J&A Number: YOK 15-0061.1

Justification and Approval for Sole Source Procurement Under Simplified Acquisition Test Program at FAR 13.5

1. Name of Requiring and Contracting Activity

Requiring Activity: Naval Medical Research Unit Number 2, Detachment Phnom Penh (NAMRU-2 PP)

Contracting Activity: NAVSUP Fleet Logistics Center, Site Singapore

2. Nature and/or Description of the Action Being Approved:

This Applied Biosystems Genetic Analyzer is required for use with NAMRU-2 testing. Research involving human use requires specific, detailed standard operation procedure (SOPs) to be developed and approved by Naval Medical Research Center and the Cambodian National Ethics Committee for Health Research Institutional Review Boards (IRB). These protocols support ongoing multi-year studies (4 to 6 years on average) and were adapted from scientific literature and historical experiments. The standard operating procedures that specify the exact brand and model of equipment to be used in human research are listed in the following protocols; N2.2012.0001; N2.2005.0004; and N2.2012.0007. As part of these approved protocols the specific equipment and manufacturer is specified and must remain the same due to manufacturer to manufacturer variations in formulations. Failure to comply with the SOPs will result in the creation on non-comparable results that may invalidate the study. In addition, failure to follow IRB protocols will result in violation of Department of Navy Human Research Protection Program (DON-HRPP) regulations as established by SECNAVINST 3900.39D.

In order to change equipment manufacturer, a comparison study, known as a bridging study, would be required. Bridging studies require head-to-head comparison of equipment; these studies generally require a minimum of 6 months of dedicated work to complete. Bridging studies are cost prohibitive ranging in cost from $20,000 to $50,000+, depending on the complexity of data produced and require significant man power (3,000-8,000 man hours). The integrity of research and continuity of human use studies must be maintained to ensure both compliance with required DON-HRPP and IRB regulations and the validity of the study. Even with the completion of bridging study, alternate equipment may be deemed to be incompatible with the study design resulting in the loss of both time and money required to complete the study. During the development of original SOPs, the equipment was competed in purchasing calls and evaluated for suitability for use in human research. Once the SOPs were finalized they were submitted as part of IRB package. At that point, the brand of equipment specified become a fixed part of the protocol necessitating continued use of a particular brand.

3. Description of the Supplies and Services Being Procured:

The 8-capillary AB 3500 Genetic Analyzer sets a new standard in capillary electrophoresis. The 3500 instrument is the first genetic analyzer designed with a specific feature set and workflow for the Human Identification application. The complete product combines the instrument with Applied Biosystems® reagents, consumables and software, as well as industry leading support, to provide an integrated HID system solution that significantly improves ease-of-use and application efficiencies.

Features of the AB 3500 Genetic Analyzer include:
- 8-capillary system that can be easily upgraded to a 24-capillary system when ready
- Sanger (Dye Termination), capillary sequencer
- Single-line, 505 nm, solid-state, long-life laser that uses a standard power supply and requires no heat-removal ducting
- Powerful, integrated data collection and primary analysis software that provides real-time assessment of data quality
- PC based work station

Encl (2)

- Advanced multiplexing capabilities for DNA fragment analysis with up to six unique dyes Application flexibility—one array and one polymer are used for most applications
- POP-7 Polymer compatible
- 505nm Solid state laser
- 96 well plate compatible
- 36 and 50 cm Capillary lengths
- Active temperature control form 18-70 centigrade
- BigDye Terminator v1.1 compatible
- Simple setup, operation and maintenance

4. Statutory Authority to Procure Requirement under Sole Source Procedures:

Section 4202 of the Clinger-Cohen Act of 1996 – a sole source acquisition under the authority of the test program for certain commercial items, as implemented by FAR 13.501(a).

5. Description of the Unique Capabilities or Qualifications, which Requires Acquisition under Sole Source Procedures:

The AB 3500 Genetic Analyzer is a complete system which includes each of the following components:
1) A capillary electrophoresis (8-cap) instrument includes Dell Workstation and Monitor

2) 3500 Data Collection Software - An Integrated software for instrument control, data collection, quality control and auto-analysis of sample files for base-calling and fragment sizing

3) DNA Sequencing and Fragment Analysis reagents and consumables for system qualification

4) Limited Warranty with one-year parts, labor and travel, Reference E328890 for uL and cUL Approval

5) A qualified Technical Applications Specialist will perform an initial on-site training, for up to 2 people. The training session is valid only during the initial warranty period of the instrument.

6. Description of Efforts Made to Ensure that Offers Are Solicited from as Many Potential Sources as Is Practicable (i.e., FACNET, CBD Synopsis or Documentation Explaining Exception to Synopsis Requirement):

The Solicitation was sent to three potential offerors in Cambodia - Dynamic Pharma, Kuang Hsien Medical, Europ Continents and two in Singapore - Fisher Scientific Pte Ltd, AITBiotech Pte Ltd and posted on AsiaNECO.

7. Determination that the Anticipated Cost to the Government Will Be "Fair and Reasonable":

NAMRU-2 needs to develop capillary electrophoresis ability. To use a system other than the AB 3500 would result in the need to train research partners on a new platform. Additionally if a platform other than AB 3500 is used, data will not be able to be shared and analyzed by our research partners. BDRD currently houses technical experts allowing for no-cost technical support and advanced training and data analysis of the AB 3500 system and data. It would not be cost prohibitive to develop similar expertise in a different system and negate the advantage of having research partners using similar systems. The Applied Biosystems™ 3500 Genetic Analyzer is a eight capillary instrument which can perform a wide variety of applications, including but not limited to, *de novo* sequencing, microsatellite analysis, fragment length analysis and SNP analysis. A variety of applications can be run using a single type of capillary array and polymer. This provides increased efficiency as the majority of applications will use the same reagents and consumable supplies.

All Applied Biosystems Genetic Analyzers are equipped with the same proven capillary electrophoresis technology, application-specific software, industry-leading BigDye® Terminator chemistry, and world-class support.

8. Description of the "Market Research" Conducted and the Results or a Statement Explaining the Reason Market Research Was Not Conducted:

The AB 3500 Genetic Analyzer instrument is the state-of-the-art platform for capillary electrophoresis of DNA sequences for both nuclear and mitochondrial DNA. The Applied Biosystems™ 3500 HID Genetic Analyzer data collection software integrates seamlessly with several downstream software packages to provide comprehensive analysis of genetic data. Specifically, the combination of the instrument and software package can perform multiple aspects of DNA sequencing analysis including *de novo* sequencing, mutational profiling, single nucleotide polymorphism (SNP) detection, comparative sequencing, resequencing, sequence confirmation, DNA library construction and identification. On the fragment analysis side alone, a variety of platforms are available for microsatellite analysis including LOH, SNP, MLPA, AFLP and t-RFLP. Human identification analysis can be performed using the traditional STR typing analysis, but in addition microbial DNA typing can also be performed. The majority of these applications can be run in a single capillary array and polymer type, therefore allowing the ability to multitask various applications.

NAMRU-2 conducted market research utilizing resources provided by various biotechnology companies including Beckman Coulter, Illumina, Roche and Pacific Biosciences. All systems produced by the various manufacturers were compared for functionally, capabilities, equipment cost and acceptance/use by other research partners.

The marketing research team investigated 6 parameters: initial cost, cost per sample, ability to meet research requirements, ease of use, support in Cambodia, used by collaborating institutions.

Numerous US research institutions including Naval Medical Research Center (NMRC), Armed Forces Research Institute of Medical Science, US Centers for Disease Control and Prevention and Johns Hopkins University Applied Physics Laboratory currently use the AB 3500 platform. NAMRU-2 PP currently has an ongoing collaboration with NMRC that has agreed to provide bioinformatic support to NAMRU-2 PP. In order for NAMRU-2 PP to receive the support and/or share data with other collaborating institutions, it is imperative that all data be generated on the same platform.

Applied Biosystems also provides dedicated access to cloud computing, which means data generated by the AB 3500 can be automatically uploaded into the cloud to allow for remote access and analysis by collaborating institutions. This option allows for increased throughput of data and will allow bioinformatic experts outside of Cambodia to have access to the data.

Based on the criteria developed by the market research team and the information outlined above, only the AB 3500 meets the research requirements of NAMRU-2 PP. Additionally the AB 3500 is supported by NAMRU-2 PP collaborators allowing for free data management support and analysis.

The Applied Biosystems 3500 Genetic Analyzer is the only product available in the market with the specifications required by NAMRU-2.

9. Any Other Documentation that Would Lend Support to the Sole Source Justification:

Sanger sequencing is known as the "gold-standard" for its accuracy, reliability, the Applied Biosystems® 3500 Genetic Analyzer is the only Sanger sequencing platform cleared for sequencing analysis as an IVD-labeled instrument. No other products meet the needs of NAMRU-2 for use of sequencing-based typing/subtyping of influenza viruses. With the Applied Biosystems® 3500 Genetic Analyzer, NAMRU-2 will develop sequenced-based diagnostic assays for influenza.

Applied Biosystems is the industry leader for capillary electrophoresis (CE) applications of DNA sequencing and DNA typing analysis. The 3500 Genetic Analyzer is recognized by the scientific community as providing the highest level of data quality and reliability in a capillary-based platform. This instrument has improved upon

previous CE systems in both hardware and software, which have been designed to optimize data quality, reliability and performance. Since this platform supports a wide variety of DNA sequencing and typing applications, this instrument can be utilized across a variety of research fields.

10. Listing of Interested Source:

Fisher Scientific Pte Ltd
8 Pandan Crescent
LL4, #05-05
Singapore 128464

11. Statement of Actions, if any, to Remove Barriers to Competition:

Not Applicable

12. Contracting Officer Certification that the Justification Is Accurate and Complete to the Best of the Contracting Officer's Knowledge and Belief with Supporting Data:

The Contracting Officer determines that the anticipated price(s) will be fair and reasonable based on prices found during market research and compare favorably to the Independent Government Estimate.

13. Total Estimated Dollar Value of the Acquisition Covered by this J&A:

The total dollar value for this acquisition is $160,200.

14. Contracting Activity Point of Contact: The Contract Specialist for the proposed contract action is: Mabel Koh Siew Kwan, Tel No: 6750-2567, Email: Mabel.Koh.SN@fe.navy.mil

CERTIFICATION AND APPROVAL PAGE –

All evidence supporting data that verify the Government's minimum needs or requirements or other rationale for a sole source and form a basis for this justification are accurate and complete to the best of my knowledge and belief.

02 SEP 2015

Technical or Requirements Personnel Certification — **Date**

This justification is accurate and complete to the best of my knowledge and belief.

Mabel Koh — 02 SEP 2015

Contracting Officer — **Date**

☒ **Approval**
(Actions between $150,000 ~ $650,000)
☐ **Certification**
(Actions exceeding $650,000)

Marie Jaworski — 9 Sept 15

Competition Advocate — **Date**

☐ **Approval**
(Actions between $650,000 ~ $6.5 million)
☒ **Concurrence**
(Actions between $150,000 ~ $650,000)

9/8/15

Legal Counsel — **Date**