

**Institution:** Infectious Diseases Institute (IDI)  
Kampala, Uganda  
<http://www.idi.ac.ug/index.php>  
[www.idi-makerere.com](http://www.idi-makerere.com)

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## LAB RESOURCES

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**Please describe the laboratory facilities available in your research institute, including the items listed below (if applicable):**

Lab space and equipment (general):	Full-service CAP certified clinical core laboratory with chemistries, CD4, CBC, serologies, O&P, malaria smears, HIV viral load, HHV-8 viral load.
BSL-2 lab space and equipment:	None at IDI, full service TB lab at MakCHS
BSL-3 lab space and equipment:	planned
Flow cytometry equipment:	2 FACSCALIBUR machines, FACS Canto II
Other:	Chemistry platforms and HPLC Machine for PK studies

- Clinical laboratory services at the IDI are provided by the Makerere University-Johns Hopkins University (MU-JHU) Laboratory, which is located on the second floor of the IDI building and occupies 10,000 sq ft of space. This laboratory moved to its current location in 2004, but had been operating in another location on the Mulago Hospital campus since 1989. The laboratory is operated under the



supervision of Dr. Brooks Jackson, Chairman of Pathology at Johns Hopkins University, and has been accredited annually by the College of American Pathologists (CAP) since 2003. External Quality Assurance (EQA) testing is in place for every laboratory assay performed.

- Currently used EQA proficiency surveys include: CAP (College of American Pathologist), UKNEQAS (United Kingdom National External Quality Assurance Schemes), CDC-MPEP (Center for Disease Control – Model Performance Evaluation Program), QASI (Quality Assurance and Standardization for Immunology), and API (American Proficiency Institute). The MUJHU lab has a current four years successful record of External Proficiency testing participation.

**Please list the research groups in your institute, including the size and areas of expertise for each group:**

- Pharmacokinetics (6)
- TB diagnostics and research (8)
- Immune reconstitution inflammatory syndrome (6+)
- ARKS-Kaposi Sarcoma study group (5-7): clinical trial on ART in HIV infected patients with KS
- COAT trial team (12): research on optimal timing of ART in HIV-infected patients with Cryptococcal meningitis
- EARNEST: 2<sup>nd</sup> line Antiretroviral Therapy

## **BIOLOGICAL SPECIMEN REPOSITORY**

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**Please describe the biological specimens stored at your institute:**

- TB suspect repository (sputum)
- Urine repository (TB and sepsis)
- Cerebral spinal fluid
- Plasma, whole blood, serum
- Peripheral blood mononuclear cells (PBMCs)

**Does your institute have a database of stored samples:**

Yes

**Please provide details on methods for biological specimen storage at your institute (e.g., are Standardized Operating Procedures used?):**

- SPO-driven, aliquoted at room temperature within 6 hours of collection, stored at -80C

**Please describe the equipment/facilities available for sample storage at your institute, including items listed below (if applicable):**

-80C freezers	10
Nitrogen storage tanks	None, but available at Walter Reed site
Dry ice availability	None
Use of a nitrogen generator	None, but available at Walter Reed site

## **TRAINING AND EDUCATION**

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**Please describe the training initiatives your institution has in place for individuals prior to working in clinical studies?**

- Good Clinical Practice (GCP) training quarterly. Human subjects and GCP training available online monitoring training through INTERACT.
- The site houses facilities for the ACREM course, which is specifically for training research-oriented health care professionals.
- HIV/AIDS core courses are conducted for doctors, nurses, and other allied health care professionals.

**Please describe the training initiatives your institution has in place for individuals prior to working in the laboratory?**

- The site houses facilities for the ACREM course, which is specifically for training research-oriented health care professionals.

**What assays/techniques do you excel in at your institute?**

- As above, all tests are validated. Some ELISA based assays, viral load assays (RT-PCR), some pharmacokinetic assays (HPLC), LAM assay for TB diagnosis.
- HIV screening, standard assay techniques for renal function and liver function testing, Coulter assays, flow cytometry but limited to CD4 and CD8 testing.

**What training could you provide to visiting scientists?**

- As above
- Laboratory diagnostics for malaria, TB
- Flow cytometry

**What rank are the majority of your trainees? (e.g., approximate numbers of undergraduate students, Masters, PhD, post-doc, MDs)**

- IDI has established capacity building programs with strong academic outputs
- Masters >30
- PhD 18
- post-docs (2)
- MOs - many

**Do you offer training classes/courses for any of the following?**

- Grant Writing
- Manuscript/abstract writing
- Presentation skills
- Epidemiology
- Biostatistics
- Computer skills, excel, prism, endnote, word, powerpoint

**Does your institute receive funds to support training initiatives?** Yes

**Please provide details about the funds your institute receive to support training initiatives:**

- We have 5 core capacity building grants: 1) VLIR- Belgian government for HIV research 2) INTERACT - EuropeAID and Dutch government funding for TB, HIV and malaria 3) Gilead Foundation for Masters and PHD training 4) NIH sociobehavioral grant 5) EDCTP
- Funds are from Pfizer Inc, Exxon Mobil, Gouvernement of Uganda, Pangea, Gilead Sciences, Accordia

**Does your institution send trainees abroad for additional training?** Yes

**Please indicate the number of trainees sent abroad per year, the source of funding, the location of training, and the type of training received.**

- 2-5/year to USA, Australia, Belgium (Masters level)

**What Masters and/or Doctoral programs does your institution offer?**

- None, but IDI provides training opportunities for students registered at MakCHS and other institutions.

## **COLLABORATIONS**

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**Please list and briefly describe your current collaboration with any African institutions for either research or training purposes:**

- In Uganda: Joint Clinical Research Centre (JCRC), Uganda Virology Research Institute (UVRI), Uganda Medical Research Council (MRC), Lacor Hospital in Gulu
- EACCR - (Muhimbili, NIMR-Mbeya, KEMRI, Ifakara Health Institute), University of Zimbabwe, Albert Schweitzer MRU, Gabon University of Limpopo, South Africa's Catholic University, Beira (Mozambique).
- Butare National University of Rwanda, through the INTERACT programme

**Please list and briefly describe your institution's collaborations and/or partnerships with entities outside of Africa (e.g., organizations and networks in the USA, Europe, etc. – including CFARS, NIH clinical trials networks, HPTN, HVTN, AMC, leDEA, USAID, PEPFAR, etc.):**

- leDEA-East Africa
- PEPFAR funding for 6 Western districts and Kampala City Council Clinics
- EDCTP
- INTERACT

## **CLINICAL COHORTS**

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**Do you have access to existing clinical cohorts in Africa or USA?**      Yes

**Please describe the clinical cohorts that you are planning to establish, including specifics such as "HIV-TB infected HAART naïve adults", sample type, sex, and age:**

- 6500 strong ART cohort at IDI
- Gulu - TB database at Lacor Hospital
- Cryptococcal Meningitis cohort through the COAT trial, with another site in Capetown. Sample size 500, both male and female, clinical samples available.
- KS study

**Are you planning to establish any new clinical cohorts over the next 5 years?**

- Yes - pending
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## DATA MANAGEMENT

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**Please describe the DATA MANAGEMENT FACILITIES available in research institute, including the items listed below (if applicable):**

Data management expertise, including staff complement (general):

- DataFax Data Management Center (approximately 10-17 staff ). The DataFax system relies on clinical report forms (CRFs) to collect data during patient visits and fax machines to collect data into a central server via optical character recognition. Data from the CRFs are collected, reviewed, and processed by the DataFax central office, housed at the Infectious Disease Institute. The DataFax system is used to assess errors on the CRFs and perform additional quality control and quality assurance procedures. The DataFax system is also utilized by data managers to develop study-specific reports. This enables real-time quality assurance for the multi-site study. Individual sites receive weekly error queries for missing CRFs or labs, protocol deviations, and overdue visits. The IDI DataFax system has been audited by NIH/NIAID/DAIDS personnel and is fully compliant with all GCP and U.S. DHHS, NIH, FDA, etc. regulations.

On-site database design, implementation and trouble-shooting:

- Through the DataFax system working with investigators as studies begin.

Details of off-site support (by whom):

- Data entry personnel, at sites where DataFax is not available.
- Server housed in Bethesda, USA (NIH)

## BIOSTATISTICAL SUPPORT

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**Please describe the BIOSTATISTICAL SUPPORT available in your research institute, including the items listed below (if applicable):**

Biostatistical expertise, including staff complement/composition of PhD and Masters level biostatisticians :

- 3 biostatistitians on site (2 Masters)

Specific areas of biostatistical expertise/excellence:

- Longitudinal cohorts

Details of off-site support (by whom):

- Multiple international collaborations
- Mentorship through the University of Indiana