HIV Testing Guidelines 2024

1. Introduction

Early on in the HIV pandemic, the Federal Office of Public Health developed an HIV Testing Policy in a bid to guarantee standardised and 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 National Reference Center for Retroviruses (NCR). 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 with the early days of the HIV epidemic. Alongside the improvements in antiretroviral therapy, in-vitro diagnostics for the detection and monitoring of HIV infections has also been further developed. CE-marked tests 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 Federal Office of Public Health 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 and apply to everyone aged over 18 months. 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 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.

The National Reference Center for Retroviruses (NCR) will continue to operate as a national reference laboratory with a functional specification adapted to the challenges.

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 dispensed with. 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, and for the conclusive assessment and diagnosis.

As part of the basic assessment, the doctor in charge is responsible for patient care, timely verification of the HIV infection based on a second 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 National Reference Center and to have the HIV diagnosis checked.

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 in principle made from a single submission. This requirement is due to the tight time window stipulated for HIV diagnosis. It is therefore mandatory that the samples needed for all tests are delivered in one submission. Ideally, the whole HIV diagnosis can be carried out with one EDTA tube of blood. If native blood/serum is required for the tests used 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 laboratory algorithm with decision-making criteria (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. If the HIV screening test is negative, the process is terminated and the result is 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 second 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 done electronically, no need to notify the cantonal medical officer). The time from the reactive screening test to the reporting of an HIV diagnosis should not normally exceed two working days.

In terms of confirmatory analyses, laboratories have two equivalent but methodologically different test principles at their disposal: serological testing and molecular testing (laboratory process A or laboratory process B, see Figure 1). 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 carried out with a second confirmatory test using the same sample, but changing the type of test used (Figure 2). 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 either, 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, 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 (Table 1). The standardisation of the comments is designed to ensure that

they are always technically accurate and comply with the latest guidelines and that further diagnostic procedures only have to be regulated individually in exceptional cases. The standard comment is always cited on the report, regardless of whether a telephone call also takes place between the doctor ordering the tests and the laboratory to discuss the case.

The standard comments are made up of several elements. Firstly, they comprise 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 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, so 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 also have to report it 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 need to have a recency test.

In the interests 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 [5,6,7]. 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 National Reference Center in the new HIV Testing Guidelines. For this purpose the laboratories forward the samples that tested HIV positive to the Swiss National Center for Retroviruses (NCR). The arrangements for forwarding samples can be obtained from the NCR. 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 for all analysis 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 quality checks run by a quality control centre 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 (NCR) is the point of contact for doctors and for all laboratory service providers that offer HIV testing. The NCR 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 NCR 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 means 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 diagnosis of an HIV infection must be reported.

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

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