

**Statement of Work  
Center for Food Safety and Applied Nutrition**

**Title: Purchase of an Iseq Sequencer**

## **1. Background**

Development of an extraction and characterization protocols for detection of enteric viruses utilizing timely and sensitive techniques will allow improved monitoring in shellfish, shellfish growing areas, and shellfish associated outbreak investigations. There is no cell culture propagation for human norovirus. The definitive means for characterization of human noroviruses is sequencing of representative RT-PCR products. RT-qPCR has become the gold standard for molecular based detection of microorganisms. To date, rapid molecular based methods such as RT-qPCR are the only means for detecting non-culturable enteric viruses at low levels. Characterization via sequencing of these enteric viruses allows FDA to create an epidemiological link between the clinical and food samples during surveillance and outbreak investigations. This instrument technology has been selected to be used by FDA and CDC for next generation sequencing and there are protocols that have been standardized for this platform technology. This instrument assigns quality scores to generated sequences which help filter out low quality data. In addition, the instrument requires no need for ancillary amplification systems or IT infrastructure. Our bench space is limited, and this instrument has a very low footprint (12"x13"x15").

The CFSAN scientists will use the instrument requested by the above-mentioned vendor to assist with development and validation of methods used for the characterization of foodborne enteric viruses. The protocols developed will be used in conjunction with CDC's Calicivirus group and Viral Hepatitis group for foodborne outbreak investigations and surveillance. The knowledge and information obtained using these detection and characterization methods for foodborne disease and associated phenomena will enhance CFSAN's ability to protect the safety of the food supply.

The FDA has a critical need for instrumentation to facilitate rapid detection characterization of foodborne pathogens. All items will include the GSA pricing in the purchase agreement, if available.

## **2. Objectives**

The objective is to purchase an ISeq instrument. ISeq System Integrated system for automated generation of DNA clonal clusters by bridge amplification, sequencing, primary and secondary analysis. The iSeq 100 System is a low-cost benchtop next generation sequencer. The system is 1 cubic feet and includes a mounted 10 inch screen. This system also comes equipped with on board bioinformatics capabilities. The system is self-installable by the customer and does not include installation services. The system is covered by a twelve (12) month warranty after customer installation.

### **3. Specific Requirement**

The vendor shall furnish the appropriate instrument:

A low cost benchtop next generation sequencer. The system is 1 cubic feet and includes a mounted 10 inch screen. This system also comes equipped with on board bioinformatics capabilities. The system is self-installable by the customer and does not include installation services. The system is covered by a twelve (12) month warranty after customer installation.

### **4. Deliverables**

- a. The vendor must deliver an iSeq 100 System.
- b. The vendor must deliver a twelve (12)month warranty on the iSeq 100 System, starting upon installation of the instrument.