

RULES OF PROCEDURE FOR MEDICAL LABORATORY ACCREDITATION

1.0 INTRODUCTION

- 1.1 **Scope:** The purpose of these rules is to establish procedures governing accreditation of Medical Laboratories by International Accreditation Service, Inc. (IAS).

IAS accreditation does not make any representation nor should it be construed as making representation regarding attributes not specifically addressed by the accreditation. Accreditation also does not constitute an endorsement or recommendation for use of a particular laboratory or the specimens/samples, examined by the laboratory.

1.2 Reference Documents

- 1.2.1 IAS Accreditation Criteria for Medical Laboratories, AC780.
- 1.2.2 IAS Rules of Procedure for Appeals Concerning International Accreditation Service, Inc.,
- 1.2.3 ILAC-R7 Rules for the Use of the ILAC MRA Mark
- 1.2.4 ILAC-P8 ILAC Mutual Recognition Arrangement (Arrangement):
Supplementary Requirements for the Use of Accreditation Symbols and for
Claims of Accreditation Status by Accredited Conformity Assessment Bodies

2.0 INITIAL ACCREDITATION

2.1 Initial Application, Fees and Assessment Costs

- 2.1.1 Each initial application must be submitted through the IAS Customer portal.
- 2.1.2 The new applicant must submit appropriate basic fee and assessment cost as identified in your quotation.
- 2.1.3 The basic fee covers one field of examination, as applicable and as provided in your quotation.

- 2.1.4 If any additional fields are identified during the course of accreditation, additional fees may apply. Fields of examination are broadly categorized as immunology, genetics, chemical pathology, etc.
- 2.1.5 Initial applications held for more than 180 days, without the applicant's having fulfilled IAS requirements for accreditation, are subject to cancellation unless such term is extended by the IAS president or his/her designee.
- 2.1.6 All IAS fees are nonrefundable.
- 2.1.7 **Taxes and charges:** All sales, use, excise, value-added and similar taxes and charges are the responsibility of the applicant, and the applicant agrees to reimburse IAS for any such taxes and charges imposed on IAS with respect to services provided by IAS.
- 2.1.8 Required documentation as noted in Sections 4 and 5 of IAS AC780 must be submitted.
- 2.1.9 Desired scope of accreditation detailing the examination methods for which accreditation is sought must be submitted. As an example, the following format is recommended:

Materials/Product Tested/ Sample type	Specific Examination/Property Measured (Determinant)	Examination Method/Procedure/ Technique/Equipment
Field: Immunology		
Serum/Plasma	HIV Screening	Electrochemiluminescence Immunoassay "ECLIA"
Serum/Plasma	HBsAg Screening	Electrochemiluminescence Immunoassay "ECLIA"
Field: Genetics		
Whole blood / Serum (EDTA, Clot accelerator)	DNA Profiling of HLA - A region	Molecular/Sequence Specific Primers (SSP)
Whole blood / Serum (EDTA, Clot accelerator etc.)	DNA Profiling of HLA - A region	Bead based hybridization/ SSOP

- 2.1.10 IAS may at any time, in addition to the required documentation noted above, require other information.

- 2.1.11 Initial applicants will be invoiced for the balance of costs and expenses resulting from the onsite assessment.
- 2.1.12 Additional fees, if any, due to identification of any additional fields of examination (refer to section 2.1.4) at the conclusion of the accreditation process will be invoiced.

2.2 Initial Assessment

- 2.2.1 Upon receipt by IAS of the application, applicable fees, required documentation and the desired scope of accreditation, IAS will process the application as follows:

- 2.2.1.1 A review of submitted documentation will be conducted to determine preliminary compliance with applicable requirements. In case of inadequate documentation, the review comments shall be reported to the medical laboratory.

- 2.2.1.2 An (optional) onsite pre-assessment visit may be scheduled at the discretion of the applicant for the purpose of determining preliminary compliance with applicable requirements. IAS and assessors shall ensure that no consultancy is provided during this pre-assessment exercise. A quotation will be provided for such an activity.

- 2.2.1.3 In agreement with the applicant, an initial onsite assessment will be scheduled to verify compliance with the accreditation requirements. If there are exceptional circumstances, the initial assessment may be performed remotely based on the *IAS guidelines to perform remote assessments*. Upon completion, an assessment report will be provided outlining any Corrective Action Requests and Concerns noted.

- 2.2.1.4 **Response to Assessment Report:** A written response to any Corrective Action Requests (CARs) and Concerns identified during the initial assessment shall be submitted to IAS within thirty (30) days of the conclusion of the assessment as follows:

- 2.2.1.4.1 Corrective Action Requests (CARs) require a mandatory response on actions taken by the laboratory to resolve the CARs, including objective evidence substantiating the actions taken. The response must include an analysis of the extent and cause (e.g. root cause analysis) with the objective evidence implemented to support CAR closures.

Resolution of CARs requiring revisions to the laboratory's management and technical system must be documented and submitted to IAS. Objective evidence may be in the form of revisions to procedures, additional training, mentoring and monitoring given to personnel accompanied by appropriate records, and/or other data.

2.2.1.4.2 Concerns require a mandatory written response from the laboratory within 30 days of submission of the assessment report. While objective evidence addressing Concerns is not mandatory, the laboratory must include an analysis of the extent and cause (e.g. root cause analysis) with the actions planned to be taken to support closure of concerns. The actions taken by the medical laboratory to implement actions to resolve concerns will be verified at the next scheduled assessment or during a follow-up assessment.

2.2.1.4.3 If more than 30 days are needed to resolve CARs or Concerns, the laboratory must request, in writing, for an extension from IAS. Requests for an extension should be accompanied by a reasonable estimate on when the responses will be submitted for review.

2.2.1.4.4 IAS reserves the right to conduct a follow-up assessment to determine if CARs and Concerns have been satisfactorily resolved. If follow-up assessment is conducted, costs incurred will be invoiced accordingly.

2.2.1.4.5 Failure to resolve all CARs and Concerns within six months from the date of assessment will result in a reassessment or further action against the accreditation as called for in these rules.

2.2.2 IAS will grant accreditation upon determination that based on the onsite assessment and review of evidence submitted, the applicant has met all the accreditation requirements as a medical laboratory for the examination methods noted in the scope of accreditation certificate and available on the IAS website.

- 2.2.3 IAS may decide not to grant accreditation to the applicant for not fulfilling accreditation requirements. Any applicant denied accreditation may appeal this decision as per requirements noted under Section 6.2 of these rules.
- 2.2.4 Each initial accreditation is valid for a one-year period from the accreditation date.

2.3 **Transfer of Accreditation:** Applicant laboratories currently accredited by a signatory to the ILAC Mutual Recognition Arrangement (MRA) seeking transfer of accreditation, in addition to fulfilling IAS accreditation requirements, must provide the following:

- 2.3.1 A complete copy of the most recent assessment report from the current accreditation body.
- 2.3.2 Corrective actions for any deficiencies noted in the assessment report, including acknowledgement of acceptance of the corrective actions by the current accreditation body. If the applicant and the accreditation body differ on the corrective actions or deficiencies, IAS will review them and make a decision as to status.
- 2.3.3 A copy of the most recent accreditation certificate issued by the current accreditation body.
- 2.3.4 Other information as deemed pertinent by IAS.
- 2.3.5 IAS shall assess the submitted material and determine the scope of the on-site assessment prior to accrediting the application organization. IAS will be invoicing the applicant for the on-site assessment accordingly.

3.0 MAINTENANCE OF ACCREDITATION

3.1 **Renewal Application, Fees and Assessment Costs**

- 3.1.1 Each renewal application must be submitted through the IAS Customer portal.
- 3.1.2 An application to renew accreditation must be filed at least 15 days prior to the expiration date if continued accreditation is desired and shall be accompanied by the applicable fee as identified in the renewal notice.
- 3.1.3 Accreditation is subject to cancellation if an application to renew accreditation is not completed by the renewal date.
- 3.1.4 **Taxes and charges:** All sales, use, excise, value-added and similar taxes and charges are the responsibility of the applicant, and the applicant agrees to

reimburse IAS for any such taxes and charges imposed on IAS with respect to services provided by IAS.

- 3.1.5 All expenses, including but not limited to travel and staff time, related to the assessments are reimbursable to IAS by the laboratory.
- 3.1.6 Additional fees, if any, due to identification of any additional fields of examinations (refer to section 2.1.4) at the conclusion of the accreditation process will be invoiced.

3.2 Rules applicable to all assessment types

- 3.2.1 The management systems/technical documentation can be in the local language. However, an English translation of key documents needs to be provided to IAS, preferably before the assessment, or a translator has to be available during the assessment. In such instances, additional assessment time will be charged to the laboratory.
- 3.2.2 If more than 30 days are needed to resolve CARs or Concerns, the laboratory must request, in writing, an extension from IAS. Requests for an extension should be accompanied by a reasonable estimate on when the responses will be submitted for review.
- 3.2.3 For currently-accredited laboratories, lack of responsiveness to an IAS assessment report within 90 days will result in suspension of accreditation and removal of the laboratory's accreditation certificate from the IAS website.
- 3.2.4 Failure to resolve all CARs and Concerns within six months from the date of assessment may result in a complete/partial follow-up assessment or further action against the accreditation as called for in these rules upon discretion of the management. If follow-up assessment is conducted, costs incurred will be invoiced accordingly.
- 3.2.5 IAS may decide not to continue accreditation to the accredited medical laboratory for not fulfilling accreditation requirements. Any applicant denied accreditation may appeal this decision as per requirements noted under Section 6 of these rules.

3.3 Surveillance Assessment after Initial Year of Accreditation

- 3.3.1 All accredited medical laboratories are subject to a surveillance assessment at the end of the initial year of accreditation. IAS will determine whether the surveillance assessment may be conducted remotely or onsite. Determination

will be based on factors including: severity of CARs and Concerns from the initial assessment, changes in the management system as indicated in the renewal application, results of proficiency testing, if any, complaints received by IAS in the past year and the risk associated with the scope of accreditation. IAS will grant continuation of accreditation upon determination based on the surveillance assessment that the accredited medical laboratory has met the accreditation requirements for the examination methods noted in the scope of accreditation certificate available on the IAS website, and upon completion of the renewal application.

3.3.2 Onsite Surveillance Assessment

3.3.2.1 If IAS determines an onsite surveillance assessment is required, IAS staff will contact the laboratory to schedule the assessment.

3.3.2.2 At a minimum, the following information shall be reviewed during the onsite surveillance assessment: the laboratory's internal audit and management review reports/minutes; any complaints; actions resulting from any Concerns noted in the previous assessment report; results of External Quality Assurance Programs, if any; any major changes in key personnel, facilities, equipment or in the laboratory's management system and final reports for examination methods that are within the laboratory's scope with IAS.

3.3.2.3 The surveillance assessment process is similar to the initial assessment process noted above.

3.3.3 Remote Surveillance Assessment

3.3.3.1 If IAS determines that the laboratory qualifies for a remote surveillance assessment, the medical laboratory shall provide the following information: the laboratory's internal audit and management review reports/minutes; any complaints; actions resulting from any Concerns noted in the previous assessment report; results of External Quality Assurance Programs, if any; any major changes in key personnel, facilities, equipment or in the laboratory's management system and reports for examination methods that are within the laboratory's scope with IAS.

3.3.3.2 IAS will review the submittals and make a determination if the accreditation can be continued or an onsite surveillance assessment is required.

3.4 Onsite Reassessment

3.4.1 An onsite reassessment is required at the end of every two-year term commencing from the date of initial accreditation.

3.4.2 No more than 24 months shall elapse between reassessments

3.4.3 In consultation with the accredited laboratory, an onsite assessment will be scheduled to verify compliance with the accreditation requirements.

3.4.4 The onsite reassessment process is similar to the initial assessment process noted above.

3.4.5 Remote Reassessment

3.4.5.1 A remote assessment will be performed in exceptional circumstances, when the onsite assessment is not possible, and will be performed according to IAS guidelines to perform the remote assessments.

3.4.5.2 In consultation with the accredited laboratory, assessment will be scheduled to verify compliance with the accreditation requirements.

3.5 Scope Extension Assessments

3.5.1 Requests for extension of scope require submission of a formal request detailing the extension (e.g., examination methods) requested.

3.5.2 Laboratories seeking extension of scope may be subject to an onsite scope extension assessment.

3.5.3 In agreement with the accredited laboratory, an onsite assessment will be scheduled if deemed necessary.

3.5.4 Costs incurred will be invoiced accordingly

3.6 Extraordinary Assessments

3.6.1 Extraordinary onsite assessments may be conducted, including unannounced assessments, to investigate formal complaints or other changes in a laboratory's status that may affect the ability of the laboratory to fulfill IAS requirements for accreditation.

3.6.2 All costs associated with the extraordinary assessment will be the responsibility of the accredited laboratory.

4.0 RESPONSIBILITIES OF MEDICAL LABORATORY

4.1 Changes to Laboratory's Accreditation Status: Laboratories accredited under these rules shall notify IAS in writing within thirty days concerning the following:

- 4.1.1 Change in laboratory name.
- 4.1.2 Change in laboratory ownership.
- 4.1.3 Change in laboratory address. (*If a laboratory has relocated, it needs to notify IAS immediately and the 30-day time period does not apply for relocation.*)
- 4.1.4 Changes in equipment, policies or procedures that affect the laboratory's accreditation.
- 4.1.5 Major physical changes to the laboratory facility.
- 4.1.6 Changes in key technical or supervisory personnel.
- 4.1.7 Change in status, including but not limited to cancellation, revocation, suspension or withdrawal of other accreditations maintained by the laboratory.

4.2 Laboratories Operating Under Special Jurisdictional/Governmental Regulations

- 4.2.1 Regulatory entities may place specific compliance requirements on laboratories operating within their jurisdiction. If a laboratory intends to seek acceptance of its reports of its examinations by these entities, they must agree to comply with the additional assessment requirements, including more frequent onsite assessments, as applicable.
- 4.2.2 By executing the IAS application for medical laboratory accreditation, the laboratory agrees to furnish all needed documentation, pay the required fees, perform additional examinations or otherwise fully comply with the requirements of the regulatory entities.

4.3 Indemnification: All applications for an IAS accreditation contain indemnification provisions.

4.4 Unannounced Assessments: The laboratory agrees to permit unannounced assessments of its office and facilities by the IAS for cause, such as formal complaints, pattern of nonconformance, regulatory requests, etc.

4.5 **Accreditation Certificates:** Accreditation certificates issued by IAS will be in English. If any translations are made by the accreditation organizations for business reasons, it is their responsibility to ensure the accuracy of the information of the translated document.

4.6 **Usage of the IAS Name or Symbol by Accredited Laboratories**

4.6.1 An accredited laboratory can make reference to its IAS accreditation in examination reports, on its website, in its general literature and promotional materials, and in business solicitations, under the following provisions:

4.6.1.1 The laboratory may not reference its accredited status in any way that indicates or implies accreditation in areas outside the actual scope of the specific IAS accreditation; or that indicates or implies IAS endorsement of any particular product, material or service.

4.6.1.2 When the IAS name and/or the registered symbol are used, it shall be accompanied by the word “ACCREDITED.” The symbol must also include the name of the accredited program, e.g., “Medical Laboratory.”

4.6.1.3 When the IAS name or the registered symbol is printed on letterhead and/or other laboratory stationery, such stationery **may not** be used for work proposals or quotations if none of the work is within the laboratory’s current scope of accreditation with IAS.

4.6.1.4 The IAS accredited laboratory is encouraged to use the IAS registered symbol on IAS-endorsed examination reports. The IAS registered symbol may not be changed in any way, although it may be enlarged or reduced.

4.6.1.5 The IAS registered symbol displayed on the laboratory’s IAS-endorsed examination reports must make reference to the accredited program by including “Medical Laboratory” next to the IAS Accredited symbol, provided the reports relate to examinations that are within the laboratory’s IAS-approved scope of accreditation. Whenever the IAS symbol is used on a report covering multiple examinations, some of which are within the laboratory’s scope of accreditation and some of which are outside the scope, the laboratory must clearly identify whatever portion of the report is not covered by IAS accreditation.

- 4.6.2 It is the laboratory's responsibility to not misrepresent its accreditation status in any way, and to secure IAS approval in advance whenever there is a question about the laboratory's intended use of the IAS name and/or symbol.
- 4.6.3 If the laboratory wishes to display the combined IAS/ILAC MRA mark, the laboratory must enter into a separate sub-license agreement with IAS. In addition, all the provisions of 4.6.1 and 4.6.2 apply, as well as ILAC R7 Rules for the Use of the ILAC MRA Mark.
- 4.6.4 **Reference to ISO 9001:**
An accredited laboratory may mention on its examination reports that it operates a laboratory quality management system in accordance with the principles of ISO 9001 using the following statement:
- 4.6.4.1 "This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 15189. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated January 2015)".
- 4.6.4.2 An accredited laboratory choosing to use the above statement on its reports or certificates should also either supply, or provide access to (via a website), the Joint ISO-ILAC-IAF Communiqué as part of the package for its customers.
- 4.6.4.3 If a laboratory operates under a management system certified by a certification body, it may not make reference to such certification or display the certification body's symbol on its examination certificates or reports.

5.0 RESPONSIBILITY OF INTERNATIONAL ACCREDITATION SERVICE

- 5.1 **Accreditation Documents:** A certificate of accreditation and scope of accreditation document shall be issued and maintained current for each accredited laboratory upon satisfactory completion of the accreditation requirements. For each accredited laboratory, the scope of accreditation shall be posted on the IAS website. Accreditation actions will also be noted on the IAS website.
- 5.2 **Fee Modifications:** Any modifications to the fees must be reviewed and approved by the IAS president or his/her designee.

5.3 Proprietary Data: Data in any accreditation file or application are considered proprietary to the applicant. The data may be disclosed by IAS only upon the written consent of the applicant or pursuant to subpoena issued by a court or other governmental agency of competent jurisdiction. Proprietary data may also be disclosed to a staff member of IAS or an authorized representative of IAS having a legitimate interest therein; any duly identified representative of any laboratory, or like person or organization who initially prepared the data, or a duly authorized representative thereof stated to be an employee or principal thereof having a legitimate interest therein. Governmental regulatory bodies may be granted access in the interest of public safety or preservation of property as it relates to enforcement of laws/regulations upon receipt of an official written request.

5.4 Access to Proprietary Data: From time to time, IAS records and files are audited by national and international bodies on a random basis to establish conformance with international accreditation and conformity assessment standards. It is understood that, by executing an accreditation application, laboratories grant IAS the authority to allow such access.

5.5 Appeal to Change of Assessment Team: IAS will provide an opportunity to the applicant or accredited laboratory to appeal against an assessor or assessment team assigned to assess the laboratory. This appeal must be requested in writing with the reasons identified. IAS, in mutual agreement with the medical laboratory, may arrange to assign a different assessor or assessment team for the scheduled assessment.

6.0 DENIAL, REVOCATION, MODIFICATION, SUSPENSION OR CANCELLATION OF THE ACCREDITATION, AND APPEALS

6.1 Any accreditation is subject to denial, revocation, modification, suspension or cancellation upon occurrence of any of the following:

- 6.1.1 Failure by the laboratory to comply with the current or updated Rules of Procedure.
- 6.1.2 Failure to comply with the current or updated Accreditation Criteria.
- 6.1.3 Failure to comply with any condition to the issuance of the accreditation.

- 6.1.4 Any misstatement, whether intentionally or unintentionally made, in the application or any data or documentation submitted in support thereof.
- 6.1.5 Failure to comply with any provision contained in the application.
- 6.1.6 Failure to comply with any terms of the management system documentation on which the IAS accreditation was based.
- 6.1.7 Any other grounds considered as adequate cause in the judgment of IAS.

6.2 Appeals

- 6.2.1 The denial, revocation, modification, suspension or cancellation of accreditation may only be appealed by the holder of the accreditation.
- 6.2.2 Procedures for appeals of denial, revocation, modification, suspension or cancellation of accreditation shall be in accordance with the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions. The IAS president or his/her designee, or the Board of Directors, as the case may be, may shorten any of the time periods set forth in the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions, if such action is deemed necessary, in their discretion, in the interest of public safety and welfare.

6.3 With Limited Consideration for Appeal: Notwithstanding anything in these rules to the contrary, any initial application, or accreditation may be denied, revoked, modified, suspended or cancelled by the IAS president or his/her designee for any of the following reasons with no right of appeal:

- 6.3.1 Failure to pay required fees to IAS within thirty days from the date of the mailing by IAS of written demand for payment, unless extended by the IAS president or his/her designee.
- 6.3.2 Failure to perform any examination or to furnish any material or data relating to laboratory accreditation required by IAS within the specified time limit, unless extended by the IAS president or his/her designee.
- 6.3.3 Failure to respond and resolve IAS Corrective Action Requests or Concerns resulting from an IAS assessment report in the allotted time, unless extended by the IAS president or his/her designee.

- 6.3.4 Failure to permit or submit to an assessment as set forth in Sections 2 and 3 and, if applicable, the special oversight requirements stipulated in Section 4.3 of the Rules of Procedure.

6.4 Results Of Denial, Revocation, Modification, Suspension or Cancellation

- 6.4.1 Upon the occurrence of any of the events set forth in Section 6.1 or Section 6.3, IAS, by the decision of its president or his/her designee, may choose any of the following actions:
- 6.4.1.1 Denial of the application.
 - 6.4.1.2 Revocation of the accreditation.
 - 6.4.1.3 Modification of the accreditation, on such terms as determined by the IAS president or his/her designee.
 - 6.4.1.4 Suspension of the accreditation for such period on such terms as determined by the IAS president or his/her designee.
 - 6.4.1.5 Cancellation of the accreditation.
- 6.4.2 The decisions of the IAS president or his/her designee with respect to any of the actions set forth in this section may become effective immediately if deemed necessary, in the interest of public safety and welfare, may be stayed pending an appeal pursuant to the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions, or may be otherwise stayed on such terms and conditions as determined by the president or his/her designee.
- 6.4.3 Upon revocation or cancellation of the accreditation or during any period of suspension, unless this provision is specifically modified by the terms of the suspension, the accredited laboratory shall discontinue all use of the IAS symbol. The laboratory shall also immediately discontinue any references to IAS accreditation on any reports, certificates, or promotional material.
- 6.4.4 IAS shall have the right to immediately notify governmental jurisdictions and any other interested parties of any improper and unauthorized reference to the continuation of the accreditation, when in the sole judgment of IAS, as determined by its president or his/her designee, such notification is necessary in the interest of public safety or welfare.
- 6.4.5 Upon the determination by IAS that cause exists for any of the actions specified in this section, with respect to the accreditation, IAS shall deliver to the

laboratory a written statement, signed by the IAS president or his/her designee, setting forth the factual basis for such action. This written statement shall include a specific reference to the cause for the action which is set forth in the Rules of Procedure. ▪