

7. APPENDICES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)

Ref: R14/49 Sherman

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M02-01-16

PROJECT Early Diagnosis of Human Immunodeficiency
Virus Infection Status In Vertically Exposed
Infants In A Low Resource Area

INVESTIGATORS Dr GG Sherman

DEPARTMENT School of Pathology, NHLS

DATE CONSIDERED 02-01-25

DECISION OF THE COMMITTEE *

Approved unconditionally

DATE 02-02-12 **CHAIRMAN**..........(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Prof BV Mendelow
Dept of School of Pathology, NHLS

Works2\ain0015\HumEtr97.wdb\M 02-01-16

=====

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

SUBJECT INFORMATION FORM FOR INFANT HIV DIAGNOSTIC STUDY

The staff of our Paediatric HIV Clinic are conducting a study that will help us and other healthworkers know how soon we are able to confirm the HIV result of a child whose mother is HIV infected. This study invites you to participate as a parent whose child may either become HIV infected or remain uninfected. Most babies born to HIV positive mothers are NOT infected with the virus. For every 10 babies born to HIV positive mothers, about 3 will be infected. Nevirapine further decreases the number of babies who will be infected.

To test if a baby is HIV positive before it is 18 months old is very expensive so most babies in South Africa are only tested when they are 15-18 months old. This means that all babies born to HIV positive mothers have to come to clinic and be on medicines until they can be tested for HIV even though most of them are HIV negative. The reason for doing this study is to look at cheaper HIV testing and see if it is as good as the expensive testing. If good, cheaper testing can be done then parents in South Africa may be able to find out much earlier if their baby is HIV positive or negative.

The babies on the study will have the expensive and the cheap HIV testing done and be told if they are HIV positive or negative when they are 4 months old. This testing is routinely done at Coronation Hospital so even if you decide not to join the study, your child's results will be available to you when he/she is 6-7 months of age.

If you are part of the study you will need to come to the Specialist Clinic at Coronation Hospital for the doctor to check the baby at least four times i.e. when the baby is 6 weeks old, 3 months old, 7 months old and 1 year old. The baby will have blood taken at all 4 visits which is more often than if the baby was not on the study. No more than 1 teaspoonful of blood will be taken at each visit.

You will be given R40.00 at each visit for transport to the clinic.

If your baby is HIV negative you will be discharged from the clinic when the baby is 1 year old otherwise the doctors at the clinic will continue to look after your baby.

The information we collect is to remain totally confidential. Your child's information will at no stage be made public alongside his/her identity. The results of the study will be used at medical meetings or in medical journals where the identities of those who participated in the study will not be disclosed. Your child's results will be referred to through our own identifying numbering system.

I understand that taking part in this study is my choice and that if I decide not to; it will not cause any problems with the treatment that my baby or I will receive at this hospital.

I may decide to stop taking part in the study at any time and my withdrawal from the study will in no way compromise the care my child receives from the clinic.

SUBJECT CONSENT FORM FOR INFANT HIV DIAGNOSTIC STUDY

I understand what this study is about and have had all my questions about this study answered.

I understand that taking part in this study is my choice and that if I decide not to; it will not cause any problems with the treatment that my baby or I will receive at this hospital.

I may decide to stop taking part in the study at any time and my withdrawal from the study will in no way compromise the care my child receives from the clinic.

All information from this study is strictly confidential and only the people involved in the study will have access to it.

I would like to take part in the study and understand that it involves coming back to the Specialist Clinic at Coronation Hospital until my baby is 1 year old.

If you would like to know more about this activity, please ask Dr Stephanie Hinrichs who will be happy to answer your questions.

This process was approved by the Ethics Committee of the University of the Witwatersrand on 25 January 2002 [Protocol number M02-01-06]. If you would like to have more information regarding the ethical considerations of the study, you are welcome to call the Chairperson of this committee at the following number

Professor P. Cleaton Jones, Committee for Research on Human Subjects,
University of the Witwatersrand. Tel: 011 717 2229

I have been given a copy of the Information sheet and the consent form, which I have read, or its contents explained to me through an interpreter. I have had all my questions and concerns answered to my satisfaction by the clinic staff.

I understand that I may refuse to participate in this process or withdraw at any stage without giving a reason for doing so and this will in no way influence the way my child will be treated.

Mother's signature:

Mother's name:

Date:

Witness signature:

Witness name:

Name and signature of person who obtained informed consent:

.....

PATIENT IDENTIFYING DETAILS FOR DIAGNOSTIC STUDY

CHILD

Study number
Name
Surname
Date of birth
Sex
Race
Hospital number
Telephone number
Address
.....
Neighbour's name
Neighbour's telephone number

MOTHER

Name
Surname
Date of birth
Hospital number

Appendix 4

BLOOD & ORAL FLUID SAMPLES FOR INFANT HIV DIAGNOSTIC STUDY

VISIT	TESTS	BLOOD VOLUME	MIN VOLUME	SPECIMEN STORAGE (-70 degrees Celsius)
6 weeks	HIV DNA PCR HIV RNA PCR Dried blood spots	5 ml EDTA 2 drops per 'spot'	2-3ml EDTA 4 'spots'	buffy coat plasma filter paper *
3 months	HIV DNA PCR HIV ELISA	2-3 ml EDTA 2 ml clotted	2ml 1ml	buffy coat plasma serum
7 months	HIV ELISA (HIV DNA PCR)	2 ml clotted 3 ml EDTA	2ml 2ml	serum buffy coat plasma
12 months	HIV ELISA OraSure / Vironostika ELISA OraQuick (HIV DNA PCR)	3 ml clotted oral fluid oral fluid 3 ml EDTA	2ml 2ml	serum - - buffy coat plasma

HIV tests listed in order of importance per visit

EDTA (ethylenediaminetetraacetic acid) = purple top test tube; Clotted = red top test tube
(HIV DNA PCR) to be stored for later processing in case additional checks are necessary

* Filter paper stored at room temperature

REPORTING OF CLINICAL FINDINGS (RES105-01) for clinical records

CLINICAL EXAMINATION

Wasted is used in a clinical sense since height and weight data are captured.

Rashes and candida - please indicate 'Yes' if present but specify under 'details' whether severe or not and detail type of rash

Indicate 'Yes' only if *lymphadenopathy*, *hepatomegaly* or *splenomegaly* is clinically **significant**:

Lymphadenopathy

Significant if node/s > 0.5cm:

- This definition includes epitrochlear nodes and inguinal nodes (at any age) i.e. only significant if >0.5cm
- Please stipulate if 'right', 'left' or 'bilateral' particularly where right axilla

'Details': Shotty nodes & their sites noted here as well as any local pathology that may explain any lymphadenopathy noted.

Hepatomegaly

Any hepatomegaly > 2cm below the costal margin in the midclavicular line that is not due to hyperinflation is significant.

'Details': note size of palpable hepar irrespective of whether significant or not.

Splenomegaly

Significant if palpable below the costal margin provided there is no hyperinflation.

Exception: Tip of spleen at 6 weeks of age is considered within normal limits

'Details': note size of spleen irrespective of whether significantly enlarged or not.

CLINICAL IMPRESSION

Applies to that particular visit which includes a past medical history.

Previous examination notes are not to be taken into account.

PROGRESSION

If obviously symptomatic then 'Rapid', otherwise 'Slow' progressor.

If borderline, please group as 'Slow'.

2 clinical data sheets to follow

COST ANALYSIS QUESTIONNAIRE

NAME: _____
 HOSPITAL NUMBER: _____
 STUDY NUMBER: _____
 DATE: _____
 VISIT (circle appropriate visit): 6 week; 3 / 4 / 7 / 12 month

1. ACCOMPANYING ADULTS:

Number: _____

	1	2	3
Relationship to child:			
Employed?			
If yes, state type of job or profession:			
Average Monthly salary:	R	R	R
Did the adult/s accompanying the child lose any income as a result of the visit?			
If yes, Loss of income due to visit:			

How far is it to the hospital from your house (about): _____ kms

What transport are you using to get to the hospital and back:

Taxi: Bus: Private Car: Other: describe: _____

How much does it cost to travel to the hospital and back: R _____

How long did it take you to get to hospital today? _____ hours/mins

Do you think it will take the same time to get home? Yes No

If no, estimate time and reason: _____

What other costs are there for the visit:

Food and drink:

R _____

Child care:

R _____

Other Describe:

R _____

2. TIME SPENT IN THE HOSPITAL AND OTHER HOSPITAL EXPENSES

<i>Event</i>	<u>Time</u>	<u>Duration</u>
Left Home		
Arrived At Hospital		
File Collected		
Arrived In Clinic		
Observations Done		
Attended Support Group		
Seen By Doctor		
Interpreter		
Investigations		
Obtaining results		
Pharmacy		
Left Hospital		
Arrived Home		

What investigations were done on this visit:

Blood tests: _____

Radiology: _____

Other: _____

OTHER STAFF TIME

<u>Position</u>	<u>Duration (mins)</u>
Dietician	
Social Worker	
Psychologist	
Other:	

3. MEDICATION

Please specify all medication that was prescribed at this visit.

<u>Medication</u>	<u>Dose</u>	<u>Duration</u>
Bactrim		

4. OUTCOME OF VISIT

What was the outcome of the visit? (Please tick relevant box)

- Routine Appointment made. Date: _____
- Other appointment made. Date: _____
- Child admitted. Ward: _____ Reason: _____
- Child discharged from the clinic

5. OVERALL CLINIC DATA :

- Number of children seen at the clinic that day: _____
- Number of staff at the clinic:
 - Doctors: _____ Professional nurses: _____
 - Enrolled nurses: _____ Therapists: _____
 - Lay counsellor: _____ Psychologist: _____
 - Other: _____

Time clinic started: _____ Time clinic ended: _____

INCONSISTENCIES

The Ethics certificate for this study (Appendix 1) was issued after the study commenced however, Ethics clearance certificate M01-05-03 covered the initiation period (Appendix 16).

At the time of this study national policy recommended HIV testing at 12-months of age. However, HIV DNA PCR testing had already been introduced at CWCH PMTCT follow-up clinic at 3 and 6 months of age therefore an HIV diagnosis was available earlier at CWCH viz. at 6-7 months of age (Appendix 2).

The percentage of infants with a positive HIV ELISA test at 12-months of age was 48% at the time that 90% of the study was complete and 45% (Publication 5) on study completion. This reflected the infants requiring further HIV tests after 12 months of age. The costing analysis was performed using 48% (Publication 6) instead of 45% however a sensitivity analysis performed at 35% did not change the findings of the costing study.

Appendix 9

Dear Gayle
Permission granted as requested - best wishes for the thesis!
Regards
JP

Prof JP van Niekerk
Deputy editor
Private Bag X1
Pinelands 7430, Cape Town
Tel: 021 530 6520
Fax: 021 531 4126
Cell: 083 269 8601
Email: jpvann@hmpg.co.za

-----Original Message-----

From: online@samedical.org [mailto:online@samedical.org]

Sent: 02 February 2006 07:14

To: JP Van Niekerk

Subject: Fw: Permission to include SAMJ publication in thesis for PhD purposes

Importance: High

Please could you advise regarding obtaining written permission to include the article detailed below, of which I am 1st author, in an unedited format in my PhD thesis entitled "Early diagnosis of HIV in infants in low resource settings" to be submitted to the University of the Witwatersrand for examination.

Sherman GG, Jones SA, Coovadia AH, Urban MF, BoltonKD. PMTCT from research to reality – results from a routine service. **S Afr Med J** 2004;94(4):289-292.

Thank you,

Gayle Sherman

Associate Professor: Dept of Molecular Medicine & Haematology
Johannesburg hospital
National Health Laboratory Service



September 4, 2006

Gayle Sherman

Associate Professor: Dept of Molecular Medicine & Haematology,
National Health Laboratory Service and University of the Witwatersrand
Johannesburg Hospital, Johannesburg, South Africa

VIA EMAIL TO: gayle.sherman@nhls.ac.za or gayle.sherman@telkomsa.net sent February 1, 2006

FEE: NONE

RE: Sherman GG, Stevens G, Stevens WS. Affordable diagnosis of human immunodeficiency virus infection in infants by p24 antigen detection. *Pediatr Infect Dis J* 2004;23(2):173-176.

Sherman GG, Jones SA. Oral fluid HIV tests: superior to serum in diagnosing HIV infection in young children. *Pediatr Infect Dis J* 2005;24(3):253-256.

Sherman GG, Stevens G, Jones SA, Horsfield P, Stevens WS. Dried blood spots improve access to HIV diagnosis and care for infants in low-resource settings. *J Acquir Immune Defic Syndr* 2005;38(5):615-617.

Sherman GG, Cooper PA, Coovadia AH, Puren AJ, Jones SA, Mokhachane M, Bolton KD. HIV-1 DNA polymerase chain reaction for diagnosis of HIV infection in infancy in low resource settings. *Pediatric Infect Dis J* 2005;24(11):993-997

USE: Thesis

CONDITION OF AGREEMENT

Permission is granted upon the return of this signed agreement to Lippincott Williams & Wilkins (LWW). Please sign and date this form and return to:

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Requestor accepts: _____ Date: _____

Appendix 11

Dear Gayle Sherman

Thank you for your email request. Permission is granted for you to use the material *below* for your thesis subject to the usual acknowledgements and on the understanding that you will reapply for permission if you wish to distribute or publish your thesis commercially.

Good luck!

Best Wishes
Zoë

Zoë Ellams (Miss)
Permissions Co-ordinator
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OX4 2DQ
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From: Gayle Sherman [mailto:gayle.sherman@nhls.ac.za]
Posted At: 01 February 2006 08:34
Posted To: 30th Jan - 3rd Feb
Conversation: Permission to reprint article in thesis for Doctorate (PhD)
Subject: Permission to reprint article in thesis for Doctorate (PhD)

Sherman GG, Matsebula TC, Jones SA.
Is early HIV testing of infants in poorly-resourced PMTCT programs unaffordable?
Tropical Medicine and International Health 2005;10(11):1108-1113.

I would like to request written permission to include the full, unedited version (pdf) of the abovementioned article, of which I am first author, in a thesis to be submitted for my Doctorate (PhD) at the University of the Witwatersrand, Johannesburg, South Africa



Boehringer Ingelheim (Pty) Ltd

To whom it may concern

Boehringer Ingelheim (Pty) Ltd

3 May, 2004

PMTCT from research to reality – results from a routine service

In September 2003 Boehringer Ingelheim South Africa received a request from the Medicines Control Council (MCC) asking for data to defend the registration of nevirapine in the indication of the prevention of mother-to-child transmission (pMTCT). The submission included data collected from two South African studies which assessed the implementation of a program that provided a single dose of nevirapine to an HIV infected mother, at the onset of labour, and her infant, within 72-hours of life. The two studies submitted to the MCC were the only studies which were found to address pMTCT with this particular regime (outside of the research sponsored by the pharmaceutical industry); and whose study had progressed to allow for an analysis of the transmission rates.

The study conducted by Drs Sherman, Jones, Coovadia et al was considered to be of significance in the submission to the MCC, since it illustrated that the use of nevirapine, during labour and post-delivery, decreased the transmission rate of HIV to the infants.

The submission, including the data collected from Dr Sherman's study, was sent to the MCC on 5 March 2004. Boehringer Ingelheim has received confirmation that the data is currently being reviewed.

Pauline Carr
Head of Operations (Medical Department)

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Directors
Paul B. Stewart*
(Managing Director)
B. Barras**
(Director)

The Star: Monday 8th December 2003

Mon 8th Dec 2003

New ray of hope for 1 000 Aids orphans

BY JILLIAN GREEN
Health and Science Reporter

One thousand Aids orphans in Johannesburg are to have access to HIV tests and anti-retrovirals.

The children, in the past denied testing and treatment because doctors could not obtain consent from a parent or legal guardian, can now receive treatment with the consent of their caregivers.

This was the decision by the Johannesburg High Court on Friday.

Liesl Gerntholtz of the Aids Law Project, the attorneys of record, said the court application was brought on behalf of Wits University's Paediatric HIV Working Group.

It requested permission from the high court to treat eight children who urgently needed anti-retroviral treatment and three who required HIV tests.

"They have also asked the court to allow them to get permission to treat other children directly from the persons responsible for the daily care of the children, even though the law presently does not allow them to do so."

Gerntholtz said the project would not be demanding a change to the Child Care Act just yet, but was looking at taking a less confrontational approach.

Currently the Act requires that before any medical treatment can be administered to a child under 14, permission must be obtained from the parent or a legal guardian.

If this were not possible, permission had to be sought from the Minister of Social Development or the high court.

However, the law did not anticipate that the Aids epidemic would leave large numbers of children without parents or legal guardians.

On Friday, the court granted permission to the working group to treat and test the 11 children as well as to treat "any child under 14 who does not have a parent or guardian or whose parent or legal guardian cannot be readily located".

Aids Law Project statistics show there are 7 000 Aids orphans in Johannesburg. About a quarter of them do not have legal guardians. They therefore were unable to access medical treatment.

The application was unopposed.

From: Vidette Allan [mailto:vidette.allan@inl.co.za]

Sent: 10 February 2006 16:03

To: Infant Dx

Subject: RE: Request for permission to use articles in Phd

Importance: High

The Editor has given permission for use of these articles, provided acknowledgement is made to The Star.

STANDARD OPERATING PROCEDURES FOR TAKING BLOOD FROM INFANTS FOR THE HIV DNA PCR TEST

There are two types of blood samples from which one can do a HIV DNA PCR test:

1. Dried blood spots (DBS)
2. Whole blood in an EDTA/purple top tube

Dry blood spots are technically easier to obtain, and are suitable for blood sampling in the primary health care setting.
Handle all specimens as if they are capable of transmitting infectious agents.

1. DRIED BLOOD SPOT COLLECTION AND STORAGE

Dried blood spots (DBS) can be collected from a heel-stick (or toe-stick or finger-stick) or venous blood and dried on a FDA approved paper (Schleicher & Schuell N°903 Guthrie Cards). The paper is preprinted with circles and space for labeling.

Materials Required:

- Powder-free gloves
- Disinfectant for skin
- Cotton wool or gauze
- Lancets
- Lancing device
- Guthrie Cards (Figure 1: correctly labeled)
- Drying rack
- Zip-lock plastic bags (biohazard bags)
- Desiccant sachets
- NHLS laboratory green request forms with bar-code (Figure 2: correctly labeled)

Method for collection (see Figures 7 - 11)

Label the Guthrie card with the patient's name, date of birth and clinic number, as well as the date that the sample was obtained. Use a ballpoint pen or other water-indelible marker directly on the paper. (Figure 1)

Complete the NHLS laboratory form and stick the bar-code from that form onto the corner of the Guthrie card (Figure 2).

Clean the selected area of skin (heel, toe or finger) with a skin disinfectant and allow to dry.

Position the foot or hand with the puncture-site downwards

Use the loaded lancing device to puncture the skin with sufficient force to allow the blood to flow.

Allow a drop of blood to form and then lightly touch the filter paper (Guthrie card) to the drop of blood and allow it to soak onto the marked circle on the filter paper.

Allow the next drop of blood to form, and allow it to soak onto the adjacent marked circle on the filter paper.

Repeat until the blood stops flowing or all marked circles are adequately filled with blood. The preprinted circles must hold between 50-100 μ L blood each when fully filled (Figure 3). Samples with insufficient blood cannot be processed (Figure 6). Fill at least two of the marked circles. If insufficient blood flow occurs, a second puncture may need to be made. Do not squeeze or “milk” the puncture site as this may dilute the blood with tissue fluid. Do not excessively saturate the card with blood. Do not touch or attempt to smear the blood spots. Apply gauze or cotton wool to the puncture site after obtaining sufficient blood. Dispose of the lancet into a sharps container.

Method for drying:

Place the Guthrie cards in a drying rack (e.g. S&S #903 Dry Rack) and dry horizontally (Figure 4). Place only one card per drying slot in the drying rack and do not allow the cards to touch each other.

Allow to dry for at least three hours. The blood spots should be a dark brown colour once properly dried.

Do not dry artificially with heat and do not expose to direct sunlight.

Method for storing/submission to laboratory:

After the blood spots have dried, place each card in a separate zip-lock plastic bag. Insert one desiccant sachet per bag (Figure 5).

Fold the corresponding, completed NHLS form in half and insert into the pocket of the plastic bag with the patient details facing outwards.

Ensure all information is provided on the NHLS form including:

Baby's date of birth

Contact details for the sister or doctor concerned

Clear description that this is the baby's sample if the mother's hospital number is used

(If for storage only, store individually packaged with desiccant sachet in a dry area at room temperature.)

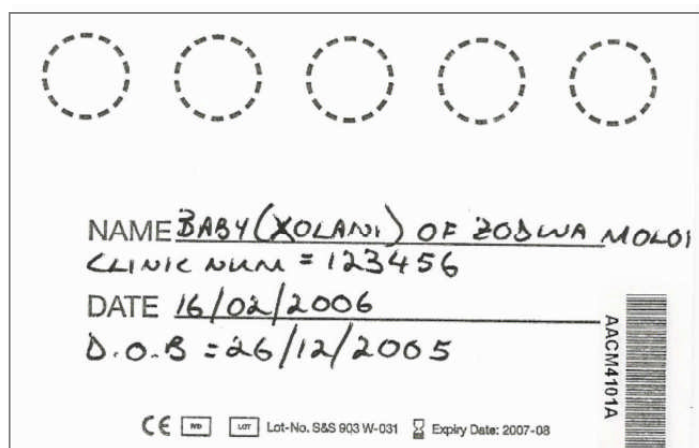



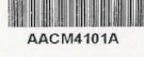

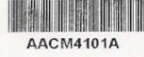


Figure 1. Guthrie card correctly labeled with bar-code

NATIONAL HEALTH LABORATORY SERVICE

P A T I E N T	IDENTITY NO.				A C C O U N T	NAME				
	HOSPITAL NO.	123456				ADDRESS				
	HOSP./CLINIC	ASIPHILISANE CLINIC				TEL. NO.	H			W
	WARD	PA5DS				CELL				
	SURNAME	MOLOI				EMPLOYER				
	FIRST NAMES	BABY (XOLANI) OF ZODWA				HEALTH CARE WORKER	SR TSHABALALA			
	ADDRESS					TEL. NO.	(011) xxx -xxxx	FAX		
	DATE OF BIRTH	26/12/05	GENDER	M		ETHNIC GROUP				
	SPECIMEN TYPE	D.B.S.				ICD CODE				
	DATE TAKEN	16/02/06	TIME TAKEN	H: M: S		HOSP CLASS				
MED. AID NAME				S E N D E R	ADDRESS					
MED. AID NO.					DEP CODE					
PRINCIPAL MEMBER					COPIES TO					
PROJECT A/C DETAILS	GAUTENG ZARV0003				ADDRESS					
Other funder (eg. NGO), Further name:					HEALTH DISTRICT					
					RESP. CODE					
CLINICAL INFORMATION										
COMPREHENSIVE CARE, TREATMENT AND MANAGEMENT PROGRAMME SPECIFIC TESTS										
<input type="checkbox"/> HIV EIA (ELISA) <input checked="" type="checkbox"/> HIV PCR <input type="checkbox"/> Differential <input type="checkbox"/> Cryptosporidium <input type="checkbox"/> TB Culture <input type="checkbox"/> HIV RAPID <input type="checkbox"/> ALT <input type="checkbox"/> Lactate (on ice) <input type="checkbox"/> Isospora belli <input type="checkbox"/> TB Sens <input type="checkbox"/> CD4 (PLG) <input type="checkbox"/> AST <input type="checkbox"/> Cholesterol <input type="checkbox"/> Hepatitis B sAg <input type="checkbox"/> VIRAL LOAD <input type="checkbox"/> FBC <input type="checkbox"/> Triglyceride <input type="checkbox"/> TB Direct (AFB)										
THE FOLLOWING DETAILS MUST BE COMPLETED										
ID Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					PLEASE NOTE					
Current HIV intervention <input checked="" type="checkbox"/> Patient on PMTCT programme <input type="checkbox"/> Patient has never been on antiretrovirals <input type="checkbox"/> Patient has been on antiretrovirals but is currently no longer on them <input type="checkbox"/> Patient is currently on the antiretrovirals marked alongside <input type="checkbox"/> Patient has attended a VCT centre for HIV testing <input type="checkbox"/> Patient is currently attending a CHC for CD4 staging <input type="checkbox"/> Patient is about to start ART					Current HIV treatment <input type="checkbox"/> 3TC <input type="checkbox"/> d4T <input type="checkbox"/> NVP <input type="checkbox"/> KLT (Kaletra) <input type="checkbox"/> ddi <input type="checkbox"/> AZT <input type="checkbox"/> EFV <input type="checkbox"/> SQV <input type="checkbox"/> ABC <input type="checkbox"/> RTV <input type="checkbox"/> TDF <input type="checkbox"/> INH <input type="checkbox"/> RIF <input checked="" type="checkbox"/> Cotrimoxazole <input type="checkbox"/> Other: _____ Please state: _____					
Has this patient been transferred in from another program, e.g. TBCP YES NO					Please note that only the tests listed above may be requested for the Comprehensive Care, Treatment and Management Programme. You need to also provide the correct project account (if applicable).  AACM4101A  APPLY BAR CODE LENGTHWISE DO NOT WRAP AROUND  AACM4101A  AACM4101A  AACM4101A  AACM4101A					
Months since first enrolling on ART at this facility irrespective of stops and restarts <input type="text"/>										

http://www.nhls.ac.za

Figure 2. NHLS requisition form correctly completed.

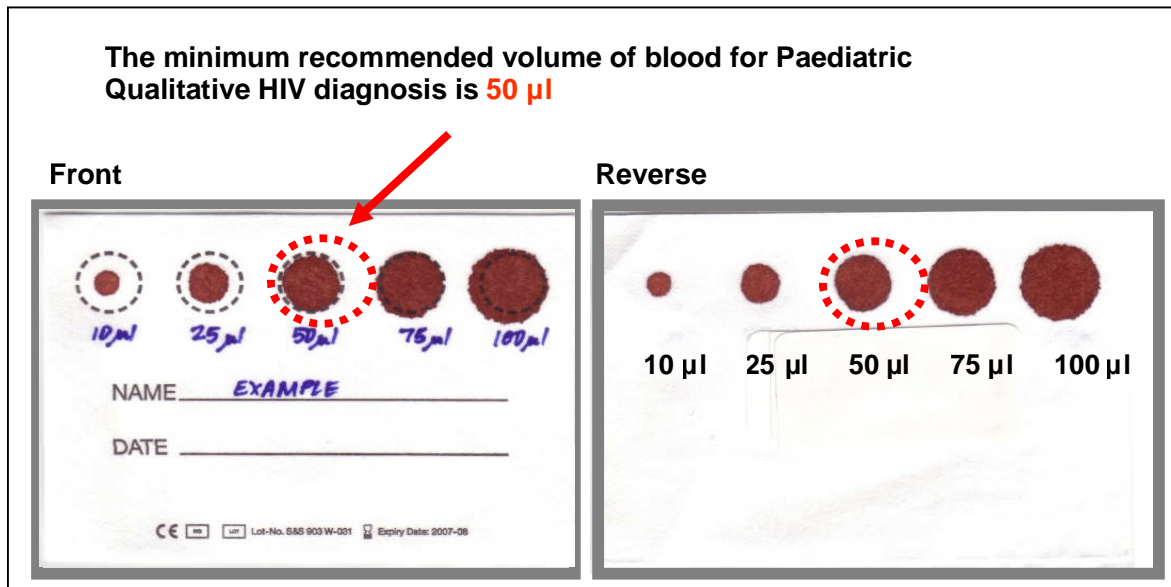


Figure 3. The **size** of the blood spot and the **penetration** of the spot through to the reverse side of the card allow for some assessment of the blood volume.

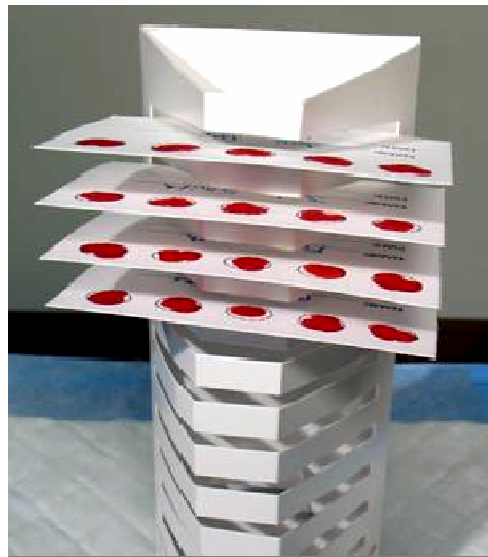


Figure 4. Dry completely before packing (blood turns dark red)

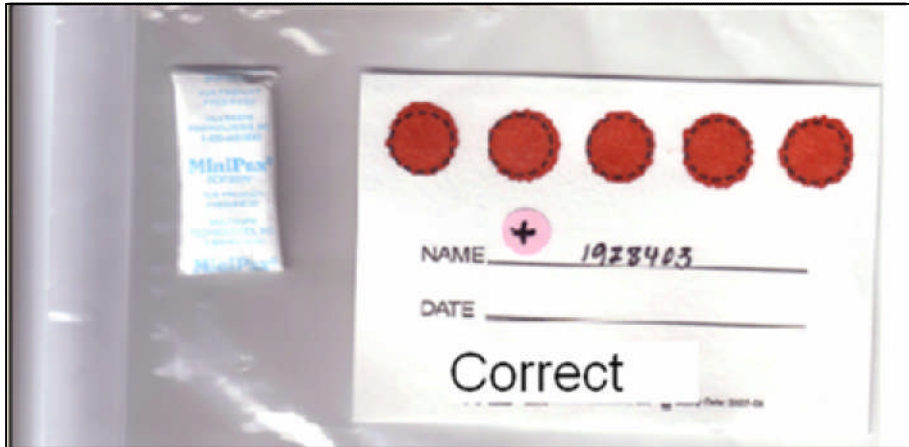


Figure 5. One Guthrie card and one desiccant sachet per biohazard bag.



Figure 6. Insufficient sample for processing – samples rejected



Figure 7. Correct holding position by mother and handling of heel



Figure 8. Allow large drop of blood to collect



Figure 9. Collect a minimum of two circles



Figure 10. Lateral view of correct grip for heelprick



Figure 11. Collection from toe-prick

2. WHOLE BLOOD COLLECTION

Materials Required:

EDTA tube
[BD microtainer with BD Microgard closure; 8mm diameter; BD catalogue no. 365975)
23 Gauge needles (blue)
Powder-free gloves
Disinfectant for skin
Cotton wool or gauze
Zip-lock plastic bags
NHLS laboratory request forms with bar-code (Figure 2)

Collect blood in an approved purple top (EDTA) microtainer by using one of the following methods:

1. Heel/Finger Prick Method

Clean the proposed puncture site and position as mentioned above.
Puncture heel or finger using the lancing device.
Allow drops of blood to collect and fall into the purple top microtainer. Do not squeeze as the blood will become diluted with tissue fluid.
Ideally there should be 500µl (microlitres) of blood (minimum volume of 250µl)
Place the lid on the microtainer and invert several times to prevent the formation of clots.
Complete the NHLS laboratory request form with all the patient's details.
Label the microtainer with the corresponding bar code from the completed NHLS laboratory request form.

2. 'Vein Drain' Method

Using a 23 Gauge (blue) needle, prick the baby on the dorsal vein of the hand. (usually overlying the 4th metacarpal)
Allow blood to drop out slowly out of the back of the needle into the purple top microtainer.
Ideally there should be 500µl (microlitres) of blood (minimum volume of 250µl)
Place the lid on the microtainer and invert several times to prevent the formation of clots.
Remember to maintain universal precautions as there is a greater risk of sustaining a needle-stick injury when using this method.
Complete the NHLS laboratory request form with all the patient's details.
Label the microtainer with the corresponding bar code from the completed NHLS laboratory request form.

3. Formal venesection

Blood can also be sampled into larger EDTA Vacutainer / purple top tubes.
Minimum volume of whole blood is 1ml to allow for dilution with EDTA in tube.

REFERENCES:

1. NHLS Dried Blood Spots Specimen Collection and Transport
2. WHO 2005 ART of HIV infection in infants and children in resource-limited settings (Draft Revision October 2005) – Diagnosis of HIV Infection
3. National Department of Health Khomanani Guidelines for the management of HIV infected children “HIV Testing Guidelines” 2005
4. “Dried Blood Spot Collection and Handling”. Botswana Department of Health and Human Services
5. “Laboratory Requirements For Dried Blood Spot Collection” CLS, National Health Laboratory Service (NHLS) and WITS Health Consortium (Pty) Ltd. 2004
6. “Coronation ARV Rollout Document”, December 2004. Wits Paediatrics HIV Working Group, University of the Witwatersrand.

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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)

Ref: R14/49 Coovadia

CLEARANCE CERTIFICATE

PROTOCOL NUMBER M01-05-03

PROJECT

Early Diagnosis of Human Immunodeficiency Virus Infection Status In Vertically Exposed Infants In A Low Resource Setting To Facilitate Better Management of Paediatric HIV Disease

INVESTIGATORS

Dr AS Coovadia

DEPARTMENT

School of Clinical Medicine, Coronation Hospital

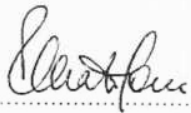
DATE CONSIDERED

01-05-04

DECISION OF THE COMMITTEE *

Approved Unconditionally

DATE 01-05-18

CHAIRMAN..........(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Prof KD Bolton

Dept of School of Clinical Medicine, Coronation Hospital