

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

Hellenic Accreditation System



Annex G1/20 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. 13 th , 13/03/2019 |
| 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. 5 th 25/06/2021 and Facs Calibur (Becton Dickinson)* BM-59 Ver. 6 th 03/12/2019 |
| 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 |
| 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 |