Hellenic Accreditation System

ACCREDITATION CERTIFICATE

No. 410-5

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 15189:2012 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 February 07, 2024, provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, November 03, 2020

Spyridon Podaras
CEO of ESYD

ESYD is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement for the activities covered by this certificate.

Hellenic Accreditation System

Annex G1/21 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 white blood cells and of the red blood cell count	Automated haematological analyzer CELLTAK MEK 6400K NIHON KOHDEN* BM-01 Ver. 15th, 27/07/2022
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 Cytomics FC500, (Beckman-Coulter) BM-71 Ver. 5th 25/06/2021 and Facs Calibur (Becton Dickinson)* BM-59 Ver. 8th 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. 3rd 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. 8th 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 *Treponema pallidum* – with the use of rapid plasma reagin	Visual inspection-flocculation test /RPR Carbon Test* BM-58 Ver. 3rd 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 *Treponema pallidum* – Syphilis.	Electrochemiluminescence Cobas e411 BM-116 1st 23/03/2021 I-RES-03-19 Ver. 1st 10/04/2019
Molecular Microbiology		
1.Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA)	1a. Qualitative detection of Hepatitis B virus DNA (HBV), genotypes A-D 1b. Qualitative detection of Hepatitis B virus DNA (HBV), genotypes A-D, with pooling of 10 samples.	HBV (RUO) Real-TM Qual kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)* BM-51 7th 06/09/2019 and BM-54 8th 06/09/2019
	2a. Qualitative detection of Hepatitis C virus RNA (HCV), genotypes 1-6 2b. Qualitative detection of Hepatitis C virus RNA (HCV), genotypes 1-6, with pooling of 10 samples.	HCV (RUO) Real-TM Qual kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)* BM-52 7th 06/09/2019 and BM-55 8th 06/09/2019
	3a. Qualitative detection of human cytomegalovirus DNA (CMV – HHV5) 3b. Qualitative detection of human cytomegalovirus DNA (CMV – HHV5), with pooling of 10 samples.	CMV (CE-IVD) Real-TM Qual kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)*)* BM-96 2th 06/09/2019 and BM-97 2th 06/09/2019
	4a. Qualitative detection of human immunodeficiency virus RNA (HJV), M group. 4b. Qualitative detection of human immunodeficiency virus RNA (HJV), M group, with pooling of 10 samples.	HIV (CE-IVD) Real-TM Quant Dx kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)* BM-53 8th 04/12/2020 και BM-56 10th 04/12/2020

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
2. Oropharyngeal swab and nasopharyngeal swab	1. Qualitative detection of SARS-CoV-2 RNA, genes E, N and RdRp **	LightCycler Multiplex RNA Virus Master (ROCHE), LightMix Modular Sarbecovirus SARS-CoV-2 (CE-IVD), LightMix Modular SARS-CoV-2 (COVID19) RdRp (RUO) from TIB MOLBIOL in Rotor-Gene 6000 (Corbett)* SOP-PR-22 6th 08/06/2021

**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 14.09.2021.
The Accreditation Certificate No.**410**-5, to ELOT EN ISO 15189:2012, is valid until 07.02.2024.

Athens, 20th March 2023

Christos Nestoras
CEO of ESYD