



<b>ATF-LS-FB26</b> <b>Outsourced Casework Samples</b>	Published Online: <b>March 2018</b>
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## 1. Scope

Outsourcing is the utilization of a qualified vendor laboratory to provide DNA analysis services to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). ATF retains ownership of the DNA data for entry into CODIS, when applicable. This procedure covers outsourcing of casework samples and ensures that a technical review is performed to verify the integrity of the DNA data received from the vendor laboratory.

## 2. References

- 2.1. The Genetic Non-Discrimination Information Act (exception for laboratories conducting DNA analysis for law enforcement purposes) 42 USC 2000FF-1 § (b)(6)
- 2.2. FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (current version)
- 2.3. FBI Quality Assurance Standards for DNA Databasing Laboratories (current version)
- 2.4. ATF-LS-FB19 CODIS Manual
- 2.5. ATF-LS-FB22 Staff DNA Index
- 2.6. ISO/IEC 17025

## 3. Equipment

- 3.1. Not applicable

## 4. Safety/Quality Assurance

- 4.1. Not applicable

## 5. Procedure

On occasion, it may be necessary to outsource casework samples to a qualified vendor laboratory. The DNA Technical Leader shall approve the technical specifications of the outsourcing agreement prior to it being awarded to a vendor laboratory. The following procedures shall be used for those samples to be outsourced.

### 5.1. Site Visit of Vendor Laboratory

- 5.1.1. An initial on-site visit shall be conducted prior to any samples being analyzed by the vendor laboratory. This visit may be conducted by the DNA Technical Leader or a designated employee. This employee shall be a DNA analyst, currently or previously qualified in the technology, analysis platform, and amplification kit used to generate the DNA data. An on-site visit shall include, at a minimum, a review of the facilities where the analysis will be performed, meeting with key personnel, and a review of relevant method or instrument validations. A record of the visit to include the date, personnel that conducted the audit, personnel from the contract laboratory present, and summary shall be prepared by the individual conducting the visit and maintained in the contract vendor file.

- 5.1.2. Annual on-site visits may be conducted if the agreement extends more than one year. If additional annual on-site visits are conducted, they shall occur once every calendar year and be at least six (6) months and no more than eighteen (18) months apart.
  - 5.1.2.1. In lieu of an actual on-site visit, the DNA Technical Leader may accept documentation of an on-site visit by another NDIS laboratory using the same technology, analysis platform, and amplification kit, as long as it was conducted within the past twelve (12) months. In addition, the DNA Technical Leader may accept an on-site visit conducted by a designated FBI employee.
- 5.1.3. The FBI Quality Assurance Standards Audit document from the most recent external audit of the vendor laboratory shall be reviewed by the DNA Technical Leader and documentation of the review shall be maintained in the contract vendor file.
- 5.1.4. The vendor laboratory shall be accredited to ISO/IEC 17025. Documentation regarding this accreditation, to include a copy of the accreditation certificate and scope of the accreditation, shall be maintained in the contract vendor file.
- 5.1.5. Prior to accepting data from the vendor laboratory for upload to CODIS, the DNA Technical Leader shall document the approval of the technical specifications of the outsourcing agreement and/or the approval of acceptance of ownership of the DNA data.
- 5.2. Vendor Laboratory Protocols
  - 5.2.1. Prior to analysis of samples, analytical procedures to be used by the vendor laboratory shall be reviewed and authorized by the ATF Laboratory DNA Technical Leader or his/her designee. A record of this review shall be documented and maintained in the contract vendor file.
- 5.3. Sending Samples for Analysis
  - 5.3.1. Samples sent to the vendor laboratory shall be organized into batches. A list of the ATF lab numbers and the number of samples in each batch shall be compiled and maintained.
  - 5.3.2. The samples shall be delivered to the vendor laboratory by a secure, traceable means (e.g. FedEx) or hand delivered. If the samples are hand delivered, an acknowledgement of receipt (including date) shall be obtained.
- 5.4. Reviewing Data Received
  - 5.4.1. A technical review shall be conducted on all of the data in each batch of samples processed by the vendor laboratory. This review shall be conducted prior to the official acceptance of the data from the vendor laboratory.
  - 5.4.2. A technical review shall be conducted by an examiner who participates in the ATF's proficiency-test program, and is currently or previously qualified in the technology, analysis platform, and amplification kit used to generate the DNA data. The technical review shall be documented on the Outsourced DNA Case Record Review form.
    - 5.4.2.1. All DNA types shall be reviewed to verify that they are supported by the raw or analyzed data (electropherograms).
    - 5.4.2.2. All associated controls, internal lane standards, and allelic ladders shall be verified to ensure that the expected results were obtained.
    - 5.4.2.3. The vendor laboratory's final report (if provided) shall be reviewed to verify that:
      - 5.4.2.3.1. The results/conclusions are supported by the DNA data.

- 5.4.2.3.2. Each tested item (or its probative fraction) submitted is addressed in the final report.
    - 5.4.2.4. If applicable, the DNA types, eligibility, and correct specimen category shall be verified for entry into CODIS.
  - 5.4.3. Upon successful completion of the technical review, a copy of the vendor laboratory report and a copy of the vendor laboratory's data shall be placed in the case jacket.
  - 5.4.4. Samples or batches that do not pass the technical review shall be evaluated for return to the vendor laboratory for re-analysis.
- 5.5. CODIS Entry of Outsourced Samples
  - 5.5.1. After the technical review of data received from the vendor laboratory, a qualified DNA analyst with access to CODIS shall determine CODIS eligibility and verify the DNA types obtained for those eligible samples. Furthermore, the analyst shall determine the correct specimen category for entry into CODIS.
  - 5.5.2. The DNA analyst shall enter appropriate profiles into CODIS and issue a written report to the submitter.
  - 5.5.3. The verification of the DNA types, CODIS eligibility, and the correct specimen category for entry into CODIS, shall be covered during the normal technical review of the DNA analyst's report.
- 5.6. Disposition of Evidence and DNA Extracts
  - 5.6.1. The remainder of the samples sent to the vendor laboratory and/or any DNA extracts remaining after analysis shall be returned to the ATF Laboratory.
  - 5.6.2. Remaining evidence shall be returned to the original submitter by the ATF Laboratory.
  - 5.6.3. DNA extracts shall be stored in the evidence room freezer.