



**AURUM INSTITUTE LABORATORY-
GAVIN J CHURCHYARD LEGACY
CENTRE**

The laboratory preparation for a
new study –a pragmatic approach

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October 2011



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WHO WE ARE

- ▣ We are the Aurum Institute and our laboratory is situated in Klerksdorp in the Northwest Province and is centrally situated in the business area of the city
- ▣ The greater city area of Klerksdorp incorporates the town of Orkney, Stilfontein, Kanana, Khuma, Hartbeesfontein and Tigane and has a population of approximately 350,000 inhabitants. Klerksdorp is considered to be the hub of the gold mining industry

Our Lab



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Our Staff

- ▣ Our present staff complement is :
 - Laboratory Manager
 - Medical Technologist
 - Medical Technician (BSc graduate)



Here we are!



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Notification of a New study

- ▣ In most instances the laboratory manager is informed by the site director of the new study
- ▣ Site inspections (including the laboratory) is carried out prior to the implementation of the study by elected persons of the sponsor and any deficiencies or requirements are discussed and implemented
- ▣ Staff informed of new study implementation



Oh no! How on earth are we
going to cope!



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Protocol Overview

- ▣ Laboratory manager will obtain a copy of the protocol and will give an overview to the relevant laboratory staff
- ▣ Staff are encouraged to familiarise themselves with the study especially areas associated with
 - Site specific procedures
 - Laboratory manual
 - Specimen management



A practical approach



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A more serious approach



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Test requirements

▣ Local testing

- ▣ Validation and EQA(IQC & EQC) for all rapid tests carried out on site as per sponsors requirements

▣ Referred testing

- ▣ Tests that are to be referred to a preferred service provider usually of the sponsors choice
- ▣ Laboratory manager will contact the preferred provider to ensure compliance with testing procedures , TAT's and reference ranges
- ▣ Completion of lab activation summary ,protocol analyte lists, analytical plan



Equipment

- ▣ All new equipment if acquired to be validated and current validation and maintenance certificates of existing equipment to be available



Staff requirements

- ▣ Laboratory manager together with operations manager will assess whether present staff complement is adequate or whether further staff is required
- ▣ If further staff is required then adequate budgeting, advertising of the posts, interviews and appointments will be carried out as per company policy



Best suited for the post



Stock requirements

- ▣ Laboratory manager will estimate the required stocks necessary for the completion of the study
- ▣ Quotations for the necessary reagents consumables and collection kits are obtained and orders are placed as per company policy



Oops! Sometimes orders do slip through!



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Staff preparation for the study

- ▣ Relevant visit requisitions, worksheets and logs are devised in conjunction with the Quality department
- ▣ All files necessary for the filing of documents are prepared
- ▣ Shipping documents and shipping timetable is made available which will include export and import permits if required and courier contracts



Staff preparation (cont)

- ▣ LDMS storage guide is made available to assist with specimen management and storage



Staff training

- ▣ Training is arranged by the study coordinator prior to the implementation of the study
- ▣ Training is usually carried out by representatives of the sponsor which will incorporate all aspects of the protocol including laboratory training
- ▣ New and current staff should be GCP ,GCLP and IATA compliant as well as to have passed PBMC proficiency testing and be familiar with the laboratory LIS system(LDMS)

Visit schedules and specimen requirements

- ▣ Weekly meetings between the laboratory and clinic staff are arranged in the initial stages of the study
- ▣ Problems are reported, identified and resolved
- ▣ Laboratory staff compile own visit and specimen type schedules and workflow charts to assist when receiving specimens



IAVI B003 VISIT 01 HVTN 091 VISIT 01.0

TUBE	VOLUME	TEST	CENTRIFUGE	DESTINATION	COMMENT
EDTA	4.0 ml	Plasma storage	Yes	Local	0.5ml aliquots
SST	5.0 ml	Serum storage	Yes	Local	0.5ml aliquots
EDTA	2.0 ml	HIV Rapid	Yes	Local	Uni gold & Determine
SST	3.5 ml	ALT,AST,Creat	Yes	BARC	
SST	3.5 ml	HBsAg,AntiHCV,RPR	Yes	BARC	
EDTA	2.0 ml	FBF,Diff,FI	No	BARC	
EDTA	3.0 ml	CD4/CD8	No	BARC	
Urine	50 ml	bHCG/Urinalysis	No	Local	bHCG (F); Urinalysis (F+M)

IAVI B003 VISIT 02 HVTN 091 VISIT 02.0

EDTA	10.0 ml	HIV/PCR Diagnostics	YES	NICD	3 X 1.1 ml vials
EDTA	4.0 ml	Plasma storage	YES	Local	0.5 ml aliquots
SST	2 x 5 ml	Serum storage	YES	Local	0.5 ml aliquots
NaHep	17 x 10 ml	PBMC + Plasma storage	YES	Local	Remove 6 ml plasma, aliquot 0.5 ml (12 vials)
Urine	50 ml	bHCG	No	Local	Females

IAVI B003 VISIT 02C HVTN 091 VISIT 02.1

EDTA	2.0 ml	FBC Diff Pl	No	BARC	
SST	5.0 ml	ALT,AST,Creat	Yes	BARC	
EDTA	2.0 ml	HLA Typing	No/Yes	Local	1.0ml WB into 1.8ml vial / Additional plasma storage
EDTA	4.0 ml	Plasma storage	Yes	Local	0.5 ml aliquots
SST	5.0 ml	Serum storage	Yes	Local	0.5 ml aliquots
NaHep	8 x 10 ml	PBMC + Plasma storage	Yes	Local	Remove 6 ml plasma, aliquot 0.5 ml (12 vials)
Urine	50 ml	bHCG	No	Local	Females

IAVI B003 VISIT 03 HVTN 091 VISIT 03.0

SST	2 x 5 ml	Serum storage	Yes	Local	0.5 ml aliquots
NaHep	16 x 10 ml	PBMC + Plasma storage	Yes	Local	Remove 6 ml plasma, aliquot 0.5 ml (12 vials)

IAVI B003 VISIT 05 HVTN 091 VISIT 05.0

EDTA	2.0 ml	FBC Diff Pl	No	BARC	
SST	5.0 ml	ALT,AST,Creat	Yes	BARC	
EDTA	2.0 ml	Plasma storage	Yes	Local	0.5 ml aliquots
EDTA	4.0 ml	Plasma storage	Yes	Local	0.5 ml aliquots
SST	5.0 ml	Serum Storage	Yes	Local	0.5 ml aliquots
NaHep	8 x 10 ml	PBMC + Plasma storage	Yes	Local	Remove 6 ml plasma, aliquot 0.5 ml (12 vials)
Urine	50 ml	bHCG/Urinalysis	No	Local	bHCG (F) Urinalysis (F+M)



VISIT	TYPE OF TUBE	TEST	BARC	KOSH
SCREENING	1 x URINE	BhCG		X
ENROLLMENT		SDA	X	
	1 x 5ML SST	ALT, AST, TBIL, CREAT,ALP	X	
	1 x 5ML SST	RPR	X	
	1 x 4ML EDTA	FBC/DIFF	X	
	1 x 4ML EDTA	CD4	X	
	1 x 4ML EDTA	HIV RNA (VL)	X	
	5 x 10ML EDTA	PBMC & PLASMA STORAGE		X
	1 x VAGINAL SWAB	RAPID FOR BV*		X
	1 x VAGINAL SWAB	WET MOUNT FOR KOH*		X
	1 x VAGINAL SWAB	TRICHOMONAS		X
	2 x VAGINAL SWAB	STORAGE		X
	1 x LBC	PAP SMEAR	X	
	1 x CVL	STORAGE		X
	1 X 5ML SST	SERUM STORAGE		X
Month 1 POST	1 x 4ML EDTA	CD4	X	
SEROCONVERSION	1 x 4ML EDTA	HIV RNA (VL)	X	
	5 x 10ML EDTA	PBMC & PLASMA STORAGE		X
	2 x VAGINAL SWAB	STORAGE		X
	1 x CVL	STORAGE		X
*ONLY IF CLINICALLY INDICATED				
Month 3, POST	1 x 4ML EDTA	CD4	X	
SEROCONVERSION	1 x 4ML EDTA	HIV RNA (VL)	X	
	1 x 4ML EDTA	FBC/DIFF		
	5 x 10ML EDTA	PBMC & PLASMA STORAGE		X
	2 x VAGINAL SWAB	STORAGE		X
	1 x CVL	STORAGE		X
MONTH 6, Q6	1 x 5ML SST	ALT, AST, TBIL, CREAT, ALP	X	
POST SEROCONVERSION	1 x 4ML EDTA	FBC/DIFF	X	
	1 x 4ML EDTA	CD4	X	
	1 x 4ML EDTA	HIV RNA (VL)	X	
	5 x 10ML EDTA	PBMC & PLASMA STORAGE		X
	2 x VAGINAL SWAB	STORAGE		X
	1 x CVL	STORAGE		X
ANNUALLY	1 X URINE	SDA	X	
POST SERO	1 x 5ML SST	ALT, AST, TBIL, CREAT, ALP	X	
	1 x 5ML SST	RPR	X	
	1 x 4ML EDTA	FBC/DIFF	X	
	1 x 4ML EDTA	CD4	X	
	1 x 4ML EDTA	HIV RNA (VL)	X	
	5 x 10ML EDTA	PBMC & PLASMA STORAGE		X
	1 x VAGINAL SWAB	RAPID BV*		X
	1 x VAGINAL SWAB	WET MOUNT FOR KOH		X
	1 x VAGINAL SWAB	TRICHOMONAS		X
	2 x VAGINAL SWAB	STORAGE		X
	1 x LBC	PAP SMEAR	X	



In Conclusion

- ▣ Thorough preparation by the laboratory staff is essential prior to the start of the study
- ▣ A broad overview of the protocol especially areas related to the laboratory requirements is necessary
- ▣ Equally important is a good relationship with other role players such as the study co-ordinator, clinic staff ,Quality department and referral laboratory amongst others



Acknowledgements

- ▣ Lindiwe Nhlangulela for her valuable inputs
- ▣ Aurum Institute for still allowing me to practise my profession as a Medical Technologist





THANK YOU



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