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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 product(s) calibrated by the laboratory.

1.2 **Reference Documents**

1.2.1 IAS Accreditation Criteria for Medical Laboratories, AC780.

1.2.2 IAS Accreditation Criteria for Calibration Laboratories, AC204.

1.2.3 IAS Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions

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 testing, 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 testing 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 test methods for which accreditation is sought must be submitted. As an example, the following format is recommended:

Test Method/ Technique	Discipline/ Subdiscipline	Test Samples	Test Description
Gram stain	Microbiology/Bacteriology	Urine specimens	Preparation of films for microscopic examination Microscopic examination of clinical specimens
Direct Coombs Complete Blood Count	Immunohaematology Haematology	Blood Serum ➢ Blood counts ➢ Visual examination of blood films	➢ Blood group antibody screening ➢ Blood grouping, including ABO, Rh(D) and other antigens by manual methods ➢ Direct Antiglobulin Test (Poly and monospecific)

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 testing (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. A letter summarizing preliminary observations will be relayed to the applicant, including a request for any additional data which may be required prior to scheduling the initial assessment.

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.

2.2.1.3 **Initial Assessment:** In consultation with the applicant, an initial onsite assessment will be scheduled to verify compliance with the accreditation requirements.

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 root cause analysis to support CAR closures where appropriate. 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 inform IAS on the action taken or intended action to be undertaken with a timeline for completion. The action taken by the organization to implement actions to resolve concerns will be verified at the agency's 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 laboraotry 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.

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 test 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 laboratory currently accredited by a signatory to the ILAC Mutual Recognition Arrangement 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 your 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.

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 testing (refer to section 2.1.4) at the conclusion of the accreditation process will be invoiced.

3.2 Surveillance Assessment after Initial Year of Accreditation

3.2.1 All accredited 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.

3.2.2 **Onsite Surveillance Assessment**

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

3.2.2.2 At 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; any major changes in key personnel, facilities, equipment or in the laboratory's management system

and test reports for test methods that are within the laboratory's scope with IAS.

3.2.2.3 Surveillance assessment process is similar to the initial assessment process noted above.

3.2.2.4 IAS may decide not to grant accreditation to the accredited laboratory for not fulfilling accreditation requirements. Any applicant denied accreditation may appeal this decision as per requirements noted under Section 6 of these rules.

3.2.2.5 For currently-accredited laboratories, failure to respond 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.

3.2.3 **Remote Surveillance Assessment**

3.2.3.1 If IAS determines that the laboratory qualifies for a remote surveillance assessment, the 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 proficiency testing, if any; any major changes in key personnel, facilities, equipment or in the laboratory's management system and reports/methods that are within the laboratory's scope with IAS.

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

3.2.3.3 IAS may decide not to grant accreditation to the accredited laboratory for not fulfilling accreditation requirements. Any applicant denied accreditation may appeal this decision as per requirements noted under Section 6 of these rules.

3.2.4 IAS will grant accreditation upon determination based on surveillance assessment and completion of renewal application that the accredited laboratory has met the accreditation requirements for the test methods noted in the scope of accreditation certificate and available on the IAS website.

3.3 **Onsite Reassessment**

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

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

3.3.3 Onsite reassessment process is similar to the initial assessment process noted above.

3.3.4 For currently-accredited laboratories, failure to respond 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.

3.4 **Scope Extension Assessments**

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

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

3.4.3 In consultation with the accredited laboratory, an onsite assessment will be scheduled.

3.5 **Extraordinary Assessments**

3.5.1 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.

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

4.0 RESPONSIBILITIES OF 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.

4.1.4 Changes in equipment, policies or procedures that affect the laboratory's accreditation.

4.1.5 Major physical changes to the test/calibration facility.

4.1.6 Changes in principal officers, 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 tests/calibrations 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 laboratory accreditation, the laboratory agrees to furnish all needed documentation, pay the required fees, perform additional witness inspections, 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 **Usage of the IAS Name or Symbol by Accredited Laboratories**

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

4.5.1.1 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.

4.5.1.2 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.”

4.5.1.3 When the IAS name or the registered symbol is printed on letterhead and/or other laboratory stationery, such stationery **<u>may not</u>** be used for work

proposals or quotations if none of the work is within the laboratory's current scope of accreditation with IAS.

4.5.1.4 The IAS registered symbol is to be used on IAS-endorsed test/calibration reports. The IAS registered symbol may not be changed in any way, although it may be enlarged or reduced.

4.5.1.5 The IAS registered symbol displayed on the laboratory's IAS-endorsed test/calibration reports must include the name of the accredited program, e.g., "Medical Laboratory," provided the reports relate to tests that are within the laboratory's IAS-approved scope of accreditation. Whenever the IAS symbol is used on a report covering multiple tests, 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.

4.5.2 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.

4.5.3 An accredited medical laboratory may mention that it operates a laboratory quality management system that meets the principles of ISO 9001 on its test reports and calibration certificates using the following statement: "This laboratory is accredited in accordance with the recognized International Standard ISO 9001:2012."

4.6 **Proficiency Testing**: Medical laboratories are required to participate in applicable proficiency testing periodically, to assess their technical competence and to help identify sources of error.

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 **Selection 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 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 No Right To 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.

6.3.2 Failure to perform any test or calibration 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.

6.3.5 Failure to furnish information and/or submit to a remote surveillance assessment as required in Section 3.2.3 of these rules within the specified time limit.

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. ▪