

Hellenic Accreditation System



Annex G1/26 to the Certificate No. **410-5**

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. 15 th , 27/07/2022
2. Umbilical cord blood and nucleated cells from umbilical cord blood	1. Enumeration of viable CD45+dim/CD34+ haematopoietic progenitor cells	Automated haematological analyzer Sysmex XS-1000i
		BM-119 Ver. 1 st , 22/06/2023
3. Umbilical cord blood before processing	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. 6 th 14/09/2023 and Facs Calibur (Becton Dickinson)*
		BM-59 Ver. 8 th 27/07/2022.
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. 3 rd 22/09/2016
Microbiological Tests		
1. Umbilical cord blood	1. Test for bacterial infection (aerobic / anaerobic / yeasts)	Fluorescent medium, closed method (BACTEC/ BECTON DICKINSON)*
		BM-02 Ver. 8 th 10/01/2020

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 non-specific antibodies against <i>Treponema pallidum</i> – with the use of rapid plasma reagin	Visual inspection-flocculation test /RPR Carbon Test* BM-58 Ver. 3 rd 21/12/2011
	2. 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) 6) antibodies against HTLV I/II and 7) total antibodies against <i>Treponema pallidum</i> – Syphilis.	Electrochemiluminescence Cobas e411 BM-116 1 st 23/03/2021 I-RES-03-19 Ver. 1 st 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.**

****Branch – sampling site: 63 Imittou str. & 47 Formionos str., Athens, Greece.**

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

This scope of Accreditation replaces the previous one dated 02.10.2024.

The Accreditation Certificate No.410-5, to ELOT EN ISO 15189:2012, is valid until 07.02.2025, according ESYD decision.

Athens, 28th November 2024

