DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK MD 21702-5014

Control No: JA17219

Sole Source Justification (SSJ) in accordance with FAR subparts 13.106 or 13.5 using Simplified Acquisitions Procedures (SAP) BRAND NAME ONLY

1. Contracting Activity: The U.S. Army Medical Research Acquisition Activity (USAMRAA), 820 Chandler Street, Fort Detrick, MD 21702-5014.

2. Requiring Activity: Armed Forces Medical Examiner System, DNA Identification Laboratory (AFDIL).

3. Nature of Action:

☒ Commercial Item ☐ Non-Commercial Item
☒ New Requirement ☐ Follow-on Requirement
☐ Mod to Existing Purchase Order/Contract Number _____

Pricing: ☒ Firm-Fixed Price* ☐ Time & Materials** ☐ Cost*

* See FAR 12.207(a)
** See FAR 12.207(b).

For Hybrid Contracts, list percentage of each type of pricing:
* Firm Fixed Price: _____
**Time & Materials: _____
* Cost: _____

Funds: ☐ RDT&E ☒ Operations and Maintenance, Army (OMA)
☐ Other Funds: _____

Fiscal Year of Funds: 2017

Estimated Total Dollar Value including Options: $ 190,000

4. Contractor Name:

Name of Proposed Contractor: Advanced Analytical Technologies Inc.
Street Address: 2450 SE Oak Tree Court; #101
City, State, Zip: Ankeny, IA, 50021-7102
Phone: (515) 296-4305
DUNS: 179360854
Cage Code: 1XRG7

5. Description of Supplies/Services: To support the increased workload in the Armed Forces DNA Identification Laboratory (AFDIL) DNA identification and data basing activities, and to provide novel methods for recovering DNA data from the most difficult specimens, the AFDIL has recently validated new PCR amplification and sequencing techniques, specifically next generation sequencing (NGS), utilizing the Illumina MiSeq NGS instrument.

Currently the Armed Forces DNA Identification Laboratory (AFDIL) performs amplification and Next Generation Sequencing (NGS) library quality control checks using the 2100 Bioanalyzer (Agilent) instrument. Proper optimization of methods, library preparation and sequencing on the Illumina MiSeq NGS instrument require reliable, reproducible and sensitive quantitation results. Additionally, it is necessary for these quantitative and qualitative assays to be amenable to high throughput (HTP) processing in order to detect DNA quickly from a 96-well plate. Although useful, the aforementioned instrument has significant issues that complicate the required analyses, and in some cases, prevent reliable detection of the DNA of interest. Based on market research, product demonstrations, and current validation studies, it has been determined that the acquisition of two Fragment Analyzer™ (Advanced Analytical) instruments, is required.

The Fragment Analyzer™ (Advanced Analytical), in both the 48-capillary and 96-capillary format, meets all the required specifications to assess the quality and quantity of both NGS libraries and PCR amplicons. In particular, the high throughput (HTP) capability of these instruments allows for up to 288 samples to be analyzed without intervention; with 96 samples processed as little as 20 minutes. The available kits for the Fragment Analyzer™ ensure the sensitivity (as low as 5pg/µL) and sizing capabilities (≥10,000 bp), necessary for use in multiple AFDIL methods. Additionally, the method of detection prevents carryover (cross-contamination) between runs, negative impact from inhibitors and adverse effects from temperature fluctuations. The accompanying software allows the analysis of both amplification products and smears. The size, concentration and molarity can be determined and these results can be output for further analysis or usage in downstream processing. The functionality and appropriateness of the Fragment Analyzer™ was confirmed with a demonstration at the AFDIL in January 2015 and through the subsequent use of the instrument by AFDIL's

Emerging Technologies Section over the past year. Performance in the AFDIL laboratory has proven that the instrument can successfully meet the current needs of the AFDIL for automated fragment analysis. The introduction of the Fragment Analyzer™ into DNA casework will eliminate the need for continued use of twenty high-voltage gel electrophoresis workstations, which require the use of harmful teratogenic chemicals and present the risk of staff exposure to concentrated UV light. In addition to reducing safety hazards in the laboratory, the throughput of the analyzers will cut manpower requirements in half and sample processing time by 75%.

Fragment Analyzer™ Automated CE System -48/96 capillary Specifications:

- Analyze between 48-288 samples without user intervention
- Analyze 48-96 samples in less than 1 hour
- Less than $3.00 cost per sample
- Sample usage less than 2µL
- Sensitivity down to 5pg/µL for amplicons; 100pg/µL for smears
- Resolution down to 2 bp
- No carryover of assayed sample between runs; i.e. no cross-contamination
- Detection of fragments ≥10,000 bp
- Reliable calculation of size and concentration of amplicons and smears
- Automatic determination of molarity
- Ability to export reports and results to PDF or Excel
- Vendor supplied analysis software
- 24 in deep, 40 in wide, and 34 in height (minimum) required for placement of Fragment Analyzer™ system and computer workstation
- Computer Workstation
- 96-Capillary Array Cartridge 50 um (ID) 33 cm (EFF), 55 cm (TOT), 10mL (RES)
- 48-Capillary Array Cartridge 50 um (ID) 33 cm (EFF), 55 cm (TOT), 10mL (RES)
- Fluorescent System Installation and Training
- Fragment Analyzer Operational Qualification Kit

Fragment Analyzer™ Automated CE System Reagent Specifications:

dsDNA 920 Reagent Kit, 75-15,000 bp (1000 samples)

- DNF-920-K1000
- For use on the Fragment Analyzer system
- Provides sizing and qualitative analysis of PCR fragments up to 15,000bp

- Sizing Range: 75 bp – 15,000 bp (defined by lower/upper marker)
- Input Concentration Range: 0.5 ng/µL – 50 ng/µL

dsDNA 935 Reagent Kit, 1-1,500 bp (1000 samples)

- DNF-935-K1000
- For use on the Fragment Analyzer system
- Provides sizing and qualitative analysis of PCR fragments up to 1,500bp
- Allows for fast separation in under 20 minutes
- Sizing Range: 1 bp – 1,500 bp (defined by lower/upper marker)
- Input Concentration Range: 0.5 ng/µL – 50 ng/µL

High Sensitivity Genomic DNA Analysis Kit, (500 samples)

- DNF-488-0500
- For use on the Fragment Analyzer system
- Provides sizing and quantitative analysis of genomic DNA
- Sizing Range: 50 bp – 40,000 bp
- Input Concentration Range: 50 pg/µL – 5 ng/µL

High Sensitivity Large NGS Fragment Analysis Kit, (500 samples)

- DNF-493-0500
- For use on the Fragment Analyzer system
- Provides sizing and quantitative analysis of NGS libraries with large fragments
- Sizing Range: 50 bp – 20,000 bp
- Input Concentration Range: 50 pg/µL – 5 ng/µL

Standard Sensitivity Large NGS Fragment Analysis Kit, (500 samples)

- DNF-492-0500
- For use on the Fragment Analyzer system
- Provides sizing and quantitative analysis of NGS libraries with large fragments
- Sizing Range: 50 bp – 20,000 bp
- Input Concentration Range: 5 ng/µL – 100 ng/µL

High Sensitivity NGS Fragment Analysis Kit (1 bp - 6000 bp), (500 samples)

- DNF-474-0500
- For use on the Fragment Analyzer system
- Provides sizing and quantitative analysis of NGS libraries
- Sizing Range: 25 bp – 5,000 bp
- Input Concentration Range: 50 pg/µL – 5 ng/µL

Standard Sensitivity NGS Fragment Analysis Kit (1 bp - 6000 bp), (500 samples)

- DNF-473-0500

- For use on the Fragment Analyzer system
- Provides sizing and quantitative analysis of NGS libraries
- Sizing Range: 25 bp – 5,000 bp
- Input Concentration Range: 5 ng/µL – 100 ng/µL

6. Authority Cited: ☒ 41 U.S.C. 1901 **OR** ☐ 41 U.S.C. 1903

☐ (a) FAR 13.106-1(b)(1)(i): Only one source reasonably available (e.g., urgency, exclusive licensing agreement, brand name or industrial mobilization); OR

☐ (b) FAR 13.106-1(b)(1)(ii): Only one source can provide a portion of the purchase that is a particular brand-name item; OR

☒ (c) FAR 13.501(a)(1)(i): Only one source reasonably available (including brand name); OR

☐ (d) FAR 13.501(a)(1)(ii): Only one source can provide a portion of the purchase that is a particular brand-name item.

7. Reason for Authority Cited:

a. The AFDIL has forensically validated the newly developed next generation sequencing methods. The validation experiments were done in accordance with the Federal Bureau of Investigations Quality Assurance and the International Standards Organization (ISO) 17025 DNA forensic laboratory standards. Casework cannot effectively progress without an improved and reliable method to calculate size, concentration, and molarity of amplicons and smears. Having the Fragment Analyzer available during this new phase of validated methods will ensure that the laboratory will not be required to repeat all of the initial proof of concept and development and optimization experiments as alterations to any process that is currently being validated for these next generation sequencing methods will significantly delay the validation and implementation of the optimized procedure by approximately two years. In addition, the need to repeat the previous experiments to verify that the alterations did not affect the reproducibility, reliability or increase the chance for contamination will cost the government a significant amount of money.

b. The AFDIL core missions are to assist the Armed Forces Medical Examiner System (AFMES) with recent death investigations of military and civilian personnel lost in training mishaps, conflicts, and war; and the Defense POW/MIA Accounting Agency (DPAA) with past accounting of military and civilian personnel lost during World War II, the Korean War, Viet Nam and the Cold War. AFDIL's research and development of novel extraction and next generation sequencing techniques for processing chemically

modified samples have substantially increased AFDIL's support of the past accounting mission. These reagents are needed so AFDIL can continue to support the AFMES and DPAA.

c. AFDIL is an American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), ISO/IEC 17025:2005 accredited forensic lab, which means the FBI's Quality Assurance Document is followed. Based on accreditation adherence (Volume III of the Quality Manual and the FBI's Quality Assurance Surveillance (QAS) document), all reagents and equipment must be developmentally validated by the manufacturer and internally validated by the laboratory as well as pass a stringent quality control before being released for casework. Developmental validation is costly and AFDIL does not possess the resources to carry out a developmental validation in order to change instrumentation or reagents. Further, AFMES' mission requires consistency and standardization of testing to accomplish its overall mission and to maintain credibility, therefore, accuracy is critical to AFMES' mission. Commercial kits are used by forensic laboratories to make human identification possible through the use of DNA profiling. Commercial kits make use of standardized combinations of short tandem repeat loci (sequences of genetic material, also known as STR) in specific types of polymerase chain reactions (also known as PCR technology), which results in human identifications made with an extremely high degree of certainty. By using commercial kits with PCR technology, DNA profiles can be generated from exceedingly small, very old, badly preserved, or partially decomposed samples. Vital to the DNA identification mission is the need for reproducible and accurate test results with no lot-to-lot variability as determined through extensive internal validation studies. The sequencing, typing, amplification, quantitation, and other stages of the DNA identification process are performed using reagents compatible with the specific analysis laboratory equipment/instruments.

8. Efforts to obtain Competition: Not applicable. No effort will be made to solicit offers from any other source as there is only one BRAND NAME source capable of providing the solution, given the nature of the mission and the need to ensure consistency and validity of the DNA test results. Five different systems were evaluated during market research and the Fragment Analyzer, in the 48-capillary and 96-capillary format, meets all the required specifications to assess the quality and quantity of both NGS libraries and PCR amplicons; additionally, it allows for up to 288 samples to be analyzed without user intervention.

a. *Effective competition.* N/A

b. *Subcontracting competition*. N/A

9. Actions to remove or overcome barriers Competition: Not applicable: It is the policy of USAMRAA to promote the use of competitive procedures whenever and

wherever possible. However, this is a unique product which makes efforts to increase competition very difficult. Market research with future procurements of this nature or similar to will include a search for competitive suppliers, testing and validation that has already been accomplished. For this requirement, solicitation will be BRAND NAME only.

10. Market Survey: Extensive market research was conducted. Currently the Armed Forces DNA Identification Laboratory (AFDIL) performs amplification and Next Generation Sequencing (NGS) library quality control checks using the 2100 Bioanalyzer (Agilent). For proper optimization of methods, library preparation and sequencing on the Illumina MiSeq reliable, reproducible and sensitive quantitation results are required. Additionally, it is necessary for these quantitative and qualitative assays to be amenable to high throughput (HTP) processing in order to detect DNA quickly from a 96-well plate. Although useful, the 2100 Bioanalyzer has significant issues that complicate the required analyses and in some cases prevent reliable detection of the DNA of interest.

The QIAxcel Advanced System uses capillary electrophoresis of 12 samples in approximately five minutes, and allows for analysis of 96 samples without user intervention. This system meets the HTP requirement however it lacks in sensitivity and reproducibility. The specifications for this instrument indicate that it can detect DNA as low as 100pg/µL, however this assumes that the product is purified and void of any inhibitors such as PCR buffer. At the AFDIL, there is a need to quantify unpurified amplification product prior to the expensive and time-consuming purification step for both sample enrichment and library preparation. In the presence of inhibitors from the PCR reaction, the already lower sensitivity of the QIAxcel is greatly impacted and further decreases its ability to detect small amounts of DNA. Additionally, the QIAxcel ScreenGel software is not able to analyze smears and assess molarity automatically, which is required for sequencing of the NGS libraries. If this assessment is incorrect, sequencing on the MiSeq may be impacted requiring additional reagents and time to be used to reprocess the improperly quantified libraries. Lastly, it has been observed in the usage of this instrument at the AFDIL that the reproducibility and repeatability of this system varies greatly between runs including significant carryover. So although relative comparison within a run is possible, it is difficult to compare results from run-to-run making method optimization nearly impossible. A more sensitive and robust instrument is required for HTP analysis of unpurified amplification products and NGS libraries.

The 2100 Bioanalyzer meets many of the needs for amplification product and library detection; however it is only able to process up to 12 samples per 45-minute run. In order to assess 96 samples, significant user hands-on time is required and would require approximately 6 hours. Additionally, the AFDIL has had major issues with the High Sensitivity DNA Analysis Kit, potentially due to routine/unavoidable temperature fluctuations in the laboratory or manufacturing/shipping inconsistencies. Numerous attempts to minimize the frequency of failed runs have been performed, including

several solutions recommended by the vendor, but failures continue to be seen on a semi-regular basis. Based upon the Bioanalyzer's inability to analyze samples in a HTP manner and repeated failed runs with the kit used predominantly, an alternative instrument is required for quality and quantitative assessment.

The 2200 Tapestation (Agilent) and the LabChip GX Touch HT (PerkinElmer) are other options for instrumentation. The 2200 Tapestation offers similar functionality as the Bioanalyzer while also allowing for higher throughput. A 96-well plate can be placed on the Tapestation but user intervention is required every 16 samples. For this reason, the Tapestation does not meet the HTP capabilities required at the AFDIL. The LabChip GX Touch HT does have the requisite HTP processing ability (96 samples in less than an hour) but does not have the necessary sensitivity (100pg/µL versus the desired 5pg/µL) and is therefore also not a suitable option.

The Fragment Analyzer (Advanced Analytical), in the 48-capillary and 96-capillary format, meets all the required specifications to assess the quality and quantity of both NGS libraries and PCR amplicons. In particular, the HTP capability of this instrument allows for up to 288 samples to be analyzed without intervention with 96 samples processed as little as 20 minutes. The available kits for the Fragment Analyzer ensure the sensitivity (as low as 5pg/µL) and sizing capabilities (≥10,000 bp) necessary for use in multiple methods. Additionally, the method of detection prevents carryover between run, impact from inhibitors and effects from temperature fluctuations. The user-friendly software allows the analysis of both amplification products and smears. The size, concentration and molarity can be determined and these results can be output for further analysis or usage in downstream processing. The functionality of the Fragment Analyzer was confirmed with a demonstration at the AFDIL in January 2015, and the instrument was determined to meet the needs of the AFDIL for automated fragment analysis.

11. Interested Sources: This is a unique requirement and there are no other interested sources available to meet the mission needs of this requirement.

12. Procurement History and any other facts:

Contract# W81XWH-15-P-0265 – Fragment Analyzer and reagents purchased in 2015.

Previously competed? N/A

Previous authority for less than Full & Open Competition: The statutory authority used permitting other than open competition is 10 U.S.C. 2304c (1). The FAR citation was 6.302-1 citing that only one responsible source and no other supplies or services will satisfy agency requirements.

13. Technical / Requirements Certification: I certify that the support data under my cognizance which are included in this SSJ are accurate and complete to the best of my knowledge and belief.

Submitted by Signature: LALANI.SHAIROSE.A.1060346573
Digitally signed by LALANI.SHAIROSE.A.1060346573
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=DHA, cn=LALANI.SHAIROSE.A.1060346573
Date: 2017.07.10 10:34:09 -04'00'

Printed name: Shairose Lalani
Agency/Position/Title: DNA Program Specialist
E-Mail Address: Shairose.a.lalani.civ@mail.mil
Date: 10 July 2017

14. Contracting Officer Certification and Approval: I certify that this justification is accurate and complete to the best of my knowledge and belief. Based upon the facts described herein, I hereby determine that the anticipated price/ cost to the Government will be fair and reasonable, and a determination of price reasonableness will be documented and placed in the contract file.

Contracting Officer Signature: HARRIS.PATRICK.K.1395451320
Digitally signed by HARRIS.PATRICK.K.1395451320
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=HARRIS.PATRICK.K.1395451320
Date: 2017.07.10 10:21:06 -04'00'

Printed name: Patrick K. Harris
Agency/Position/Title: Contracting Officer
E-Mail Address: patrick.k.harris11.civ@mail.mil
Date: 10 July 2017