

**JUSTIFICATION AND APPROVAL  
FOR OTHER THAN FULL AND OPEN COMPETITION**

**1. Contracting Activity:** U.S. Army Research, Development, and Engineering Command, Edgewood Contracting Division, ATTN: CCRD-ED, Aberdeen Proving Ground (EA), MD 21010-5401

**2. Description of Action:** Request approval to solicit for a new contract in support of the Edgewood Chemical Biological Center (ECBC) on the basis of other than full and open competition. Specifically, this purchase will support the Air Force sustainment requirements for the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Reagent/Assay Kits. A firm-fixed-price (FFP) supply contract with the sole manufacturer of the reagent/assay kits, Idaho Technology Inc. (ITI), 390 Wakara Way, Salt Lake City, UT 84108, USA, is contemplated. Fiscal Year (FY) 10 Procurement funds will be used.

**3. Description of Supplies/Services:** This contract will procure the reagent/assay kits used solely with the JBAIDS Polymerase Chain Reaction (PCR) for the JBAIDS units. The Reagent/Assay kits have an 11-12 month shelf life at time of shipment and cannot be manufactured more than 30 days before the required ship date.

**3.1** The proposed acquisition will consist of procurement of the following items that are included in the Reagent/Assay Kits:

Item	NSN/ITI Part Number	U/I	Quantity
PBS packets (10 packets/Box)	6550-01-528-9630 ASY-ASY-0061	EA	54
Triton-X (100ml)	6550-01-528-9651/ ASY-ASY-0062	EA	54
REAGENT, JBAIDS Module, 1-2-3™ RNA	6550-01-529-4839/ ASAT/ASY-501	EA	54
With TEMPTALE	6685-01-525-1328/ 6685015251328	EA	18
Extraction Control Kit – DNA	6550-01-550-0953/ 6550-01-550-0953	EA	126
Inhibition Control Kit – DNA	6550-01-550-0972/ JRPD-ASY-0126	EA	720
Q-FLOW KIT – DNA (replaces 1-2-3™ FLOW)	6550-01-550-1267/ ASY-ASY-0503	EA	180

**4. Authority Cited:** The statutory authority permitting other than full and open competition is 10 U.S.C. 2304( c )(1), as implemented by FAR 6.302-1, Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.

**5. Reason for Authority Cited:** As stated in FAR 6.302-1(a)(2)(ii), “When the supplies or services required by the agency are available from only one responsible source, or, for DoD, NASA, and the Coast Guard, from only one of a limited number of responsible sources, and no other type of supplies or services will satisfy agency requirements, full and open competition need not be provided for. The following supports the recommendation for a sole source effort:

a. The DoD JBAIDS contract (DASG60-03-C-0094) was awarded to Idaho Technology, Inc. (ITI) in September 2003, after a competitive fly-off of competing system design (eight offerors). The contract covered development and three production options. The current dollar value of the contract is \$74.284M between Sept 2003 and June 2010. The program office expended \$42.9M to develop the JBAIDS analyzer, software, and consumables to date. Additionally, the program office expended approximately \$60.0M to manufacture production systems, and purchase JBAIDS support equipment sets for DoD JBAIDS Users. The JBAIDS has been tested in three DoD operational test events, e.g., 2004 Operational Assessment, 2006 Multi-Service Initial Operational Test and Evaluation (MIOT&E), 2008 Follow-on Test and Evaluation (FOT&E), plus a system software reliability demonstration. The cost of the development and operational test events was \$7.4-\$8.0M (JBAIDS TEMP Funding Matrix). To date, 419 JBAIDS analyzers have been manufactured and distributed worldwide to all four DoD military Services, the National Guard, and DoD test laboratories.

b. The Government does not own the Technical Data Package (TDP).

c. ITI is the sole manufacturer of the JBAIDS and its unique consumables, in particular, Reagent/Assay kits. ITI’s JBAIDS is the only FDA approved medical device designed to meet operational requirements identified in the JBAIDS Joint Operation Requirement Document (JORD). Only their Reagent/Assay Kits have been validated with their analyzer.

d. ITI owns the design for the JBAIDS PCR analyzer, software program, the final Reagent/Assay Kits and Sample Purification/Control Kits.

e. Manufacture of another PCR analyzer or consumable by a manufacturer other than ITI would required additional licensing/patent royalty fees already paid to ITI and additional expenditure of DoD funds to test and to obtain FDA clearance of the systems through the DoD operational test and evaluation community.

**6. Efforts to Obtain Competition:** This effort is a one-time requirement to bridge the gap in obtaining the needed Reagent/Assay Kits. The U.S. Air Force is currently pursuing establishment of an Electronic Catalog (ECAT) contract to provide a procurement tool for the sustainment of the JBAIDS. This ECAT contract is expected to be in place by the end of calendar year 2010. In addition, as stated in Section 5 above, the Government does not own the technical data package for these items. Manufacture of another PCR analyzer or consumable by a manufacturer other than ITI would require additional licensing/patent royalty fees already paid to ITI and additional expenditure of DoD funds to test and to obtain FDA clearance of the

systems through the DoD operational test and evaluation community. Based on this information, no actions have been taken to obtain competition for this action.

**7. Actions to Increase Competition:** As stated in paragraph 6 above, the Air Force is currently pursuing establishment of an Electronic Catalog (ECAT) contract to provide a procurement tool for the sustainment of the JBAIDS. This ECAT contract is expected to be in place by the end of calendar year 2010 and will be utilized to fulfill the sustainment needs for the JBAIDS.

**8. Market Research:** Based on the information presented in Section 5 and 6 above, no additional market research has been conducted.

**9. Interested Sources:** The notice required by FAR 5.201 has been published and no vendors have responded to date. Any response to the Federal Business Opportunities notice will be considered solely for the purpose of determining whether to conduct a competitive procurement.

**10. Other Facts:**

**a. Procurement History:**

(1) The DoD JBAIDS contract (DASG60-03-C-0094) was awarded to Idaho Technology Inc., by JPM CBMS in September 2003, after a competitive fly-off of competing system designs (eight bidders). The contract covered development and three production options. The current dollar value of the contract is \$74.284M between Sept 2003 and June 2010. The program office expended \$42.9M to develop the JBAIDS analyzer, software, and consumables to date. Additionally, the program office expended approximately \$60.0M to manufacture production systems, and purchase JBAIDS support equipment sets for DoD JBAIDS Users. The JBAIDS has been tested in three DoD operational test events, e.g., 2004 Operational Assessment, 2006 Multi-Service Initial Operational Test and Evaluation (MIOT&E), 2008 Follow-on Test and Evaluation (FOT&E), plus a system software reliability demonstration. The cost of the development and operational test events was \$7.4-\$8.0M (JBAIDS TEMP Funding Matrix). To date, 419 JBAIDS analyzers have been manufactured and distributed worldwide to all four DoD military Services, the National Guard, and DoD test laboratories.

(2) Purchase order FA7014-09-P-0144 was awarded by the US Air Force on a sole source basis to Idaho Technology, Inc. on 08 September 2009. Award was made under the authority of 10 U.S.C. 2304(c)(1), as implemented by FAR 6.302-1, Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements. The same reagent/assay kits that are the subject of this J&A were procured under purchase order FA7014-09-P-0144. The J&A prepared by the Air Force to support their procurement cites the same sole source rationale utilized herein.

**b. Acquisition Data Availability:** A competitive Technical Data Package (TDP) is not currently available and the Government does not currently own the data developed under the JBAIDS contract DASG60-03-C-0094. It is not feasible to develop a complete TDP to enable

competition as this would cause an unacceptable schedule delay and prevent the Government from satisfying the Warfighters' requirement.

**c. Unusual and Compelling Urgency:** Not applicable

**d. Subcontracting Competition:** FAR clause 52.244-5, Competition in Subcontracting, will be included in the contract.

**e. Follow on Contracts:** The original systems and reagent/assay kits were procured from ITI after a competitive fly-off of competing system designs (eight bidders). The contract covered development and three production options. The current dollar value of the contract is \$74.284M between Sept 2003 and June 2010. The program office expended \$42.9M to develop the JBAIDS analyzer, software, and consumables to date. Additionally, the program office expended approximately \$60.0M to manufacture production systems, and purchase JBAIDS support equipment sets for DoD JBAIDS Users. The JBAIDS has been tested in three DoD operational test events, e.g., 2004 Operational Assessment, 2006 Multi-Service Initial Operational Test and Evaluation (MIOT&E), 2008 Follow-on Test and Evaluation (FOT&E), plus a system software reliability demonstration. The cost of the development and operational test events was \$7.4-\$8.0M (JBAIDS TEMP Funding Matrix). To date, 419 JBAIDS analyzers have been manufactured and distributed worldwide to all four DoD military Services, the National Guard, and DoD test laboratories. Manufacture of another PCR analyzer or consumable by a manufacturer other than ITI would require additional licensing/patent royalty fees already paid to ITI and additional expenditure of DoD funds to develop, test and to obtain FDA clearance of the systems through the DoD operational test and evaluation community. This cost is considered to be a substantial duplication of cost that could not be recovered through competition.