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## **Evidence Definitions**

## Forensic FBI QAS 7.3.1 / Database FBI QAS Standard 7.3.1

**Questioned (or Q) sample:** evidence collected from an alleged crime scene, for which the source(s) of any DNA present on the evidence may be unknown.

**Known (or K) sample:** a reference sample collected directly from an identified individual, typically collected as a buccal swab or drawn blood.

**Evidence:** Per the Quality Assurance Manual, items received at the laboratory with an agency case number and item number are considered to be evidence; and the CODIS individual characteristic database items are treated as reference materials.

**Work product:** a material that is generated as a function of analysis, which may include extracts, spermatozoa search slides/extract slides, and amplified products.

## **Unique identifiers:**

<u>Casework:</u> To ensure that each sample can be distinguished throughout processing, tubes are labeled with laboratory case number, item number, sub-item number, and/or differential fraction, as applicable.

<u>Database</u>: Database samples are typically batch processed. Each batch of samples is assigned a batch name comprised of the date of initial digest or batch set-up, the processing analyst's initials, and a plate identifier to indicates processing order (such as 23-0101LDS\_A, 23-0101LDS\_B, and so on). Racks of sample tubes comprising a batch are labeled with the batch identifier. To ensure that each sample can be distinguished throughout processing, sample tubes within the batch are assigned codes that include plate identifier and order within the plate (e.g., A12). In combination with a batch name, this creates a unique identifier for each database sample.

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## **Retaining Technical Records and Casework DNA Extracts**

AR 3125 7.5.3.1

#### **Documentation Generated During DNA Analysis**

Observations of casework and database analysis must be documented contemporaneously with the lab work process.

Casework technical records consist of:

- Bench notes, retained in the LIMS case file
- Central log documentation, stored in SharePoint
- Raw data files from genetic analysis, stored in SharePoint.
  - NOTE: If Level 2 discovery requests do not already include raw data files, they must include documentation that raw data files will be provided upon request.

Database technical records consist of:

- Central log documentation, stored in SharePoint
- Raw data files from genetic analysis, stored in SharePoint
- Exported GeneMapper ID-X database projects, stored in SharePoint

## **Forensic Biology Casework Bench Notes**

Bench notes consist of any documentation generated during analysis of a case and specific to that case. All bench notes pages in the case record contain the case number, analyst's initials, item # (if appropriate, i.e., digital images) and page number (page X). The total number of pages is indicated either by "page X of Y" numbering or by marking the last page as "last page".

**Note**: All pages in the file must be page numbered before handing in for technical review.

When one analyst performs an analysis on behalf of another analyst, the notes pages should contain the handwritten initials (or secure electronic equivalent) of each analyst.

**Note**: For Proficiency Tests, the results pages of the paperwork from the test provider are completed and become the first pages of the bench notes.

The bench notes are placed in the case images for the request in the LIMS. All bench notes must be in LIMS and the report marked draft complete (by the analyst) prior to submitting the case for technical review. Upon completion of the technical and administrative reviews, the final bench notes with the review checklist will be added to the case images. See the PDF guidance document on the network for more details on preparing bench notes for LIMS retention.

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The worksheets contain details of all the items processed and include the item packaging, contents and description, images of the evidence processed (when applicable), documentation of all presumptive tests performed and the test results, the location of all testing, the location of all isolated stains/samples, trace evidence collected (if applicable), the reagents used, and the date testing began (where applicable).

The bench notes for each case may contain the following worksheets:

- Victim Assault Kit Worksheet
- Suspect Assault Kit Worksheet
- Evidence Examination Worksheet
- Electropherograms for all the samples amplified. All electropherograms must contain the lab case # and item #.
  - If the sample has no labeled peaks, the electropherogram must also include the primer peaks [Analysis method: 3500 Blank-Casework]
  - When an OL is a true allele or a potential tri-allele exists, a casework artifact view is also required that includes the relevant locus for an allelic ladder and the sample with the potential tri-allele.
  - The following handwritten notations may be included on the electropherogram:
    - Artifacts (i.e., pull-up, dye blobs, etc.) are struck and initialed (or electronic equivalent) on the full view electropherogram and the artifact view
    - For peaks in stutter positions (that appear close to the expected stutter percentages) indicate the % of the peak relative to the main peak and the maximum expected stutter percentage (for example, 12%>5% or 5.2%~5%). When the peak can be reasonably interpreted as elevated stutter, add a notation to this effect. When it is not possible to discern whether the peak is a stutter peak or a true allele, add "A/TA".
    - If able to determine a major vs. minor profile, () around the minor alleles. [] is used to indicate alleles that could not be separated into major/minor components.
    - 'NS' or 'NS major' at loci determined not to be suitable for inclusion in a statistical analysis
- Optional: Mixture Interpretation Worksheet is used to document profile deduction. Documentation included on this worksheet includes:
  - Stated assumptions
  - o Reference profile used
  - Reasoning for deduction (or not deduced)
  - Profile for CODIS entry if applicable
- Popstats/YHRD printouts for all samples for which a statistical analysis was performed will include:
  - Specimen ID: lab case # and Item#
  - Comments section: add any additional info (ie sperm fraction, major profile)
  - Print for all reported populations
- The casework review checklist, completed and initialed by the analyst and reviewers.
  - Analyst will complete the first column of boxes before handing in for technical review

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## **Forensic Biology Casework Central Log Records**

Each batch of cases assigned to a DNA analyst will be named with the batch date (typically, this is the day you take custody of the evidence or first begin analysis) and the analyst's initials (i.e.YY-MMDDinitials 06-0102MLC). This batch name is recorded for each case in the LIMS. Upon completion of the technical review of a batch, the central log documentation is retained in SharePoint.

The templates for the worksheets that comprise the central log are controlled documents and can be found in SharePoint. The templates may be modified as required for the batch. The central log for each batch of cases will contain at least the following information in an appropriate format:

A central log review checklist, completed and initialed by the analyst and technical reviewer. Analyst will complete the first column of boxes before handing in for technical review

A batch extraction worksheet containing for each extracted item in the batch:

- Lab number
- Item number
- Brief description of the item (e.g., vaginal swabs, breast swab, etc.)
- Code number (e.g., Q1, RBS1, etc.)

The Casework Standards, Controls and Reagents worksheet detailing:

- Serology controls
- Extraction methods and dates
- Specific instrument(s) used
- Elution volumes
- Extraction controls
- Reagent blanks and internal control standards
- Extraction reagent lot numbers and reagent expiration dates. (reagents not used can be deleted from worksheet)

The Master Mix Worksheet detailing

- Number of samples per master mix type
- Master mix calculations

The Quantification Set-up Worksheet, to include the following:

- Plate layout
- Reagent lot numbers and reagent expiration dates
- Master mix calculations

The Quantification Experiment Results Report, to include the following:

- Experiment summary
- Note 7500 instrument used (add to front page)
- Note ROX passing (add to front page)

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- Note date that interpretation/decisions were completed (add to front page)
- Plate layout
- T-L, T-S, and T-Y standard curves
- Results table

The amplification/electrophoresis worksheet(s) detailing:

- the samples/controls amplified (clearly identify the Positive Control sample provided by the PCR kit vendor).
- the well plate locations
- the amount of sample amplified
- lot numbers and expiration dates of reagents used in amplification and electrophoresis (the lot #s
  for the polymer, capillary array and running buffers are embedded in the raw data file for each
  sample and need not be recorded separately)

If electrophoresis results indicate that a sample should be re-extracted, re-amplified or re-injected, the reason should be documented in the comments/notes field of the amp/3500 worksheet. These might include:

- Instrument failure
- ILS failure
- Noisy baseline
- Data below reporting threshold
- Drop-out
- Saturation
- Off-ladders
- Artifacts (i.e., pull-up, dye blobs, spike, bubbles, shoulder)
- Potential Tri-allele
- Data above reporting threshold in a blank/negative control

It is recognized that not all cases may be submitted to technical review simultaneously. Therefore, page numbering of the central log does not need to be completed until all laboratory work is completed for all cases in the batch. However, all reagent blank(s) should be confirmed at a minimum before any cases are submitted for technical review.

#### **Forensic Biology Database Central Log Records**

Each batch of database samples assigned to a DNA analyst will be named with DB followed by the batch date (typically, this is the day you take custody of the evidence or first begin analysis) and the analyst's initials, often followed by a letter which indicates the batch's order for that analyst's annual workload. (i.e.YY-MMDDinitials DB24-0102MLC\_A). Upon completion of the technical review of a batch, the central log documentation is retained in SharePoint.

The templates for the worksheets that comprise the central log are controlled documents and can be found in SharePoint. The templates may be modified as required for the batch. The central log for each batch of cases will contain at least the following information in an appropriate format:

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A central log review checklist, completed and initialed by the analyst and technical reviewer. Analyst will complete the first column of boxes before handing in for technical review

#### An SDIS Import Reconciliation Report

 This captures the number of new specimens uploaded to SDIS, as well as any specimen updates or upload problems.

A batch worksheet includes a batch identifier and interpretation dates. For each item in the batch:

- Sample number (LIMS case number)
- Sample code
- Specimen category
- · Gender listed in LIMS
- Amplification/genetic analyzer plate well number
- Quantification and amplification set-up, if applicable
- Concordance check results, if applicable
- Suitability for upload
- If rejected, reason for rejection and course of follow-up action
- Comments about unusual samples (such as off-ladders, tri-alleles, etc.)
- Documentation of technical review including reviewer initials

The Standards, Controls and Reagents worksheet(s) detailing:

- Batch identifier
- Analysis methods and dates
- Specific instrument(s) used
- Master mix volumes
- Raw data file names
- Reagent lot numbers and reagent expiration dates. (reagents not used can be deleted from worksheet)

If quantification is performed, the Quantification Set-up Worksheet, to include the following:

- Plate layout
- Reagent lot numbers and reagent expiration dates
- Master mix calculations

If quantification is performed, the Quantification Experiment Results Report, to include the following:

- Experiment summary
- Note 7500 instrument used (add to front page)
- Note ROX passing (add to front page)
- Note date that interpretation/decisions were completed (add to front page)
- Plate layout
- T-L, T-S, and T-Y standard curves
- Results table

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If electrophoresis results indicate that a sample should be re-extracted, re-amplified or re-injected, the reason should be documented in the comments/notes field of the batch worksheet, such as poor injection or (partial) drop-out.

#### **Retention of DNA extracts**

- All questioned extracts created during analysis will be retained.
- If an entire item of evidence (e.g., penile swabs, fingernail scrapings, contact DNA swabs, etc.) is used for DNA extraction owing to potentially limited amounts of biological material, then at least half of the DNA extracted from that item will be retained, unless written permission from Department of Law for consumption of the sample has been obtained and documented in LIMS.
- Best practice for if a casework reference sample extract is generated but no corresponding
  questioned samples are proceeding to amplification, the reference sample extract can EITHER
  be amplified with documentation included with the bench notes or dried down and stored
  with the evidence. If the extract is not amplified, the analyst must ensure that corresponding
  ICS and reagent blank controls are either amplified or also dried down for future analysis at the
  same time as the reference sample extract. If controls will need to be amplified along with the
  reference extract, that must be clearly documented on the reference extract packaging.
- In situations where the entire item of evidence has been used for DNA extraction and when quantitation results suggest that the entire volume of the DNA extract will be required for PCR amplification to attempt to obtain interpretable data, the laboratory shall require written permission from the Department of Law to consume the entire extract.
- Database (CODIS) samples are considered as reference material. As such, they are not treated as evidence, and extracts are not retained.

## Retention of electronic data

- Electronic data from quantitation is not retained.
- All raw data files generated during casework and database electrophoretic analysis shall be retained in SharePoint.
- Because discipline manuals contain sufficient information to recreate the GeneMapper ID-X
  project from the raw data files, casework GeneMapper ID-X project files are not retained long
  term and may be deleted after the technical and administrative reviews of a batch are
  completed. Database projects are retained because there is no individual case record for each
  profile.

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## Rejected data in technical records

## • Rejected quantification data

- When an entire quantification run is rejected, the quantification report will be included in the central log documentation. The front page of the failed report must indicate the reason the data was rejected (e.g., no data obtained, quality control failure, etc.) and data was not used, along with analyst date and initials.
- When an individual quantification result is rejected, a reason must be noted on the original quantification report (e.g., low quant atypical of internal body swab – quant re-attempted) along with the analyst date and initials

#### • Rejected electrophoresis data

- When an entire injection (or run) is rejected, the raw data file is retained in SharePoint. The
  relevant amplification worksheet in the central log must give a reason why the data was
  rejected (e.g., no passing allelic ladder, no data obtained from injection, master mix did not
  include ILS, etc.) along with analyst date and initials. The raw data file name must be listed
  in the central log documentation.
- When individual sample data is rejected, the relevant amplification worksheet in the central log must give a reason why the data was rejected (e.g., broad peaks detected, injection failed, etc.) along with analyst date and initials.

## Rejected bench note documentation

- When the technical review process indicates that new pages must be added to address corrections (recalculation of population frequency statistics) or additions (re-amplification of a sample), the original pages must be kept in the bench notes. A note must be added to the rejected data indicating why the data was rejected, along with analyst date and initials, and clear marking to indicate that the data was not used. New pages must clearly indicate what was added, as well as analyst date and initials.
- If an individual calculation or observation is rejected, it can be struck and corrected with the
  analyst date and initials noted. If the reason for rejection was incorrect or missing
  calculation, the corrected number is considered documentation of the reason for rejection.
  Other reasons for rejection must be stated in the bench notes.

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# Forensic Biology Discipline Locker Key Policy

# Forensic FBI QAS Standard 7.2 / Database FBI QAS Standard 7.2

Evidence lockers in the Forensic Biology discipline are self-assigned. An analyst may choose any locker(s) for storing evidence. When lockers are not in use, keys are stored in the locks.

When a locker is being claimed by an analyst for long term use, the analyst shall take custody of the key in the LIMS.

A master set of locker keys is stored in the discipline supervisor's office. These may only be used with permission from the discipline supervisor or designated individual.

If one of the locker keys is lost, the discipline supervisor shall be notified.

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# **Forensic Biology Literature Review Policy**

# Forensic FBI QAS Standard 16.1.2 / Database FBI QAS Standard 16.1.2

Any member of the Forensic Biology discipline may put forward an article of scientific literature for members of the discipline to read, as appropriate to their areas of competency. Literature reviews are included as a part of regular discipline meetings. In general, analysts will be expected to present one article per year in a discipline meeting.

Analysts document their literature reading in SharePoint in the discipline meeting minutes. In addition to the check boxes for attendance, for each meeting where literature was reviewed, the meeting minutes will have a list where analysts will record the date by which they completed the assigned reading.

Articles reviewed by the group are retained in <u>Biology Literature</u> in Sharepoint with appropriate tags completed (such as year of review, year of publication, and topic) so that they can be found by search. At least some of the annual literature reviews should be current (published within the last 1-2 years).

<u>Literature review documentation is monitored annually by the DNA Technical Manager.</u>

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# **Extended Absence Retraining Policy**

Forensic FBI QAS standard 6.12 and 6.12.1 / Database FBI QAS Standard 6.10 and 6.10.1

When an analyst is away from the laboratory for an extended period (three months or longer, or such that a scheduled proficiency test is missed), the technical leader shall evaluate the need for, assess the extent of any necessary retraining, and approve the retraining plan. At a minimum, the returning analyst will be required to successfully complete an internal competency test before resuming casework analysis. The scope of the competency test and authorization to resume casework are the responsibility of the DNA Technical Manager and/or the discipline supervisor.

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# **Forensic Biology Case Management**

## Incoming requests for service

Requests for biology services are received from the evidence discipline and are usually managed by the discipline supervisor(s).

#### New requests are evaluated using the following criteria:

- Ability of laboratory to perform requested service
- Evidence requiring examination has been submitted
- Required reference samples submitted
- Items requiring analysis in multiple disciplines marked as such
- Information in LIMS consistent with Request for Laboratory Services (RLS) form
- Adequate case information provided to make analytical decisions

Case managers ensure that all relevant individuals and offenses are related to the request. This does not necessarily mean that there has been evidence submitted from all related individuals. When multiple offenses are included on the Request for Laboratory Services, only the highest level or most severe offense should remain related to the testing request.

If the laboratory has received sufficient evidence and information to proceed, requests are made available to be assigned in the LIMS.

If permission to consume has been granted, check the appropriate box (on the evidence tab) for each item in which consumption has been authorized.

Refer to the <u>JT manual</u> for detailed information on tracking additional testing requests for previously submitted items.

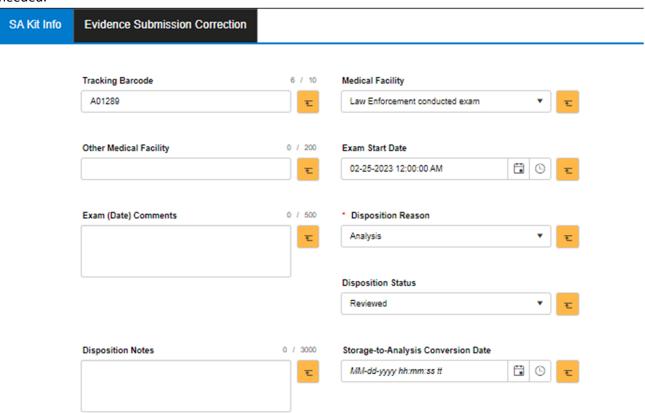
All cases will be completed in Justice Trax. Evidence received in Themis will be reported under the Justice Trax request. All items that were received in Themis have now been created in Justice Trax and the chain of custody will be maintained in Justice Trax going forward.

If the laboratory requires additional evidence and/or information to proceed, the laboratory will contact the submitting agency via telephone or e-mail, and the request may be pended. The agency may be informed that the request will be suspended if the case is not remedied within 30 days. Communications are retained in the LIMS. The case manager may retain a hard copy of the RLS to monitor the case.

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#### Management of Cases with Sexual Assault Kits

Sexual Assault Kits have additional data (related to kit tracking and laboratory performance) recorded in a custom form on the item of evidence. The tracking barcode, exam date and medical facility information are typically logged by the evidence discipline and may be updated by Biology staff, as needed.



The Disposition Reason and Status default to Analysis and Not Reviewed. The following updates are made by the case manager, as appropriate.

- If items that are typically submitted within an SA kit are instead submitted as individual items, one of the question items (typically the most intimate) is selected and updated with an evidence type of Victim/Suspect/Pediatric SA Kit, as appropriate. Once the item has a kit evidence type, the custom form will be available. At a minimum, the case manager will enter the disposition reason and status.
- If the case is ready to proceed for analysis, the Status is updated to Reviewed.
- If the case requires further management prior to analysis, changes are not made until a final disposition is determined. Notes may be added to indicate the reason for the delay in final dispositioning.

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- If analysis will not occur, the appropriate reason is selected in the drop-down.
- The final disposition status is selected as follows:
  - o If the final disposition is Analysis or Anonymous and is the same as that indicated by the submitting agency, the Status is changed to Reviewed.
  - If the final disposition is a change from that indicated by the submitting agency, the disposition Status is Changed Upon Review.
  - O If the final Reason is either Not an SA Crime by Statute or False Report, and is the same as that indicated by the submitting agency, the Status is Status Confirmed. Cases with a possible final Reason of Not an SA Crime by Statute or False Report require a secondary review by the designated department individual. A case management case activity is recorded to capture the final determination, preferably in the form of an e-mail.

Occasionally, a non-viable kit (suspect kit missing required victim reference or Anonymous kit) becomes viable by the submission of the required reference sample or a previously anonymous victim deciding to report. In these situations, the following actions are taken:

- The Reason will be updated to Analysis and the Status will be updated to either Anonymous Conversion or Unviable to viable.
- The Storage-to-Analysis Conversion Date is populated as the date that the required sample was received by the lab, or the lab was advised that the victim has now reported to law enforcement.
- On the Individual tab, the Anonymous Victim individual type is updated to Victim and personally identifiable information is updated.
- Advise a Track-Kit administrator of the status update.

## Case prioritization

Requests for service are generally prioritized as follows:

- Cases with upcoming trial certain dates
- Sexual Assault of a Minor/Homicides with significant public safety threat
- Sexual Assault/Homicides not included above
- Non-sexual assault
- Property Crime

## Forensic Biology Hand-off Requests

Initially, all casework requests for DNA analysis are created as Forensic Biology Analysis.

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When the laboratory work will be completed by one qualified analyst, with the report to be written by another, the Forensic Biology Analysis request is changed to Forensic Biology Hand-off and a Forensic Biology Analysis request is created as a child of the Hand-off request.

- On the agency tab, ensure the SCDL is added as a related agency. It is not necessary to add an agency case # for the SCDL.
- On the Forensic Biology Analysis request, use the right-click feature to Change Request /
   Change Lab/Service from Forensic Biology Analysis to Forensic Biology Hand-off.
- On the Forensic Biology Hand-off request, use the right-click feature to Edit the request, changing the Requesting Party Information to the SCDL. The Agc Rep will be either \*Rep, Lab or the analyst who will be authoring the DNA report, if known at this time.
- Assign the request to the analyst who will be performing the lab work, if known. The evidence that was related to the original request will remain related to the Hand-off request.
- On the Forensic Biology Hand-off request, use the right-click feature to Add Related Request, changing the Requesting Party Information to the agency and agency rep who submitted the request and/or were previously designated as the parties to receive the DNA report.
  - The next screen will default to the Service type of Forensic Biology Hand-off. Change to Forensic Biology Analysis.
  - Assign the Forensic Biology Analysis request to the analyst who will be authoring the DNA report, if known.
  - Relate the appropriate evidence items. This should be identical to those related to the Hand-off request.

## **CODIS Interstate Requests**

A CODIS Interstate Request is created when confirmation and or interstate case information is needed to report to an intrastate agency (via a CODIS Communication Request).

- On the agency tab, the out of state lab must first be added as a related agency. It is not necessary to add an agency case # for the out of state laboratory.
  - Consult a CODIS Administrator to ensure the agency is in the LIMS database and has been updated with the ORI, agency e-mail and current agency rep / rep e-mail.
- The Interstate Request (to the out of state laboratory) will be a parent request and the subsequent CODIS Communication Request (to the investigating Alaska law enforcement agency) is created as a child of the Interstate Request.
  - Create a CODIS Interstate request to the out of state laboratory and assign the request to the analyst who will be authoring the communication.
  - On the newly created Interstate request, use the right-click feature to Add Related
     Request and create the CODIS Communication request.

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- Change the Requesting Party Information to the investigating Alaska agency and agency rep who will receive the CODIS Communication.
- o Assign the CODIS Communication request to the analyst who will be authoring.
- Use the pending function in LIMS to pend the CODIS Communication Request while awaiting the response from the out of state laboratory on the Interstate Request.

#### <u>DNA Database Requests and CODIS Confirmation Requests</u>

- DNA Database parent/child requests are used for all offender collections that are being processed for CODIS entry.
- CODIS Confirmation Requests are used only to verify an offender profile previously entered into CODIS.

#### Cancelled biology requests

Requests may be cancelled for a variety of reasons (based on results of previous examinations, probative results previously obtained, notification from agency or Department of Law that analysis no longer required, case adjudicated prior to testing).

- It is incumbent on the individual who cancels a request to ensure that the reason is documented in the LIMS and that the requesting agency is informed.
- The individual who cancels a request should also ensure that the intended disposition of relevant items is correct (in Justice Trax), as per the guidelines in the following section.
- If analysis has already been started, completed worksheets/data will be submitted for a technical review and DNA metrics recorded.
- If samples were amplified, electropherograms will be interpreted with appropriate notations. Deductions are not required, if not yet completed.
- The analyst will enter findings in LIMS, indicating only that no report is being issued and the reason.
- The report and documentation are subject to technical and administrative review.

## Forensic Biology Case Report Close-Out

Once a forensic biology report has been completed, the following administrative tasks must be completed. These tasks may be completed by the analyst or an administrative designee, but it is the responsibility of the analyst to confirm that all the above tasks have been completed correctly.

- DNA Central Log files retained in a designated location on the lab network or Sharepoint.
- Report sent to submitting agency (and prosecutor, if required). This may become automated in the LIMS.

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## **Forensic Biology Evidence Retention Policy**

## Forensic FBI QAS Standard 7.4.1 / Database FBI QAS Standard 7.4.1

Items submitted for Forensic Biology examinations are routinely triaged for processing, with the items most likely to yield relevant, interpretable results being given priority. Additional testing will not typically occur once probative results are obtained. More details on item selection policies are provided on the crime lab webpage.

The following guidelines will apply to most cases. Evidence may be returned or sent to another laboratory at the request of the submitting agency.

- Sexual assault kits will be retained by the laboratory indefinitely.
  - When creating sub-items from a kit, the kit evidence type must be cleared/removed from the sub-item.
- Stains/samples isolated (by laboratory personnel) from larger items will be retained indefinitely
- Non-consumed questioned DNA extracts will be retained
- Stains/samples isolated by law enforcement (or laboratory staff at the crime scene) and submitted as swabs for analysis will only be retained by the laboratory if they are tested by the DNA unit.
- Untested questioned samples/items will be returned to the submitting agency after completion of the case
- Control swabs/stains are not typically processed and will be returned
- Reference samples are typically retained indefinitely (including database reference samples as well as casework)
  - o These items may be returned if no other items are being retained in a case.

Sample/Evidence consumption policies for forensic casework and database analysis are found in the Forensic Biology Procedure Manual.

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# Annual Forensic Biology Quality Review, Annual Case Review, and Performance Monitoring

Forensic FBI QAS standard 3.3 and 3.4 / Database FBI QAS Standard 3.3 and 3.4

## Annual Forensic Biology Quality Review

In fulfillment of QAS standard 3.3, an annual review of the quality system in the Forensic Biology discipline will occur concurrently with the lab wide annual quality system review.

The quality review of the Forensic Biology discipline will be completed under the direction of and approved by the DNA Technical Manager. At a minimum, the quality review of the Forensic Biology discipline will include the following:

- Audit (internal and/or external) of the Forensic Biology discipline
- Summary of performance monitoring for Forensic Biology discipline members
- Review of a sample of case files (annual case review), in fulfillment of QAS 3.4. The scope of this
  review will be modified annually and approved by the Technical Manager, in advance of the
  review. At a minimum it must include a representative sample of cases worked, specifically
  including cases which demonstrate the elements required for the performance monitoring plan
  outlined later in this section.
- Inventory of long-term biological evidence storage
- Inventory of GMID-X and CODIS staff elimination databases
- Collection of feedback from discipline members regarding improvements to discipline manuals
- Review and updates to manuals
- Review of all verifications, validations, and performance checks. Follow-up as required.
- Review of all performance monitoring conducted in the previous year
- Conduct an overview of all Forensic Biology CARs and QARs for the preceding year.
- Assessment of discipline-wide adherence to literature review policy
- Assessment of discipline-wide adherence to laboratory and QAS continuing education requirements

Documentation of the Forensic Biology quality system annual review will be by memo to the lab QA Manager.

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## **Performance Monitoring**

In addition to monitoring reagents, equipment, and protocols, the casework and database functions of analyst responsibilities are monitored through a performance monitoring program. The program ensures that a representative sample of qualified analysts are monitored through a lab accreditation cycle in each of the topics listed below:

Task	Method of performance monitoring		
Casework / Database Analysis			
Swabbing for transfer DNA	In-house ground truth performance check		
Locating blood stains	Second analyst witness on first ten negative items		
	for newly qualified analysts and the first negative		
	item for each analyst each calendar year		
Kastle-Meyer presumptive test	PT – screening; second analyst witness on first ten		
	negative items for newly qualified analysts and the		
	first negative item for each analyst each calendar		
	year		
ABAcard HemaTrace	In-house ground truth performance check; Second		
	analyst witness on first ten negative items for		
	newly qualified analysts and the first negative item		
	for each analyst each calendar year		
Locating semen stains, including ALS	Second analyst monitors on first ten negative cases		
(clothing, bedding, pads/tampons,	for newly qualified analysts and the first negative		
condoms)	case for each analyst each calendar year		
AP Spot Test	PT – screening; For non-swab items, second analyst		
	witness on first ten negative items for newly		
	qualified analysts and the first negative item for		
	each analyst each calendar year		
Abacus ABA card	PT - screening		
Microscopic sperm search	In-house ground truth performance check of slide		
	making and/or slide reading		
Triage practices by case/evidence type	Annual case review		
From swab (blood, saliva, contact,	PT – DNA (FA test + database analyst)		
reference samples)			
From object (cigarette butt, isolated stain)	PT – DNA (CTS)		
From human tissue from decedents (fetal	Witness by a second qualified analyst		
tissue, human remains)			
From other human samples (fingernail	In-house ground truth performance check		
scrapings/clippings, hair)			
Differential – from swab (from SAKs or	PT – DNA (FA test)		
condoms)			

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Differential – from object (isolated semen	PT – DNA (CTS)		
stain) Direct	DT DNA and database		
Differential	PT – DNA and database		
	PT - DNA		
Quantifiler Trio	PT - DNA		
RapidHIT – known buccals	PT - DNA		
Triage based on quant results	Annual case review		
Direct amp (GlobalFiler Express)	PT – database		
STR (GlobalFiler)	PT - DNA		
Y-STR (PowerPlex 16)	PT - DNA		
Evaluation of controls / central log	Annual case review		
documentation			
STR and Y-STR	In-house ground truth performance check		
Database - passing	PT – database; Annual case review		
Database - failing	Annual case review		
STR – number of contributors	Annual case review		
STR – single source - full	PT - DNA		
STR – single source - partial	Annual case review		
STR – single source - inconclusive	Annual case review		
STR – single source major	Annual case review		
STR – two source major	Annual case review		
STR – single source minor	Annual case review		
STR - deduction	Annual case review		
STR – 2-source indistinguishable	PT – DNA; Annual case review		
STR - inconclusive	Annual case review		
Y-STR – number of contributors	Annual case review		
Y-STR – single source - full	PT - DNA		
Y-STR – single source - partial	Annual case review		
Y-STR – single source - inconclusive	Annual case review		
Y-STR – single source major	Annual case review		
Y-STR – single source minor	Annual case review		
Y-STR - deduction	Annual case review		
Y-STR - inconclusive	Annual case review		
STR – single source statistic	Annual case review		
STR – mixture statistic	Annual case review		
Y-STR statistic	Annual case review		
Report writing	Annual case review		
Documentation and archiving of reports	Annual case review		
and notes			
CODIS			
CODIS Database entry – bulk upload	Recon reports indicate success of upload and are		
. ,	included in admin review process		

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Evaluating casework profiles for CODIS suitability	Annual case review		
CODIS Manual profile entry	Annual case review		
CODIS Expungement	Checklist requires witnessing and double initials on		
	checklist		
CODIS Profile removal	When profiles have gone to NDIS, deletions get a		
	double check when removed and are reviewed and		
	archived annually with recon reports		
CODIS Keyboard searches	Recorded in CODIS maintenance log and reviewed		
	and archived annually		
CODIS Match dispositioning	Moderate stringency casework matches are		
	reviewed by CODIS administrator in each monthly		
	match report; monthly match reports are reviewed		
	and archived annually. Analysts must complete an		
All CODIC confirmations (lateraty and about	in-house quiz on match dispositioning annually.  Annual case review		
All CODIS confirmations (latent, qual check,	Annual case review		
moderate stringency matches, profile confirmation) performed and/or			
documented correctly			
Issuing CODIS communications	Annual case review		
CODIS Upload to NDIS	Recon reports received from NDIS indicate success		
CODIS Opioad to NDIS	of upload. Quarterly checks are run to ensure		
	casework profiles have been uploaded to NDIS as		
	appropriate.		
Maintenance	тре организа		
Reagent verification – GenTegra-DNA	TM sign off required		
Reagent verification – GF or PPY23 kit	TM sign off required		
Reagent verification - other	Review at end of calendar year		
EZ1 and 2 – in use	Review at end of calendar year		
EZ1 and 2 – monthly	Review at end of calendar year		
EZ1 – semi-annual performance checks	Review at end of calendar year – passing PC		
·	indicates success of instrument maintenance		
EZ2 – annual performance check/PM	Review at end of calendar year – passing PC		
	indicates success of instrument maintenance		
QIAcube – in use	Review at end of calendar year		
QIAcube - monthly	Review at end of calendar year		
QIAcube – biannual maintenance	Review at end of calendar year		
QIAcube – performance check	Review at end of calendar year – passing PC		
	indicates success of instrument maintenance		
Thermomixer - biannual	Review at end of calendar year		
7500 – in use	Review at end of calendar year		
7500 - monthly	Review at end of calendar year		

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7500	Davieus et and ef enlandens en		
7500 - semiannual	Review at end of calendar year		
7500 – annual	Review at end of calendar year		
7500 – performance check	Review at end of calendar year – passing PC		
	indicates success of instrument maintenance		
Thermal cycler - monthly	Review at end of calendar year		
Thermal cycler – performance checks	Review at end of calendar year – passing PC		
	indicates success of instrument maintenance		
3500 – in use	Review at end of calendar year		
3500 - monthly	Review at end of calendar year		
3500 – capillary change	TM sign off required; review at end of calendar		
	year		
3500 performance check	Review at end of calendar year – passing PC		
	indicates success of instrument maintenance		
Pipettes – annual calibration	Review at end of calendar year		
Other instrument logs (incubators, heat	Review at end of calendar year		
blocks)			
Other calibrations (balances, probes)	Review at end of calendar year		
Cleaning/housekeeping	Review at end of calendar year		

## Mentoring for newly qualified analysts:

- Newly qualified database analysts will work half-sized batches initially (typically three sets) with additional opportunities for feedback from senior analysts and prompt technical reviews.
- Newly qualified casework analysts will have required mentoring sessions with a senior analyst
  at critical decision points, including triage/sampling and amplification (typically first three
  casework batches).
- Additional mentoring batches may be added as needed or used for analysts returning from extended leave.

## Assessment of performance monitoring:

- Performance of instrumentation is monitored via ground truth positive and negative controls as well as regular ground truth performance checks for robotic instrumentation.
- Passing criteria for each performance check are defined in appropriate manuals, and 100% compliance is expected.
- A review of maintenance documentation is performed annually.
- Performance of reagents is monitored by verification prior to use in casework/database, as well as evaluation of ground truth positive and negative controls.
- Passing criteria for each verification are defined in the Forensic Biology General Laboratory Maintenance Manual, and 100% compliance is expected.
- A review of verification documentation is performed annually.

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 Performance of analyst lab techniques including blood and semen presumptive tests, extraction, quantification, amplification, and capillary electrophoresis is monitored semiannually by ground truth proficiency tests created and graded by vendor providers.

- Passing criteria are full concordance with expected vendor results, with exceptions made for differences resulting from lab-specific policies that are clearly documented.
- Proficiency test results are monitored by lab QA Manager, DNA Technical Manager, and CODIS administrator as soon as results are available.
- Lab technique potentially leading to contamination is monitored using the staff database in the genotyping software for comparison to amplified casework and database samples.
- Passing criteria is that no interpretable profile (or part of a profile, such as a major or minor component) is 100% consistent with and attributable to a staff member or a known DNA source handled by an analyst (identifiable cross-contamination) when analyzed with the Profile Comparison Tool in GeneMapper ID-X. Note that coincidental matches of up to 90% are often observed in casework complex mixtures of three or more sources
- Contamination is monitored through GMID-X Profile Comparison Tool for all generated casework and database analysis. Contamination assessment forms or QARs are used to document investigation of contamination that is sufficient in quantity for comparison.
- Performance of analyst adherence to interpretation and comparison protocols is monitored through a 100% technical review of all casework and database analysis. In addition, the annual case file review required under FBI QAS includes a further technical review of a range of technical case and database records.
- Scope of the annual case review is defined prior to the annual review and approved by the technical leader.
- Passing criteria for the annual case file review are adherence to laboratory protocols, with exceptions pre-approved and documented, fully correct reported interpretations, and minimal administrative errors (fewer than one per case on average).
- Performance of screening and sampling techniques not addressed by proficiency tests will be monitored by administering a set of ground truth mock casework evidence for processing.
   These samples will be extracted, quantified, and amplified (if necessary) to assess analyst success at the given task.
- Passing criteria are test-specific but generally require accurate results as compared to ground truth, consistent results between participants, correct DNA profiles, and no introduced contamination, as applicable
- Specific answer keys are required for all in-house prepared tests and include the range of
  acceptable answers, including when results must be positive or negative as well as when
  inconclusive may be appropriate, if applicable

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 Performance monitoring related to CODIS software is achieved through a combination of methods.

- Supplemental forms submitted at the same time as analyst proficiency tests will address
  decision-making related to CODIS suitability as well as the calculation of population frequency
  statistics.
- Passing criteria will be identical statistic results for analysts with identical profiles, identical CODIS Forensic Unreviewed entries for analysts with identical profiles, and full agreement in CODIS eligibility with the determination made by the CODIS administrator or alternate.
- Batch uploads, NDIS uploads, and profile deletions are monitored directly via the CODIS software use of Recon reports
- Passing criteria will be 100% concordance between the expected upload/deletion and the Recon report results. Recon reports are regularly monitored by the CODIS administrator and/or alternate.
- In accordance with OSAC recommendations, performance of mixture interpretation protocols
  will be monitored by administering a set of ground truth mixtures to a subset of analysts for
  interpretation.
- Passing criteria will be that all analysts arrive at the same ultimate reported conclusion, that
  analysts perform and document their interpretation with high consistency (no more than two
  minor discrepancies per analyst per mixture), and that the conclusion is not incorrect with
  respect to the ground truth (inconclusive results may be appropriate).
- Performance elements for some laboratory techniques are not suitable for mock
  casework/database ground truth samples. For example, it would not be appropriate to maintain
  human remains for mock casework ground truth reference material. Where ground truth
  solutions are not possible or practicable, witnessing by a second qualified analyst will be the
  preferred method of performance monitoring.
- Passing criteria for direct observations of lab protocols, such as processing human remains, will be that correct protocols are followed, correct documentation is compiled, and any exceptions requiring deviations from protocol are approved in advance.
- Passing criteria for direct observations of negative screening results for blood or semen will be that the primary analyst does not overlook or incorrectly observe test results as negative for any areas subsequently identified by the observing analyst as testing positive.

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# **Professional Development and Continuing Education**

## Forensic FBI QAS Standard 16 / Database FBI QAS Standard 16

All DNA personnel (except for technicians) annually receive a minimum of 8 cumulative hours of continuing education specific to DNA, in accordance with the FBI QAS requirements.

**Note**: <u>Literature reviews</u> can count as one hour of continuing education per article toward the lab wide continuing education requirement but cannot be used toward the FBI QAS mandated 8 hours per year.

Continuing education is documented in the analysts training record in LIMS. The record is reviewed and approved by the discipline supervisor and the DNA technical manager. The following information is required in the record:

- Course title
- Documentation of attendance (may include certificates, agenda/syllabus, etc.). Shall include an attendance list for internal training
- Training date(s) and number of continuing education hours
- Evaluation of course (content, instruction, relevance, etc.)

Additionally, the following documentation is required for continuing education provided by lab personnel:

- A record of the presentation
- The curriculum vitae of the presenter

Programs based on multimedia or internet delivery require written documentation of approval by the DNA technical manager.

Documentation required specifically for internal and/or multimedia education is retained in the Forensic Biology discipline share or designated location.

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# **Contingency Plans for DNA Technical Manager Vacancy and Fewer than Two Full-Time Oualified Analysts**

## Forensic FBI QAS Standard 4.1.6 / Database FBI QAS Standard 4.1.6

#### Contingency Plan for DNA Technical Manager vacancy

Pursuant to the FBI QAS, the laboratory must have a documented contingency plan if the technical manager position is vacated. The plan will be as follows:

- If a current staff member is qualified to serve as DNA Technical Manager, that individual will be appointed as an interim technical manager. If the laboratory has more than one qualified individual, the discipline supervisor will coordinate with top management to appoint an interim technical manager.
  - o Time period: This individual will serve until a permanent replacement is hired.
  - Casework and database analysis: The laboratory may continue to do work and issue reports under this scenario.
- If no current staff members are qualified to serve as the DNA Technical Leader, the DNA Technical Leader from another laboratory will be hired to serve in an interim capacity.
  - Notifications: The NDIS Custodian and State CODIS Administrator must be notified within 5 days if no current staff members are qualified to serve as the DNA technical manager, and a contingency plan shall be submitted to the FBI's NDIS Custodian within 14 days of the vacancy, using the QAS Contingency Plan Notification Form.
  - Time period: The interim DNA Technical Manager will serve until a suitable replacement can be found.
  - Casework and database analysis: The laboratory may not begin new casework or database analysis until an interim technical manager is in place and FBI approval of the contingency plan has been received. Casework or database analyses in which DNA analytical procedures have been initiated prior to the technical leader's vacancy may be completed.

## Contingency Plan for <2 Full-Time Employees who are Qualified Analysts

Pursuant to the FBI QAS, the laboratory must have a documented contingency plan if the number of qualified analysts falls below two full-time employees who are qualified analysts.

This policy affects both casework and database functions, and these functions must each be considered. If two full time analysts are each qualified in both casework and database analysis, then this policy does not take effect.

- If either casework or database does not have two full time qualified analysts, then those work functions are affected by this policy.
  - Top management will coordinate with the DNA Technical Manager to hire and train new analysts, re-assign previous qualified analysts working in other laboratory

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- disciplines, and/or notify customers of options for having analysis performed by a vendor laboratory without possible CODIS entry.
- Notifications: The NDIS Custodian and State CODIS Administrator must be notified if the number of database-qualified or casework-qualified analysts falls below two full-time employees, using the QAS Contingency Plan Notification Form.
- Casework and database analysis: The laboratory may not begin new casework or database analysis until FBI approval of the contingency plan has been received.
   Casework or database analyses in which DNA analytical procedures have been initiated may not be able to be completed if the number of qualified analysts falls below two full-time employees who are qualified analysts.

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# **Outsourcing and On-Site Visits**

## Forensic FBI QAS standard 17 / Database FBI QAS Standard 17

Outsourcing of DNA casework must follow applicable requirements of FBI QAS Standard 17 (current version). Because details may vary between outsource contracts, this section of the Guidance Document will be updated as needed to reflect the procedures specific to the outsource contract.

This procedure has been updated to reflect the procedures specific to outsourcing with DNA Labs International.

## Requirements to be met before vendor laboratory begins analysis.

In order for the Alaska Scientific Crime Detection Laboratory (AK SCDL) to maintain compliance with FBI QAS Standard 17 (current version), several requirements must be met prior to the vendor laboratory beginning its analysis of items which ultimately may be entered into CODIS. This manual defines procedures and the required documentation associated with Standard 17 compliance, for cases analyzed and reported at a vendor laboratory for the purpose of subsequently taking ownership of the vendor laboratory's work product, including but not limited to:

- Extracts which could later be amplified at AK SCDL
- DNA profiles which may later be entered into CODIS
- DNA profiles which may later be interpreted for compared against DNA profiles generated at AK SCDL.

Note: These procedures are not required for vendor laboratory analysis where the AK SCDL does not subsequently take ownership of extracts or DNA profiles.

## Vendor laboratory compliance with FBI QAS and Accreditation Requirements (FBI QAS Standard 17.1)

- The vendor laboratory must provide documentation of compliance with FBI QAS standards and accreditation requirements of federal law.
- The AK SCDL Technical Leader will review the vendor laboratory's compliance with these standards as part of the on-site visit procedure (see below)
- The AK SCDL will retain documentation of audit and assessment records and certificates.
- The vendor laboratory will provide updated assessment and audit reports as they become available, for the duration of the contract.

The AK SCDL DNA Technical Leader will review and approve the technical specifications of the outsourcing agreement with the vendor laboratory before analysis begins. (FBI QAS Standard 17.2.1)

The AK SCDL will retain documentation of the approved technical specifications.

#### On-site Visit Procedure for vendor laboratory performing forensic casework (FBI QAS Standard 17.4)

- The on-site visit must happen prior to the vendor lab beginning casework, and annually thereafter for the life of the contract.
- If available, the laboratory shall review and evaluate the most recent (within one year) on-site visit performed by a designated FBI employee.
  - Review of the on-site visit must include review of the vendor laboratory's compliance with federal and FBI QAS standards
- Documentation for the on-site visit must include:

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- The date the on-site visit was performed
- A summary of the visit
- The personnel who performed the on-site visit
- Acceptance by the Technical Leader
- If no FBI on-site visit is available for review for a future contract, an on-site visit conducted by another NDIS laboratory using the same technology, platform, and typing amplification test kit may be sought for review.
- If no alternative is available, the Technical Leader will design and document an on-site visit protocol prior to performing an on-site visit.

## Vendor laboratory must designate a point of contact

• The DNA Technical Leader or designee will be the point of contact for the AK SCDL.

## Vendor laboratory must provide a sample case file for review

• This may be used to aid in developing a specific review procedure.

## Technical review procedure for outsourced casework

Outsourcing of DNA casework must follow applicable requirements of FBI QAS Standard 17.3 Because details may vary between outsource contracts, this section will be updated as needed to reflect the procedures specific to the outsource contract.

The AK SCDL takes ownership of outsourced casework only when it will enter and search a DNA profile in CODIS from data generated by a vendor laboratory, or when it will use samples, extracts, or materials from the vendor laboratory for the purposes of forensic testing. Technical and administrative review of DNA casework will be conducted by qualified DNA analysts at the AK SCDL following the checklists provided either in this document or as separate controlled document.

If the technical reviewer finds any issues with an outsourced case, those issues should be brought to the attention of the DNA Technical Manager or designee, who will coordinate efforts with the vendor laboratory to resolve the issues. Profiles may not be entered into CODIS until technical issues have been resolved.

Together with the vendor laboratory review checklists, this section serves as guidance for the review of vendor laboratory data, reports, and documentation specific to cases submitted for analysis to DNA Laboratories International (DLI), for evidence submitted by law enforcement agencies.

TL = Technical Leader

FB sup = Forensic Biology supervisor

AK SCDL TR = qualified technical reviewer at Alaska Scientific Crime Detection Laboratory The AK SCDL technical reviewer must be:

- Qualified in the technology (STR)
- Qualified in the platform (3500 xl genetic analyzer)
- Qualified in the typing test kit (GlobalFiler, including mixture interpretation)
- Participating in the AK SCDL's proficiency testing program

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#### **Initial Case Assessment**

As a part of the initial assessment of each returned case, a FB sup or TL will check the following:

- All DLI documentation for cases, controls, and reviews is downloaded to the laboratory network.
- DLI issued a report for each submitted case, and the report has been added to the LIMS
- DLI releases results directly to the submitting agency as well as AK SCDL.
- Appropriate submitted evidence was analyzed for each submitted case
- If the case has potentially CODIS eligible data,
  - Relevant elimination samples must be requested from the submitting agency. This may be communicated verbally or via e-mail, but documentation must be maintained in the LIMS case file.
  - The RLS and any available case information must be reviewed to assess whether the profile would be suitable for CODIS entry. Additional information may be needed from law enforcement; this would then be documented in the LIMS case activities.
- Typically, the AK SCDL does not take ownership of outsourced casework that does not yield
  potentially CODIS eligible profiles. Cases identified as not having potentially CODIS eligible
  results will not routinely undergo technical review. Exceptions would be for cases with extracts
  that may require amplification at AK SCDL, or cases with DNA profiles to be compared against
  reference samples run at AK SCDL, regardless of CODIS eligibility.

## **Technical review by AK SCDL Technical Reviewer**

Technical review of reports with possible CODIS profiles and their corresponding controls will be performed by AK SCDL TR, who reviews report elements as listed on Outsource Casework Review Checklist, including:

- a. General: Batch/Central Log/ Control documentation includes a list of all applicable related cases. Any troubleshooting or quality issues raised in the batch controls are also appropriately documented.
- b. Extraction: Each set of concurrently extracted samples includes at least one reagent blank. All reagent blanks are quantified. At least one reagent blank per extraction set is amplified. Any contamination issues with reagent blanks have been documented and satisfactorily investigated.
- c. Quantitation: standard curves have appropriate R<sup>2</sup> and slope values (and/or other QA parameters, as applicable); NTC values are appropriate, and reagent blanks were quantitated.
- d. CE: reagent blanks, allelic ladders, positive controls, and negative controls are amplified with expected results obtained; ILS is confirmed for all controls.
- e. Case files: all tested items (or probative fractions) are addressed, the AK SCDL TR agrees with the reported conclusions, the conclusions are supported by the associated data, and the agency case and item numbers are correct.

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f. If AK SCDL does not agree with or finds issues to be addressed in the report, AK SCDL TR notifies TL and works with DLI to resolve the concern.

## **CODIS** entry of eligible profiles

- 1. Upload of profiles is performed by the AK SCDL TR, who checks the following items prior to CODIS upload:
  - a. Case was not determined to be No Crime Occurred or Unfounded
  - b. Evidence suitable for CODIS entry based on location, evidence type, etc.
  - c. Correct specimen category identified.
  - d. Profile is suitable for comparisons under current interpretation guidelines in Forensic Biology Procedure Manual.
  - e. Profile meets MME/MRE eligibility requirements specified in the CODIS manual
- 2. AK SCDL TR uploads profile to CODIS (if appropriate).
- 3. AK SCDL TR completes their section of the case checklist. The checklist and the CODIS specimen detail report are submitted to another analyst, FB sup or TL for final case assessment.

#### Final case assessment

The final case assessment is typically performed by the TM or FB sup but can be performed by an AK SCDL CODIS qualified analyst, if designated. The final case assessment includes the following elements:

- a. Review of CODIS entry, including the profile, specimen category, and NDIS/SDIS eligibility.
- b. Scan the completed and reviewed CODIS specimen detail report to the case file in LIMS.
- c. Notify the law enforcement agency that the profile has been entered into CODIS. This does not require a report but must be documented in the LIMS case file.
- d. Ensure that DLI reports and case notes are retained in LIMS
- e. Create and assign any CODIS hit letter requests that arise from CODIS entries. Hit letters will be released as they are completed.
- f. Scan the completed review documentation to the case file in LIMS

#### Actions arising from technical review and/or CODIS entry:

• Any issues discovered during initial case review at AK SCDL or during technical review or CODIS entry will be routed through the TL to the technical point of contact at DLI. The TL will review DLI's responses to ensure that quality concerns are adequately addressed. If corrected reports are issued, either the TL or designee will distribute to the submitting law enforcement agency. If corrected case documentation or control documentation is provided, the TL will ensure that it is added to AK SCDL documentation archives, either in the LIMS if case specific, or the lab network if more general, as appropriate.

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## **Overview of DNA Labs International documentation**

All documentation necessary to complete a technical / ownership review must be submitted to AK SCDL and will be retained following review. This documentation typically includes:

- Report
- Case File (PDF containing case-specific data, control data, and administrative documentation)
- Electronic data (zip file; only needs to be examined if the above documents do not allow for full technical review)

Based on a sample case file provided by DLI, the Case File contains the following:

- Allele table for casework samples
- Search results against DLI employees
- Population frequency statistics printouts
- Extraction worksheets
- Quantification plate layout
- Quantification standard curve and quality metrics summary page
- Quantification results table
- Amplification plate layout
- Deviation request form was included in file adjacent to relevant procedure)
- CE plate layout
- Positive amp control electropherograms, with ILS
- Negative amp control electropherograms, with ILS
- Allelic ladder electropherograms, with ILS
- Reagent blank electropherograms, with ILS
- Casework item electropherograms, with ILS
- Amplification worksheet
- Preliminary Analysis worksheets (documentation of evidence images, biological screening, and sampling)
- Reagent worksheet
- Case Submission Form (contains customer specifications)
- Shipping information / Chain of custody
- Technical and Administrative review documentation

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#### Notes:

- The sample case file negative control electropherograms did not include primer peaks, but checking primer peaks is a requirement for AK casework. If AK case file printouts of negative controls and reagent blanks do not include primer peaks, they will need to be checked by importing data into GMID-X.
- The sample case file included a deviation request form which was adjacent to relevant procedure documentation.
- The sample case file provided did not include a positive extraction control, but one is required for Alaska casework. Extraction positive control profile:

Loci	Allele 1	Allele 2	Allele 3	Allele 4
D3S1358	15	17		
vWA	15	18		
D16S539	11	13		
CSF1PO	11	12		
TPOX	8	10		
Yinde1				
Amelogenin	X			
D8S1179	13	15		
D21S11	28	31.2		
D18S51	15	16		
DYS391				
D2S441	10	11		
D19S433	13	14.2		
TH01	7	10		
FGA	22	24		
D22S1045	15			
D5S818	12	13		
D13S317	8	9		
D7S820	10			
SE33	21.2	25.2		
D10S1248	14	15		
D1S1656	11	15		
D12S391	18	20		
D2S1338	23	25		

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# Management and Use of DNA Elimination Databases

As a part of its quality assurance practices, the laboratory maintains a searchable database of elimination DNA profiles. These profiles are retained in the CODIS software and/or the GeneMapper ID-X (GMID-X) for use with the profile comparison tool.

#### Purpose of the elimination databases

Elimination database profiles are searched against forensic casework and database profiles to increase the chance that contamination introduced during DNA analysis will be detected and will not be inadvertently uploaded to NDIS, as well as to assess the performance of samples used as internal positive controls.

## Generation of the elimination database

The elimination databases consist of the following elements: reference samples (such as buccal swabs), the raw data generated from analysis of those samples, and the DNA profiles resulting from genetic analysis.

The elimination database is comprised of two groups

Group A - CODIS and GMID-X (STR profiles)

- Laboratory personnel who have routine direct contact with evidence / evidence outer packaging
- Laboratory personnel who have routine direct contact with forensic biology laboratory workspaces

Group B - GMID-X only (STR and Y-STR profiles)

- Laboratory personnel and submitting agency representatives who have occasional contact with evidence / evidence outer packaging and/or forensic biology laboratory workspaces
- Visitors and vendor staff who may enter the forensic biology laboratory workspaces
- Profiles attributable to consumable manufacturing staff
- Unattributable contamination profiles
- Positive control sample profiles (such as body fluid standards and positive controls associated with amplification kits)
- Volunteer samples for validation and QA/QC purposes

Individuals newly added to the elimination database are typed with the current STR and Y-STR kits, as applicable.

When amplification kits with additional loci are brought online, laboratory personnel who have routine direct contact with evidence / evidence outer packaging or who have routine direct contact with forensic biology laboratory workspaces should be typed with the new amplification chemistry and have their elimination profiles updated in the relevant elimination databases, as applicable.

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Other previously typed individuals do not need to be re-typed with new typing kits except for specific instances of troubleshooting.

## Management of elimination database

*Identification information forms:* 

- Prior to upload of a profile to the elimination database, all individuals providing samples for the elimination database must receive and sign the Authorization to Obtain, Use, and Store Confidential Identification Information Form.
- Completed forms are submitted to a CODIS administrator or the DNA Technical Manager, who assigns the individual a unique code which is then noted on the authorization form.
  - Coding convention is that the sample will have a category and a number (such as Staff 33 or Vendor Qiagen 2).
- Completed forms are retained on the secure laboratory network or designated secure electronic location. Profiles are not named with personally identifiable information, but they can be tracked back to the individual by way of the Identification Information Forms.

#### Personnel with read access to the elimination databases:

All CODIS-qualified authorized casework and database analysts have access to the staff profiles uploaded to the Combined DNA Index System (CODIS). All casework- or database-authorized analysts who have access to GMID-X software have access to the profiles in the Profile Comparison database.

#### Personnel with version control of the elimination databases:

Profiles are uploaded to the State DNA Index System (SDIS) by CODIS administrators and once uploaded, can only be modified by CODIS administrators. Profiles are uploaded to the GMID-X Profile Comparison database by DNA Technical Leader or supervisors and cannot be modified in the GMID-X software once they are uploaded.

## Security:

Elimination samples are retained in secure forensic biology evidence storage space, with controlled access limited to authorized personnel. Raw data from analysis of these samples is stored on the secure laboratory network, which is backed up nightly and only accessible to authorized users. Both CODIS and GMID-X are password-controlled and require authorization prior to access.

#### Retention times:

Elimination database samples are stored indefinitely in the Forensic Biology evidence locker room. Raw data from analysis of elimination samples is retained indefinitely on the laboratory network or other designated secure location. Because evidence may be analyzed well after initial collection, submission, or processing, elimination profiles are stored indefinitely in GMID-X, unless profile removal is requested by the individual. Profiles from Group A individuals are removed from CODIS when an employee is no longer employed by the laboratory.

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#### Annual review of database contents:

As a part of the annual quality review, the GMID-X and CODIS databases will each be reviewed to ensure that all relevant individual profiles have been typed and uploaded to appropriate databases, and staff profiles for individuals no longer working in the discipline are removed from CODIS.

#### Searching, evaluation, and resolution of elimination database matches:

Refer to the Forensic Biology Procedure Manual and CODIS Manual for procedures regarding search, match evaluation, and reporting matches to elimination database profiles.

## Search policy:

For purposes of quality assurance, internal positive control samples and unidentified profiles are routinely searched against the elimination database in GMID-X. Profiles that cannot be confirmed against another related sample (such as a previously typed sample from the same individual or a body swab against an owner reference profile) are treated as unidentified profiles. This search happens prior to submitting a case for technical review and/or prior to NDIS upload, as applicable. Since these potential matches should be caught in GMID-X, the procedures are written specifically to the GMID-X

## Match evaluation policy:

When data suitable for comparison is matched to an elimination database profile, or when an interpretable source of contamination cannot be identified, analysts will use appropriate quality assurance forms to document their evaluation of potential contamination. Depending on the nature and severity of the incident, this could be a Contamination Assessment Form and/or a Quality Assurance Review. Potential contamination issues should be resolved through retesting of evidence where possible.

#### Resolution of elimination database match policy:

When a match to an elimination database profile has been identified and attributed with certainty to a known individual, that individual should be notified, if possible. For individuals outside the laboratory, (e.g., nurses, vendors, consumable manufacturers, etc.) this communication should be routed through discipline management. For individuals within the laboratory, the DNA Technical Manager will ensure that appropriate personnel are notified. When matches to an elimination database profile are determined to be inconclusive, or when the exact source of point contamination cannot be isolated to a single vendor, no match will be reported.

#### Reporting of elimination database matches:

Reporting procedures in the FBPM are written for instances in which a source was identified prior to release of the report. For matches identified after the initial report has been distributed, the association must be communicated to the submitting agency.

## **Amplification Cycling Parameters**

```
GlobalFiler
```

Program: gf-cswk

Max ramping mode is used for amplification

95°C for 1 minutes, then:

ramp 100% to 94°C for 10 seconds ramp 100% to 59°C for 90 seconds for 29 cycles, then:

60°C for 10 minutes 4°C hold

PowerPlex Y23 (~1:40 amplification time)

Program: Y23-30cyc

Max ramping mode is used for amplification

96°C for 2 minutes, then:

ramp 100% to 94°C for 10 seconds ramp 100% to 61°C for 1 minute ramp 100% to 72°C for 30 seconds for 30 cycles, then:

60°C for 20 minutes 4°C hold

## **GlobalFiler Express**

HOLD

95°C for 1 minute, then:

26 CYCLES of 94°C for 3 seconds 60°C for 30 seconds

**HOLD** 

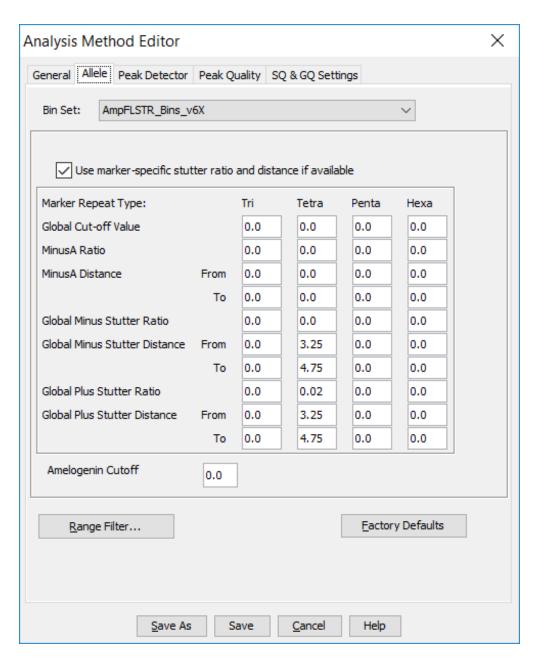
60°C for 8 minutes

HOLD 4°C

## **Analysis Method Settings**

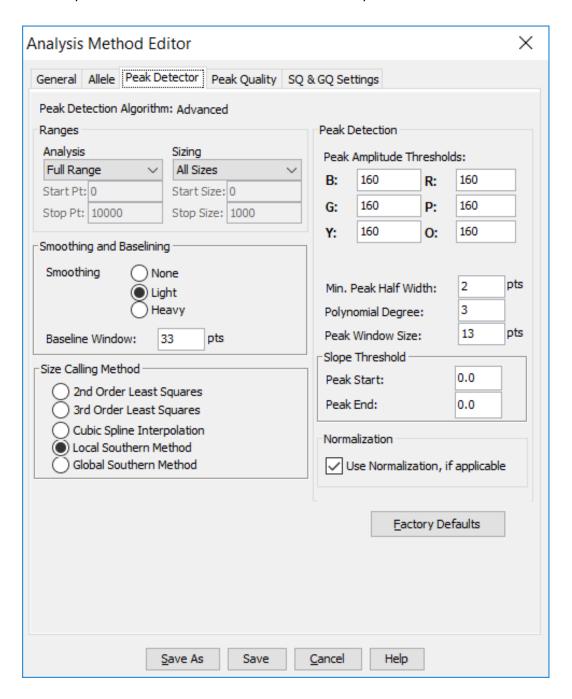
The settings for the Analysis Methods are viewed by selecting GeneMapper ID-X Manager under the Tools drop-down menu, then clicking on the Analysis Methods tab then double clicking to select a particular Analysis Method. These methods shall not be modified. New methods shall only be created or modified with permission from the DNA Technical Manager.

## GlobalFiler Casework Allele Tab Settings



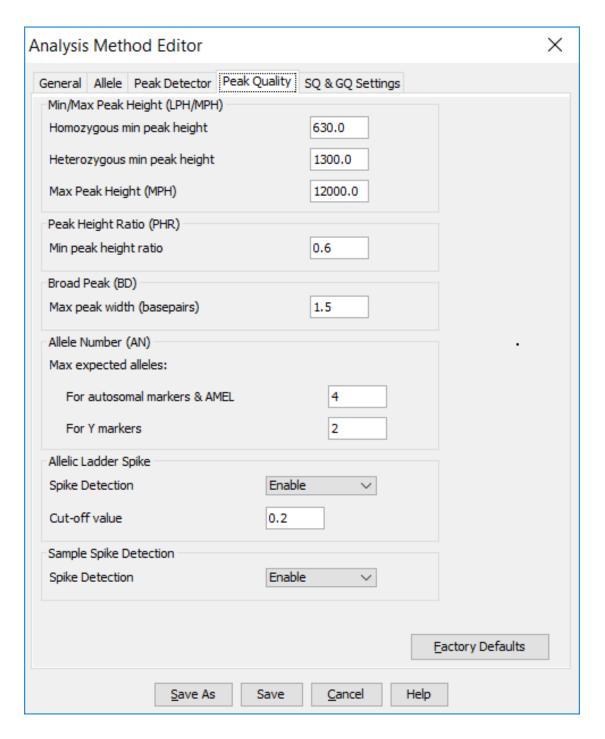
#### GlobalFiler Casework Peak Detector Tab Settings

The Analytical Threshold for all GlobalFiler casework analysis is 160RFU.



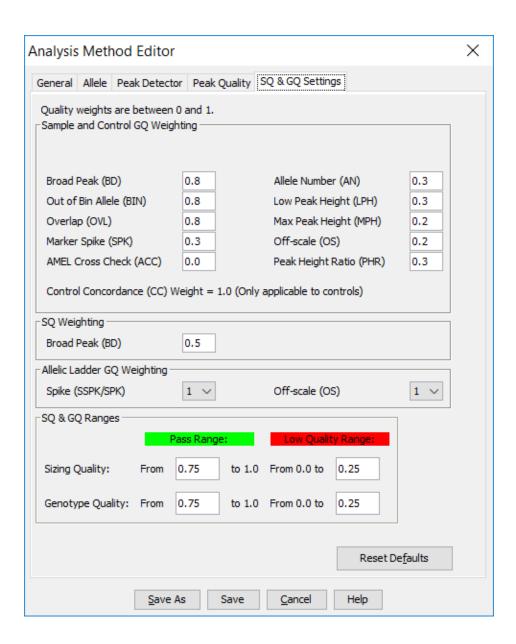
## GlobalFiler Casework Peak Quality Tab Settings

These settings are not relevant in analysis of any samples where the sample type is set to Negative Control.

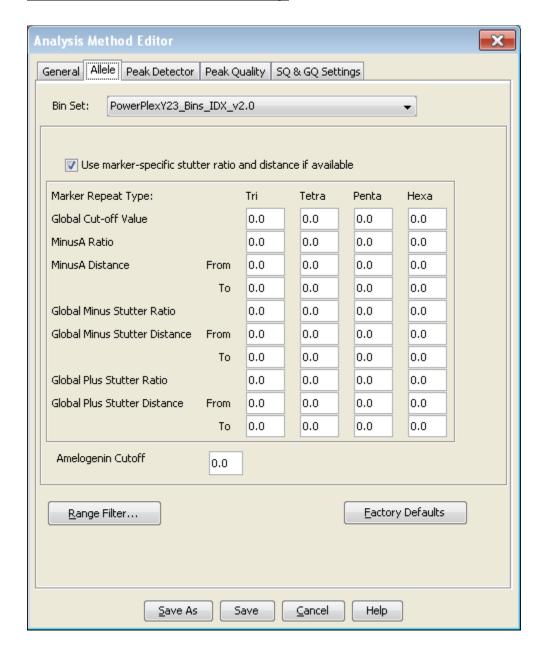


## GlobalFiler Casework SQ and GQ Tab Settings

These settings are not relevant, as all samples are currently manually reviewed and interpreted, regardless of flagging.

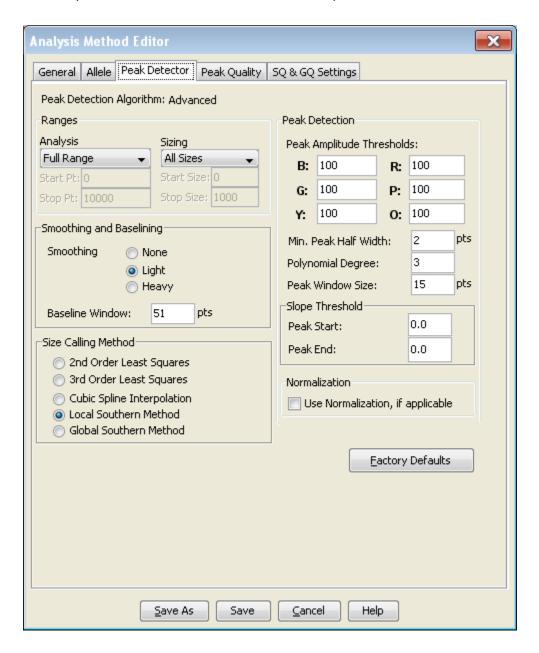


## PowerPlex Y23 Casework Allele Tab Settings



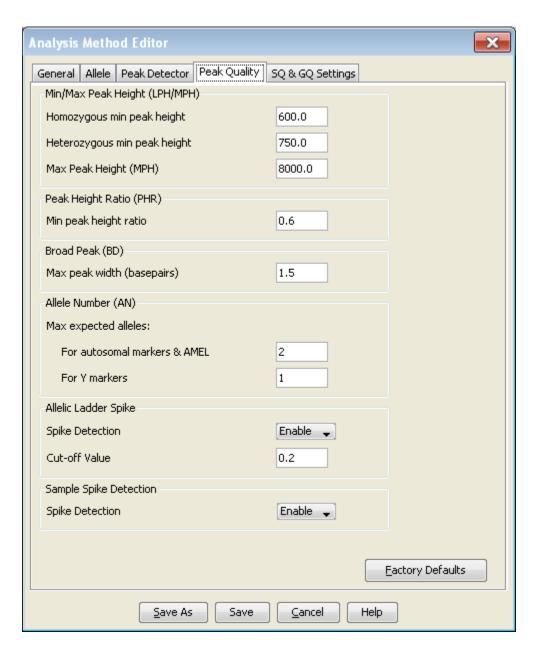
## PowerPlex Y23 Casework Peak Detector Tab Settings

The Analytical Threshold for all Y-STR casework analysis is 100RFU.



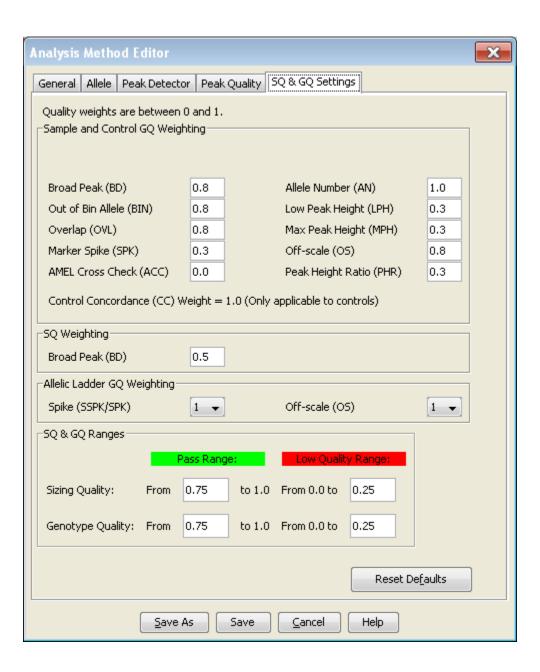
## PowerPlex Y23 Casework Peak Quality Tab Settings

These settings are not relevant in analysis of any samples where the sample type is set to Negative Control.

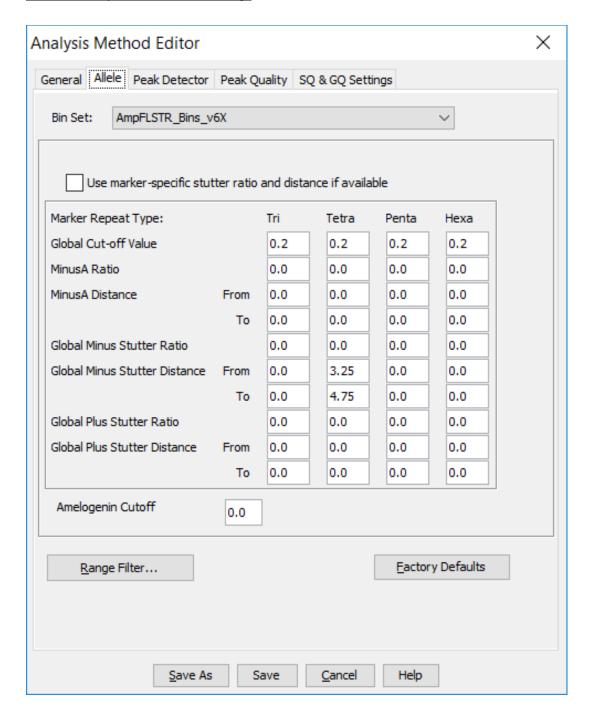


## PowerPlex Y23 Casework SQ and GQ Tab Settings

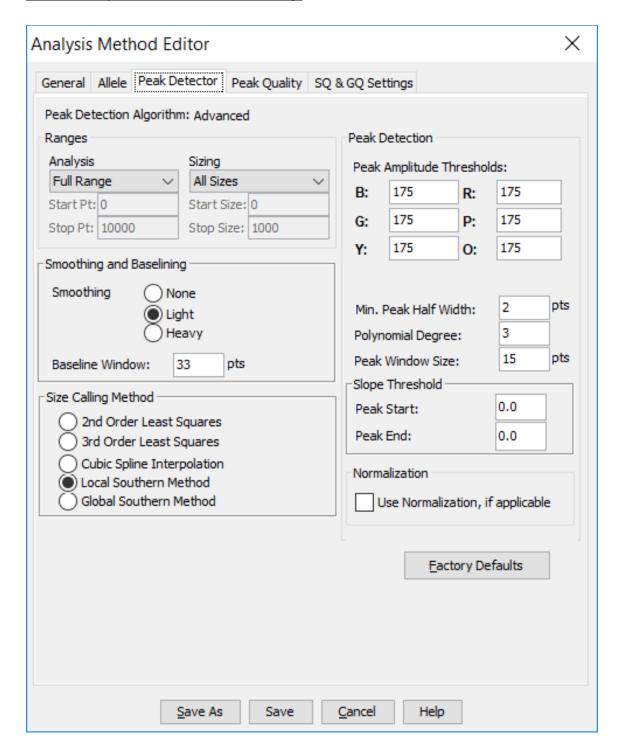
These settings are not relevant, as all samples are currently manually reviewed and interpreted, regardless of flagging.



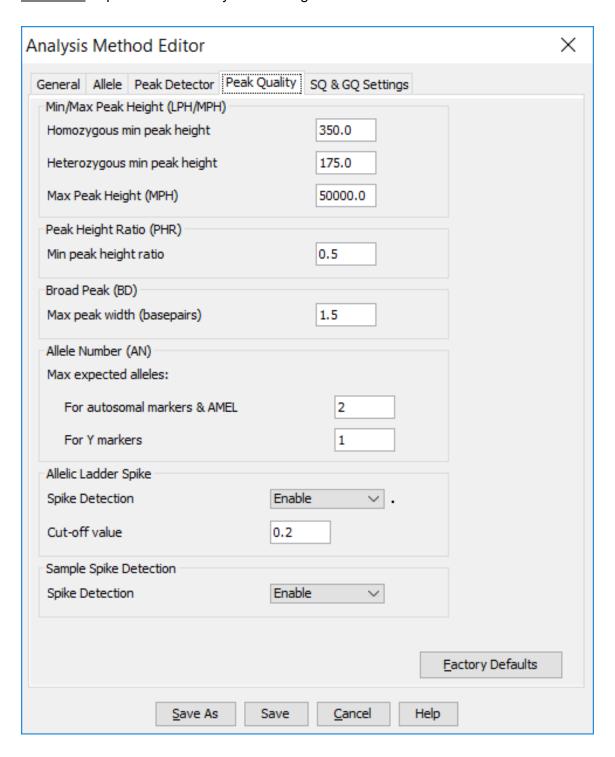
## GlobalFiler Express Allele Tab Settings



## GlobalFiler Express Peak Detector Tab Settings

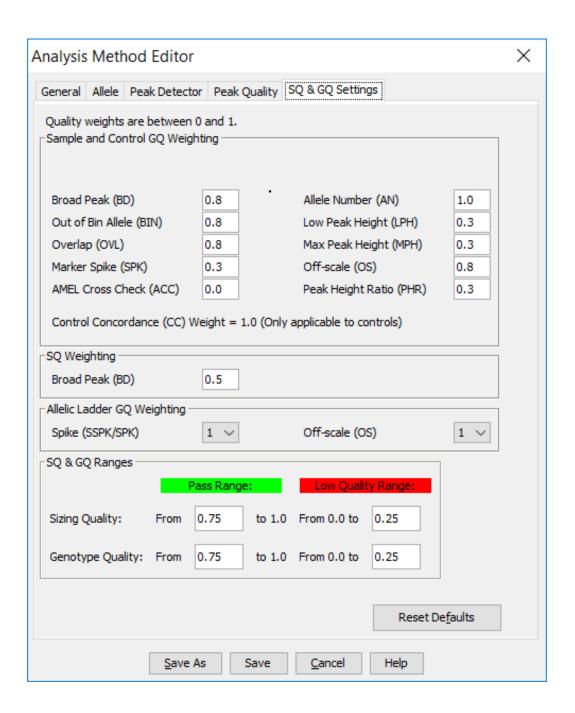


## GlobalFiler Express Peak Quality Tab Settings



#### GlobalFiler Express SQ and GQ Tab Settings

These settings do not vary and are not relevant, as all samples are currently manually reviewed and interpreted, regardless of flagging.



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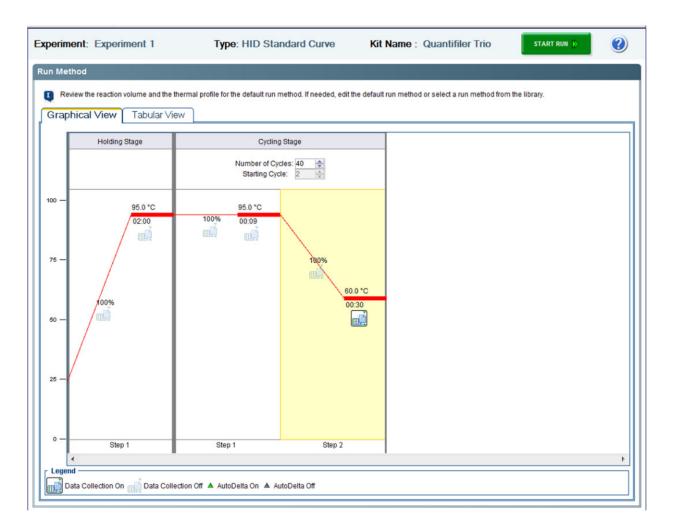
## RAPID HIT

These threshold settings are programmed into the GeneMarker HID STR Human Identity Software used in conjunction with the RapidHIT instrument:

System Threshold	RapidHIT ID ACE GFE Sample Cartridge
Analytical threshold	35 RFU
Stochastic threshold (inconclusive	All loci 91 RFU, except:
homozygous or IHO flag)	TPOX = 105
	Y indel = 35
	DYS391 = 35
	TH01 = 140
	SE33 = 105
	D12S391 = 105
	D2S1338 = 105
Minimum peak height ratio threshold	40%
(heterozygote imbalance or IMB flag)	
Stutter filters	20%
Locus-specific filter	20%
Ploidy threshold (maximum number of	2
expected peaks)	
Global filter (between loci)	20%
Minimum off-ladder intensity	30 RFU

## **Quantifiler Trio Cycling Parameters**

(as defined in the Quantifiler HP and Trio DNA Quantification Kits User Guide)



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## Reinterpretation of Data Typed with a Legacy Amplification Kit

## Forensic FBI QAS standard 6.7 and 6.8

On occasion, the laboratory may be asked to revisit a case where analysis has been performed using a legacy amplification kit, defined as an amplification kit no longer covered by the current SOP (e.g., PowerPlex 16 or Profiler / CoFiler). Examples of this situation would include:

- Evaluation of a moderate stringency match in CODIS
- Submission of new questioned evidence in an old case
- Submission of new reference samples in an old case

Legacy data is suitable for comparisons if it can be used "as is" – in other words, as originally interpreted by the analyst. Typically, this would include:

- Single source questioned profiles
- Single source major component profiles from questioned mixtures
- Single source deduced profiles
- Two-source indistinguishable mixtures where a stochastic threshold was in place
- Reference profiles
  - While most reference profiles will not need to be retyped, it may be beneficial to retype reference samples when complex mixture interpretation is required in the current amplification kit.

<u>Reinterpretation of legacy data is not permitted:</u> Reinterpretation includes assessing or evaluating allele calls or genotype calls (including potential for drop out), changing assumptions used, or removing loci from statistical calculations.

- Owing to extensive changes in mixture interpretation policy over time, indistinguishable mixtures in legacy data with more than two sources as well as all indistinguishable mixtures interpreted without a stochastic threshold would require reinterpretation.
- Exceptions may be possible if the analyst and technical reviewer have been proficiency tested in the legacy kit within two years of the reinterpretation request. However, this would require documented and technical manager approved review of relevant validation studies and legacy SOPs.
- Consult with the Technical Manager first if a situation arises that involves legacy data
  requiring interpretation. If reinterpretation of legacy data is requested, the analyst should
  discuss options with the requesting agency, possibly including re-amplification of previously
  generated extract.
- Most CODIS profiles generated by legacy kits do not require reinterpretation and can be used "as is", as described above. However, some CODIS profiles from previously analyzed casework may require reinterpretation for comparison. When CODIS profiles that would require reinterpretation of legacy data are encountered, notify the CODIS Administrator or alternate CODIS Administrator. If the Administrator agrees that the profile would require reinterpretation for comparison, then the profile will be removed from CODIS.

# **Appendix A: Revision History**

Location	Revision made
throughout	Corrections to grammar and spelling, minor (non-
	substantive) updates to language, addition of
	hyperlinks.
	Updated QRF to QAR.
	Updated references to FBCP and other discipline manuals.
Definitions, page 2	Added that database batch name date could also
	be batch set-up date.
Retaining technical records and	Added new section
casework DNA extracts	Added New Section
Literature Review,	Added that some literature reviews should be
previously page 4	published within the last 1-2 years.
Extended Absence,	Added that this policy also applies when an analys
previously page 5	misses a scheduled proficiency test.
	Added information on relating individuals and
Case Management,	offenses to a request and that requests may be
previously page 6	pended while awaiting additional evidence and/o
	information from a submitting agency.
Case Management	Added details on designating an item as a kit
Case Management, previously page 7	evidence type when kit type samples are not
previously page /	submitted as a kit.
Case Management,	Added to advise Track-Kit administrator when a
previously page 8	previously non-viable kit becomes viable.
Case Management,	Removed steps to relate evidence to CODIS
previously page 9	Interstate and CODIS Communication requests
	Added that evidence may be sent to another
	laboratory at the request of the submitting
Evidence Retention,	agency.
previously page 11	
	Added reference to Forensic Biology Procedure
	Manual for consumption policies.
	Added that annual quality review is under the
	direction of the TL.
Annual Review,	
previously page 12	Added that annual case file review scope is
	"approved" by TL.

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	Added that review includes continuing education.
Outsourcing, previously page 22	Revised section to include procedures specific to
	DNA Labs International
Elimination Databases,	Updated to reflect that elimination profiles are
previously page 25	only stored indefinitely in GMID-X, not CODIS.