



LABORATORY EQUIPMENT MANAGEMENT

Guidance to African
Union Member States

August 2023



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Acknowledgements

The Africa Centres for Disease Control and Prevention (Africa CDC) is grateful to the substantial contribution made by Partners in developing the Equipment Management Guideline. The Africa CDC particularly appreciates the technical inputs provided by the Members of the Africa Laboratory Technical Working Group (AfLTWG) whose deliberations enriched the guidance to Equipment Management. This guiding document recommends comprehensive strategy for equipment management to ensure accurate, reliable and timely testing, and maintain a high level of laboratory performance.

In addition, the Africa CDC would like to recognize and acknowledges the individual listed here below for the review and inputs provided during the development of this Equipment Management guideline:

- Abdourahmane SOW (West Africa Health Organization)
- Anafi Mataka (African Society for Laboratory Medicine)
- Aytenev Ashenafi Eshete (Africa Centres for Disease Control and Prevention)
- Fatim Cham-Jallow (The Global Fund)
- George Alemnji (United States Centers for Disease Control and Prevention)
- Jane Carter (Amref Health Africa)
- Jane Cunningham (World Health Organization)
- Jumoke Sule (UK Health Security Agency)
- Juliet Bryant (The Global Fund)
- Kekeletso Kao (FIND)
- Ndlovu Nqobile (African Society for Laboratory Medicine)
- Osborn Otieno (The Global Fund)
- Pascale Ondo (African Society for Laboratory Medicine)
- Rosanna Peeling (London School of Hygiene & Tropical Medicine)
- Samuel Yingst (United States Centers for Disease Control and Prevention, Zambia)
- Toni Whistler (The Global Fund)
- Trevor Peter (Clinton Health Access Initiative)
- Yenew Kebede Tebeje (Africa Centres for Disease Control and Prevention)

Acronyms

AIP	All-inclusive pricing
BSC	Biosafety cabinet
EoL	End of life
IHR	International Health Regulations
MALDI-TOF	Matrix assisted Laser Desorption Ionization -time of flight
NMIs	National Metrology Institutes
PM	Preventive maintenance
POCT	Point-of-care testing
SOP	Standard operating procedure
TDF	Time of Flight

Executive Summary

In recent years, African countries have made great advances in capacity for laboratory testing for clinical use, surveillance and public health emergency management, and for research and development through substantial investments in infrastructure, including the deployment of large numbers of laboratory analyzers. However, weaknesses in laboratory equipment management remain key concerns and threaten to undermine these advances. Challenges include lack of appropriate maintenance, limited formal equipment operation and maintenance training, failure to implement regular calibration and institute service contracts, and inadequate designated equipment space, among others. Equipment management, which includes the administration, monitoring and maintenance of laboratory equipment, is an essential component of patient care, public health research, technology transfer, and public health emergency management.

Significant experience in equipment management has been gained in some settings in recent years and this provides a source for best practices that member states can adapt to support the establishment of well-organised equipment management programs. These include key considerations for procurement and acquisition of laboratory equipment, equipment operation, maintenance and calibration and retirement and disposal of equipment. Documentation and records are also essential management requirements, including a full and accurate inventory of all laboratory equipment, materials provided by the manufacturer on operation, maintenance and troubleshooting, and records of all preventive maintenance and repair actions.

This document assembles these best practices and provides a resource for the proper management of equipment in the laboratory to ensure accurate, reliable and timely testing, and maintain a high level of laboratory performance. Improved equipment management also lowers repair costs, lengthens instrument life, reduces interruption of services due to breakdowns and failures, and enables laboratory accreditation and the achievement of high quality and accessible laboratory services at all levels of healthcare service delivery.

Contents

Acknowledgements	2
Acronyms	3
Executive Summary	4
Introduction	6
Challenges with equipment management	7
Key considerations and best practices for management of laboratory equipment	9
1) Preparation and planning	9
2) Procurement of laboratory equipment	10
3) Donation of laboratory equipment	12
4) Installation, qualification and validation of newly acquired equipment	12
5) Equipment maintenance policy development	13
5a) Service level agreements	13
6) Equipment operation	15
6a. Equipment maintenance	15
6b. Equipment calibration	18
7) Retiring and disposal of equipment	19
8) Managing equipment records	20
References	22
Annexes	23

Introduction

Laboratory systems and services are one of the core capacities that countries must develop for the implementation of the International Health Regulations (IHR (2005)) (1), and therefore well-functioning laboratories are a critical component for strengthening health systems in Africa. The quality and effectiveness of laboratory services relies significantly on the availability of reliable equipment, well trained and skilled laboratory personnel, reagents and other supplies that meet quality standards. Laboratory operations are often time-sensitive and require uninterrupted equipment functionality to ensure quality of results is not jeopardised. Equipment breakdowns result in reduced productivity, poor patient outcomes, low staff morale and financial loss due to wasted time and resources.

Laboratory systems across many countries have been challenged by prolonged equipment downtime; lack of advance planning for post-warranty service; inadequate capacity to address instrument breakdowns in a timely manner; and poor adherence to preventive maintenance (PM) protocols (2, 3). For example, of the 3,500 laboratories in 16 African countries reported in a Laboratory Mapping Programme (4), approximately 73% lacked equipment replacement parts, 60 % of the equipment was not regularly maintained, and nearly 81 % of laboratories lacked a system for routine equipment calibration. An assessment of biosafety cabinets (BSCs) painted a similar picture whereby 88% lacked current certification (4). Additionally, a recent integration readiness assessment piloted in 17 counties revealed 6/17 (35%) had no documented procedures for selection and placement of equipment, and only 5/17 (29.4%) received some guidance from disease specific programmes (HIV/TB) (5).

Laboratory equipment represents a large portion of the overall budget expenditure of health facilities. Repair services and replacement parts for equipment tend to be costly, and these rise when laboratory equipment is poorly maintained. It is critical to perform PM to keep these costs low. The practices of regular servicing, comprehensive training, and proper cleaning go a long way to ensuring equipment performs optimally for as long as possible. Repair and maintenance services are critical to laboratory operations and generally come through in-house repairs, equipment manufacturers' service contracts, or third-party service contracts. Each has benefits and drawbacks.

Different laboratory equipment platforms have been noted within countries' diagnostic networks. To enhance quality and efficient resource use, there has been a call for equipment to be standardised wherever possible within a tiered laboratory network¹. Standardization and harmonisation of equipment has economic and logistical benefits including consolidated reagent purchasing and reduced service, maintenance, and training costs. Standardization can lead to more efficient and rational use of laboratory tests and may streamline product selection, forecasting, quantification and procurement practices.

Many countries have undertaken efforts to harmonise laboratory policies across disease programmes, to standardise laboratory equipment (manufacturers, models and assay formats) appropriate for each level of tiered diagnostic networks. However, there are still challenges within the four phases of the equipment lifecycle: planning, procurement and acquisition, operation and maintenance, and disposal. Each phase is critical in supporting longevity and performance of the equipment.

The purpose of this document is to serve as a resource for equipment management in Africa.

These guidelines will enable countries to standardise the management, and efficient and effective use of laboratory equipment in their countries. It offers choices for countries to consider as they address the challenges faced at all the stages of the equipment life cycle for both general and specialised equipment. It also provides essential information to member states, partners, healthcare professionals and manufacturers to optimise the continent's equipment life cycle.

¹ Laboratory standardization and harmonization is a process of aligning test offerings and equipment with the needs and volumes at each level of the national health system.

Challenges with equipment management

The Africa region faces a myriad of challenges related to laboratory equipment including funding limitations and lack of infrastructure, i.e., inadequate space to house the equipment, and reliable power supplies. Laboratory equipment can be expensive, making it difficult to afford the latest technologies and maintain a well-equipped laboratory. High costs also restrict the number of instruments that can be procured, limiting the range of tests that can be performed at the different tiers of the laboratory network.

Countries face challenges with the procurement of closed platforms or specialised equipment which means that the equipment cannot be used for their own testing priorities thereby increasing the costs of laboratory operations.

Equipment donations (Box 1 below): Countries face challenges when receiving donated equipment (6) if they do not have a clear policy which outlines eligibility and acceptance/rejection criteria, and evaluation and screening procedures to assess equipment suitability, maintenance and repair services, and communication/publicity associated with the donation. All donated equipment must meet each country's minimum eligibility criteria (Box 2) otherwise countries may be burdened with obsolete equipment without spare parts or reagents (7).

Half-life of equipment technology: There are rapid advances in equipment technology presenting challenges to country specific guidelines and testing algorithms as countries are required to change guidelines frequently.

Funding: Countries are faced with limited funding for laboratory equipment which is worsened by disease outbreaks caused by a wide range of pathogens being faced by the different countries. Maintenance, calibration and repair costs should be built into a country's funding stream.

Box 1: Core Principles for Equipment Donations

1. Laboratory equipment donations should benefit the recipient to the maximum extent possible, as determined by an expressed and validated need of the recipient.
2. Donations should be given with full respect for the recipients and their authority within the laboratory system and be supportive of existing policies and administrative arrangements. Equipment donations must be based on a sound analysis of the needs, and their selection and distribution must fit within existing technology policies and administrative systems.
3. Double standards in quality are unacceptable: items not acceptable to the donor country are unacceptable as donations.
4. There should be effective communication between the donor, the recipient authority and, whenever possible, the end-user, before, during and after the donation.
5. All equipment should be covered by service and maintenance contracts for a minimum period outlined in the national guidelines.
6. Ideally, there should be some provisions articulated about how final disposal of the instrument will be handled after it has reached end of life.

Box 2: Minimum eligibility criteria for donated equipment

1. The recipient needs the equipment, has the expertise to operate and maintain it.
2. Compliance with specifications and standards.
3. Non-obsolescence and appropriateness for the user environment.
4. Ensure infrastructure requirements for installation are met – electricity, water quality, physical space, air conditioning, humidity control, etc.
5. Cover plans for trainings for users and maintenance staff.
6. Availability of operating supplies/consumables and spare parts for the equipment, whether new or used.
7. Adhere to national policy and regulatory requirements.
8. How and who covers the recurrent costs of running the equipment.
9. Are warranties and guarantees included in the package for a reasonable period.
10. Consider compatibility with existing LIS.
11. Conform to the national algorithm or testing policy.
12. Conform to national requirements regarding selection of equipment.
13. Plans for service and maintenance and local support capabilities.

Point of care vs conventional technologies: With the advent of point-of-care testing (POCT) and newer advanced molecular diagnostics being used for disease surveillance, there is an urgent need for countries to develop and/or amend policies and guidance on the use of these technologies. Guidance is required on procurement, selection, quality assurance, staff training, and monitoring and evaluation of the different technologies at country and facility levels.

Setting up local equipment manufacturing companies: Most countries do not have local equipment manufacturing companies because of limited access to technology, skilled engineers, patents and licences. This is worsened by limited funding for research and development in local colleges and universities which is coupled with brain drain that is on the increase in resource limited settings.

Environmental challenges: Equipment functionality is affected by changes in temperature and humidity and the presence of dust, and these environmental factors need to be addressed for the accurate functioning of equipment in the laboratory. Inadequate utilities, both electricity and water, are also basic services essential to prevent equipment malfunction. The use of electrical stabilisers and uninterrupted power supplies is important to help prevent rapid deterioration of sensitive instruments. Alternative electrical sources such as solar panels or generators should be available for laboratories with known erratic power supplies. Laboratories should operate in an air-conditioned space to ensure the equipment functions within the manufacturers' specified temperature range. Humidity levels need to be monitored to ensure sensitive equipment is protected from electrostatic discharges, and to reduce the risk of damage from excessive moisture build-up in the equipment.

Decommissioning: There are no specific requirements for decommissioning of laboratory equipment in many settings. When instruments reach their end of life (EoL), removal and disposal often pose challenges to ensure compliance with relevant local directives regarding administrative policies for asset management, as well as environmental and safety concerns.

Standardization and harmonization: Countries have not developed frameworks to guide on standardization and harmonisation of laboratory equipment in line with Maputo Declaration 2008 (8). Standardization as a public health approach promotes most efficient and cost-effective use of equipment through strategic placement in tiered laboratory networks. This will support harmonization of test procedures, reagents and service and maintenance.

Key considerations and best practices for management of laboratory equipment

The following section details the key considerations and best practices for management of laboratory equipment through the lens of equipment life cycle phases (9).

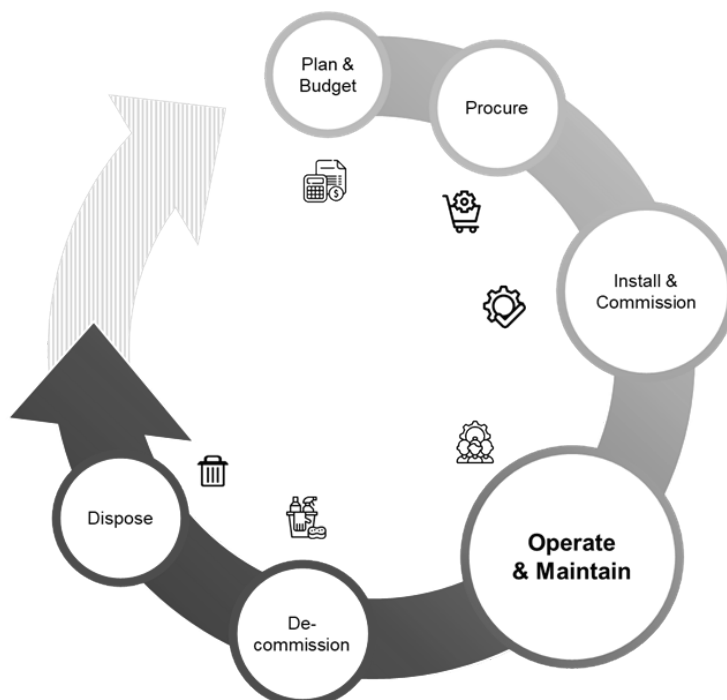


Figure 1. Equipment life cycle

1) Preparation and planning

An important step in the equipment preparation and planning phase is assessing the organisation's needs and determining the most cost-effective strategy for establishing the mechanism for equipment procurement and maintenance.

Key Considerations

- **Diagnostic network:** It is important for the country to define the structure of its diagnostic network and determine if testing will be centralised or decentralised. The Essential Diagnostic List should be used to make informed decisions when purchasing equipment. Focusing on the tests listed in the EDL, will ensure that the equipment investment is aligned with the country's healthcare priorities and needs.
- **Regulation:** Ensure that the equipment meets the necessary compliance standards to meet the national regulatory requirements.
- **Demand for testing:** Identify all disease program needs, specimen and test types. Estimate the volume of samples to be handled on a regular basis. This assists with equipment choice and obtaining the appropriate throughput capacity to handle the workload efficiently.
- **Maintenance support requirements:** Assess the maintenance requirements of the equipment as some equipment may need frequent maintenance or calibration to maintain accuracy. Factor in the cost and time associated with maintaining the equipment into facility budgets. Availability of local biomedical engineering capacity for basic service and maintenance should be considered, and if possible, have the bioengineers present when the manufacturer installs the equipment in the laboratory.

Best practices

- Use diagnostic network optimisation data prior to equipment procurement, this will help determine the additional capacity needs and the best placement of instruments within the network thus informing the procurement and ensuring the equipment is utilised effectively.
- Develop equipment selection criteria. This selection should be based on:
 - Epidemiological context of the country.
 - Data to justify the need for additional equipment which includes review of diagnostic network assessments, optimisation reports and/or other laboratory network assessment reports.
 - Review of equipment lists including utilisation rates, placement, system needs and support, sample transport networks and data systems.
 - Operational readiness of sites where proposed equipment will be placed.
 - Clearly defined technical specifications, performance criteria, and features required for the equipment.
 - Integration of equipment into the existing laboratory setup, including software requirements, data capture and management systems with laboratory information systems, and compatibility with needed ancillary equipment.
 - Evaluate evidence of user-friendliness and equipment resilience under local conditions of power fluctuations, climate control and dust exposure, etc.
 - Consideration of compatible reagent availability and handling and disposal of hazardous chemical waste.
- Create an environment for competitive bidding by suppliers. This can be achieved by introducing an open tender system which allows different companies with different pricing systems to compete and allows the country to benefit from lower prices.
- To evaluate bidders, determine if they are reputable vendors/manufacturers known for producing high-quality laboratory equipment. Compare prices, warranties, and support services offered by the different vendors.
- Advocacy for procurement models is recommended to promote leasing instead of outright purchase, as a way of addressing some challenges associated with equipment procurement, such as introduction of newer models. Other options include all-inclusive pricing (AIP) or possible reagent rental agreements. AIP offers several advantages to the laboratory: consolidation of purchases and the ability to acquire multiple services (preventive and curative maintenance) as a package deal, simplifying procurement, and allowing for better forecasting for budget planning.
- A national equipment policy should be implemented to address issues of selection, procurement (with use and life cycle costing), installation, validation, calibration and maintenance (with information on use of preventive and curative maintenance contracts). The policy should also cover equipment management, training, development of local capacity, standardisation, documentation, and donations (10, 11). This should be accompanied by equipment management guidelines, officially endorsed by the Ministry of Health.

2) Procurement of laboratory equipment

Procuring laboratory equipment involves various mechanisms and considerations to ensure the acquisition of high-quality, appropriate, and cost-effective tools for diagnostic testing and scientific research. Several options are available including:

- **Direct Purchase:** This involves buying equipment directly from manufacturers, suppliers, or authorized distributors. Outright purchase is best used for non-automated equipment e.g., fridges, microscope, centrifuges etc. Key considerations and best practises for this option are:
 - **Specifications:** Clearly define the equipment specifications and performance requirements to ensure compatibility with testing needs.

- **Supplier evaluation:** Research and evaluate potential suppliers based on their reputation, product quality, customer service, and track record.
- **Pricing:** Compare prices from multiple sources and negotiate to get the best value.
- **Warranty and support:** Ensure that warranty terms, technical support, and maintenance options are clearly defined and satisfactory.
- **Verification:** Verify the authenticity of the equipment and the supplier to avoid counterfeit products.
- **Documentation:** Maintain proper documentation of the purchase, including invoices, contracts, and warranty information.
- **Reagent lease/rental:** Instead of purchasing equipment outright, leasing allows you to use equipment for a specified period in exchange for regular payments. Reagent rental enables renting of specialised instrumentation with the commitment to buy a minimum annual volume of diagnostic test kits. This is often an attractive option when considering use of advanced, highly technical analysers as laboratories can maintain the flexibility to switch to a more suitable system as technology and service requirements change. Some considerations and best practises for reagent rental/ equipment leasing include:
 - **Usage needs:** Determine if leasing or renting suits the laboratories usage patterns, such as short-term projects or testing throughput.
 - **Cost analysis:** Compare the total cost of ownership for leasing/renting versus direct purchase, including factors like maintenance and depreciation.
 - **Supplier reputation:** Select a reputable lessor/rental agency with a history of well-maintained equipment and reliable service.
 - **Terms and conditions:** Review lease/rental agreements carefully, considering factors like maintenance responsibilities, insurance, and equipment return conditions.
 - **Exit strategy:** Plan for equipment return or purchase at the end of the lease period, and ensure the agreement accommodates this transition.
- **Tendering:** A more formal procurement process suitable for large-scale acquisitions, involving issuing a public invitation for bids from interested suppliers. Key considerations and best practises:
 - **Preparation:** Develop a comprehensive tender document with detailed technical specifications, evaluation criteria, and terms and conditions.
 - **Bidder qualification:** Screen and prequalify suppliers based on their financial stability, experience, and capacity to fulfil the requirements.
 - **Evaluation committee:** Set up a committee to objectively evaluate bids and select the best-suited supplier.
 - **Fairness and transparency:** Ensure the tender process is transparent, fair, and follow regulations
 - **Contractual clarity:** Clearly define contractual terms, delivery schedules, payment milestones, and penalties for non-compliance.
 - **Post-award management:** Monitor the supplier's performance and adherence to the contract to ensure successful project completion.

Whatever the procurement mechanism, it is crucial to prioritize quality, reliability, and suitability of the equipment. Additionally, following these general best practices can improve the success of the process:

- **Due diligence:** Thoroughly research suppliers, equipment specifications, and reviews to make informed decisions.
- **Specifications:** Clearly define your requirements in terms of performance, functionality, compatibility, and technical specifications.
- **Quality assurance:** Prioritize equipment with quality certifications and standards compliance to ensure accurate and reliable results.
- **Total cost analysis:** Consider not only the upfront cost but also factors like maintenance, calibration, consumables, and long-term operational expenses.
- **Risk mitigation:** Identify and address potential risks, such as equipment downtime, compatibility issues, and supplier reliability. The equipment supplier should have a local

office in the country with trained engineers to provide technical support and training to users and local biomedical engineering staff.

- **Supplier relationship:** Foster a positive relationship with suppliers based on communication, transparency, and a long-term perspective.
- **Documentation and records:** Maintain accurate records of all procurement-related documentation, including quotes, invoices, contracts, and warranties.
- **User training:** Budget for proper training to ensure effective and safe use of the equipment by technical and maintenance staff.
- **Maintenance plan:** All automated laboratory equipment should be purchased with at least three years' service contract, and this should align with the maintenance plan that outlines regular servicing, calibration, and troubleshooting procedures.
- **Supplies:** All equipment should be on the approved equipment lists to enable medical stores to stock the relevant supplies and consumables.

The WHO has several guidance documents and manuals that highlight the necessary factors to consider when procuring in vitro diagnostic medical devices and other laboratory items (12, 13). These should be reviewed as part of the purchasing process. Ultimately, the most suitable procurement mechanism will depend on the specific equipment needed, budget constraints, and timelines. Proper planning, careful consideration, and adherence to best practices will contribute to successful procurement.

3) Donation of laboratory equipment

Laboratory equipment donations are an important component of the provision of quality health care services. However, this requires commitment on the part of all stakeholders to address anticipated problems (Box 1). The donation process is often not optimal, and tools such as the WHO guidelines (11) are available to help improve the process. These guidelines address context, content and the process of donations. They are not international regulations but will serve as a basis for national or institutional guidelines, to be reviewed, adapted, and implemented by governments and organisations dealing with healthcare equipment donations. Each country should develop an equipment donation policy.

4) Installation, qualification and validation of newly acquired equipment

The installation and validation of laboratory equipment are crucial steps to ensure that the equipment functions accurately and reliably while producing valid and accurate results (9). The essential requirements for installation and subsequent validation include:

- **Site evaluation and preparation:** The appropriate location for the equipment should consider space, ventilation, and proximity to other equipment or resources. The laboratory must meet temperature, humidity, and other environmental requirements specified by the manufacturer. Amenities such as electrical supply and water must be reliable. If there are power stability issues uninterruptible power supplies should be used to provide backup power, protecting equipment from damage in the event of grid power failure.
- **Equipment installation:** Use qualified personnel or certified technicians for the installation to ensure accuracy and safety. If the equipment does not require professional installation, follow the manufacturer's installation instructions meticulously.
- **Qualification and validation:** These are commonly performed during installation by the installing technician. Qualification involves verifying that the equipment is properly installed, works correctly and operates within predetermined specifications, so includes installation, operational and performance qualifications.
- **Calibration:** Regular calibration is crucial to ensure that the equipment remains accurate and provides reliable measurements and should be performed according to the manufacturer's recommendations or industry standards.
- **Compliance and regulations:** Ensure that the equipment installation and validation

processes adhere to relevant regulatory and industry standards, such as ISO, FDA, GLP, or GMP, depending on the type of laboratory and equipment.

- **Standard operating procedures (SOPs):** Develop and document SOPs for equipment use, maintenance, cleaning, and troubleshooting for all equipment. Ensure that all personnel operating the equipment are trained in these procedures. User and service manuals should be readily available in a language that the user better understands.
- **Training:** Train operators and users on proper equipment operation, safety protocols, and emergency procedures. Regularly update training as needed.
- **Documentation:** Maintain detailed records of installation, qualification, calibration, and maintenance activities. Document any deviations, repairs, or modifications made to the equipment.
- **Risk assessment:** Identify potential risks associated with the equipment's use, maintenance, and malfunction. Develop strategies to mitigate these risks and ensure safety.
- **Maintenance and monitoring:** Ensure facility budgets include funding for contracts and general maintenance for the new equipment. To estimate the cost planners can approximate annual expenses at around 7% of the equipment replacement value. Establish a regular maintenance schedule and perform PM as recommended by the manufacturer. Monitor the equipment's performance over time and address any deviations promptly.
- **Requalification and recalibration:** Regularly requalify and recalibrate the equipment to ensure ongoing accuracy and compliance.
- **Change control:** Implement a change control process to manage any modifications, upgrades, or changes to the equipment or its processes.

5) Equipment maintenance policy development

Every country should have an equipment maintenance section covered within the equipment policy which at a minimum provides information on the following aspects:

- **Personnel:** There should be adequate, competent staff who support equipment maintenance in the diagnostic network. Maintenance personnel need various capacities and skills including management, trouble-shooting skills and adequate training in general biomedical engineering. On-going training is critical, especially with the introduction of new or different models of equipment.
- **Equipment stores:** It is important that maintenance staff have the infrastructure and space for a well-equipped maintenance workshop with the appropriate maintenance tools, test and calibration equipment.
- **Requirements for acquisition of spare parts:** Spare parts are an essential requirement in the provision of quality servicing of equipment. A successful maintenance workshop will need appropriate spare parts for their equipment. Spare parts must be specific to equipment and are supplied mostly by the manufacturer. A budget for the acquisition of spare parts is very important.
- **Acquisition of consumables and accessories:** A budget for the acquisition of consumables and accessories (i.e., calibration kits, replacement parts) that are critical for equipment functionality must be provided to the bioengineering facility.

5a) Service level agreements

A laboratory service-level agreement (SLA) is a formal contract or agreement between a laboratory and a service provider or vendor. It outlines the specific services to be provided by the vendor, along with the expected quality, response times, and other performance metrics. The SLA typically covers a wide range of laboratory services, including instrument maintenance, repair, calibration and technical support.

Key features of a laboratory SLA may include:

- **Scope of services:** Defines the services to be provided by the vendor, such as routine maintenance, emergency repairs, instrument calibration, and software updates. An increasing number of manufacturers are offering All-inclusive Pricing Service-level agreements (AIP SLAs) that also include initial training and updating, key performance indicator (KPI) monitoring, connectivity solutions, and vendor managed inventories.
- **Performance metrics:** Specifies the expected performance levels for the services, including response time, resolution time, uptime guarantees, and other relevant parameters.
- **Service availability:** Outlines the vendor's service hours and availability, including emergency support and after-hours assistance.
- **Responsibilities:** Clearly defines the responsibilities of both the laboratory and the vendor, including obligations related to equipment access, data backup, and confidentiality.
- **Escalation procedures:** Outlines the steps to be followed if there are service issues or disputes, including escalation paths and resolution mechanisms.
- **Replacement** and/or upgrades of equipment if new models become available.
- **End of life** disposal of the instrument.

A Preventive Maintenance (PM) contract specifically focuses on regular maintenance and servicing of laboratory instruments to prevent breakdown and optimise performance and has a smaller scope than the SLA. These contracts or agreements are typically offered by the equipment manufacturer or a specialised service provider. The goal is to proactively ensure that the instruments are kept in optimal working condition, reducing the likelihood of unexpected breakdowns and maximising their lifespan.

A PM contract should include:

- **Scheduled maintenance:** Specifies the frequency of maintenance visits or inspections to be conducted on the instruments. These visits are typically performed at regular intervals, such as monthly, quarterly or annually, depending on the instrument type and usage.
- **Maintenance tasks:** Outlines the specific maintenance tasks to be performed during each visit, including cleaning, lubrication, calibration and performance verification. This helps to identify potential issues early and take corrective actions.
- **Spare parts and consumables:** Define whether the contract includes the provision of spare parts and consumables required for maintenance or if they are billed separately.
- **Emergency support:** Specifies the availability of emergency support services outside of the scheduled maintenance visits, such as priority response for critical instrument failures.
- **Reporting and documentation:** Specifies the requirement for detailed reports after each maintenance visit, documenting the work performed, any issues found, and recommendations for further action.

PM, rental or leasing contracts, placement, and AIP are types of SLA offered and negotiated by a country or laboratory based on need, allowing laboratory management officials to set the specific level of care and control the costs of equipment maintenance. The difference in service may vary from basic care which includes annual PM and performance verification, to comprehensive or extended care that adds priority technical support, on-site emergency services, and replacement parts, all covered in one fixed price. It is important to note that in developed countries, most of the principal laboratory diagnostic equipment within clinical facilities are rented or leased and are not owned outright by the facility.

Important considerations for each of the above investments include:

- What is the availability of replacement parts?
- Who is responsible for travel charges or overtime expenses?
- How long does it take for the service engineer to arrive after a service request is made?
- What will the laboratory be expected to do prior to the arrival of the service engineer?
- Is any component of the instrument not covered under this contract?

6) Equipment operation

6a. Equipment maintenance

Laboratory equipment maintenance is critical for ensuring accurate and reliable test results, which are essential for diagnosing and treating diseases, and for control of diseases of public health importance. When implementing a laboratory equipment maintenance programme, there are several key considerations aimed at ensuring the effectiveness and efficiency of the programme while minimising downtime and maximising the lifespan of the equipment.

Key Considerations

- **Infrastructure:** All laboratories need adequate infrastructure such as a stable, continuous electrical supply, proper ventilation, and temperature and humidity control systems. Without these essential components, laboratory equipment may be damaged and require frequent repairs. Governments should invest in infrastructure improvements to ensure laboratories are equipped with reliable power sources, proper ventilation and temperature and humidity control.
- **Funding:** Laboratory budgets should always include funding for routine maintenance and repairs. All funding requests to donor organisations for the purchase of equipment should also include service and maintenance costs. It is important to understand annual operating budgets for equipment maintenance and calibration, to be able to plan for mobilisation of resources.
- **Equipment warranties:** Warranties protect laboratories for a defined period after purchase of an instrument. Warranties provide the assurance that items purchased operate as promised and covers the replacement or correction of issues according to conditions stipulated in the agreement for the duration of its term. Warranties vary, so it is important to understand the contract duration, whether it begins at the time of purchase, receipt or delivery in-country, or installation. Warranties generally include repair and/or replacement of defective parts, or the entire equipment itself, but not damages caused by mishandling or misuse. Generally, warranties only apply if the equipment is used as intended for certain applications. If equipment is used for other applications, or exposed to certain chemicals, voltages or conditions, there is a risk that the manufacturer will deny the warranty claim. The warranty should stipulate if the distributor, seller or manufacturer is the point of contact to initiate a warranty claim. If equipment needs to be repaired or replaced, the warranty should stipulate who is responsible for the shipping costs or service provider travel expenses, and how any additional costs associated with a claim will be handled.

Best practices

Central to any maintenance programme, best practices should form the baseline for implementation. Best practices aid the operationalisation of effective laboratory equipment maintenance programmes that maximise the performance, reliability, and lifespan of equipment while ensuring accurate and consistent results.

- **Equipment inventory:** A comprehensive inventory of all the laboratory equipment serves as the foundation for an equipment maintenance programme. Record must be available on equipment type, model, serial number, manufacturer, and installation date. The initial inventory assessment should document equipment functionality under one of six categories, based on the condition of the equipment:
 - inoperable due to obsolescence of parts or components,
 - repairable but in need of components,
 - incompatible with the local infrastructure,
 - operating under inappropriate conditions,
 - redundant or otherwise not needed and/or
 - fully functional and in use.

- **Service providers:** Prepare a list of calibration and maintenance service providers by equipment type.
- **Documentation and record keeping:** Maintain a database to record all maintenance activities, repairs, and equipment history including maintenance schedules, work orders, service reports, calibration certificates, and any equipment modifications. Good record-keeping enables tracking equipment performance, identifying trends, and demonstrating compliance. This log aids in identifying recurring problems and scheduling maintenance.
- **Scheduling:** Develop a comprehensive maintenance schedule that includes calibration, PM tasks, and equipment checks. The frequency of PM activities should be based on factors including equipment usage, criticality, and operational requirements. The type of maintenance will vary depending on the equipment, manufacturer's recommendations, and national regulatory requirements.
- **SOPs:** Develop clear and concise SOPs for each equipment type outlining all maintenance tasks. SOPs should include step-by-step instructions, safety guidelines, required tools, and any specific considerations for the equipment. Well-documented procedures facilitate consistent maintenance practices and help minimise errors. Ensure that all staff members have access to these SOPs and follow them consistently.
- **Staff training:** Provide comprehensive training to laboratory personnel on the proper use, care, and maintenance of each equipment type. This training should cover routine cleaning procedures, troubleshooting common issues, and any specific maintenance requirements. Staff should be knowledgeable about safety procedures and troubleshooting techniques.
- **Assign responsibility:** Designate specific individuals or teams responsible for equipment maintenance. They should follow and track implementation of service contracts. Clearly communicate their roles and responsibilities, and review and update as required.
- **Inspection and cleaning:** Implement a routine inspection process to identify any signs of wear, damage or malfunction. Additionally, develop a regular cleaning schedule for each item of equipment to prevent contamination and ensure accurate results.
- **Monitor and track performance metrics:** Establish performance metrics for equipment, such as uptime, mean time between failures, and mean time to repair. Regularly review these metrics to identify trends, evaluate maintenance effectiveness, and make data-driven decisions regarding equipment replacement or upgrades.
- **Vendor associations:** Cultivate relationships with equipment vendors, service providers and manufacturers. Stay informed about software updates, recalls, and other relevant information. Engage with qualified service technicians and seek their expertise when needed.
- **Utilise digital technology:** Laboratory managers and directors should encourage the use of technology to monitor and maintain their laboratory equipment. For example, remote monitoring systems can be used to track performance of equipment and identify potential issues before they become major problems (e.g., wireless temperature loggers for refrigerators, freezers, incubators). Laboratory information systems asset management modules can facilitate monitoring of maintenance plans, provide notifications when calibration or maintenance is due, and record compliance with specific maintenance requirements for each instrument type.
- **Program evaluation:** Evaluate the effectiveness of the maintenance programme based on feedback from staff, equipment manufacturers, and industry best practices. This information should be used to identify areas for improvement and to implement corrective actions to enhance the programme's efficiency and reliability.
- **Emergency response:** Establish a backup plan for critical equipment. It is important to have contingency plans and procedures for addressing equipment failures, breakdowns and emergencies. This includes availability of backup equipment, establishing communication channels, and defining roles and responsibilities in such situations.
- **Prioritise equipment:** Priority should be given to equipment that is used or needed most or that which is essential to the functioning of the laboratory. Always perform preventative maintenance on prioritised equipment.

- **Capacity building on equipment maintenance:**
 - Establish reliability-centred maintenance. Train laboratory equipment operators to troubleshoot common equipment failures. Addressing the root causes of laboratory equipment failures prevents their recurrence.
 - Invest in employee training on routine preventive equipment maintenance. This allows laboratories to identify and rectify defects before they cause costly equipment failures.

Countries should invest in local capacity development for the maintenance and repair of general laboratory equipment. This can be through private sector engagement or development of bioengineering hubs that service laboratory as well as health facility equipment. Having a supply of spare parts for basic equipment repairs (i.e., fuses, bulbs, automatic pipette parts) available through a bioengineering hub will enable timely repair and prevent having to call out the manufacturer for simple problems.

 - Note that this is where standardisation of equipment within the laboratory network can provide important cost savings.
 - Information on spare parts can be gathered by bioengineers from equipment inventory lists. Spare parts should be included in the equipment maintenance budget.
 - **Extended warranties:** For larger investments, an extended warranty can provide assurance that the laboratory will not be faced with high replacement or repair costs in the event of a malfunction. Extended warranties may differ from standard warranties and should be reviewed prior to purchase. Once the original warranty agreement expires, securing the appropriate level of maintenance coverage is important.
 - **Maintenance logs:** An equipment maintenance log is a useful document to record asset maintenance activities. A log enables the monitoring of system check-up processes and tracks maintenance tasks performed by technicians, the exact time the tasks were performed, and each specific task's purpose. Ultimately, an effective equipment maintenance programme will reduce repair and operating costs, improve equipment operating efficiency over the lifetime of the equipment, increase laboratory efficiency and provide accurate testing data.

Establish a core maintenance facility supporting the national laboratory network.

It is recommended that laboratory directorates and ministries of health establish a national bioengineering calibration and maintenance facility to service, maintain and calibrate instruments within the laboratory network as recommended by the Africa-CDC (14). Trained bioengineers within this facility should be able to provide maintenance and calibration services for basic laboratory equipment such as microscopes, spectrophotometers, incubators, pipettes, autoclaves and balances if provided with the right training and equipment. Ministries can also collaborate with National Metrology Institutes (NMIs) for calibration of ancillary equipment. The more sophisticated instruments such as real-time thermocyclers, Matrix assisted Laser Desorption Ionization -time of flight (MALDI-TOF) etc. will require the services of trained service engineers from the instrument distributor or manufacturer.

BSCs are critical pieces of equipment in laboratories that protect workers and the environment from exposure to infectious and hazardous materials. International standards recommend annual certification of BSCs to ensure they are functioning properly and provide the required level of protection. Bioengineers can be equipped and accredited to perform BSC certifications. For example, BSC maintenance and certification training programs for bioengineers in Tanzania and Kenya are helping to build local capacity in this particular field (15, 16).

To establish a bioengineering hub for the maintenance of laboratory equipment, there are several key requirements:

- **Space and infrastructure:** A suitable location with sufficient space to accommodate the different activities, inventory and equipment storage, workstations and administrative

functions.

- **Equipment and supplies** with associated inventory management. Equip your maintenance facility with the necessary tools, instruments, and resources required for equipment maintenance and repair. This includes specialised toolkits, diagnostic devices, calibration standards, replacement parts, and technical manuals. Establish an inventory management system to track and manage equipment lists from supported laboratories, spare parts, consumables, and supplies required for equipment maintenance. This helps ensure timely availability of critical components and minimises downtime for laboratory instruments.
- **Expertise and staff training:** bioengineers should receive appropriate training and certification in equipment maintenance, safety protocols, and regulatory compliance. This can be achieved through external training programmes, manufacturer training and in-house training conducted by experienced personnel.
- **Funding:** Develop an operating budget for the core bioengineering facility that covers operational costs including travel, per diem, parts, supplies.
- **Scheduling and data management:** At the laboratory level develop a robust documentation system (preferably electronic rather than paper-based) to track maintenance history, calibration records, service schedules, and any repairs performed on equipment. This information is crucial for maintaining regulatory compliance, troubleshooting issues and identifying trends for PM. Nationally equipment should be tracked across facilities.

6b. Equipment calibration

Key considerations

Laboratory equipment calibration maintains the accuracy and reliability of equipment, ensuring high-quality and trustworthy results. Important considerations include:

- Ensure that the calibration standards used are traceable to national or international standards.
- Choose reputable and qualified calibration providers that have the necessary expertise, accreditation and equipment to perform calibrations accurately. The calibration providers should follow recognised standards and procedures, and the calibration certificates should provide detailed information on the calibration process and results.
- Consult specific equipment manuals and guidelines provided by manufacturers for development of the laboratory individual equipment calibration SOP. These documents may contain additional calibration recommendations and requirements. Regular calibration can prevent costly errors, as inaccurate measurements may lead to experimental failures, reagents wastage, or the need to repeat experiments.

Best practices

- Follow established maintenance schedules that include calibration frequency for each item of equipment.
- Maintain detailed records of calibration activities in the equipment maintenance database, including dates, results and certificates. This is needed for regulatory compliance, audits, and troubleshooting.
- For some laboratory equipment, in-house verification using reference standards or secondary calibration equipment is needed, (e.g., analytical balances, incubators (CO₂ and temperature), liquid and gas chromatography instruments). Critical parameters are checked to ensure equipment measurements remain within acceptable tolerances. This equipment should be periodically calibrated by an external accredited service.

7) Retiring and disposal of equipment

Proper disposal of laboratory instruments is important to address health and safety risks due to exposure to residual clinical infectious material, concerns regarding release of climate damaging gases (e.g., hydrofluorocarbons present in any instruments involving refrigerated compartments or coolants), and explosion and pollution risk from batteries.

Key considerations

- Local legal and regulatory requirements may differ from manufacturers' recommendations and may not be well understood or communicated to health facilities, and there may be a general lack of understanding regarding compliance measures for health facilities.
- For instruments covered by leasing or rental SLAs, the responsibility to support proper removal and disposal lies with the manufacturer, and is coordinated during replacing or upgrading equipment.

Best practices

- The local Safety, Security, Health and Environment Officer is generally responsible for coordinating the EoL instrument disposal and the local Biosafety Officer is typically responsible for mitigating possible risks during instrument handling. The local sales or commercial manager (representing the manufacturer) is typically responsible for organising logistics on the timing, location and details of the removal. In facilities with human resource constraints, the lack of clear roles and responsibilities for organising removals may be one of the major barriers to best practices.
- Develop local decommissioning guidance and adopt EoL processes as recommended by major manufacturers. Typically, these comprise the following key steps:
 - Planning: establishing timelines and budget.
 - Vendor selection: identifying responsible entities for different processes involved in decommissioning equipment (i.e., pre-treatment, transport, recycling and/or incineration) for disposal.
 - Decommissioning:
 - The reason for equipment decommissioning and disposal should be defined:
 - Unserviceable: It is damaged beyond economical repair
 - Obsolete: It is clinically, and technology outdated or changes in local policies for device's use.
 - Unsafe: It no longer complies with safety requirements from the manufacturer.
 - Ineffective: It is unable to provide accurate results.
 - Costly: It breaks down continuously and hence it is not economical to meet repair costs.
 - The initial surface decontamination, draining all fluids and removing waste receptacles, spare parts' recovery, and preparation for transport by wrapping in plastic should occur.
 - Pre-treatment: sterilisation, hydrofluorocarbon gas recovery and destruction, battery removal.
 - Removal: transport to an interim facility, typically a warehouse or recycling or incineration centre².
 - Issuance of a Destruction Certificate: Note that disposal of laboratory diagnostic equipment in sanitary landfills may be acceptable by some government standards if full sterilisation has been conducted, however it is not authorised by most major manufacturers (e.g., Roche).
- Potential for recovery and recycling. Depending on the type of equipment, several different vendors may be involved in each of these steps, such as specialists for dismantling and recovery of spare parts, haulers used for transport, warehousing, and recycling vendors.

² Industrial-sized incinerators suitable for most laboratory equipment are not currently available in Africa.

Typically, for larger automated diagnostic instruments, as much as 70% of the weight of the instruments comprises ferrous or non-ferrous metals. The potential value of recovered metals and materials from EoL instruments may be sufficient to cover the costs of disposal; however, there is currently a dearth of recycling hubs in Africa, particularly those capable of separating and using rare earth minerals (available from printed circuit boards), and other types of electronic waste.

Key challenges to instrument recycling include the limited recycling infrastructure, and lack of trained personnel and established procedures for transport of EoL instruments across borders. There is a key need to develop collaborative projects to promote development of recycling hubs, and to increase awareness of the possible health and environmental risks and impacts of improper handling. The Africa Circular Economy Network (<https://www.acen.africa/>) has recently been established to promote these opportunities.

Where equipment is underutilised, it is recommended to develop a cross-laboratory programme pool of common equipment that can be redistributed and utilised for maximum benefit. Any savings can be channelled into training and spare parts.

8) Managing equipment records

Managing laboratory equipment records is essential for ensuring the accuracy, safety, and compliance of laboratory operations and ultimately helps to improve overall laboratory efficiency and safety. Best practices for effectively managing laboratory equipment records include:

Best practices:

- Maintaining a facility or laboratory database (electronic or paper-based) to store all equipment-related records, makes it easier to access information, track changes, and ensure data integrity.
- Each item of equipment should be assigned and labelled with a unique identifier (e.g., asset tag or barcode) for easy referencing and tracking.
- Detailed records should be kept of equipment acquisitions, including purchase date, vendor information, model and serial numbers, specifications, warranty details, and cost. Attach copies of purchase orders and invoices to the records.
- Document the disposal process for equipment that is no longer in use or has reached its EoL. Include the date of disposal, method of disposal (e.g., donation, recycling, or proper disposal), and any relevant disposal certificates or receipts.
- Calibration and maintenance schedules for each item of equipment should be created that adhere to the manufacturer's recommendations and any regulatory requirements. Keep records of all maintenance activities and the date of each service.
- Maintain detailed logs for equipment maintenance and repairs. Include information such as the date of service, issue description, actions taken, replacement parts used, service provider details (if applicable), and the name of the technician performing the service.
- Document all deviations and incidents from normal equipment performance, or incidents related to equipment failures or malfunctions. Investigate the cause of these incidents and document the corrective actions taken.

Key considerations:

- Ensure laboratory staff are adequately trained in the proper use, maintenance, and handling of equipment. Develop and follow SOPs for equipment operation and maintenance. Have this information readily accessible to all laboratory staff.
- Regularly review equipment records to identify potential issues or areas of improvement. Be prepared for internal and external audits by maintaining accurate and up-to-date records.
- Regularly back up equipment records to prevent data loss in case of system failures. Implement appropriate security measures to protect sensitive equipment information.

- Establish clear accountability for equipment users regarding proper handling, maintenance, and recordkeeping. Encourage a culture of responsibility and ownership among laboratory staff.
- Retain records for regulatory compliance and be aware of the legal requirements for equipment record retention. Some records may need to be retained for a specific period as mandated by regulations.
- Integrate equipment recordkeeping with inventory management systems to ensure accurate tracking of equipment locations and availability.

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Annexes

Annex 1: Table of maintenance requirement examples by different entities for general and specialised laboratory equipment.

This list is not exhaustive, merely illustrative. Instruments should be maintained according to manufacturers' recommendations.

General equipment	Entity responsible for equipment maintenance		
	Laboratory Technician*	Bioengineer	Manufacturer
Autoclave	Biological indicators (each run or weekly)	<i>Temperature & pressure monitoring (annual)</i>	Installation, validation and verification. Large: Annual PM including certification and replacement of parts as recommended by manufacturer. Small: PM
Balance	Clean regularly	<i>Mass calibration</i>	
Biosafety cabinet	Decontaminate surfaces after use.	<i>Certification (annual)</i>	Installation and certification
Centrifuges <ul style="list-style-type: none"> - General purpose - Dedicated, fixed RPM (e.g., microhematocrit) - Refrigerated - Stand-alone 	Clean rotor compartments monthly Verify the locking / safety mechanism of the centrifuge's cover. Check the lubrication state of O-rings as manufacturer recommends	<i>Calibration of speed, (temperature). Determine exactitude of time controls. (As needed)</i>	
Fume hood	Keep hood clear of clutter - not for storage. Periodic function inspection.	<i>Certification (annual)</i>	
PCR workstation	Clean work surfaces, walls with an appropriate disinfectant Change the UV light after the manufacturer recommended operating hours		

General equipment	Entity responsible for equipment maintenance		
	Laboratory Technician*	Bioengineer	Manufacturer
Microscope	Regular cleaning of oculars and objectives. Protect from direct sunlight, high temperature, humidity, dust & vibration. Cover when not in use.	Replace microscope bulb	
Microtome	Good microtome maintenance is cleanliness and minimum lubrication		
Oven	Occasionally clean or decontaminate	<i>Temperature calibration</i>	
pH meter	Calibration using known pH solution. Electrode cleaning - quarterly		
Spectrophotometer	Calibration every two weeks.	<i>Linearity check and wavelength calibration.</i>	Preventive maintenance
Refractometer	Clean the measuring prism		
Shaker	Test and document the accuracy of the temperature calibration, speed, time and alarms.		
Refrigerator	Clean condenser fins and fan blades. Defrost	<i>Temperature calibration</i>	
Freezer	Pay attention to the alarms. Keep door gaskets clean. Remove ice or frost build-up regularly. Vacuum the external condenser coils. Defrost annually.	<i>Temperature calibration. Replace batteries needed to display temperature (some models).</i>	
Incubator	Clean interior surfaces 70% EtOH weekly If water-jacketed change H ₂ O monthly	<i>Temperature, (CO₂) calibration</i>	
Water bath	Drain, clean, and refill water-filled bath weekly. Refill with distilled water.	<i>Temperature calibration</i>	
Timer	Clean. Change battery as needed.		

General equipment	Entity responsible for equipment maintenance		
	Laboratory Technician*	Bioengineer	Manufacturer
Water purifier	Filter & tubing replacement.		
Tissue processor	Change paraffin bath weekly. Change solutions by half every 1-3 days. Check clearing agent and change weekly. Clean instrument thoroughly.		
Pipettes mechanical	Decontaminate after use.	<i>Volume calibration (annual), disassemble and clean, change O-rings.</i>	
Specialised Instrumentation			
Blood cell (hematology) analyser	Operational verification for each cell type. Daily maintenance per instrument manufacturer recommendation.		Preventive maintenance
Blood chemistry analyser	Daily calibration		Preventive maintenance
Blood gas analyser			Preventive maintenance
ELISA washer	Before use: Verify volume distributed & fill uniformity. Verify aspiration. Clean with dH ₂ O Quarterly: Disassemble clean channels & connectors.		
Gel electrophoresis tanks	Clean after use.		
Flow cytometer	Daily cleaning and monthly long cleans		Preventive maintenance
Mass spectrometer		There is no regular schedule for cleaning the mass spectrometer source. This is done when there are indications that the source is contaminated.	Preventive maintenance; Annual calibration.
Automated haemoculture			Preventive maintenance

General equipment	Entity responsible for equipment maintenance		
	Laboratory Technician*	Bioengineer	Manufacturer
Automated ID/AST	Conduct daily (temperature and optical system checks) and monthly (general cleaning) maintenance as outlined in instrument user guide.		Serviced annually under a preventative maintenance agreement. Verify densitometer for optical density measurement.
Thermocycler	Weekly cleaning of sample wells, hot lid and exterior surfaces. Annual check controls and display. Decontamination as needed.		Preventive maintenance: validation of temperature accuracy, uniformity, and hold time and certification. Check heating and cooling times.
Liquid handlers	Keep attached computer "clean" and programs backed up. Weekly spot cleaning		Preventive maintenance: regular calibration and servicing
Urine analysers	User calibration & QC with test samples		Preventive maintenance
Next generation sequencer	Perform post-run wash and/or maintenance wash with regularity (refer to the appropriate instrument guide).		Preventive maintenance

* All equipment should be wiped down and cleaned after use with a soft, lint-free absorbent cellulose cloth. In most cases, water is a suitable solvent.

Daily, weekly maintenance should be performed according to the manufacturer's instructions.

Reference: WHO Maintenance manual for laboratory equipment (15); CLSI Laboratory instrument implementation verification and maintenance (9).



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