Informal translation

Surveillance Agreement

For Accreditation in Accordance with ISO/IEC 17025 *

Prepared and signed on _____ in Airport City, Israel

Between

The Israel Laboratory Accreditation Authority

on 12 Kinneret St., Airport City, P.O.Box 89, Lod, Ben Gurion Airport, Israel 7015002

(Hereinafter: "ISRAC") on one hand;

And

Company / NPO «Name» «Company No.»

On «Address»

(Hereinafter: "the Company") on the other hand;

WHEREAS, The Company operates a testing and/or calibration laboratory (hereinafter: "the Test"), whose number is «Number» (hereinafter: "the Laboratory");

AND WHEREAS, ISRAC operates in accordance with the Israel Laboratory Accreditation Authority Law, 1997;

AND WHEREAS, ISRAC grants the Laboratory a certificate of accreditation and agenda indicating the scope of its accreditation;

AND WHEREAS, The validity period of this Surveillance Agreement is from _____ until _____;

AND WHEREAS, The accreditation is based upon the trust held by ISRAC in the Laboratory and in the reliability of its tests and reports;

AND WHEREAS, The Laboratory commits to operate and provide services as an accredited laboratory in accordance with the scope of its accreditation;

AND WHEREAS, the Laboratory commits to continue operating in accordance with the accreditation requirements after being granted accreditation, and to fulfill the accreditation requirements; as published in the document 1: 432000: Quality Manual on ISRAC's Web site, www.israc.gov.il under publications/regulations

* For medical laboratories: for every place in this Agreement where ISO/IEC 17025 is mentioned, ISO/IEC 15189 will be substituted.

For inspection bodies: for every place in this Agreement where ISO/IEC 17025 is mentioned, ISO/IEC 17020 will be substituted.

For proficiency testing providers: for every place in this Agreement where ISO/IEC 17025 is mentioned, ISO/IEC 17043 will be substituted.

For laboratories performing activity that falls under ISO/IEC 17025 as well as ISO/IEC 17020 (or any other combination), the Agreement will apply to both.

NOW, THEREFORE, the Parties have agreed and stipulated as follows:

1. **General:**

1.1. The preamble to this Agreement forms an inseparable part hereof.

1.2. For the purpose of this Agreement, “supervision” is defined as:

A process including a number of stages in which ISRAC evaluates the ability and professional and managerial qualification of the Laboratory to perform tests in

accordance with the appropriate laws, ordinances, standards, directions, internal policies, specifications, or other attribution documents.

As for the assessment types and their frequency, see procedure number 2-671001: Surveillance of Accredited Organizations, published on ISRAC's website, under Publications Procedures.

2. **Reporting obligations:**

The Laboratory commits to report to ISRAC in writing and ahead of time, inasmuch as this as possible, and in any case no later than 14 days after the change in question, of any change that may affect the Laboratory's capabilities and/or the scope of its accreditation and/or its ability to fulfill the requirements as per this agreement and/or any other criterion that is relevant to the accreditation granted by ISRAC.

In addition, and without diminishing the aforementioned clauses in this Article, the Laboratory commits to submit reports as follows:

2.1. Changes in ownership and in senior management staff:

The Laboratory commits to inform ISRAC in writing of any changes in ownership and/or in the job description, areas of authority or designation of its senior staff, including the Laboratory's General Management, Technical management, Quality management, Sites/subsidiaries management and any other position carrying managerial responsibility. The Laboratory also commits to examine and document the suitability of the person to the position, and to present to ISRAC evidence of his suitability, as per ISRAC's request. The position requirements will be fulfilled in accordance with the laws and regulations of the State of Israel.

For this purpose, "areas of authority" include signatory privileges.

2.2. Changes to the quality system, location, equipment and the Laboratory's status:

The Laboratory commits to inform ISRAC in writing of any proposed change in location, equipment, laboratory status, and quality system, as defined in ISO/IEC 17025, including changes in legal status, and substantive changes to its quality manual, policy statement, procedure guidelines and professional management and recognition/external certificates (e.g. certificate of recognition/regulator or professional body) related to its scope of accreditation. In addition, ISRAC shall be notified of any deficiency causing lack of activity for more than two weeks.

It is agreed that in the event that ISRAC opposes to the change in question and/or places conditions upon it, its position will be explained, and the Laboratory will be given the opportunity to describe its case prior to ISRAC's final decision.

The Laboratory hereby declares and confirms its understanding that an essential condition of the entire activity and efficacy of the accreditation system is the continuous and accurate reporting of all changes mentioned in this Article and its Sub articles.

3. **Control and Monitoring:**

The Laboratory commits to cooperate with ISRAC and to meet any requirement arising from accreditation matters, including but not limited to, assisting ISRAC in investigating and resolving complaints concerning the Laboratory.

3.1. The Laboratory commits to allow representatives or employees of ISRAC to perform Surveillance of the Laboratory and its premises, at any time during the operation of the Laboratory, and without prior notice under the security procedures to which it is bounded.

3.2. Prior to assessments or when needed, the laboratory undertakes to make available on loan, relevant standards, required for performing the assessment.

3.3. The Laboratory commits to assist ISRAC to the best of its ability in performing the Surveillance, including presentation, by request of ISRAC, of documents (and delivering copies thereof) of any kind as related to the issues of Surveillance and accreditation, preparation and testing of samples, allowing an opportunity to ask questions of employees, and presentation of any information that may be required by ISRAC, its representatives or its employees.

In the event that security clearances are needed for presentation of information, ISRAC will act to produce them in accordance with the Laboratory's request.

3.4. The Laboratory commits to assist ISRAC to the best of its ability in performing the Surveillance, subject to restrictions resulting from the Laboratory's objective limitations, including as specified in the end of Article 3.3.

3.5. The laboratory shall have, where applicable, legal arrangements with its clients that commit the clients to provide, on request, access to assessment team to assess the laboratory's performance when carrying out testing/calibration activities at the client's site.

3.6. The Laboratory shall act according to ISRAC procedure number 1-681001: ISRAC Policy for Conduction Comparison Testing in Accredited Laboratories, and ISRAC directions, as published from time to time on the website www.ISRAC.gov.il, under the "Publications" section.

Comment: This clause does not refer to labs which perform testing and supervision acts.

3.7. It his hereby declared and clarified that a refusal on the part of the Laboratory to cooperate with ISRAC on issues of Control and Monitoring, or violation of any of the directions described in Articles 3.1 to 3.6, may result in the suspension of the Laboratory's accreditation to perform certain tests, or to the suspension of its status as an accredited laboratory for the duration and conditions that will be specified by ISRAC as appropriate for the circumstances of the violation.

4. **Revocation or withdrawal of accreditation and consequences thereof:**

4.1. Any basic or fundamental violation, whether by action or by failure to act, of the requirements of the accreditation or of the Laboratory's commitments in this Agreement, will grant ISRAC the right to take action against the Laboratory, including the right to revoke or suspend its accreditation to perform certain tests, or to revoke it entirely.

The suspension or revocation of accreditation as described will be done by written notice of ISRAC, either by registered mail or by personal delivery.

4.2. ISRAC will not decide upon suspension or revocation of the accreditation granted to the Laboratory without having given the Laboratory an opportunity to present its responses or oppositions (hereinafter: "the Hearing") regarding the facts constituting the basis for said suspension or revocation. The Hearing will be conducted according to the Hearing procedure (2-651002) publish on ISRAC's website.

4.3. In any event of a final decision to revoke or suspend the Laboratory's accreditation, ISRAC will publish a notice regarding the suspension or revocation of the Laboratory's accreditation, in the manner by which the notice of accreditation was published, or by any other means.

4.4. ISRAC will have the right to limit or place conditions upon the revocation or suspension in question, in accordance with a time frame or conditions as it sees fit.

4.5. The laboratory undertakes not to make use of the accreditation certificate or its appendices, in a copy of the certificate or in the scope of the accreditation, in a manner that may mislead the public / customers of the organization or endanger the reputation of ISRAC. The laboratory undertakes that all customers of the organization will be notified of suspension, reduction or withdrawal of accreditation and the expected effect thereof. If the accreditation of the organization has been removed, any mention of accreditation shall be immediately terminated.

4.6. The Laboratory commits to cease displaying its status as an accredited Laboratory on its certificates, reports, notices, or any other document, immediately upon receipt of the notice of suspension or revocation of accreditation.

In the event of a partial revocation or suspension, the Laboratory may continue noting its status as an accredited Laboratory in the valid areas of accreditation only, and in such manner as does not mislead its customers.

4.7. The Laboratory commits to inform its relevant customer group of the suspension or revocation of its accreditation immediately upon receipt of such notice from ISRAC.

4.8. A laboratory that, after revocation of its accreditation, violates any of the directions included in Articles 4.5 to 4.7 above, will not be eligible to submit requests for the renewal of its accreditation, for a set period of time, which will be determined by ISRAC.

4.9. A laboratory whose accreditation has been suspended, and that violates one of the directions included in Articles 4.5 to 4.7 above, will have its accreditation revoked, and will be subject to the sanction described in Article 4.8 above.

5. **Relinquishment of accreditation:**

5.1. In the event that the Laboratory decides to relinquish its accreditation in part or in full, it must notify ISRAC of its decision in writing and return its accreditation certification.

5.2. In the event that the Laboratory submits notice of its intention to cease being an accredited Laboratory, it will be considered a laboratory whose accreditation was revoked for the purpose of its being subject to the publication laws, and will be subject to Articles 4.5 to 4.8 above, with the required changes.

6. **Prohibition on transference of accreditation:**

6.1. The Laboratory may not transfer or assign its accreditation certificate or any privileges it entitles, to any other entity.

6.2. The accreditation received by the Laboratory may not be transferred, either in part or in full, temporarily or permanently, to any other laboratory, or to the same laboratory under a new identity.

The above clause will not apply to changes to the company's name, under the condition that the change of name is the only change taking place, and subject to ISRAC's approval.

6.3. A laboratory will inform ISRAC in writing and ahead on any transference of accreditation.

In this case ISRAC will be permitted to determine if it implies a new accreditation certificate.

6.4. A laboratory may not grant accreditation to another laboratory as an accredited independent or branch laboratory, whether in part or in full, temporarily or permanently.

7. Rules for mention of the Laboratory's accreditation:

An accredited laboratory may mention the details of its accreditation in result reports and/or test certificates, in a manner that ensures that a reasonable group of its customers will not be misled, and will be able to differentiate easily between tests for which the Laboratory is accredited, and other tests performed by it. In every place where the Laboratory mentions its accreditation, such mention will be made in a manner that ensures unambiguity. The Laboratory therefore commits to act as follows:

7.1. The Laboratory will present its customers the accreditation certificate with all its addenda.

7.2. The Laboratory will act in accordance with ISRAC's Procedure number. 1-455001 (Policy for the Use of the ISRAC Symbol).

7.3. Authorization of test certificates or result reports:

7.3.1. Each certificate or report of test results must be approved by the personal signature of the approved professional signatory who was authorized for the purpose by the Laboratory and presented to ISRAC, including by means of supporting documents. The full name and position of the signatory must appear by his signature.

7.3.2. The signature of the approved professional signatory will constitute confirmation that the tests have been performed in accordance with the customer's requests, and in accordance with professional policies and policies appearing in the Laboratory's quality system, and that the results displayed in the certificate or report accurately reflect all the results obtained in the test.

7.3.3. In cases where the certificate or report in question displays results of different tests, for which are responsible different approved signatories, each of these signatories must personally sign the document and authorize in their signature the tests performed under their responsibility.

7.3.4. The Laboratory hereby commits that in every certificate or report of test results in which the accreditation is mentioned, the following statement will be included:

"This document must be dealt with in its entirety, and sections hereof may not be copied to other documents".

7.3.5. The signature of the approved signatory on the certificate or report will serve as evidence of his responsibility for their contents and for the reliability of the test results specified therein.

7.4. Mention of tests performed by other laboratories:

7.4.1. The Laboratory commits to act in accordance with ISRAC's Procedure number 1-000010 "Employment of subcontractors", as published on its website under the Publications section.

7.5. **Rules for mention of the accreditation in the Laboratory's publications:**

7.5.1. The Laboratory commits to refrain from presentation of partial information that may result in misleading of customers or of any other person.

7.5.2. The Laboratory commits to refrain from mentioning the accreditation, whether in speech or in writing, in areas that are beyond its area of accreditation, including those areas in which its accreditation has been suspended or partially revoked.

7.5.3. The Laboratory will include in its quality manual a policy which will describe the rules for mention of the accreditation, in accordance with and subject to the directions of this Agreement. For this purpose, "mention" will include both in speech and in writing.

7.5.4. The Laboratory hereby declares and confirms that any violation of the rules for mention of the accreditation as listed in Articles 7 and 7.5 above, including all of their Subarticles, will constitute a fundamental breach, and may result in suspension or revocation of its accreditation, in part or in full, in accordance with the severity of the violation, and subject to the contents of Article 4 above.

8. **Information and instruction:**

8.1. ISRAC commits to inform the accredited Laboratory, in advance and within a reasonable period of time, of any change in the accreditation and Surveillance requirements, in such manner as will allow time for the Laboratory to organize and prepare to meet the new requirements.

The notice will be delivered to the Laboratory's address as specified in this Agreement, or to any other address delivered from time to time by the Laboratory.

"Notice" shall include by means of ISRAC's newsletter and website.

8.2. The Laboratory commits to keep track of updates to ISRAC's directions and those procedures that fall under the Laboratory's areas of obligation, and to act in accordance with those updates.

9. **Payment:**

9.1. An accredited laboratory is required to pay an annual fee of 12% of the calculated full accreditation cost.

The fee will be paid to ISRAC by the lab no later than two months before the laboratory's accreditation expires accreditation for the next two years (the sum of two annual fees).

The payment for conducting the surveillance assessments or re-accreditation assessments, according to supervision program, will be paid by the laboratory according to ISRAC rates and according to instructions in form number TA-621001-19: Method of pricing and surveillance, following an invoice from ISRAC.

9.2. Unpaid funds as mentioned above shall be considered as a breach of contract and may result in suspension or termination of the accreditation, or any other ramification that ISRAC can perform, by this agreement or by law.

10. **Applicability:**

The commitments of the parties as described in this Agreement will apply immediately after the Laboratory receives written notice of its accreditation from ISRAC, if and when such accreditation is granted.

11. **Statement of confidentiality:**

11.1. ISRAC hereby commits that any information, whether professional or commercial, which it receives from the Laboratory as part of this Agreement, and owing to its authority under any law, will not be transferred to any other person or entity, and will not be published without the consent of the Laboratory.

11.2. To dispel any doubt, it is hereby clarified that the commitment described in Article 11.1 will not apply to information that ISRAC is required to deliver by law, or to information that cannot be used to identify or harm the Laboratory or its customers (statistical data).

The Israel Laboratory Accreditation Authority	«Lab Name»
	Full Name of signatory
	Signature and Laboratory post