

## **CHAPTER 6: HIV TESTING PROTOCOL**

### **EXPLANATORY MEMORANDUM**

The attached HIV Testing Protocol forms part of the Code of Conduct of the Association and is therefore binding on all member offices. The Board of Directors may amend the HIV Testing Protocol from time to time, upon the recommendation of the Medical and Underwriting Standing Committee (MUSC). MUSC may however make technical changes to the Code and revise annexures 2 to 8 without referral to the Board of Directors.

The purpose of the HIV Testing Protocol is to ensure that the life industry follows the highest standards in all aspects of HIV screening of applicants for life insurance. This Code applies to all HIV tests performed by LOA member offices. It addresses issues such as identification, confidentiality, informed consent, pre- and post-test counselling, transmission of test results and accreditation of test kits and laboratories.

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**A) PREAMBLE & BACKGROUND**

The aims of the LOA Protocol remain as follows:

- a) The use of quality tests by accredited laboratories
- b) The elimination of false positive results
- c) The restriction of false negative results to an absolute minimum
- d) The strict identification of the person whose blood has been taken
- e) Maintenance of confidentiality of results
- f) That the insurance industry is only involved in **screening** for HIV in order to determine the insurability of an applicant
- g) To ensure that proper steps are taken to identify and treat appropriately participants in vaccine trials

**B) PRE-TEST PROCEDURES****1. HIV testing information sheet**

- 1.1 To ensure that each applicant receives a copy of the HIV testing information sheet (Annexure 2). This document must be attached to the pathology requisition form as a single document.
- 1.2 The wording of the **HIV testing information sheet** shall not be altered, except in consultation with the LOA Medical and Underwriting Standing Committee. This "LOA document" should be printed by member offices and distributed to appropriate doctors and laboratories. A specimen is attached to this protocol.
- 1.3 The questions on the **HIV testing information sheet** are the minimum required in terms of the HIV testing protocol.
- 1.4 Every life to be assured requiring an HIV test must be handed the **HIV testing information sheet** and advised that voluntary personal pre-test counselling (PPTC) is available in terms of this Protocol. Ideally the client should receive this sheet from the sales intermediary but, failing this, must be provided by the doctor or laboratory taking the blood specimen. Member offices must ensure that adequate supplies of this documentation are made available to doctors, laboratories and sales intermediaries.
- 1.5 In addition to providing each client with the LOA HIV Testing Information Sheet, each client must be made aware of the optional free telephonic pre-test counselling service. This is available in any of the official languages, from 07h00 – 19h00 on weekdays, at the following toll-free number 0800 562 562. The client must be informed that the following information will be required when the call centre is called:
  1. Full name
  2. Name of the insurance company
  3. Policy number or quotation number

**2. Flowchart (copy attached as Annexure 1)**

- 2.1 When an HIV test is requested, the sales intermediary should warn the client that an original identity document will be required when the blood specimen is taken, and that he will be requested to supply the name of a nominated doctor or medical clinic.
- 2.2 The following identity documents are acceptable in terms of this Protocol:
  - 2.2.1 Valid original South African identity documents and passports, issued by the Department of Home Affairs and card-type driver's licenses issued by the Department of Transport;

- 2.3 The LOA recommends that temporary documents not be accepted, but should be dealt with at the discretion of each office.
- 2.4 Foreign passports are not allowed, except where approval is given in a specific case by the Chief Medical Officer or Chief Underwriter or his/her designate. Member offices are urged to take care in cases where it is not possible to verify the validity of such passports with the relevant consulate.
- 2.5 Identity documents and passports issued by the former 'TBVC/'"homeland" states are not acceptable in terms of this Protocol.
- 2.6 Photocopies or faxed copies of identity documents are not acceptable, regardless of whether such documents are certified or not.
- 2.7 Where the HIV test is to be performed on a minor\*\*, the consent of the legal guardian will be required. In cases where the minor is unable to obtain an identity document (as required in 2.2 above) because of his age, the identity document of the legal guardian (who consents to the HIV test) will be required.
- 2.8 Where there is a discrepancy between the name on an identity document and the name on the pathology request form (such as where the client now uses a married name but his/her identity book has not been reissued) and the client is identifiable as the applicant in issue, this discrepancy has to be noted on the form and reported to the life office together with the test result.

Notes:

- \*\* A minor is a person below the age of 12 years in terms of the Children's Act, for purposes of signing informed consent for HIV Testing.

**C) VENESECTION (blood collection)**

1. One tube of clotted blood must be collected from all applicants for purposes of testing for HIV by the methodologies as described later.
2. It is important that one tube of EDTA (purple capped tube) blood be collected only from applicants who are/have been participants in a vaccine trial. This EDTA sample is required for a Polymerase Chain Reaction Test (PCR) in cases where the Elisa Immuno-Assay test is reactive.

Substitutions for insurance HIV tests have reached alarming proportions in South Africa. In order to restrict the possibility of substitution and sample swapping, the LOA **strongly recommends** that venesections only be performed by a Medical Officer of the insurance company concerned or the staff of the laboratory performing the tests.

3. In terms of this Protocol, blood specimens may be taken by any of the following:
  - 3.1 Any medical practitioner registered with the Health Professionals Council of SA (HPCSA). However, medical practitioners with limited registration are not allowed to do venesections in terms of the Protocol.
  - 3.2 Any registered individual entitled to perform venesections by the HPCSA or SA Nursing Council, registered medical practitioner or accredited pathology laboratory.
4. House (office, factory etc.) calls for taking blood:

In terms of this Protocol, the following options exist:

- The service may be delivered by medical practitioners as in paragraph 3.1 above, or registered persons entitled to perform venesections as in 3.2 above.
- Persons who are in the salaried employment of the Life Office and also qualified in terms of paragraph 3 above.
- Third party providers, i.e. registered persons entitled to perform venesections, who have an independent contract or relationship with each specific company. It is the responsibility of the company to manage the risks associated with this service.

**D) AT THE LABORATORY****1. Accreditation**

All private laboratories must be accredited by the Life Offices' Association Laboratory Accreditation Committee (LOASPA) to perform HIV tests in terms of the HIV Testing Protocol. Any decisions in regard to accreditation shall be made on the basis of the accreditation guidelines set by the LOASPA from time to time, as available on the LOA Website at: <http://www.loa.co.za/downloads/LOALAC260100.pdf>.

All applications for accreditation should be directed to the LOA office.

A list of accredited pathology laboratories is annexed as annexure 9 and updates are also posted to the LOA Website at <http://www.loa.co.za>.

**Different types of HIV tests kits used are also accredited by the LOA.  
Laboratories may not use other tests not listed in paragraph 3.1 for insurance HIV testing.**

**2. Pre-test procedures**

- 2.1 Blood specimens must be collected by the laboratory staff and transported to the laboratory by means of the official channel of collection and transportation used by the laboratory.
- 2.2 If no documentation is received with the blood specimen by the laboratory, the laboratory shall refuse to perform the HIV test.
- 2.3 If the blood specimen and documentation are received from any source other than those detailed in section C of the Protocol, the laboratory shall refuse to conduct the HIV test and discard the blood specimen.
- 2.4 If the laboratory does the HIV test in the absence of the required documentation, the member office shall ignore the result and no fee will be payable. A further test will be required, conducted in terms of the Protocol.
- 2.5 Pathology laboratories will batch the HIV testing information sheets and send these to the Head Offices of the insurers concerned. If this arrangement is not satisfactory, the insurer must notify the pathology laboratory of any alternative arrangement desired by the insurer.

**3. Methodology**

An LOA accredited laboratory may follow one of two approved HIV testing protocols for insurance HIV screening:

- 3.1 The 3-Elisa Protocol
- 3.2 The 4<sup>th</sup> Generation Combi Protocol

3.1 The 3-Elisa Protocol

This protocol is based on the WHO recommended strategy for use as a screening procedure. All blood samples are screened with an Elisa immuno-assay approved by the LOASPA committee. Non-reactive results are reported as such, and all reactive results are followed up with a second and third Elisa test from a different manufacturer. All Elisa tests used must be from the LOASPA approved list below.

The first Elisa screening test analysis system should identify a specimen by its bar code and must test the sample using the primary tube. All pipetting procedures should be fully automated for the first Elisa screening test. Fully automated pre-analytical systems need to be approved by the LOA if primary tube sampling is not utilized (e.g. aliquoted samples). The following system has been approved for this use:

- Roche Modular Pre-analytical instrument, and Roche Modular P-analyzers for biochemistry and E-analyzers for Immunochemistry.

Primary tube sampling and automated test procedures are recommended, but not mandatory, for the second and third Elisa screening test.

All Elisa tests must use a highly sensitive method based on recombinant antigens. The inclusion of sub-type O is mandatory. The following test kits contain a recombinant antigen to HIV-1/2 and may be used for Elisa screening tests **in the 3-Elisa Protocol**:

- Access HIV 1/2 New (Sanofi)
- AxSYM (Abbott)
- Bayer Advia Centaur HIV 1/2/0 Assay
- Enzygnost
- Murex
- Vitros ECI HIV 1+2 (Clinical Diagnostics)
- Vironostika
- Vironostika HIV Uniform II Plus O (Omnimed)

No Insurance Company will compensate the costs of any further form of testing e.g. Western Blot or PCR, without the permission of the insurance company concerned.

### 3.2 The 4<sup>th</sup> Generation Combi Protocol

This protocol uses one of the LOASPA approved 4<sup>th</sup> Generation Combination HIV tests (Combi test) as a first screening test.

The first Combi screening test analysis system should identify a specimen by its bar code and must test the sample using the primary tube. All pipetting procedures should be fully automated for the first Combi screening test. Fully automated pre-analytical systems need to be approved by the LOA if primary tube sampling is not utilized (e.g. aliquoted samples). The following system has been approved for this use:

- Roche Modular Pre-analytical instrument, and Roche Modular P-analyzers for biochemistry and E-analyzers for Immunochemistry.

Primary tube sampling and automated test procedures are recommended, but not mandatory, for the second and third tests. The Combi test tests for the HIV antibodies (antibody component), and the virus itself (antigen component).

A non-reactive Combi test result is reported as such and no follow-up test is done. Any low-reactive or reactive result will be re-tested with a 3<sup>rd</sup> generation Elisa HIV assay to re-test the antibody component. If this does not confirm the results of the first test, it will be followed with a P-24 antigen test to re-test the antigen component. Any low-reactive 3<sup>rd</sup> generation test will also be followed with a P-24 antigen test. All second and third line follow-up tests will be from a different manufacturer than that of the first Combi test.

Low-reactive values for all LOASPA approved 3<sup>rd</sup> generation ELISA tests as well as 4<sup>th</sup> generation Combi tests, will be defined from time to time by mutual agreement between the NPG and MUSC. Reactive results below these cut-off levels will be reported as low-reactive.

A flow-diagram (Annexure 1) is attached to illustrate this graphically.

The following test kits may be used for the first line 4<sup>th</sup> Generation Combi Protocol:

- Abbott AxSYM Combo
- Abbott Architect Combo
- Roche Elecsys HIV Combo
- Vidas HIV Duo (HIV6) (Seperation Scientific)

Low-reactive values on the Combo tests will be reported according to the following table:

Test	Supplier	Reference range	“Low Reactive value”
1.1 Elecsys HIV Combi	Roche	< 0.90 = Non-reactive 0.90 – 1.1 = Greyzone > 1.1 = Reactive	0,9-10
1.2 Architect Combo	Abbott	< 1.00 = Non-reactive ≥ 1.00 = Reactive	1-10
1.3 Axsym Combo	Abbott	< 0.90 = Non-Reactive 0.90 – 0.99 = Greyzone ≥ 1.00 = Reactive	0,9-10
1.4 Vidas HIV Duo (HIV6)	Omnimed	< 0.25 = Negative ≥ 0.25 - < 0.35 = Borderline ≥ 0.35 = Positive	0.25-3.0

Second line follow-up tests with a 3<sup>rd</sup> generation Elisa test (refer flow diagram Annexure 3) for all first line Combi test that test reactive or low-reactive, may only be done with the following approved Elisa tests:

- Bayer Advia Centaur HIV 1/2/0 Assay
- Abbott Axsym
- Sanofi Beckman Access HIV 1/2 new
- Omnimed Vironostika HIV Uniform II Plus 0
- Vitros EciHIV 1 & 2 (Scientific Group)
- Enzygnost

As low-reactive values are only available for the above list of Elisa tests, they will be the only 3<sup>rd</sup> generation Elisa tests allowed for follow-up tests in the 4<sup>th</sup> Generation Combi protocol.

Low-reactive results for the Elisa tests will be reported according to the following table:

Test	Supplier	Reference range	“Low Reactive value”
2.1 Advia Centaur HIV 1/2/0 Assay	Bayer	< 1.00= Non-reactive > 1.00 = Reactive	1-10
2.2 Axsym	ABBOTT	< 1.00= Non-reactive > 1.00 = Reactive	1-10
2.3 Access HIV 1/2 New	Sanofi Beckman	< 0.90 = Non-Reactive 0.90-0.99 Equivocal > 1.00 = Reactive	0.9-10
2.4 Vironostika HIV Uniform II Plus 0	Omnimed	ELISA method – plate cut-off	Labs to determine own low cut-off values

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2.5 Vitros Eci HIV 1 + 2	Scientific Group	<0.90 = Non-reactive 0.90-1.00 =Borderline >1.00 = Reactive	0.9-15
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Equivocal results cannot (are not) accommodated in the LOA Protocol.

4. **HIV vaccine trial participants**

Where a client has indicated that he/she is/was a participant in an HIV vaccine trial, and his/her unique trial identity number has been supplied, the laboratory should do a PCR test on any case yielding a reactive Elisa result, irrespective of whether one, two or three results are reactive. An EDTA sample of blood would have been provided for this purpose in these cases.

**E) REPORTING RESULTS****1. Format of results:****1.1 The 3-Elisa Protocol**

The results from the 3 Elisa immuno-assays used in this protocol will be described as either non-reactive or reactive. The result field should refer to which test kit was used, e.g. Abbott AxSYM, Access etc.

In addition, the following **descriptors** should follow the results:

- HIV Elisa non-reactive  
No descriptor
- HIV Elisa reactive  
“This is a screening test. Because of the possible implications of this result, a further specimen should be sent to confirm both the identity of the client and reactivity of the specimen”.
- HIV Elisa discordant, i.e. one or more reactive and rest non-reactive.

“This is a screening test. According to the World Health Organization these results represent a discordant result. It is recommended that a further specimen be submitted after a minimum period of 3 weeks.”

**1.2 The 4<sup>th</sup> Generation Combi Protocol**

The results of the first line 4<sup>th</sup> Generation HIV Combi test, as well as the second line 3<sup>rd</sup> Generation Elisa test, will be reported as either non-reactive, low reactive or reactive. The P-24 antigen test will be either non-reactive or reactive. The cut-off values for a low-reactive result will be decided upon from time to time jointly by the LOA and the NPG technical committee.

In addition, the result field should show which assay was used, e.g. Roche Elecsys Combi, Abbott AxSYM 3<sup>rd</sup> generation etc.

The following **descriptors** should follow the results:

- First 4<sup>th</sup> Generation Combi: non-reactive  
No descriptor
- First 4<sup>th</sup> Generation Combi: reactive

These cases will be followed up with a 3<sup>rd</sup> generation Elisa test, and if this is not a reactive result (i.e. either non-reactive or low reactive) also with a P-24 test. The descriptors for the permutations of different second- and third line test results following a reactive first 4<sup>th</sup> Generation Combi test, are described in Tables I and II. TABLE I : RESULT

**TABLE I : RESULT DESCRIPTORS**

		<b>COMBI REACTIVE</b>		
		<b>3<sup>rd</sup> Generation Elisa</b>		
		<u>Non-reactive</u>	<b>Low-Reactive</b>	<b>Reactive</b>
P-24	Reactive	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Because of the possible implications of this result, a further specimen should be sent to confirm both the identity of the client and reactivity of the specimen.”
	Non-Reactive	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”

**TABLE II : RESULT DESCRIPTORS**

		<b>COMBI LOW-REACTIVE</b>		
		<b>3<sup>rd</sup> Generation Elisa</b>		
		<u>Non-reactive</u>	<b>Low-Reactive</b>	<b>Reactive</b>
P-24	Reactive	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Because of the possible implications of this result, a further specimen should be sent to confirm both the identity of the client and reactivity of the specimen.”
	Non-Reactive	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”	“This is a screening test. Due to the discrepancy in test results, it is recommended that a further specimen be submitted after a minimum period of 10 days.”

### 1.3 Qualitative PCR results:

*This should be reported as either a positive or negative result.*

2. **Reporting results from laboratory to insurer:**

2.1 **Electronic Mail and EDI**

Member offices are responsible for ensuring confidentiality in their offices.

The preferred method for result reporting should be via EDI.

Non-reactive results will be advised to the head office of the life office concerned. The CMO or chief underwriter may arrange for local result communication to the nearest underwriting office, provided that he is satisfied that suitable arrangements are in place to ensure the confidentiality of this information. These arrangements can be decided directly between the CMO or chief underwriter and the laboratory concerned.

2.2 **Breach of Confidentiality**

Any breach of the confidentiality rules must be reported to the LOA and will then be pursued by the LOASPA.

It must be emphasised that under no circumstances is any HIV test result ever to be communicated to any sales intermediary or other unauthorised person. Any attempt by a sales intermediary to obtain such information will lead to disciplinary action.

**F) POST-TEST PROCEDURES AT THE LIFE OFFICE****Handling of results, communicating with the client and post-test counselling:****1. 3-Elisa Protocol**

If the HIV test is reported as **non-reactive**, it is accepted that the person is insurable as far as HIV is concerned and further underwriting may proceed.

1.2 In cases where the first test is **reactive** but both the second and third tests are **non-reactive** (+--), the result should be viewed as **reactive but insurable**. Such results are not notifiable on the Life Register. No letter is sent to the client. Although not compulsory in terms of this Protocol, it is strongly recommended that the letter set out in Annexure 3 is sent to the nominated doctor as well as a copy of the document set out in Annexure 6.

1.3 If the HIV test is reported as **reactive** (+++) and in cases where the results are discordant (++- or +-+) the result should be seen as **reactive and uninsurable**. The following procedure will then be followed:

- a) The case is declined.
- b) The necessary entry is made on the LOA Life Register.
- c) The client is informed that the medical evidence has been submitted to his nominated doctor (letter - Annexure 4). A copy of the laboratory report, clearly marked "Private and Confidential", is sent to the nominated doctor (letter set out in Annexure 5 as well as a copy of Annexure 6).
- d) The company concerned will pay for one counselling session at the LOA rate.
- e) Any further tests that may be undertaken will be at the client's own expense.

1.4 Interpretation of PCR test results in clients who participate in an HIV vaccination research project should be as follows:

1.4.1 The combination of any number of reactive (positive) HIV Elisa Tests with a negative PCR test, indicates that

- The Elisa test result(s) is reactive (positive) due to the vaccine
- The client has not been infected by the HIV virus
- The client is therefore insurable.

No correspondence in these cases is necessary with the client or his/her nominated doctor.

- 1.4.2 If the PCR test is positive (reactive), indications are that the client has been naturally infected with the HIV virus, in addition to receiving the vaccine.

These applicants are not insurable for conventional risk products.

The following procedure will then be followed:

- a) The case is declined.
- b) The necessary entry is made on the LOA Life Register.
- c) The client is informed that the medical evidence has been submitted to his nominated doctor (letter – Annexure 4)
- d) A copy of the laboratory report, clearly marked “Private and Confidential”, is sent to the nominated doctor (letter set out in Annexure 7).
- e) The company concerned will pay for one counselling session at the LOA rate.
- f) Any further tests that may be undertaken will be set at the client’s own expense.

## 2. **4<sup>th</sup> Generation Combi Protocol**

Tables III and IV summarise the interpretation of the results, recommended underwriting decisions, the necessary LOA register entries, as well as the format of letters to be sent to the nominated doctor and the client:

**TABLE III: 4<sup>th</sup> GENERATION COMBI TEST PROTOCOL: RESULT INTERPRETATION AND UNDERWRITING RECOMMENDATIONS**

		COMBI REACTIVE			
		3 <sup>rd</sup> Generation Elisa			
		<u>Non-reactive</u>	<b>Low-Reactive</b>	<b>Reactive</b>	
P-24	Reactive	- Possible sero-converter	- Likely sero- converter	- No P-24 done	<b>Interpretation</b>
		- Reactive	- Reactive	- Reactive	<b>Result</b>
		- Decline	- Decline	- Decline	<b>U/W decision</b>
		- LOA entry added	- LOA entry added	- No P-24 done - LOA entry added	<b>LOA register entry</b>
		- Annexure 6 & 7	- Annexure 6 & 7	- Annexure 6 & 7	<b>Letter to doctor</b>
		- Annexure 5	- Annexure 5	- Annexure 5	<b>Letter to client</b>
	Non-Reactive	- False reactive	- Reactive with low ab titres (beyond antigen phase)	- No P-24 done	<b>Interpretation</b>
		- False reactive	- Reactive	- Reactive	<b>Result</b>
		- Insure	- Decline	- Decline	<b>U/W decision</b>
		- No entry	- LOA entry added	- No P-24 done - LOA entry added	<b>LOA register entry</b>
		- Annexure 4 & 7	- Annexure 6 & 7	- Annexure 6 & 7	<b>Letter to doctor</b>
		- No letter to client Policy issued	- Annexure 5	- Annexure 5	<b>Letter to client</b>

**TABLE IV: 4<sup>th</sup> GENERATION COMBI TEST PROTOCOL: RESULT INTERPRETATION AND UNDERWRITING RECOMMENDATIONS**

		<b>COMBI LOW-REACTIVE</b>			
		<b>3<sup>rd</sup> Generation Elisa</b>			
		<u>Non-reactive</u>	<b>Low-Reactive</b>	<b>Reactive</b>	
P-24	Reactive	- Possible false reactive - Probable seroconverter	- Reactive	- Reactive	<b>Interpretation</b>
		- Discordant	- Reactive	- Reactive	<b>Result</b>
		- Insure	- Decline	- Decline	<b>U/W decision</b>
		No entry	LOA entry added	LOA entry added	<b>LOA register entry</b>
		Annexure 4 & 7	Annexure 6 & 7	Annexure 6 & 7	<b>Letter to doctor</b>
		No letter	Annexure 5	Annexure 5	<b>Letter to client</b>
	Non-Reactive	- False reactive	- Probable false reactive	- Probable reactive	<b>Interpretation</b>
		- Discordant	- Discordant	- Reactive	<b>Result</b>
		- Insure	- Insure	- Decline	<b>U/W decision</b>
		No entry	No entry	LOA entry added	<b>LOA register entry</b>
		Annexure 4 & 7	Annexure 4 & 7	Annexure 6 & 7	<b>Letter to doctor</b>
		No letter to client Policy issued	No letter to client Policy issued	Annexure 5	<b>Letter to client</b>

**G) GENERAL**

1. The HIV Testing Protocol will be continuously monitored and updated by the LOA MUSC, after consultation with the appropriate medical experts.
2. Member offices which do not have a Chief Medical Officer (“CMO”) may appoint one Senior Underwriter, who should be the Chief or most Senior Underwriter in the company, to receive HIV reactive results. This responsible position shall not be delegated to junior officials. Those member offices who do not have a medical officer or medical consultant should consider the part time employment of an appropriate medical expert to assist in dealing with HIV-related decisions and communications.
3. Member offices operating in territories outside of South Africa's borders may use this protocol to set up similar arrangements with laboratories in these neighbouring territories.
4. Laboratories may only supply intermediaries with the following information about the sample taken for testing purposes:
  - whether the client has presented himself for a sample to be taken
  - the date the sample was collected

Laboratories may **not** supply intermediaries with any other information about the sample taken for testing purposes, including the laboratory reference number given to the sample.

5. Laboratories may also supply the underwriting departments and the medical divisions of life offices with the above information (as well as the laboratory reference number), but then only if they have been authorised in writing by the Chief Underwriter and/or CMO to provide the information to specified officials at the life office concerned.
6. Exclusion clauses
  - No member office may use HIV/AIDS exclusion clauses for new business, with effect from 1 January 2005. This provision applies to all types of business including group life, credit life business and assistance business but does not apply to exclusion clauses on existing business (in force prior to 1 January 2005). A guideline has been drafted to assist member offices in dealing with existing HIV/AIDS exclusion clauses (see Annexure 10). The guideline is not compulsory but it is recommended that member offices use it as best practice.
  - HIV/AIDS specific waiting periods may not be used by member offices for new business, with effect from 1 June 2006.
  - The LOA board agreed on 28 February 2007 that the LOA should issue a best practice (i.e. non-binding) LOA guideline indicating that the LOA recommends that member offices should waive the application of HIV/AIDS exclusion clauses in respect of all claims submitted from 1 April 2007.

*Please note that;*

- This best practice guideline applies to all types of business including group life, credit life business and assistance business. However, it only applies to lump-sum life and disability business, and not to income replacement or any other “living benefits”.
- This best practice guideline does not apply to policies requiring retesting.
- This best practice guideline is not intended to impact in any way on normal claims practices regarding material non-disclosure, and all information requested at application stage (including HIV related information) must still be disclosed.

7. MUSC recommends 6 weeks as an appropriate period for validity of any HIV test result, but offices are left with the discretion to extend this period.

8. Vaccine Trials

A person who has received an Aids vaccine may also develop antibodies in response to this vaccine. Trials to test the efficacy of those vaccines are being run by SAAVI (SA AIDS Vaccine Initiative), supported by Government. It is expected that approximately 50% of healthy individuals who will receive the vaccine, will develop sufficient antibodies to render the Elisa HIV test positive (reactive). The implications of this are that:

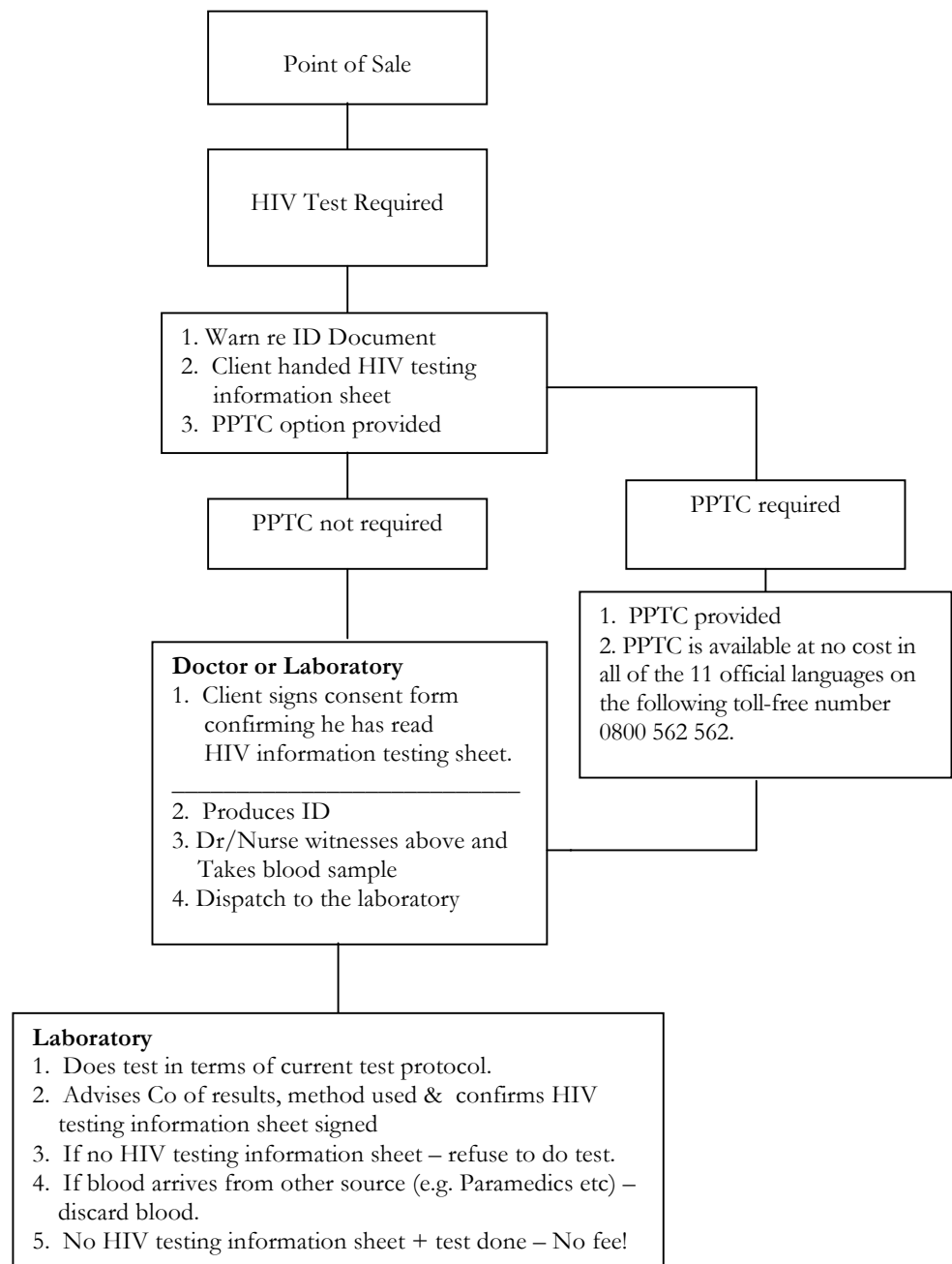
- The person has not contracted AIDS/HIV
- The test is actually false positive (reactive) due to the vaccine
- The person is insurable at standard rates, as far as HIV risk is concerned, if a pre-existing natural infection can be excluded.

As a person who has participated in a vaccine trial can apply for insurance many years after having received the vaccine, it is theoretically possible that he/she may have become infected with the HIV virus after having received the vaccine. A reactive HIV Elisa test will not be able to distinguish between these possibilities.

Additional steps have been introduced into the Protocol to distinguish between reactive Elisa results due to natural infection or due to having received an AIDS vaccine. Refer to Paragraph 4 under section F in this regard.

**ANNEXURE 1**

**FLOWCHART**



**ANNEXURE 2****LOA HIV TESTING INFORMATION SHEET**

**IF YOU HAVE ANY PROBLEM UNDERSTANDING THIS DOCUMENT, ASK  
THE NURSE OR LABORATORY ASSISTANT OR DOCTOR  
TO EXPLAIN IT TO YOU**

**WHAT ARE MY RIGHTS?**

You have the following rights:

1. *Not to be tested* for the AIDS virus without your free and informed consent.
2. *To be given all relevant information on the harms, risks and benefits* of taking, or not taking, the AIDS test.
3. *To refuse to take the test.* If you do this, your application for insurance may be denied.

You may however wish to consider other alternatives such as special life products offered by some companies, endowment or other pure financial products. Consult your financial advisor.

4. *To receive pre-test counselling* which is private and confidential, and which will inform you more about the test and its implications before you give consent. Should you in any way be unfamiliar with the issues involved, you are strongly advised to seek pre-test counselling. Confidential counselling in your home language is available at no cost from 7 am to 7 pm weekdays on a toll-free call centre line at 0800 562 562. You are also within your rights to waive the personal pre-test counselling.
5. *To have your test result treated confidentially.* An abnormal test result will be made available to your doctor and this test result will also be stored on the Life Offices' Association's central database in an encoded form. This information can only be accessed by other insurance companies with your consent. You also have the right to access this information to check that it is correct.
6. *To post-test counselling if the test is positive,* at the expense of ABC.

**WHY DO LIFE INSURANCE COMPANIES TEST FOR THE AIDS VIRUS?**

Underwriting is the basis of assurance to ensure that each applicant pays a premium appropriate to the risk. The insurance company requires information from the applicant to help it assess the

risk of granting the insurance and to establish an appropriate premium. Insurance companies screen applicants for serious diseases or habits that may affect their state of health. This may be done through questionnaires, medical examinations and other tests including a test for the AIDS virus.

### **IS THE TEST ALWAYS CORRECT? CAN THERE BE MISTAKES?**

Even though the tests are very accurate, and are performed by registered laboratories they must be regarded as screening tests only and not diagnostic. If your test result shows that you may be infected with the AIDS virus, you can have this confirmed by having further tests done.

As with any biological test, a false positive result may occur in a small number of cases, i.e. the test shows positive when the person is not infected with the virus. This is not the fault of the laboratory or the insurance company, but the true HIV status of the person can be ascertained by doing further tests. The insurance companies and laboratories follow a strict protocol to eliminate potential mistakes. In order to minimize false positive results second and/or third line tests are performed on all first-line positive results.

### **WHAT DOES IT MEAN IF THE TEST IS NEGATIVE?**

If your test result is negative, it means that you are not currently infected, but it does not mean that you may not become infected in the future. There is a period of one to six weeks after the infection before an HIV test will be positive.

Your risk of becoming infected is increased if you have more than one sexual partner or if you engage in unprotected sex. It is also important to get prompt treatment for other sexually transmitted diseases, e.g. syphilis and gonorrhoea that make you more susceptible to the AIDS virus.

### **WHAT DOES IT MEAN IF THE TEST IS POSITIVE?**

If your test result is positive, it means that you may be infected with the AIDS virus and your application for insurance will be declined. All existing cover will remain valid unless periodical retesting for the AIDS virus is required. As from 1 January 2005 insurance companies may no longer have AIDS exclusion clauses on new business. Some insurance policies that were taken out before 1 January 2005 may have an AIDS exclusion clause. This means that if you develop any AIDS related illness, a claim will not be paid.

Existing policies that do not have an AIDS exclusion clause will not be invalidated as a result of the test results being positive. The implications of a positive test should be discussed with your doctor. It is shown that there was a false positive result, the company will reconsider a further application for insurance.

## NOTIFICATION OF RESULTS

### **If your test result is negative:**

Cover will be granted if all other requirements have been met.

### **If your test is positive:**

A trained person should discuss the information with you so that you can understand clearly what the test result means.

Consequently it is of the utmost importance that you think carefully about the doctor who should receive the results. You will be advised to contact this doctor.

Please note that if you receive a letter to contact the nominated doctor, that this does not automatically mean that the AIDS test result is positive, as many other medical impairments may lead to the refusal of the insurance application. The doctor will be fully informed and will inform you accordingly.

*FOR ANY FURTHER ASSISTANCE ON THIS MATTER, CALL THE AIDS HELP LINE: 0800-012-322.*

The HIV testing information sheet is also available in the other 10 official languages. Click on the links below to download:

- [Afrikaans](#)
- [Zulu](#)
- [Xhosa](#)
- [Ndebele](#)
- [Venda](#)
- [Swati](#)
- [Sesotho](#)
- [Sepedi](#)
- [Tsonga](#)
- [Tswana](#)

**The Pathologist**

Policy no. : \_\_\_\_\_  
 Surname and full first names : \_\_\_\_\_  
 Date of birth : \_\_\_\_\_  
 Address : \_\_\_\_\_  
 Marketer : \_\_\_\_\_ Marketer's code : \_\_\_\_\_  
 Life office : \_\_\_\_\_ Tel.no. : \_\_\_\_\_

Dear Doctor

Thank you very much for your willingness to do the necessary test(s) I.r.o. the above-mentioned client.

To consider our client's proposal for assurance, we require the test(s) as indicated.

	Item no.	
<b>Urine</b>	5101	Chemical and microscopic urinalysis
<b>Blood</b>	5224	Fasting blood sugar estimate
	5201	Glucose tolerance test after 12-hour fast with fasting, one-hour and two-hour values and indication of type of test used
	5210	HbA1c
<b>Haematology</b>	5202	Full blood count (FBC)
	5225	FBC, platelets and ESR
	5226	Mean Corpuscular Volume (MCV)
<b>Serum lipids</b>	5204	Serum total cholesterol
	5205	Triglycerides
	5217	High-density lipoprotein estimate (HDL)
<b>Liver function tests</b>	5212	Bilirubin total
	5218	Alkaline phosphatase
	5219	ALT
	5219	AST
	5219	Gamma GT
<b>Renal function</b>	5213	Serum urea
	5220	Serum Creatinine
<b>Aids</b>	5221	HIV antibody test
<b>Serology</b>	5230	TPHA haemagglutination test
	5231	Cotinine test
	5232	HIV antibody test + Cotinine test

In accordance with the provisions of the LOA HIV Testing Protocol no samples may be processed without documentary proof that;

- In the case of an HIV test, the client has received the pre-testing information (included in this form), and
- A photographic identity check has been carried out by the person taking the blood and/or urine sample.

If the above-mentioned prescriptions are not complied with, Life Company A reserves the right to withhold payment for the service.

Please note that the proposer/life assured has authorised us to obtain this information from you (and has requested you to provide us with this information) and to share it with other life offices directly or through the LOA for purposes of underwriting and/or claims assessment.

In terms of the LOA protocol the proposer/life assured may enquire about information held by the LOA and such information will be made available to him/her by his/her nominated medical practitioner.

Yours faithfully  
 Chief Medical Adviser / Chief Underwriter

29 August 2006

6.25

**TO BE COMPLETED BY APPLICANT**

**Note:** As from 1 July 2008 PPTC is available to applicants at no cost in any of the 11 official languages on the following toll free number – 0800 562 562 or at designated pathology laboratories as mentioned on the LOA website – <http://www.loa.co.za>.

A. Do you require personal pre-test counselling for HIV testing?  Y  N

B. EVALUATION OF PERSONAL HIV COUNSELLING

To be completed only by applicants after having undergone a personal counselling session on HIV testing.

1. Details of counselling session:

Date : \_\_\_\_\_ Duration : \_\_\_\_\_ mins.

Name of Counsellor : \_\_\_\_\_

Name of Applicant (optional): \_\_\_\_\_

2. Did you understand what you were told?  Y  N

3. Were you given the opportunity to ask questions?  Y  N

Was the time well spent?  Y  N

What is your level of satisfaction with the information received?

Very satisfied  Satisfied  Not satisfied

Comments \_\_\_\_\_  
 \_\_\_\_\_

Signature of applicant : \_\_\_\_\_

C. ARE YOU A PARTICIPANT IN AN HIV VACCINE TRIAL  YES NO

IF YES, PLEASE SUPPLY YOUR VACCINE TRIAL IDENTIFICATION NUMBER:

\_\_\_\_\_

**WHERE THE CLIENT HAS UNDERGONE PPTC AT THE PATHOLOGY LABORATORY, THIS PAGE MUST BE FAXED TO THE LOA OFFICE (FAX NUMBER 021-4212599) BY THE LABORATORY.**

**TO BE COMPLETED BY APPLICANT**

**D. INFORMED CONSENT TO HIV ANTIBODY TESTING** (*Need only be completed if an HIV test is done*)

- I understand the information contained in the LOA HIV testing information sheet
- I freely consent to the withdrawal of blood from me.
- I freely consent to the testing of that blood.
- I understand that the results of my tests will be kept confidential, except for the disclosure of any reactive result to the doctor whom I have named below.
- I have read the information on this form about what a test result means.
- I understand that I should contact my nominated doctor for further information and counselling if required.
- I understand that Life Company A will pay for one session of post-test counselling with a doctor of my choice, if I desire it, and if the test result is positive.
- I understand that I have the right to request and receive a copy of this form.
- I understand that details of a positive test result will be held confidentially by the LOA on its register.
- In the event I elected to undergo PPTC, I hereby confirm that all my questions and queries were answered satisfactorily.

Name of nominated doctor/clinic: \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_ Postal Code : \_\_\_\_\_

Signature of person being tested : \_\_\_\_\_

Date : \_\_\_\_\_

**E. IDENTIFICATION OF APPLICANT FOR ALL PATHOLOGICAL TESTS** (*Must always be completed*)

Identity Number of person being tested : 

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Name of person being tested: \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_ Postal Code : \_\_\_\_\_

Signature of person being tested : \_\_\_\_\_

**F. IDENTIFICATION OF AND DECLARATION BY PERSON DRAWING SAMPLE** (*Must always be completed*)

Name of person drawing sample : \_\_\_\_\_

Practice number : \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_ Postal Code: \_\_\_\_\_

I have satisfied myself that the person being tested has received the Informed Consent Document, and I have verified the identify of the applicant and that he/she has freely consented to have the sample drawn and tested for HIV antibodies.

In compliance with the provisions of the LOA HIV Testing Protocol, I have inspected the following document to verify the identify of the applicant:

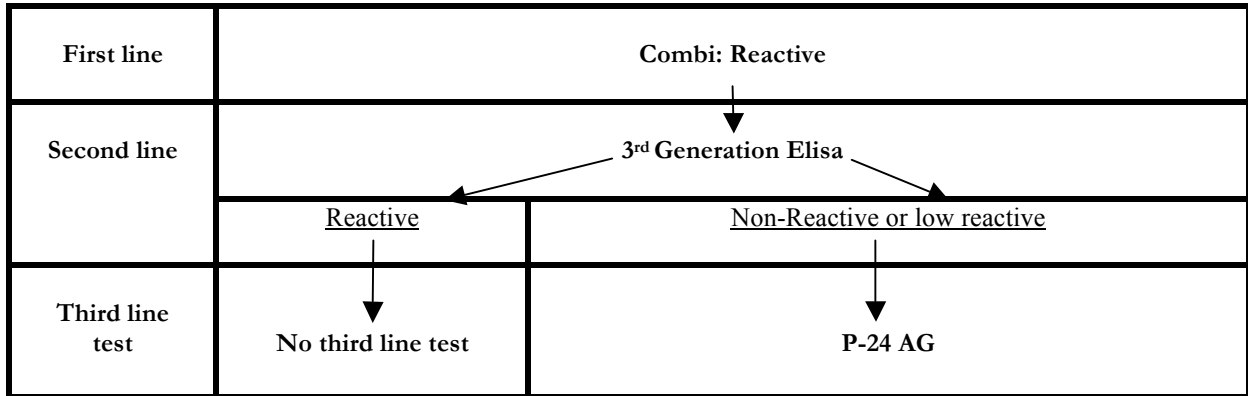
Valid South African identity document       Valid temporary South African identity document

Valid South African passport       Card type drivers license

Signature of person drawing the sample: \_\_\_\_\_ Date: \_\_\_\_\_

**Annexure 3**

NEW 4<sup>TH</sup> GENERATION HIV TEST PROTOCOL



**ANNEXURE 4**

**LETTER TO NOMINATED DOCTOR**

Use this letter for all cases where the client is regarded as insurable (i.e. policy issued), but the HIV tests are not all non-reactive. Refer to Table IV in this regard.

Dear Dr .....

**CLIENT:** .....

**DATE OF BIRTH:** .....

**APPLICATION NUMBER:** .....

This person proposed for insurance with our company. An HIV test was performed, adapted from the World Health Organisation protocol. A copy of the result is enclosed for your records.

In terms of the LOA protocol, this person is regarded as insurable although the HIV-tests were not all non-reactive. Further confirmatory testing may be required for clinical purposes in terms of the attached documentation. Any further tests will be for the client's own costs.

If you have any further queries, please contact the undersigned.

Yours faithfully

**CHIEF MEDICAL ADVISOR / CHIEF UNDERWRITER**

**ANNEXURE 5**

**LETTER TO CLIENT**

**Use this letter for all cases where the application for insurance is declined, irrespective of how many tests are reactive or low-reactive.  
Refer to Tables III and IV in this regard.**

Mr/Ms .....  
.....  
.....  
.....

Dear Sir/Madam

**RE: APPLICATION NO. \_\_\_\_\_**

We thank you for the opportunity you have given to assess your application for assurance.

It is with regret, that after careful consideration of all the information provided, we advise that we are unable to offer the required assurance.

We strongly recommend that you consult with your personal medical attendant,  
Dr \_\_\_\_\_, as nominated in your application, who is being provided with copies of your medical evidence.

Any contribution received by us in respect of the application, will be refunded.

Yours faithfully

**CHIEF MEDICAL ADVISOR / CHIEF UNDERWRITER**

**ANNEXURE 6****LETTER TO NOMINATED DOCTOR FOR POST-TEST COUNSELLING**

Use for: Any application that is declined, or when post-test counselling may be indicated.

**PRIVATE & CONFIDENTIAL**

Dear

**CLIENT:**

**DATE OF BIRTH:**

**APPLICATION NUMBER:**

**CLIENT'S ADDRESS:**

**CLIENT TEL:**

The above patient recently proposed for assurance with our organisation and was required to undergo a HIV test for underwriting purposes.

The applicant nominated you as the doctor to whom, in the event of a serological abnormality, the results were to be notified. A copy of the patient's HIV test is enclosed. I have contacted your patient and asked him/her to contact you.

Please note that the HIV testing protocols utilized by the Insurance Industry are screening procedures based on the original World Health Organisation recommendation. It is important that your patient understands that he/she cannot be regarded as being HIV positive before confirmatory diagnostic tests have been done on a second blood sample. Please refer to attached document entitled "HIV Test Results Interpretation".

Our organisation is prepared to pay (R x) (VAT inclusive) for the first post test counselling consultation. At ABC Company we regard this consultation as very important as it is likely to be the first face to face counselling of HIV/AIDS which your patient receives. In the event of the confirmatory tests being positive, it is important that the patient should be advised as to where to go for further information or assistance with regard to HIV/Aids.

Please submit your account together with the attached letter, signed by your patient.

The patient will be responsible for any further costs, except for the above-mentioned counselling consultation, for example the follow-up consultation or treatment. Based on the test results received, we have declined your patient's application for life cover. If follow-up tests prove your patient to be HIV-negative, he/she can reapply for insurance within three months and submit the follow-up tests.

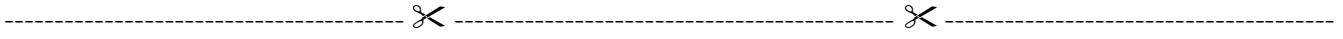
We will accept this follow-up test for insurance purposes only if:

- it was done with the proper identification according to the LOA protocol at the pathologists, and
- it includes a diagnostic test failing which we may require a third blood sample for HIV-testing.

You may also wish to advise your patient that ABC Company could provide alternative financial advice to meet his/her personal circumstances. If they wish to enquire about this service, they should contact their financial adviser. Alternatively, you may wish to contact 'The Life Offices' Association at (021) 421 2586 or access the website, [www.loa.co.za](http://www.loa.co.za) to obtain information about life cover and other products offered by other companies in the Industry.

Yours faithfully

Chief Medical Officer



**PLEASE RETURN TO ME FOR PROMPT PAYMENT**

**APPLICATION(S):**

**CLIENT:**

**Signature of the client:**.....

**Date of consultation:** ..... **Practice number:** .....

**ANNEXURE 7****INTERPRETATION OF HIV TEST RESULTS FOR INSURANCE PURPOSES**

The insurance industry is very aware of its social responsibilities and is constantly addressing the methodology by which HIV testing is performed. The industry is committed to provide information to enable intermediaries to deal with the HIV testing process responsibly, with empathy while maintaining confidentiality.

Pre-test counselling information is mostly carried out by means of an information document which is an internationally accepted protocol whilst in addition personal pre test counselling is also available free of charge at selected venues, should the client elect such an option. In addition, one post test counselling session is funded by the insurance industry.

The HIV testing process as practised by the insurance industry is in itself a significant contribution to AIDS education and community health. The industry acts on behalf of all its members to enable it to continue conducting life insurance in an environment in which HIV infection is prevalent. The industry is not only concerned about the financial impact of the AIDS epidemic, but also cares about the effects it may have on individuals and communities.

In order to determine a person's insurability, SCREENING tests are performed to detect possible exposure to the HIV virus by one of two protocols.

These protocols are based on the WHO recommendation for HIV Screening. The protocols go to great lengths to eliminate as far as possible human error e.g. sample swapping and laboratory error. Copies of the protocols are available on the LOA website, <http://www.loa.co.za>. It must be emphasised that this procedure cannot be seen as diagnostic. These are all biological tests and are not infallible. Even so the sensitivity and specificity of the tests is in the order of 99.5%. It is therefore clear that both false positive and false negative results may occur. There is also a possibility that the tests may cross react with other antibodies in persons living in Africa due to a high exposure to other infectious illnesses.

The two protocols are:

1. The Three Elisa Protocol
2. The 4<sup>th</sup> Generation HIV Test Protocol (called the Combi Test Protocol).

Different result permutations are possible with both protocols. For your convenience, we have attached guidelines on how to best interpret these results.

**Summary:**

Underwriting is the cornerstone of individual life assurance. Each applicant must pay a premium appropriate to the risk. Therefore, as part of its normal underwriting process, the insurance industry undertakes a SCREENING procedure to detect possible exposure to the HIV, before deciding whether a person is insurable or not.

Under certain circumstances, further diagnostic tests may be indicated to determine the person's exact serological status. This responsibility lies with the applicant and their personal medical attendant and NOT with the insurance company. Any further tests will be for the client's own costs.

If it is proved that a person has not been exposed to the virus, they may reapply for the insurance, which application will be normally underwritten, including further HIV tests.

#### RESULT INTERPRETATION: THREE ELISA TEST PROTOCOL

A number of different combinations of results may occur.

##### **1. Initial ELISA test non-reactive (only one Elisa test done)**

A non-reactive result suggests that the person has not been exposed to the virus. However, as with any biological test, false negative results may occur or the person may be early in the window period of infection. The insurance industry accepts that this person is probably not infected and is insurable.

##### **2. First ELISA test reactive, second and third test non-reactive (three Elisa tests done)**

This person has tested reactive to one ELISA test. On the balance of probabilities, this represents a cross-reaction with other antibodies in the person's serum (i.e. a false-positive result), but there is a possibility that the person is in the window period of infection. The insurance industry considers this person to be insurable, but further tests may need to be undertaken to determine the person's HIV status. These are the responsibility of the applicant and their doctor.

##### **3. Two reactive, one non-reactive ELISA test (three Elisa tests done)**

This person has reacted to two of three ELISA tests. This represents a discordant result and there is a possibility that the person has been exposed to the virus. Further diagnostic tests at the client's expense should be undertaken to confirm the person's serological status. This person is regarded as uninsurable at this point in time.

##### **4. All three ELISA tests reactive**

It is highly probable that this person has been exposed to the HIV virus. The chance of false reactive results to all three tests is remote. A repeat test may be indicated to confirm the identity of the person and diagnostic testing at the client's expense may be undertaken if any doubt exists. This person is regarded as uninsurable at this point in time.

If it is proved after further testing that the person has not been exposed to the virus they may re-apply for the insurance, when the application will be normally underwritten.

We will accept this follow-up test for insurance purposes only if:

- it was done with the proper identification according to the LOA protocol at the pathologists, and
- it includes a diagnostic test

failing which we may require a third blood sample for HIV-testing.

#### RESULT INTERPRETATION: 4<sup>TH</sup> GENERATION COMBI TEST PROTOCOL.

The 4<sup>th</sup> generation combination HIV tests test for both the viral antibody and the antigen (P-24 component). A significant advantage of these tests for clinical purposes, is the shortening of the window period.

The Life Industry, however, is concerned not to increase the incidence of false-reactive tests through the introduction of any new test. The Industry is sensitive to the emotional trauma that could be avoided in such cases.

For this purpose, a sequential follow-up test protocol has been agreed with the National Pathology Group. Although the whole protocol should still be regarded as a screening procedure, second and sometimes third line tests will be done to eliminate possible false-reactive results.

All first line Combi tests that test reactive, are followed by an approved 3<sup>rd</sup> generation Elisa test. If this confirms a reactive result, the result will be considered reactive. The insurance application will be declined, however, you will need to arrange for a re-test or confirmatory test on your patient to confirm both the identity and reactivity of test result.

When the second line test (3<sup>rd</sup> generation Elisa) does not confirm the first reactive test, a third line P-24 antigen test is done. If this test is non-reactive, the first test is regarded as false-reactive and the client will be accepted for insurance. Again, you will need to follow this up with repeat test or confirmatory tests.

When the third line test (P-24 Antigen) confirms the first line test (Combi HIV), the client will also be regarded as uninsurable at this point in time. Follow-up testing and/or confirmatory testing is advised to establish the true status.

A cut-off value has been determined for each first- and second line test, below which the result will be reported as low-reactive. All low-reactive tests will be followed by a 3<sup>rd</sup> generation Elisa and a P-24 antigen test to minimize false-reactive results.

The following table summarises the results and interpretation of the different outcomes of the new protocol:

#### 4<sup>th</sup> GENERATION COMBI TEST PROTOCOL: RESULT INTERPRETATION AND UNDERWRITING RECOMMENDATIONS

##### COMBI REACTIVE

		3 <sup>rd</sup> Generation Elisa			
		<u>Non-reactive</u>	Low-Reactive	Reactive	
P-24	Reactive	- Possible sero-converter	- Likely sero- converter	- No P-24 done	<b>Interpretation</b>
		- Reactive	- Reactive	- Reactive	<b>Result</b>
	Non-Reactive	- False reactive	- Reactive with low ab titres (beyond antigen phase)	- No P-24 done	<b>Interpretation</b>
		- False reactive	- Reactive	- Reactive	<b>Result</b>

##### COMBI LOW-REACTIVE

		3 <sup>rd</sup> Generation Elisa			
		<u>Non-reactive</u>	Low-Reactive	Reactive	
P-24	Reactive	- Probable sero-converter - Possible false-reactive	- Reactive	- Reactive	<b>Interpretation</b>
		- Discordant	- Reactive	- Reactive	<b>Result</b>
	Non-Reactive	- False reactive	- Probable false reactive	- Probable reactive	<b>Interpretation</b>
		- Discordant	- Discordant	- Reactive	<b>Result</b>

**PCR TEST RESULT POSITIVE ON AIDS VACCINE RECIPIENT: LETTER TO NOMINATED DOCTOR FOR POST-TEST COUNSELLING**

*PRIVATE & CONFIDENTIAL*

Dear .....

CLIENT : .....

DATE OF BIRTH : .....

CLIENT'S ADDRESS : .....

CLIENT TELEPHONE : .....

APPLICATION NUMBER : .....

The above patient recently proposed for assurance with our organisation and was required to undergo a HIV test for underwriting purposes.

The applicant nominated you as the doctor to whom, in the event of a serological abnormality, the results were to be notified. A copy of the patient's HIV results is enclosed. I have contacted your patient and asked him/her to contact you.

Please note that your patient is a participant in a HIV vaccine trial. Up to 50% of patients receiving a HIV vaccine, will develop sufficient antibodies to render an Elisa test positive (reactive). To exclude a possible co-existing natural infection with the HIV virus, all positive (reactive) Elisa results in vaccine trial participants are followed up by testing for the presence of the virus antigen itself through the PCR test.

Patients who test Elisa positive (reactive) due to the vaccine received, should test PCR negative. A positive PCR test result indicates a co-existing natural HIV infection, as the PCR tests for the virus itself and not for the antibodies.

The result of your patient's PCR test is: Positive.

Although every effort is taken to avoid human error in the testing process, it is essential that your patient undergoes a second PCR test to confirm the diagnosis because of the serious consequences of this diagnosis. The costs of this second test will be for your patient's account.

Your patient will need post-test counselling. Our organisation is prepared to pay (Rx) VAT inclusive for the first post-test counselling consultation.

At ABC Company we regard this consultation as very important as it is likely to be the first face to face counselling of HIV/AIDS which your patient receives. In the event of the confirmatory tests being positive, it is important that the patient should be advised as to where to go for further information or assistance with regard to HIV/AIDS.

Please submit your account together with the attached letter, signed by your patient.

Your patient will be responsible for any further costs, except for the above-mentioned counselling consultation, for example the follow-up consultation or treatment. Based on the test results received, we have declined your patient's application for life cover. If follow-up tests prove your patient to be HIV-negative, he/she can reapply for insurance within three months and submit the follow-up tests.

We will accept this follow-up test for insurance purposes only if:

- it was done with the proper identification according to the LOA protocol at the pathologists, and
- it includes a diagnostic test failing which we may require a third blood sample for HIV-testing.

You may also wish to advise your patient that ABC Company could provide alternative financial advice to meet his/her personal circumstances. If they wish to enquire about this service, they should contact their financial adviser. Alternatively, you may wish to contact The Life Offices' Association at (021) 421 2586 or access the website, [www.loa.co.za](http://www.loa.co.za) to obtain information about life cover and other products offered by other companies in the Industry.

Yours faithfully

**Chief Medical Officer**

-----  
**PLEASE RETURN TO ME FOR PROMPT PAYMENT**

**APPLICATION(S):**                      **CLIENT:**

**Signature of the client:** \_\_\_\_\_

**Date of consultation:** \_\_\_\_\_ **Practice number:** \_\_\_\_\_

**ANNEXURE 9****ACCREDITED LABORATORIES**

The following laboratories may perform HIV tests on behalf of the members of the LOA:

AMPATH, Cape Town (N1 City) (Drs. Du Boisson, Bruinette & Kramer)  
 AMPATH, Durban (Dr. Bouwer & Partners, Durdoc)  
 AMPATH, Port Elizabeth (Drs. Swart, Maré & Partners)  
 Du Buisson & Partners (Drs. Du Buisson, Bruinette & Kramer Inc/Ing)  
 Global Clinical & Viral Laboratory  
 Lancet Lab, Durban (Pillay & Mackintosh)  
 Lancet Lab, Johannesburg  
 Lancet Lab, Pretoria  
 Metropolis Pathology Laboratories Taljaard Inc (Cape Town)  
 NHLS Tygerberg Coastal  
 Pathcare, Bloemfontein (Drs Dietrich, Voigt, Mia Inc)  
 Pathcare, Cape Town (Dietrich Voigt Mia Incorporated)  
 Pathcare, George (Dr's Laing, Soldin, Venter)  
 Pathcare, Port Elizabeth (Drs. Hofmeyr, Kasongo & Partners)  
 Pathcare, Vereeniging (Soldin – Le Roux)  
 Pathcare, Klerksdorp  
 Van Rensburg Pathologists, Bloemfontein  
 Vermaak & Partners Pathologists

PPTC will be offered at the following venues in major urban centres:

<b><u>TRADENAME</u></b>	<b><u>COMPANY NAME</u></b>	<b><u>ADDRESS</u></b>
<b>CAPE TOWN</b>		
Dietrich Voigt Mia Incorporated	Pathcare	1 <sup>st</sup> Floor Melomed Hospital Cnr Voortrekker & AJ West Street Bellville Tel: 021-9461078
Drs. Du Boisson, Bruinette & Kramer	AMPATH	N1 Medical Chambers Ground Floor Louwtjie Rothman Street (Next to N1 City Hospital) Tel: 021-5963120

**TRADENAME****COMPANY NAME ADDRESS**

**JOHANNESBURG  
LANCET**

LANCET

Lancet Corner  
Cnr Stanley & Menton Roads  
Richmond, Johannesburg  
Tel: 011-3580836

Suite 2, First Floor  
Bedford Gardens Medical Suites  
Bradford Road  
Tel: 011-6151049

3 Boshoff Street  
Krugersdorp  
Tel: 011-6652808/41

Drs. Du Buisson, Bruinette  
& Kramer Inc/Ing)

AMPATH

Eva Park  
C/o Beyers Naude & Judges  
Avenue  
Nedbank Building Room 303

Wilgeheuwel Hospital  
Amplifier Road  
Radiokop  
Tel: 011-7943235

Pell Meadow Depot  
60 Civin Drive  
Bedfordview  
Tel: 011-4538975

Ground Floor  
Flora Clinic  
Florida Hills  
Tel: 011-4755250

173 Rivonia Road  
Rochester Place  
Morningside  
Tel: 011-7832055

**TRADENAME****COMPANY NAME ADDRESS**

25 Owl Street  
Auckland Park  
Tel: 011-4824999

**PRETORIA**

Lancet

Lancet

Eugene Park Hospital  
Suite 10, cnr Fifth Avenue &  
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**ANNEXURE 10****GUIDELINE TO THE APPLICATION OF AIDS EXCLUSION CLAUSES****1. Introduction**

A HIV/Aids exclusion clause can only be applied by an Insurer to repudiate or limit the benefits payable for a death claim, if on the balance of probabilities a cause and effect relationship can be proven by the Insurer between the cause of death and HIV/Aids.

In this regard, the evidence needed is listed in order of decreasing reliability:

1. A positive HIV test.
2. Clinical diagnosis of Aids or Aids-related Complex (ARC) by the treating physician, based on the temporal progression of the disease and the presence of Aids-defining conditions specific to HIV/Aids.
3. HIV-definitive conditions as listed by the World Health Organisation (WHO) and the Centres for Disease Control (CDC), which can be categorised into three groups:
  - 3.1 Conditions specific to HIV/Aids, and which can be a cause of death.
  - 3.2 Conditions specific to HIV/Aids but which cannot cause death.
  - 3.3 Non-specific conditions typically associated with HIV/Aids in a high-prevalence community.

In addition to the above diagnoses and tests, the cause of death needs to be established. When a HIV/Aids definitive diagnosis has been made which can lead to death (3.1), one only needs to establish that death was due to natural causes. If an HIV/Aids related diagnosis has been made of a condition that is not specific to HIV/Aids only (3.3 above), or a condition that cannot lead to death (3.2 above), additional evidence is required as described later.

**2. Aids-defining conditions**

These are attached as Appendix A and can be categorised into 4 lists:

**List 1: CDC Aids defining conditions**

This is a comprehensive list of 18 diagnoses.

Any one condition of this list, **with** a positive HIV test result, **and** death confirmed as being due to natural causes, is sufficient to prove that the death was HIV/Aids related.

**List 2: WHO HIV definitive conditions**

These conditions are taken from the WHO stage IV Definitive Diagnostic Criteria of Aids. Conditions that need an HIV test result to confirm the diagnosis (e.g. HIV associated dementia), and conditions not prevalent in our country, have been omitted.

This list of 5 diagnoses can be considered diagnostic of HIV/Aids when death is confirmed as due to natural causes.

In such a case, one diagnosis of this list is sufficient to prove causality with HIV/Aids. Clinical confirmation of Aids or ARC is not required, and an HIV test result is not a requirement.

**List 3: WHO HIV specific conditions**

The 3 conditions listed here are also from the WHO stage IV Definitive Diagnostic Criteria. They are specific to HIV/Aids, but does not usually cause death.

In order to repudiate a claim on the basis of an exclusion clause, one condition of this list is required **as well as** a clinical diagnosis by the treating physician of Aids or ARC, **and** cause of death specified as due to natural causes. An HIV test result is not a requirement in this category.

**List 4: Non-specific WHO stage 3 conditions**

The 4 conditions listed here are commonly associated with HIV/Aids, but are non-specific, i.e. can be due to other causes as well, especially in developing countries.

- These conditions can only be used if the clinical diagnosis of Aids or ARC was confirmed by the treating physician, and one condition listed in either the WHO HIV Definitive list (List 2 above), or the WHO HIV specific list (List 3 above), has also been diagnosed in the deceased.

**Appendix B** is attached as a flow diagram for ease of reference.

3. References

1. Centres for Disease Control, Atlanta, USA. Revision of CDC surveillance case definition for acquired immuno-deficiency syndrome. Mor. Mortality Wkly Rep. 1987; 36: suppl. 1, 15-155
2. WHO. Aids Interim proposal for a staging system for HIV infection and disease. Weekly Epidemiol Rec. 1990; 65: 221-228
3. Centres for Disease Control, Atlanta, USA. 1993 US CDC Aids surveillance definition. Mor. Mortality Wkly Rep. 1992 ; 41 (RR41) : 1-19

**Appendix A****List 1: CDC Aids defining conditions**

- 1.1 Pneumocystis carinii pneumonia
- 1.2 Toxoplasmosis of the brain in adult
- 1.3 Cryptosporidiosis with diarrhoea persisting for > 1 month.
- 1.4 Candidiasis of the oesophagus, trachea, bronchi or lungs.
- 1.5 Extrapulmonary cryptococcosis.
- 1.6 Cytomegalovirus infection of an internal organ other than liver in an adult.
- 1.7 Herpes simplex virus infection causing a mucocutaneous ulcer that persists for more than 1 month, or bronchitis, pneumonitis, or oesophagitis for any duration in an adult.
- 1.8 Progressive multifocal leucoencephalopathy.
- 1.9 Primary lymphoma of the brain in a patient < 60 years of age.
- 1.10 Kaposi's sarcoma in a patient <60 years of age.
- 1.11 Isosporiasis with diarrhoea persisting > 1 month.
- 1.12 Extrapulmonary or disseminated mycobacterial infection other than tuberculosis or leprosy.
- 1.13 Any noncutaneous extrapulmonary or disseminated mycobacterial infection other than tuberculosis or leprosy.
- 1.14 Recurrent non-typhoid Salmonella septicaemia.
- 1.15 Primary lymphoma of the brain at any age.
- 1.16 Other non-Hodgkin's lymphoma of B-cell immunologic phenotype:

Small noncleaved lymphoma (Burkitt's tumour or Burkitt-like lymphoma)

Or

Immunoblastic sarcoma (large cell lymphoma diffuse histiocytic lymphoma, diffuse undifferentiated lymphoma, reticulum cell sarcoma, or highgrade lymphoma).

Note : Lymphomas are not included if they are of T-cell immunological phenotype or are described as "lymphocytic", "lymphoblastic", "small cleaved" or "plasmacytoid lymphocytic".

- 1.17 HIV encephalopathy ("AIDS demential complex")
- 1.18 HIV wasting syndrome ("slim disease")  
This is:
  - Loss of >10% of weight compared to best attained weight in last 6 months, plus
  - Chronic diarrhoea > 1 month, or
  - Recorded temperature > 37,5°C on 3 occasions within 1 month with no obvious cause identified.

**List 2: WHO Definitive conditions**

- i. Pheumocystis carinii pneumonia
- ii. Extrapulmonary cryptococcus
- iii. Cytomegalo virus infection of an internal organ other than the liver
- iv. Disseminated atypical mycobacteriosis
- v. Visceral Leischmaniasis.

**List 3: WHO HIV specific conditions**

- i. Kaposi sarcoma, excluding kidney transplant patients
- ii. Candidiasis of oesophagus, trachea, bronchi or lungs
- iii. Oral hairy leukoplakia

**List 4: Non-specific WHO stage 3 conditions**

- i. HIV wasting syndrome as defined by CDC.  
This is:
  - Loss of >10% of weight compared to best attained weight in last 6 months, plus
  - Chronic diarrhoea > 1 month, or
  - Recorded temperature > 37,5°C on 3 occasions within 1 month with no obvious cause identified.
- ii. Herpes simplex infection, muco-cutaneous > 1 month, or visceral any duration.
- iii. Unexplained chronic diarrhoea > 1 month
- iv. Oral thrush

**Appendix B**

**FLOWDIAGRAM: EVIDENCE NEEDED TO APPLY HIV/AIDS EXCLUSION CLAUSES**

