Background

On January 13, 2014, the National DNA Index System (NDIS) Procedures Board approved the designation of the American Association for Laboratory Accreditation (A2LA) as an accrediting agency under the United States Federal DNA Identification Act (42 U.S.C. §14132).

As a designated agency, A2LA, through its Forensic Accreditation Program, is now recognized to accredit:
- Laboratories performing DNA analyses on DNA samples obtained from identified subject(s) for purposes of entering the resulting DNA profile or DNA record into a DNA database.
- Laboratories performing DNA analyses on known or casework reference samples considered evidence by that laboratory.

To assist in the continued compliance of NDIS approved facilities, A2LA also performs biennial external audits to the FBI Quality Assurance Standards in accordance with FBI QAS, Section 15.2 which requires that at least every two years, an external audit be performed.

All auditors contracted by A2LA to perform FBI DNA QAS assessments meet the requirements specified in the Quality Assurance Standards for Forensics DNA Testing and/or DNA Databasing Laboratories and have signed a conflict of interest and nondisclosure agreement.

Preface A - Before You Begin

Please take the following steps before you begin this application to ensure an effective application process.

1. Obtain and review the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories (as applicable).
2. Read the policies found in the “Policies” section (Preface B) of this application.
3. Assemble all required documents as outlined in Part V. Supporting Information.

Preface B - Policies

1. **A2LA Confidentiality Policy:** A503 – A2LA Code of Conduct, Section 4 Confidentiality and Intellectual Property Policies\(^2\). All information provided by applicants in connection with a request for an application package, an application for FBI QAS assessment, an assessment or proficiency test is confidential. Such information is examined by a small group of A2LA staff, assessors and external bodies as needed for recognition of the program. These groups must treat this information with utmost confidentiality. Such information shall not be released to others unless the applicant provides A2LA permission in writing to do so or unless required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

2. **Language Policy:** 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.

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\(^1\) [http://www.fbi.gov/about-us/lab/biometric-analysis/codis](http://www.fbi.gov/about-us/lab/biometric-analysis/codis)

\(^2\) A2LA document A503 is not available on the A2LA website, but will be provided to applicants upon request.
### Part I. Application Information

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<thead>
<tr>
<th>A. Authorized Representative’s Name</th>
<th>Authorized Representative’s Title</th>
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<tr>
<td>Mr. □  Ms. □  Mrs. □  Dr. □</td>
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**B. Organization Legal Name** (as it will appear on your completed FBI QAS audit document)

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

**D. Telephone Number**

**Fax Number**

**E. Mobile Number [If applicable]**

**Email Address**

**F. Website Address.**

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

**H. Billing Address** (Number and Street, City, State and Zip Code)
Part I. Application Information (continued)

I. Name and address of Owners (If privately held)

J. 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>
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<tr>
<th>Contact Name</th>
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Part II. Type of Laboratory

Type of Laboratory (check all that apply):

☐ A forensic DNA testing laboratory performing forensic DNA testing (identification and evaluation of biological evidence in criminal matters using DNA technologies) or utilizing the Combined DNA Index System (CODIS) **Error! Bookmark not defined.**

☐ A forensic DNA databasing laboratory performing DNA testing on database, known or casework reference samples for inclusion in the Combined DNA Index System (CODIS) **Error! Bookmark not defined.**

Please select the appropriate box:

<table>
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<tr>
<th>☐ Requiring assessment and accreditation</th>
<th>☐ Requiring assessment only</th>
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<tbody>
<tr>
<td>Please note: When seeking accreditation to ISO/IEC 17025 and assessment to the FBI QAS, you must complete A2LA application documents F101 and F235</td>
<td>(FBI QAS, section 15.2 external assessment)</td>
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Part III. Conditions for Participation – DNA QAS Assessment

To attain A2LA assessment to the FBI QAS audit documents, an applicant must agree to:

1) Afford accommodation and cooperation as is necessary to enable A2LA to verify compliance with the requirements for assessment including provision for examination of documentation (including documents that provide insight into the level of independence of the applicant from any other related activities undertaken by their organization, where applicable) and access to all calibration and testing areas, equipment, records and personnel for the purposes of assessment, reassessment and resolution of complaints;

2) Comply at all times with these conditions for participation – DNA QAS assessment;

3) Maintain impartiality and integrity;

4) Retain all quality records and technical records supporting reported results (as defined in the FBI Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories (as applicable)) throughout the period between external FBI QAS assessments bearing in mind that adequate records (e.g. measurement uncertainty estimates, complaint records, etc.) must be available to demonstrate full compliance with the requirements for NDIS approval;

5) Pay such fees as shall be determined by A2LA, including
   a. An assessment deposit and system fees – due to A2LA at the time of application and which are required prior to an assessor being assigned to the assessment. Such fees are determined by A2LA upon review of any prior credit and/or payment history with A2LA;
   b. All applicable assessment fees and assessor travel expenses less the assessment deposit – due to A2LA within 30 days upon receipt of the final invoice.

6) Not use records of FBI QAS assessment performed by A2LA in such a manner as to bring A2LA into disrepute and not make any statement relevant to its assessment which A2LA may consider misleading or unauthorized;

7) Not use assessment by A2LA to imply product approval by A2LA;

8) Endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner; and

9) Authorize A2LA to release information regarding the organization’s application status to the NDIS board. In order to apply, the applicant’s AUTHORIZED REPRESENTATIVE and the AUTHORIZED DEPUTY REPRESENTATIVE must agree to the above conditions for participation and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. An applicant organization’s AUTHORIZED REPRESENTATIVE and AUTHORIZED DEPUTY REPRESENTATIVE are officials who represent the organization in all matters related to participation in the FBI QAS assessment. This official is A2LA’s primary point of contact with the organization. An applicant organization’s Authorized Representative shall be in a position of authority to ensure that the organization complies with the A2LA criteria. Furthermore, this representative is responsible for ensuring that all of the relevant conditions for participation are maintained.
As the applicant organization's Authorized Representative, I agree to the above conditions for participation. I attest that all statements made on this application are correct to the best of my knowledge and belief.

_____________________________ ____________________________       ______________
AUTHORIZED REP. NAME (PRINTED) AUTHORIZED REP. SIGNATURE      DATE

As the applicant organization's Authorized Deputy Representative, I agree to the above conditions for participation. I attest that all statements made on this application are correct to the best of my knowledge and belief.

_____________________________ _____________________________     ______________
AUTHORIZED DEPUTY NAME (PRINTED)    AUTHORIZED DEPUTY SIGNATURE   DATE

Part IV. Supporting Information

Please enclose the following supporting documentation along with this completed application:

☐ A current copy of your quality manual.

☐ A copy of relevant SOPs (if available and practicable).

☐ DNA QAS Appendix C with Section 1 completed for both DNA testing and databasing, where applicable. (A2LA has an electronic form available upon request)

☐ DNA QAS page 7 – Checklist of General Laboratory Information for both DNA testing and databasing. (A2LA has an electronic form available upon request)

☐ Completed F101 application and supporting documentation (if seeking ISO/IEC 17025 accreditation)

Part V. Fee Schedule

A. Fees:

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

**Assessor Deposit:** An Assessor Deposit is required per application. The laboratory will be billed (or refunded) the difference between the actual cost of the assessment and the amount of this deposit. Actual costs are computed based on:

- Total Assessment Time per 8-hour day per assessor;
- Travel\(^3\) (airfare, rental car, or private auto at the IRS allowable rate);
- Accommodations & Miscellaneous (hotel, meals\(^4\), parking, calls, etc.).

\(^3\) Travel time is billed at one half the assessment rate.

\(^4\) Meals are based on A2LA per Diem of $35 per day. International per Diem is based on the U.S. Department of State most recently published rates. Travel days where work is not performed will be 50% of the per diem rate.

L:\FORMS\F235 – Application for Assessment to the FBI Quality Assurance Standards for DNA Testing and Databasing Facilities
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, scope of work, 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.

Grant Funding: A2LA is aware that grant funding for assessment to the FBI QAS documents is available. If your organization is a recipient of grant funding, A2LA will bill at the grant stipulated rate.

If your Laboratory is a recipient of grant funding check here. □
(Please provide a record of your facility being awarded a grant to fund your assessment costs.)

B. Payment Options:

A2LA accepts checks, VISA / MasterCard / Discover / American Express, 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 assessment/accreditation? ☐
Yes ☐ No ☐

If yes, when, and under what MASTER CODE?

Date:

MASTER CODE:

A free estimate can be obtained by completing and submitting the A2LA F119 - Estimate Request Form or contact A2LA at sales@A2LA.org or 301 644 3204.

At a minimum, a completed copy of this document must be provided if submitting payment prior to submission of all required supplemental information.

Call A2LA Financial Services at 301-644-3248 for more information.
Part VI. Supplemental Information

A. Please indicate your reason(s) for pursuing assessment 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 current and/or past accreditations with any other accreditation body, accreditation/recognition with a government agency, or additional supplier audits.

Part VI. Mailing/Emailing Instructions

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

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

If emailing, please submit to: applications@A2LA.org
If emailing the application, please mail payment of fees to the address above.

Please direct all questions regarding this application to our office at 301 644 3248.

END OF APPLICATION
## Document Revision History

<table>
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<th>Date</th>
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<tr>
<td>11/16/2012</td>
<td>► Original issue of this document.</td>
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</table>
| 07/01/2013 | ► Revised Background, first paragraph.  
► Added a reference to footnote 1 for each reference to the FBI DNA QAS documents.  
► Revised Preface B. The A2LA confidentiality policy was recently added to A503-Code of Conduct.  
► Editorial changes were made to Part III Conditions for Participation.  
► Revised fee portions of application.                                                                                                                                                                                                                                    |
| 02/04/2014 | ► Revised Background to include A2LA’s approval as an accrediting body and availability to perform biennial external assessments.  
► Revise Preface A – removed requirement that laboratories gain accreditation from an NDIS Board approved accrediting body prior to application.  
► Added check box for laboratories seeking assessment and accreditation and laboratories seeking assessment only.  
► Revised Part III – removed reference to pilot programs, added language related to fees the applicant is required to pay  
► Revised Part IV – added F101 as required supplemental information.  
► Revised Part V – editorial changes. Payment options moved to Part B, Fees moved to Part A.                                                                                                                                                                         |