Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Prevention and Public Health Services Directorate
Communicable Diseases Division

HIV Testing Guidelines 2025

Version 3, 03.09.2025

1. Introduction

Early on in the HIV epidemic, the Federal Office of Public Health (FOPH) developed an HIV Testing Policy in a bid to guarantee standardised, high-quality HIV diagnostics and to ensure that every new HIV diagnosis is reported to the authorities. To implement the policy, a three- level organisational structure was defined and/or set up: screening laboratory, HIV confirmatory/reporting laboratory, and a Swiss National Reference Center for Retroviruses (SNCR). The revised and updated policy was last amended in 2013 [1]. The HIV Testing Policy guaranteed high-quality HIV testing and diagnostic certainty, as well as optimal patient care following an HIV diagnosis. This was achieved by not only testing for the presence of an HIV infection, but also determining the characteristics of the virus (type, O viruses, resistance to antiretrovirals); whether the measured viral load is plausible or potentially underestimated, and the proportion of recent infections among newly-diagnosed cases.

However, in its organisation, this system of an initial comprehensive laboratory test combined with the pooling of HIV laboratory reports was complex, challenging, time-consuming and entailed follow-up costs. The availability of highly-effective combination antiretroviral therapy, and the knowledge that early treatment can prevent transmission and that people with an undetectable viral load do not transmit the virus [2] have drastically changed the environment and the demands of HIV testing compared to the early days of the HIV epidemic. Alongside the improvements in antiretroviral therapy, in-vitro diagnostics for the detection and monitoring of HIV infections have also been further developed. CE-marked tests[1] have been continually improved by manufacturers so that now – if used correctly – only in very rare exceptional cases can an HIV infection not be reliably diagnosed or ruled out.

The organisation and procedure of HIV diagnostics set out in the HIV Testing Policy is no longer considered the optimal solution to meet future challenges. The FOPH, in collaboration with the relevant working group of the Federal Commission for Issues relating to Sexually Transmitted Infections (FCSTI) and the Swiss National Center for Retroviruses (SNCR), has therefore decided to abolish the previous HIV Testing Policy that was applied as a regulation, and to replace it with HIV Testing Guidelines.

2. The HIV Testing Guidelines

The HIV Testing Guidelines lay the foundation for rapid and high-quality HIV testing and therefore swift referral of newly-diagnosed patients to a doctor for treatment. They describe the process to follow in the event of a suspected HIV infection which applies to everyone aged 18 months and over. Diagnostic testing in the context of needlestick injuries is regulated elsewhere [3] and does not fall under the HIV Testing Guidelines. The diagnosis of newborn babies born to HIV-infected mothers is not covered by the Testing Guidelines either, but still follows the recommendations published in 2018 [4].

To effect this changed focus in HIV diagnostics, the new HIV Testing Guidelines comprise a number of

[1] The CE marking indicates that a product has been assessed by the manufacturer and found to comply with European Union (EU) requirements for safety, health and environmental protection.

substantial changes compared with the previous Testing Policy. They concern authorisation to perform HIV testing, the requirements of the diagnostic process in the laboratory, responsibility for ordering diagnostic confirmation in the area of HIV testing, and the notification procedure.

2.1. New organisation of HIV laboratory diagnostics

HIV testing is being brought into line with the guidelines for other viral infections. When the HIV Testing Guidelines are introduced, the HIV Testing Policy and its structures will be repealed, in other words the roles of the HIV screening laboratory and HIV confirmatory laboratory/reporting laboratory will be abolished. Instead, under the new HIV Testing Guidelines, every laboratory that holds an establishment license issued by Swissmedic as a microbiological laboratory is authorised to perform HIV confirmatory diagnostics.

Pursuant to Article 17 of the Federal Act of 28 September 2012 on the control of communicable diseases in humans (Epidemics Act, EpG; RS 818.101), the FOPH has designated a national reference centre for retroviruses. The list of national reference centres for notifiable communicable diseases can be found on the FOPH website.

2.2 Separation of diagnosis and patient care

The linkage of diagnosis and patient care, which is monitored and coordinated by the HIV confirmatory laboratories under the existing HIV Testing Policy, is being discontinued. For HIV diagnostics, new general conditions will be defined and responsibility for diagnosis and patient care will be subject to new regulations.

In terms of testing for an HIV infection; the laboratory is responsible for performing the necessary analyses correctly and fully, as well as for the conclusive assessment and diagnosis.

As part of the basic assessment, the primary care physician is responsible for patient care, timely verification of the HIV infection based on a secondary sample, and for carrying out an HIV resistance test. The HIV infection is usually verified through a detectable viral load. If the HIV infection cannot be verified as part of the basic medical assessment, it is the doctor’s responsibility to contact the laboratory or the SNCR and to have the HIV diagnosis verified.

Doctors play a particularly important role for people who have recently settled in Switzerland and who were already diagnosed with HIV abroad. These cases must also be reported, and the diagnosis of an HIV infection must also be verified in these patients. In such cases, doctors are responsible for supplying the laboratories with this medical history information.

2.3. HIV diagnosis with one submission

Under the HIV Testing Guidelines, the conclusive diagnosis is made from a single submission. This requirement is due to the tight time window for HIV diagnosis. It is therefore mandatory that the samples needed for all tests are delivered in one submission. Ideally, the entire HIV diagnosis can be carried out with one EDTA tube of blood. If native blood/serum is required for the tests or other laboratory analyses in the same order, a combination of native blood/serum and EDTA blood can be provided in one submission.

The laboratories are responsible for implementing this requirement.

2.4. HIV diagnosis procedure

Under the new HIV Testing Guidelines, diagnosis of an HIV infection in Switzerland is still based on a two-stage process with at least two positive test results using two different testing principles. To describe the laboratory diagnostics, laboratories will be provided with a universally applicable algorithm with decision-making criteria (Annex A: figure 1).

The HIV testing process always starts with at least a fourth-generation HIV screening test to detect HIV-specific antibodies and HIV-1 p24 antigen. Fourth-generation screening tests have a serological window of six weeks [5][2]. If the HIV screening test is negative, the process is terminated, and the result reported.

In the case of a reactive HIV screening test, a confirmatory test is carried out with the samples from the same submission. No interim report is issued with the result of the HIV screening test, and no secondary sample is required. If the confirmatory test is clearly positive, the result is reported and the laboratory sends a notification to the FOPH and the competent cantonal medical officer (if FOPH reporting is done electronically, there is no need to notify the cantonal medical officer). The time from the reactive screening test to the reporting of an HIV diagnosis should not exceed two working days.

In terms of confirmatory analyses, laboratories have two equivalent but methodologically different testing principles at their disposal: serological testing and molecular testing (laboratory process A or laboratory process B, see Annex A: figure 1). Molecular confirmation can be quantitative or qualitative[3]. Laboratories are free to decide which test principle to use. If using a fifth-generation HIV screening test with separate results for HIV-specific antibodies and HIV-1 p24 antigen, the laboratory process that is diagnostically conclusive should be selected. It is also the responsibility of the laboratory to ensure that the confirmatory tests used are specifically intended by the manufacturer for the diagnosis of an HIV infection.

If the confirmatory test yields a negative or inconclusive result, a follow-up is to be carried out with a second confirmatory test ~~using the same sample~~[4], however, the the type of test used must be an alternative to the first. In this case, the party placing the order is notified through an interim report. If no clear interpretation is possible after the second confirmatory test, the HIV status is reported as 'inconclusive' and, if possible, a new blood sample must be requested. If no clear assessment is possible after the second submission either[5], the National Center for Retroviruses will be involved for further diagnostic confirmation.

2.5. Standard comments

As the results of more than one test are taken into account for the diagnosis of an HIV infection, the HIV Testing Guidelines stipulate as a quality requirement that when determining the presence of an HIV infection, an overall assessment of the reported analysis results must be provided in the form of a comment on the findings. However, comments on findings entail scope for misunderstanding or misinterpretation. The new guideline therefore contains standard comments on test findings and their use is strongly recommended (Annex B: table 1). The standardisation of the comments is designed to ensure that they are always technically accurate, comply with the latest guidelines and that further diagnostic procedures must only be regulated in exceptional cases. The standard comment is always cited on the report, regardless of whether or not the ordering doctor and the laboratory discuss the case.

The standard comments are made up of several elements. Firstly, they contain the overall interpretation of HIV status based on the results of the diagnostic HIV tests performed (HIV NEGATIVE, HIV POSITIVE, HIV INCONCLUSIVE). If the interpretation of the HIV status is subject to a reservation, this is recorded. The interpretation is then justified. If further diagnostic confirmation is needed to make a conclusive assessment, this is mentioned at the end of the comment.

2.6. Recommendations regarding deviating procedures

The algorithm in the new Testing Guidelines is designed so that when implemented consistently, it allows laboratories to make a correct laboratory diagnosis or in inconclusive cases to prevent a false

[2] New in version 2.

[3] New in version 2.

[4] Removed in version 2.

[5] Modified in version 2.

interpretation for all medical history situations. In three situations, however, a procedure is recommended that deviates from the laboratory processes described:

A. Primary HIV infection: If the responsible doctor suspects that a patient has a symptomatic primary HIV infection, the previous recommendation applies: perform an automated, at least fourth-generation HIV screening test, not a rapid HIV test. In addition, a molecular HIV test (laboratory process A with parallel rather than sequential screening) should always be performed at the same time as the HIV screening test.
B. Reactive HIV self-test: If there is a preliminary report of a reactive HIV self-test, HIV screening with an automated, at least fourth- generation test must be carried out. In this case, a rapid HIV test is not advisable. In such cases, the laboratories are responsible for confirming/refuting the medical history findings. For this purpose, tests should be used that are based on a different measurement principle and that exhibit the best possible sensitivity and specificity.

C. Immigration of a person from abroad with a known HIV infection: People with an already known HIV infection must report this if they take up residence in Switzerland. In general, comprehensive HIV laboratory diagnostics are not necessary for these people. A detectable viral load is sufficient to verify the HIV infection, or a reactive HIV screening test in the case of a suppressed viral load. People from abroad who undergo a verification test do not require a recency test.

In the interest of efficient order processing, however, laboratories are encouraged to enable doctors to share this information on medical history when placing the order with the laboratory (electronically or on paper).

2.7 Assessing the recency of the HIV infection

As part of its HIV epidemic monitoring, the FOPH assesses the number of infections taking place in a calendar year (recent infections). Under the HIV Testing Policy, the recency of infection was determined in the HIV confirmatory laboratories through an additional analysis of the results of the compulsory and standard line immunoassay following a uniform algorithm [6,7,8]. With the abolition of a compulsory antibody differentiation test to confirm an HIV infection and the possibility of using other CE-marked tests for antibody differentiation, this task is delegated to the SNCR in the new HIV Testing Guidelines. For this purpose, the laboratories forward the HIV positive samples to the Swiss National Center for Retroviruses (SNCR). The arrangements for forwarding samples can be obtained from the SNCR. The former HIV confirmatory laboratories are exempt from the forwarding obligation. They can continue to determine recency using the same method (Fujirebio INNO-LIA HIV I/II Score Test) while maintaining their accreditation.

3. Quality assurance

The current high quality of HIV diagnostics in Switzerland must be maintained under the new HIV Testing Guidelines. It is important that all diagnostic analyses are conducted with care, from sample collection to reporting. All in-vitro diagnostic products used in the framework of the HIV Testing Guidelines must be CE-marked. The laboratory is responsible for using the tests correctly, in other words in accordance with the intended purpose as stated by the manufacturer. The tests used must be intended for screening and/or diagnosis of HIV and not only for monitoring of viral loads. It is expressly encouraged[6] for all analytical methods used by a laboratory for HIV diagnostics to be accredited. This also applies to laboratory tests used to verify an HIV infection as part of medical patient care following a primary laboratory diagnosis.
In addition to the laboratory's own quality assurance measures, all microbiological and immunological laboratories that perform analyses to diagnose HIV infections are required to participate in external

[6] Modified in version 2.

quality checks run by a quality control center recognised by the QUALAB for the analysis methods used and to meet the criteria.

4. Tasks of the Swiss National Reference Center

The Swiss National Reference Center for Retroviruses is the point of contact for doctors and laboratory service providers that offer HIV testing. The SNCR provides advice and support on questions relating to HIV diagnostics and on the HIV Testing Guidelines.

The Reference Center handles inconclusive cases, where no clear result was found using the testing algorithm or where a diagnosed HIV infection could not be verified through follow-up testing by the responsible doctor. The SNCR advises laboratories and doctors, arranges further laboratory tests, performs these tests and carries out a concluding assessment.
Depending on the chosen laboratory process, the laboratory algorithm retained in the Testing Guidelines indicates that in the event of an HIV-1 and HIV-2 co-infection, only the HIV-1 infection may be detected. In the rare cases where a co-infection is suspected, the National Reference Center is available to confirm the diagnosis using antibody differentiation assays and/or nucleic acid tests.

As part of the epidemic monitoring, the National Reference Center carries out recency assays for newly diagnosed HIV infections on behalf of the FOPH.

5. Changes to HIV reporting

Every new HIV diagnosis must be reported in accordance with Art. 12 para. 1 and 2 LEp in conjunction with Art. 6 and 8 of the Ordinance on Epidemics of 29 April 2015 (OEp; RS 818.101.1) and Annex 1 and 3, point 22, of the Ordinance of the Federal Department of Home Affairs of 1 December 2015 on the reporting of observations relating to communicable diseases in humans (ODMT; RS 818.101.126).

The result of the laboratory test must be reported within seven days of the laboratory diagnosis to the cantonal medical officer in the canton of residence and to the FOPH (no need to report to the cantonal medical officer if the notification is submitted electronically). The laboratory conducting the first test has a reporting obligation (starting from at least fourth generation HIV screening test). If analyses carried out by more than one laboratory are used for the diagnosis (e.g. in the case of subcontracting or additional tests), the laboratory conducting the first test is responsible for obtaining the information relevant to the notification. Under the relevant Ordinance, HIV patients must be reported using the FOPH first name code (first letter plus number of letters in the first name).

The responsible doctor reports the clinical findings to the cantonal medical officer within one week. The laboratory can help the doctor with this task on request.

The recency of the infection is reported to the FOPH directly by the Swiss National Reference Center or by the former HIV confirmatory laboratories.

6. References

1. HIV Testing Policy 2013. FOPH Bulletin 2013: 851-853.

2. Vernazza P, Hirschel B, Bernasconi E, Flepp M. HIV-infizierte Menschen ohne andere STD sind unter wirksamer antiretroviraler Therapie sexuell nicht infektiös. Bulletin des médecins suisses 2008;89:165–69. Available at: https://saez.swisshealthweb.ch/fr/article/doi/bms.2008.13252/

3. Suva. Ich habe mich gestochen ! Massnahmen nach Exposition mit Blut und bluthaltigen Körperflüssigkeiten. Suva Publikation no. 2865.f. www.suva.ch/2865.f

4. Recommendations from the Federal Commission for Sexual Health (FCSH) on medical care for HIV-positive women and their children. FOPH Bulletin 50/2018: 10-22.

5. Reassessment of the Diagnostics Window Period for HIV Diagnostics, Work Group 2 Diagnostics & Laboratory HIV & STI, EKSG, August 29 2018.

6. Schüpbach (2007). Assessment of recent HIV-1 infection by a line immunoassay for HIV-1/2 confirmation. PLoS Med **4**: e343.

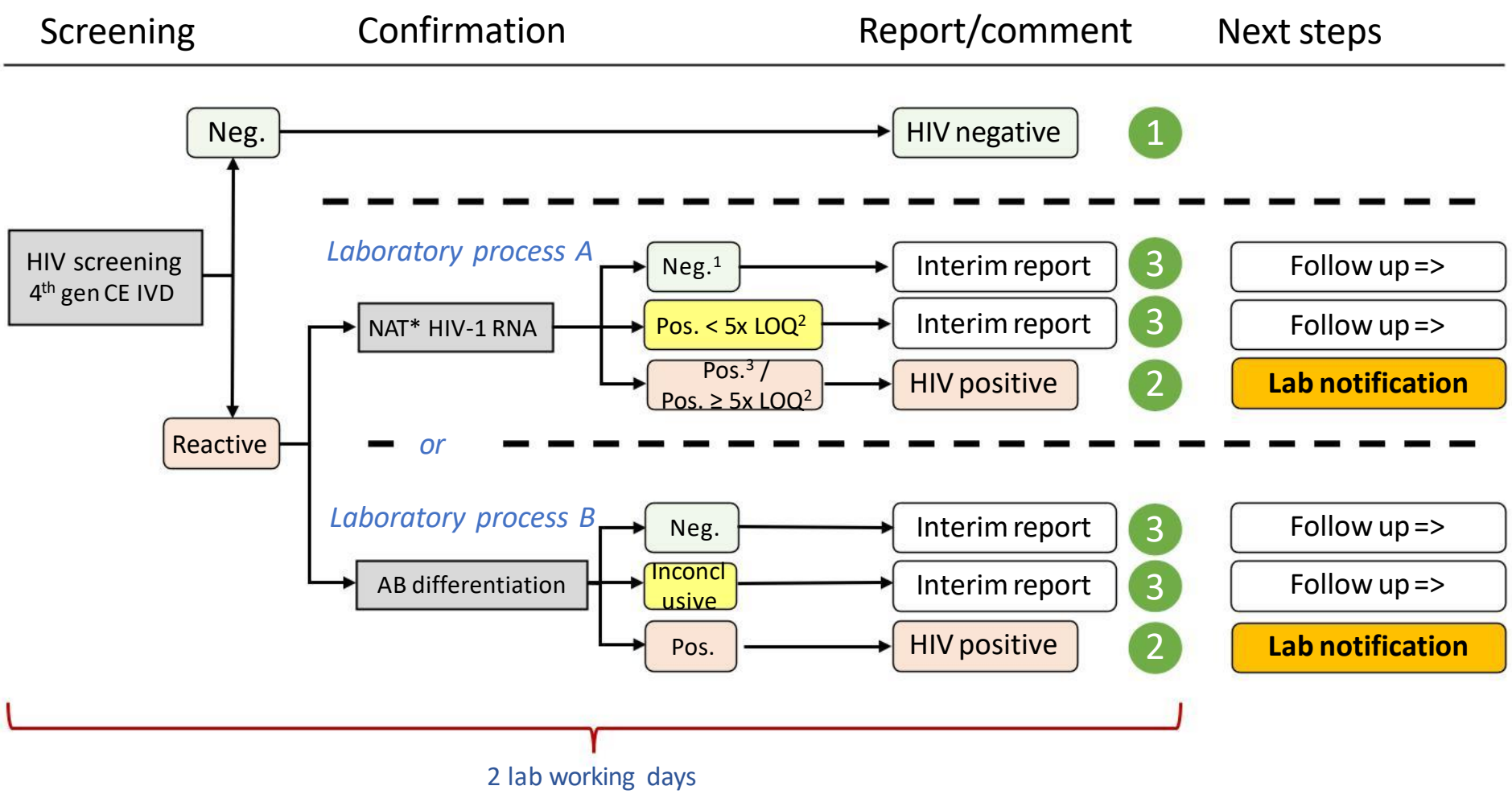
7. Schüpbach (2011). High specificity of line-immunoassay based algorithms for recent HIV-1 infection independent of viral subtype and stage of disease. BMC Infect Dis **11**: 254.

8. Schüpbach (2012). Diagnostic performance of line-immunoassay based algorithms for incident HIV-1 infection. BMC Infect Dis **12**: 88.

7. Annexes

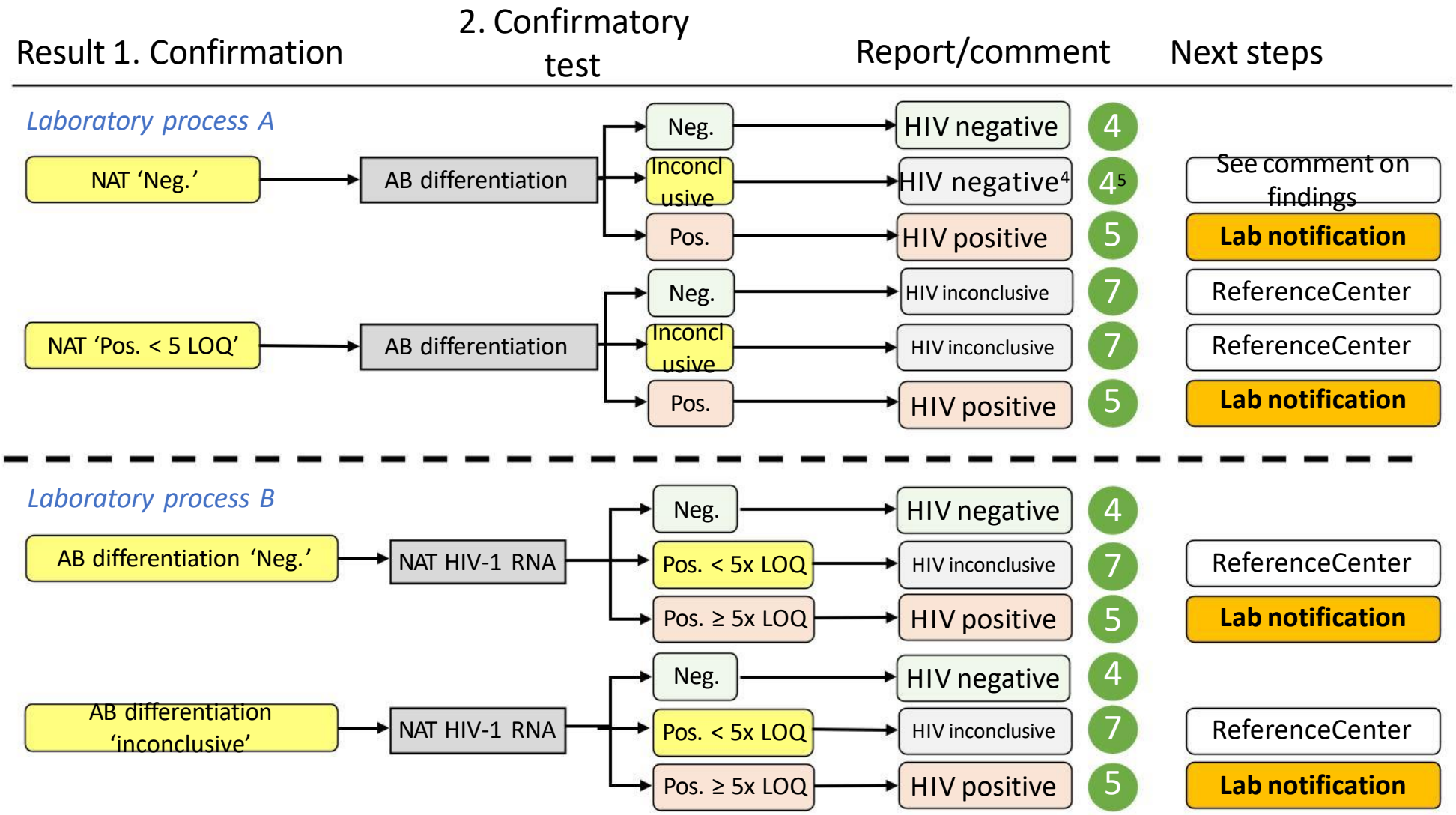
1. Annex A: Algorithm
   Figure 1. HIV testing algorithm
   Figure 2. Follow-up to HIV screening of reactive, unconfirmed cases
2. Annex B: Standard comments
   Table 1. Standard comments with numbers in accordance with figures 1 and 2 (Annex A)

Figure 1
HIV testing algorithm



*NAT = Nucleic acid-based detection
1 For qualitative and quantitative tests
2 For quantitative tests
3 For qualitative tests

Figure 2
Follow-up to HIV screening of reactive, unconfirmed cases



4 Modified in version 3 (previously « HIV inconclusive »).
5 Modifed in version 3 (previously « 6 »).

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Prevention and Public Health Services Directorate
Communicable Diseases Division

Annex B : Standard comments

Table 1. Standard comments with numbers in accordance with figures 1 and 2 (Annex A)

1. HIV diagnosis: HIV NEGATIVE. The HIV screening test was negative. An infection can only be ruled out if potential exposure is more than six weeks ago (window period).

2. HIV diagnosis: HIV POSITIVE. The reactive result of the initial HIV screening test was confirmed with a confirmatory test. The sample comes from a person infected with [HIV, HIV-1, HIV-2, HIV-1 and HIV-2]. HIV NOTIFICATION.

3. HIV diagnosis: INTERIM REPORT. The reactive result from the initial HIV screening test failed to yield a conclusive result in the confirmatory test. For a conclusive assessment, the submitted sample must undergo further tests in the laboratory, which require extra time.

4. HIV diagnosis: HIV NEGATIVE. The reactive result of the initial HIV screening test could not be confirmed in two different confirmatory tests and has been assessed as false-reactive. An infection can only be ruled out if potential exposure is more than six weeks ago (window period).

5. HIV diagnosis: HIV POSITIVE. The reactive result of the initial HIV screening test was confirmed in one of two confirmatory tests performed. The sample comes from a person infected with [HIV, HIV-1, HIV-2, HIV-1 and HIV-2]. HIV NOTIFICATION.

6. ~~6a) *(For first submission)*~~
   ~~HIV diagnosis: HIV INCONCLUSIVE. The reactive result of the initial HIV screening test could not be confirmed in either of the two confirmatory tests performed. In order to conclusively rule out an HIV infection, the test needs to be repeated using a new blood sample at an interval of around four weeks after the first sample.~~

   ~~6b) *(For repeated submission according to comment 6a with unchanged serology result/negative immunoblot)*~~
   ~~HIV diagnosis: HIV NEGATIVE. The reactive result of the initial HIV screening test could not be confirmed in either of the two confirmatory tests performed and has been assessed as false-reactive.~~

   ~~6c) *(For repeated submission according to 6a with increased HIV serology)*~~
   ~~HIV diagnosis: HIV INCONCLUSIVE. The reactive result of the initial HIV screening test [and/or] the antibody-based confirmatory test shows a clear increase in markers compared with the first test performed a month ago. An atypical HIV infection is suspected. Please contact the NCR for further diagnostic confirmation.~~[1]

7. HIV diagnosis: HIV INCONCLUSIVE. For a definitive assessment, the test needs to be repeated on a new blood sample. Please send a new blood sample as soon as possible to [our laboratory/the NCR].

[1] Removed in version 3.

Federal Office of Public Health FOPH
Schwarzenburgstrasse 157, 3003 Bern
Communicable Diseases Division
infreport@bag.admin.ch