

Answered Questions and Addenda for:

Request for Proposals (RFP)

For

LC-QTOF System for Seized Drugs Testing

Addenda:

9/19/2024: **Proposal Time/Date” means at or before 2:00 p.m. in Houston, Texas, on October 11, 2024**

has been changed to:

Proposal Time/Date” means at or before 2:00 p.m. in Houston, Texas, on October 25 , 2024

Answered Questions:

9/6/2024:

Question: Will HFSC be willing to accept multiple proposals from one company?

Answer: Yes, HFSC will accept multiple proposals from one company, the proposals will be reviewed and scored as separate responses.

9/9/2024:

Question: Could you please clarify as to what is meant by “workstations” in the RFP?

Answer: “Workstation” refers to the hardware and software necessary to operate the LC/QTOF system. This would include but may not be limited to computer, monitor, keyboard, mouse, printer, cords/cables, and all software for data acquisition and data analysis. “Workstation” is not meant to refer to benches or tables on which the equipment will sit.

9/12/2024:

Question One – A Tap Transformer is requested on the quote, however this might not be necessary depending on the voltage available. What voltage is available in the lab where this instrument will be placed?

Answer: The electrical line would be installed after the selection of the system so the voltage would be dependent on the system needs. The tap transformer is primarily for the nitrogen generator and would be beneficial if in the future another instrument is placed on the same electrical line as it would help to stabilize the voltage distribution among two instruments. Another consideration is

the reliability of the building's electrical and if any harm would come from not using a tap transformer if something with the electrical would go wrong.

Question Two – A solvent selection system is requested on the quote. Is this to be automated, or manually operated? For each LC pump, how many mobile phases do you want the ability to select amongst?

Answer: An automated solvent selection system is preferred with a minimum of two mobile phases available. The overall solvent selection system needs would be dependent on the pre-made method options provided.

9/25/2024:

Question: With respect to Tab 3, could you please clarify what “validation” means?

- a. FROM TAB 3 - “Systems and processes – Describe your proposed plan and timeline to ensure timely installation, validation, calibration, implementation and quality assurance so the product, service and training meets expected HFSC needs.”

Answer: With respect to Tab 3, “Validation” means for the vender to be able to assist with any issues regarding the validation process performed by HFSC. Assist means providing any validation material available from the vendor for the pre-made method (see Scope of Work 5.8), having a direct contact that can assist with any issues during the validation process performed by HFSC, and/or service calls that require an individual to come to the lab for troubleshooting.

Question: With respect to section 4.2 of the Scope of Work, could you please clarify whether HFCS will be purchasing the 1, 2, or 3 years upfront with the instrumentation? Or is the request for the pricing of 1, 2, and 3 years of warranty for informational purposes once the initial manufacturer's warranty has expired?

- a. “4.2. Service Plan/Warranty - The Proposer shall provide pricing for instrument service plans for 1 year, 2 years, and 3 years. The Proposer shall also specify the warranties that will accompany the hardware and software.”

Answer: If additional coverage/services are available in addition to the initial manufacturer's warranty (such as preventative maintenance), then the cost of this coverage should also be included for consideration with the initial purchase. The request for multiple year pricing for instrument service plans beyond the initial manufacturer's warranty will be evaluated for inclusion in the upfront purchase, but will also be useful when considering the instrument's long-term cost.

Question: With respect to section 4.2 of the Scope of Work, could you please provide details on the level of warranty you desire for the instrumentation and the software?

- a. “4.2. Service Plan/Warranty - The Proposer shall provide pricing for instrument service plans for 1 year, 2 years, and 3 years. The Proposer shall also specify the warranties that will accompany the hardware and software.”

Answer: If various levels of service/warranty are available, then list those with the services included and the corresponding costs. At a minimum the services/warranty should include preventative maintenance, part replacement, service calls, updates regarding software, etc.

Question: We note that both a Nitrogen Generator and a UPS are included in the Pricing Proposal table. Would you want the Nitrogen Generator to run on the UPS? If so, would your lab be able to support a 50 ampere UPS?

Answer: The UPS listed is to be used for the LCQTOF, but if the UPS can support both the nitrogen generator and the LCQTOF then that is certainly acceptable. If however two UPS are required then please list that as well. A dedicated electrical line will be installed during the installation of the instrument in order to ensure that all electrical needs will be met.

Questions:

1. What methods are currently being employed by the HFSC for the identification of seized drugs in the laboratory?
2. Under which standards, guidelines, and/or accreditations are these methods qualified?
3. Specifically, which of these methods, screening and/or confirmation, will transfer to this newly purchased instrument? Do laboratory QA/QC procedures require additional validation studies that fall outside of the scope referenced standards/guidelines/accreditations?
4. What methods does the lab currently not employ but will require method validation on this instrument?

Answers to the above question 1 thru 4: HFSC is accredited by ANAB to ISO/IEC 17025:2017 Accreditation Requirements for Forensic Testing and Calibration (2023). The Seized Drugs section does not currently utilize an LC or LC-QTOF system; therefore does not have any existing methods for such a system so this will be a new technology to be added to the existing analytical methodologies for drug identification. Any pre-made method provided by the vendor (see Scope of Work 5.8) will need to go through a validation performed by HFSC following ANAB accreditation requirements. Any validation material for the pre-made method provided by the vendor will help to facilitate the HFSC validation process. During this process the vender should have a direct contact

available that can assist with issues encountered, and/or service calls that require an individual to come to the lab for troubleshooting.

Question: What LIMS system does HFSC currently use?

Answer: The HFSC Seized Drugs section currently uses LIMS-plus version 5.3.37.0 by Justice Trax for its LIMS system.