Federal Department of Home Affairs FDHA

Federal Office of Public Health FOPH
Prevention and Public Health Services Directorate
Communicable Diseases Division

Circular email

CH-3003 Bern FOPH - infreport@bag.admin.ch

To:

FAMH, SULM, FMH, swissmedic, all cantonal medical officers and all laboratories licensed to diagnose infectious diseases in humans

Bern, 13. November 2024

Replacement of the current HIV Testing Policy with new HIV Testing Guidelines as of 01.01.2025 and corresponding changes in the Notification Ordinance (VMüK)

Dear Sir or Madam

The FOPH is sending out this circular to all doctors and laboratories to inform them about the roll-out of the new HIV Testing Guidelines, valid from 1 January 2025, which will replace the HIV Testing Policy that has been in place since 2013. The Guidelines were developed in collaboration with the Swiss National Center for Retroviruses and the competent working group at the Federal Commission for Issues relating to Sexually Transmitted Infections.

The aim of the new HIV Testing Guidelines is to guarantee standardised and high-quality HIV diagnostics and to ensure that every new HIV diagnosis continues to be reported to the authorities. Thanks to successes in HIV prevention and treatment in recent years, and the associated reduction in case numbers, the HIV Testing Guidelines are more streamlined than the previous testing policy and the process has been brought into line with the laboratory testing of other viral diseases.

The new HIV Testing Guidelines introduce a number of significant changes that will have a direct impact on doctors and laboratories. One of the key changes is the possibility for <u>all</u> microbiological and immunological laboratories that perform diagnostic or epidemiological analyses in the area of human transmissible diseases (and are licensed by swissmedic) to conduct HIV confirmatory testing. The other key change is the new requirement to forward positive samples after confirmation to the National Reference Center designated by the FOPH to assess the recency of the infection. Doctors are now responsible for verifying the HIV infection in a second sample and for arranging further diagnostic confirmation (e.g. a resistance test). Further details on these changes are set out below:

Extended authorisation to carry out HIV testing (abolition of the HIV Testing Policy)

The current structure of HIV diagnostics, including the specific roles of screening/confirmatory/notification laboratories, is being changed (abolished). From 1 January 2025, every microbiological or immunological laboratory with a swissmedic license will be authorised to carry out HIV confirmatory testing.

Single submission for confirmatory testing

Under the new HIV Testing Guidelines, the samples needed for the HIV confirmatory diagnosis are submitted in one go, which will accelerate the diagnostic process. Ideally, a single EDTA blood tube is sufficient to ensure that the whole diagnostic process can be concluded within two working days. As part of the basic assessment, the doctor in charge is responsible for patient care, for verifying the HIV infection based on a second sample, and for carrying out an HIV resistance test.

Standard comments on test findings

To avoid misinterpretations, standard comments on the findings of diagnostic tests are being introduced, and their use is strongly recommended (see attachment on new HIV Testing Guidelines).

Changes to the notification processes

The laboratory carrying out the first test now has a reporting obligation. As before, the time allowed for the notification is one week. The HIV reporting form for laboratories has been updated in line with the new HIV Testing Guidelines. From 1 January 2025, the HIV laboratory notification can also be sent to the FOPH electronically via the FHIR interface or Infreport (web portal).

Quality assurance

The new HIV Testing Guidelines require the high level of diagnostic quality to be maintained and stipulate that all laboratories use CE-marked tests and participate in external quality checks

Role of the Swiss National Reference Center for Retroviruses

The Center will remain the contact point for inconclusive cases and is responsible for further tests and certain assessments, such as determining the recency of infections.

Webinar explaining the new HIV Testing Guidelines

To coincide with the roll-out of the new HIV Testing Guidelines, the FOPH is running one one-hour webinars (in German and in French) for anyone interested. The webinars will also cover the new electronic notification options for reporting laboratories and notification using a code to represent the patient's name.

You can dial in to the webinar without registering:

Webinar on 21 November from 1:00 to 2:00 p.m.: Join the meeting now

Attachments

Please find attached further information on the new HIV Testing	g Guidelines
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Mirjam Mäusezahl, Head of Section Epidemiological Assessment

Federal Office of Public Health, Communicable Diseases Division

Cc to:

- Working group notification processes involving cantonal medical offices