



The American Association for Laboratory Accreditation

F658 – Ownership Confirmation: ISO 15189

Document Issued:
January 18, 2010

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Part I: Instructions

A. General Information - In order to achieve A2LA medical testing accreditation, 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 ISO 15189:2007 Assessor Checklists, 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 C650 - A2LA Medical Testing Program General Requirements -ISO 15189 Checklist, please complete the following form and fax it to A2LA.

Form with fields for: 1. Your Name, 2. Laboratory Name, 3. Laboratory Address (Number and Street, City, State, Zip Code), 4. Email Address, 5. Telephone Number

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.

Form with fields for: 1. Your Name, 2. Your Signature, 3. Today's Date



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 only, without exception:

- C650 – General Checklist: ISO 15189:2007 Medical Laboratory Accreditation Program - contains the full text of ISO 15189:2007.*
- 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.*
- C660 – Specimen Collection Site Checklist - Contains the A2LA special requirements (from ISO 15189) for assessing Collection Sites.*

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

- C651–Technical Checklist: Chemistry – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Chemistry.*
- C652–Technical Checklist: Cytogenetics – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Cytogenetics.*
- C653–Technical Checklist: Diagnostic Immunology – Contains the relevant text of ISO 15189:2007, Section 5, relating to the Specialty of Immunology (Diagnostic Immunology and Syphilis Serology).*
- C6548–Technical Checklist: Hematology – Contains the relevant text of ISO 15189:2007, Section 5, relating to the Specialty of Hematology.*
- C655–Technical Checklist: Pathology – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Pathology, including Anatomic, Clinical, and Surgical Pathology.*
- C656–Technical Checklist: Histocompatibility – Contains the relevant text of ISO 15189:2007, Section 5, relating to the Specialty of Histocompatibility.*
- C657–Technical Checklist: Immunohematology – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Immunohematology including the subspecialties of ABO/RH Grouping and Typing, Antibody Detection and Identification, and Compatibility Testing.*



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- C658–Technical Checklist: Microbiology* – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Microbiology including the subspecialties of Bacteriology, Mycobacteriology, Mycology, Virology, and Parasitology.
- C659–Technical Checklist: Radiobioassay* – Contains the relevant text of ISO 15189:2007, Section 5 relating to the Specialty of Radiobioassay.
- C661–Technical Checklist: Molecular Pathology* – Contains the relevant text of ISO 15189:2007, Section 5, relevant to the the Specialty of Molecular Pathology.
- C662–Technical Checklist: Cytopathology* – Contains the relevant text of ISO 15189:2007, Section 5, relating to the Specialty of Cytopathology.

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

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

For A2LA Use Only:	Date Received:	Date Processed:	By:
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