

# MTN 003 LAB

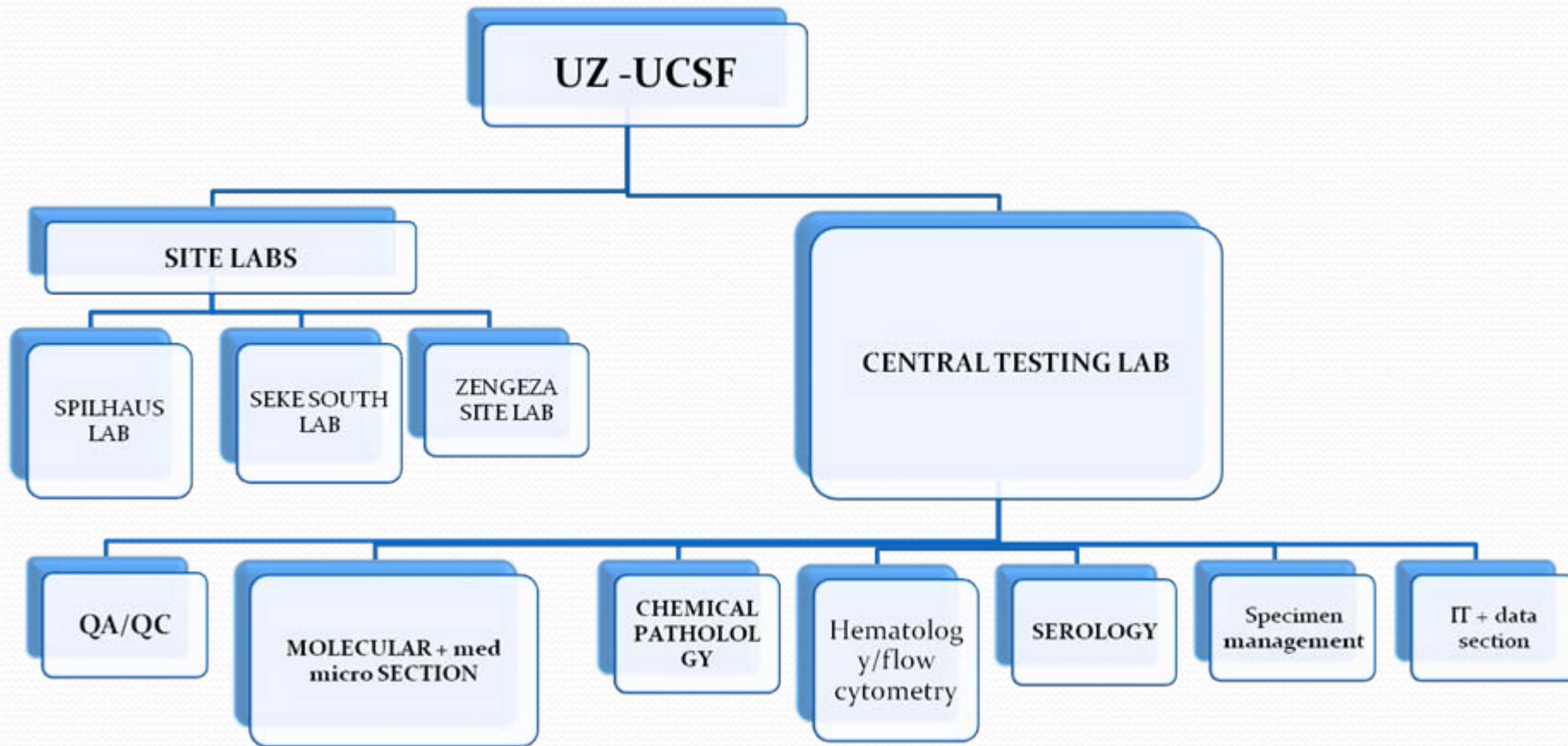
# ZIMBABWE SITE EXPERIENCE

Pardon Gomani

# CALENDAR OF EVENTS

- Prior to site activation the following events were lined up
  - October 2008 – Operational walk through in JHB
  - 9 to 17 July study specific training- Harare
  - 27 August 09 site specific activation notice for the Spilhaus site
  - 1 Sept 09 – voice dry run
  - 7 Sept 09 first screening samples received in the lab
  - 2 Oct 09 site specific activation notice for the Seke south site
  - 8 Oct 09 first screening samples from the Seke South clinic

# STRUCTURE OF THE LAB





# Overview of the lab activities

- Site labs
  - Spilhaus site lab is located about 15 minutes drive to the central testing lab
  - Seke south clinic lab – about 30 to 45 minutes from the central lab
  - Zengeza (not activated yet) – also located about 45 min from the central testing lab
  - Each site lab is manned by 1 member of staff

## Site Lab activities

- Pregnancy testing
- HIV rapid testing
- Rapid BV and Trich testing
- Urine dipstick analysis
- Preparing and packaging samples for shipment to the central testing lab
- Daily test counts
- Weekly Inventory control for all site reagents and consumables



# Site activities

For each sample to be sent to the central lab the following checks are made by the site lab tech

1. PTID on the specimen and on the request form
2. Completeness of forms
3. Specimen quality and adequacy
4. Preparing the specimen transport log
5. Samples are packaged for transport

# Overview of Central lab activities

- 1 Specimen management section
  - Manned by 5 staff members
  - Receives the specimens from the site lab.
  - Specimen processing commences with the assignment of a lab accession number generated on LIS as specimens are registered.
  - LIS labels generated are attached to corresponding primary tubes and aliquots.
  - Staff in this section are responsible for all the required separation and archiving of specimens. -LDMS entries
  - Samples for testing are placed in corresponding pending testing boxes for responsible sections



# Testing sections

## 2. Chemical pathology

- Manned by one staff member
- Test menu includes ALT, AST, phos, creat, urea/bun, Na, K, CL, bicarbonate, lactate, LDL-C, HDL-C, trig, cholesterol, ALP, alb, tbilirubin, direct bilirubin, GGT, Tprotein, glucose, magnesium, calcium, csf protein + glucose, CK ,lipase and amylase
- Analyser in use – Hitachi 902
- EQA programs- CAP + ZINQAP and average performance is above 98%
- Results are manually transcribed onto LIS



# Testing sections

## 3. Hematology/flowcytometry

- Manned by 2 members of staff
- FBC/CBC- Sysmex SF 3000 interfaced with LIS, XT - 2000i validation in progress
- CD4/CD8 – Facs calibur not interfaced with LIS
- Blood films- Aerospray slide stainer
- Coagulation- ACL 7000 + ACL 3000
- EQA –UK NEQAS, CAP, ZINQAP

## 4. Molecular techniques

- Manned by 4 members of staff
- CT/NG SDA – BD Probe Tec
- CT/NG PCR – Roche
- HIV DNA – Roche
- HIV Viral load – Roche Amplicor (standard + ultra sens)
- EQA- VQA, UK NEQAS (viral load), CAP for CT/NG SDA



## 5. Serology

- Manned by 1 member of staff
- Tests includes Western Blot, RPR/TPHA, HBsAG. HBsAB, HIV rapids, HIV Elisa
- Batched runs for WB, HbsAg, HBsAB, 1 run per week
- EQA- CAP viral markers



# Test statistics so far –Spilhaus and Seke south

Test	SPIL SEPT TOTALS	SES SEPT TOTALS	UPTO 15 OCT SPIL TOTALS	UPTO 15 OCT SES TOTALS
PREG TEST	61	0		
HIV DET/ORQUICK	42	0		
BV RAPID	0	0		
RAPID TRICH	17	0		
URINE DIPSTICK	42	0		
WET MOUNT (CANDIDA)	0	0		
SERUM CHEM	38	0	13	17
FBC	38	0	13	17
HBSAG	38	0		
HBSAB	38	0		
URINE SDA	38	0		
RPR	38	0		

# Reporting results

- All sections send out result from the LIS and this report captures the PTID, visit code, clinic of origin, clinic staff id, date and time of specimen collection, time received in the lab, date and time of generation of result report, result in units as per CRF form, date of result review.
- Three copies of results are printed .
- The designated lead scientist ensures that all results are attached and are being sent out within TAT
- The lead scientist is also the communication link between the MTN clinic staff and the central lab
- The data staff ensures that all the photocopying and packaging is complete
- The QA/QC staff does a final check on 100% of all the results.

# Turnaround times

Test	Turnaround times	
	routine	Urgent/critical
PREG TEST	10 minutes	
HIV DET/ORQUICK	45 minutes	
BV RAPID	15 minutes	
RAPID TRICH	15 minutes	
URINE DIPSTICK	10 minutes	
WET MOUNT (CANDIDA)	15 minutes	
SERUM CHEM	4 days	24 hours
FBC	4 days	24 hours
HBSAG	7 days	48 hours
HBSAB	7 days	48 hours
URINE SDA	10 days	72 hours
RPR	7 days	48 hours



# Challenges

- Site lab
  - Occasional delays in specimen transportation to the central testing lab
  - Communication is not so good since site staff have no email access and currently do not have a site phone

# Challenges at the central lab

- The calibrator in the HbsAB ELISA kit running out before all the other components are exhausted
- Formation of a fibrin clot/gel-like in 5ml plain tubes
  - making separation difficult during processing
  - The clot may interfere with sample aspiration during chemistry runs
- Gram slides tracking sheets



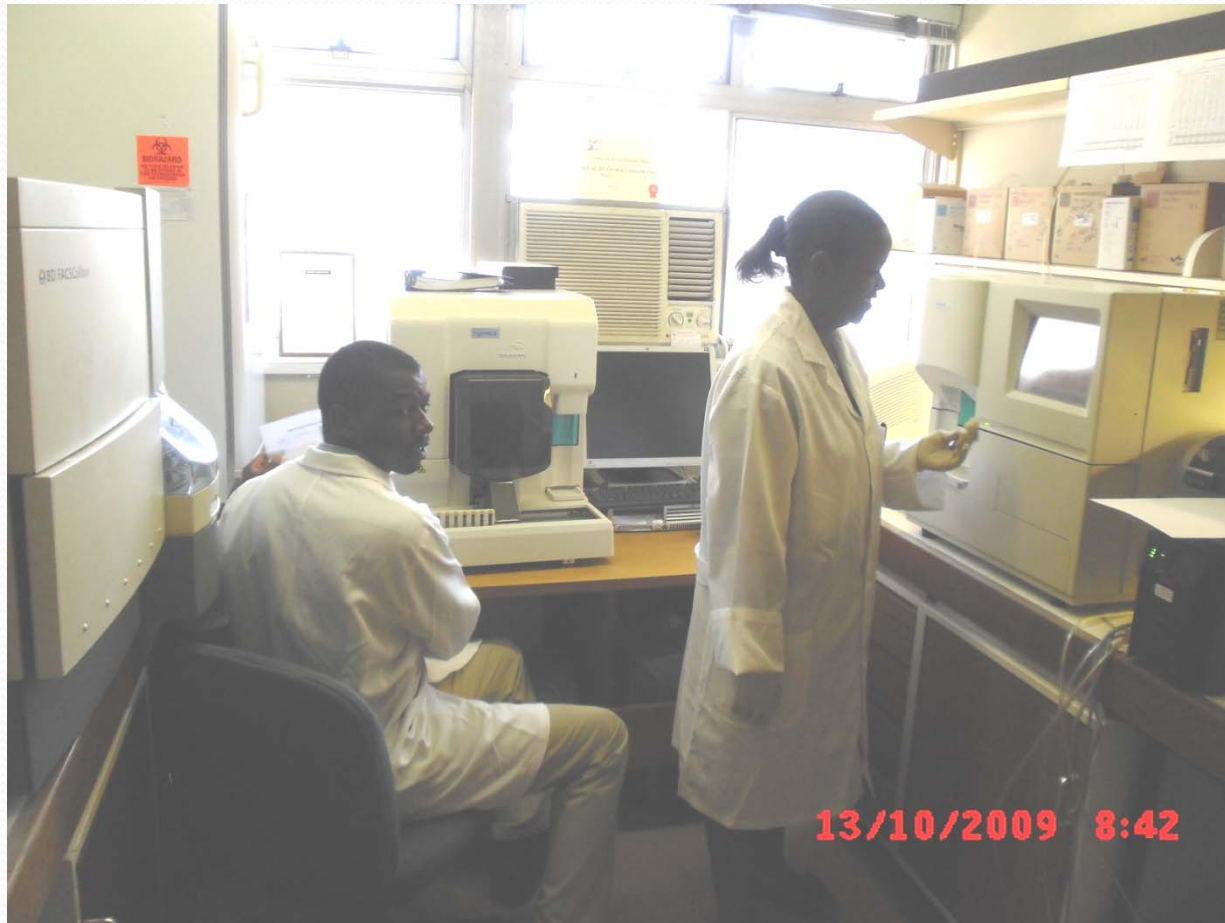
# Lessons learnt so far

- The biggest lesson learnt was launching the MTN 003 lab was fairly easy with the experience gained from HPTN 035
- Important highlights were made during the VOICE operational walkthrough
- The staggered activation of the different sites allows for in house training /exposure of staff as they wait to open at their own sites
- Lead scientist role is valuable
- Effective usage of the HBsab ELISA kit
- The site lead checks are critical



# Photo action

## hematology



# Chem path





# serology





# Molecular tech-area 2 specimen prep





# Probe tec area





# Pcr (amplification+ detection)





# Specimen management





# IT and data





# QA/QC







Thank you