**Hellenic Accreditation System**

**Annex G1/17 to the Certificate No. 410-4**

**SCOPE of ACCREDITATION**

of the  
Clinical Laboratory  
of the  
**BIOHELLENNIKA S.A.**

<table>
<thead>
<tr>
<th>Materials/Products tested</th>
<th>Types of test/Properties measured</th>
<th>Applied methods/Techniques used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Haematology Tests</strong></td>
<td></td>
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<tr>
<td>1. Peripheral blood, umbilical cord blood and nucleated cells from umbilical cord blood</td>
<td>1. Determination of the number of nucleated cells (granulocytes, lymphocytes, monocytes) and of the red blood cell count</td>
<td>Automated haematological analyzer CELLTAK MEK 6400K NIHON KOHDEN* BM-01 Ver. 13th, 13/3/2019</td>
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<tr>
<td>2. Umbilical cord blood and nucleated cells from umbilical cord blood</td>
<td>1. Enumeration of viable CD45+dim/CD34+ haematopoietic progenitor cells</td>
<td>Flow cytometry according to ISHAGE guidelines and with STEM KIT (BECKMAN-COULTER) in Cytomixics FC500, (Beckman-Coulter) BM-71 Ver. 3rd 15/11/2018 and Facs Calibur (Becton Dickinson)* BM-59 Ver. 6th 3/12/2019</td>
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<td><strong>Microbiological Tests</strong></td>
<td></td>
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<tr>
<td>1. Umbilical cord blood</td>
<td>1. Test for bacterial infection (aerobic / anaerobic /yeasts)</td>
<td>Fluorescent medium, closed method (BACTEC/ BECTON DICKINSON)* BM-02 Ver. 7th 12/6/2015</td>
</tr>
<tr>
<td>2. Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA)</td>
<td>1. Detection of non-specific antibodies against <em>Treponema pallidum</em> – with the use of rapid plasma reagin</td>
<td>Visual inspection-flocculation test /RPR Carbon Test* BM-58 Ver. 3rd 21/12/2011</td>
</tr>
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<td>Detection of 1) total antibodies against <em>Treponema pallidum</em> – Syphilis 2) surface antigen of Hepatitis B (HBsAg), 3) IgG and IgM antibodies against core antigen of Hepatitis B (anti-HBc), 4) antibodies against HIV1 and HIV2 (anti-HIV1/2) 5) antibodies against Hepatitis C (anti-HCV) 6) IgG antibodies against cytomegalovirus (CMV) and 7) antibodies against HTLV I/II</td>
<td>Electrochemiluminescence Cobas e411 I-RES-03-19 Ver. 1st 10/04/2019</td>
</tr>
</tbody>
</table>

**Molecular Microbiology**

1. Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA)

1. Qualitative detection of Hepatitis B virus DNA (HBV), genotypes A-D

2. Qualitative detection of Hepatitis C virus RNA (HCV), genotypes 1-6

3. Qualitative detection of human immunodeficiency virus RNA (HIV), M group

4. Qualitative detection of human cytomegalovirus DNA (CMV – HHV5)

   HBV (RUO) Real-TM Qual kit (SACACE Biotechnologies) in Smart Cycler PCR (Cepheid)* and in Rotor-Gene 6000 (Corbett)* BM-51 7th and BM-54 8th 6/9/2019 both

   HCV (RUO) Real-TM Qual kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)* BM-52 7th and BM-55 8th 6/9/2019 both

   HIV (RUO) Real-TM Quant kit (SACACE Biotechnologies) in Rotor-Gene 6000 (Corbett)* BM-53 7th and BM-56 9th 6/9/2019 both

   CMV (CE-IVD) Real-TM Qual kit (SACACE Biotechnologies) in Smart Cycler PCR (Cepheid)* and in Rotor-Gene 6000 (Corbett)* BM-96 2th and BM-97 2th 6/9/2019 both

*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 17.01.2020.
The Accreditation Certificate No.410-4, to ELOT EN ISO 15189:2012, has been expanded until 07.11.2020.

Athens, July 31, 2020

[Signature]

**Psyrritha Podaras**
CEO of ESYD

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31.07.2020