



ISO 15189: 2012

מעבדות בדיקה-רפואה

תעודת הסמכה מס' 83 מרכז שירותי הדם – תל השומר מגן דוד אדום בישראל

כתובת אתר ייחוס: תל השומר 52621

עד יום: 31.12.2021

בתוקף מיום: 19.08.2019

הארגון נבדק ונבחן על ידי הרשות הלאומית להסמכת מעבדות (להלן הרשות) ונמצא ראוי להסמכה בהתאם לנספח פירוט היקף ההסמכה המצורף לתעודה זו, המהווה חלק בלתי נפרד ממנה ומספרו זהה למספר התעודה. הסמכה מצביעה על כשירות מקצועית ותפעול מערכת ניהול איכות בעלת הכרה בינלאומית. הארגון המוסמך על ידי הרשות, עומד בתקנים/ בדרישות המפורטים למעלה. דרישות התקנים הם לכשירות מקצועית ולמערכות ניהול, שהינן הכרחיות למתן תוצאות אמינות. הסמכה זו ניתנה בהתאם לכללי ISO/IEC 17011:2017 לפיהם פועלת הרשות ובמסגרתם מקיימת פיקוח שוטף על הארגון לצורך בחינת תפקודו המתמשך בהתאם לדרישות ההסמכה. ההסמכה תקפה כל עוד הארגון עונה לאמות המידה שנקבעו על ידי הרשות. תעודה זו אינה מהווה אישור לפי סעיף 12 לחוק התקנים.

אתי פלר
מנכ"ל
הרשות הלאומית להסמכת מעבדות

תאריך הסמכה ראשון: 01/01/2003



הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority

Testing Laboratory-Medical

ISO 15189: 2012

Accreditation Certificate No. 83

Blood Services Center – Tel Hshomer, Magen David Adom in Israel

Main site address: Tel Hshomer 52621, ISRAEL

Valid from: 19.08.2019

Until: 31.12.2021

The organization was assessed by the Israel Laboratory Accreditation Authority (ISRAC) and found to be worthy of accreditation to the detailed schedule attached.

The schedule is an integral part of this certificate and is numbered with the above certificate number.

Accreditation demonstrates technical competence and operation of an internationally recognized quality management system.

The organization accredited by ISRAC complies with the standards/requirements mentioned above, meets the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically competent results. This accreditation is granted in accordance with the requirements of ISO/IEC 17011:2017, and entails periodic surveillance and reassessment by ISRAC to ensure that the organization continues to comply with the accreditation requirements.

The accreditation is valid provided that the organization continues to meet the criteria as laid down by ISRAC.

This certificate does not constitute an approval in accordance with article 12 of the standard law.

Etty Feller
General Manager
Israel Laboratory Accreditation Authority

Date of first accreditation: 01/01/2003

Date of signature 19/08/2019

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Name and Address:

Laboratory name	Blood Services Center – Tel Hashomer, Magen David Adom in Israel
Address	Tel Hashomer 52621, Israel
Phone	+972-3-530-0400
Fax	+972-3-530-0500

Site: P or T or M , P-Permanent, T-Temporary, M-Mobile

A permanent (P) or temporary (T) place, or a stationary or mobile (M) facility, at or from which the organization performs activities forming part of its scope of accreditation, starting from sampling to final issuance of a report or certificate and / or quality system activities. A temporary (T) site is a site established under the responsibility of an accredited permanent site. All activities performed at a temporary site are the responsibility of the permanent site. An outdoors work is also considered to be a temporary site. Temporary site will be a site that involves work for special project and the activity will be defined in time (up to 2 years).

Type of Scopes: A- Fixed, C- Flexible scope in analytical tests : Type of matrix, analytes, experimental systems and/or analytical characteristics may be subject to changes, in accordance with the laboratory's approved and documented procedures. For details, please refer to the list of Accredited Tests, available from the laboratory upon request.



Item	Scope Type	Site	Types of Test / Properties Measured	Materials / Samples Tested	Test principle / Characteristics	Equipment used / Work station	Opinion and Interpretation	Remarks	
Group of products: Health, Medicine - Blood Bank					משפחת מוצרים: בריאות, רפואה - בנק דם				
Blood Component Preparation, CBC					הכנת מרכיבי דם, ספירת דם				
1	A	P	Determination of factor VIII	קביעת פקטור VIII Plasma, Cryoprecipitate	פלסמה, פלסמה, Cryoprecipitate	Clotting time	ACL TOP 350 coagulation system	---	
2	A	P	Hct (Hematocrit)	Hct (Hematocrit)	Whole blood	דם מלא	Calculation from RBC count and mean red cell volume	UniCel DxH 600 Coulter Cellular Analysis System	---
3	A	P	Hgb (Hemoglobin)	המוגלובין	Whole blood	דם מלא	Photometric measurement	UniCel DxH 600 Coulter Cellular Analysis System	---
4	A	P	PLT(Platelets)	PLT (Platelets)	Whole blood	דם מלא	Coulter principle	UniCel DxH 600 Coulter Cellular Analysis System	---
5	A	P	RBC (Red Blood Cells)	תאי דם אדומים	Whole blood	דם מלא	Coulter principle	UniCel DxH 600 Coulter Cellular Analysis System	---
6	A	P	WBC (White Blood Cells)	תאי דם לבנים	Whole blood	דם מלא	Coulter principle	UniCel DxH 600 Coulter Cellular Analysis System	---

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