MEMORANDUM

TO: Steve Ehlmann, County Executive
FROM: Bob Schnur, Director of Finance
DATE: February 19, 2016

RE: Request for Council Action – Life Technologies
    RE: Sole-Source Purchase Request
    DNA Validation Services

Attached please find a Request for Bid Approval for Life Technologies in the amount of $40,000.00, to provide DNA Validation Services for the Police Department's Crime Lab.

The account number that will be charged for this purchase is 0018315-43000

Enclosure

km
MEMORANDUM

TO: Finance

FROM: Bryan Hampton
      Laboratory Director

RE: Sole Source Justification for DNA Validation Services

DATE: February 8, 2016

Background: The FBI has required CODIS participating laboratories to expand the number of DNA core loci in uploaded profiles to 20 by January 1, 2017. The St. Charles County Police Department Criminalistics Laboratory (SCCPDCL) DNA Section currently uses 13 loci and must validate a DNA kit capable of amplifying 20 loci to comply with new CODIS requirements. Based on research and study to evaluate which kit best meets the CODIS criteria while best meeting the specific needs of our laboratory, we have selected Life Technologies' Global Filer DNA amplification kit.

The SCCPDCL also needs to validate recently purchased DNA quantitation equipment and an upgraded quantification kit. The equipment and kit are exclusively manufactured and provided by Life Technologies. Internal validations are an extremely labor intensive process. In the past we have performed our own internal validations, but due to the extensive amount of down time and the impending FBI deadline, it is most efficient in cost and time to have Life Technologies perform our internal validations.

Justification: The Criminalistics Laboratory is set up and validated to use the complete Life Technologies DNA profiling platform which includes a genetic analyzer, Real Time PCR system typing kits, and proprietary data analysis software. The laboratory’s DNA analysts have been extensively trained to operate and maintain these platforms. The Life Technologies consumables, instruments and software have been developmentally validated for use in human identity and forensic applications. There are no authorized third-party distributors of Applied Biosystems Instrumentation.

The validation services to be performed are unique to our laboratory. The technical requirements for these validations are such that the services can be uniquely provided by Life Technologies. The services include:
  - Validation of Life Technologies Global Filer DNA Amplification Kit
  - Validation of Life Technologies Quantifiler Trio DNA Quantification Kit
  - Validation of the laboratory's 7500 DNA Quantitation system recently purchased from Life Technologies. To have this equipment validation performed at the same time furthers the efficiencies of the process.

See attached documents for further details of the services provided. Modifications, including any addition of validation components, will be coordinated with Life Technologies to best meet the specific needs of our laboratory.

The chemistries from Life Technologies are designed to work together throughout the DNA analysis process. The SCCPDCL DNA Section currently uses and has validated Life Technologies’
chemistries for quantitating, amplifying and profiling DNA. Involving a third party to validate Life Technologies' amplification and quantitation kits using Life Technologies' equipment and proprietary operating and analysis software can lead to problems between parties and delays in troubleshooting and completion of validation services. Selection of Life Technologies to perform the requested validation services ensures continuity of workflows and the seamless transition to updated amplification and quantitation systems; thereby allowing the continued expediency in processing DNA evidence by the laboratory. The timely completion of the validations is of the essence because of the impending CODIS deadline. Clearly the most efficient, in cost and time, is to have the validation services performed by Life Technologies.

The cost for Life Technologies' validation services is considered fair and reasonable based on our distinct knowledge of the market after attending recent forensic DNA meetings, networking with other crime laboratories and vendor discussions. There are no additional costs associated with this validation. All supplies including kits, reagents and consumables are included. No future or reoccurring costs are required.

Life Technologies is the most practicable choice to ensure the services provided meet our exacting needs. The SCCPDCL is requesting to sole source as a single project the above validations Life Technologies. For all reasons stated here, it is most economical and efficient to have the manufacturer of the equipment and the manufacturer of the chemistries provide all validation services requested.

Our laboratory has an existing working relationship with Life Technologies and key Life Technologies personnel involved in the validation are familiar with our laboratory and DNA Protocols, contributing to the overall efficiencies of the validations.

If you have any questions or require additional information, please contact me.
REQUEST FOR BID APPROVAL

Upon selecting preferred bid, Department Director or Elected Official must sign a completed Request for Bid Approval form and send to the Purchasing Manager. If the bid is over $5,000 but less than $25,000, the Finance Department will obtain the County Executive’s signature. If the bid is $25,000 or more, the Finance Department will route to the County Executive along with a Request for Council Action and Routing Form for signature and inclusion on the Council Agenda. Once all approvals are obtained, copies will be sent to the Originating Department and back to Finance.

BID # AND ITEM OR SERVICE BID: DNA Validation Services

DEPARTMENT: Police / Crime Lab CONTACT PERSON: Bryan Hampton EXT. 7488

BID OPENING HELD ON: ___________________ BIDS OPENED BY: N/A

The following bids were received (indicate vendor name and home office location):

<table>
<thead>
<tr>
<th>VENDOR:</th>
<th>PRICE: 40,000.00</th>
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<tbody>
<tr>
<td>Life Technologies</td>
<td>☑ Yes ☐ No</td>
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<tr>
<th>VENDOR:</th>
<th>PRICE:</th>
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<td>☐ Yes ☐ No</td>
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Additional vendors and failure to meet specification justification should be added to the table on page 3.

REQUESTS BID BE AWARDED TO: Life Technologies

ACCOUNT NUMBER PURCHASE WILL BE CHARGED AGAINST: 001-8315-43000

If bid was not awarded to lowest bidder, please explain reason:

Sole Source

If paying for with grant funds please indicate (1) grant name, (2) total grant amount, (3) what portion of purchase is being paid for by a grant, and (4) when grant period ends as applicable.

N/A
REQUEST FOR BID APPROVAL

Describe the product or service for which bids were received. Describe whether the product or service is part of a larger project:

DNA validation services include:
Validation of Life Technologies' Global Filer DNA Amplification Kit
Validation of Life Technologies’ Quantifiler Trio DNA Quantification Kit
Validation of the laboratory’s 7500 DNA Quantitation system recently purchased from Life Technologies.

See attached Validation Scope documents for details.

This validation project enhances the services provided by the DNA laboratory and is integral to the DNA section's overall efficiency and continuing participation in CODIS.

Describe whether the purchase is for replacement or continuation of existing goods and/or services or whether the purchase is for new products or services not currently used by the department:

The validation services are integrated into the DNA laboratory's overall workflow management system. The new amplification and quantitation kits will replace the laboratory's current kits with upgraded and more discriminating forensic chemistries. This project will also enable expanded testing of DNA evidence, particularly from sexual assaults.

Any additional information:

If the bid is sole source, the Department Director or Elected Official must provide a separate memo providing the justification for the sole source purchase. In addition, the sole source vendor must provide a letter outlining why it is the sole vendor for such product or service.

*Department Director/Elected Official must sign the request prior to routing to the Purchasing Manager.*

Department Director/Elected Official Signature  2-1678

Date

BELOW TO BE COMPLETED ONLY FOR BIDS GREATER THAN $5,000 AND LESS THAN $25,000. See instructions above.

Director of Administration Signature  Date

County Executive Signature  Date
## Validation Scope

**GlobalFiler™ PCR Amplification Kit**  
**Applied Biosystems 3130 Genetic Analyzer**  
**GeneMapper™ ID-X v1.5**

### Minimum Threshold & Contamination Study

| Goal | Establish the minimum threshold or background noise value for the instrument and kit using negative controls  
| Evaluate negative controls for contamination |
| Laboratory | A minimum of 15 negative controls will be amplified alongside validation samples  
| Negative controls will be analyzed at 1 RFU to determine background noise level  
| The following statistics will be calculated for peak heights (RFU) in each dye channel: maximum, average, standard deviation, average plus three standard deviations (limit of detection), and average plus ten standard deviations (limit of quantification) |
| Analysis | Negative controls will be analyzed at the minimum threshold to assess for contamination |

### Sensitivity & Stochastic Study

| Goal | Demonstrate successful amplification of a range of DNA quantities  
| Provide data that may be used to establish interpretation guidelines and determine appropriate thresholds |
| Laboratory | Two genomic DNA samples, one male and one female, will be amplified in triplicate with the following target DNA amounts: 4.0, 2.0, 1.0, 0.5, 0.25, 0.125, 0.0625, 0.0313, and 0.0156 ng |
| Analysis | Average peak heights, peak height ratios, dropout of alleles/loci, peak height of surviving sister allele, and inter-locus balance will be assessed |

### Precision Study: Repeatability & Reproducibility

| Goal | Assess repeatability (variation within a plate) of size variation using alleles of the allelic ladder and repeatability of peak heights using replicate samples from the Sensitivity & Stochastic Study dilution series  
| Assess reproducibility (variation across plates) of peak heights using Control DNA 007 and reproducibility of genotypes using Control DNA 007 and NIST SRM 2391c Components |
**Precision Study: Repeatability & Reproducibility**

- Allelic ladder will be injected from four wells of a 96-well plate a minimum of five times, for a total of 20 allelic ladders to be assessed.
- Two genomic DNA samples, one male and one female, will be amplified in triplicate with the following target DNA amounts: 4.0, 2.0, 1.0, 0.5, 0.25, 0.125, 0.0625, 0.0313, and 0.0156 ng.
- Positive controls prepared with Control DNA 007 will be amplified alongside samples; NIST SRM 2391c Components A – D will be amplified.
- The following statistics will be calculated for allelic ladder base pair sizes: minimum, maximum, average, and standard deviation; data will be evaluated for standard deviations greater than 0.15 base pairs.
- Peak heights of replicate samples from the Sensitivity & Stochastic Study will be assessed for repeatability, and peak heights of Control DNA 007 controls will be assessed for reproducibility.
- Genotypes of Control DNA 007 and NIST SRM 2391c Components will be compared to reference genotypes.

**Analysis**

**Accuracy Study: NIST Concordance**

- Demonstrate that genotype results are concordant with expected results for samples processed at another laboratory.
- Demonstrate compliance with Standard 9.5.5 of *The FBI Quality Assurance Standards for Forensic DNA Testing Laboratories*.

**Laboratory**

- NIST Standard Reference Material 2391c Components A-D will be amplified.

**Analysis**

- Genotype results will be compared to published NIST results.

**Known & Non-Probative Sample Study**

**Goal**

- Demonstrate concordance of results for single-source known samples, and performance of non-probative casework samples.

**Laboratory**

- Samples encompassing a range of types and quality typically encountered in casework will be supplied by the laboratory.
- Thirty non-probative casework-type sample extracts will be quantified and amplified.

**Analysis**

- Samples will be analyzed for concordance and expected performance when compared to previous results supplied by the laboratory.
- Inter-locus peak height balance for single source samples will be assessed.

**Mixture Study**

**Goal**

- Determine ratios at which minor contributor alleles can be detected and accurately interpreted for two-person male:female DNA mixtures.
- Provide genotype data for mixture samples with greater than two known sources at varying ratios which may be supplied by the laboratory and may be used to establish mixture interpretation guidelines for complex mixtures.
Mixture Study

- Male:female genomic DNA mixtures will be prepared, quantified, and amplified in the following ratios: 1:0, 80:1, 40:1, 20:1, 10:1, 4:1, 2:1, 1:1, 1:2, 1:4, 1:10, 1:20, 1:40, 1:80, 0:1
- Complex mixture samples will be quantified and amplified with a 1 ng input DNA target

Analysis

- Peak heights of alleles in male:female mixtures will be analyzed for mixture ratios and the presence, absence, or masking of minor component alleles
- Genotypes obtained for complex mixture samples will be compared to reference genotypes provided by the laboratory

Assessment of Non-Allelic Peaks

Goal

- Assess non-allelic peaks including pull-up, plus stutter, and normally filtered stutter (for example, N-4), minus A, and dye artifacts present in validation samples

Analysis

- Normally filtered stutter will be assessed for all single-source samples in the validation and compared to manufacturer marker-specific stutter ratios
- Pull-up, plus stutter, and other artifacts will be summarized and discussed

Default protocols will be followed, including the following:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Conditions</th>
</tr>
</thead>
</table>
| Amplification | 25 µL reaction volume  
| | 29 cycles  
| | 0.4 µL GeneScan™ 600 LIZ™ v2, 9.6 µL Hi-Di™ Formamide, 1 µL amplification product or allelic ladder  
| | 3 kV for 5 seconds |
# VALIDATION SCOPE

## Quantifiler™ Trio DNA Quantification Kit

**Applied Biosystems 7500 Real-Time PCR System**

**HID Real-Time Analysis Software v1.2**

### Contamination Study

**Goal**
- Evaluate non-template controls for positive results

**Laboratory**
- Multiple non-template controls prepared with TE-d buffer and Quantifiler THP DNA Dilution Buffer will be quantified on each plate

**Analysis**
- Non-template controls will be assessed for a change in normalized reporter signal above 0.2 in 40 cycles and for reported concentration

### Sensitivity & Stochastic Study

**Goal**
- Assess the reliability of results and the lower limit of detection for samples with concentrations below the lowest standard dilution series concentration (5 pg/μL)
- Assess the reliability of results for samples with concentrations exceeding the highest standard dilution series concentrations (50 or 100 ng/μL, as chosen by the laboratory)

**Laboratory**
- To generate the low concentration dilution series, two genomic DNA samples (one male and one female) will be diluted to 2 ng/μL, 1 ng/μL, 0.5 ng/μL, 0.25 ng/μL, 0.125 ng/μL, 62.5 pg/μL, 31.3 pg/μL, 15.6 pg/μL, 7.81 pg/μL, 3.91 pg/μL, 1.95 pg/μL, 0.977 pg/μL, 0.488 pg/μL, and 0.244 pg/μL and quantified in triplicate

**Analysis**
- Samples with a concentration of 3.91 pg/μL and lower will be amplified at maximum DNA input volume with an STR amplification kit selected by the laboratory
- To generate the high concentration dilution series, a male genomic DNA sample with a high concentration (>100 ng/μL) will be diluted to neat, 1:2, 1:4, 1:8, 1:16, 1:32 and quantified in triplicate

### Precision Study: Repeatability & Reproducibility

**Goal**
- Assess the variation observed in the concentrations of genomic DNA dilutions quantified in triplicate within a quantification plate and across three plates
- Assess the variation observed in the Cₚ values of the Quantifiler Trio standard dilution series quantified on at least five quantification plates
HID Professional Services
Validation Scope: Quantifier Trio on 7500

**Precision Study: Repeatability & Reproducibility**

**Laboratory**
- Male and female genomic DNA dilutions described in the Sensitivity & Stochastic Study will be quantified in triplicate, and dilutions of 1, 0.5, 0.25, and 0.125 ng/µL will be quantified in triplicate on two additional quantification plates.
- Three independent standard dilution series (50, 5, 0.5, 0.05, 0.005 ng/µL) will be prepared and quantified in duplicate on at least two plates; two standard dilution series will be quantified in duplicate on at least five plates.

**Analysis**
- Average, standard deviation, and relative standard deviation of sample concentrations will be determined.
- Variance in C_T values for all standard dilution series will be converted to percent change in concentration and assessed.

**Accuracy Study: NIST Samples**

**Goal**
- Compare quantification results obtained from NIST Standard Reference Material™ 2372 components to reported concentrations.

**Laboratory**
- Neat and 1:10 dilutions of NIST SRM Components A and B will be quantified in triplicate.

**Analysis**
- Results will be compared to values listed in the Certificate of Analysis.

**Mixture Study**

**Goal**
- Demonstrate strengths and limitations of the Quantifier Trio kit for quantification of male:female mixtures.
- Demonstrate the utility of the Quantifier Trio kit for mixed samples.

**Laboratory**
- A genomic DNA mixture series will be prepared with one male component and one female component at a total concentration of ~0.5 ng/µL in the following ratios: 1:0, 80:1, 40:1, 20:1, 10:1, 4:1, 2:1, 1:1, 1:2, 1:4, 1:10, 1:20, 1:40, 1:80, 0:1; samples will be quantified in triplicate.

**Analysis**
- Results will be assessed for observed versus expected concentrations.

**Non-Probative Sample Study**

**Goal**
- Demonstrate that the Quantifier Trio kit can reliably quantify samples routinely analyzed by your laboratory.
- Assess the advantages and limitations of Quantifier Trio results for case type samples.

**Laboratory**
- Samples encompassing a range of types and quality typically encountered in casework will be supplied by the laboratory.
- Thirty non-probative casework-type sample extracts will be quantified and amplified with an STR amplification kit selected by the laboratory.

**Analysis**
- Samples will be assessed for expected performance as it relates to sample type.
- IPC C_T values and degradation index values will be assessed for indications of PCR inhibition and degradation.
HID Professional Services  
Validation Scope: Quantifier Trio on 7500

**Standard Curve and Control Metrics**

**Goal**
- Provide standard curve quality metrics (range of values obtained for y-intercept, slope, and R²) for all standard curves from the validation data
- Demonstrate variation in concentration for replicate data points analyzed with a single standard curve versus multiple standard curves
- Provide range of IPC C_T values and degradation index values obtained for all validation samples and controls

**Laboratory**
- Three independent standard dilution series will be prepared; two standard dilution series will be run on a minimum of five plates
- The dilution series prepared from high concentration (>100 ng/μL) male genomic DNA in the Sensitivity & Stochastic Study will be quantified in triplicate
- Two standard curves from each plate will be assessed
- Variation across standard curves will be assessed for standard deviation and relative standard deviation of concentrations
- Three replicate C_T values for each dilution in the genomic DNA series will be converted to concentration and assessed for variation when analyzed with a single standard curve versus multiple standard curves

**Analysis**
- IPC C_T values for all samples and standards will be plotted against concentrations obtained for each target
- Degradation Index values for all samples and standards will be plotted against small autosomal target concentration

Default protocols will be followed, including the following:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Conditions</th>
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<tbody>
<tr>
<td>Analysis</td>
<td>Manual threshold setting of 0.1 for IPC, 0.2 for all other targets</td>
</tr>
<tr>
<td></td>
<td>Manual setting of baseline start cycle of 3 and baseline end cycle of 15</td>
</tr>
<tr>
<td>Standard curves</td>
<td>All data will be analyzed either with or without the optional 100 ng/μL data point in standard curves, as determined by the laboratory before the validation</td>
</tr>
</tbody>
</table>
Quotation

Life Technologies Corporation
North American
Service Products
5781 Van Allen Way
Mail Stop: Service Products
Carlsbad, CA 92008 U.S.A.
Tel: 1-888-435-6862

To: Bryan Hampton
101 Sheriff Dierker Ct
Saint Charles County
101 Sheriff Dierker Ct
O FALLON MO 63366

Quote No.: 20961505
Quote Valid To: 03/18/2016
Quote Date: 01/29/2016
Pay Terms: Net 30 Days
Freight Terms: FOB FACTORY - FRT PPD & ADD

Please reference Quote No. when placing your orders.

<table>
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<tr>
<th>Item</th>
<th>Part Number</th>
<th>Description</th>
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<th>Unit List Price</th>
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<tr>
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<td>Validation of Trio &amp; GF HID consumables and reagents.</td>
<td>1.00</td>
<td>75,800.00</td>
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Estimated Shipping and Handling: 79.95

*** All orders made in reference to this quotation must include all part numbers and quantities as listed. If you would like to modify this order, please contact your Sales Representative at 1-800-874-9868.

To place your Life Technologies order:

For fastest turnaround time of your CONSUMABLES order, please visit us at www.lifetechnologies.com
Email: customerservice@lifetech.com | Fax: 800.331.2266
Phone: 800.955.0288

For INSTRUMENTS Email: NALinstrumentOrders@thermofisher.com
Fax (877) 680-2537 | Attn: Instruments Pricing Administration

For TRAINING orders, please email CustomerTraining@lifetech.com or call (800) 711-2088

To reduce the number of pages we have to send you with every quotation, we are taking advantage of the internet to direct you to Life’s General Terms and Conditions of Sale on our website. Please read the important statement below carefully.

This quotation, and Life’s GENERAL TERMS AND CONDITIONS OF SALE (which are incorporated by reference into this quotation and any resulting contract), set out the terms on which Life is offering to sell the product(s) or service(s) listed in this quotation. By issuing a purchase order or otherwise ordering or accepting product(s) or services, you expressly confirm that you intend to be bound by and agree to the terms of this quotation and Life’s General Terms and Conditions of Sale to the exclusion of all other terms not expressly agreed to in writing by an authorized representative of Life, and that the purchase and sale transaction between you and Life is subject to and will be governed by this quotation and Life’s General Terms and Conditions of Sale.

Life’s General Terms and Conditions of Sale can be found on Life’s website at http://www.lifetechnologies.com/termsandconditions under the “terms and conditions” link at the bottom of Life’s webpage.

If you have any questions, please visit our website at www.lifetechnologies.com.

Sales Representative: Phillip Czar
Prepared by: Justin Hoover

ACCEPTANCE OF THIS QUOTATION IS LIMITED TO THE ATTACHED TERMS
To: Bryan Hampton
101 Sheriff Dierker Ct

QUOTE NO.: 20961505
QUOTE VALID TO: 03/18/2016
QUOTE DATE: 01/29/2016

Please reference Quote No. when placing your orders.

Thermo Fisher Financial Services (TFFS) can arrange competitive and flexible customer financing solutions for Life Technologies instruments, maintenance services and consumables.

We now offer highly competitive financing options with low monthly payments. Please contact your local sales representative for more information on how we can meet your financing needs.

*TFFS financing solutions are subject to credit approval and satisfactory documentation.
LIFE SERVICE AGREEMENT TERMS AND CONDITIONS

1. These Service Agreement Terms and Conditions shall govern all orders for and purchases from Life Technologies Corporation ("Life") of services and parts under a Life Service Plan and other services relating to instruments and other equipment, including the maintenance, repair, installation, relocation or servicing of instruments and other equipment and including instrument training; and sets forth the agreement between Life and its customer regarding the performance of such services, unless other terms are specifically designated by Life to apply to a specific service (See Section 20 below).

2. Services are provided during normal working hours (Monday through Friday, 8:00 AM to 5:00 PM, excluding holidays). Telephone support hours are 5:00 AM to 5:00 PM Pacific Standard Time, excluding holidays. Planned maintenance ("Planned Maintenance") will be performed in accordance with Life's Planned Maintenance procedures and checklist for the instrument or component being serviced. Training services will be conducted by Life in accordance with the course agenda indicated in Life's estimate, if any. Except as indicated in Life's estimate, if any, training will be conducted at an Life's location and customer will bear the travel, accommodation and other expenses of customer's employees. Life may require instrument recertification on a time and materials basis as a condition to performing services if an instrument has not been under warranty or a service plan immediately prior to the time of service.

3. The decision to repair or replace any parts of the instrument will be made by Life on the basis of which approach will provide the customer with the best service. Parts and components replaced or otherwise utilized in the repair of the instrument may be either new or refurbished at the discretion of Life.

4. Life will use reasonable efforts under the circumstances to provide services as quickly as possible. The service will be scheduled at a time mutually agreed upon by Life and the customer.

5. Life warrants that it will provide its services at least in accordance with generally accepted standards prevailing in the instrument repair industry, or instrument training industry with respect to training services, at the time and place performed. Warranty claims must be made within ninety (90) days after services are performed. LIFE MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY WITH RESPECT TO ITS SERVICES, WHICH WARRANTIES ARE EXPRESSLY DISCLAIMED. LIFE'S SOLE LIABILITY AND RESPONSIBILITY UNDER THIS AGREEMENT FOR BREACH OF WARRANTY IS RE-PERFORMANCE OF THE SERVICES WITHIN A REASONABLE TIME OR RETURN OF THE FEE PAID FOR THE DEFECTIVE SERVICES AT LIFE OPTION. THESE ARE CUSTOMER'S SOLE AND EXCLUSIVE REMEDIES FOR ANY BREACH OF WARRANTY.

6. Service Plans do not cover replacement of parts, costs, repairs or adjustments for defects resulting from or necessitated by acts of nature, damage not caused by Life, accident, neglect, carelessness misuse, including without limitation: operation with incompatible solvents or samples in the system; operation outside of the environmental or use specifications or not in conformance with the instructions for the instrument system, software, or accessories; improper or inadequate maintenance by the user; installation of software or interfacing, or use in combination with software or products, not supplied or authorized by Life; or modification, repair, service transfer to another location of the instrument made by the customer, customer's employees, agents or an unauthorized contractor, or intrusive activity, including without limitation computer viruses, hackers or other unauthorized interactions with instrument or software that detrimentally affects normal operations. Service Plans also do not cover repair or replacement of parts that are radioactive or contaminated with biological, toxic or other dangerous materials or substances.

7. Service Plans do not cover costs, repairs or adjustments made necessary by connection of the instrument to electrical services or other utilities not in accordance with the installation requirements for the instrument, or by any interruption or surge in voltage (see Instruction Manual for specifications). Service Plans also do not cover replacement of parts, costs, repairs or adjustments due to Year 2000 non-compliance.

8. Payment terms are net 30 days from date of Life's invoice to customer. If payment is not received by the due date, Life may assess and customer agrees to pay a late payment charge at the rate of 1% per month (12% per year) or the maximum legal rate, whichever is less, of the amount due from the due date to the date of payment. If Life retains a collection agency and/or attorney to collect unpaid amounts, Life may invoice customer for, and customer will pay, all costs of collection, including without limitation reasonable attorneys fees.

9. Life may accept or reject at its discretion a purchase order for Service or a Service Plan. Unless otherwise expressly stated by Life in writing or under the terms of the purchased Service Plan, the initial term of a Service Plan and this Agreement is one year, commencing on the date designated by Life in its estimate or otherwise specified to customer. A Service Plan may be terminated by either party upon at least thirty (30) days written notice to the other party. Termination will be effective thirty (30) days after the receipt of such notice, or at a later date if one is so specified in the notice ("Termination Date"). Termination cannot be made effective prior to thirty (30) days after notice is received, provided, however, that Life may terminate a Service Plan immediately in the event that the instrument covered by the Service Plan is transferred to another location. Life will cease Service under this Agreement and underlying Service Plan on the Termination Date unless the customer specifies a
separate, earlier date in writing ("Cessation Date"). In that event, Life will cease Service under this Agreement and underlying Service Plan on such Cessation Date.

10. In the event of termination of a Service Plan under Section 9, if the termination is by customer, Life shall calculate at its sole discretion the total price of services actually performed and expenses actually and reasonably incurred in servicing the covered equipment under the underlying Service Plan from its effective date until the Termination Date. Customer’s total payment obligation to Life under this Agreement shall equal (1) the amount so calculated or (2) the prorated price of the underlying Service Plan from its effective date until the Termination Date, whichever is greater, plus fifteen percent (15%) of the total fee paid for the underlying Service Plan, not to exceed the total amount paid. Any payments made by customer to Life in excess of this amount shall be credited to customer’s account within thirty (30) days after the Termination Date toward future purchases of Life instruments, consumables or Service Plans. Any unpaid portion of this amount shall be immediately due upon customer’s receipt of an invoice from Life. If the termination is by Life, other than for cause, Life will credit the customer with or refund to customer one hundred percent (100%) of the fee paid by customer for the underlying Service Plan, provided that if the underlying Service Plan is for a period of more than one year, Life will refund to customer the amount paid by the customer for all periods after the most recent anniversary date of the Service Plan. If a Service Plan is terminated early in connection with the trade in of a used Life instrument for a new Life instrument, the credit may be applied toward purchase of a Service Plan for the new instrument. Contact your Life service representative for details. No cash refunds will be made on account of the early termination of any Service Plan or other agreement for services.

11. Life will indemnify and hold customer harmless from and against any and all claims for injury or death of persons, or damage to tangible property, occurring while Life personnel are on customer’s premises performing services under a Service Plan to the extent caused by the negligent acts or negligent omissions of Life, provided Life is given prompt notice of any such claim and the opportunity to control the defense and settlement of same.

12. TO THE FULLEST EXTENT ALLOWED BY LAW, IN NO EVENT SHALL LIFE BE RESPONSIBLE OR LIABLE, WHETHER IN CONTRACT, TORT, WARRANTY OR UNDER ANY STATUTE OR ON ANY OTHER BASIS, FOR SPECIAL, INDIRECT, INCIDENTAL, MULTIPLE, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE SERVICES OR FAILURE TO PERFORM SERVICES OR OTHERWISE, EVEN IF LIFE IS ADVISED IN ADVANCE OF THE POSSIBILITY OF SUCH DAMAGES; AND IN NO EVENT SHALL LIFE BE LIABLE FOR ANY LOSS OR INJURY THAT IS THE RESULT OF INSTRUMENT OR PRODUCT ERROR OR THE FAILURE OF AN INSTRUMENT OR OTHER PRODUCT TO PERFORM IN ACCORDANCE WITH ITS SPECIFICATIONS. WITHOUT LIMITING THE FOREGOING, EXCEPT SOLELY FOR ANY PAYMENTS MADE UNDER LIFE’S INDEMNITY SET FORTH IN SECTION 11, LIFE’S TOTAL CUMULATIVE LIABILITY IN CONNECTION WITH THIS SERVICE AGREEMENT AND ANY UNDERLYING SERVICE PLAN, INCLUDING WITHOUT LIMITATION SERVICES RENDERED THEREUNDER, OR BREACH THEREOF OF FAILURE TO PERFORM IN CONTRACT, TORT, WARRANTY OR OTHERWISE, WILL NOT EXCEED THE AMOUNT OF FEES PAID TO LIFE FOR THE UNDERLYING SERVICE PLAN.

13. Parts in contact with any liquid are considered wetted and may be deemed user replaceable and not covered by any Service Plan, including, but not limited to seals, filters, gaskets, etc.

14. Use of any non-Life’s parts or reagents that deposit or cause to be deposited residual matter in the instrument flow path or that otherwise interrupt the flow path that are reasonably determined by Life to have caused instrument failure will require remedial repairs of the effected parts to be completed outside a Service Plan at Life’s then prevailing rates for billable service.

15. Ancillary equipment not manufactured by Life, such as third party computers, may be excluded from any Service Plan, at Life’s discretion. Life will pass on to customer any manufacturer’s warranty of any such ancillary equipment, to the extent permitted by the manufacturer.

16. Life makes no representation whatsoever that services provided by Life satisfy or will satisfy any requirements of any governmental body or other organization, including, but not limited to, any requirement of the United States Food and Drug Administration or the International Organization for Standardization. Customer agrees that it is customer’s responsibility to ensure that such services are adequate to meet its regulation/certification requirements and that all requirements of any governmental body or other organization, including, but not limited to, any requirement of the United States Food and Drug Administration or the International Organization for Standardization are the responsibility of customer.

17. Neither this Service Agreement nor any Service Plan is assignable or otherwise transferable by customer. Any assignment or transfer or attempt to assign or to transfer by customer shall be void.

18. Life may require a completed Certificate of Decontamination, or transfer of an instrument to a suitable safe and secure location reasonably determined by Life, as a condition to servicing any instrument. Customer warrants that any instrument or component to be serviced will be fully decontaminated of radioactive, biological, toxic or other dangerous materials or substances prior to servicing so that the service technician will not be exposed to any such materials. Customer shall not assign Life personnel to work in biosafety level 3 laboratories without prior written notice to Life and Life’s written consent. Life does not service instruments in biosafety level 4 laboratories.
19. Service Plans do not include customer training or services related to the relocation of instruments unless otherwise specifically stated in writing by Life in any particular case.

20. Neither party shall be liable for delays in performance or nonperformance in whole or in part, or for loss, injury, delay, expenses, damages or other casualty suffered or incurred on account of or due to, any causes that are beyond its reasonable control, such as, without limiting the generality of the foregoing, acts of God, fires, strikes, trade disputes, riots, embargos, earthquakes, storms, acts of the government, power losses or shortages, or inability to obtain parts or supplies, provided that the foregoing shall not apply to any obligation to pay money due.

21. These Service Agreement Terms and Conditions, together with Life’s estimate regarding the Service Plan(s) or other services subject to these terms and conditions, and Life’s description of the services provided under the Service Plan purchased by customer (collectively, “Life’s Terms”), represents the entire agreement between the parties with respect to the subject matter herein and supersedes and entirely replaces (i) any previous agreements between the parties with respect to the subject matter herein and (ii) any pre-printed, standard or other terms (except for the statement of Services or Service Plan selected and, if accurate, price) set forth in customer’s purchase order (if accepted by Life) or any other document not signed by an authorized representative of Life and agreed to by Life, which are hereby rejected and shall be void. Customer’s submission of a purchase order or other instrument regarding the purchase of Services in response to Life’s estimate or any other Life document that includes or incorporates these terms shall be deemed acceptance of these terms to the exclusion of any other terms and conditions appearing in or referenced in such purchase order or other instrument, which are hereby deemed to be material alterations and notice of objection to which is hereby given, notwithstanding anything contained in the contrary in such purchase order or other instrument or elsewhere. Any acceptance by Life of any offer of customer is expressly conditioned on customer’s assent to and acceptance of Life’s Terms to the extent they are additional or different terms. Except as otherwise provided in these terms, in the event of an inconsistency between these terms and the terms appearing on Life’s estimate or other agreement signed by an authorized representative of Life, the terms appearing on Life’s estimate or such other agreement shall supersede and take precedence over the inconsistent provision(s) of these terms, and all other provisions of these terms shall remain in full force and effect.

22. Life and customer shall keep confidential and shall not without prior consent in writing of the other disclose to any third party any technical or commercial information acquired from the other as a result of discussions, negotiations and other communications between them in relation to the services.

23. No amendment of these terms or modification thereof shall be binding unless in writing and signed by a duly authorized representative of both Life and customer. Life’s failure to exercise any rights hereunder shall not constitute or be deemed a waiver or forfeiture of such rights or any other rights hereunder. Headings are included herein for convenience of reference only and shall not constitute a part of these terms for any other purpose. If any provision of these terms shall be held to be invalid or unenforceable for any reason, such provisions shall, to the extent of such invalidity or unenforceability, be severed without in any way affecting the remainder of such provision or any other provision thereof, all of which shall continue in full force and effect. Nothing in this Agreement shall be deemed or construed as a license or grant of any intellectual property rights, whether express, implied, by estoppel or otherwise by Life, or to limit Life’s rights to enforce its patent or other intellectual property rights. No additions or modifications to this Service Agreement shall be valid unless specifically agreed to in writing by both parties. This Service Agreement and any underlying Service Plan shall be governed by the laws of the State of California, exclusive of its conflict of laws rules.
HID Professional Services Differentiating Features

To Whom It May Concern,

Life Technologies is the leading manufacturer of genetic analysis systems that include instrumentation, consumable kits and data analysis software that is validated for the Human Identification (HID) and forensic DNA markets. Included in the components of these systems are various products including PrepFiler™ Forensic DNA Extraction Kits, AutoMate Express™ Instrument, Quantifiler™ HP and Quantifiler™ Trio Human DNA Quantification kits with the Applied Biosystems 7500 HID Real-Time PCR System, AmpFISTR® Identifier® Plus PCR Amplification Kit, GlobalFiler™ PCR Amplification Kit, Applied Biosystems 3130 HID Genetic Analyzer, and others. Life Technologies employ scientists on staff that participated in the developmental validation of these reagents and/or instruments for forensic use, and therefore possesses in-depth expertise in the expected range of performance capabilities and limitations of these technologies. These technologies were developed specifically for human identification applications and are made exclusively by Life Technologies, who is the sole manufacturer of these products and they are not sold through any distributor or third party.

Validation Services

The Life Technologies HID Professional Services (HPS) team employs forensic scientists with broad and extensive validation experience for forensic DNA applications. Validation project work at customer laboratories will be performed by Life Technologies’ Validation Application Specialists (VAS), who have all worked as forensic scientists and understand the workflow, standards, and unique needs of forensic DNA laboratories, having previously been employed in government and/or private forensic DNA laboratories. Many members of the HPS team have previously been employed in other relevant roles within Life Technologies, including the position of HID Field Application Specialists (FAS). External consultants with the relevant qualifications may also be involved in some areas of the validation process.

Training Services

Instrument and software training can be provided by a certified Field Service Engineer (FSE) and/or a specialized HID Field Application Specialist (FAS) and/or a specialized HID Validation Application Specialist (VAS). The FSE, FAS and VAS will have been trained specifically to obtain a high level of expertise on Life Technologies chemistries, instruments, and software. Only Life Technologies FSE, FAS and VAS receive ongoing factory training and certification. They have exclusive access to Life Technologies’ latest technical developments, instrument
modifications, application updates and planned maintenance procedures. The validation services and training will be subsidized with the FSE and FAS trainings that are provided with the purchase of Life Technologies instrumentation. Furthermore, the FSE, FAS and VAS are backed by Technical Support and Research and Development teams at Life Technologies.

Life Technologies understands that a team approach to validation projects results in the most success. As part the HPS product offering, we work in conjunction with the laboratory to design, implement, train and complete technology transfer to the laboratory personnel along every step of the project to ensure efficient and successful execution of all validation projects, followed by faster implementation of the new technology in the laboratory.

Further documentation regarding unique characteristics of each of the relevant Life Technologies products may be found in the relevant User Guide documents, or please contact your local Life Technologies HID representative.
Benefits of Working with Life Technologies HID Professional Services

Life Technologies will function as a single-source contractor to provide all support personnel, validations, and trainings associated with the validation. Our proposal includes all costs required to execute this project including all reagents and consumables, and travel costs for our personnel.

Project Management

The validation project at the St Charles County Crime Lab will be managed under the technical direction of Joanne B. Sguglia. Joanne has a wealth of validation and QA/QC experience from her previous roles at the Massachusetts State Police Crime Laboratory and as a participant of SWGDAM (invited guest from 2008 – 2011).

The HID Professional Services Team

HID Professional Services employs a team of forensic scientists with broad and extensive validation experience for forensic DNA applications. Our Validation Application Specialists (VAS) have all worked as forensic scientists and understand the workflow, standards, and unique needs of forensic DNA laboratories. The HID Professional Services organization chart is presented below. It is from this organization that the appropriate individuals will be assigned to participate in this project. External consultants may also be involved.
Benefits of Working with Life Technologies

Personnel

Life Technologies has an extensive network of service and support personnel positioned globally for Human Identification laboratories. Our teams include:

- Human Identification Field Application Specialists (FAS)
- Technical Support Scientists (TSS)
- AB-certified Field Service Engineers (FSE), including HID-certified FSEs with specialized training including forensic applications, with exclusive access to the most current content, software patches, and support documentation
- Validation Application Specialists (VAS), a team of forensic scientists with extensive experience in forensic DNA applications
- Developmental validation team
- Outside consultants, with experience as forensic scientists, laboratory directors, and auditors

Our in-depth knowledge of forensic DNA laboratories and workflows will provide you with a comprehensive suite of offerings, including vast troubleshooting capabilities. Life Technologies is uniquely positioned globally to offer this level of support.

Audit Support

Life Technologies will provide support to the St Charles County Crime Lab as necessary through their next audit for any additional questions, clarifications, or additional documentation associated with this Validation Project. This includes consultation on the experimental process and results, as well as off-site support, at no additional cost to the St Charles County Crime Lab.

Throughout this project, there will be opportunities to meet via conference call, or in person, to discuss the progress of the project, and to make adjustments as necessary to meet the needs of the St. Charles County Crime Lab.

Travel

Life Technologies will send personnel to perform the experimental portions of the Validation Project and to deliver the teachback. This is provided as part of the Validation Project at no additional charge. We will cover all costs associated with travel, hotel, meals, and transportation for our personnel.

Supplies

Life Technologies will coordinate the delivery and implementation of all products associated with this project, including all kits, reagents, and consumables associated with the Validation Project, which will be ordered separately from Life Technologies and approved by the St. Charles County Crime Lab Quality Assurance Manager and/or Laboratory Manager.
All supplies associated with the Validation Project will be provided by Life Technologies, with only a few exceptions. We request that the laboratory provide personal protective equipment (PPE) such as laboratory coats, masks, and gloves to comply with their laboratory’s safety and contamination prevention standards. It will also be necessary for the laboratory to provide recently calibrated pipettes and associated tips, so that the validation work best reflects the environment in which the validated kit and instrument will be used. Access to the appropriate instrumentation, refrigerators, freezers, centrifuges, and routine laboratory equipment will also be necessary during the course of the experimental execution phase.
January 22, 2016

Dear St. Charles County Purchasing:

Please accept this letter to document that Life Technologies is the sole manufacturer and distributor of Applied Biosystems models 3130, 3500, 7500, 9700, and ProFlex instrument systems. These unique instruments are validated for Human Identification applications. The AB Genetic Analyzers are the only capillary electrophoresis instruments that are fully validated for the purpose of forensic Human Identification. Life Technologies is the exclusive distributor of all AmpFISTR kits, reagents, software, capillaries, service, and related consumables used in conjunction with these instrument models. This includes the forensic kits and consumable products described on Quote H-592432. These products are sold direct, and are available exclusively from Life Technologies.

Further documentation describing the unique, detailed specifications of the Life Technologies AB Genetic Analyzers, and other AB Instrument Systems, can be found in our user manuals, and are available upon request.

**Life Technologies does not have authorized distributors in the USA.**

This information should justify Life Technologies as your "Sole Source" supplier for all Applied Biosystems instruments, software, consumables and services that you need to perform DNA Analysis, for the purpose of Human Identification.

If you need any further information please feel free to contact me at your convenience.

Regards,

**Phillip Czar**  
Account Manager  
Life Technologies  
(210) 286-1414  
phillip.czar@lifetech.com