



**Coronavirus Support: Mitigating risk and ensuring emergency preparedness and compliance for your programs, hospitals, and laboratories in the US, Africa, and Middle East**



**Our Certifications**  
ISO 9001 & 17025

**NAICS Codes:**  
541330 541380 541511  
541690 811219 334513  
541990 519120 541714

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**Where We Currently Work:**  
**Continental United States**

**East Africa**

Kenya  
Tanzania

**Central Africa**

Cameroon

**West Africa**

Ghana  
Liberia

Sierra Leone  
Senegal

**Middle East**

Iraq

Amethyst is a Woman Owned Small Business, SBA8(a) graduate prime contractor providing technical assistance for Department of State in Iraq, PEPFAR, PMI, Ebola in Africa, DoD technical support, and CDC emergency preparedness services. With experience mobilizing teams for health programs within two weeks in Baghdad, Basrah, Tanzania, Kenya, and Liberia. We have 13 years of experience in BSL-4, BSL-3, and BSL-2 laboratories supporting emerging infectious disease vaccine manufacturing, research, and healthcare delivery.

**Our expertise: setup and outfitting laboratories, training healthcare workers, diagnostics, logistics, contact tracing, quality assurance, process improvement, independent verification and validation, assessments, standard operating procedures**

**Prime Contractors to US Army, National Institutes of Health, US FDA, USAID, and Department of State**

**Providing Expert Services for Emergency Response, Diagnostics, and Research**

**Amethyst solutions related to COVID-19 response based on Ebola, Malaria, HIV/AIDS experience:**

Amethyst provided technical assistance in Liberia during Ebola our work included training healthcare workers and laboratory technicians (safety, diagnostics, sanitization procedures, preparation of sanitizing agents, handling difficult patients, modification of ambulance to safely transport Ebola patients, general processes for healthcare workers to protect themselves from their colleagues, process for daily temperature measurements, general Q&A for past Ebola outbreak experiences.)

Amethyst provided training and procedures to Ghana Military for Ebola preparedness including safety training, PPE, design of ebola isolation centers, emergency response protocols,

Amethyst Site Assessments for PEPFAR HIV/AIDS program: assessments of hospitals, community programs, and government programs on response to HIV/AIDS; development of recommendations for program improvement related to diagnostics, care and treatment, prevention

Amethyst implements Quality Improvement for HIV/AIDS response in Tanzania which includes development of change packages to improve healthcare delivery and preparedness for USAID implementing partners (supply chain, care and treatment, diagnostics, safety, waste management, facilities).

Amethyst has a CDC contract to validate storage units at the biorepository for emergency preparedness in Lawrenceville Georgia; we have experience managing biorepositories, developing SOPs, performing daily checks/verification of equipment (generators/storage units).

Amethyst has developed 3,000 SOPs for US Army laboratories related to facilities, quality assurance, supply chain, materials, equipment, validation, software, processes, documentation, risk management, corrective and preventive action, and training.

Amethyst improved malaria microscopy and managed the US Army malaria research program in Tanzania.



## Amethyst in Action: Delivering quality services for global health and standards creation In Challenging Environments



**Amethyst Technologies LLC**

"Rock Solid" Validation

### **Cancer Diagnostics- Government of Kenya (2016-)**

- Contracted by Bomet County government to develop Country partnerships with US Cancer Centers.
- Assessed quality of diagnostics in Bomet County hospitals.
- Developed a plan for a comprehensive cancer diagnostic center (design, capacity building).
- Implementing an esophageal cancer study with Johns Hopkins Sidney Kimmel Cancer Center.

### **Amethyst's INNOVATE Center of Laboratory Excellence in Ghana, Opening in 2021:**

ICOLE is a 6,000-square foot state-of-the-art laboratory owned by Amethyst that will provide services for health, agriculture, water and sanitation, mining, and manufacturing sectors including technical assistance, training, a biorepository, and laboratories for contract research and manufacturing.

- Microbiology Lab
- cGMP Cleanrooms
- Chemistry Lab
- Quality Control Lab
- Biorepository
- Training Center (eLearning)
- Office Space



### **A Quality Management System for US Army Laboratories (2008-)**

- Created a quality management system and 2,000 standard operating procedures.
- Training programs for personnel that covered quality assurance, change control, test methods, maintenance, and documentation.
- Performed validation and calibration for equipment in BSL-2, BSL-3, and BSL-4 labs.
- Developed, implemented, and managed the transition for new labs. User requirements were managed and communicated to vendors.
- New equipment procurement.
- Cold chain management of temperature sensitive materials.

### **PEPFAR Quality Improvement (QI) in Tanzania for USAID (2018-)**

- Mentoring and Coaching on quality assured HIV testing country wide.
- Improving patients' stability categorization in compliance with new HIV guidelines through training, procedures, assessments.
- Quality Improvement Package development and mentoring focused on improved retention of HIV clients and increased utilization of viral load data by clinicians.

### **PEPFAR Laboratory Strengthening in Kenya USAID HSDSA (2018-)**

- Quality Improvement for HIV diagnostics in 10 counties (50,000 HIV patients)
- Management and procurement of maintenance of critical equipment
- Biosafety training and waste management
- Performing SIMS assessments
- Strengthening the use of viral load data for decision making
- Supporting External Quality Assurance (EQA)

### **US Army Tanzania Malaria and HIV Support Contract (2018)**

- Malaria Research Program Support including facilitation of collection and testing of samples, training, quality assurance, supply chain management strengthening, assessments, and laboratory certification.
- Technical assistance and support for an HIV Behavioral and Biological Surveillance Study
- Conducting Data Quality Assurance and SIMS

### **JFK Hospital Liberia and National Public Health Reference Lab (2014)**

- Training for hospital staff on safety, Ebola outbreak best practices, disinfection, waste
- Training on sample collection and handling, diagnostics, and recordkeeping

### **US Army Tanzania Malaria Research Program Management (2008-2016)**

- Developed quality assurance procedures tailored specifically for the remote labs in Tanzania that covered materials, equipment, labeling, storage, waste, safety, and quality control for performing malaria diagnostics.
  - Performed 400 comprehensive assessments.
  - Facilitated training courses on malaria diagnostics and WHO certification.
- Results?** Reduced false positives; quality control improved; reagent costs reduced 25%.

### **PEPFAR Site Improvement through Monitoring System (SIMS) Assessments in Tanzania (2016-2018)**

- USAID Tanzania partner implementing SIMS assessments at above sites, health facilities, and community sites as Prime Contractor.
- Performing data collection and analysis of quality indicators for HIV programs.
- Providing gap analyses feedback to organizations and stakeholders on methods for performance improvement.
- Development of the work plan and logistic plan and performing all logistics to travel and assess sites within budget and on schedule.

### **Assessments of Hospitals for Quality Assurance and Compliance in Iraq -Department of State (2017)**

- Developed plans for assessing hospital biomedical equipment programs.
- Performed Independent Verification and Validation for hospitals in Iraq to determine the adherence to Joint Commission, FDA.
- Developed detailed reports on the results of assessments and recommendations for strengthening maintenance programs.

### **Quality Control for ISO 15189 HIV Diagnostics (2012-2013)**

- Provided quality control mentors for hospitals in Tanzania to provide training on lab management, HIV diagnostics, safety, maintenance, supply chain, and records.
- Performed emergency on-call HIV testing.

### **Equipment Validation for FDA Compliance- NIH (2008-)**

- Performing temperature mapping, calibration, and validation services for equipment.

### **US Army Medications Procurement in Ghana (2013-)**

- Annual procurement of medications for training healthcare professionals in Ghana at reduced rates and short timeframes.