



THE NEED FOR ANNUAL SERVICE AND PREVENTATIVE MAINTENANCE CONTRACTS FOR ANALYTICAL INSTRUMENTS

SUMMARY

Regular preventative maintenance and priority access to instrument repair services are critical to public health by ensuring timely and accurate testing capability and capacity in public health laboratories. Instrument manufacturers offer the most comprehensive service contracts including priority repairs, authentic instrument parts and instrument software support. Instrument service contracts with manufacturers may come at a higher initial cost, and offer several advantages that can positively affect laboratory performance and operations. They are able to meet public health laboratory requirements for instrument service support avoiding the potential for delays, utilize certified and standard consumables, and offer instrument software support. Therefore, APHL recommends that instrument service contracts be maintained with the original instrument vendor whenever feasible.

BACKGROUND

Public health laboratories maintain a significant number of analytical instruments for chemical and microbiological testing purposes. These instruments support testing in foodborne outbreaks, disease surveillance, newborn screening, biomonitoring and emergency response under federal programs such as the Laboratory Response Network (LRN) or Food Emergency Response Network (FERN). Continued operation of these instruments is critical to meet turnaround times for sample analysis that are mandated by federal or state regulatory requirements, or certification programs such as CLIA, NELAP or ISO.

Contracts for these services with instrument vendor approved technicians are essential to continued operation of analytical instruments used for emergency response, exposure assessment and public health surveillance. Additionally, service contracts are a requirement of funding under the Public Health Emergency Preparedness (PHEP) cooperative agreement, a critical source of funding for state, local and territorial public health departments. To ensure the readiness of the instrumentation, a full-service contract with regular preventative maintenance visits is required by many federal programs and certifying bodies.

CONSIDERATIONS FOR THIRD PARTY SERVICE CONTRACTS

Before contracting for services with a third party, ensure they describe how each service component will be delivered to your organization. Confirm what constitutes acceptable standards for each measurable service item and ramifications for those standards not being met, and make sure these terms are incorporated into the underlying contract that governs the relationship for the applicable services.

- **Timeliness in completing service calls:** Third-party providers that do not perform service functions directly are reliant on other agents to repair or service instrumentation. Since the repair agent must have all repair costs approved in advance, this can result in delays of weeks to months in completing service calls as information is relayed between the laboratory, third-party service provider and the repair agent. These delays negate the utility of mandated response times that are standard in instrument vendor provided contracts and create unacceptable barriers to completing public health testing.
- **Accreditation standards:** Accreditation by standards such as ISO require that the entity performing the service also be ISO-accredited if they are performing calibrations on the instrument. As third-party contractors have the discretion to choose their own subcontractors, there is no guarantee of ISO-certified service for the instrument. This directly violates ISO accreditation standards and will lead to noncompliance for the laboratory.

PHEP REQUIREMENTS FOR INSTRUMENT MAINTENANCE CONTRACTS AND SOFTWARE UPGRADES

Instrument maintenance must be performed following manufacturer instructions/requirements. If using an instrument maintenance vendor other than a manufacturer, documentation should be obtained describing the vendor's training and certification by the appropriate manufacturer.

Maintenance contracts and software upgrades for instruments utilized with LRN assays are acceptable to be purchased with PHEP funding. Please ensure that maintenance contracts and software upgrades are included in your PHEP budget request..

LRN-B

Laboratory Response Network for Biological Threats (LRN-B) advanced and standard laboratories are required to obtain and sustain maintenance agreements for LRN-B equipment valued at more than \$25,000, and for LRN-B equipment used for US Food and Drug Administration (FDA) 510(k) cleared assays.

LRN-C

LRN-C Level 1 and Level 2 laboratories are required to obtain and sustain maintenance agreements for LRN-C equipment valued at more than \$25,000. They should budget sufficient funding to obtain and sustain service agreements for analytical equipment and extraction platforms valued at more than \$25,000. Instrument service must be performed by the manufacturer or a company certified by the manufacturer. Annual service agreements typically cost 10-12% of the instrument purchase price.

APHL has negotiated public health pricing for service agreements with some vendors. Please see the [APHL public health pricing list](#) for available discounts (membership required).

- **Instrument performance:** Using third-party providers runs the risk of having service performed or consumable materials used that are non-standard and do not meet the original specifications of the instrument vendor. Over the long run, use of non-certified technicians and non-standard consumables may result in poor or unacceptable performance of the instrumentation.
- **Software upgrades:** The third-party service providers often do not support software upgrades for newer versions of instrument operating systems, or computer operating systems such as the conversion to Windows 10. Instrument operating systems are proprietary and typically only available through the original vendor.

REFERENCE

Association of Public Health Laboratories. APHL PHEP BP3 Guidance Tool. 2021. Available at https://www.aphl.org/programs/preparedness/Documents/2021_Budget_Period%203_APHL_PHEP_Guidance_Tool.pdf

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