US Department of Agriculture (USDA)

Statement of Work

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Project

Procurement of an automated plasmid purification system

General Information

1.0 Scope of Work

The scope of work for this project is to purchase and install a fully automated plasmid purification system and receive any initial training required for operation of the instrument. This equipment will greatly increase the capacity of reagent production in support of the diagnostic mission of the Foreign Animal Disease Diagnostic Laboratory (FADDL) and National Bio and Agro-defense Facility (NBAF) as a whole.

2.0 Background

As part of the FADDL operational transition to NBAF, development of assays supporting the expansion of the diagnostic mission is underway. This mission expansion includes providing diagnostic capabilities for highly pathogenic, zoonotic pathogens that pose a grave threat to American agriculture. The first step in providing diagnostic support for these pathogens is developing reagents for the assays that will be performed. One type of critical reagent in development is recombinantly expressed proteins to be used as antigens directly in diagnostic assays or indirectly in the production of other reagents. Producing these proteins at the scale and quality needed requires purification of the plasmid expression vectors at large scale and very high purity. Transformation of genetic material into a host expression system is an inherently inefficient process that requires a large amount of plasmid that is free of any contaminants that would hinder transformation efficiency further. The current method for plasmid purification is a manual process that can produce plasmid that is pure but is labor and time intensive that requires a highly trained individual 6-8 hours of work. This manual process decreases the scale and throughput able to be achieved and the purity results are viable due to the amount of handling and movement of the sample through the various steps and equipment required. Due to the number of expression vectors being onboarded currently and trend towards expanding that number in the future, the manual process is non-viable. The answer to this problem is transitioning to fully automated plasmid purification. Automated plasmid purification systems relieve the labor intensive burden, increase the efficiency at scale and high throughput, and ensures a consistent high purity product.

Contractor Requirements

3.0 Technical Requirements / Tasks

Contractor will deliver an automated plasmid purification system within 60 days of award that fits the following technical requirements, as well as, conduct any on site installation, verification of performance, and training required to operate the system.

Technical requirements for automated plasmid purification system

- System must be fully automated with the user able to load bacterial culture, walk away during purification process, and only come back to instrument to remove purified plasmid.
- System must be able to consistently and reliably purify plasmids >3kb in size.
- System must be able to produce, in a single run, maxiprep-scale plasmid yields (500 ug – 1mg) that is endotoxin free and ready for transfection immediately upon removal from system.
- System must fit within an approximately 24x24 inch footprint on the benchtop and be self contained, not requiring an external computer and software for operation.
- System must be able to go from bacterial culture to purified plasmid at maxi scale in under 90 minutes.

4.0 Government Furnished

Contractor will require access to:
National Bio and Agro-Defense Facility (NBAF)
1980 Denison Ave
Manhattan, KS 66506

The laboratory in which this system will be installed is, at this time, a BSL-2 containment facility; however, personnel performing installation and training might be required to enter BSL-3 laboratories. Depending on the operational status

of the containment space, entering BSL-3 containment requires an exit shower and dedicated tools/supplies to be left inside the lab. USDA will provide escorted access to the laboratory for any service and maintenance visits, as well as biosafety training for operating within the laboratory. Access to the facility requires a suitability assessment and approval from NBAF security prior to the visit (will take up to 2 weeks for US citizens and 45 days if the non-US citizens are involved). The facility is closed on all federal holidays. RealID is required for entry to NBAF.

5.0 Deliverables / Schedule

Key Deliverables

Item No.	*Deliverable*	*Objective*	*Due*
1	*Delivery of system*	*Provide automated plasmid purification system that meets the technical specifications listed above.*	*Within 60 days of award*
2	*One contractor for any required installation, training, or verification of function.*	*Provide suitable technician for any required installation, training, or verification of function visits.*	*Within 60 days of delivery*

6.0 Travel

Travel cost will not be reimbursed to the contractor installing and/or performing the initial training on usage of the instrument as the costs of travel are covered under the purchase.

7.0 Contractor's Key Personnel

Personnel must be trained and certified to install the system and provide training by the vendor providing the system.

8.0 Security Requirements

Specify security requirements that apply to the contract performance. Specify the level of clearances required and identify positions that are applicable.

The visiting personnel must be capable of meeting facility entry security requirements which may include (but not be limited to) U.S. citizenship, criminal background investigation, and submission of access paperwork in a timely fashion. Independent access to the facility will not be permitted – the technician/contractor must be accompanied by a federal employee (escort) at all times.

9.0 Data Rights

Any Confidential Business Information (CBI) data that would need to be sent for troubleshooting purposes must be redacted as appropriate. The contractor does not have permission to share any data generated in the laboratory with outside vendors, firms, stakeholders, or personnel without specific approval from Veterinary Services Management personnel.

10.0 Section 508 – Electronic and Information Technology Standards

N/A