ASISA HIV TESTING GUIDELINE

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INDEX

These guidelines are made up of seven sections namely:

Annexures:

1. INTRODUCTION

1.1. HIV presents a primary burden of disease in South Africa.

1.2. The purpose of the HIV Testing Guideline ("**Guideline**") is to recommend best practice guidelines for HIV screening and testing in the life insurance sector.

1.3. This Guideline has accordingly been established in the interests of consumers

1.4. This Guideline applies to all HIV tests performed by ASISA members. It addresses issues such as identification, confidentiality, informed consent, pre- and post-test counselling, transmission of test results and approval of test kits and laboratories.

1.5. The Guideline is being shared with ASISA members and the public at large for their consideration and voluntary implementation, and is non-binding on ASISA members.

2. GOALS OF THE GUIDELINES

The goals of this Guideline are:

2.1. to minimise false-reactive results and the resultant emotional trauma to the client;

2.2. to encourage the utilisation of tests that meet specified sensitivity and specificity levels;

2.3. to restrict of false negative results to an absolute minimum;

2.4. to facilitate the mandatory identification of the person whose sample has been taken;

2.5. to encourage the maintenance of confidentiality of results

2.6. 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.

2.7. to encourage the taking of proper steps to identify and treat participants in vaccine trials appropriately.

3. GENERIC PRINCIPLES

It is recommended that all HIV tests used for insurance purposes meet all of the following generic criteria:

3.1. THE PROCESS

3.1.1. Identification

To be done according to this Guideline.

3.1.2. Pre-test counselling

Clients to be offered the ASISA HIV information document, Annexure 1.

3.1.3. Informed Consent

Clients to sign voluntary informed consent as specified in the Guideline, see Annexure 1.

3.1.4. Nomination of party to receive result

Clients to nominate a party as recommended by the Guideline in paragraph 4 to receive reactive results.

3.1.5. Sample collection

3.1.5.1. Sample collection should be done only by persons recommended by the Guideline for such purposes.

3.1.5.2. All samples should be identifiable as the specific client's sample after collection.

3.1.5.3. If a blood specimen is to be sent to the laboratory, the sample should be sufficient to allow for second- and third-line testing in cases of reactive first line tests.

3.1.5.4. Blood specimens should be suitable for storage for the minimum period as per the Guideline (reasons include possible re-testing in cases of dispute, fraud, etc).

3.1.6. Transport of samples

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

3.1.7. Laboratory testing facilities

3.1.7.1. In-house testing by ASISA members

- Each member is liable for its own quality control measures.

3.1.7.2. External laboratories

- All HIV testing laboratory facilities should be approved 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 should be done as specified in the Guideline.

3.1.8. Interpretation of test results

The interpretation of the test results by insurers should be done according to the Guideline, however the underwriting of each test result should be done according to each insurers' own underwriting guidelines.

3.1.9. Communication of results

Only the nominated person authorised by the client to receive the reactive result, should communicate with the client, and do the post-test counselling.

3.2. TEST SPECIFICATIONS

Any HIV test not listed in **Annexure** 3 as an approved test will be considered by the ASISA Medical and Underwriting Standing Committee ("**MUSC**"), according to the following

guideline:

Irrespective of the type of test used, any test should conform to the following minimum criteria:

1. Test sensitivity: 99%

2. Test specificity: 99%

All testing methods will be submitted to an expert consultant for validation.

4. PRE-TEST PROCEDURES

It is recommended that the following principles in terms of identification, counselling options, informed consent, nomination of party to receive results, sample collection and transport of samples are adhered to irrespective of the test methodology followed.

4.1. Identification

It is recommended that:

4.1.1. When an HIV test is requested, the sales intermediary informs 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 healthcare provider to receive the HIV test result.

4.1.2. The following identity documents are acceptable:

4.1.2.1. valid original South African identity document or passport, issued by the Department of Home Affairs;

4.1.2.2. valid official South African Card-type driver's license.

4.1.3. Temporary ID documents should be dealt with at the discretion of each member.

4.1.4. Foreign passports should be dealt with at the discretion of each member.

4.1.5. The use of copies of identity documents are not recommended, regardless of whether such documents are certified or not.

4.1.6. 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 is to be noted on the form and reported to the insurer together with the test result.

4.1.7. Refugee documents should be dealt with at the discretion of each member.

4.2. Counselling options

It is recommended that:

4.2.1. Every client be offered pre-test counselling by reading a copy of the HIV testing information sheet.

4.2.2. The wording of the HIV testing information sheet attached as Annexure 1 is used and that it is not altered, except in consultation with the ASISA MUSC.

4.2.3. The client receives this sheet from the sales intermediary but, failing this, it is be provided by the person collecting the specimen. Member offices should ensure that this documentation (either paper or electronic versions) is made available to those parties collecting specimens, and sales intermediaries.

4.2.4. Post-test counselling services may be done through the client's nominated healthcare provider.

4.3. Informed consent

It is recommended that:

4.3.1. Each client signs a voluntary informed consent to undergo a HIV test, see Annexure 1B.

4.3.2. If the client is not prepared to sign the consent, the sample is not collected.

4.4. The nomination of a party to receive the result

4.4.1. It is recommended that each client nominates a party to receive reactive results. These parties should at least be able to:

4.4.1.1. receive, handle and store the results confidentially;

4.4.1.2. do adequate post-test counselling;

4.4.1.3. arrange for confirmatory testing;

4.4.1.4. institute treatment when indicated or refer the client to an appropriate facility for this purpose.

4.4.2. These parties may be one of the following:

4.4.2.1. family practitioners;

4.4.2.2. independent medical practitioners;

4.4.2.3. other healthcare providers.

4.5. Sample collection

It is recommended as follows:

4.5.1. Sample collection is done only by persons approved by the Guideline for such purposes:

4.5.1.1. medical practitioners;

4.5.1.2. aualified nursing sisters;

4.5.1.3. staff nurses;

4.5.1.4. registered phlebotomists.

4.5.2. All venesection samples be identifiable as the specific client's sample after collection, containing at least the clients' initials and surname.

4.5.3. For finger prick testing, photographic identification is captured.

4.5.4. The venesection sample be sufficient to allow for second and third line testing in cases of reactive first line tests.

4.5.4.1. The sample should be suitable for storage for the minimum period to allow for re-testing. Reasons include for example cases of dispute, or fraud.

4.5.4.2. The minimum storage period in cases of reactive results is 6 months.

4.5.4.3. The minimum storage period in cases of non-reactive results is 2 weeks.

4.5.5. HIV Testing should be done on a whole blood sample obtained by venesection or finger prick.

4.5.6. In terms of the Guideline, the following types of samples are recommended for insurance HIV testing:

Whole blood samples:

4.5.6.1. For venesection, one tube of clotted blood should be collected from all applicants for purposes of testing for HIV by the methodologies as described below. 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.

4.5.6.2. It is important that one tube of EDTA (purple capped tube) blood also be collected from applicants who are/have been participants in an HIV vaccine trial. This EDTA sample is required for a Polymerase Chain Reaction Test (PCR) in cases where the Elisa (serology) Immuno-Assay test is reactive in persons who have received a vaccine.

4.5.6.3. Finger prick sampling is allowed for first line screening testing. If this test result is non-reactive no further testing is required and the result is

documented for underwriting purposes. Any other test result will require a venesection sample for laboratory testing. It is recommended that a clotted blood sample and an EDTA tube are submitted. The laboratory will follow the normal procedure as set out in section E1 as if no prior testing was performed.

Oral fluid samples:

These are not recommended 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.

4.6. Transport of venesection samples

It is recommended that:

4.6.1. samples be packaged individually with the relevant documentation to ensure that the chain of custody is maintained;

4.6.2. samples be transported in such a manner to meet the requirements of the manufacturer of the test kit.

5. TESTING PROCEDURES

5.1. LABORATORY TESTING

5.1.1. Approval of laboratories

It is recommended that:

5.1.1.1. All laboratories be approved by ASISA to perform HIV tests for insurance purposes and that any decisions be made on the basis of approval guidelines set by ASISA MUSC from time to time.

5.1.1.2. All applications for approval be directed to the ASISA office. The list of approved pathology laboratories is in Annexure 2.

5.1.1.3. Laboratories only use the HIV testing kits approved by ASISA as listed in Annexure 3 for insurance HIV testing.

5.1.2. **Laboratory receipt of specimens**

It is recommended that:

5.1.2.1. If no documentation is received with the blood specimen by the laboratory, the laboratory refuses to perform the HIV test.

5.1.2.2. If the blood specimen and documentation are received from any source other than those persons approved in Paragraph 4.5.1, the laboratory refuses to conduct the HIV test and discards the blood specimen.

5.1.2.3. If the laboratory does the HIV test in the absence of the required documentation, the member office ignores the result, and no fee is payable. A further test is recommended, to be conducted in terms of the Guideline.

5.1.3. **Methodology**

It is recommended that:

5.1.3.1. An ASISA approved laboratory only uses the 4th Generation Combi HIV testing protocol for insurance HIV screening.

5.1.3.2. This protocol uses one of the ASISA approved 4th Generation Combination HIV tests (Combi test) as a first screening test.

5.1.3.3. The first Combi screening test analysis system identifies a specimen by its bar code and test the sample using the primary tube. All pipetting procedures should be fully automated for the first Combi screening test.

5.1.3.4. Primary tube sampling and automated test procedures are also recommended for the second and third tests.

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

5.1.3.6. Please see Annexure 3 for the approved first line 4th Generation Combi tests.

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

Test	Supplier	Reference range	"Low reactive value"
Elecsys Roche HIV Combi PT 4th generation test	Roche	< 0.90 = Non-reactive 0.90 – 1.1 = Greyzone > 1.1 = Reactive	0.9-10
Architect Combo	Abbott	< 1.00 = Non-reactive ≥ 1.00 = Reactive	1-10
Axsym Combo	Abbott	< 0.90 = Non-Reactive 0.90 – 0.99 = Greyzone ≥ 1.00 = Reactive	0.9-10
Vidas HIV Duo (HIV6)	Omnimed	< 0.25 = Negative ≥ 0.25 - < 0.35 = Borderline ≥ 0.35 = Positive	0.25-3.0
Bio-Rad HIV Combi (Dxl/Access)	Bio-Rad	< 0.9 = Non-Reactive 0.9 - <1.0 = Gray-zone 1.0 and > 1.0 = Reactive	0.9 - 10
Centaur CHIV v Combo	Siemens	0 to 0.29 = Non-reactive	1 - 10

		0.30 to 0.99 = Grey zone >1.00 = Reactive	
Abbott Alinity i HIV Ag/AB Combo	Abbott	< 1.00 = Non-reactive < 1.00 = Non-reactive	1-20
Diasorin HIV Ab/Ag		< 1.00 = Non-reactive ≥ 1.00 = Reactive.	1. Antibody 1-30 and HIV Ab/Ag ≥ 1.00 = Reactive antigen non-reactive. 2. Antigen 1-30 and antibody non-reactive. 3. Antibody 1-30 and antigen 1-30

The Guideline does not lend itself to equivocal results.

5.1.4. **HIV vaccine trial participants**

It is recommended that, 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 does a PCR test on any case yielding a reactive Elisa (serology) 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.

6. REPORTING RESULTS

Finger prick testing results: If the result is non-reactive the client should be regarded as HIV negative. The client may be informed if they request the result. Any other result should be regarded as indeterminate and should be followed up by a venesection sample sent to the laboratory. This sample should be regarded as a first test sample by the laboratory. It must be emphasized that this

is a screening test only and no client can be regarded as HIV positive until confirmatory testing has been done. It is recommended that the algorithm in Annexure 4 is followed.

6.1. Format of laboratory results

It is recommended as follows:

6.1.1. The results of the first line 4th Generation HIV Combi test be reported as either non-reactive, low 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.

6.1.2. For the purposes of this Guideline, molecular testing means acceptable molecular testing as per SANAS accreditation.

6.2. Reporting results from laboratory to insurer

6.2.1. Member offices are responsible for ensuring confidentiality in their offices. The recommended method for reporting all results is via electronic means. All results should be sent confidentially to the insurer; reactive results should be sent to the designated contact person in the insurer assigned to dealing with HIV reactive results.

7. POST-TEST PROCEDURES AT THE LIFE OFFICE

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

4th Generation Combi Protocol

See Annexure 4.

Test procedures on HIV Vaccine trial participants

7.1. A person who has received an 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 (serology) HIV test positive (reactive). The implications of this are ordinarily that:

7.1.1. the person has not contracted AIDS/HIV;

7.1.2. the test is actually false positive (reactive) due to the vaccine.

7.2. As a person who has participated in an HIV 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 (serology) test will not be able to distinguish between these possibilities.

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

7.4. It is recommended that interpretation of the PCR tests results in these cases be as follows:

7.4.1. A reactive HIV Combo test and negative PCR tests indicate that:

7.4.1.1. the combo test is reactive due to the vaccine;

7.4.1.2. the client has not been infected by HIV.

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

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

The same procedure as for reactive tests should then be followed.

ANNEXURE 1A

ASISA HIV TESTING INFORMATION SHEET

IF YOU HAVE ANY PROBLEM UNDERSTANDING THIS DOCUMENT, ASK THE NURSE OR OTHER HEALTHCARE PROVIDER TO EXPLAIN IT TO YOU.

WHAT ARE MY RIGHTS?

You have the following rights:

1. ***Not to be tested*** for 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 an alternative product and it is suggested that you consult with a 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. This information sheet provides you with the necessary information to constitute pre-test counselling.

5. ***To nominate a healthcare provider to receive reactive results.***

6. ***To have your test result treated confidentially.*** An abnormal test result will be made available to your nominated healthcare provider and this test result may also be stored on a 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 HIV.

IS THE TEST ALWAYS CORRECT?

Even though the tests are very accurate, they must be regarded as screening tests only and not diagnostic. If a test result is reactive, further testing must be done to confirm the status.

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. No party can be held responsible for false positive results including the laboratory, or the insurance company. The true HIV status of the person can be ascertained by doing further tests. The insurance companies and laboratories follow strict procedures to eliminate potential inaccurate results. To minimize false positive results being communicated to the client, further testing must be performed on all initial reactive tests. However, all tests done by the insurance company must be regarded as screening tests and further testing must be performed by the client.

WHAT DOES IT MEAN IF THE TEST IS NON-REACTIVE?

If your test result is non-reactive, 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.

WHAT DOES IT MEAN IF THE TEST IS REACTIVE?

If your test result is reactive, it is regarded as an inconclusive result meaning either that you may be infected with HIV or this is a false positive result. If this testing indicates you are HIV positive, you will be notified about the outcome of your policy application by the company involved. In order

to confirm your inconclusive status, further testing must be done. If it is shown that there was a false positive result, the company may reconsider a further application for insurance. For new applicants who are HIV positive insurance products are available. This should be discussed with your financial advisor. All your existing cover will remain valid.

NOTIFICATION OF RESULTS

If your test result is negative:

Your application will be assessed, and the outcome communicated to you.

If your test is reactive:

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 healthcare provider who should receive the results. You will be advised to contact this person.

Please note that if you receive a letter to contact the nominated healthcare provider, this does not automatically mean that the HIV test result is positive. The healthcare provider will be fully informed and will inform you accordingly.

FOR ANY GENERAL QUERIES REGARDING HIV, CALL THE AIDS HELP LINE: 0800-012-322.

ANNEXURE 1B

HIV INSURANCE TESTING CONSENT FORM

A. INFORMED CONSENT TO HIV TESTING TO BE COMPLETED BY APPLICANT

☐ I understand the information contained in the ASISA HIV testing information sheet.

☐ I freely consent to the collection of my blood sample, whether by finger prick and/or venesection, 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 healthcare provider, 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 healthcare provider, for further information and counselling if required.

☐ I understand that your Life Company will pay for one session of post-test counselling with a healthcare provider of my choice, if I desire it, and if the test result is reactive.

☐ 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 on a central register.

☐ I hereby confirm that all my questions and queries were answered satisfactorily.

Name of nominated healthcare provider: _____

Address: _____

_____ Postal Code: _____

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 *(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 Guidelines, 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

APPROVED LABORATORIES

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

AMPATH laboratories

Du Buisson & Partners

JDJ Diagnostics, Durban

Lancet laboratories

Motion Pathology, Pretoria

Neuberg Global laboratories

Pathcare laboratories

Proteus Laboratory, Ekurhuleni

Toga Laboratory, Edenvale

Universal Pathology Laboratory, Durban

Van Rensburg Pathologists, Bloemfontein

Vermaak & Partners Pathologists

ANNEXURE 3

APPROVED TEST KITS

First line 4th Generation Combi Protocol:

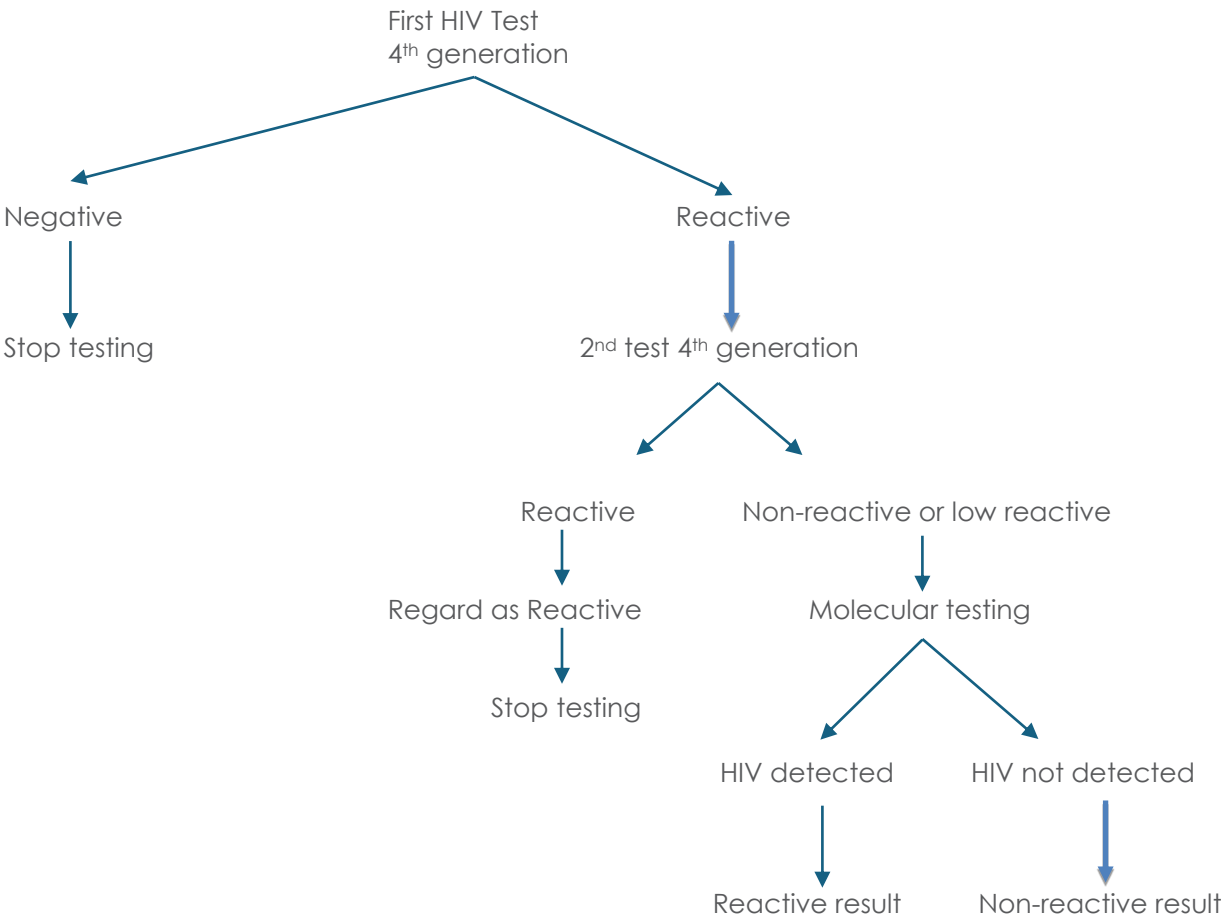
- Abbott Axsym Combo
- Abbott Architect Combo
- Elecsys Roche HIV Combi PT 4th generation test
- Vidas HIV Duo (HIV6) (Seperation Scientific)
- Bio-Rad Access HIV Combo test (on Beckman Coulter DXI and Access)
- Siemens HIV 1/0/2 Ag/AB Combo test

Accredited Rapid Tests

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

Acceptable Molecular testing as per SANAS accreditation.

ANNEXURE 4


First HIV Test
4th generation
Negative
Stop testing
Reactive
2nd test 4th generation
Reactive
Regard as Reactive
Stop testing
Non-reactive or low reactive
Molecular testing
HIV detected
Reactive result
HIV not detected
Non-reactive result

ANNEXURE 5

LETTER TO NOMINATED HEALTHCARE PROVIDER

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 …….

CLIENT: ……

DATE OF BIRTH: …..……

APPLICATION NUMBER: ..……..……

This person is 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 6

SAMPLE LETTER TO THE CLIENT

This example can be used for all cases where your company decides to decline the application for insurance, irrespective of how many tests are reactive or low-reactive.

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 or other healthcare provider to receive any abnormal test results, we strongly recommend that you contact this nominated person, who is being provided with copies of your test results.

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

Yours faithfully

CHIEF MEDICAL ADVISOR / CHIEF UNDERWRITER

ANNEXURE 7

SAMPLE LETTER TO NOMINATED HEALTHCARE PROVIDER FOR POST-TEST COUNSELLING

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 healthcare provider 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 utilized by the Insurance Industry is a screening procedure. 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 regarding 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 Guidelines at the pathologists, and
- it includes a diagnostic test,

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

Yours faithfully

Chief Medical Officer

PLEASE RETURN TO ME FOR PROMPT PAYMEN

APPLICATION(S) OR POLICY NUMBER: **CLIENT:**

Signature of the client: .....

Date of consultation:

..... **Practice number: .....**

ANNEXURE 8

INTERPRETATION OF HIV TEST RESULTS FOR INSURANCE PURPOSES

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

The HIV Testing guidelines go to great lengths to minimize possible false positive tests and human error. A copy of these guidelines is 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 99%. 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 *(attach Annexure 4 of the Guidelines)*.

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: 4TH GENERATION COMBI TEST PROTOCOL.

The 4th 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.

ANNEXURE 9

PCR TEST RESULT POSITIVE ON HIV 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 4th Generation combination test positive (reactive). To exclude a possible co-existing natural infection with the HIV virus, all positive (reactive) 4th 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 HIV Testing guidelines at the pathologists, and
- it includes a second PCR test

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

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:** _____

DOCUMENT HISTORY

Date	Publication/Amendments
26 October 2021	Changed from a Standard to a Guideline
26 July 2024	Competition Law Review

RESPONSIBLE COMMITTEES AND SPA

Responsible Board Committee	Life & Risk BC
Responsible Standing Committee	Medical & Underwriting Standing Committee
Responsible SPA	Point Person to the Life & Risk BC