

CYPRUS ORGANIZATION FOR THE PROMOTION OF QUALITY
CYPRUS ACCREDITATION BODY



ACCREDITATION CERTIFICATE no. L011-3

The Board of Governors
of the Cyprus Organization for the Promotion of Quality
acting as the authorized Cyprus Accreditation Body
according to the Article 7 of the Law 156(I)/2002

grants accreditation to the

***LIFELINE CELLULAR THERAPY PRODUCTS LABORATORY
- C.B.B. LIFELINE BIOTECH LTD***

in Nicosia, Cyprus

which has been assessed according to the Accreditation Criteria for Testing
Laboratories as defined in the standard

CYS EN ISO 15189:2012

as **competent to perform the Methods** defined in the Scope of Accreditation referred to in the **Annex** of this certificate; the said Annex represents inextricable part of the certificate. The **Accreditation Scope** can only be modified after a decision of the Cyprus Accreditation Body.

The current Accreditation Certificate, no. **L011-3**, is issued on **October 30th 2019** replacing the one issued on **April 8th 2019** and it is valid until **August 4th 2020**.

Accreditation was granted for the first time on August 5th 2008.


Antonis Ioannou
Director

Date: 30th October 2019

This laboratory is accredited in accordance with the recognised International Standard ISO 15189:2012. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management System (ISO-ILAC-IAF Communiqué, January 2015).



Annex of the Accreditation Certificate number L011-3

Scope of Accreditation of LIFELINE CELLULAR THERAPY PRODUCTS LABORATORY - C.B.B. LIFELINE BIOTECH LTD

Valid from August 5th 2016 until August 4th 2020
 *Valid from April 8th 2019 until August 4th 2020
 **Valid from October 30th 2019 until August 4th 2020

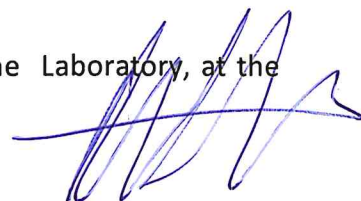
| Materials / Products | Type of testing / Countable properties | Methods / Techniques |
|--|---|--|
| Haematology Tests | | |
| Umbilical Cord Blood and nucleated cells from umbilical cord blood | Determination of 11 parameters | Sysmex XE-2100 |
| | 1. Hemoglobin (HGB) | |
| | 2. Red Blood Cells (RBC) | |
| | 3. White Blood Cells (WBC) | |
| | 4. Platelets (PLT) | |
| | 5. Haematocrit (HCT%) | |
| | 6. Neutrophils (NEUT x10 ³ /μl) | |
| | 7. Lymphocytes (LYMPH x10 ³ /μl) | |
| | 8. Monocytes (MONO x10 ³ /μl) | |
| | 9. Eosinophils (EO x10 ³ /μl) | |
| | 10. Basophils (BASO x10 ³ /μl) | |
| | 11. Nucleated Red Blood Cells (nRBC x10 ³ /μl) | |
| | Determination of 6 parameters | DiaMed-ID (DiaClon) |
| | Determination of Blood Groups (A, B, AB, O) and Rhesus D (+/-) typing | Monoclonal antibodies method using the DiaMed-ID (DiaClon) Micro Typing System |
| Flow cytometry | | |
| | Determination of 2 parameters | Miltenyi MACSQuant Analyser |

| Materials / Products | Type of testing / Countable properties | Methods / Techniques |
|--|--|---|
| Umbilical Cord Blood and nucleated cells from umbilical cord blood | Viability testing of nucleated cells and enumeration of haematopoietic progenitor cells CD45+dim/CD34+ | Flow cytometry analysis on Miltenyi MACSQuant Analyser according to the protocol of the Stem-Kit™ Reagent kit and ISHAGE guidelines |
| Microbiology Tests | | |
| | Determination of 1 parameter | BacT/ALERT3D |
| Umbilical Cord Blood | Testing for microbiological contamination (aerobic and anaerobic bacteriology screening) | Colorimetric system for microbial detection using the BacT/ALERT3D System (Biomérieux) |
| Serology/Immunology Testing | | |
| | Determination of 5 parameters | Biomérieux VIDAS |
| Blood Serum | 1. Detection of anti-cytomegalovirus IgM (CMVM) | ELFA (Enzyme Linked Fluorescence Assay) |
| | 2. Detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobulins and HIV-1 p24 antigen | |
| | 3. Detection of total antibodies against the Hepatitis B core antigen (Anti-HBc Total II) | |
| | 4. Detection of Hepatitis B surface antigen (HBsAg ultra kit) | |
| | 5. Detection of IgG antibodies of Hepatitis C | |

Authorised person to sign test reports is Mr Zacharias Kallis

General Remarks

This Annex refers only for testing that is carried out at the premises of the Laboratory, at the following address*, Proponitidos Str 28, 2033 Strovolos, Nicosia



Antonis Ioannou
Director

Date: October 30th 2019