Preamble: Explaining the Technical Aspects of HIV Testing

A. What is the difference between an antibody, antigen, viral load and CD-4 count?

The presence of an HIV infection in a person can be determined through a direct or indirect method of testing.

Direct methods test for the presence of the HIV virus itself, by one of two ways:

1. **An antigen test.** The outer core of the virus consists of various protein elements, or antigens. Some tests are designed to test for one or more of these antigens. If this test is positive, it means that there must be circulating viruses in the bloodstream of the person.

2. **A viral load test** counts the number of circulating viruses in the blood stream. The higher the viral load, the more severe is the infection. Conversely, the lower the viral load, the better the disease control. Viral load tests are typically done to measure the efficacy of anti-retroviral drugs (ART) or HIV treatment protocols.

An indirect test measures the host person's reaction to the infection. These can be one of the following:

1. **An antibody test.** This measures the presence of the antibodies that the person's immune system has manufactured to fight the infection. Once infected, these antibodies appear in the blood stream after an initial period of about 10-30 days, called the window period. Thereafter the antibody tests will stay positive for life, as the antibodies will remain in the blood stream even if the viral load is zero.

2. **A CD-4 count.** The CD-4 cell is a type of white blood cell, and is the host cell for the virus. These cells are destroyed when the virus uses the cell to replicate. The extent of CD-4 cell count decline is an indication of the severity of the disease. CD-4 count can remain fairly normal for years if the person is compliant with ART treatment regimes. In clinically advanced stages of Aids, the CD-4 count drops progressively, which gives rise to recurrent opportunistic infections.

B. Which types of samples can be used for HIV testing?

HIV tests can be done on different types of samples:

1. **A blood sample**, which can be either whole blood or serum. Whole blood is blood containing all the blood cells and platelets, whereas serum is the fluid that remains when the cells have been removed. Serum is usually obtained when a whole blood sample is being spun in a centrifuge, a process that separates the cells from the fluid.

   Blood can be collected in one of three ways:

   a. A whole blood sample by taking blood from the arm with a needle and syringe into a tube. This process is currently used by most insurers and doctors in clinical practice.
   b. A finger prick whole blood sample by pricking the finger. This sample may contain blood cells as well, but usually less than a sample collected by needle. If blood is allowed to flow freely from a finger after pricking it with a needle, whole blood would be collected. If the finger is squeezed to get some blood from the prick, more serum than whole blood will be collected.

c. A dried blood spot, whereby a drop of blood is obtained through a finger prick, and dried and saved on a piece of blotting paper. This spot of blood can be reconstituted in a laboratory before performing an HIV test.

2. **An oral fluid sample**, which can be either an oral exudate or a saliva sample.
   a. An oral exudate sample is obtained when a specific collection device is held between cheek and gum for a specified time, to allow fluid inside the epithelial cells lining the mouth, to diffuse into the collection device. This is therefore intracellular fluid and contains high concentrations of antibodies and antigen. If the sample is collected correctly, and the test is performed in a laboratory, the test accuracy may be comparable to a blood test.

   b. A saliva sample is obtained by swiping a collection pad through a person's mouth. This collects the fluid excreted by the salivary glands (saliva), and contains much lower concentrations of antibodies and antigen. Tests performed on saliva samples yield an unacceptably high number of false positive and false negative tests.

3. **What types of HIV tests can be done on the different types of samples?**

HIV tests can be broadly classified into two types of tests: those performed on automated machines in laboratories (an Elisa test or 4th generation Combination test), and those read on the spot off a test strip (a rapid test).

Any type of blood sample can be tested either in a laboratory by Elisa or Combi test methods, or by using a rapid test. A rapid test can be performed inside or outside a laboratory.

Oral fluid samples can be tested via the Elisa or Combi test methods in a laboratory, or with a rapid saliva test kit. Whereas the accuracy of the former method is more acceptable, the rapid test does have unacceptably high false negative results.

The following different types of tests are used commonly in commercial HIV testing:

Types of tests	
Elisa test (3rd generation)	Tests for antibodies only
Combo test (4th generation)	- Tests for antibodies and antigen - The antigen component shortens the window period
P-24 AG test	Tests for antigen only
Western Blot	- Tests for antibodies only - Very specific, but in disuse
PCR – Polymerase chain reaction test	Tests for the virus itself
CD-4 count	White cells: used to measure extent of immune suppression. A lower count indicates more suppression of the immune system.
Viral load	Tests the number of viruses in bloodstream

C. What are the possible result outcomes?

1. Negative result: this means that the test for HIV was negative at the point in time tested. In the majority of cases, this means that the client is not infected. It is important to realise that a person who has recently contracted the disease, could still be in the window period, and may test positive when tested two weeks later.

2. Reactive result: The test result tested positive for the HIV virus. However, as this is a screening test only, the result needs to be confirmed with a second test on another sample so that the HIV positive status can be verified. This is why the initial result is reported as reactive and not positive.

3. A false negative test: this is where the test shows a negative result for HIV, but actually the person tested is HIV positive. This can happen in tests with low sensitivities, where the test does not pick up low numbers of the virus.

4. A false reactive test: this is where the test shows a reactive result for HIV, but actually the person tested is HIV negative. It could be due to a cross-reaction with other antibodies, or due to a possible human error like sample switching), or due to a true test result error. This leads to significant emotional distress until the actual result is known.

D. What are the advantages of using a traditional blood sample?

i. The test results are the most reliable of all testing methodologies.
ii. All second and third line testing can be completed before the results are given to the applicant. This removes almost all false reactive results, and minimises any emotional trauma of having to wait for further testing.
iii. The samples can be stored indefinitely in case of any dispute.
iv. A paper trail is available for purposes of any audit and/or forensic investigation.
v. A number of additional non-HIV tests, such as cholesterol and cotinine, can be performed on the same sample.

E. What are the disadvantages of a traditional blood sample?

i. It is perceived to be a more invasive process than doing a finger prick. This applies however only to cases where an HIV test only is required, as a traditional blood sample is required for any other non-HIV test.
ii. It can be significantly more expensive than a rapid test.
iii. Many additional non-HIV pathology tests can be performed on the same sample.

F. What are the advantages of using a blood sample collected by a finger prick?

i. It is perceived to be less invasive and more customer friendly.
ii. If this sample method is combined with a rapid test outside the laboratory, it does reduce the cost of an HIV test significantly.
iii. A limited number of additional non-HIV tests, such as cholesterol and cotinine, can be done on a blood sample obtained by a finger prick.

G. What are the disadvantages of using a blood sample collected by a finger prick?

i. Depending on the specific type of testing kit used, it can be less specific and less sensitive, and may result in more false positive and false negative results.
ii. No second and third line tests can be done to minimise false positive results. Obtaining a second blood sample from the client causes emotional trauma and anxiety until the final result is known.
iv. The sample cannot be stored.
v. In most instances no paper trail exists for purposes of auditing.
vi. It is open to fraud as the result can be read and manipulated by the operator on the spot.
vi. No other non-HIV tests can be done with one drop of blood collected on a rapid test strip.
vii. The test is more prone to operator error, therefore the results are more likely to be inaccurate.

H. What are the pros and cons of a saliva HIV test?

i. The test is less invasive, but significantly less accurate. It particularly has a higher incidence of false negative tests.
ii. The sample cannot be stored.
iii. No paper trail exists for purposes of auditing.
iv. It is open to fraud as the result can be read by the operator on the spot.

v. No other non-HIV tests can be done except a cotinine test. The cost of the test, if done in a laboratory, is more expensive than a traditional blood test. If done on a rapid test strip, it is cheaper.

ASISA HIV TESTING PROTOCOL

INDEX

The protocol is made up of nine sections namely:

A: Introduction (Explanatory memorandum)
B: Goals of the Protocol
C: Generic Principles
D: Pre-test procedures
E: Testing procedures
F: Reporting results
G: Post-test procedures at the Life Office
H: General

Annexures:

1. ASISA HIV Testing Information Sheet
2. HIV Counselling Script:
   2.1 HIV Counselling script for Pre-test counselling
   2.2 HIV Counselling script for Post-test counselling
3. List of ASISA approved laboratories
4. List of ASISA approved test kits
5. Flowchart 1: 4th Generation Combi Test protocol (4th Gen + 3rd Gen + P24)
6. Flowchart 2: two 4th Generation Combi Tests protocol (4th Gen + 4th Gen)
7. Flowchart 3: Alternative protocol to allow for molecular testing instead of 3rd gen testing in discordant cases.
8. Flowchart 4: Rapid Test Protocol
9. Sample letter to nominated doctor: Client insurable
10. Sample letter to the client: Application declined
11. Letter to nominated party for post-test counselling
12. Note to nominated doctor: Interpretation of HIV test results
13. PCR test result positive on AIDS vaccine recipient: Letter to nominated party for post-test counselling
14. Approved Facilities for pre-test and post-test counselling

SECTION A: INTRODUCTION

The ASISA Life and Risk Board Committee 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 Protocol and revise any of the annexures without referral to the ASISA Life and Risk Board Committee.

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 Standard applies to all HIV tests performed by ASISA 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.

SECTION B: GOALS OF THE PROTOCOL

- To minimise false-reactive results and the resultant emotional trauma to the client.
- To this end, the tests utilised must meet the specified sensitivity and specificity levels, and all second and third line tests must be completed on a primary sample before any communication with the client.
- The restriction of false negative results to an absolute minimum
- The strict identification of the person whose sample has been taken
- Maintenance of confidentiality of results
- To make it clear that the insurance industry is only involved in **screening** for HIV in order to assist in the risk assessment of an applicant.
- To ensure that proper steps are taken to identify and treat participants in vaccine trials appropriately
- To ensure that the principles of this protocol are flexible enough to be applicable to all role players in an application for insurance, regardless of the type of sample, the test method or process followed.

SECTION C: GENERIC PRINCIPLES

All HIV tests used for insurance purposes must meet all of the following generic criteria:

A. THE PROCESS

1. Identification

   To be done according to current protocol requirements.

2. Pre- test counselling

   All clients, regardless of geographical area or language group, must be offered one of 3 choices:
   - Reading the ASISA HIV information document
   - Attending a personal face to face counselling
   - Using an approved call centre option

3. Informed Consent

All clients must sign voluntary informed consent as specified in the protocol

4. Nomination of party to receive result

All clients must nominate a party allowed by the protocol to receive reactive results.

5. Sample collection

- Sample collection can be done only by persons approved by the protocol for such purposes.
- All samples must be identifiable as the specific client's sample after collection.
- The sample should be sufficient to allow for second and third line testing in cases of reactive first line tests.
- The sample must be suitable for storage for the minimum prescribed period as per the protocol (reasons include possible re-testing in cases of dispute, fraud etc).

6. Transport of samples

Samples should be transported in a manner as required by the manufacturer of the test in question.

7. Testing facility

7.1 In-house testing by life office

Each office will be liable for its own quality control measures.

7.2 Outsourced services

- All HIV testing facilities operated by third parties must be accredited by ASISA to ensure consistency in testing methods, administration requirements and accuracy of results.
- All aspects of the testing methodology and processes followed, including for e.g. sample collection, chain of custody, sample receipt, testing methodology, result interpretation and result delivery must be done as specified in the protocol.

8. Interpretation of test results

The interpretation of the test results by life offices must be done in accordance with the protocol, however the underwriting of each test result should be done according to its own underwriting guidelines.

9. Communication of results

- Only the nominated person authorised by the client to receive the reactive result, must communicate with the client and do the post-test counselling.
- Options for further testing, review of underwriting decision and available products are addressed in the sample letters, as well as the post-test counselling.

10. Changes to the protocol

Any deviation from this protocol must be approved by MUSC and the ASISA Risk Board.

B. **TEST SPECIFICATIONS**

Any HIV test not listed in the protocol will be considered by MUSC after evaluating the test performance according to the testing criteria prescribed by the ASISA Protocol for the Validation of Commercial HIV Essays.

Irrespective of the type of test used, any test must, when subjected to the ASISA Protocol for the Validation of Commercial HIV Essays, conform to the following minimum criteria:
1. Test sensitivity: 98%
2. Test specificity: 97%

While these criteria may change with time, these figures have been provided by the expert consultant based on current research.

SECTION D : PRE-TEST PROCEDURES

The following principles in terms of identification, counselling options, informed consent, nomination of party to receive results, sample collection and transport of samples should be adhered to irrespective of the test methodology followed.

1. **Identification**

1.1 When an HIV test is requested, the sales intermediary should inform the client that an original identity document as specified below, will be required when the sample specimen is collected , and that he/she will be required to nominate a third party to receive the HIV test result. A third party could be the client's family doctor, an independent doctor, nominated clinic or hospital, or an approved Call Centre.

1.2 The following identity documents are acceptable in terms of this Protocol:

1.2.1 Valid original South African identity document and passport, issued by the Department of Home Affairs
1.2.2 Valid official South African Card-type driver's licenses

1.3 ASISA recommends that temporary ID-documents should not be accepted. This however, should be dealt with at the discretion of each office.

1.4 ASISA recommends that foreign passports should not be accepted, except in cases where it is possible to verify the validity of such passports with the relevant consulate. This however, should be dealt with at the discretion of each office.

1.5 Photocopies or faxed copies of identity documents are not acceptable, regardless of whether such documents are certified or not.

1.6 Where the HIV test is to be performed on a minor**, the written consent of the legal guardian will be required. In cases where the minor is unable to obtain an identity document (as required in 1.2 above) because of his age, the identity document of the legal guardian (who consents to the HIV test) will be required.

1.7 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.

1.8 ASISA recommends that refugee documents should not be accepted. This however, should be dealt with at the discretion of each office.

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.

2. Counselling options

2.1 Every client should be offered the opportunity to elect one of the following counselling options:

2.1.1 Counselling by ASISA HIV testing information sheet
2.1.2 Telephonic pre-test counselling by an approved call centre (toll-free)
2.1.3 Personal pre-test counselling. This can be provided by selected laboratories, or other approved third party service providers (approved by ASISA or direct life offices).

2.2 The HIV testing information sheet is attached as Annexure 1. The wording of this **HIV testing information sheet** shall not be altered, except in consultation with the ASISA Medical and Underwriting Standing Committee. This document should be printed by member offices and distributed to appropriate doctors and laboratories.

2.3 Ideally the client should receive this sheet from the sales intermediary but, failing this, it must be provided by the person collecting the specimen. Member offices must ensure that adequate supplies of this documentation are made available to those parties collecting specimens, and sales intermediates.

2.4 Pre- and Post-test counselling services can also be done through an approved Call Centre. The service of such Call Centres should include at least the following:

- The counselling script should conform to a minimum standard as set out in Annexure 2.
- Counselling should be available in all official languages
- Must be accessible from 07h00 – 19h00 on weekdays
- A toll-free number must be provided for inbound calls
- Post-test counselling must also be available through this call centre for clients who have reactive test results, and who have voluntarily elected the option to have their results delivered to the call centre.

Annexure 14 contains a list and contact details of approved pre-test counselling centres and Call Centres.

3. Informed consent

Each client must sign voluntary informed consent to undergo a HIV test. The client must confirm that he/she understands the following:

- I understand the information contained in the ASISA HIV testing information sheet, or provided by the call centre or personal pre-test counselling service.
- I freely consent to the collection of a blood samples or other sample from me for the purposes of HIV testing.
- I freely consent to the testing of those samples.
- I understand that the results of my tests will be kept confidential, except for the disclosure of any reactive result to the doctor, hospital, clinic, or call centre that 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, hospital or clinic for further information and counselling if required.
- I understand that if I have nominated a call centre to receive my results, that I will be called by this call centre. I also understand that this will only happen if the result is abnormal.
- 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 reactive test result will be held confidentially by the ASISA on its register.
- I hereby confirm that all my questions and queries were answered satisfactorily.

If the client is not prepared to sign the above consent, the sample should not be collected.

4. The nomination of a party to receive the result

Each client must nominate a party to receive reactive results. Each Life office should verify that these parties must at least be able to:

- Receive, handle and store the results confidentially.
- Do adequate post-test counselling
- Arrange for confirmatory testing
- Institute treatment when indicated or refer the client to an appropriate facility for this purpose.

These parties may be one of the following:

- Family practitioner
- Independent Medical practitioner
- Nominated clinic or hospital
- ASISA approved Call Centre

5. Sample collection

- Sample collection can be done only by persons approved by the protocol for such purposes:
  - Medical practitioners
  - Qualified nursing sisters
  - Staff nurses
  - Registered phlebotomists

- All samples must be identifiable as the specific client's sample after collection, containing at least the client's initials and surname.
- The sample should be sufficient to allow for second and third line testing in cases of reactive first line tests.
    - The sample must be suitable for storage for the minimum prescribed period as per the protocol to allow for re-testing. Reasons include for example cases of dispute, fraud.
    - The minimum storage period in cases of reactive results is 9 months.
    - The minimum storage period in cases of non-reactive results is 2 weeks.

HIV Testing is done internationally on the following types of samples:

- Whole blood sample obtained by venesection or finger prick.
- Oral fluid sample
- Urine sample

In terms of this protocol the following types of samples are acceptable for insurance HIV testing:

Whole blood samples:

- For venesection, one tube of clotted blood and one tube of EDTA blood must be collected from all applicants for purposes of testing for HIV by the methodologies as described later. If a life office plans to do a rapid test on a tube of collected blood, a separate tube should be collected for this purpose to prevent contamination of any tubes sent to the laboratory in cases where reflex testing is indicated. Also, if any additional non-HIV pathology tests are required, additional tubes of blood should be collected in the appropriate tubes for this purpose, as the HIV tests are done on dedicated lines within laboratories.

  It is important that one tube of EDTA (purple capped tube) blood also be collected 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 in persons who have received a vaccine

- Finger prick sampling:
  Finger prick sampling is not allowed in terms of this protocol, as it does not provide sufficient blood volume to do second and third line testing, and is also not storable for the minimum periods described above. However rapid testing is allowed as described in section E2.

Oral fluid samples:
These are not acceptable in terms of the minimum sample criteria, as they cannot be stored for the specified period, and do not meet the minimum sensitivity and specificity criteria.

6. Transport of samples

- Samples must be packaged individually with the relevant documentation to ensure that the chain of custody is maintained.
- Samples should be transported in such a manner to meet the requirements of the manufacturer of the test kit.

SECTION E: TESTING PROCEDURES

SECTION E1: LABORATORY TESTING

1. Accreditation

All laboratories operating as third party service providers to ASISA, must be accredited by ASISA to perform HIV tests for insurance purposes 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 ASISA from time to time, as available on the ASISA website at: http://www.asisa.org.za.

All applications for accreditation should be directed to the ASISA office. A list of approved pathology laboratories is annexed as Annexure 3.

Different types of HIV tests kits used are also approved by ASISA. Laboratories may not use any HIV test not listed in annexure 4 for insurance HIV testing.

2. Laboratory receipt of specimens:

2.1 If no documentation is received with the blood specimen by the laboratory, the laboratory shall refuse to perform the HIV test.

2.2 If the blood specimen and documentation are received from any source other than those persons approved in Section A5, the laboratory shall refuse to conduct the HIV test and discard the blood specimen.

2.3 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.

3. Methodology

An ASISA accredited laboratory may only use the 4th Generation Combi HIV testing protocol for insurance HIV screening.

This protocol uses one of the ASISA approved 4th 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.

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 (refer to Flowchart 1 or Annexure 5).

Any low-reactive or reactive result must be re-tested in one of the following ways:

- 4th Gen + 3rd Gen + P24: with a 3rd 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 3rd 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** (refer to Flowchart 1 or Annexure 5).
- 4th Gen + 4th Gen + P24: with a second 4th generation Combi test from a different manufacturer than that of the first 4th Gen test. If this does not confirm the results of the first test, it must be followed with 3rd generation Elisa and P-24 antigen tests from different manufacturers. Refer to Flowchart 2, or Annexure 6.
- For laboratories that do not have 3rd gen Elisa tests available to do the above re-testing of discordant samples (with a P-24 antigen test if indicated), an alternative flow diagram option is provided in flowchart 3, Annexure 7, that uses one of three molecular testing methodologies.

Low-reactive values for all ASISA approved 3rd generation ELISA tests as well as 4th generation Combi tests, will be defined from time to time by MUSC with expert opinion. Reactive results below these cut-off levels will be reported as low-reactive.

Please see annexure 4 for the approved first line 4th Generation Combi tests.

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

Test	Supplier	Reference range	"Low Reactive value"
1.1 Elecsys Roche HIV Combi PT 4th generation test	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
1.5 Bio-Rad HIV Combi (DxI/Access)	Bio-Rad	< 0.9 = Non-Reactive 0.9 - <1.0 = Gray-zone 1.0 and > 1.0 = Reactive	0.9 - 10
1.6 Centaur CHIV Combo	Siemens	0 to 0.29 = Non-reactive 0.30 to 0.99 = Grey zone >1.00 = Reactive	1 - 10

Second line follow-up tests with a 3rd generation Elisa test (refer flow diagram Annexure 5) for all first line Combi tests that test reactive or low-reactive, may only be done with one of the approved third generation Elisa tests as listed in annexure 4.

As low-reactive values are only available for the list of Elisa tests below, they will be the only 3rd generation Elisa tests allowed for follow-up tests in the 4th 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	Siemens	< 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
2.5 Vitros Eci HIV 1 + 2	Scientific Group	<0.90 = Non-reactive 0.90-1.00 =Borderline >1.00 = Reactive	0.9-15

Equivocal results are not accommodated in the ASISA 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.

SECTION E2: RAPID TESTING

Whereas the performance of rapid tests is acceptable according to the criteria of the protocol, rapid tests should not be used with finger-prick collection of a drop of blood – refer to section A5 regarding the principles of sample collection. Instead, a whole blood sample should be collected in a venesection tube.

The rapid test itself should then be performed on a different site than where the sample is collected, so that the client does not have immediate access to the results. The main reasons for this are to i) reduce the number of false reactive results by doing the required second and third line tests, and ii) to allow all applicable reflex tests to be performed before the result is relayed to the client.

Although whole blood can be added from a finger-prick or blood tube to the rapid test devices, it is recommended that all blood samples are collected in a tube, centrifuged, and the serum tested with the rapid test. If such tests were to be performed at a small site at the insurance company with, for

example, a nurse or technologist and a centrifuge and fridge, all meeting the generic principles as described in this protocol, this would be satisfactory.

The rapid test protocol is depicted in the flow diagram in Annexures 7.

Note: The sensitivity of the antigen component of the 4th generation rapid tests is not ideal; however, the sensitivity and specificity of the antibody component remains the same as with the 3rd generation equivalents, and therefore sensitivity overall for the test is increased, even though not all patients with only antigen (i.e. sero-converters) will be detected.

SECTION F: REPORTING RESULTS

1. **Format of results:**

The results of the first line 4th Generation HIV Combi test, as well as the second line 3rd 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 by MUSC in consultation with an expert.

Proviral DNA PCR tests on whole blood, and qualitative nucleic acid testing (NAT) on plasma or serum, will be reported as either positive or negative. Note: only accredited adult assay nucleic acid tests may be used for this purpose.

Quantitative RNA assays (viral loads) will be reported in copies per mL. Any detectable viral load should be regarded as a positive result, and a non-detectable viral load as a negative result. These levels vary according to the specific test used.

In addition, the result field should show which test was used, e.g. Roche Elecsys Combi, Abbott Axsym 3rd generation etc.

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

- First 4th Generation Combi: non-reactive No descriptor
- First 4th Generation Combi: reactive Refer to table below

These cases will be followed up with a 3rd 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 4th Generation Combi test, are described in Tables I and II.

TABLE I : RESULT DESCRIPTORS

		COMBI REACTIVE		
		3rd Generation Elisa		
		Non-reactive	Low-Reactive	Reactive
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

		COMBI LOW -REACTIVE		
		3rd Generation Elisa		
		Non-reactive	Low-Reactive	Reactive
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."

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

Member offices are responsible for ensuring confidentiality in their offices.

The preferred method for reporting all results, is via electronic means.

Reactive results should be delivered confidentially to either the Chief Medical Advisor or Chief Underwriter or the designated person in the company assigned to dealing with HIV reactive results.

Non-reactive results will be delivered to the head office of the life office concerned. The Chief Medical Advisor 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 Chief Medical Advisor or Chief Underwriter and the laboratory concerned.

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

It must be emphasised that under no circumstances is any HIV test result 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.

SECTION G: POST-TEST PROCEDURES AT THE LIFE OFFICE

Handling of results, communicating with the client and post-test counselling:

1. 4th Generation Combi Protocol

Tables III and IV summarise the interpretation of the results and examples of the format of letters to be sent to the nominated doctor and the client:

TABLE III: 4th GENERATION COMBI TEST PROTOCOL: RESULT INTERPRETATION.

		COMBI REACTIVE			
		3rd Generation Elisa			
		Non-reactive	Low-Reactive	Reactive	
P-24	Reactive	Possible sero-converter	No P-24 done	No P-24 done	**Interpretation**
		Reactive	Reactive	Reactive	**Result**
		Annexure 11 & 12	Annexure 11 & 12	Annexure 11 & 12	**Example of Letter to doctor**
		Annexure 10	Annexure 10	Annexure 10	**Example Letter to client**
	Non-Reactive	False reactive	No P-24 done	No P-24 done	**Interpretation**
		False reactive	Reactive	Reactive	**Result**
		Annexure 9	Annexure 11 & 12	Annexure 11 & 12	**Example of Letter to doctor**
		No letter to client Policy issued	Annexure 10	Annexure 10	**Example of Letter to client**

TABLE IV: 4th GENERATION COMBI TEST PROTOCOL: RESULT INTERPRETATION.

		COMBI LOW-REACTIVE			
		3rd Generation Elisa			
		Non-reactive	**Low-Reactive**	**Reactive**	
P-24	**Reactive**	- Possible false reactive - Probable seroconverter	- Reactive	- Reactive	**Interpretation**
		- Discordant	- Reactive	- Reactive	**Result**
		Annexure 9 & 12	Annexure 11 & 12	Annexure 11 & 12	**Example of Letter to doctor**
		No letter	Annexure 10	Annexure 10	**Letter to client**
	Non-Reactive	- False reactive	- Probable false reactive	- Probable reactive	**Interpretation**
		- Discordant	- Discordant	- Reactive	**Result**
		Annexure 9 & 10	Annexure 9 & 12	Annexure 11 & 12	**Example of Letter to doctor**
		No letter to client Policy issued	No letter to client Policy issued	Annexure 10	**Example of Letter to client**

Test procedures on HIV Vaccine trial participants

A person who has received a HIV vaccine may also develop antibodies in response to this vaccine. It is expected that a significant number 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

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 the received the vaccine. A reactive HIV Elisa test will not be able to distinguish between these possibilities.

For this reason all reactive first line HIV tests in HIV vaccine trial participants, must undergo a qualitative PCR as the second line test.

Interpretation of the PCR tests results in these cases should be as follows:

a) A reactive HIV Combo test and negative PCR tests indicate that:
   - The combo test is reactive due to the vaccine
   - The client has not been infected by the HIV virus

In these cases no correspondence is necessary to the client or his/her nominated doctor.

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

The following procedure will then be followed:
- The case is declined
- The necessary entry is made on the ASISA Life Register
- The client is informed that the medical evidence has been submitted to his/her nominated doctor. (Annexure 13)
- A copy of the laboratory report, clearly marked private and confidential, is send to the nominated doctor.
- The company concerned will pay for one post-test counselling session.
- Any further test will be at the client's own expense.

SECTION H: GENERAL

1. The HIV Testing Protocol will be continuously monitored and updated by the ASISA 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 take responsibility for receiving and dealing with HIV reactive results.

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 him-/herself 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.

ANNEXURE 1

ASISA 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 virus that causes AIDS (HIV) 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 HIV test.

3. ***To refuse to take the test***. If you do this, your application for insurance may be denied, if the insurer requires an HIV test as part of their risk assessment.

   You may however wish to consider other non-risk alternatives such as 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. You have one of three options available for pre-test counselling;

   a) Reading this information document.
   b) 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.
   c) Personal pre-test counselling through selected laboratories in cosmopolitan areas. Please consult your broker/intermediary in this regard.

5. ***To nominate a doctor to receive reactive results, if*** you do not have a personal doctor to nominate to whom the test result should be given in case of a reactive result, you may nominate the above mentioned call centre for this purpose.

6. ***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 ASISA 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.

7. ***To one session of post-test counselling if the test is reactive***, at the expense of the Life company involved.

WHY DO LIFE INSURANCE COMPANIES TEST FOR HIV?
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 HIV virus.

IS THE TEST ALWAYS CORRECT?
Even though the tests are very accurate, they must be regarded as screening tests only and not diagnostic. If your test result shows that you may be infected with HIV, 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 a reaction when the person is not infected with the virus. This is not the fault of the laboratory or the insurance company, and 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 inaccurate results. In order to minimize false positive results further tests are performed on all initial positive results, before any results are communicated to the client.

WHAT DOES IT MEAN IF THE TEST IS NEGATIVE?
If your test result is negative, it means that you are either not infected, or the disease is in too early stage for the test to detect its presence (window period). 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 may also increase if you are an intravenous drug user sharing needles. 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 HIV. You will be notified about the outcome of your policy application by the company involved. All your existing cover will remain valid. As from 1 January 2005 insurance companies may no longer have HIV/AIDS exclusion clauses on new business.

The implications of a positive test should be discussed with your doctor. If 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:
Your application will be underwritten and the results communicated to you.

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, this does not automatically mean that the HIV test result is positive, as your doctor will be notified of any medical impairment that you are not aware of. . 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

TO BE COMPLETED BY APPLICANT

A. INFORMED CONSENT TO HIV TESTING

- I understand the information contained in the ASISA HIV testing information sheet, or provided by the call centre or personal pre-test counselling service.
- I freely consent to collection of a blood sample 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 or institution who 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 the Life Company involved 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 ASISA on its register.
- I hereby confirm that all my questions and queries were answered satisfactorily.

Name of nominated doctor/clinic: _____

Address : _____

_____ Postal Code: _____

I elect to receive reactive test results and post-test counselling through the ASISA approved call centre:

Y ☐ N ☐

I prefer to be contacted by the Call Centre on the following number: _____

I am a participant in an HIV vaccine trial YES ☐ NO ☐

If yes, please supply your vaccine trial identification number:

_____

Signature of person being tested : _____ Date :

_____

B. 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 : _____

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

Name of person drawing sample : _____

Name of employer: _____

Telephone number : _____

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

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

☐ Valid South African identity document

☐ Valid temporary South African identity document

☐ Valid South African passport

☐ Valid official South African Card type driver's license

Signature of person drawing the sample: _____ Date: _____

ANNEXURE 2

HIV Counselling script for Pre-test counselling

Why do companies test for HIV for Insurance?

- Principle of insurance is dividing people with certain health problems into risk groups; people in the same risk group pay the same premium.
- People in a higher risk category for example smokers, people with high blood pressure or high cholesterol will pay a higher premium as their health condition is considered manageable and the likely outcome of the condition predictable. Some conditions are uninsurable for example recent cancer, uncontrolled diabetes and serious heart problems.
- HIV is an infection contracted through sexual activity with an HIV positive partner, or through exposure to blood or other body fluids from an HIV positive person. It is a chronic disease managed with medication namely anti-retroviral drugs (ARVs).
- Although treatment has improved the life expectancy of HIV positive people, it is still reduced compared to HIV negative people.
- Because of this increased risk, HIV positive people may not qualify for standard insurance policies. This varies from one company to another.
- Special policies for HIV positive people are now available, premiums are higher and certain conditions apply.
- In the same way that Insurance companies are allowed to underwrite for other health conditions, they are allowed to underwrite on HIV status because it can be justified on statistical and actuarial grounds that the added risk of developing complications is great.

Client's rights

- Not to be tested without informed consent
- Confidentiality with regards to all medical information
- To refuse HIV testing
- Pre-test counselling to indicate the possible outcomes of the testing
- Post-test counselling to indicate what to do should the test be positive or negative.

Client's rights – informed consent

- The client has the right not to be tested without his/her informed consent
- Consent must be given by signing the laboratory form
- Information is available
    - By document in 11 languages
    - Telephonic pre -test counselling in 11 languages
    - ASISA webpage
- If there is no consent form for an HIV test signed by the client, then no test may be performed on that blood specimen.
- If the client does not want the result, or does not give the name of a nominated medical practitioner or call centre to whom the test result can be sent, then the test cannot be done.
- This is for the following reasons:
    - There is an Ethical/moral responsibility on the company to ensure that all HIV positive test results are communicated.
    - The ASISA Protocol ensures that the communication of HIV test results follows a standard

Confidentiality

Who will be notified:

- Results will only be communicated to the nominated doctor;
- The doctor must be nominated in writing on the consent form
- Any change in nominated doctor must be done in writing.

Who else will know the result:

- Within the Insurance company: designated underwriter, Medical Officer. The laboratory will send the result electronically to the insurance company where it will be assigned to the designated underwriter for underwriting. Nobody is allowed to contact the insurance company or the laboratory to find out the result.
- All records are kept strictly confidential, all staff members sign confidentiality agreements
- ASISA register entry in encrypted form which does not allow anyone outside the insurance industry to know the result.

Who will not be notified:

- Your financial advisor.
- Employer
- Spouse
- It is assumed that the client accepts responsibility for who to inform of the result should this be necessary.

The right to refuse undergoing a HIV test

The client has the right to refuse to undergo a HIV tests but the company then has the right to refuse the cover/policy applied for.

Pre-test counselling

- By document
- Available in the 11 official languages, available in all laboratory depots or from the intermediary/broker
- Telephonic pre-test counselling in all 11 languages.

Post-test counselling

- Life Office will pay for one post-test counselling session done by the nominated doctor in the event of a reactive test.
- Confirmatory tests, follow-up consultations and treatment are for the client's own account.
- Importance of the nominated doctor – this is the doctor who will receive the result and convey the message to the client in person. This must be someone the client is comfortable with receiving confidential information. This might not be the usual medical attendant. The insurance industry will only send results to a medical doctor, ~~or~~ designated clinic, or approved call centre nominated by the client.
- Post-test counselling services are also available at no costs through approved call centres if the client has selected this option.

Method of testing

- Currently HIV tests are only performed on blood specimens. Saliva or oral fluid tests are not acceptable because the sample cannot be stored and retested. Reactive blood samples are kept for a minimum of one year by the laboratory in case of queries.

- Accredited methods by Accredited laboratories
- Ensures the highest standards of accuracy, reduces human error as far as possible with automated testing procedures, electronic transfer of results, standardization to ensure all laboratories follow the same processes and protocols.

Process of going for a HIV test

Application submitted -> Underwriting requirements (HIV Test) called -> client notified -> client presents for test – laboratory, own doctor, nurse -> client gives informed consent, nominates doctor-> client identified -> sample taken and identified -> sample goes to laboratory for analysis ->results go to company -> underwriting ; Reactive test –nominated doctor notified in writing, client requested to see his doctor, doctor counsels patient, arrange for confirmatory tests

HIV test

- Antibody and / or antigen test ensures greatest accuracy
- False reactive tests – low probability due to the accuracy of the testing protocol and may be due to a cross reaction with other viruses. Further confirmatory testing may be required. False non-reactive – in the window period which may be as short as 10 days.
- Always get a second test on a second sample
- No diagnosis should be made on a screening test, and further testing should be recommended.

What does a non-reactive test mean?

- No contact with the virus, unless tested in the window period where no antibodies have yet developed, or no viral components can be detected yet.
- Window period is the time between exposure to the virus and the infection showing/being detectable in the blood.
- DOES NOT IMPLY IMMUNITY. If this test is performed in the window periodit means the virus is present but not showing in the blood test performed yet.

What does a reactive test mean?

- May be infected with the virus
- Confirmatory tests necessary which must be performed by the nominated doctor.

Insurance implications of a positive test

- Maintain premiums on existing policies. Existing cover will remain in force as long as the premiums are paid
    - Do not lapse or cancel existing policies
- HIV exclusions are no longer applied on new business and are waived on older policies
- Waiting periods can still apply on funeral policies
- The outcome of the current proposal will be communicated with you by the company involved.
- Products are available for HIV positive people. See the ASISA website www.asisa.org.za for further information.

Do not make hasty decisions

- Think carefully before resigning employment and do not give up group life cover ~~and~~ or any other insurance. If employed ask the confidential advice of the Human Resources department who will be able to advise regarding the group schemes in place.
- HIV is a treatable, manageable disease.

Who must be told about a positive result

- Doctor or health care worker
- Previous, present and future sexual partners

- Support system; - close friend, family member
- There is no need to tell broker, co-workers, manager, employer.

Other financial options

- Some companies offer life cover for HIV positive applicants. Information is available on the ASISA webpage www.asisa.org.za
- Investment type products e.g. endowments and unit trusts. For advice on these products contact your financial advisor.

Identification acceptable by insurance companies for HIV testing:

- South African ID document
- South African passport
- South African Card type driver's licence
- Foreign passport – individual consideration, please contact the company concerned. Your financial advisor will know who to talk to in underwriting.
- Temporary IDs and Driver's licence – individual consideration, contact the company concerned.
- All forms of identification must be the originals and photocopies will not be accepted.

HIV Counselling script for Post-test counselling

SCRIPT FOR HIV REACTIVE CLIENTS FROM THE ASISA CALL CENTRE

Good morning/afternoon Mrs/Mr/Ms XXXXX. You are speaking to XXXXX from the ASISA call centre. I am calling you in connection with your XXXXX ***(fill in the company name)*** application for insurance.

Is it convenient to speak to you now?

YES

Firstly I would like to inform you that all our calls are recorded for quality control.
Before we proceed, may I ask you a couple of questions as security checks?
Please confirm that I am speaking to *(Name, surname)*
Please confirm your ID Number?

_____

Thank you.
Please confirm your residential address?

_____

Thank you.

NO

When may I call you back?
Confirm date and time to be called

_____

Should I phone you on the same number?

YES	NO
Confirm number	Get alternative number and confirm the time and date.

Can you recall what blood tests were done for your policy application?

YES

Yes – HIV/AIDS test.
(If the client states a cholesterol or any other test than HIV was done, remind him of the test and follow the prompts as in the **NO** block)
That is correct.

NO

An HIV test was requested and the blood sample was taken on XXXXX ***(date)***.
Do you recall this?

_____

YES

(NO If the client denies going for a blood test, or is unaware that an HIV test was done terminate the call and refer back to the insurance company)

Can you recall that you requested the **call centre** to contact you about your results?

YES

Are you ready to receive your results?

YES	NO
Proceed with post test counselling	Should we call back later or do you want your doctor to contact you? Call Back : confirm time and number. Doctor: confirm name and contact details (feedback to insurance company) or offer names of doctors who can assist

NO

On the consent form you selected that the call centre contact you with your results. Would you prefer your doctor to discuss these results with you?

YES	NO
Please give me your doctor's name and contact details so that I can forward the results. _____ We will inform your doctor, please make an appointment to see your doctor in a week's time. Feedback to insurance company, normal doctor's letters to doctor	Proceed with script if client is ready to receive the results.

1. **<u>Post-test counselling</u>:**
   - Did you receive counselling on HIV before this blood test was done?
     - No – Do you know what HIV is? (Use pre-test counselling guidelines to ensure member understands what HIV is). *(Proceed with test results once the client understands what HIV is)*
     - Yes – Your tests results were reactive, which means that you may have been in contact with HIV.

2. **<u>Screening tests</u>:**
   This is a screening test. **Please note that you cannot be regarded as being HIV positive before further tests have been done** to confirm the presence of the virus. As with all biological tests false positive and false negative results are possible. False positive tests occur when there is a cross reaction with other viruses or after immunization. False negative results can occur in the 'window period' before the virus causes the body to produce antibodies. (*Call centre can explain this)*

   Further testing on a second sample will distinguish between a true positive or a false positive test result and confirm your HIV status.

3. **Outcome of confirmatory**

   tests: What happens if:

   - The follow-up test is negative: ~~(~~contact insurance company to review application or resubmit a new one. The follow up test must be performed according to the ASISA HIV testing protocol where consent and identification are mandatory in order to reassess the application.
   - The follow-up test is positive (all the issues of post-test counselling, e.g. who do I tell, safe-sex practices, treatment options and facilities etc. Also HIV positive insurance products available on ASISA website)

4. **HIV/AIDS, the disease:**
   - HIV is now **a treatable disease.**
     Treatment has become more affordable and effective. It is important to join an HIV disease management program either via a doctor of your choice or your medical aid or clinic. This will ensure that your disease progress is monitored and that the correct treatment is instituted at the appropriate time. It is also important to follow the doctor's prescription in order to prevent resistance to the medication and progression of the disease.

   - HIV is now an **insurable disease.**
     Certain companies are offering HIV positive life insurance products. The companies are available on the ASISA website or through your financial advisor--------
     It is important to keep current insurance policies, as your existing cover will not be affected by the outcome of this test. Although alternative products are available it will probably be more expensive, so it is in your interest to keep existing cover in force. **You must please consult your financial advisor before making any decisions on your existing cover or future financial planning.**

     Also bear in mind that you may have life cover through your work, so it is important to think about existing cover before you resign your job or change jobs.

5. **Alternative products for people living with HIV:**
   Would you like to get more information about insurance products for HIV positive clients now?
   - No: *Proceed to section 6*

- Yes:
  - Life cover as well as disability cover is available. You may be required to manage your health on an ongoing basis and to comply with prescribed medical protocol *(Please contact the companies offering the cover for further and more detailed information.)*

  - A **healthy life style** is even more important now. A healthy diet, not smoking or drinking, exercise, and safe sex all play a role in staying healthy longer. Safe sex will prevent other sexually transmitted diseases and re-infection with other strains of HIV which will damage the immune system further.

  - A **good support system** is important. Do you have someone that you can tell about this that will support you? *(If the client does not have anyone, refer to a HIV clinician. There is a list of names in all provinces available on www.sahivsoc.org)* You do not need to tell colleagues or anyone at work, but you need to tell current and previous sexual partners and health care workers.

  - You must go for **further testing** and will need to go to a clinic or a doctor to do this. Please note that further testing and treatment (if needed) will be for your own account. Will you be able to do so? Do you need help finding a clinic or doctor? *(The HIV Clinicians Society website can be used for referrals www.sahivsoc.org)*

6. Do you have **any other questions**?
   Would you like us to phone you again tomorrow to see how you are doing? *(If yes, confirm time and number)* If you need further information you can contact *name of counsellor* on 0800 00 00 06.

ANNEXURE 3

APPROVED LABORATORIES

The following laboratories have been approved to perform HIV tests on behalf of the members of the ASISA:

AMPATH, Cape Town
AMPATH, Centurion
AMPATH, Durban
AMPATH, Port Elizabeth
Neuberg Global (Durban)
Neuberg Global (Sunninghill)
Lancet, Bloemfontein
Lancet, Cape Town
Lancet, Durban
Lancet, Johannesburg
Lancet, Nelspruit
Lancet, Pretoria
Pathcare, Bloemfontein
Pathcare, Cape Town
Pathcare, East London
Pathcare, George
Pathcare, Kimberley
Pathcare, Klerksdorp
Pathcare, Port Elizabeth
Pathcare, Vereeniging
Pathcare, Welkom
Toga Edenvale Laboratory
Vermaak & Partners Pathologists
JDJ Diagnostics (Durban)

ANNEXURE 4

APPROVED TEST KITS

First line 4th Generation Combi Protocol:

- Abbott Axsym Combo
- Abbott Architect Combo
- Abbott Alinity i HIV Ag/AB Combo
- Elecsys Roche HIV Combi PT 4th generation test
- Vidas HIV Duo (HIV6) (Seperation Scientific)
- Bio-Rad Access HIV Combo test (on Beckman Coulter DXI and Access)
- Siemens HIV 1/0/2 Ag/AB Combo test
- Roche Elecsys® HIV Duo Assay
- Diasorin Liaison HIV Ab/Ag kit

Second line follow-up tests with a 3rd generation Elisa test for all first line Combi tests that test reactive or low-reactive, may only be done with the following approved Elisa tests:

- Siemens 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

Approved P24-Antigen tests

- Biorad Genetic systems P-24 antigen test
- Vidas HIV P-24 antigen II test (Biomerieux)
- Roche Elecsys P-24 antigen test

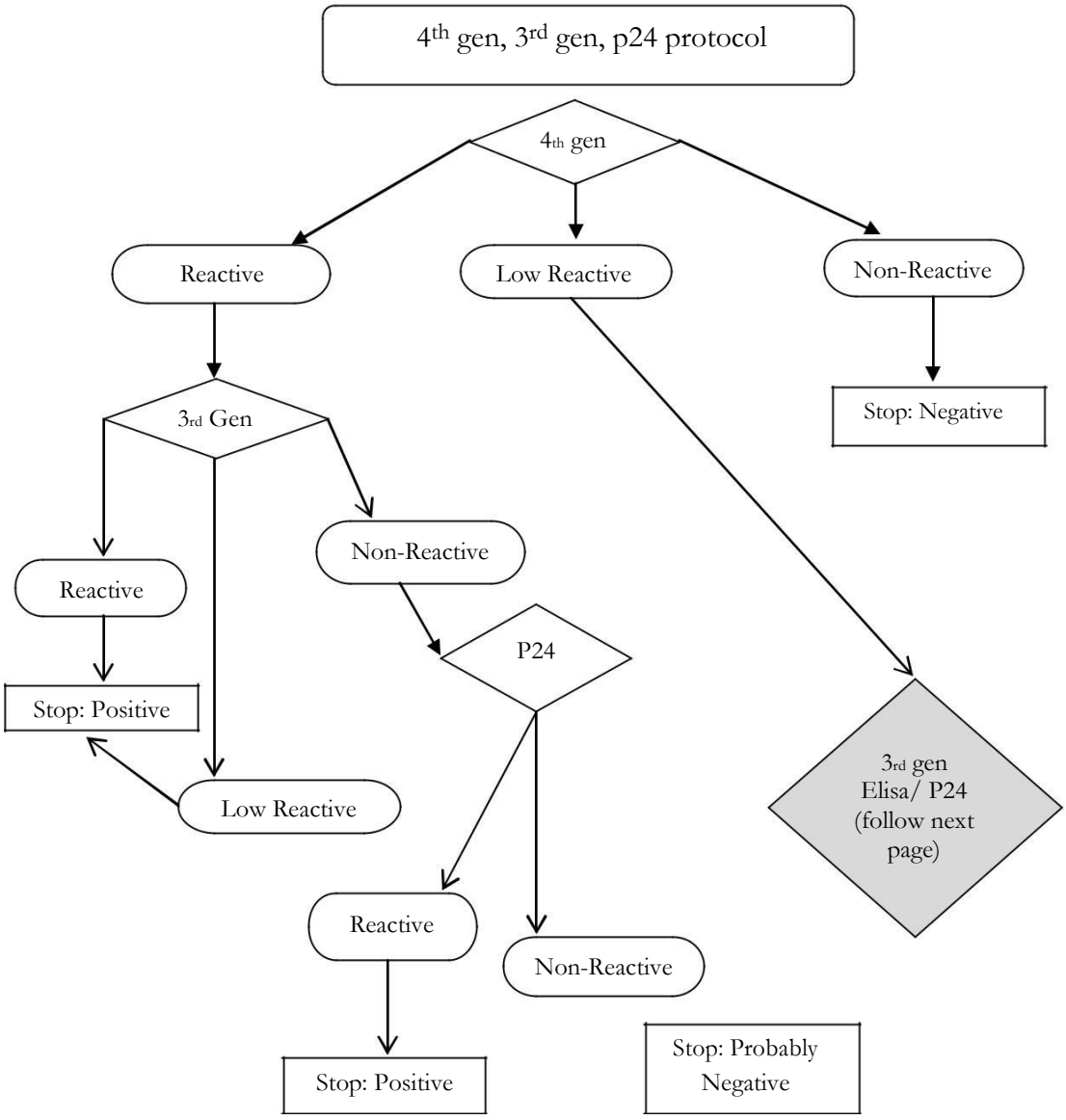
Accredited Rapid Tests

- Alere Determine HIV ½ Ab/Ag Combo
- iMed HIV 1/2 Ab Cassette (Whole Blood) Test
- Toyo Anti-HIV ½ Liaison XL Murex HIV Ab/Ag
- Uni-Gold Recombigen HIV 1/2
- Vikia HIV 1/2
- Homemed HIV 1/2 Single Test Kit
- Healgen HIV 1/2 Ab Cassette with single unitised buffer

Annexure 5

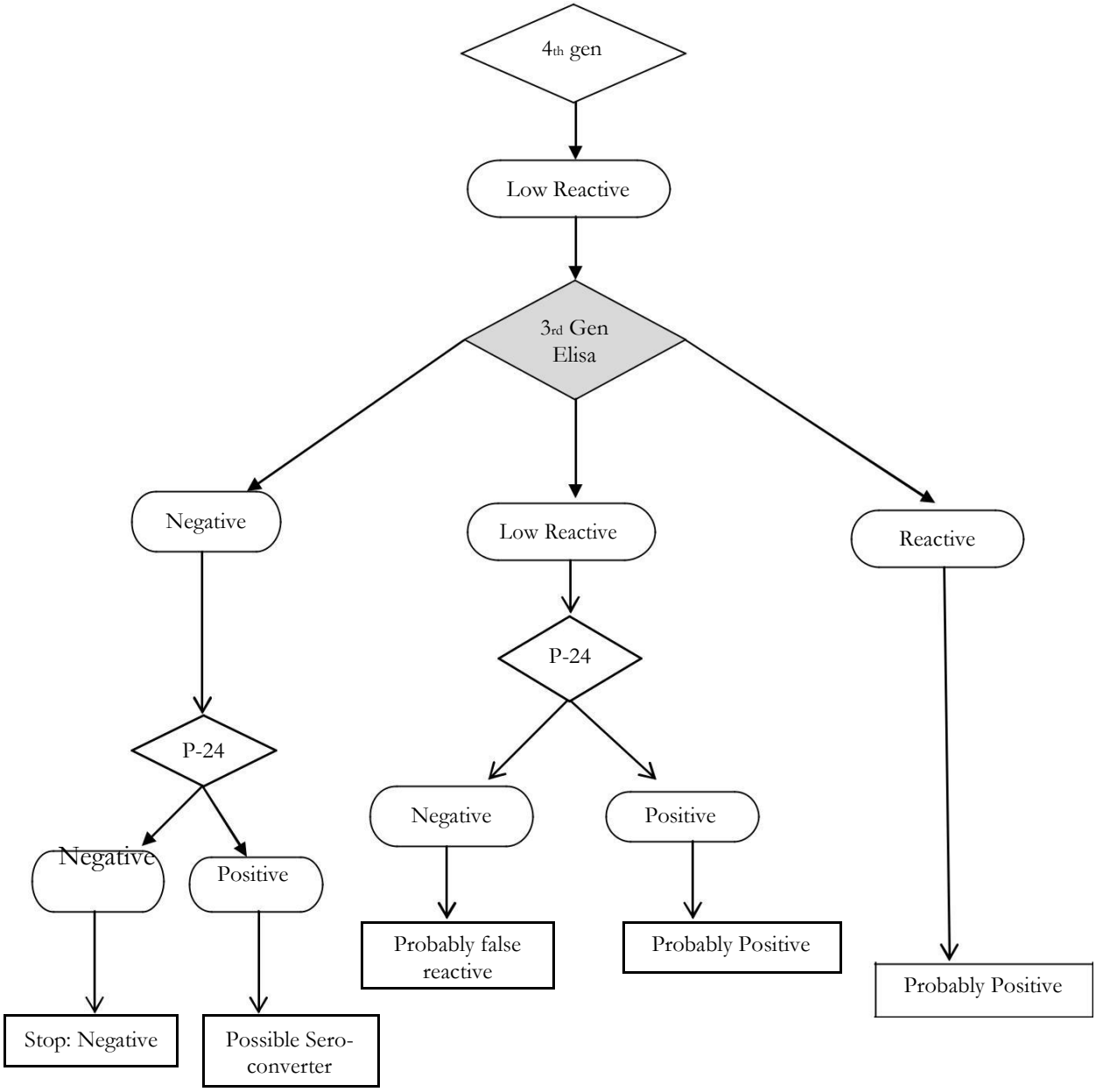
Flowchart 1

4th Generation Protocol (a)



Flowchart 1 (cont.)

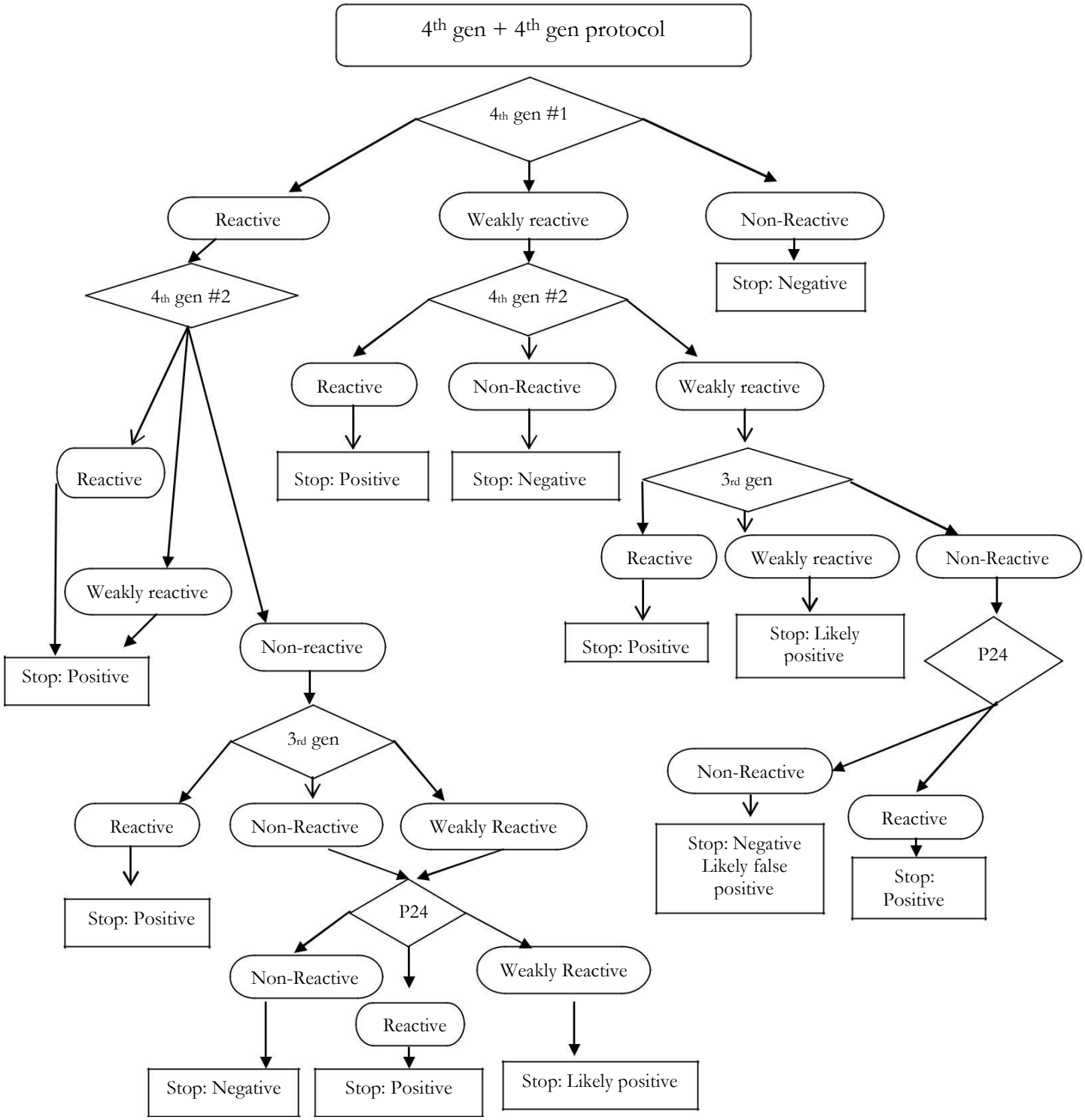
4th Generation Protocol (a)



Annexure 6

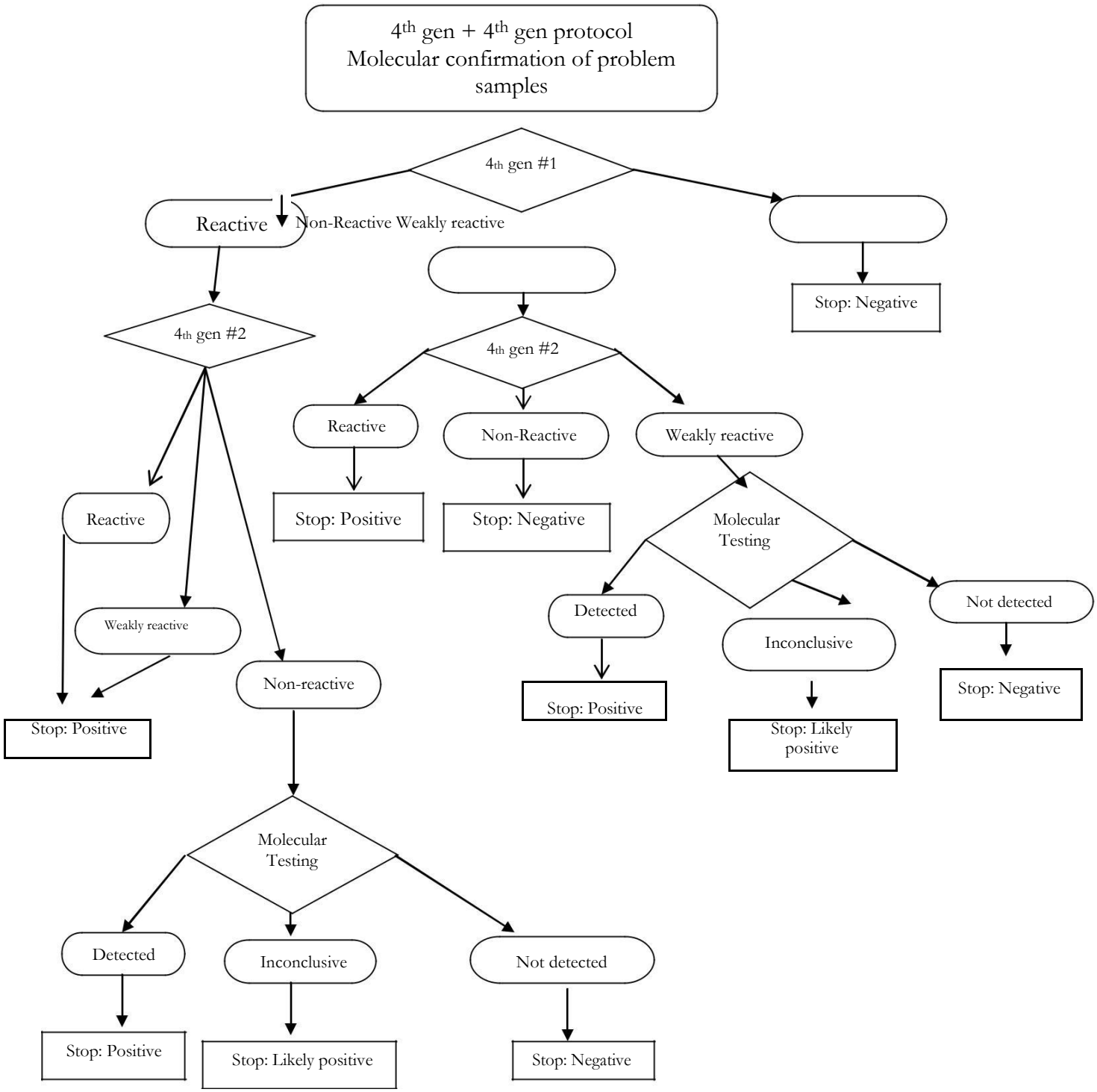
Flowchart 2

4th Generation Protocol (b)



Annexure 7

Flowchart 3



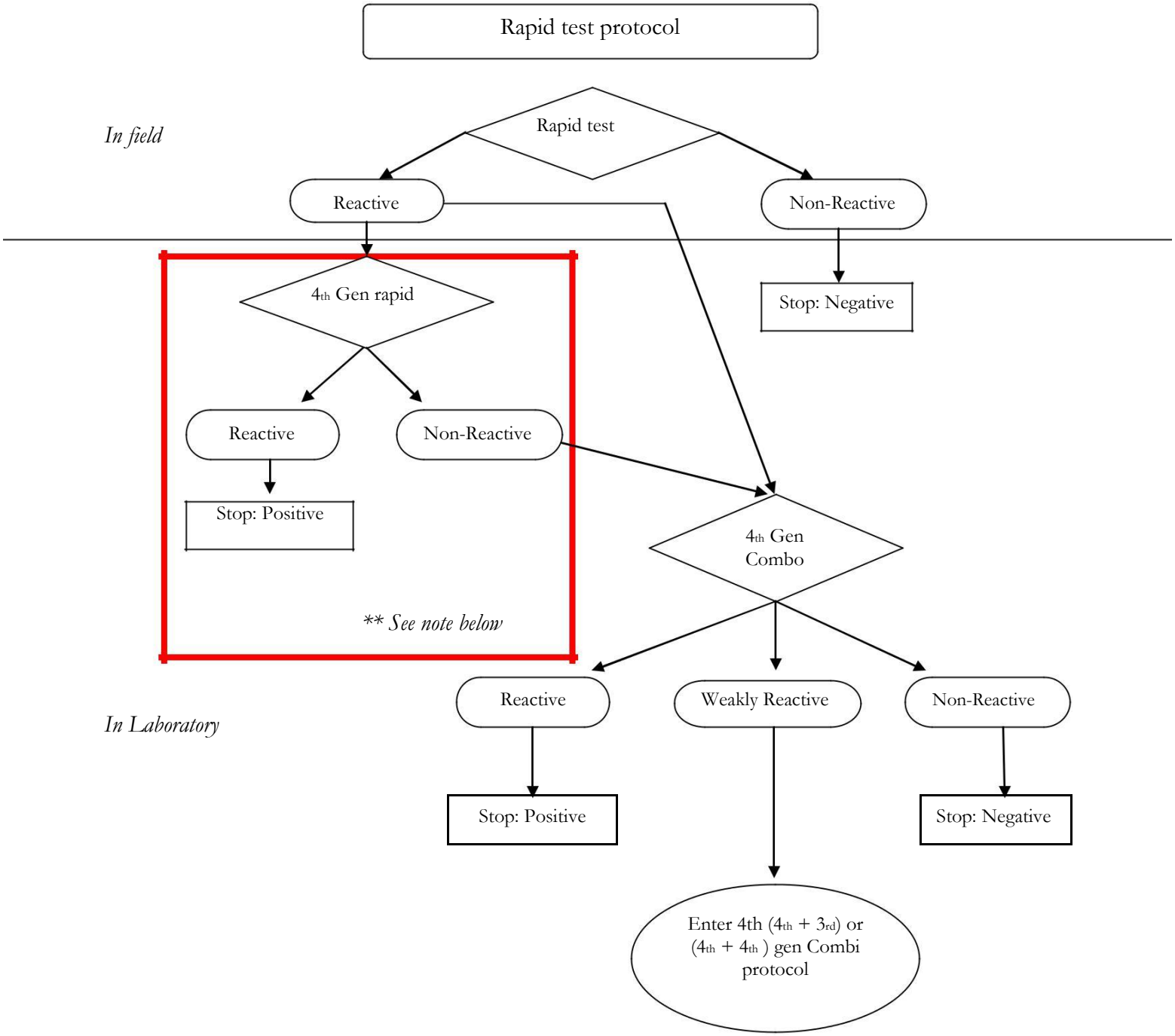
Note 1: The molecular testing may be one of the following methods:

- A proviral DNA PCR
- An accredited adult assay qualitative nucleic acid test (NAT)
- A quantitative RNA viral load test

Note 2: The quantitative viral load test will be reported in copies/mL. Any detectable viral load should be regarded as a positive result, and any undetectable[41] viral load as a negative result.

Annexure 8

Flowchart 4



*** Note: ** Note: The second rapid test in the lab alternative has not been arranged with the laboratories. As some of them may not be able to comply with this, it is recommended that each life office either follows the alternative route of a follow-up Elisa test in the lab, or negotiates the feasibility of a second rapid test with the laboratories themselves.*

ANNEXURE 9

LETTER TO NOMINATED DOCTOR

Use this letter for all cases where the application is accepted (i.e. policy issued), but not all the HIV tests are non-reactive.

Dear Dr …….

CLIENT: ……

DATE OF BIRTH: ….……

APPLICATION NUMBER: ..…….……

This person proposed for insurance with our company. An HIV test was performed and a copy of the result is enclosed for your records.

This person's application for cover was accepted. We are sending this information to you as some of the HIV tests were not non-reactive, and may need further action from a clinical perspective. 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 10

LETTER TO CLIENT

Use this letter for all cases where your company decides to decline the application for insurance, 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.

If you have nominated a doctor, clinic or hospital to receive any abnormal test results, we strongly recommend that you contact this nominated person or institution, who is being provided with copies of your test results. If however, you nominated a Call Centre to receive any abnormal test results, they will be contacting you on the number you have provided.

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

Yours faithfully

CHIEF MEDICAL ADVISOR / CHIEF UNDERWRITER

ANNEXURE 11

LETTER TO NOMINATED DOCTOR FOR POST-TEST COUNSELLING

Use for any application that your company decides to decline, 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 receive any abnormal test results. A copy of the patient's HIV test is enclosed. We 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. 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. If our initial screening test has been confirmed as 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 and submit the follow-up tests results.

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

- it was done with the proper identification according to the ASISA 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, the client may wish to contact the Association for Savings and Investment SA at (021) 673-1620 or access the website, www.asisa.org.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) OR POLICY NUMBER: **CLIENT:**

Signature of the client: .....

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

ANNEXURE 12

INTERPRETATION OF HIV TEST RESULTS FOR INSURANCE PURPOSES

Most applicants undergo SCREENING tests to detect possible exposure to the HIV virus.

The protocols go to great lengths to minimize possible false positive tests and human error. Copies of the protocols are available on the ASISA website, http://www.asisa.org.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 exceed 97%. It is therefore clear that both false positive and false negative results may occur although by exception. 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.

For your convenience, we have attached guidelines on how to interpret the test results.

Further diagnostic tests on a second blood sample are 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.

RESULT INTERPRETATION: 4^{TH} GENERATION COMBI TEST PROTOCOL.

The 4^{th} 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 mindful of not increasing 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 implemented. 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.

Instruction to life offices:

INSERT ANNEXURE 5 (two pages of flow diagrams) and ANNEXURE 6 (one page of flow diagram) for the information of the doctor, to aid with the interpretation of the results.

ANNEXURE 13

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. We have contacted your patient and asked him/her to contact you.

Please note that your patient is a participant in a HIV vaccine trial. A significant proportion of patients receiving a HIV vaccine, will develop sufficient antibodies to render a 4^{th} Generation combination test positive (reactive). To exclude a possible co-existing natural infection with the HIV virus, all positive (reactive) 4^{th} Generation 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 HIV positive (reactive) due to the vaccine received, should test PCR negative. A positive PCR test result indicates a co-existing 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. If our initial PCR test result is confirmed with a follow-up test 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, an underwriting decision has been made. If follow-up tests prove your patient to be HIV-negative, he/she can ask for the decision to be reviewed 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 ASISA protocol at the pathologists, and
- it includes a second PCR 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, your patient may wish to contact the Association for Savings and Investment SA (ASISA) at (021) 673 1620 or access the website, www.asisa.org.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) / POLICY NUMBER: **CLIENT:**

Signature of the client: _____

Date of consultation: _____ Practice number: _____

ANNEXURE 14

1. Pre- and Post-test counselling Call centres

Pre- and post-test counselling services are available in all official languages as a toll-free service at the following number:

- ASISA Call Centre 0800 562 562

2. List of approved personal pre-test counselling service providers

If the client elects to have a personal pre-test counselling session the following numbers can be used to find the available facilities:

- Du Boisson
  - Ampath 614 Pretorius Str, Pretoria 012-427 1812
- Global laboratory 031-904 0500
- Lancet Durban 031-308 6500
- Lancet Nelspruit 013-745 9000
- Lancet Pretoria (Eugene Marais) 012-404 0560
  - Wonderboom Intercare 012-543 0668
  - Louis Pasteur 012-442 0060
  - Medforum 012-322 5880
  - Heart Hospital 012-341 7470
  - Pencardia sisters 012-483 0113
  - Muelmed 012-341 7399
  - Eting 012-344 5956
  - Little Company of Mary 012-424 9540
  - Unitas 012-644 9440
  - Zuid-Afrikaans 012-3438434
  - Sunnyside 012-3416051
  - Glenfair 012-365 2267
- Metropolis Main laboratory 021-551 6372
  - Metropolis Bellville depot 021-910 1006
  - Metropolis Vincent Pallotti 021-531 4985
  - Metropolis Christiaan Barnard 021-424 1390
  - Metropolis Library Square 021-671 0759
  - Metropolis Mutual park 021-531 0050
- Toga Laboratory
  - Harmelia Health Stop 011 663 6575