



ISO/IEC 17025:2017

מעבדות בדיקה

תעודת הסמכה מס' 0240 המרכז הלאומי לרפואה משפטית - המעבדה הביולוגית

כתובת אתר ייחוס: בן צבי 67, תל-אביב, 6108401

בתוקף מיום: 26.05.2025

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 מעלה. 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.

הרשות חתומה על הסכם הכרה רב צדדי (MLA) מול ארגון European Accreditation Cooperation (EA).

תעודה זו אינה מהווה אישור לפי סעיף 12 לחוק התקנים.

תאריך הסמכה ראשון: 16.06.2011

אתי פלר מנכ״ל הרשות הלאומית להסמכת מעבדות

Date of signature 26.05.2025 Page No. 1 of: 6





Testing Laboratories

ISO/IEC 17025:2017

Accreditation Certificate No. 0240 The National Center of Forensic Medicine - Biology Laboratory

Main site address: 67 Ben Zvi st., Tel-Aviv ,6108401, Israel

Valid from: 26.05.2025 Until: 15.06.2027

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. ISRAC is an EA-MLA (European Accreditation Cooperation Multi-Lateral Agreement) signatory.

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

Date of first accreditation: 16.06.2011

Etty Feller
General Manager
Israel Laboratory Accreditation Authority

Date of signature 26.05.2025 Page No. 2 of: 6

Department: Testing Laboratory ISO/IEC 17025: 2017 Accreditation No. 0240

Name and Address:

Organization Name Biology Laboratory, The National Center of Forensic Medicine

Address Ben Zvi 67, Tel-Aviv 6108401

Phone +972-3-512-7838 **Fax** +972-3-512-7835

E-Mail <u>morielbz@forensic.health.gov.il</u>

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.

Date of signature 26.05.2025 Page No. 3 of: 6

Department: Testing Laboratory ISO/IEC 17025: 2017

Accreditation No. 0240

I		Scope Type	Site	Materials / Products Tested	Types of Test / Properties Measured		Standard / Method	Opinion and Interpretation	Remarks	
Group of products: Forensic Exhibits						משפחת מוצרים: <i>מוצגים פורנסיים</i>				
E	Biological Testing, Human Genetic Identification					<i>בדיקות ביולוגיות</i> , זיהוי גנטי אנושי				
	1.	A	P	DNA דנייא	Determination, analysis and comparison of DNA profiles	קביעה, ניתוח והשוואה של פרופילי דנייא	- Applied Biosystems® 3500 / 3500xL Genetic Analyzer 3500 Series Software 2 Publication Part Number 4476988 Rev. C USER BULLETIN GeneMapper® ID-X Software Version 1.6 SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories – APPROVED 01/12/2017			
	2.	С	P	DNA TUNA	PCR DNA Quantification	PCR-כימות דנייא	Quantifiler HP and Trio DNA Qunatification Kits User Guide. Precision ID mtDNA Panels with the HID Ion S5TM/HID Ion GeneStudioTM S5 System: Library Preparation on the HID Ion ChefTM System		For flexible scope in materials tested for DNA Quantification measurement see list DNAquant (Table 3)	

Department: Testing Laboratory ISO/IEC 17025: 2017

Accreditation No. 0240

Item	Scope Type	Site	Materials / Products Tested	Types of Test / Properties Measured		Standard / Method	Opinion and Interpretation	Remarks	
Group of products: Forensic Exhibits					משפחת מוצרים: <i>מוצגים פורנסיים</i>				
Biological Testing, Human Genetic Identification					בדיקות ביולוגיות, זיהוי גנטי אנושי				
3.	С	P	DNA	PCR DNA amplification	שכפול דנייא ב-PCR	PowerPlex® ESI 16 Fast System for Use on the Applied Biosystems Genetic Analyzers Technical Manual. GlobalFiler TM Plus PCR Amplification Kit USER GUIDE Catalog Number Publication Revision0 COL110245 0919 YfilerTM Plus PCR Amplification Kit user guide		For flexible scope in materials tested for DNA Amplification measurement see list DNAam (Table 4) בנוחל 805.007.01.	
4.	С	Р	Forensic exhibits	DNA extraction by Autolys Hamilton	מיצוי דנ״א בשיטת Autolys Hamilton	PrepFiler TM and PrepFiler TM BTA Automated Forensic DNA Extraction Kits		For flexible scope in materials tested for DNA Extraction by AutoLys Hamilton (DEBAH) see list DEBAH (Table 2) 805.007.01	
5.	С	Р	Forensic exhibits	DNA extraction by Automate Express	מיצוי דנ״א בשיטת Automate Express	PrepFiler Express TM and PrepFiler Express BTA TM Forensic DNA Extraction Kits		For flexible scope in materials tested for DNA Extraction by Automate Express (DEBAE) see list DEBAE (Table 2) 805.007.01	



Department: Testing Laboratory ISO/IEC 17025: 2017

Accreditation No. 0240

Item	Scope Type	Site	Materials / Products Tested Types of Test / Pro		perties Measured	Standard / Method	Opinion and Interpretation	Remarks		
Group of products: Forensic Exhibits						משפחת מוצרים: <i>מוצגים פורנסיים</i>				
Biological Testing, Human Genetic Identification						<i>בדיקות ביולוגיות</i> , זיהוי גנטי אנושי				
6.	С	P	Forensic exhibits	מוצגים פורנסיים	DNA extraction by Chelex		Based on: Walsh P.S., D.A. Metzger and R. Higuchi, 1991. Chelex® 100 as a Medium for Simple Extraction of DNA for PCR-Based Typing from Forensic Material. BioTechniques Vol. 10 No. 4: p506		For flexible scope in materials tested for DNA Extraction by Chelex (DEBC) see list DEBC (Table 1) 805.007.01 בנוהל	