

Hellenic Accreditation System



ACCREDITATION CERTIFICATE

No. 410-6

The Hellenic Accreditation System (ESYD), as the national accreditation body of Greece in accordance with the Law 4468/2017,

ACCREDITS

the
Clinical Laboratory
of the
BIOHELLENIKA S.A.

in Thessaloniki, Greece

under the terms of the ELOT EN ISO 15189:2022 Standard and the ESYD Criteria, to carry out tests, as specified in the attached Scope of the Accreditation, which may be revised by decisions of ESYD.

The initial assessment was issued on February 08, 2008. This Certificate renews the accreditation and it is valid until the 7th of February, 2029, provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, 16th December 2024



Hellenic Accreditation System

Annex G1/27 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. 17 th , 25/07/2024
		Automated haematological analyzer Sysmex DxFlex
		BM-119 Ver. 1 st , 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. 8 th 25/08/2024
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. 5 rd 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. 8 th 10/01/2020
2. Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA)	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*
Umbilical cord blood plasma		BM-58 Ver. 3 rd 21/12/2011

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
(CPD) and peripheral blood plasma (EDTA) (continued)	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) and 6) 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.**

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

This scope of Accreditation replaces the previous one dated 28.11.2024.

The Accreditation Certificate No.**410-6**, to ELOT EN ISO 15189:2022, is valid until 07.02.2029.

Athens, 16th December 2024

