14 and Michalakopoulou 125, P.O.11527, Athens, Greece.**
Authorized signatories: **Evangelos Papakonstantinou.**

This scope of Accreditation replaces the previous one dated 25.11.2024.
The Accreditation Certificate No.**1207**-2, to ELOT EN ISO 15189:2022, is valid until 28.05.2029.

Athens, 19th of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD