

## NOTICE TO THE PUBLIC

### QuantStudio 5 Real-Time PCR System with Laptop

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR 12.6. This announcement constitutes the only solicitation, and a written solicitation will not be issued.

This requirement is “Subject to the Availability of Funds” The Following FAR Clause applies: AVAILABILITY OF FUNDS (52.232-18) (APR 1984)

This synopsis, NAICS code 334516, identified as REQ#114031 is to notify contractors that the government intends to issue a Purchase Order in accordance with FAR Part 13.106 for the following specifications, under the simplified acquisition procedures.

### **Background**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is responsible for carrying out the regulations within the Food Drug & Cosmetic (FD&C) Act which provided FDA with regulatory authority over the sale of food products. The Southeast Food and Feed Laboratory (SFFL) is located in Atlanta, Georgia and is one of the Office of Regulatory Affairs (ORA) testing labs to uphold the mandates of the FD&C Act. CFSAN sets the regulatory guidelines on food safety and SFFL is responsible for providing regulatory support.

### **Objective**

SFFL has a requirement for 1 QuantStudio 5 Real-Time PCR System with Laptop and RapidFinder Analysis Software to prepare and homogenize samples. These instruments are utilized to analyze food and feed samples for the presence of filth elements contained in various food products. The use of this specific equipment is described in methods currently used by the laboratory for the analysis of imported and domestic food products for the presence of filth elements.

### **Scope**

The Contractor shall be able to provide an instrument that can perform as specified in the Statement of Work and provide Preventative Maintenance in accordance with the manufacturer’s specification during the contract period of performance.

### **Salient Characteristics**

All the following are minimum requirements. Equivalent requirements that differ from these minimum requirements must be justified by the proposing vendor and evaluated by the Government.

- The instrument includes an OptiFlex System which combines 4 coupled excitation and emission filter sets to enable collection of up to 4 unique combinations of wavelengths during a single run for multiplexing.
- The instrument software can control the instrument and analyze instrument's data from a remote computer within the same network.
- The instrument online software provides status monitoring of connected instruments and real time run plots.
- The instrument has real-time quantitative PCR installation specifications which demonstrate the ability to distinguish between 5,000 and 10,000 template copies with a 99.7% confidence level.
- Instrument's touch screen interface allows users to edit sample and target assignments.
- The instrument's melt curve or dissociation takes place in steps varying from  $0.015^{\circ}\text{C} \leq \Delta T \leq 3.66^{\circ}\text{C}$ .
- The 96-well sample block is made up of at least 3 separate Peltier-controlled blocks (known as VeriFlex zones). The maximum temperature difference that can be programmed across the block is  $10^{\circ}\text{C}$ . The maximum difference in temperature allowed between adjacent blocks is  $5^{\circ}\text{C}$ .
- The instrument's dimensions are 27 W x 50 D x 40 H cm, designed to maximize horizontal and vertical bench space.
- Instrument installation does not require dye calibration
- Instrument can be connected to an online ecosystem and instrument data/status will be automatically uploaded.

An instrument software that is desktop based, which allows for single plate run setup and analysis.

### **Delivery**

The QuantStudio 5 RT-PCR System with Laptop will be delivered and installed at:

Southeast Feed and Food Laboratory, ORA  
 Food and Drug Administration  
 60 Eighth Street NE  
 Atlanta, GA 30309  
 POC: David Malakauskas  
 404-575-1526  
[David.malakauskas@fda.hhs.gov](mailto:David.malakauskas@fda.hhs.gov)

### **Period of Performance**

Delivery to include transportation to final destination site at vendor's cost, installation, testing and training, expected within 90 days of award with one year of post-warranty depot service that will include a QuantStudio 5 loaner for use during repairs.

### **Contracting Officer Authority**

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in

the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms, or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

### **Contract Type**

Firm-Fixed-Price (FFP). All deliverables shall be clearly identified, complete with clear descriptions; due dates, and at a predetermined, agreed-upon price.

### **Government Contacts**

#### **Contracting Officer: (CO):**

Office of Acquisitions Grants and Services

Michael Gemmill

Email: Michael.Gemmill@fda.hhs.gov

#### ***Contracting Office Representative (COR): TBD***

### **Government Holidays**

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day.

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

January (New Year's Day)

January (Martin Luther King Day)

February (President's Day)

May (Memorial Day)

June (Juneteenth)

July (Independence Day)

September (Labor Day)

October (Columbus Day)

November (Veterans Day)

November (Thanksgiving Day)

December (Christmas Day)

### **BASIS OF AWARD**

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method. Award will be made on the basis of the lowest evaluated price meeting or exceeding the non-cost factor (technical conformance to the requirements of the solicitation). The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

In order to facilitate the award process, ALL quotes shall include a statement regarding the terms and conditions herein. Additionally, all quotes shall include price (s); FOB point; a poc (name and telephone number); a statement from the offeror verifying that they are Registered in SAM.gov under NAICS code; 334516\_delivery date (delivery date is of the utmost importance); business size; and payment terms. Delivery shall be to FDA.

FDA intends to make an award soon after the response date of this notice and all quotes must be submitted via email to Michael.Gemmill@fda.hhs.gov and be received by 5:00 PM (1700) on , August 4,2022 to the attention of Michael Gemmill. Offerors shall ensure the RFQ number is visible in the header of the email.

**ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICIATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1700) on , August 4,2022. FAX QUOTES SHALL NOT BE ACCEPTED.**