Background

The international standard ISO 15189:2012 “Medical laboratories – Requirements for quality and competence” is the basis for this accreditation. These requirements not only require a management system and quality manual in the clinical laboratory but also require that the laboratory be found competent to perform specific clinical tests or types of tests.

A2LA also has specific requirements as cited in R901- General Requirements: Accreditation of Clinical Testing Laboratories Meeting the ISO 15189 Requirements; R902 - Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements and R903 General Requirements-Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements.

Preface A - Before You Begin

Please see the summary of the A2LA accreditation process for applicant clinical laboratories on page 8.

Preface B - Policies

A. A2LA Confidentiality Policy, Pre-Assessment Policy, Language Policy, Delayed Assessment Policy, and Accreditation Transfer Policy: Please see page 8-10.

B. R902 - Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements states that all information regarding your application, with certain exceptions, is confidential. To maintain confidentiality regarding an applicant’s status it is the policy of A2LA that upon public inquiry, staff will only confirm whether a laboratory is or is not accredited. Please provide the required written permission (check one).

1. I authorize A2LA to release information regarding our application status.
2. I do not authorize A2LA to release information regarding our application status.

Part I. Application Information

A. Laboratory Legal Name (as it appears on your CLIA Certificate/Scope of Accreditation and on the A2LA website) and Legal Status (e.g. Sole Proprietorship, Limited Liability Corporation, etc.)

B. Laboratory Address (Number and Street, City, State and Zip Code)
<table>
<thead>
<tr>
<th><strong>C. Telephone Number</strong></th>
<th><strong>Fax Number</strong></th>
</tr>
</thead>
<tbody>
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</table>

<table>
<thead>
<tr>
<th><strong>D. Mobile Number [If applicable]</strong></th>
<th><strong>Email Address</strong></th>
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**E. Website Address.** IF YOU DO NOT WISH YOUR WEBSITE TO BE INCLUDED AS A LINK ON THE A2LA WEBSITE, PLEASE PLACE A CHECK MARK HERE □

<table>
<thead>
<tr>
<th><strong>F. Mailing Address</strong> (if different from the laboratory address - Number and Street, City, State and Zip Code)</th>
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</table>

<table>
<thead>
<tr>
<th><strong>G. Billing Address</strong> (Number and Street, City, State and Zip Code)</th>
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</table>

**H. Accounts Payable:** Enter the name, telephone number, fax number and email address of the accounts payable staff member who will represent the laboratory in all financial matters.

<table>
<thead>
<tr>
<th><strong>Contact Name</strong></th>
<th><strong>Telephone</strong></th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Fax Number</strong></th>
<th><strong>Email</strong></th>
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</tbody>
</table>
**American Association for Laboratory Accreditation**

**F901 – Application for Accreditation: ISO 15189 Testing Laboratories**

**Document Revised:** March 25, 2014

**Page 3 of 18**

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**Part II. Laboratory Director Information**

LABORATORY DIRECTOR (qualified by experience and/or education):

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Telephone Number</th>
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<table>
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<tr>
<th>Printed Name</th>
<th>Date</th>
<th>Fax Number</th>
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<table>
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<th>Email address</th>
<th>Website</th>
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**Part III. Type of Laboratory**

**A. Type of Clinical Laboratory:** A main laboratory is an organization that maintains a single location only. A branch system is one that consists of two or more laboratories owned and operated by the same organization, utilizing the same management system and whose accreditation is managed by a Corporate Representative. Please review page 9, Branch Lab Policy for more information.

Note 1: A separate application (main, branch, satellite, or mobile lab application) must be completed for each location.

Note 2: The branch system option may not be selected if an application has not been received for a main laboratory.

Note 3: A separate application must be completed for each branch or mobile laboratory.

<table>
<thead>
<tr>
<th>Main Laboratory</th>
<th>Branch Laboratory</th>
<th>Satellite</th>
<th>Mobile Laboratory</th>
<th>If a branch or satellite laboratory, please indicate the A2LA Master Code of the Main Laboratory:</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

How many Laboratory Personnel are performing regulated and/or accredited activities?

Number of laboratory personnel at this location, associated with the clinical testing requested for accreditation:

---

**B.** Please complete the *F922 – ISO 15189 Program Scope Selection List.* Check and/or List all of the testing that is to be included on the Scope of Accreditation.

Are any of your tests modified versions of standard methods (i.e. FDA approved)? Yes ☐ No ☐
### C. Shift Work:
If the laboratory works in shifts, please note the times for each shift:

<table>
<thead>
<tr>
<th>Time</th>
<th>Shift</th>
<th>Notes</th>
</tr>
</thead>
</table>

### D. Specimen Collection Sites:
Is the applicant laboratory seeking accreditation for specimen collection sites?
- [ ] Yes
- [ ] No

If yes, please indicate the number and location(s) of any specimen collection sites associated with this applicant laboratory (a separate document can be submitted to describe a large collection system):

### E. Point of Care Testing (POCT):
Is the applicant seeking accreditation for POCT? (POCT is defined as tests done at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the (applicant) clinical laboratory.)
- [ ] Yes
- [ ] No

Please describe any POCT requested for accreditation and the location(s) where this POCT is performed (a separate document can be submitted to describe a large POCT system):

### F. Please identify the month/year when you would be ready to undergo the on-site assessment:

### G. Please indicate the annual test volume for the laboratory requesting accreditation:

### Part IV. Commercial Status

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
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<tbody>
<tr>
<td>A.</td>
<td>Commercial service available (C1): Select this option if you plan to offer all testing services from your clinical scope of accreditation to the general public. [ ]</td>
</tr>
<tr>
<td>B.</td>
<td>Conditionally available for commercial service (C2): Select this option if on certain occasions you plan to offer testing services from your clinical scope of accreditation to the general public. [ ]</td>
</tr>
<tr>
<td>C.</td>
<td>Normally not available for commercial service (C3): Select this option if you never plan to offer testing services from your clinical scope of accreditation to the general public. [ ]</td>
</tr>
</tbody>
</table>
Part V. Laboratory Information Management System

It is important to provide complete information about the laboratory LIMS used for any accreditation compliance functions. In most cases the on-site assessment team will have the necessary experience to evaluate the utilization of a LIMS within the compliance requirements. In some cases A2LA may determine that the on-site assessment team should include an IT specific assessor. Please provide the following information and any other information that may assist A2LA in preparing for the laboratory assessment.

1. Is the Laboratory LIMS part of a larger organizational system?  Yes ☐  No ☐
   e.g. A hospital IT system that has a laboratory component.

2. Does the laboratory LIMS connect to another data management system?  Yes ☐  No ☐
   e.g. A LIMS developed for the laboratory that interfaces with a hospital system.

3. If the LIMS is a Computer Off the Shelf (COTS) system that includes the hardware and software, complete this section:
   3.a. LIMS Manufacturer: ____________________________________________
   3.b. Initial Installation Date: ________________________________
   3.c. Last Software Revision:  Version: __________ Date: ______________

4. If the LIMS was developed in-house or is a hybrid system with some COTS components and some in-house developed systems or has more than one COTS system complete this section:
   4.a. Complete this information for each COTS component. (Use additional sheets if necessary)
   4.b. What is the COTS component used for? ________________________________
   4.c. LIMS Manufacturer: ____________________________________________
   4.d. Initial Installation Date: ________________________________
   4.e. Last Software Revision -  Version: __________ Date: ______________

5. Complete this information for the in-house developed LIMS components (list components): (Use additional sheets if necessary.)
   5.a. What is the in-house developed LIMS component used for?
5.b. Describe the in-house or in-house/COTS hybrid system in detail. *(Attach additional information if necessary)*

6. Laboratory LIMS Security

- Does the application allow for temporary passwords that expire after a first log on? Yes ☐ No ☐
- Does the application enforce strong passwords? Yes ☐ No ☐
- Does the application allow for the expiration of passwords after a configurable amount of time? Yes ☐ No ☐

7. Access control

- Does the application allow user role based access to functions? Yes ☐ No ☐
- Does the application provide reporting for review of user defined roles? Yes ☐ No ☐

8. Interfaces and error logging

- Does the application provide transaction based interfacing capabilities - in HL7 format? Yes ☐ No ☐

If no to question above, please list transaction based interfacing capabilities format: __________________________

- How is error handling done for exceptions in interfaces in and out of the LIMS?

- How are exceptions in the interfaces communicated and resolved?

9. Performance monitoring

- What tools does the application provide for performance monitoring?

- How often is performance monitoring done in this application?

- How are exceptions in the performance monitoring communicated to laboratory management?

10. Report distribution

- What reports are produced out of the system with patient data?

- How is the delivery of reports to various destinations monitored?
• How are exceptions to the report delivery communicated and resolved?

• Are reports with patient data time-stamped and can reports be retrieved from the system after being delivered?  
  Yes ☐  No ☐

11. Order Processing
• Does the LIMS time-stamp each order received and the user that entered each order?  
  Yes ☐  No ☐

Part VI. Supporting Information

1. ☐ Please submit this application, with all areas completed.

2. ☐ If your laboratory currently maintains accredited status with any other accreditation body, please provide a copy of the accreditation certificate and scope of accreditation.

3. ☐ Attach an up-to-date laboratory organization chart and identify, by name, the key personnel involved for each function using the Technical Staff Matrix attached (see page 16).

4. ☐ If the laboratory is part of a larger organization, attach a chart of its position and reporting relationships within that organization.

5. ☐ Provide documentation of credentials of key staff members (Directors, Managers, Supervisors, etc.) using the Key Staff Matrix on page 17 of this application.

6. ☐ Please include your Proficiency Testing Plan describing how your laboratory will meet the minimum proficiency testing participation requirements described in ISO/IEC 15189, Subpart H, 42CFR493 (for proficiency testing, inter-laboratory comparison, performance evaluation) and the A2LA document, R903 General Requirements-Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements. Attach copies of the latest summary results using the F904 - ISO 15189 Program Proficiency Testing Form and any corrective action response(s) for unacceptable values obtained.

7. ☐ Please include an uncontrolled copy of the current version of your quality manual and any supporting documentation referenced in the assessor checklist(s), i.e. operating procedures and work instructions related to the quality system. Submitting your quality manual and supporting documentation via email or electronically on disc is preferred.

8. ☐ Please include a list of all equipment used to perform patient testing or to support the testing for which accreditation is sought, (see page 18) and indicate which of this equipment is calibrated in-house and which is calibrated by a commercial calibration or biomedical service. Please review P905 - A2LA Metrological Traceability Policy for Clinical Laboratory Testing and P903 – Policy on Estimating Measurement Uncertainty for Clinical Testing Laboratories. Please also include the identity, location, and accreditation status of any commercial calibration or biomedical service utilized.

9. ☐ Please provide a floor plan of the applicant laboratory and supporting offices.

11. ☐ A completed C950 - General Checklist: ISO 15189 Clinical Testing Laboratory Accreditation Program. Note: Due to copyright restrictions this checklist is NOT available on our website.

12. ☐ A completed C915 - General Checklist: Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements

**Part VII. The A2LA Accreditation Process for Applicant Clinical Laboratories (Summary)**

1. The applicant clinical laboratory obtains an official copy of ISO 15189:2012. The laboratory then confirms this to A2LA by completing and emailing the F902 - Ownership Confirmation - ISO 15189 Form to A2LA at info@A2LA.org.

2. The laboratory can also request G901 - Guidelines for A2LA Clinical Laboratory Accreditation.

3. A2LA provides the laboratory with an electronic or hard copy version of the application for accreditation including: R901 - General Requirements for Accreditation of Clinical Testing Laboratories Meeting ISO 15189 Requirements and C950 – General Checklist: ISO 15189 Clinical Testing Laboratory Accreditation Program so the laboratory can perform a self-assessment to verify compliance with all requirements. If specimen collection sites or POCT are included in the accreditation process, those assessor checklists will also be provided to the applicant laboratory.

4. The applicant clinical laboratory completes and returns this full application for accreditation with payment, F922 – ISO 15189 Program Scope Selection List, and all required supporting documentation outlined on Pages 7-8.

5. A2LA reviews the application documents and appropriate clinical assessors are assigned, with laboratory concurrence.

6. The lead clinical assessor contacts the laboratory to discuss the scheduling of the on-site assessment and request any additional quality or procedural documentation that may be needed to allow the lead assessor to perform a pre-assessment document review. Once documentation is reviewed for completeness, the assessment can be scheduled with the clinical assessment team.

7. The assessment or the pre-assessment is performed and includes: entry briefing; records, sample handling; interviews with technicians; demonstrations of tests and techniques; examination of equipment calibration and maintenance records; review of quality documentation; written report of assessor's findings; and exit briefing.

8. The clinical laboratory responds to any deficiencies with a written corrective action response, including the laboratory’s root cause analysis.

9. The corrective action is reviewed by the A2LA staff with consultation from the assessor(s). Once complete, is forwarded to the Accreditation Council for a vote.

10. Accreditation is granted when affirmative votes are received, all concerns are resolved, and all fees are paid in full.

**Part VIII. Policies for Applicant Clinical Laboratories**

**Language:** All documentation must be provided in English and the assessment conducted in English. An appropriate English translation of pertinent documentation must be provided as well as a translator, if needed, to facilitate the on-site assessment.

**Branch Laboratories:** If you are applying as a multi-laboratory system, a separate application must be completed for each clinical laboratory. A2LA currently offers discounts on annual fees for all clinical laboratories applying as a ‘branch’ of another laboratory that is either applying or enrolled in our program or that is currently accredited. Please review P106 - Branch System Policy for more information. The conditions for applying as a branch of another laboratory are as follows:

- All application, renewal of accreditation and annual review processes must be coordinated through one central person, the Corporate Representative;
All fee payments and invoices must be coordinated through the Corporate Representative;

All laboratories within a single branch system are given related certificate numbers (e.g., 301.01, 301.02, 301.03, etc.);

All laboratories within a single branch system must be visited, assessed and accredited regardless if they are performing the exact same testing as the main laboratory.

This central coordination and arrangement within our database allows for greater efficiency in handling various processes, therefore a discount on fees is offered to all branch laboratories. Branch laboratories can choose to have the same anniversary date or to have different anniversary dates based on the date of their assessment. Please understand, however, that for large branch systems, this central coordination with the same anniversary date can become cumbersome and all branch laboratories within the system are often unable to complete the various processes (renewals and annual reviews) by the same anniversary date or deadline.

Please see R901- General Requirements: Accreditation of Clinical Testing Laboratories Meeting the ISO 15189 Requirements for further information on hospital satellite and mobile laboratories.

Please consider these issues carefully as you decide whether or not to apply as a branch laboratory system. If you have any questions concerning this arrangement, please contact us at 301 644 3248.

Pre-assessment: A2LA clinical assessors are permitted to conduct pre-assessments. There are two situations when a pre-assessment may be conducted:

1. When the lead assessor finds major gaps in the laboratory’s quality manual, or actually begins the assessment and finds a large number of problems. In this case, the assessor identifies them and suggests to the laboratory that a full assessment should wait until the problems have been addressed. This first identification of the problems would be considered a pre-assessment; or
2. When a laboratory requests a pre-assessment to better prepare for the final assessment. In this case, the clinical laboratory has applied, but is unsure of its documentation or system and wants someone to perform a pre-assessment to identify problems. The full assessment follows later.

To implement the pre-assessment program, the laboratory must first apply for accreditation, paying the appropriate fees and assessor deposit. A lead clinical assessor is assigned, with the laboratory’s concurrence. If, during the discussions between the laboratory and assessor in preparation for the assessment, the laboratory concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the laboratory wants a pre-assessment. The daily rate of the pre-assessment is the same as the regular assessment rate, and can be deducted from any assessor deposits held on account at A2LA. Please note, however, that careful attention to the requirements should preclude the need for a pre-assessment.

Delayed Assessment Policy: If a clinical laboratory fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the laboratory is prompted by A2LA to agree to the assessment within a sixty (60) day timeframe. If the assessment is not scheduled within thirty (30) days of that reminder, the laboratory is required to begin the application process again and pay the laboratory accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy.

Confidentiality: A2LA is responsible for seeing that confidentiality is maintained by its employees and assessors concerning all confidential information with which they become acquainted as a result of their contacts with laboratories. The Association agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for assessment purposes, and shall not be used for any other purpose, nor shall it be disclosed to any third party without written consent of the applicant except as noted in the R902 - Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements or as required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

Provider Performed Microscopy (PPM): A2LA provides accreditation to any clinical laboratory performing non-waived (moderate or high complexity) testing (as defined in CLIA). Laboratories that provide only waived or Provider Performed Microscopy (PPM) are not eligible for accreditation through A2LA. If the laboratory does perform moderate or high complexity testing along with waived testing and/or PPM, A2LA will accredit for all of this testing and microscopy.
Refund Policy: The A2LA application fee is non-refundable. If an organization withdraws the application before completion of the assessment, it may apply for a refund of up to 50% of the A2LA annual fee(s), the entire program specific surcharge and the balance of the unexpended assessor deposit. There will be no refund of annual fees after the assessment has been completed. Refunds of any balance remaining on the assessor deposit will be made at the time of the accreditation decision. Any withdrawal or refund request must be in writing.

Part IX. Conditions for Accreditation

In order to apply for accreditation, the applicant's applicant Laboratory Director and/or Authorized Representative must agree to the A2LA R902 – Conditions for Accreditation for Clinical Laboratories Meeting ISO 15189 Requirements and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. The Laboratory Director and/or Authorized Representative of an accredited laboratory are responsible for ensuring that all of the relevant conditions for accreditation are met as of the date this document is signed. During the on-site assessment, the assessor will examine records and documentation to verify compliance with these Conditions for Accreditation as of the date they are signed and will determine that the Laboratory Director and laboratory management team are knowledgeable about the accreditation requirements and that those requirements are upheld.

Furthermore, the Laboratory Director is responsible for ensuring that all of the relevant conditions for accreditation are met as of the date this document is signed and that a complete internal audit (and management review) has been conducted by the laboratory in accordance with their documented procedure and planned intervals. During the on-site assessment, the assessor(s) will examine records and documentation to verify compliance with these Conditions for Accreditation.

As the applicant Laboratory's LABORATORY DIRECTOR, I agree to the R902 – Conditions for Accreditation for Clinical Laboratories Meeting ISO 15189 Requirements. I attest that all statements made on this application are correct to the best of my knowledge and belief.

Signature of Laboratory Director (from page 3, Part II)   Today’s Date

Authorized Representative Printed Name   Authorized Representative Title

☐ Mr.  ☐ Ms.  ☐ Mrs.  ☐ Dr.

Authorized Representative Signature   Today’s Date

Telephone Number   Fax Number   Email Address
Part X. Accreditation Fees

Initial Application Fee: A one-time fee for the first facility and for each additional facility. This fee is non-refundable.

Annual Fee: Although accreditation is granted for two years, payment of an Annual Fee is required to continue accreditation into the second year. There is a discount per laboratory for two to five laboratories and also for more than one field; and a greater discount per laboratory for six or more laboratories, provided a central figure, (Authorized Representative), coordinates all of the applications and fee payments for all laboratories and all fields. A discount is available on the recurring annual fee for the main laboratory locations once accredited, for those organizations that have purchased an organizational membership with A2LA. (Please visit http://www.a2la.org/membership/member.cfm for more information about membership within A2LA.)

Assessor Deposit: An Assessor Deposit is required per initial application. The laboratory will be billed (or refunded) the difference between the actual cost of the assessment and the amount of this deposit. Accreditation will not be granted until all fees are paid. Actual costs are computed based on:

- Specific Specialties and Sub-specialties on your desired Scope of Accreditation;
- Travel (airfare, rental car, or private auto at the IRS allowable rate);
- Accommodations & Miscellaneous (hotel, meals*, parking, calls, etc.).

*Meals are based on an A2LA per diem of $35 per day. International per diem is based on the U.S. Department of State’s most recently published rates. Travel days where work is not performed will be 50% of the per diem rate.

The assessor deposit is only a partial payment of the assessment costs and it is likely that the actual assessor charges will exceed the deposit amount. Variable factors such as the laboratory’s size, desired scope of accreditation, documentation structure and adequacy of its preparation for the assessment as well as the costs of assessor travel and lodging will impact on the actual accrued assessment costs.

An assessment of one laboratory can take from 2 to 5 days within the laboratory with additional time taken for preparation and report writing. For U.S. domestic assessments, travel time is not billed. For international assessments, travel time is billed at one half the assessment rate. It is to the laboratory’s advantage to be prepared and to help prepare the assessors beforehand. If any part of the management system documentation is not sent to assessors beforehand, assessors will need additional time at the laboratory. If the scope of accreditation changes significantly as the assessment progresses, assessors may also need more time. If there are significant deficiencies, assessor follow-up review time may be charged. A2LA audits the expenses and pays the assessors. Applicants shall not pay assessors directly; however, applicants are responsible for checking the assessor’s written estimate of assessment costs.

Payment Options: A2LA accepts checks, VISA / MasterCard, electronic transfers and ACH transactions. If your organization utilizes Purchase Orders/Contracts please place a checkmark in the box. Please be sure to include the purchase order/contract with the application. An invoice will be provided by A2LA for payment. If you elect to make payment with VISA or MasterCard, please contact the Financial Services Department at 301-644-3248 or visit our website at www.A2LA.org.

If your Laboratory utilizes Purchase Orders/Contracts please check here. ☐

Have you ever received an estimate for the costs of A2LA accreditation? ☐ Yes ☐ No

If yes, when, and under what MASTER CODE?

Date:

MASTER CODE:

To determine the assessment costs associated with your laboratory, please complete and submit an A2LA F969– ISO 15189 Program Estimate Request Form or contact A2LA at sales@A2LA.org or 301 644 3204.

Please provide pages 1-3, along with this page, if submitting payment prior to the completed application.
Call A2LA Financial Services at 301-644-3248 for more information.

**Part XI. Supplemental Information**

A. Please indicate your reason(s) for pursuing accreditation with A2LA.

B. Please indicate how you heard about A2LA (e.g. tradeshow, trade magazine, colleague, website, presentations, etc.). Please also identify any A2LA Staff Members that assisted you with this application.

C. Please list all accreditations currently maintained with any other accreditation body, accreditation/recognition with a government agency, or additional supplier audits:
Part XII. Mailing/Emailing Instructions

If mailing, please return the entire application along with the requested supporting documentation and payment of fees to:

The American Association for Laboratory Accreditation
5301 Buckeystown Pike, Suite 350, Frederick, MD 21704

If emailing, please submit the entire application along with the requested supporting documentation to:

applications@A2LA.org

If emailing the application, please mail payment of fees to the address above.

Please direct all non-fee related questions to our office at 301 644 3248.

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F920 - ISO 15189 Program Contract and Service Provider Matrix

To facilitate your A2LA assessment, please provide information about the contractors and services that are used to support the clinical testing capabilities that are being requested for accreditation. The following matrix may be used, with additional sheets attached as needed:

<table>
<thead>
<tr>
<th>Service</th>
<th>Provider</th>
<th>Type of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment Maintenance: Centrifuges</td>
<td>Biomedical Maintenance, Our hospital</td>
<td>External Contract: X</td>
</tr>
</tbody>
</table>
### F910 - ISO 15189 PROGRAM TECHNICAL STAFF MATRIX

Please list all technical personnel responsible for performing each of the **technologies or methods** for which accreditation is sought or has been granted as well as which Specialty(ies) each has been fully trained and deemed competent to perform. **The following matrix may be used, with additional sheets attached as needed:**

<table>
<thead>
<tr>
<th>Technologies and Methods</th>
<th>Examination Staff</th>
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</tbody>
</table>

Use an “X” to indicate “trained and competent”; Insert a “#” symbol for anyone that is the KEY staff person for an examination.
F918 – ISO 15189 PROGRAM KEY STAFF MATRIX

Please list all Key personnel with in the laboratory and the position(s) which he/she is qualified to fill. Please note that it is likely that some individuals will qualify under multiple titles. The following matrix may be used, with additional sheets attached as needed:

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Laboratory Director</th>
<th>Technical Supervisor</th>
<th>Clinical Consultant</th>
<th>General Supervisor</th>
<th>Cytology Supervisor</th>
<th>Cytotechnologist</th>
<th>Testing Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Smith</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Please list all equipment used in performing each of the **technologies or methods** for which accreditation is sought as well as model, serial number and location. **The following matrix may be used, with additional sheets attached as needed:**

<table>
<thead>
<tr>
<th>Item</th>
<th>Manufacturer / Model</th>
<th>Serial Number and/or Unique identifier</th>
<th>Check if interfaced to LIMS</th>
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## DOCUMENT REVISION HISTORY

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<td>6/15/11</td>
<td>Key Staff Matrix (ISO 15189 Only) renumbered to F652.</td>
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| 02/01/2013 | -Updated references to ISO 15189 to 2012 version  
             -Deleted requirement for technical checklists and LIMS checklist  
             -Updated Fax number and email address for ownership confirmation form (section XII)  
             -Changed PT checklist from C615 to C663  
             -Revised Fee portions of application (section X)  
             -Updated website for F622 selection list  
             -Updated Conditions of Accreditation to contain Internal Audit and Management Review requirement (section IX)  
             -Added signature section to Conditions of Accreditation and removed requirement to submit separate R652 (section IX)  
             -Added emailing application instructions (section XIII)  
             -Added P106 Branch System policy link (section VIII)  
             -Inserted hyperlinks to A2LA documents referenced  
             -Added P603e reference for item #8 under (section VI)  
             -Added C650 and C663 checklists to Supporting Information (section VI) |
| 03/25/2014 | -Renamed from F651 to F901  
             -Document references updated throughout for new numbering system (900 series):  
             -Added a question regarding modified tests in section III, B.  
             -Revised Part I, B to ask for “Legal Status” of applicant |