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I. Purpose

The objective of the IMPAACT international laboratory quality assurance program is to have a system in place that emphasizes problem prevention; identifies and corrects problems when they occur; verifies that appropriate follow-up action has occurred, while keeping all stakeholders informed. The system is designed to ensure the quality and competence of international laboratories providing services for the IMPAACT network in the areas of specimen management, laboratory analyses and reporting, and data management.

II. Introduction

International laboratories funded by the Division of AIDS (DAIDS) of the U.S. National Institutes of Health (NIH) seeking participation in IMPAACT studies must meet specific requirements before they are approved to participate. These specific requirements are available on the DAIDS website.

Once a laboratory is approved by DAIDS to participate, they are continuously tracked and monitored by the IMPAACT network laboratory for successful performance while participating in IMPAACT protocols. This monitoring forms the basis for the IMPAACT International laboratory quality assurance program.

III. Responsibilities

IMPAACT International study sites are required to adhere to standards of good clinical laboratory practice (GCLP), and standard operating procedures (SOPs) for the proper collection, processing, labeling, testing, transportation, and storage of laboratory specimens.
A copy of the protocol document and protocol-specific Laboratory Processing Chart (LPC) or a Manual of Operations (MOPs) is provided to the laboratory site by the IMPAACT Operations Center. Protocol-specific LPCs or MOPs contain detailed guidelines for specimen collection, documentation, processing, storage, transportation, and tracking. These documents are available via the IMPAACT website.

- **Cross-Network Laboratory Focus Group (XNLFG)**
  The cross-network laboratory focus group is comprised of members from **five** DAIDS funded networks: Adult AIDS Clinical Trails Group (ACTG), HIV/AIDS Prevention Trials Network (HPTN), HIV Vaccine Trails Network (HVTN), Microbicides Trails network (MTN), International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group, and individuals from Westat who represent the NICHD sponsored sites. The XNLFG receives support from the HIV/AIDS Network Coordination (HANC) group for cross network laboratory activities. These activities include: communication processes for critical information across network laboratories (NL); standardized quality assurance practices across networks; harmonization of laboratory processes and procedures to increase efficiency, especially at the shared laboratory sites.

- **Network Laboratories** are comprised of the network laboratory principal investigators and other network laboratory personnel involved in the quality assurance oversight of the international laboratories participating in DAIDS sponsored clinical trials.

- **Primary Network Laboratory (PNL)** is the network laboratory assigned to international laboratories and responsible for all international laboratory related communications. Each PNL has an assigned contact person and a PNL email address (e.g., impaact.qaqc@fstrf.org)

to facilitate communication. The international laboratories have been instructed to direct all queries and requests for assistance to the PNL contact. The PNL contact person is then responsible for communicating relevant information to other network laboratories which utilize the services of the international laboratory.

IV. Laboratory Quality Assurance (QA) Policy

The laboratory QA policy applies to all IMPAACT international laboratories and is designed to 1) monitor, evaluate, and improve the quality of laboratory data; 2) ensure the reliability of test data; and 3) evaluate the competency of site laboratory staff. The objectives of the IMPAACT laboratory QA policy (and related programs) are to:

- Ensure that the quality assessment activities are comprehensive, coordinated and that appropriate information is reviewed and reported
- Establish, maintain, support, and document an ongoing quality assessment program that includes effective and systematic mechanisms for monitoring, collecting, and evaluating information about important aspects of laboratory data in order to identify opportunities for improving data analysis and participant care
- Assist in improving care and identifying problems through the use of ongoing monitors by focusing on identification, assessment, correction, and follow-up of problems that affect data analysis and participant care
- Implement corrective action when problems or opportunities are identified
- Follow up on identified problems to assure improvement and resolution

V. Laboratory Quality Control (QC) Policy

The IMPAACT laboratory QC policy contributes to the laboratory QA program. Implementation of appropriate quality control practices will maximize the accuracy of results reported as well as provide early evidence of potential problems. As part of the laboratory quality assessment program, each site is expected to develop its own internal QC procedures.

VI. Quality Assurance Monitoring

Laboratories participating in IMPAACT studies will be evaluated by the IMPAACT network laboratory staff and other monitoring groups (e.g., DAIDS, SMILE, PPD) to assure an established standard of quality laboratory data and participant care. Key performance areas are monitored through collection of appropriate data and/or through data collected from onsite assessments. Findings are evaluated to detect trends and overall compliance with the laboratory QA program. When indicated, corrective action will be taken and documented.

Continuous monitoring assures that appropriate corrective action is taken and all issues are resolved. In addition to monitoring and oversight, sites develop and implement internal quality control plans of laboratory procedures.

Each site participating in IMPAACT studies is expected to develop a site-specific laboratory QA plan. The site-specific QA/QC plan is designed to ensure accurate, timely, and reliable test results by providing routine monitoring of the overall laboratory operation. This plan must be approved by the IMPAACT Network Laboratory before the initiation of a protocol. Listed below are the key components of laboratory performance measures, which are monitored to ensure consistency and accuracy of laboratory data.

- **Proficiency Testing**. Proficiency testing programs, also referred to as external quality assurance (EQA) programs, are used as an external check on the quality control and quality assessment of a test system.

  Laboratories are required to participate in proficiency testing programs for each test performed in the laboratory. International laboratories participating in IMPAACT studies must participate in proficiency panels from the College of American Pathologists (CAP), **Accutest**, the United Kingdom National External Quality Assessment Service (UK NEQAS) – administered by the DAIDS Immunology Quality Assessment (IQA), and the DAIDS Virology Quality Assessment (VQA) programs, as well as other approved proficiency providers (e.g., American Proficiency Institute (API). Panels are sent to the sites based on the assays performed for the specific IMPAACT study in which the site is participating.

  Each year the laboratory, with the assistance of SMILE, will renew CAP or **Accutest** proficiency testing, based on the assays that are performed for a specific IMPAACT study. The IMPAACT PNL contact will follow all correspondence between the laboratory sites, SMILE (for CAP issues), IQA (for UK NEQAS issues) and the VQA regarding any issues or problems with proficiency testing results, and work in collaboration with other network laboratories and the site laboratory to monitor the follow up and resolution of corrective actions, as needed.

  The laboratory must be sure to test all proficiency samples in the same manner as patient samples with no specified technologist assigned to run these samples. The laboratory manager or designee shall review the final result forms before they are submitted to the proficiency testing provider within the specified deadline for submission of results. All proficiency testing reports must be reviewed and signed off by the laboratory director or manager. Prior to study activation, the laboratory needs to pass two rounds of proficiency testing. Once a site is participating in a study, the process for monitoring proficiency testing performance for each of the EQA programs (CAP, VQA and IQA) is as follows:

  - *Proficiency Testing Monitoring Schedule*
    CAP or Accutest – SMILE is responsible for the enrollment and monitoring of site laboratories in the CAP or Accutest programs for chemistry, hematology, microbiology, viral markers, urinalysis, etc. Most CAP and Accutest panels are sent out three times per year, while others may only go out twice per year.

    VQA – The VQA monitors proficiency testing performance for Roche standard and ultrasensitive **and Roche and Abbott real time HIV RNA assays** every two months. HIV DNA and HIV genotypic resistance are monitored every six months.

    IQA – The IQA is responsible for the enrollment and monitoring of site laboratories in the in the UK NEQAS Immune Monitoring Program for T-cell markers CD3, CD4 and CD8 **and cryopreservation of PBMCs**. UK NEQAS panels are sent out bi-monthly. **Sites send vials of cryopreserved PBMCs every 3 months.**

  - *Unsatisfactory Performance*
    CAP – A score of less than 80% for an analyte constitutes unsatisfactory performance in a panel event. If a site laboratory fails to report that a panel has not been received, this will be considered unsatisfactory.

VQA – A score of 'P' for Probation for a panel event constitutes unsatisfactory performance. Data that are received late receive a score of 'PC1' for Provisionally Certified. A number (1 or 2) are added to the PC score if the data are received late one time (1) or more than one time (2) within four rounds of testing.

IQA – CD4/CD8 -A cumulative score of 4 or less points for each analyte is given an unsatisfactory performance rating. The target mean percentage and absolute values are calculated for each analyte and are scored accordingly: <1 SD = 2 points, 1 to 2 SD = 1 point; and >2 SD = 0 points. If the laboratory fails to report results, the performance summary report denotes that no results were submitted by the laboratory.
PBMC Cryopreservation – The IQA PBMC Cryopreservation (PT) Program measures viability and viable recovery of samples the criteria for which will go into effect in March 2010. These criteria once finalized by the IQA cryopreservation advisory group will be posted at:

https://iqa.center.duke.edu/modules/dhvi_iqa/index.php?id=1
Initially, only viability scores will be used to determine laboratory status. However, beginning with the September, 2010 round of testing both viability and viable recovery scores will be used to determine laboratory status.

- *Investigation Reports/Corrective Actions*
  When a site laboratory receives unsatisfactory results for protocol analytes during an event, then the EQA contractor in collaboration with the appropriate PNL provides instructions to the laboratory to initiate an investigation report. An investigation report must be submitted to the appropriate EQA contractor (SMILE, VQA and/or IQA) and the appropriate PNL within 30 days after notification of unsatisfactory and/or unsuccessful performance.

  The investigation report shall include an explanation of the likely cause for the unsuccessful performance and the appropriate corrective action. The PNL communicates with the appropriate network laboratories for any comments related to failed protocol analytes. Once all issues are resolved, copies of the proficiency results and investigations shall be filed with the original results by the laboratory for easy access.

- *Back-Up Testing*
  When a site laboratory receives repeated unsuccessful results for protocol analytes, the laboratory will be instructed by the PNL to implement their backup plan and to cease testing for the failed protocol analytes.

  The EQA contractor in collaboration with the appropriate PNL will confer on a corrective action plan, which may include additional panel testing and follow-up. The IMPAACT PNL will follow the recommendations of the appropriate EQA contractor and take appropriate action based on these recommendations. Other Networks may be involved if the site serves multiple networks.

- **Specimen Management**. Specimens sent to the laboratory are monitored to determine the effectiveness of the laboratory's process controls and documentation for the tracking of specimens in the following areas: date, time of specimen collection, specimen identification, transport, receipt, processing, testing, storage, lost specimens, rejected specimens, testing errors, and specimen integrity as outlined in the chain of custody or specimen management plan.

- **Reporting of Results**. The laboratory must have a policy in place which addresses the reporting of results and amended results. Results released to the clinician are monitored to determine the effectiveness of the laboratory review, reporting system, turnaround times and chain of custody. The laboratory shall select at least 5% of their test results to be reviewed against the testing worksheets to ensure the accuracy of released results. All discrepancies and amended results shall be documented with the corrective action taken.

- **Technical Delays**. Technical delays are monitored to help evaluate the overall effectiveness of the laboratory. Any reporting or time delay of patient test results due to a technical problem in the laboratory must be documented. Such delays include scheduled or unscheduled instrument downtimes, staff shortages, failed reagents, failed quality control, and supply back orders. When the delay will adversely affect the clinical trial, the laboratory should notify the clinic staff and the IMPAACT PNL to determine if back-up plans need to be implemented.

- **Complaints**. Complaints received by the laboratory from other components of the site or from other components of IMPAACT are monitored for response, corrective action, and follow-up. The supervisor or designee will respond to any written or significant oral complaint concerning the quality of service or results as outlined in the laboratory's complaints policy.

- **Process Improvement Monitoring**. The laboratory will identify potential problems areas in need of improvement within the laboratory. These areas will be monitored for frequency, possible causes, corrective action, and improvement

- **Staff Development, Training, and Performance.** Laboratory personnel are assessed through the following: review of training documentation on new procedures and equipment; continuing education records; blinded specimen analysis performance; annual competency assessments. Training and competency records are to be kept in the laboratory's personnel files and must be available for audit purposes.

- **Laboratory Procedures.** Laboratory management will review laboratory procedures on an annual basis. Any revisions or implementation of new procedures must be communicated to the appropriate laboratory personnel. Protocol-related procedures shall be reviewed by the IMPAACT PNL. These SOPs include the following:
    - Chain of Custody/Specimen Management
    - Equipment Maintenance Records
    - Procedure Review for Specific Analytes
    - Storage of Laboratory Specimens and Records
    - Result Modifications/Amendments
    - Result Reporting Changes
    - Reference/Normal Ranges
    - Instrument Validations and Comparisons
    - Back-Up Instruments/Laboratories
    - Quality Assurance Plan

- **Quality Control.** QC activities are an integral part of the laboratory quality assurance program. It is the responsibility of laboratory personnel to ensure that the required controls have been performed and are acceptable before testing and reporting patient results. Required components of a laboratory's quality control program include:
    - Internal QC for all test systems and assays
    - QC Monitoring and documentation
    - Parallel Testing - Validation of new controls and reagent lots
    - Competency Testing – Personnel proficiency testing
    - Proficiency Testing - External Quality Assurance Programs
    - Corrective Action and Preventive Maintenance Program with supporting documentation
    - Blind or Split Sample testing

VII. Laboratory Performance

International laboratories participating in IMPAACT studies are required to have an established Quality Management Plan (QMP) in lieu of US-CLIA accreditation. The laboratory must submit the QMP documentation to the IMPAACT Operations Center and/or IMPAACT Central Laboratory. International laboratories accredited to or operating in compliance with ISO/IEC 17025:2005, ISO/IEC 15189: 2003 standards or an equivalent accreditation standard are expected to have an extensive Quality Management System as a condition for their compliance. Proof of accreditation and quality management plan documentation will be required from the laboratory.

VIII. Laboratory Monitoring by IMPAACT PNL

IMPAACT PNL personnel conduct periodic site visits to assess the implementation of IMPAACT protocols, laboratory quality control procedures, including proper maintenance of laboratory testing equipment and appropriate use of reagents. The purpose and scope of the visit is discussed with laboratory site personnel prior to the visit. The HPTN, MTN, and IMPAACT PNLs may place a temporary laboratory technologist/QA/QC coordinator onsite, if the need is indicated. Whether on site or centrally located, IMPAACT Central Laboratory and IMPAACT Operations staff work directly with IMPAACT site staff to address and resolve any quality control or quality assurance problems identified through proficiency testing or site visits or by the site during study preparation or implementation.

IX. Laboratory Monitoring by DAIDS

DAIDS Clinical Laboratory Oversight Team (DCLOT) monitors and/or contractors (e.g., PPD) will conduct a complete laboratory audit prior to the activation of a new IMPAACT site. They will also conduct periodic audits of on-going IMPAACT studies in these laboratories, usually on an annual basis. The Data Management Center (DMC) provides the monitoring contractor with site-specific laboratory information to enable them to conduct expected monitoring of specimen processing and storage of study specific archived samples.

X. Specimen Handling and Processing

General requirements and procedures for specimen handling and processing are included in the **ACTG/IMPAACT Laboratory Manual** located on the HANC website.

Each laboratory is required to utilize the Laboratory Data Management System (LDMS) for data collection, testing, storage and labeling of certain biological samples designated for each study.

XI. Laboratory Data Management System (LDMS)

The IMPAACT Operations Center coordinates training courses and support to IMPAACT laboratory staff in the use of the LDMS. For each study, the protocol and Laboratory processing Chart (LPC) or Manual of Operations (MOPs) will indicate which specimens will be stored locally and which will be shipped for testing. The LPC or MOPs will also indicate, with instructions, which specimens must be entered into the LDMS and which codes to use.

XII. LDMS Data Reconciliation

On a weekly basis, the laboratory and the clinic must reconcile the data records of samples sent by the clinic for each protocol with what the laboratory has reported as received. Protocol related problems and/or concerns must be brought to the attention of the IMPAACT PNL as well as the appropriate FSTRF staff.

In addition to weekly reconciliations, FSTRF staff will send site specific reports highlighting discrepancies in exported LDMS data. The laboratory must report all corrective actions to the IMPAACT PNL and FSTRF within two weeks of receipt of the FSTRF report. Data modifications should be performed following the FSTRF procedure. This document lists the procedure of how specimen records should be corrected in the LDMS and how changes should be communicated if the specimen has been shipped to another laboratory or repository.

The laboratory should perform weekly self-audit checks of their LDMS specimen storage process. Storage reports should be printed and the physical locations of specimens verified. IMPAACT PNL staff will also perform these checks when on-site.

XIII. Specimen Shipping

IMPAACT specimens will be transported in accordance with guidelines included in the protocol-specific laboratory processing chart (LPC) or manual of operations(MOPs), and with US federal, international, and local laws. This applies to transportation of specimens on-site, to and from the clinic and the laboratory, and from the site to a specified laboratory. Study and laboratory personnel involved with packaging and transporting specimens must receive adequate and appropriate training to ensure compliance to guidelines and regulations. Documentation of training must be filed on site and a copy sent to the IMPAACT Operations Center.
The International Air Transport Association (IATA) regulates the safe transportation of dangerous goods by air in accordance with the legal requirements of the International Civil Aviation Organization. IATA requires training and certification for those involved with shipping Class 6.2 infectious and biological substances. IATA regulations define infectious substances, cultures and stocks, biologic products, and biological substances and specify the requirements for the handling and shipping of each. Biological substances and infectious substances are further separated into risk groups based on the organism that is known or suspected to be present within the sample. Definitions of key terms follow:

- **Infectious substances** are defined as Hazard Class 6, Division 6.2. In 49 CFR Part 171, the regulations subdivide infectious substances, each with their own shipping and packaging requirements. Infectious substances have been assigned to Risk Groups 2, 3, or 4 based on criteria developed and published in the World Health Organization's (WHO) Laboratory Biosafety Manual (Second Edition [revised]. Interim Guidelines 2003). The criteria stratify organisms based on the degree to which they might cause injury through disease. Risk Groups are defined in the IMPAACT Laboratory Manual located on the ACTG and IMPAACT websites.

- **Biological substances** are any human or animal materials being transported for diagnostic or investigational purposes. Most biological substances are exempted from the strict packaging and labeling requirement of Division 6.2, infectious substances, but require triple packaging and specific labeling as described in the IMPAACT Laboratory Manual. Samples sent from the sites to the US, and shipping within the US, will generally fall in this category.
- **Cultures and stocks** are the end product of a culture maintained for growth or storage of an organism. When shipped commercially, these materials must be packaged in accordance with Division 6.2 guidelines, which require UN-rated packaging and a shipper's declaration.

IATA shipping certification renewal is required every two years with a review of the IATA Dangerous Guidelines annually to check for any new or changed requirements. Each staff member who handles shipments whether shipping or receiving must be trained and certified. To facilitate staff training and certification, in collaboration with other networks, the IMPAACT Central Laboratory will provide a training CD-ROM from Saf-T-Pak to the sites every two years. On completion of the test by a staff member, a certificate showing the test results is generated. The certified staff member, as well as the supervisor, must sign the test results. The original is kept on site in the employee's file and a copy sent to the IMPAACT Operations Center. New staff must be trained within 90 days of start date. Certified staff members can train newly hired staff. IATA regulations, updated annually, should be reviewed by site personnel. The IMPAACT Operations Center provides a copy of the latest IATA manual, containing the current regulations, to each site every year. Training is also performed by the Laboratory Technologist Committee (LTC) at the ACTG or IMPAACT group meeting. Sites may send technicians to this training in lieu of using the Saf-T-Pak CD. The site will receive a certificate documenting training in the mail a few weeks after the training. The original should be placed in the employee's file and a copy forwarded to the IMPAACT Operation Center.

Each site should follow local regulations regarding transportation of samples by dedicated couriers. International sites are subject to their own country's government regulations for transportation of infectious substances.

Importation of human pathogens to the United States from abroad requires an Importation Permit from the Centers for Disease Control and Prevention (CDC). This importation permit is issued to international laboratories by the receiving laboratory (e.g., UNC-IMPAACT Central Laboratory, etc.) and/or repository (e.g., BRI) for specified protocol specimens. **In addition, specimens containing fetal bovine serum such as frozen PBMCs that are shipped to the United States require an import permit from the U.S. Dept of Agriculture. The receiving laboratory (BRI or the UNC Central Laboratory) will provide a copy of the USDA permit to the shipping laboratory upon request.**

Some countries require export permits. It is the responsibility of each site to obtain any export permit or other documentation that may be needed to export specimens. Useful web sites with information concerning specimen handling and shipment are provided in section 16.0 of this document.

XIV. Destruction of Stored Specimens

Laboratories will be notified by the specific study team(s) via the IMPAACT Laboratory Steering Committee and the Data Management Center if specimens need to be destroyed. Instructions

for specimen destruction are contained in the IMPAACT SOP: Destruction of Stored Specimens – LAB-6006-01.

XV. Laboratory-Related Site-Specific Protocol Activation Requirements

For each IMPAACT study, IMPAACT Operations Center and IMPAACT Central Laboratory approval of IMPAACT laboratory readiness, including the requirements listed below are part of the IMPAACT site-specific study activation requirements:

- IMPAACT network approval of proficiency in laboratory testing
- QA/QC procedures at the site
- **Normal reference ranges**
- Site SOP for establishing/adopting/maintaining normal ranges
- Appropriate validation for protocol-specified tests
- Local laboratory backup arrangements
- IATA specimen shipping certification
- Site SOP for local specimen handling and "chain of custody" maintenance related to primary study endpoints
- Laboratory Manager CV
- LDMS utilization

Investigational New Drug (IND) studies will require additional information regarding FDA approval for all laboratory equipment and kits, or appropriate validation data if the assay is not FDA approved for all protocol analytes.

The IMPAACT Operations Laboratory Group notifies the Site Development and Management Group for the study when the site's laboratory-related procedures, facilities, and staff are deemed ready for study activation.
As part of site-specific protocol activation requirements, each site is required to establish an SOP for local specimen handling and maintenance of "chain of custody" related to testing for primary endpoints. This SOP must be approved by the IMPAACT Network Laboratory. The SOP should state:

- Where and how samples are obtained
- How samples are transported from the clinic to the laboratory
- What documentation accompanies each sample
- How movement of samples from one place and arrival at another is documented
- The temperature at which specimens are transported
- How a specimen is handled and processed once it reaches the laboratory

Specific information that must accompany the specimen includes the Participant Identification Number (PID), collection date, volume and visit code for each specimen. Specimen labels provided by the SDMC include this key information. Accountability for the samples must be maintained, with requirements for signatures of each individual who handled the specimen. The site SOP should also detail:

- How the results are returned from the laboratory to the clinic
- How problem samples are reported back to the clinic
- How unacceptable samples are rejected (Rejection Criteria Policy)
- How to dispose of samples that arrive in unsuitable or unusable condition

XVI. Biohazard Containment

As the transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions

will be employed by all study personnel in the drawing of blood and shipping and handling of all specimens for any IMPAACT study, as currently recommended by the US Centers for Disease Control and Prevention SOP for post-exposure follow-up.

XVII. References and Useful Web Links

Web sites for general information related to topics covered in this section, as well as those specifically cited, are listed:

Specimen Shipping, Shipping Materials and Information:

WHO Laboratory Biosafety Manual	http://www.who.int/csr/resources/publications/biosafety/who_cds_csr_lyo_20034/en/
CDC Shipping Regulations	http://www.cdc.gov/od/ohs/biosfty/shipregs.htm
Code of Federal Regulations	http://www.gpoaccess.gov/cfr/index.html
US Postal Service	http://www.usps.com
Saf-T-Pak	http://www.saftpak.com
1 CDC Biohazard Policy	http://www.cdc.gov/od/ohs/biosfty/biosfty.htm

Risk Group Assessments:

NIH Listings	http://www4.od.nih.gov/oba/rac/guidelines%5F02/appendix%5Fb.htm
American Biological Safety Association	http://www.absa.org/riskgroups/index.htm
CDC Regulation	http://www.cdc.gov/od/ohs/biosfty/biosfty.htm
CDC Select Agent Listings and Regulations	http://www.cdc.gov/od/sap
USDA Plant and Animal Pathogen Select Agents	http://www.aphis.usda.gov/ppq/permits

XVIII. Acronyms and Definitions

ACRONYM	DEFINITION
ACTG	Adult Clinical Trials Group
BRI	Biomedical Research Institute – cryo storage repository
CAP	College of American Pathologists - proficiency testing provider
DAIDS	Division of AIDS
DCLOT	DAIDS Clinical Laboratory Oversight Team
EQA	External Quality Assurance (proficiency testing)
FSTRF	Frontier Science and Technology Research Foundation- administrators for the LDMS
HANC	HIV/AIDS Network Coordination – provide support to the six DAIDS-funded global HIV/AIDS clinical trials networks through cross-network coordination of critical activities.
IATA	International Air Transport Association – provide regulations for shipping specimens
IQA	Immunology Quality Assessment – contracted by DAIDS with responsibility for the monitoring and evaluation of laboratories participating in the UK NEQAS CD4 proficiency testing program.
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials
LDMS	Laboratory Data Management System
LPC	Laboratory Processing Chart
MOP	Manual of Operations
PNL	Primary Network Laboratory
PPD	Pharmaceutical Product Development, Inc. – contracted by DAIDS to audit the clinic and laboratory sites
pSMILE	patient Safety Monitoring and International Laboratory Evaluation (commonly referred to as SMILE) – contracted by DAIDS to administer the CAP and Accutest proficiency testing program and provide QA oversight in collaboration with the networks for all international laboratories funded by DAIDS to participate in clinical trials.
QA	Quality Assurance - refers to planned and systematic processes that provide confidence of a product's or service's effectiveness.
QC	Quality Control – procedures for monitoring the work processes, detecting problems, and making corrections prior to delivery of products and services.
QMP	Quality Management Plan – The quality management plan describes how an organization structures its quality system, the quality policies and procedures, areas of application, and roles, responsibilities, and authorities.
SOP	Standard Operating Procedure
UK NEQAS	United Kingdom National External Quality Assessment Service - UK based proficiency testing provider in collaboration with the IQA for monitoring laboratories performing CD4 testing for clinical trials.
VQA	Virology Quality Assessment – proficiency testing provider contracted by DAIDS with responsibility for the monitoring and evaluation of laboratories performing HIV RNA and/or HIV DNA testing for clinical trials.