



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 1 of 22

For A2LA Office use Only: MASTER CODE: ASSESSMENT NO: CERT NO:

Background

The CLIA 88 requirements and international standard ISO/IEC 15189 (2007) “Medical laboratories -Particular requirements for quality and competence” are the basis for this accreditation. These requirements not only require a management system and manual in the medical laboratory but also require that the laboratory be found competent to perform specific medical tests or types of tests.

Preface A - Before You Begin

Please see the summary of the A2LA accreditation process for applicant medical laboratories on page 13.

Preface B - Policies

- A. A2LA Confidentiality Policy, Pre-Assessment Policy, Language Policy, Delayed Assessment Policy, Refund Policy, Provider Performed Microscopy (PPM) policy and Accreditation Transfer Policy: Please see page 14.
- B. R602-Conditions for Accreditation for Medical Testing Laboratories Meeting ISO 15189 and CLIA 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 Director’s Name/Title

B. Laboratory Name (as it appears on your CLIA Certificate)

C. Laboratory Address (Number and Street, City, State and Zip Code)



The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010
Page 2 of 22

Part I. Application Information (continued)

D. Telephone Number

Fax Number

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E. Mobile Number [If applicable]

Email Address

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F. 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

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G. Mailing Address (if different from the laboratory address - Number and Street, City, State and Zip Code)

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H. Billing Address (Number and Street, City, State and Zip Code)

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The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 3 of 22

Part I. Application Information (continued)

I. 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.

Contact Name	Telephone

Fax Number	Email

Part II. Type of Laboratory

A. Type of Medical 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 12, Branch Lab Policy for more information.

Note 1: A separate application (main, branch, hospital satellite, or mobile lab application) must be completed if the lab holds a separate CLIA certificate number for that laboratory.

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 laboratory.

- 1. Main Laboratory
- 2. Branch Laboratory
- 3. Hospital Satellite
- 4. Mobile Laboratory
VIM #:
- 5. If a branch, mobile or hospital satellite laboratory, please indicate the A2LA Master Code of Main Laboratory:

How many Laboratory Personnel are performing regulated activities?

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



The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010
Page 4 of 22

SCOPE FOR MEDICAL TESTING LABORATORIES

Please check the Specialty and subspecialty(s) for which accreditation is requested.

Microbiology:

- Mycology
- Virology
- Mycobacteriology
- Parasitology
- Bacteriology

Chemistry:

- Routine Chemistry
- Endocrinology
- Toxicology
- Urinalysis
- Molecular Diagnostics

Hematology:

- Clinical Hematology
- Coagulation
- Flow Cytometry

Pathology:

- Histopathology
- Cytopathology
- Oral pathology
- Molecular Pathology

Immunochemistry:

- ABO Group and Rh Typing
- Antibody Identification
- Compatibility testing
- Antibody Detection (transfusion)
- Antibody Detection (Non-transfusion)

Diagnostic Immunology:

- Syphilis Serology
- General Immunology

Histocompatibility:

Clinical Cytogenetics:

Radiobioassay:

Other: Please describe on a separate piece of paper



The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010
Page 5 of 22

B. If the laboratory works in shifts, please note the times for each shift:

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C. SPECIMEN COLLECTION SITES? Yes No

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):

D. EQUIVALENT QC PROCEDURES? Does this applicant laboratory perform any equivalent QC procedures?

(please see CLIA Amendment Brochure #4 for further information) Yes No

If yes, please describe the test system(s) to which equivalent QC procedures are applied. A separate document can be submitted to describe a large number of test systems.

E. POINT OF CARE TESTING? Yes No

(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) medical laboratory)

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 total number of tests/examinations performed annually for the laboratory requesting accreditation:

H. Please record the CLIA certificate number assigned to the laboratory requesting accreditation. (Include a copy of the certificate with this application package):



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 6 of 22

I. 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 system 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.

Is the Laboratory LIMS part of a larger organizational system? Yes No

e.g. A hospital IT system that has a laboratory component.

Does the laboratory LIMS connect to another IT system? Yes No

e.g. A LIMS developed for the laboratory that interfaces with a hospital system.

If the LIMS is a Computer Off the Shelf (COTS) system that includes the hardware and software, complete this section.

LIMS Manufacturer _____

Initial installation Date: _____

Last Software Revision Version: _____ Date: _____

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.

Complete this information for **each** COTS component.
Use additional sheets if necessary

What is the COTS component used for?

LIMS Manufacturer _____

Initial installation Date: _____

Last Software Revision Version: _____ Date: _____



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 7 of 22

Complete this information for the in house developed LIMS components.
Use additional sheets if necessary

What is the in-house developed LIMS component used for?

Describe the In-house or In-House/ COTS hybrid system in detail.

Attach additional information if necessary

Part III. Commercial Status

Check one of the following as it applies to your Laboratory. This information is for reference by A2LA in response to inquiries and determines how your laboratory is categorized in the “Directory of Organizations” section of the A2LA website:

- A. **Commercial service available (C1):** Select this option if you plan to offer all testing services from your medical scope of accreditation to the general public.
- B. **Conditionally available for commercial service (C2):** Select this option if on certain occasions you plan to offer testing services from your medical scope of accreditation to the general public.
- C. **Normally not available for commercial service (C3):** Select this option if you never plan to offer testing services from your medical scope of accreditation to the general public.

Part IV. Laboratory Director Information

LABORATORY DIRECTOR of the laboratory who is the individual qualified by experience/and or education to serve as the Laboratory Director, as described in 42CFR493 Subpart M. The Laboratory Director may direct no more than 5 laboratories.

LABORATORY DIRECTOR

Signature	Title	Telephone Number



The American Association for Laboratory Accreditation

***F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories***

Document Issued:
February 26, 2010
Page 8 of 22

Printed Name	Date	Fax Number
Email address*	Website**	



The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010

Page 9 of 22

F620-Contract and Service Provider Matrix

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

	Service	Provider	Type of Agreement	
			Contract	Support Agreement
1	Equipment Maintenance: Centrifuges	Biomedical Maintenance, Our hospital		X
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
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18				
19				



*The American Association for Laboratory
Accreditation*

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010
Page 10 of 22

F610- 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:**

Technologies and Methods	Examination Staff								
Phlebotomy									
Manual Diff									
B/C CX7									
Assym									
Immunochemistry									
Auto Coag									
ABO/RH/AB Screen									
Compatibility testing									
GC/MS									
AA XL									
Therap. Drugs									
Pap smears									

Use an "X" to indicate "trained and competent"; Insert a "#" symbol for anyone that is the KEY staff person for an examination.



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The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010

Page 12 of 22

F619- EQUIPMENT MATRIX

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:

Item	Manufacturer / Model	Serial Number and/or Unique identifier	Check if interfaced to LIMS	Calibration		Location	
				Yes			No
				In house	External		
1	Auto Analyzer	Itsgreat / XL 2700	AA122333 / AA001	√	X		Core Lab Rm 123
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							



The American Association for Laboratory Accreditation

**F601 – Application for Accreditation: CLIA and ISO
15189 Medical Testing Laboratories**

Document Issued:
February 26, 2010
Page 13 of 22

Part V. Supporting Information

1. If your laboratory currently maintains other accreditation status with any other accreditation body, please provide a copy of the accreditation certificate and scope of accreditation. It will also be necessary to provide the results of the most recent on-site assessment including any deficiencies and related corrective action.
2. 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.
3. If the laboratory is part of a larger organization, attach a chart of its position and reporting relationships within that organization.
4. Provide documentation of credentials of key staff members (Directors, Managers, Supervisors, etc.) using the Key Staff Matrix on page 8 of this application, and identify what clause(s) under 42 CFR 493 Subpart M each member of Key staff is qualified.
5. 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, “Proficiency Testing Requirements for Accredited Medical Testing Laboratories” and attach copies of the latest summary results and any corrective action response(s) for unacceptable values obtained.
6. Obtain copies of the A2LA "Technical Criteria Assessor Checklists” for all Medical Specialties and Subspecialties for which your laboratory is requesting accreditation. Each of these checklists is to be completed and returned to A2LA with your completed application forms.
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 9) and indicate which of this equipment is calibrated in-house and which is calibrated by a commercial calibration or biomedical service. Please review the P102-A2LA Policy on Measurement Traceability. 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.



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 14 of 22

Part IV. The A2LA Accreditation Process for Applicant Medical Laboratories (summary)

1. The applicant medical laboratory obtains an official copy of ISO 15189:2007. The laboratory then confirms this to A2LA by completing and faxing the ISO 15189 Fax Confirmation Form (page 16 of this application) to A2LA. The laboratory will also be required to obtain 42CFR493 specifying the CLIA 88 regulations (available at <http://www.phppo.cdc.gov/clia/regs/toc.aspx>).
2. From the A2LA website (www.a2la.org), the laboratory can also download G601-Guidelines for A2LA Medical Laboratory Accreditation and G602-A2LA Guidelines for the International Standard: ISO 15189 Requirements.
3. A2LA provides the laboratory with an electronic or hard copy version of the application for accreditation including: R601-General Requirements for Accreditation of Medical Testing Laboratories Meeting ISO 15189 and CLIA Requirements, C601-A2LA Medical Testing Program Management System Requirements Checklist that includes *The 42CFR493 (CLIA 88) Laboratory Requirements and ISO 15189: 2007 Standard*, and C614 – Specific Checklist: ISO 15189 Annex B Requirements for Protection of Laboratory Information Systems so the laboratory can perform a self-assessment to verify compliance with all requirements. A2LA also provides the medical laboratory with an electronic or hard copy version of the A2LA Technical Criteria Checklists for the requested disciplines so that the laboratory may 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 medical laboratory completes and returns this full application for accreditation with payment, a signed copy of R602- Conditions for Accreditation For Medical Testing Laboratories Meeting ISO 15189 and CLIA Requirements, and all required supporting documentation outlined on Page 12.
5. A2LA reviews the application documents and an appropriate medical assessor(s) is assigned, with laboratory concurrence.
6. The lead medical 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 medical assessment team in accordance with A2LA's policy for limited advance notice of the medical assessment.
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 medical 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.



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 15 of 22

Part V. Policies for Applicant Medical 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 medical laboratory. A2LA currently offers a \$300.00 discount on annual fees for all medical laboratories applying as a ‘branch’ of another laboratory that is either applying or enrolled in our program or that is currently accredited. See the Laboratory Accreditation Fees page 13 for appropriate computation of fees. 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 R601- *A2LA General Requirements for Accreditation of Medical Testing Laboratories Meeting the ISO 15189 and CLIA 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 medical 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 medical 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 medical 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

L:\Medical\FORMS\F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 16 of 22

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.

Transfer Policy for Laboratories with a current CLIA Certification: A laboratory holding a current CLIA certification obtained from another accreditation body may request that A2LA provide accreditation and CLIA certification. The laboratory must notify CMS by sending notice of intent to choose a different accreditation body. Contact information for the CMS Regional Office is available at <http://www.cms.hhs.gov/apps/contacts/>.

- Laboratories must provide a copy of their previous accreditation deficiency report to A2LA.
- Demonstrate that any cited deficiencies have been completely addressed by providing the laboratory’s deficiency response from the previous assessment before A2LA accreditation is granted.”

Delayed Assessment Policy: If a medical 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 (Page 13).

Refund Policy: While the A2LA Application Fee is non-refundable, if a medical laboratory withdraws the application before completion of the assessment, it may apply for a refund of up to 50 % of the A2LA annual fee(s) 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.

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 R602-Conditions for Accreditation for Medical Testing Laboratories Meeting ISO 15189 and CLIA 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 medical 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.

Part VI. Conditions for Accreditation

R 602: Conditions for Accreditation For Medical Testing Laboratories Meeting ISO 15189 And CLIA Requirements: Please review, sign and submit with this application for accreditation.



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 17 of 22

Part VI. FEE SCHEDULE

A. 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.

B. Fee: Identify from Part II section A of these instructions the type of laboratory for which you are applying (main or branch).

1. Initial Application Fee for Main Laboratory (for new applicant, first year only). **If applying as a Branch Laboratory skip to item 2.**
2. Initial Application Fee for Branch Laboratory (for new applicant, first year only). **If applying as a Main Laboratory skip to item 3.**
3. Annual Fee¹ for the Medical field for Main or Branch Laboratory
4. Medical Program Surcharge
5. A2LA accredited organizational membership discount. **If you do not have an A2LA membership, skip to item 6.**
6. Assessor Deposit² for Medical field³ for Main or Branch Laboratory
7. **TOTAL AMOUNT DUE – Please Remit Check Payable to A2LA.**

Calculation

Fee	Total
\$800	
\$800	
\$1300	\$1300
\$5000	\$5000
Member # _____	
(\$200)	
\$2000	\$2000
\$USD _____	

Please provide pages 1-3 if submitting payment prior to completed application.

Call A2LA Financial Services at 301-644-3248 for more information.

Note 1: Annual Fee –Although accreditation is granted for two years, payment of a yearly Annual Fee is required to continue accreditation into the second year. There is a branch lab discount of \$300 for more than one laboratory, but only if a Corporate Representative centrally coordinates the applications and fee payments for all laboratories [see page 14 for more information]. There is also a discount of \$200 off the recurring annual fee, once accredited, for those laboratories that have purchased an organizational membership with A2LA.



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 18 of 22

Note 2: Assessor Deposit:

The Assessor Deposit is \$2,000 for one laboratory in the medical field. 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:

- Total Assessment Time at \$1080 per 8-hour day per assessor;
- Travel (airfare, rental car, or private auto at the IRS allowable rate)
- Accommodations & Miscellaneous (hotel, meals, parking, calls, etc.).

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.**

Note 3: Billable time

An assessment of one medical laboratory can take from 2 to 5 days in the laboratory with additional time taken for preparation and report writing. If travel takes more than two hours, an additional cost at one half the assessment rate will be added for each additional hour. It is to the medical 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 draft medical scope of accreditation changes significantly as the assessment progresses, assessors will also need more time. If there are condition level deficiencies, assessor follow-up time will be charged. A2LA audits the expenses and pays assessors. Do not pay assessors directly. Do check the assessor’s written estimate of assessment costs.

Part VII. 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.



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 19 of 22

C. Please list all accreditations currently maintained with any other accreditation body, accreditation/recognition with a government agency, or additional supplier audits.

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The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 20 of 22

Part I: Instructions

A. General Information - In order to achieve A2LA accreditation in the medical field for either ISO 15189 only or ISO 15189/CLIA, laboratories are required to have an official copy of ISO 15189:2007. There are a number of sources for ordering this international standard. Please visit the A2LA web site at www.a2la.org to view some of these sources. Once you have obtained a copy of ISO 15189:2007, under the fair use clause of U.S. copyright law, A2LA will provide you with electronic copies of the relevant C601:ISO 15189:2007 Assessor Checklist, containing the full text of the standard. A completed assessor checklist must be submitted as part of your application for accreditation. To obtain the 'full text' checklist, please complete the following form and fax it to A2LA.

1. **Your Printed Name** - Your printed name should include your full first and last name.
2. **Facility Name** - Include the Complete Facility Name.
3. **Facility Address** – Include the Street Number, Street Name, City, State Abbreviation and Zip Code.
4. **Telephone Number** - Enter your facility’s current telephone number including area code any extension information.
5. **Email Address** - Enter your current email address.

B. Affidavit – By signing this affidavit you are confirming that you have obtained an official copy of ISO 15189:2007 and will be able to show the copy to the assessor during the on-site assessment.

- a. **Your Printed Name** – Your printed name should include your full first and last name.
- b. **Signature** – Sign your full name without abbreviating it or using initials. The signature must be legible.
- c. **Today’s Date** - Enter the date the Affidavit was signed.

Part II: Form

A. General information - To obtain the C601 – A2LA Medical Testing Program Management System Requirements Checklist, please complete the following form and fax it to A2LA.

1. Your Name		2. Facility Name	
<input type="text"/>		<input type="text"/>	
3. Facility Address			
Number and Street			
City		State	Zip Code
<input type="text"/>		<input type="text"/>	<input type="text"/>
4. Email Address		5. Telephone Number	
<input type="text"/>		<input type="text"/>	

B. Affidavit - I hereby confirm that I have obtained an official copy of ISO 15189:2007 and will be able to show the copy to the assessor during the on-site assessment.

1. Your Name	2. Your Signature	3. Today’s Date
<input type="text"/>	<input type="text"/>	<input type="text"/>



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 21 of 22

- C. Assessor Checklists** – Place a check mark next to the checklists that are relevant to your requested scope of accreditation. If you are unsure as to which checklist to select please call the A2LA Office at 301-644-3248 for assistance.

Requirements for accreditation in the medical field of testing for ISO 15189/CLIA, without exception:

- C601 – General Checklist: C601 – A2LA Medical Testing Program Management System Requirements Checklist, contains the full text of ISO 15189:2007 and the relevant CLIA standards.*
- C615 – Proficiency Testing Checklist - Contains the A2LA requirements (from ISO 15189 and the CLIA standards) for proficiency testing for medical testing laboratories.*

Requirements if the laboratory has collection sites and/or a LIS system or requests accreditation for Point of Care testing

- C613 – Point of Care (POCT) Checklist – Contains the A2LA special requirements (from ISO 22870) for assessing POCT.*
- C614- Specific Checklist: ISO 15189: Annex B; Requirements for the Protection of Laboratory Information Systems (LIS) - Contains the A2LA requirements for the protection and integrity of LIS.*
- C616 – Specimen Collection Site Checklist - Contains the A2LA special requirements (from ISO 15189 and CLIA standards) for assessing Collection Sites.*

Requirements if the laboratory is requesting accreditation for the specific specialty referenced by the checklist

- C602–Technical Checklist: Chemistry – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Chemistry.*
- C603–Technical Checklist: Pathology – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Pathology, including Anatomic, Clinical, and Surgical Pathology.*
- C604–Technical Checklist: Molecular Pathology – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Molecular Pathology.*
- C605–Technical Checklist: Cytopathology – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Cytopathology.*
- C606–Technical Checklist: Cytogenetics – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Cytogenetics.*
- C607–Technical Checklist: Diagnostic Immunology – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Immunology (Diagnostic Immunology and Syphilis Serology).*
- C608–Technical Checklist: Hematology – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Hematology.*

- C609–Technical Checklist: Histocompatibility – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Histocompatibility.*



The American Association for Laboratory Accreditation

F601 – Application for Accreditation: CLIA and ISO 15189 Medical Testing Laboratories

Document Issued:
February 26, 2010
Page 22 of 22

- C610–Technical Checklist: Immunohematology* – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Immunohematology including the subspecialties of ABO/RH Grouping and Typing, Antibody Detection and Identification, and Compatibility Testing.
- C611–Technical Checklist: Microbiology* – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Microbiology including the subspecialties of Bacteriology, Mycobacteriology, Mycology, Virology, and Parasitology.
- C612–Technical Checklist: Radiobioassay* – Contains the full text of ISO 15189:2007, Section 5 and the relevant CLIA standards relating to the Specialty of Radiobioassay.

D. I would like my checklists(s): Sent to me electronically Sent to me through USPS mail

E. FAX THIS FORM DIRECTLY TO A2LA AT (301) 662 2974. Your copy of the Assessor Checklist(s) should be forwarded to you within 5 working days.

For A2LA Use Only:	Date Received:	Date Processed:	By:
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END OF APPLICATION