Institute of Human Virology Nigeria H3 Africa Biorepository Initiative (I-HAB):

2nd H3Africa Consortium Meeting
Accra, Ghana May 16-18 2013

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Laboratory capacity for Program, Training and Research in Nigeria

Figure 3: Biosafety Level 3 Laboratory Installed at NTBLTC Zaria

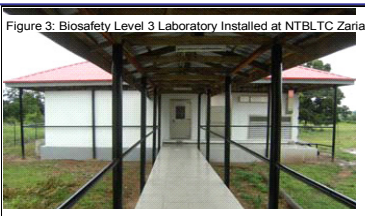
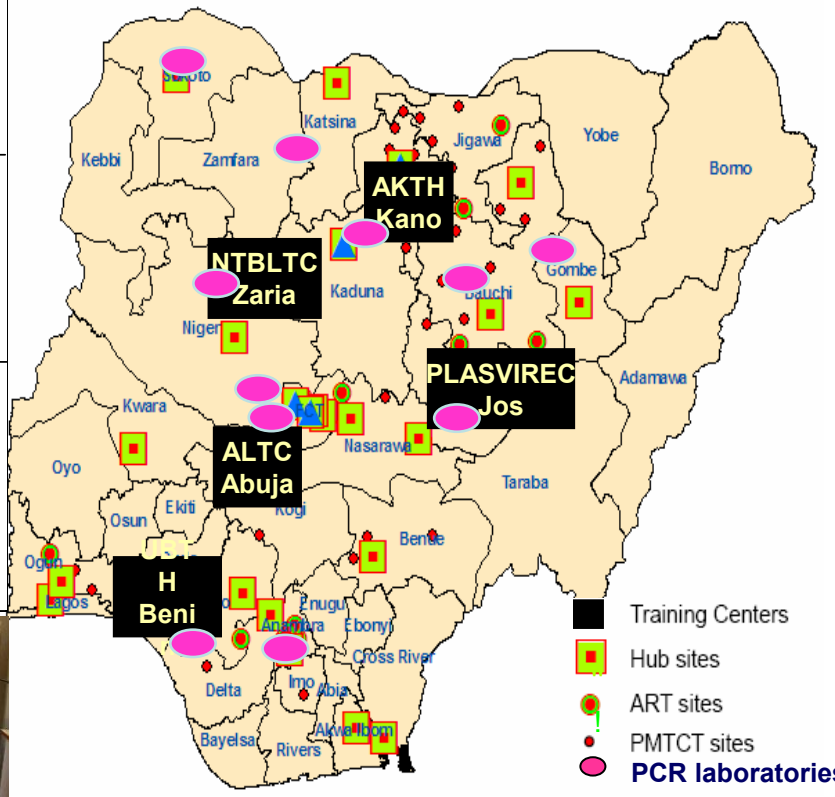


Figure 4: Interior of BL3 Laboratory Showing MGIT Culture

Figure 5: HAIN TB Molecular Diagnosis Testing being Conducted at NTBLC inZaria



- 5 Regional training labs (one dedicated to TB)
- 20 Tertiary level labs
- 15 Secondary labs
- 30 Primary sites
- 185 Health care facilities
- 11 PCR labs (EID, VL, HAIN)
- 1 BSL-3 (TB)
- 3 Developed research facilities & Biorepositories

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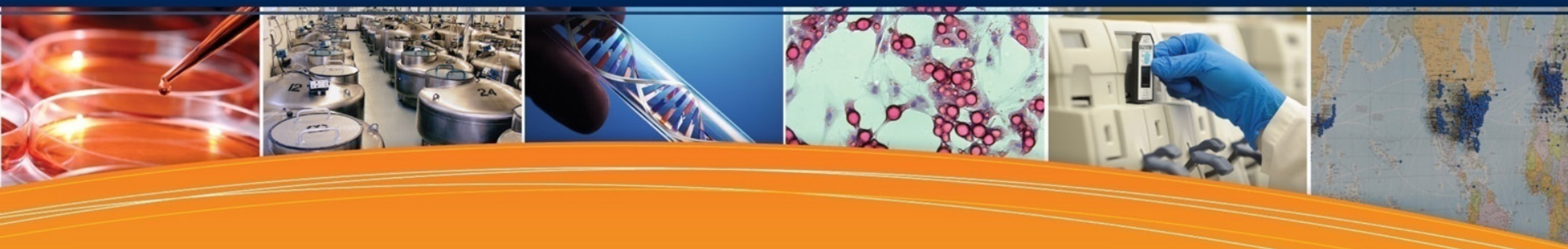
IHVN H3Africa Biorepository

Partnering with the Institute for Human Virology, Nigeria



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H3 Africa Biorepositories

- **Goal: make samples available for future research to bring new diagnostic and therapeutic benefits to PEOPLE in a timely manner**
- Centralized repositories for processing, QC, storage and distribution of large collections of biosamples (expertise and primary responsibility)
- Located in Africa—3-4 regional biorepositories
- Distribution will be controlled by African stakeholders
- Advantages
  - Standardized QC
  - Safe, secure storage of samples
  - Return of information from many research studies
  - Training in collection, processing, QC of samples
  - Return in kind

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Why use the H3Africa biorepository?

- Standardization
  - SOPs for all processes and activities.
  - Consistency among processes, which may not be achievable when performed by various clinics or without standardized measures.
  - High quality QC methods ensure sample integrity and quality.
- LIMS
  - Data security
  - Documentation of all stages of sample management & QC.
  - Sample tracking prevents sample mix-ups.
  - Sample inventories may be shared with investigators.

Organizational structure for I-HAB Phase I

Christine Beiswanger, PhD
Director BioBanking
Coriell Institute
(I-HAB Consultant)

Alash'le Abimiku, PhD M.Sc
PI and Director I-HAB

Charles Mensah
Administrative Support

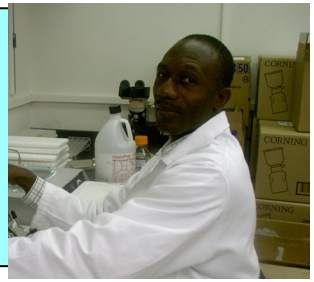
Nicaise Ndembi, Ph.D.
I-HAB Sample Quality Assessor

Tay Croxton, M.Sc
I-HAB
Managing Director

Bimpe Balogun
I-HAB Quality Assurance Officer

Muyiwa Balogun
Accession Logistics and Shipping

Ayo Famooto
Tissue sample Processing and Storage



Musa Gabadi
Data Manager

May 16-18, 2013 Accra Ghana

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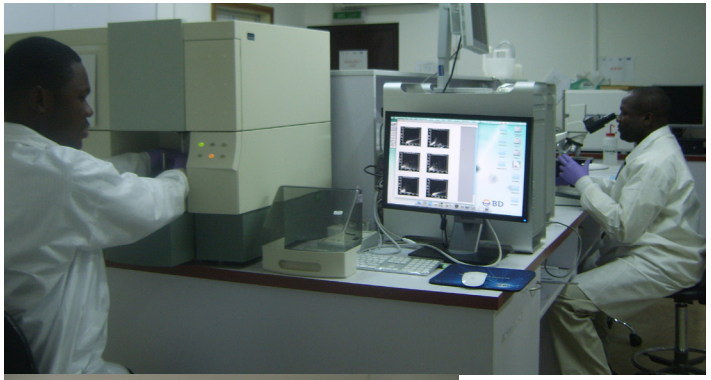
Goals of I-HAB

To partner with internationally recognized Coriell Institute for Medical Research to:

<u>Phase I</u>: Upgrade IHVN's H3Africa Biorepository (I-HAB) to achieve International Society for Biological and Environmental Repositories (ISBER) best practices and

<u>Phase II</u>: to expand it's capacity to support multiple H3Africa investigators to conduct high quality genomics and translational research in Africa using well processed, preserved and quality controlled and redundantly protected human biological samples accessible to the H3Africa and larger research community

I-HAB Current Activities: Specimen Processing



- 70% Biological fluids – Blood, saliva, breast milk processing
  - Characterize PBMCs
  - Plasma
  - Serum
  - Cell pellet
  - DNA
- 30% cancer tissues (breast, colon, head and neck, sarcoma)
  - Cytological slides
  - Extracted DNA

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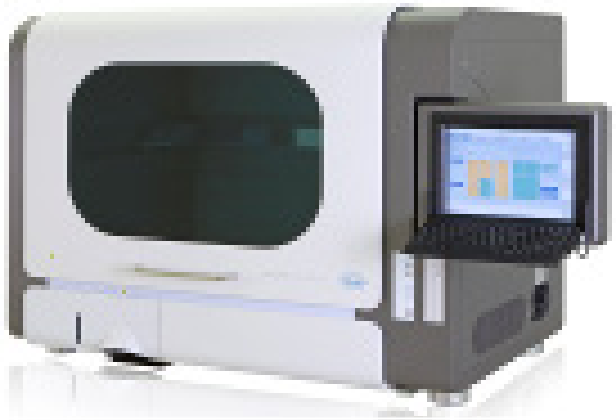
I-HAB Current Activities: DNA Extraction and processing

Sample Preparation	Nucleic Acid Isolation	Enzymatic Reaction	Amplification	Detection
Homogenisation	NA Purification Set up PCR Mixes	Reverse Transcription *In vitro* Transcription	Real Time (RT-) PCR Melting Curve	Melting Curve

MagNA Pure LC 2.0



Gene Detection
Gene Quantification
Genotyping
Gene Scanning .

LightCycler480

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I-HAB Current Activities: Archiving, Shipment, and maintenance

- Cryo-preservation and specimen storage at -20, -86 freezers
  - Dedicated back up generators
  - Dedicated back up batteries with converters
- Shipments of biological specimens
  - IATA trained staff
  - World Courier service to other parts of Africa, UK and the USA at RT, ice or dry ice with refills
- Maintenance of biorepository facilities and equipment
  - Service contracts
  - Dedicated trained IHVN biotech engineers

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Grants (UMD and IHVN faculty) supported by I-HAB

Table 1. Grant Number	Grant Titles
Health Programs	
CDC, U2G PS000651	"HIV/AIDS Prevention, Care and Treatment in the Federal Republic of Nigeria"
Global Fund NGA-S10-G16-T	The Global Fund Round 9 TB
Global Fund NGA-809-G14-M-03	The Global Fund Round 8 Malaria
Global Fund NGA-809-G12-S	The Global Fund Round 8 Health Systems Strengthening
Research Projects	
GC-3482-135-01-010	"HIV Epidemic and Surveillance in Selected Targeted Populations in Plateau State Nigeria"
CDC, 200-2003-01716	"Collection of Serum Specimens Suitable for Validation of Assays with HIV-1"
WHO, IVR, African AIDS Vaccine Program	"HIV disease awareness and willingness to participate in HIV vaccine trials differ across sub-populations at risk of HIV in Abuja Nigeria"
Bill and Melinda Gates via the University of New South Wales	"Evaluation of Novel Concepts in Optimization of antiretroviral Efficacy (ENCORE)"
NIH, NCI	"Kaletra Mono-therapy as a Simple Cost Effective Strategy in the Salvage of D4T, 3TC Nevirapine containing Regimens in Resource Limited Settings"
NIH, R01 AI074594-01A2	"Acute HIV infection and Pregnancy"
CDC U2GPS002929	Community in ACTION: Integrating PMTCT Services in Primary Health Care Setting
CHRI-CHVI (Canadian) 106356	Creating a common platform for HIV vaccine research and HIV care and treatment program

Update on Activities: Upgrade to International Standards

A 22- page report with recommendation from site visit by Coriell Institute of Medical research being addressed in these broad areas:

- Infrastructure:
  - Re-arrangement of the laboratory so that similar processes are carried out within the same room or space
  - Room temperature and humidity monitors
- Documentation (except SOPs)
  - Certification of analysis to be shipped with all samples
- Training
  - IATA shipping on line training
  - Dedicated trained IHVN biotech engineers
- Bioinformatics and IT
  - Back up freezer works to third party off site vendor on regular basis

Pilot Supporting Clinical sites

PIs: Dwomoa Adu and Lolu Ojo Obafemi: H3A kidney disease research network organization

Clinical sites in Nigeria

- Awolowo University
- University of Abuja
- University of Ibadan
- University of Illorin
- University of Nigeria

Samples

- Whole Blood (DNA)
- Serum
- Saliva
- Urine

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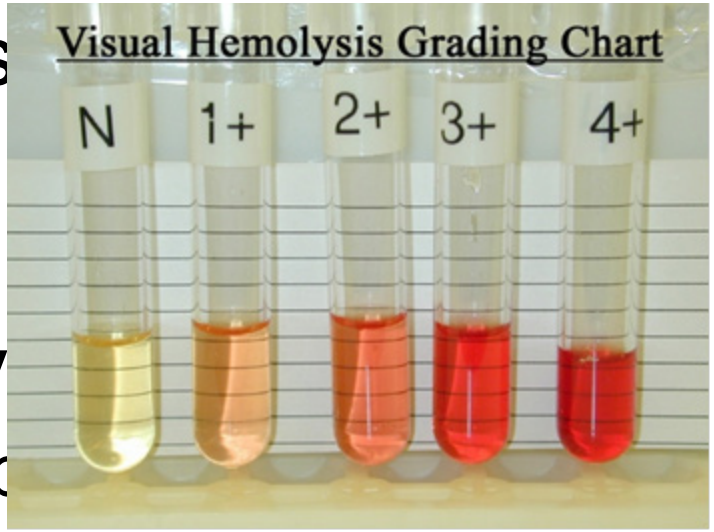
Quality assessment: Pilot with Sister South African Biorepository

- Volume
- Visual grading of hemolys
  - N: none
  - 1-4 increasing hemolysis
- ELISA Hemoglobin assay
  - Cut off ranges for acceptab
- DNA quality
  - OD260 /OD280 ratio
  - Nanodrop technology



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Quality assessment: OD readings of samples prior to shipment

#	Fraction ID#	Total # of cells (x106)	# of Aliquots	# of Cells/Aliquot (x106)	Nucleic Acid Conc. (ng/µl)	A260	A280	260/ 280	260/ 230
85	114/2 T&B	36.8	7	4.0	61.7	1.234	0.636	1.94	1.49
86	115/2 CD14	7.6	2	3.8	7.5	0.15	0.072	2.08	1.53
87	115/2 CD16	0.5	1	0.5	1.5	0.03	0.03	1.01	-1.43
88	115/2 T&B	42	9	4.7	13.8	0.277	0.143	1.93	2.45
89	116/1 CD14	6.8	2	3.4	28.5	0.57	0.312	1.83	1.43
90	116/1 CD16	2.8	1	2.8	19.1	0.382	0.201	1.9	1.96
91	116/1 T&B	43	9	4.8	105.7	2.114	1.126	1.88	2.02
92	117/2 CD14	13	3	4.3	117.6	2.352	1.276	1.84	2.42
93	117/2 T&B	9.5	2	4.8	51.2	1.025	0.572	1.79	2.76
94	118/2 CD14	10.6	2	5.3	83.7	1.674	0.898	1.86	1.69
95	118/2 CD16	1.8	1	1.8	27.9	0.558	0.304	1.84	0.91
96	118/2 T&B	23.5	5	4.7	41.8	0.837	0.442	1.89	1.46
97	119/3 CD14	6.8	2	3.4	38.4	0.768	0.396	1.94	1.89
98	119/3 T&B	26.4	5	5.3	30.7	0.614	0.322	1.91	1.85

Absorption at 260 nm : 1 A_{260} = 50 µg ds-DNA/ml

260 / 280 ratio: 1.6 - 2.0 (< 1.6 : residual proteins or phenol, > 2.0 : residual RNA)

230 / 260 ratio: 0.3 - 0.9 (> 0.9 : residual sugars)

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Shipment: Commercial Courier Comparisons

Courier	Account in Africa	Cost	Provide supplies	Maintain Coldchain	Timeliness	Access H3A Sites	Assist Permit
FedEx	X	1			X	X	X
Marken	X	3	X	X	X	X	X
World Courier		2	X	X	X	X	X

- Potential to leverage more affordable pricing through the combined business of the H3Africa consortium.

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Discussion points

1. How can the BioR effectively compliment and synergize with each other to support the H3 Africa goals?
2. What regulations or ethical processes exist in the different H3 Africa countries that may impact the function of the BioR?
3. How can the BioR augment research innovations and collaborations among the H3 Africa network?
4. What are the expectations of the H3Africa investigators from the biorepository in Phase II?

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Acknowledgements

- Institute of Human Virology Nigeria
  - Talishiea Croxton
  - Nicaise Ndembi
  - Ayotunde Famooto
  - Sam Peters
  - Clement Adebamowo
  - Patrick Dakum
  - Charles Mensah
- Coriell Research Institute:
  - Christine Beiswanger
- Institute of Human Virology University of Maryland School of Medicine, Baltimore
  - William Blattner

Sponsor: National Institutes of Health, National Human Genome Research Institute

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