IN RESPONSE TO

State of Alaska Department of Safety

Request for Proposal

RFP # 2018-1200-3757

Due Date: August 17th 2017

1:30pm

Serological Research Institute

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Serological Research Institute

Dear Ms. Mash,

On behalf of the Serological Research Institute (SERI), I would like to thank the State of Alaska for the opportunity to propose the Sexual Assault Kit (SAK) elimination plan outlined in our response to this RFP.

SERI has the capability to satisfy all of the requirements outlined in the Request for Proposal # 2018-1200-3757. All of the information contained within our response is true and accurate. SERI welcomes the opportunity to aid the state of Alaska with the testing of 550 sexual assault kits by providing the analysis of 50 kits every sixty days for the life of the contract. SERI will adhere, without exception, to all of the technical testing Requirements as outlined in RFP #2018-1200-3757 section three "Scope of Work and Contract Information." A detailed plan and explanation of how SERI will conform to all of the technical testing requirements is outlined in our response.

A forensic DNA laboratory is an important investigative tool, and like any effective tool, certain functions must be readily available to the user. In the field of forensics these functions come in the form of services. A quality forensic laboratory should provide, at a minimum, case consultations, superior sensitivity, state of the art technology, fast turnaround times, analyst availability, and the ability to interpret mixtures. Without these services, a laboratory is more likely to be a hindrance than a reliable and effective source of useful information. SERI is a well-respected investigative tool used by the FBI, U.S. Military, and hundreds of police agencies across the country. Our forensic DNA services have not been confined to the United States but have extended into agencies across the world including Israel, the United Kingdom, Australia, Canada, Mexico, Puerto Rico, Guam, Samoa and many others. Our thirty-nine years of continued service in this competitive market has taught us how to lead the industry in customer service and continuously push the frontline of cutting edge forensic DNA analysis forward.

Many small startup forensic laboratories close their doors after a few years because they do not provide the quality of services required to compete with government laboratories. SERI, however, has maintained a steady flow of business for thirty-nine years by offering superior services to our clients, many of whom have access to government laboratories. SERI has been a pioneer in the industry since conventional serology was the standard forensic practice and has continued to be a pioneer in all of the technological advancements introduced throughout the past three decades. Our laboratory is committed to remaining at the forefront of forensic DNA and body fluid analysis. We routinely accept cases that other laboratories refuse to process due to their difficulty. Agencies know that we can get results were others cannot. Constantly working on difficult cases makes the analysis of more routine case work, like the processing of SAKs, straightforward, which is reflected in the pricing we have offered to the State of Alaska.

Serological Research Institute

The Serological Research Institute has provided forensic biology services since 1978. Our long-term success can be attributed to our ideology that quality work produces quality results. We would welcome any opportunity to extend to you the same unsurpassed quality and expertise that numerous agencies throughout the United States have experienced.

I look forward to partnering with the State of Alaska and providing the Department of Public Safety the highest quality forensic services available in the field of forensic biology.

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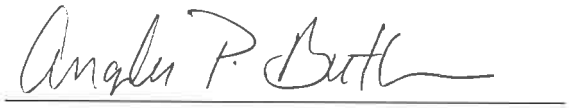

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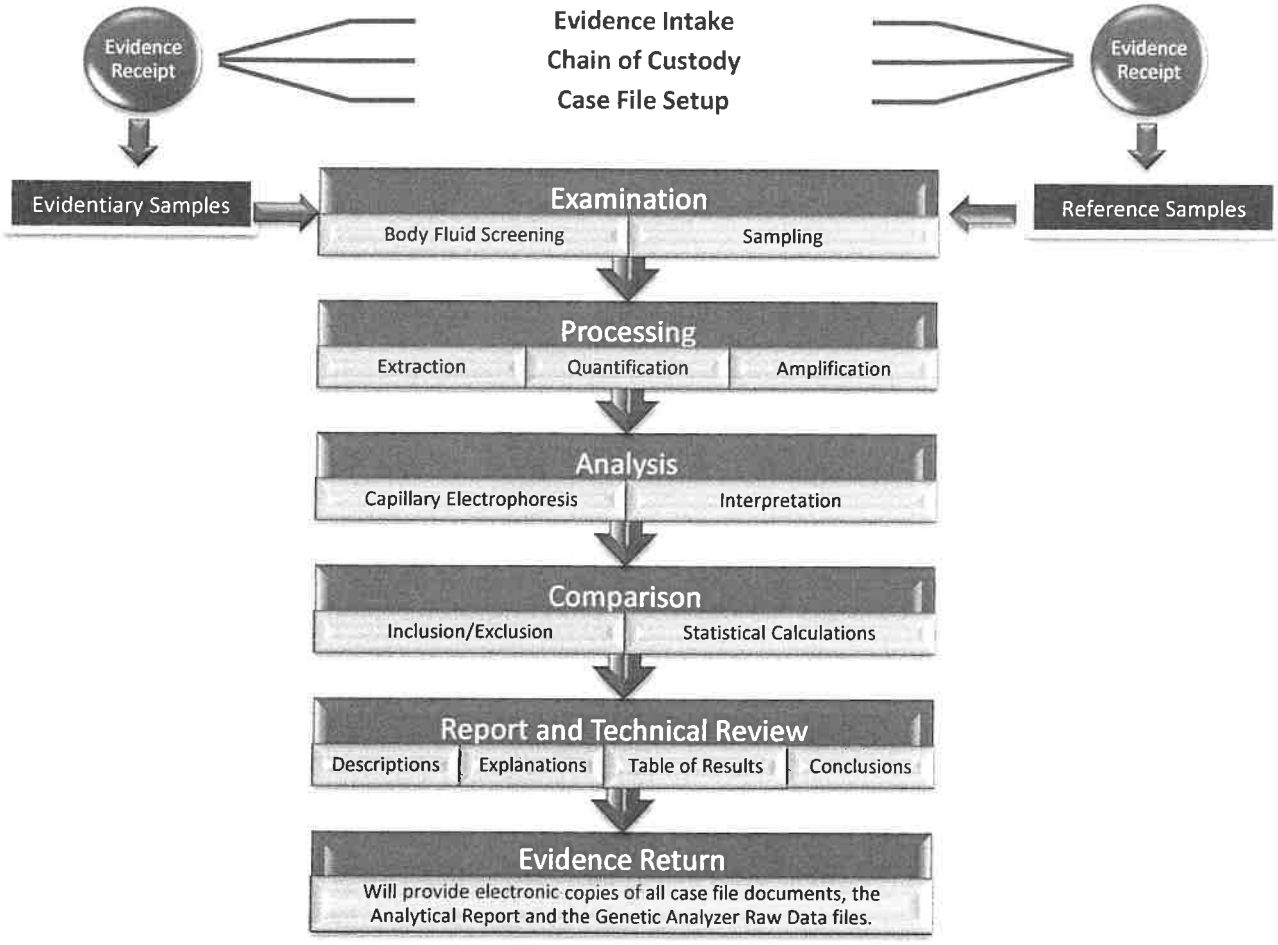
Serological Research Institute

Proposed Approach and Methodologies

The Serological Research Institute is an ASCLD/LAB-International (ISO/IEC 17025:2005) accredited forensic biology/DNA laboratory with a scope of accreditation in Forensic Biology, including body fluid identification, nuclear and mitochondrial DNA testing. SERI is the only private DNA ASCLD/LAB-International accredited laboratory in California.

In the interest of providing the State of Alaska with all of the services outlined within the Request for Proposal document, SERI proposes the following approach to the DNA analysis of forensic casework samples, outlined in the flow chart below



Evidence Handling

SERI is located at 3053 Research Drive, Richmond, California 94806 and will accept and return evidence via overnight shipping by a third party insured mail carrier capable of maintaining chain of custody.

SERI follows strict, documented chain of custody procedures, as required by our ASCLD/LAB-International accreditation, and will take every precautionary measure to ensure a valid and strong chain of custody. SERI will include the name of the individuals submitting or receiving evidence, the date of the evidence exchange, a verified list of every evidence item submitted or returned, and shipping label tracking information on its own chain of custody form. The date the evidence was examined and the identity of the analyst who retrieved the evidence for processing will also be recorded while the case is active. A copy of this chain of custody form will be provided to the State of Alaska Scientific Crime Detection Laboratory (SCDL) upon the completion of each case. In addition, SERI will fill out any chain of custody form required by the SCDL for its records. All submitted and returned evidence items will be checked for proper seals.

Any remaining DNA extracts from questioned samples will be dried down using DNA Stable LD™ and packaged in individual labeled foil envelopes (with desiccant) and repackaged in the original SAK. All SAK will be returned, sealed, in the original packaging. All shipping cost will be covered by SERI.

Examination

SERI maintains separate working areas for evidence examinations, reference sample processing, serology testing, M-Vac® DNA Collection System, DNA extractions, quantifications, amplifications, and capillary electrophoresis. The evidence examination areas are further separated into analysts' work bays, dedicated Alternate Light Source (ALS) area, large item screening areas, and a reference sample processing area where questioned samples are forbidden. To more efficiently manage and adhere to the testing timeframe and to maintain a separate testing track from the questioned samples, reference sample testing will be conducted in batches independent of evidence sample testing.

Female and Male Sexual Assault Kits

No more than half (50%) of any sample will be consumed within a SAK. Electronic copies of the documents found inside the SAK will be created and included in the electronic case file copies submitted to the SCDL. Y-Screening and presumptive semen testing will be conducted on all of the body swabs and underwear present in the Female Sexual Assault kits. Depending upon the information contained in the medical legal record, Semen and/or Saliva testing will be conducted

on all of the body swabs and underwear contained in the Male Sexual Assault kits. If no male DNA is detected by quantification, no further testing will be conducted on the female or male SAK and a report reflecting these results will be issued.

One or two samples that contain male DNA will proceed to amplification and analysis on a hierarchical basis. The medical legal records will be consulted and priority will be given to samples indicative of penetration, followed by recent intimate body contact, and lastly, less intimate contact. One probative evidence sample, victim reference sample, and suspect reference sample (if available) will be proceed to amplification for single contributor cases. If the case consists of multiple contributors, consensual sex within 72 hours of the assault, loss of consciousness, no medical legal record is available, the victim is under 12 years of age or the victim is a mentally challenged adult, two probative evidence samples, one victim reference and two suspect reference samples will proceed to amplification. One round of re-analysis will be conducted for each case type as needed.

Biological Fluid Screening (If Requested by SCDL)

SERI has the capability to screen evidence items for the presence of blood, semen, saliva, feces, urine, and vomit. SERI employs a wide range of validated presumptive and confirmatory tests for the presence of biological fluids. These tests include the acid phosphatase presumptive test for semen, the O-Tolidine presumptive test for blood, Seratec Hemdirect Cards for the identification of human hemoglobin, Seratec PSA Cards for the identification of prostate specific antigen (PSA/P30), Seratec alpha amylase cards for the identification of saliva, urobilinogen screening for the identification of feces, DMAC and creatinine screening for the identification of urine, and pepsin enzyme screening for the identification of vomit.

In addition to the variety of serology testing, SERI's laboratory staff have been extensively trained in microscopic examinations. SERI analysts routinely conduct microscopic examinations of suspected biological fluids, using Christmas tree staining, and microscopic analysis of hairs for the presence of root material.

SERI can assess evidence items with the aid of an Alternate Light Source. The ALS can assist in the visualization of potential body fluid staining that may be difficult to locate under normal lighting conditions. The utilization of the ALS will be based upon the circumstances of the case, the type of evidence item, or at the analyst's discretion. Visible and fluorescent staining will be documented through both photography and detailed notes, including diagrams.

Extraction

SERI uses two extraction methods: the more traditional organic extraction (phenol/chloroform) and an automated Qiagen EZ1™ Advanced XL bio robot extraction (silica-coated magnetic bead chemistry). Organic extraction is typically used for samples suspected to contain smaller quantities of DNA, while the EZ1™ robot is used for samples containing larger quantities of DNA, such as references, or for samples containing inhibitors. Although automated extraction methods decrease the possibility for human error, organic extraction methods have been shown to recover significantly more DNA than many of the automated extraction methods commonly used. SERI can perform both automated and manual organic extraction methods, allowing the analyst to utilize the best method for obtaining useful results from even the most difficult and/or degraded samples.

SERI has successfully implemented these extraction methods on over 60,000 casework samples. All extracted DNA samples receive a unique identification number, recorded in our DNA number log, which is used to easily track extracts throughout the remainder of the DNA analysis process. The case number, item number, item description, extraction method, and extraction date are recorded both digitally and on a hard copy kept in the case file. The dates and types of analysis performed on the DNA extracts are also recorded.

SERI will use a differential extraction method on all samples containing semen. A Christmas tree stained slide will be used to identify spermatozoa prior to the epithelial cell digestion step, unless microscopic examination has already been conducted by SCDL. The number of spermatozoa per field of view will be recorded in the case notes. Once the epithelial cells have been digested and placed into a separate tube for DNA extraction, the sperm pellet will receive three washes to remove any extraneous DNA left over from the epithelial digestion. The sperm pellet will be digested with DTT and the same type of reagents used to lyse the epithelial cell fraction.

To ensure sample contamination has not occurred, at least one extraction blank will be run for the epithelial cell fraction and the sperm cell fraction alongside each group of samples, eluted to the same volume as the lowest elution volume in the batch of evidentiary samples.

Quantification

SERI uses the Applied Biosystems Quantifiler Trio™ kit to measure the amount of DNA recovered from a sample. SERI can detect male-specific DNA and degradation using this quantification method and can assess the need for male specific YSTR amplification at this point in the analysis. Quantifications are performed using an ABI 7500 Quantitative PCR instrument with a positive and negative control as well as an internal positive control (IPC) to check for inhibition. Samples with low DNA yield will be concentrated using a Microcon-100™ or Vivicon-100™ micro-concentrators, which have been without any adverse effects on the sample

or loss of DNA. Samples that exhibit inhibition will be purified using the EZ1™ Advance XL bio robot and subsequently concentrated, if needed, prior to amplification.

Amplification

DNA extracts will be amplified by Polymerase Chain Reaction (PCR) utilizing the Applied Biosystems AmpFlSTR Globalfiler™ amplification chemistry. All amplification will be conducted on the ABI 9700 PCR thermocycler. SERI is able to obtain full DNA profiles from as little as 63 picograms of DNA, which is equivalent to obtaining a full DNA profile from as little as 14 nucleated cells.

SERI can conduct YSTR amplification on any sample containing male DNA. All of SERI's staff members have been trained, and routinely use, YSTR analysis in criminal casework. All YSTR amplifications will be conducted using Applied Biosystems AmpFlSTR Yfiler Plus ™ chemistry on the ABI 9700™ PCR thermocycler.

All amplifications are conducted alongside an extraction blank, negative reagent control, and a positive control of a known DNA profile. Each negative control will be amplified using the same volume as the lowest concentrated evidentiary sample. Any extraction blank resulting in a quantification value will be amplified.

Capillary Electrophoresis

PCR amplicons will be separated on an ABI 3500 genetic analyzer. All processed samples will be tracked by their unique identification number, item description, and the SERI assigned evidentiary item number, at a minimum. An internal lane standard (GeneScan Liz 600™) will be run in each sample lane. An extraction blank, negative control and positive control will also be included with each run. All negative controls and extraction blanks will be injected at the same time as the longest injection time for their respective evidentiary samples.

To ensure proper function, the ABI 3500 genetic analyzer is maintained under a manufacturer service contracts and receives regular maintenance, including spectral calibrations, cleaning, fluid replacement, capillary replacement, and any other procedure deemed necessary.

Data Analysis and Interpretation

SERI will use the GeneMapper ID-X™ v.1.5 analysis software to analyze STR data. Once STR data has been generated for evidentiary samples in a case, SERI will proceed with the following steps to ensure SCDL will be provided with the highest quality DNA analysis:

1. The STR data is screened for the presence of PCR or instrument artifacts and subjected to reinjection if deemed necessary. Additional steps may be taken, such as cleaning, or other trouble shooting methods, to gain highest quality STR data. All internal controls are checked and verified to have worked properly. If allelic activity is observed above the analytical threshold in the negative control or extraction blank(s), all of the samples associated with the controls will be re-analyzed (i.e. re-injected, re-sampled, or re-amplified) at no additional cost to the SCDL.

2. All off-ladder alleles (OLA) will be verified by re-injection at no additional cost to the SCDL. If possible, OLA's allelic size will be calculated using the allelic ladder and annotated on the Genemapper printouts (i.e. 10.2). If an OLA falls in-between loci, the OLA will be denoted using either > or < annotation corresponding to the nearest allelic ladder peak. The NIST website may be checked to see if the OLA has been reported. If the allele is found, a printout will be included in the case file and electronic discovery.

3. Unexpected DNA results troubleshooting will be conducted prior to the return of the DNA data and evidence at no additional cost to SCDL.

4. The electropherograms are printed and subjected to an in-depth analysis and annotation by a qualified DNA analyst. A summary table of the results will then be generated.

5. The table of results and electropherograms will be verified by a second qualified DNA analyst. Should any discrepancies arise between the two analyses, the issue will be addressed and resolved by the Technical Leader.

6. If needed, one round of re-amplification or additional sampling will be performed at no additional cost to SCDL.

Statistics

1. If available, known reference sample data will be analyzed and used to generate a table of results. A comparison will then be made to determine if the reference sample could be included or excluded as a possible contributor to the appropriate evidentiary sample's DNA results.

2. If an inclusion is made, a statistical calculation will be generated using a Likelihood Ratio (LR), Random Match Probability (RMP), a Modified RMP, or a Combined Probability of Inclusion (CPI) calculation method. The type of statistical calculation used will be based upon the evidentiary sample's DNA data, including factors such as, but not limited to, the number of contributors, major/minor contributors, peak height ratios, and stochastic effects. SERI will use a single source statistical calculation wherever possible.

The counting method and the 95% upper bound confidence interval will be used for the statistical analysis of YSTR data.

3. SERI maintains an internal DNA database to monitor possible contamination issues. All DNA samples will be cross checked against SERI employees' DNA profiles as well as past evidentiary and reference sample results. All suitable unknown and reference DNA profiles will then be added to SERI's internal DNA database to be crosschecked against future DNA analyses. New DNA uploads, and the results of the crosscheck results, will be recorded in the casefile and verified by a second DNA analyst.

4. No probabilistic genotyping software will be used for interpretation.

5. Mixture interpretations will not be conducted on mixtures of three or more people.

Reports

1. A comprehensive report will be created for all cases processed by SERI. The contents of SERI's reports will include:

    - Chain of custody information
    - Originating agency case number
    - Suspect and Victim or Business names
    - A list of all of the evidence items received
    - A description of the examined evidence items including sampling information and serology testing results
    - A summary table of all DNA results
    - A scientific explanation of the tests conducted in the case
    - Conclusions of the DNA analysis including the respective statistical significance.
    - A statement regarding evidence return
    - The analyst's signature and technical reviewer's initials.

All cases undergo a complete technical and administrative review. All aspects of the case, including photographs/photocopies, evidence intake forms, bench notes, serology tests, quantification results, amplification results, electropherograms, DNA analysis, statistical calculations, report contents, and conclusions are checked by a qualified analyst to ensure all written and validated protocols have been followed and that all testing is scientifically sound. To ensure that no aspect of the technical review is overlooked, a technical/administrative review checklist is filled out by the analyst and technical reviewer, and is maintained in the case file. In addition to the technical/administrative review, the technical reviewer shall date and initial each page of the case file that has been reviewed.

A copy of the case file including the report, electronic data, photographs, communications log, correspondence, chain of custody form, electropherograms, digital files, and all of the documentation listed above will be compiled and submitted to the SCDL via a secure file sharing method. All pages will be marked with the SERI case number, date, and the analyst and technical reviewer initials.

CODIS Uploads

SERI has extensive experience in providing DNA profiles for CODIS upload purposes, which have resulted in the generation of new investigative leads in cases that have otherwise gone cold. SERI provides this service to all of our clients through an established relationship with the San Mateo County Sheriff's Office Crime Laboratory, who accept and review our work and upload suitable DNA profiles to CODIS on our behalf. SERI welcomes the opportunity to establish a similar relationship with the SCDL and will comply with any SCDL requirements needed for CODIS upload.

Audits

SERI regularly undergoes external audits to demonstrate compliance with both the Quality Assurance Standards (QAS) for Forensic DNA testing Laboratories and the accreditation standards of the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD/LAB). SERI has maintained accreditation with ASCLD-LAB continuously since 1999 and have achieved re-accreditation under the ASCLD/LAB-International (ISO/IEC 17025:2005) standards. SERI also conducts annual internal audits to ensure new and current methodology meets or exceeds QAS and ASCLD-LAB standards.

Auditors who have conducted SERI's audits have all received training by the FBI in the use of the QAS checklist. SERI's audits have only ever resulted in minimal findings. SERI has proven itself time and again to be a quality Forensic DNA Laboratory.

Onsite Inspection

SERI agrees to allow the Scientific Crime Detection Laboratory or an approved designee to conduct site visits prior to the initiation of sample submission and at any time during the life of the contract. SERI will conduct all testing within our laboratory located at 3053 Research Drive, Richmond, CA 94806 and will not subcontract SCDL cases to outside laboratories.

Contract Award

SERI will issue a copy of our DNA analytical procedures, interpretation guidelines, quality assurance manuals and other requested documentation to the SCDL if awarded the contract.

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Project Schedule

Using the testing schedule outlined below, SERI's current staff will be able to expertly and efficiently complete batches of 50 SCDL cases every sixty days for the life of the contract.

Process Step	Weeks 1 & 2	Weeks 3 & 4	Weeks 5 & 6	Weeks 7 & 8
Evidence Inventory & Documentation	→			
Evidence Screening and Sampling	→			
Extraction	→	→		
Quantification		→		
Amplification		→		
Amplicon Separation		→	→	
Reprocessing (if needed)			→	
Analysis and Review			→	→
Report			→	→
Shipment Preparation				→

Weeks 1 and 2 (Days 1-14)

The sixty-day turnaround time will begin when evidence is transferred from the SCDL to SERI. SERI will accept evidence from the SCDL via a third party mail carrier capable of maintaining chain of custody. Once evidence has been received, all items will be inventoried and a chain of custody document will be generated. The batch of cases will be submitted to SERI's administrative staff for final setup and assignment. The expected date of completion will be clearly labeled on each case file. Analysts will be notified of all newly assigned cases verbally and via email.

Analysts will begin evidence screening the first business day after the evidence is submitted and will complete evidence screening and sampling for each batch of cases no later than the end of week 2. At the end of week 2, analysts will submit verbal and/or written progress reports to Angela Butler (Laboratory Manager) regarding SCDL cases assigned to them. Any cases where evidence screening and sampling are completed before the end of the second week will proceed to the extraction process.

Weeks 3 & 4 (Days 15-29)

At this point in the testing schedule, analysts will begin the DNA extraction process on their SCDL cases. The DNA extraction process takes one to two days. The samples will then proceed to quantification, which will be completed no later than the end of the third week. Once quantification is completed, the questioned samples will be amplified. Reference sample processing will also begin at this time, and will be examined, sampled, extracted, and quantified no later than the third day of the forth week. By the end of the fourth week, all evidence samples will have been amplified, and reference sample processing will be well underway. A second verbal and/or written progress report will also be submitted to Angela Butler by the end of the fourth week.

Weeks 5 & 6 (Days 30-44)

By the beginning of the fifth week most laboratory testing will be completed, and DNA analysis will begin. Amplicon separation of evidentiary and reference samples will occur no later than the second day of the sixth week. The data will be analyzed and annotated, and a results table will be generated. The data will be reviewed by a second qualified analyst for accuracy. Once the data has been reviewed, it will be returned to the analyst who will then begin writing the analytical report. The unconsumed DNA extracts from questioned samples will now be dried down using DNA Stable LD™ and placed in sealed individual sealed foil envelopes (with desiccant) and repackaged in the corresponding SAK. A third verbal and/or written progress report will be submitted to Angela Butler by the end of the sixth week.

Although reprocessing could occur anytime during laboratory testing, an assessment of the need for reprocessing will be conducted during the beginning of the fifth week. If reprocessing is deemed necessary, SERI will devote all resources required to complete the reprocessing by the end of the sixth week.

Weeks 7 & 8 (Days 45-60)

By the beginning of the seventh week, each SCDL case will be in the final stages of the report writing process. Once a completed report has been drafted, the case file and draft report will be submitted for technical review. Technical reviews will be conducted and completed no later than the end of the seventh week. The completed case will be submitted to SERI's evidence technician who will compile electronic copies of the report, case notes, chain of custody form, electronic data, and other necessary information for submission to the SCDL. The SAKs, will be returned to the SCDL via a mail carrier capable of maintaining chain of custody. A final verbal and/or written progress report will be submitted to Angela Butler by the end of the eighth week.

Progress Tracking

If SERI is awarded a contract with the SCDL, the progress of each case will be assessed by the appropriate managerial staff on a bi-weekly basis at a minimum. The testing schedule listed above will be used to monitor the testing progress of each case. Additional resources, including overtime, aid from a qualified analyst, or any other suitable measures will be used to ensure SCDL cases are on track and completed within sixty days.