Hellenic Accreditation System

Annex G1/28 to the Certificate No. **410**-6

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of the

BIOHELLENIKA S.A.

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Haematology Tests		
1. Peripheral blood, umbilical cord blood and nucleated cells from umbilical cord blood	1. Determination of the number of nucleated cells (lymphocytes, monocytes) and of the red blood cell count	Automated haematological analyzer CELLTAK MEK 6400K NIHON KOHDEN* BM-01 Ver. 20th, 05/05/2025
		Automated haematological analyzerSysmex DxFlex BM-119 Ver. 1st, 22/06/2023
2. Umbilical cord blood and nucleated cells from umbilical cord blood	1. Enumeration of viable CD45+dim/CD34+ haematopoietic progenitor cells	Flow cytometry according to ISHAGE guidelines and with STEM KIT (BECKMAN-COULTER) in DxFlex, (Beckman-Coulter) BM-71 Ver. 9th 03/07/2025
3. Umbilical cord blood before processing	1. Identification of blood groups, anti-A, anti-B and anti-D antibodies	Visual inspection-flocculation test BM-57 Ver. 5th 12/07/2024
Microbiological Tests		
1. Umbilical cord blood	1. Test for bacterial infection (aerobic / anaerobic /yeasts)	Fluorescent medium, closed method (BACTEC/ BECTON DICKINSON)* BM-02 Ver. 10th 02/01/2025

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2. Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA) Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA) (continued)	1. Detection of 1) surface antigen of Hepatitis B (HBsAg), 2) IgG / IgM antibodies against core antigen of Hepatitis B (anti-HBc), 3) antibodies against HIV1 and HIV2 (anti-HIV1/2) 4) antibodies against Hepatitis C (anti-HCV), 5) IgG and IgM antibodies against cytomegalovirus (CMV) and 6) total antibodies against *Treponema pallidum* – Syphilis.	Electrochemiluminescence Cobas e411 BM-116 1st 23/03/2021 I-RES-03-19 Ver. 1st 10/04/2019

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*

Site of assessment: **Permanent laboratory premises, 65th Georgikis Sxolis Avenue, Thessaloniki, Greece.**

Approved signatories: **G. Koliakos. K. Kouzi-Koliakou**.

This scope of Accreditation replaces the previous one dated 16.12.2024.
The Accreditation Certificate No.**410**-6, to ELOT EN ISO 15189:2022, is valid until 07.02.2029.

Athens, 11th of November 2025

Konstantinou Evangelos Apostolos
CEO of ESYD