GUIDELINES

2021 European guideline on HIV testing in genito-urinary medicine settings

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Abstract

Testing for HIV is critical for early diagnosis of HIV infection, providing long-term good health for the individual and prevention of onward transmission if antiretroviral treatment is initiated early. The main purpose of the 2021 European Guideline on HIV Testing in Genito-Urinary Settings is to provide advice on testing for HIV infection in individuals aged 16 years and older who present to sexually transmitted infection, genito-urinary or dermato-venereology clinics across Europe. The guideline presents the details of best practice and offers practical guidance to clinicians and laboratories to identify and offer HIV testing to appropriate patient groups.

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Background

In 2014, the Joint United Nations Program on HIV/AIDS (UNAIDS) set out global targets to end AIDS by 2030. By 2020, the target was to reach the so-called 90–90–90 treatment target [90% of all people living with HIV (PLHIV) diagnosed, 90% of those diagnosed on antiretroviral treatment (ART), 90% of those on treatment virally suppressed].[1] Progress towards these targets varies significantly between countries and regions within Europe and Central Asia.[2,3] The European Centre for Disease Prevention and Control estimates that 80% of all PLHIV in Europe and Central Asia have been diagnosed with HIV (87% in the West sub-region, 83% in the Centre, and 76% in the East).[4] Of those that have been diagnosed with HIV, a significant proportion is diagnosed late. In 2018, 53% of HIV-infected persons presented with a $CD4^+$ T-cell count below 350 cells/mm^3 and 31% presented with less than 200 cells/mm^3.[5] This implies that access to and uptake of HIV testing remain an important public health issue in Europe.

Aim

The main purpose of this guideline is to provide advice on testing for HIV infection in individuals aged 16 years and older who present to sexually transmitted infection (STI), genito-urinary (GU) or dermato-venereology (DV) clinics across Europe. Its aim is to provide details of best practice and offer practical guidance to clinicians and laboratories to identify and offer HIV testing to appropriate patient groups. The guideline may also be applied in other clinical settings including community settings where HIV testing is required, providing best practice requirements can be met. Decisions to follow this guideline must be

based on professional judgement, consideration of individual patient circumstances and available resources.

Method

The 2014 European Guidelines on HIV Testing was the starting basis for the present guidelines, which have been reviewed and updated throughout.[6] The search strategy and the grading system used in the guidelines are described in Appendix 1. In addition, the following guidelines and reports were reviewed in detail:

- British HIV Association/British Association for Sexual Health and HIV/British Infection Association Adult HIV Testing Guidelines 2020.[7]
- Centers for Disease Control and Prevention (CDC) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-care Settings.[8]
- Centers for Disease Control and Prevention Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens.[9]
- 2019 US Preventive Services Task Force. Screening for HIV Infection: US Preventive Services Task Force Recommendation Statement.[10]
- HIV indicator conditions: guidance for implementing HIV testing in adults in healthcare settings.[11]
- UNAIDS and World Health Organization (WHO) Working Group on Global HIV/AIDS/STI Surveillance Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation.[12]
- WHO Guidance on Provider-initiated HIV Testing and Counseling in Health Facilities,[13] and
- European Centre for Disease Prevention and Control. Public health guidance: HBV, HCV and HIV testing in the EU/EEA: an integrated approach. 2018.[14]

Goals of HIV testing

The primary goals of HIV testing are the following:

- Identify HIV-infected individuals as early as possible and immediately link them into appropriate medical management.
- Provide care, information and counselling for HIV-negative individuals at risk of HIV acquisition.
- Reduce HIV transmission to others from those infected; and
- Initiate partner notification and provide counselling, testing, and referral to prevention services as required for partners of HIV-positive persons.

Benefits of HIV testing

Early knowledge of HIV infection has many benefits. Initiation of antiretroviral therapy (ART) before severe immunosuppression and onset of clinical disease has been shown to dramatically improve life expectancy and quality of life. This underpins the need to test asymptomatic individuals with a high risk of acquiring HIV infection, including those attending STI clinics.[15–20] **(1 A)** Antiretroviral treatment also markedly decreases the risk of HIV transmission by reducing viral burden and consequently the infectivity of diagnosed individuals. Individuals on ART who achieve and maintain viral suppression are considered non-infective for their sexual partners, and this is often abbreviated to 'Undetectable = Untransmissable (U = U)'.[21–24] Furthermore, diagnosed individuals significantly reduce sexual and needle-sharing risk behaviours, especially with uninfected partners to whom they have disclosed their HIV status.[25–31]

Who should be tested for HIV in STI clinics?

HIV is predominantly sexually transmitted in most parts of Europe.[5] We therefore recommend universal opt-out testing of all sexually active individuals that present for medical care in the following circumstances (Table 1 includes the list of indications for HIV testing according to the grading of recommendations):

- All individuals who seek care in STI/GU/DV clinics regardless of signs or symptoms of disease or risk factors for infection should be offered an HIV test, as part of the initial screening for STI.[32] **(1 B)** It is recognized that in some settings such as DV clinics, a targeted approach may be preferred; in such settings, however a low threshold for recommending HIV testing is encouraged **(2 B)** and data show high rates of patient acceptability.[33] If universal testing is not possible, targeted testing should be recommended to those individuals particularly at risk including (but not limited to):
  - Those with symptoms compatible with acute retroviral illness, which may manifest with fever (80–90%), fatigue (70–90%), rash (40–80%), headache (32–70%) and lymph node enlargement (40–70%), as well as pharyngitis, myalgia, nausea, vomiting and diarrhoea.**(1A)**[34]
  - Those with AIDS-defining conditions or indicator conditions. **(1A)** Several 'indicator' conditions have been identified as occurring more often in HIV-infected persons and thus providing a crucial opportunity for diagnosis of HIV infection.[11] Although data on HIV prevalence across different clinical conditions are still emerging,[35–38] many testing guidelines now recommend indicator condition-guided HIV testing.[7,13,14] IUSTI guidelines endorse the adoption of the indicator disease strategy for HIV testing in healthcare settings in Europe and recommend HIV testing of individuals who present to an STI clinic with any of the indicator conditions.[11] AIDS-defining conditions and indicator conditions that are relevant for an STI/GU/DV clinic are listed in Table 2. For a more detailed list of indicator conditions, please refer to reference number.[11]
  - Those with a past or current history of STI.[11,35] **(1 A)**
  - Known sexual contacts of people infected with HIV.[39] **(1 A)**

Table 1 Indications for HIV testing according to the grading of recommendations

Strong recommendation (Grade 1)	Weaker recommendation (Grade 2)
Individuals • Who seek care in STI/GU/DV clinics regardless of clinical signs or symptoms or risk factors • With symptoms compatible with acute retroviral syndrome • With AIDS-defining conditions or indicator conditions • With a past or current history of STI • Who have been sexually assaulted • Who are known sexual contacts of people infected with HIV • Who are sexually active men having sex with men (MSM), heterosexual men and women and transgender women with casual partners • Who inject drugs and share needles • Reporting sexual contact with a partner from a country with a high HIV prevalence regardless where contact occurred • Individuals who received blood or other blood products before introduction of routine HIV screening (in most European countries this is before 1985) • Any pregnant woman regardless of risk factors • Who are using pre-exposure prophylaxis (PrEP) or postexposure prophylaxis for sexual exposure (PEPSE).	Individuals • Who voluntarily seek testing, especially if they have never been tested before • Who are sexually active transgender men with casual partners • Individuals reporting chemsex • With a new sexual partner • Who are known sexual contacts of patients with an STI • Who are sexual contacts of people at recognized risk of HIV infection • Who exchange sex for money or goods • Who are children of mothers with HIV who have no documented evidence of a previous negative test

- Sexually active men having sex with men (MSM), heterosexual men and women, and transgender women with casual partners.[40–43] (**1 A**)
- Those who inject drugs and share needles.[44,45] (**1 A**) those reporting sexual contact with a partner from a country with a high HIV prevalence regardless where contact occurred.[46,47] (**1 A**)
- Individuals who received blood or other blood products before introduction of routine HIV screening (in most European countries, this is before 1985). (**1 A**)
- Any pregnant woman regardless of risk factors.[48] (**1A**)
- Persons who are using pre-exposure prophylaxis (PrEP), which is defined as using antiretroviral medication in HIV-negative individuals to prevent HIV infection and postexposure prophylaxis for sexual exposure (PEPSE) (**1 A**)
- Individuals who have been sexually assaulted. (**1 B**)[49]
- Persons who voluntarily seek testing, especially if they have never been tested before.[50,51] (**2 B**)
- Transgender men.[42,43] (**2 C**)
- Those reporting chemsex.
- Those with a new sexual partner. (**2 D**)
- Known sexual contacts of patients with an STI. (**2 D**)
- Sexual contacts of people at recognized risk of HIV infection. (**2 D**)
- Those who exchange sex for money or goods. (**2 D**)
- Children of mothers with HIV who have no documented evidence of a previous negative test (**2 D**).

Re-testing for HIV

In addition to individuals newly presenting to the healthcare setting, all cases that tested negative for HIV should be offered and be encouraged to have repeat HIV testing if there is ongoing risk.[52–55] (**1 A**) The optimal frequency of re-testing is still unknown due to lack of data. Annual re-testing for ongoing risk is suggested unless specific aspects of risk behaviour warrant more frequent testing (e.g. every 3–4 months).[53–60] Testing frequency should be based in part on the level of risk and requires a dialogue between the provider and the patient, which will include test history and any risk behaviours. (**2 D**) Further information can be found on testing frequency for specific key populations in the Public Health Guidance on HIV, Hepatitis B and C Testing in the EU/EEA.[14] Individuals with ongoing risk exposures should be counselled about risk reduction strategies and may be candidates for HIV pre-exposure prophylaxis (PrEP) (**2 D**).

Pretest assessment and counselling

The HIV pretest assessment should be pragmatic and patient-centred, and be tailored for the individual patient. Some studies outside of the GU setting show that pretest counselling could be a barrier for HIV testing;[61–63] the key element is obtaining verbal informed consent to the test.[7,14,64] Pretest counselling is important to assess the likely window period (the time between possible exposure to the HIV and the test becoming positive) and whether repeat testing should be advised, in addition to describing how and when the test result will be given (**2 D**). One randomized controlled study in a prenatal setting reported that extensive pretest counselling would not be required and that a short pretest assessment was as effective as a long session for a patient's decision to take an HIV test.[65] However, there is no study comparing extensive and abbreviated assessment sessions in GU settings. Depending on circumstance, the components of pretest assessment may include the following:[6,66]

Table 2 AIDS-defining conditions and indicator conditions. Conditions relevant to STI/DV/GU clinics are marked bold

AIDS-defining conditions	Indicator conditions
Neoplasms • **Cervical cancer** • Non-Hodgkin lymphoma • **Kaposi's sarcoma** • Viral infections • Cytomegalovirus retinitis • Cytomegalovirus, other (except liver, spleen, glands) • **Herpes simplex, ulcer(s) >I /month** • Progressive multifocal leukoencephalopathy *Bacterial infections* • *Mycobacterium tuberculosis*, pulmonary or extrapulmonary • *Mycobacterium avium* complex (MAC) or *Mycobacterium kansasii*, disseminated or extrapulmonary • *Mycobacterium*, other species extrapulmonary/ disseminated • Pneumonia, recurrent (2 or more episodes in 1 year) bronchitis/ pneumonitis • *Salmonella* septicaemia, recurrent *Fungal infections* • *Pneumocystis* (*carinii) jirovecii* pneumonia • Candidiasis, oesophageal • Pulmonary candidiasis • **Cryptococcosis, extrapulmonary** • **Histoplasmosis, disseminated/ extrapulmonary** • Coccidioidomycosis, disseminated/ extrapulmonary • Penicilliosis, disseminated *Parasitic infections* • Cerebral toxoplasmosis • Cryptosporidiosis >1 month • Isosporiasis >1 month • Atypical disseminated leishmaniasis • Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)	*Conditions associated/likely to have an undiagnosed HIV prevalence of >0.1% where HIV testing is strongly recommended* • **Sexually transmitted infections** • Malignant lymphoma • **Anal cancer/dysplasia** • **Cervical dysplasia** • **Herpes zoster** • **Hepatitis B or C (acute or chronic)** • Mononucleosis-like illness • Unexplained leucopenia/thrombocytopenia lasting >1 month • **Seborrhoeic dermatitis/exanthema** • Invasive pneumococcal disease • Unexplained fever • Candidaemia • Visceral leishmaniasis • Pregnancy (implications for the unborn child) • Primary lung cancer • Lymphocytic meningitis • **Oral hairy leukoplakia** • **Severe or atypical psoriasis** • Guillain–Barré syndrome • Mononeuritis • Subcortical dementia • Multiple sclerosis-like disease • Peripheral neuropathy • Hepatitis A • Unexplained: o Weight loss o Lymphadenopathy o **Oral candidiasis** o Chronic diarrhoea o Chronic renal impairment • Community-acquired pneumonia • Candidiasis *Conditions where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management despite that the estimated prevalence of HIV is most likely <0.1%* • Conditions requiring aggressive immunosuppressive therapy: o Cancer o Transplantation o Auto-immune disease treated with immunosuppressive therapy • Primary space occupying lesion of the brain • Idiopatic/thrombotic thrombocytopenic purpura

- Provide information on the benefits of HIV testing including the health benefits of early diagnosis and treatment, and the opportunity to reduce risk behaviour and risk of transmission to sexual partners or babies (**2 D**).
- Obtain a full sexual history and history of other types of risk behaviour (including date of last risk activity). (**2 D**)
- Obtain HIV testing history (including the time, setting, reason and result of prior testing). (**2 D**)
- Ensure knowledge of condom use and include a practical demonstration if needed. If appropriate, discuss risk reduction and the need for referral to other services, for example drug dependency treatment, support services and groups, and needle exchange programmes. (**2 D**)
- Offer testing for other STIs. (**2 D**)
- Offer HIV postexposure prophylaxis after sexual exposure (PEPSE) if indicated and available, in agreement with national policy. Detailed information on PEPSE can be found on the BASHH website (https://www.bashhguidelines.org/current-guidelines/hiv/post-exposure-prophylaxis-following-sexual-exposure/). (**2 D**)
- Offer or refer persons to PrEP services if indicated. (**2 D**)
- Give an opportunity to the individual to ask questions and answer them clearly; give more in-depth information if required. (**2 D**)
- Advise the patient to adopt safe sex behaviours and to follow national blood donation policies until the testing process is over. (**2 D**)

- Provide information on home-based self-sampling/testing if available and endorsed by national guidelines. (**2 D**)

A novel approach for testing is online access to postal sampling/test kits, and many services offer this tool in an attempt to provide wider access to easier and early testing. Although this usually includes a web-based questionnaire to assess risk and the opportunity for high-risk individuals to be fast-tracked into face-to-face clinical services, many higher risk patients prefer to use this relatively anonymous tool for initial testing. In this case, it may be difficult to cover all the elements of the pretest assessment via an online approach. This system should allow suitable identifiers and contact details of the individuals to ensure contact with the patient and linkage to care in case a positive result is obtained. Results, particularly positive ones, should be followed up with an urgent voice call, and individuals directed into traditional services for thorough assessment, confirmatory testing and care. For those with negative tests, any risks that require modification and support should also trigger referral to a clinic. (**2 D**).

Informed consent

- HIV testing should not be coercive or mandatory[14,64] except for the screening of donated blood, organs or other bodily tissues. Verbal communication is sufficient for obtaining informed consent. (**2 B**) Obtaining written consent is a barrier to HIV testing, and opt-out testing rates were shown to increase whether testing requires only oral consent.[67–73]
- If a patient declines or defers HIV testing, this decision should be documented in the medical record but kept confidential. The reasons why they have made that choice should be explored to ensure that it is not due to incorrect beliefs about the virus, the consequences of testing or needle phobia (which can be overcome with less invasive sampling). (**2 D**)
- Declining an HIV test should not result in reduced quality or denial of services that do not depend on knowledge of HIV status.[64,66] (**2 D**)
- An information leaflet[74] (**2 B**) or a video[75,76] (**2 B**) about HIV testing can provide or replace much of the information needed prior to obtaining informed consent, and is effective in many settings. The information should be prepared in an easy to understand and informative way, be concise and be available in the languages commonly encountered in populations within the service.[66,74]

Individuals below the legal age of consent

All children born to mothers with HIV should be routinely tested for HIV as per national guidelines. A negative HIV test will usually exclude infection at 18 months but may need to be repeated at 2 years as the passive maternal antibody may still be present in some cases.[77] Children born to HIV-positive mothers who do not have evidence of a negative test (eg. born elsewhere) should be tested for HIV at the first feasible opportunity. (**2 D**).

Special considerations apply in the case of adolescents who are below the legal age of consent. The pretest discussion should be adapted to the patient's age, developmental stage and literacy level.[66] Since the legal framework, including the age of consent for sexual intercourse and offering testing and treatment services to adolescents, varies between countries, relevant national guidelines should be consulted. If a national guideline is not available, advice is available from recent WHO/UNAIDS Guidance on provider-initiated testing and counselling in health facilities.[66] (**2 D**)

Testing without informed consent

Where a patient is unable to give informed consent for HIV testing due to physical or mental incapacity (e.g. if critically ill and unconscious), HIV testing might be indicated to help diagnose the cause of the illness in the patient's best interests. In all cases where HIV testing is performed without informed consent, the healthcare provider must be able to justify their actions and must take into consideration national legal and regulatory frameworks, guidance from national professional bodies and consensus opinion from experienced colleagues.[7,64]

Confidentiality

Individuals undergoing HIV testing should be informed that testing and test results will remain confidential.[7,14,64,66] However, when indicated, individuals should also be advised that confidentiality is not absolute and that healthcare providers may be legally required to disclose HIV status information in exceptional circumstances. (**2 D**) Since this may create a major barrier for testing, testing centres offering anonymous testing may be an option to overcome this if in agreement with national policy.[78–80] (**2 D**) Self-testing is an additional option to overcome barriers related to confidentiality as they offer a highly confidential testing approach and are associated with reduced perceived stigma.[81]

Recommendations for the laboratory

Specimens

Many types of specimens such as plasma, serum, whole blood venous or finger prick, dried blood spots (DBS), and oral (gingival crevicular) fluid can be used for HIV testing. Each specimen type has specific advantages and disadvantages. The choice of the specimen depends on the population to be tested, transport options, testing site, and the chosen HIV screening/testing strategy and subsequent confirmation algorithm. For accurate and reliable results, specimens must be collected, stored, transported and tested appropriately.[14,82] (**2 D**) Especially when using samples other than venous blood, the full testing pathway should be subjected to rigorous training and quality assurance.[82] (**2 D**)

Further information on collection, storing, transportation and processing of specimens can be found in Guidelines for Using HIV Testing Technologies in Surveillance. UNAIDS/WHO Working Group on HIV/AIDS/STI Surveillance. Available at: https://www.ncbi.nlm.nih.gov/books/NBK305270/pdf/Bookshelf_NBK305270.pdf

HIV screening and confirmatory tests

Screening serology test

- The most common approach is to use a highly sensitive screening test. Fourth-generation screening assays either in the form of standard ELISA or rapid diagnostic tests (RDT) that simultaneously test for HIV-1/2 antibodies (IgG/IgM) and p24 antigen should be used wherever possible due to their ability to detect HIV infection early.[83] (**1A**) This reduction in the window period identifies patients with the highest risk of transmission, enabling behaviour modification and a reduction in risk.[84] Use of a third-generation (IgM/IgG) assay for screening must be restricted to situations where an antibody/antigen assay is unavailable due to insurmountable logistical or financial restrictions. Standard laboratory ELISA assays available in Europe have excellent sensitivities (99.78–100%) and specificities (99.5%–99.93%).[85–88] Fifth-generation assays [Conformité Européenne (CE) marked] that can both detect p24 antigen and discriminate between HIV-1 and HIV-2 antibody are becoming available. These may be used in place of a fourth-generation assay after completion of adequate local quality assurance. (**2 D**) Test providers should be fully aware of the qualifications, sensitivity and specificity of the tests, and their window period, to interpret test results accurately and to determine whether and when re-testing is required.[85,86] For more details on rapid diagnostic tests, please see below.
- Nucleic acid amplification tests (NAATs), typically plasma HIV-1 RNA testing, are not recommended for initial HIV screening because they offer only a marginal advantage over fourth-generation screening assays in detecting recent HIV infection but are more costly and can be associated with false-positive results.[83] (**2 D**) They can be useful in confirming infection and in circumstances where antibody production may be impaired.[89–91] The role of NAAT testing is controversial in PrEP users in whom acute HIV infection is suspected because HIV RNA was shown to be significantly lower among PrEP users compared to the placebo group, which may delay the detection of infection.[92,93]

Confirmation of detection in a screening assay

- Detection of HIV in the screening test should be confirmed in a laboratory with experience in HIV confirmation. (**2 D**)
- Confirmatory algorithms vary. Until recently, they included at least one additional antibody-only test that employed a different platform from the initial screening test.[94] The more recent approach is to use a sensitive and highly specific test different from the screening test for confirmation.[87,88] The confirmatory test should be an HIV-1/HIV-2 differentiation antibody assay, and the final laboratory report must clearly indicate whether the patient has an HIV-1, HIV-2 or dual infection.[94] (**2 B**) Countries should refer to their national guidelines for confirmatory algorithms.
- Repeat serology testing of a second sample is recommended to rule out mislabelling and confirm patient identity. (**2 D**) It may be replaced by testing a plasma sample for HIV-1 RNA, provided the viral load is >1000 copies/mL and HIV-2 infection has been excluded in the first sample. In patients with a lower or undetectable viral load, a second serum sample must be collected for repeat serological testing.[95] (**2 D**)

Confirmation of indeterminate/equivocal serology results An indeterminate screening test may indicate a possibility of recent infection.[81] Where there are other indicators of a possible recent infection (i.e. high-risk behaviour history, clinical signs and symptoms) and availability of fast turnaround NAAT technology, the best strategy is to test the initial specimen for HIV-1 RNA (or in some cases p24 antigen) to provide evidence of ongoing seroconversion. Otherwise, one should obtain a follow-up specimen 1–2 weeks later for repeat testing. (**2 D**) If on the follow-up sample the fourth-generation test is clearly positive, then a diagnosis of recent seroconversion can be made.[96,97] In all such cases, seroconversion should be confirmed on a follow-up specimen. (**2 D**)

Recent HIV infection For individuals who test positive with the screening test but who have negative or indeterminate results with the confirmatory test, HIV-1 RNA testing is indicated to rule out acute/recent HIV infection.[87] (**2 D**) If HIV-1 RNA is detected, then infection should be confirmed by demonstrating seroconversion in a sample collected 1–2 weeks later. Low HIV-1 RNA values (<1000 copies/mL) may represent false-positive results and should be interpreted with caution, and not considered as indicative of infection in the absence of further evidence (**2 D**). In settings where NAATs are not widely available or affordable, or in circumstances where there is no suspicion of a recent HIV infection, NAATs are replaced by a fourth generation screening test repeated 1–2 weeks later. (**2 D**) The process of seroconversion may be prolonged in some cases such as elite controllers.[98]

Quality control

- All HIV testing and confirmation should be done in accredited laboratories under strict quality control. (**2 D**) Where a national laboratory accreditation scheme is not available,

testing should be undertaken only using approved [i.e. Conformité Européenne-In Vitro Diagnostic (CE-IVD)] tests under a strict quality assurance programme; quality assurance results should be made available for inspection where requested. (**2 D**)
- RDT services should be subject to the same strict quality assurance principals as practised by accredited laboratories. (**2 D**) Backup provided by a referral laboratory is a prerequisite for all testing and counselling facilities. This includes quality assurance training for the individual with responsibility for the test (ideally this is provided by the accredited referral laboratory associated with the service), using standard operating procedures (SOPs), regular use of negative and positive controls, external quality controls and an external quality assessment process where available. Regular onsite audits should be performed to confirm that SOPs are being followed, records are maintained, adequate training has been provided, and internal and external quality standards are used. A second test is required if the RDT is reactive; this must use different antigens and/or a different platform and should be performed in an accredited laboratory whenever possible.[99–101]
- Local rules and regulations should be followed for storage of plasma/serum samples. (**2 D**)
- Laboratories should provide their latest external quality control scores to their users upon request. (**2 D**)

Interpreting HIV test results

The healthcare provider should be aware of the
- HIV testing algorithm used in their laboratory;
- HIV screening test used in their laboratory; and
- Capability of their laboratory to distinguish between HIV-1 and HIV-2 infections.

Interpreting negative HIV test results
- Individuals whose specimens test negative on the initial HIV screening should be considered uninfected unless the patient presents with symptoms of primary HIV infection or has a history of recent high-risk exposure (≤45 days for fourth-generation assays, ≤50 days for other assays). In the case of recent exposure, the tests should be repeated at 45–50 days (according to the test to be used) from the time of exposure.[83,87–89,102–104] (**1 B**)
- Individuals with a high-risk exposure to HIV should not be fully reassured until the test process is completed.[105] (**2 D**)
- When using fourth-generation assays, individuals who have a negative screening test after 45 days of exposure may be recalled for a follow-up in specific circumstances, for example if postexposure prophylaxis (PEP) was given for any reason (e.g. occupational or sexual exposure), individuals who are using PrEP, where there is impaired ability to develop antibodies and where there is microbiologically proven simultaneous acute infection with another viral pathogen, such as hepatitis B and/or C virus.[93, 104-108] In this case, the final testing time should be 12 or 24 weeks after exposure. (**2 C**)
- For individuals presenting for PEP in the occupational setting, local professional regulations may vary in terms of immediate testing for HIV or postponing HIV testing and storing a baseline venous blood sample at start of PEP medication for retrospective testing in case follow-up testing is positive. Healthcare providers should follow their relevant local rules and regulations. Patients presenting for PEPSE however should be tested at the start of PEPSE.[109] In individuals using PrEP or PEP/PEPSE, seroconversion can be delayed; thus, rapid HIV tests are not recommended as the sole mode of HIV testing in this context.[110,111] (**2 B**)
- If a patient presents with clinical symptoms suggestive of HIV infection or AIDS and the HIV screening tests are repeatedly negative, then referral of the specimen to a specialized laboratory for analysis using alternative tests to exclude uncommon HIV strains is recommended. (**2 D**)

Interpreting positive HIV test results
- A person should not be informed that he/she is HIV positive based on the initial result of a screening test alone without a confirmatory test (**2 D**).
- Attention should be paid to whether HIV-1 or HIV-2 (or both) has been diagnosed as it has important prognostic and treatment implications.

Interpreting indeterminate and unconfirmed HIV test results
- HIV screening tests occasionally produce reactive results that prove not to be consistent with HIV infection.
- In cases where the initial reactive screening test cannot be confirmed, the result is reported as 'indeterminate' and a second blood sample should be requested (**2 D**). The first and second blood sample should be separated by at least 2 weeks.[55] Please see 'Confirmation of indeterminate/equivocal serology results' above.
- Weakly reactive screening results that do not become more strongly reactive and cannot be confirmed on a subsequent, appropriately timed sample are highly likely to indicate a non-specific reaction, that is false-positive result. (**2 D**)

Rapid diagnostic tests/Point-of-care tests

Rapid HIV tests have become an important tool to encourage HIV testing. Rapid tests are typically capillary flow tests where whole blood (e.g. finger prick or venous), serum, plasma or gingival crevicular fluid (commonly identified as oral fluid) can be used as the specimen.[88] Their major advantages include the visibility of the test, simple-to-use procedures, rapid turnaround time, availability of on-site results and reduction in potential for clerical errors. These tests allow individual screening of clients, can reduce long waiting times and provide a highly confidential environment for the tested individual. They also can be used outside of healthcare facilities (i.e.

community-based testing centres or venues visited by key populations) and in the field (i.e. mobile clinics) by appropriately trained lay providers. Rapid tests have been shown to be highly acceptable[112] and to increase testing uptake in various settings such as harm reduction services, pharmacies, STI clinics and among migrant populations.[113–120]

The major drawback of rapid HIV tests has been their reduced sensitivity and specificity relative to laboratory-based tests and the likelihood of false-negative results in early HIV infection because until recently, rapid tests were only able to detect IgG with or without IgM.[99,100,121–124] While the introduction of the first combined antigen/antibody sensitive rapid test was expected to improve the performance of RDTs, its performance was also shown to vary in several studies with excellent sensitivity for antibody detection but variable, suboptimal sensitivity for p24 antigen.[125–129] A newer version of the same test has proved to have improved antigen sensitivity.[112,130–132] CE-IVD-marking in Europe, FDA approval in the US and WHO prequalification requires high sensitivity (≥99% for CE-IVD, FDA and WHO) and specificity (≥99% for CE-IVD and FDA, ≥98% for WHO) to avoid a missed diagnosis due to a false-negative or a false-positive result.[112] However, test performance may vary in real life depending on many factors such as the clinical stage of the patient, the genetic characteristics of the aetiologic agent, specimen type used or the tested population.

Specimen choice is flexible with RDTs, and most of the tests work well with capillary or venous whole blood, serum or plasma.[82,88,133,134] Gingival crevicular fluid may also be an option for several RDTs; however, it has been shown to have significantly lower antibody concentrations compared to plasma. Thus, RDTs using gingival crevicular fluid may be subject to more variation in assay performance and reduced sensitivity.[88,130,135–137]

Rapid tests that screen for HIV-1 RNA have been shown to be highly sensitive in both acute and chronic HIV infection but have had limited uptake due to technical challenges such as their requirement for plasma samples and complex specimen preparation.[138]

In the light of the above-mentioned evidence, these guidelines recommend the following:

- Healthcare providers should familiarize themselves with the performance characteristics of the test adopted to guide their use and interpretation (**2 D**).
- Healthcare providers should be aware that the performance of rapid HIV tests (including combined antibody/antigen tests) may differ and be subject to variation depending on the training of the healthcare worker performing the test, the clinical status of the patient, the genetic characteristics of the virus, specimen type used or the tested population. (**1 B**) Acute HIV infection may be a critical blind spot for RDTs, and healthcare providers should keep in mind that they may give false-negative results in early infection. (**1 B**)
- As with all tests, the positive predictive value of a reactive test is reduced in low prevalence settings, meaning that false-positive results will occur at a different frequency depending on the setting and population undergoing screening.[116]
- Obtaining a blood sample for laboratory testing is recommended in all patients with reactive or indeterminate results and in patients with a negative test if recent infection is suspected.[9,139,140] (**1 B**)
- Sites using RDTs should collaborate with the local laboratory and have robust quality assurance programmes in place.[94,121] (**2 D**) An important consideration must be staff training before RDTs ensuring that staff is aware of their interpretation and limitations.

Self-sampling and self-testing

Self-sampling is defined as the collection of a blood or saliva sample by the individual being tested him/herself and posting it to a designated laboratory for testing. Self-testing is testing of the self-collected sample by the individual using a rapid diagnostic kit and interpreting the result according to the manufacturer's instructions. Both methods are additional options to increase the uptake of HIV testing by providing a flexible and non-stigmatizing testing environment.[14]

Although experience with self-sampling and self-testing is limited, studies have reported that both are acceptable with high levels of satisfaction,[139-149]capture never-tested populations and increase testing frequency and positivity rates for HIV, compared to other options.[81,140,146,150-152]

The largest body of evidence for both methods is with MSM and migrants with very limited evidence for other populations.[81,149]

The major limitations of self-sampling are difficulty obtaining a blood sample,[153] lack of support from healthcare providers,[154] and limited evidence on linkage to care after sampling.[155,156] In addition, the testing laboratory does not have any independent verification of sample identification or the time since sampling, nor the conditions under which the sample has been taken and transported. The major perceived barriers for self-sampling and self-testing are reported as lack of support following a positive result and the individual's capacity to run the test accurately.[148,157,158] In addition, self-testing kits do not always offer integrated testing for HIV, hepatitis B and hepatitis C viruses.

Based on the evidence on self-sampling and self-testing, these guidelines recommend:

- Self-sampling and self-testing are acceptable and may contribute to increased testing uptake and case detection especially in specific key populations such as MSM. These guidelines recommend their use in STI, GU and DV clinics to increase testing uptake especially among individuals who

would not otherwise be tested, (**1 A**) providing they are allowed by national laws and regulations.
- Self-sampling and self-testing kits may be distributed through various channels including STI clinics.
- Since evidence is limited on linkage to care after self-sampling and self-testing, clear pathways should be defined for access to appropriate support and medical care. (**2 D**)
- Countries are recommended to discuss and change local regulations to facilitate the use of self-sampling and self-testing kits. (**2 D**)

Post-test issues

Healthcare providers should take care that the HIV test result remains confidential, in the same way as other healthcare associated patient information (**2 D**).

Post-test discussion for individuals who are negative

- Face-to-face post-test discussion is generally preferred for providing results, but alternative methods, such as telephone, letter or texting, may be appropriate in some instances (**2 D**). If alternative methods are used, a standard procedure should be developed to ensure that the necessary post-test information is received by the tested individual (**2 D**).
- Discuss the window period and address the need for a repeat test in those with high-risk behaviour within the last 45–50 days (according to the test used).
- Encourage safe sex behaviour, particularly addressing behaviour change regarding unsafe sex or the maintenance of safer sexual practices; provide and demonstrate how to use condoms if necessary.
- Use the opportunity to refer persons with particular high-risk behaviours to HIV and other prevention services, for example drug dependency treatment, support schemes, needle exchange programmes and PrEP. For detailed information on PrEP use, please refer to BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). (https://www.bhiva.org/PrEP-guidelines)

Post-test discussion for individuals with inconclusive test results

- Post-test discussion for individuals with inconclusive test results should be done face-to-face whenever possible (**2 D**).
- An explanation should be provided on the significance and possible reasons for an inconclusive HIV test result.
- The nature of the additional tests that are required to resolve the inconclusive result should be explained.
- The importance of ongoing follow-up until the inconclusive result is resolved should be stressed.
- Discuss safer sex and safe drug-use behaviour until the indeterminate result is resolved.
- For persons reporting high-risk behaviour, discuss the possibility of acute HIV infection and consider additional NAAT testing or ask for a repeat sample 1–2 weeks later, particularly for pregnant women who have not been tested previously.

Post-test discussion for individuals who are positive

HIV-positive results should be given in a confidential environment and in a clear and direct manner.[64,66] Patients are often very distressed when first informed about a positive HIV test result. They are faced with major adaptive challenges, such as accepting to live with a chronic condition, being subject to intense stigma and discrimination, and developing and adopting strategies for maintaining physical and emotional health. Appropriate support should be available on-site or through referral to address the behavioural, psychosocial and medical implications of HIV infection. The following issues should be covered: (**2 D**).

- Inform the patient straightforwardly that the HIV test was positive and make sure that the patient has understood the implications of a positive test.
- Plan for repeat HIV antigen/antibody test of a second sample to rule out mislabelling and to confirm patient identity. Arrangement should also be made for an initial assessment for newly diagnosed HIV-positive patients with an HIV specialist.
- Address the question of whether the patient wants to inform anyone (e.g. partner(s), friends, family) or not and discuss the advantages and disadvantages of sharing the diagnosis.
- Discuss the importance of partner notification. Encourage partner notification for providing testing and medical care if needed for the partner.
- Schedule a new consultation in the near future.
- Assess the need for psychological support or contact with other services, for example drug dependency, and refer as necessary.
- Discuss what will happen next and clarify whether the individual wants to talk further at this stage or not. Experience has shown that even when the patient expected a positive result, there is still a powerful emotional reaction. Hence, it may be wise to postpone some of the information giving to subsequent consultations. If the individual is willing to continue, inform them that treatment is available and discuss current treatment options and the benefits of early initiation of treatment. Discuss antiretroviral drugs and emphasize their ability to control HIV disease effectively. Inform them that the life expectancy of PLWH is almost equal to those who are HIV negative with early ART and that AIDS-related mortality rates have decreased significantly.[20,159] If feasible offer/refer for same-day ART.

- Discuss prevention methods such as safe sex, use of condoms, and not sharing needles to reduce transmission to others and transmission of other STIs to the patient.
- Discuss the importance of adherence to treatment and that PLWH who use their treatment regularly and achieve virologic suppression do not transmit the virus, (U = U).[22–24]

For seropositive women, the following should be included in the counselling at an early stage.

- Discuss the implications for possible future pregnancy such as the risks for the child and the need for ART during pregnancy. Inform that antiretroviral treatment if administered to women during pregnancy and to the newborn child for a short period can significantly reduce this risk of mother-to-child transmission.[160,161]
- If already pregnant, discuss the implications.

Further guidance should be sought from relevant national guidelines or, if not available, from the CDC (www.cdc.gov/hiv), the BHIVA (www.bhiva.org) or EACS (https://www.eacsociety.org/).

Following a positive HIV diagnosis, a newly diagnosed individual should be immediately referred to an appropriate specialist HIV treatment centre for further management and care.[157] However, it should be stressed that after HIV diagnosis it is important to offer not only continuous monitoring of viral and immunological parameters for HIV infection, but also regular, comprehensive and easily accessible monitoring of other STIs and repeated sexual risk reduction counselling in a context of sympathetic, non-judgemental sexual history taking.[162–165]

Non-attendance for positive results

- An agreed recall process following failure of a patient to return for an HIV-positive result should be established and contact options should be discussed with the patient at the first testing visit (**2 D**).
- Attempts should be made to contact the patient if they test positive and fail to collect the result (**2 D**); this may include making telephone calls, sending emails or text messages, sending letters, or making home visits.

Voluntary disclosure, partner notification and contact tracing

Partner notification or partner referral is a cornerstone of STI programmes worldwide. The rationale for partner notification is to reduce transmission, to identify people that have already acquired the infection to ensure early access to care, and to promote safer sexual behaviour.[166]

All patients should be strongly advised to disclose their HIV infection status to their regular, previous and new sexual or injecting partner(s) and those at risk to be tested for HIV.[166] (**2 D**) In addition, testing of all children of HIV-positive women is recommended as HIV transmission has been documented from breastfeeding from mothers who acquired their infection postnatally, and vertically acquired HIV infection can present in adolescence (**2 D**).

Healthcare providers should be aware that partner notification is a voluntary process and the core principle of confidentiality should always be respected.[64,166] It should be noted that the legal circumstances pertaining to partner notification vary from country to country and local rules and regulations should be followed.

Further information can be found in the European guidelines for the management of partners of persons with sexually transmitted infections at www.iusti.org and the ECDC Public health guidance: HBV, HCV and HIV testing in the EU/EEA: an integrated approach at https://ecdc.europa.eu/en/publications-data/public-health-guidance-hiv-hepatitis-b-and-c-testing-eueea.

Search strategies and level of evidence grading

Appendix 1

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Composition of the European STI Guidelines Editorial Board

The current composition of the European STI Guidelines Editorial Board can be found at: https://iusti.org/wp-content/uploads/2019/12/Editorial_Board.pdf.

List of contributing organizations

Current list can be found at: https://iusti.org/treatment-guidelines/

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Appendix 1

Search strategy

The present guideline was produced according to the protocol for production and revision of European STI guidelines, which has been written and approved by the IUSTI European STI Guidelines Editorial Board (https://iusti.org/wp-content/uploads/2020/04/ProtocolForProduction2020.pdf). Evidence for this guideline was provided by review of the Medline/Pubmed, Embase, Google, Cochrane Library and relevant guidelines published since the development of the 2014 European HIV Testing Guideline starting from 01.04.2013 to 31.12.2019. Publications in English language were searched. Search terms 'HIV testing' AND 'HIV guideline(s)' AND 'recommendation(s)' were used as keywords, and 1602 relevant citations were identified. For some specific recommendations, additional Medline/Pubmed searches were performed when necessary.

Grading of recommendations and quality of evidence

- A Grade 1 recommendation is a strong recommendation to do (or not do) something, where benefits clearly outweigh risks (or vice versa) for most, if not all, patients. Most clinicians and patients would want to follow a strong recommendation unless there is a clear rationale for an alternative approach. A strong recommendation usually starts with the standard wording: 'We recommend...' or 'It is recommended...'
- A Grade 2 recommendation is a weaker or conditional recommendation, where the risks and benefits are more closely balanced or are more uncertain. Alternative approaches or strategies may be reasonable depending on the individual patient's circumstances, preferences and values. A weak or conditional recommendation usually starts with the standard wording: 'We suggest...' or 'It is suggested...' The strength of a recommendation is determined not only by the quality of evidence for defined outcomes but also the balance between desirable and undesirable effects of a treatment or intervention, differences in values and preferences, and, where appropriate, resource use. Each recommendation concerns a defined target population and is actionable.

The quality of evidence is graded from A to D and is defined as follows:

- Grade A evidence means high-quality evidence that comes from consistent results from well-performed randomized controlled trials (RCTs), or overwhelming evidence from another source (such as well-executed observational studies with consistent strong effects and exclusion of all potential sources of bias). Grade A implies confidence that the true effect lies close to the estimate of the effect.
- Grade B evidence means moderate-quality evidence from randomized trials that suffers from serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias, or some combination of these limitations, or from other study designs with specific strengths such as observational studies with consistent effects and exclusion of the majority of the potential sources of bias.
- Grade C evidence is low-quality evidence from controlled trials with several serious limitations, or observational studies with limited evidence on effects and exclusion of most potential sources of bias.
- Grade D evidence is based only on case studies, expert judgement or observational studies with inconsistent effects.

Contributing organizations

A list of contributing organisations can be found at: https://iusti.org/treatment-guidelines/