Public Health England

HIV Testing and Self-Testing

Answers to frequently asked questions

About Public Health England

Public Health England's mission is to protect and improve the nation's health and to address inequalities through working with national and local government, the NHS, industry and the voluntary and community sector. PHE is an operationally autonomous executive agency of the Department of Health.

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Summary

The law on the sale of self-testing kits for HIV within the UK (HIV Testing Kits and Services Regulation 1992) was changed on 6 April 2014. It is now lawful to sell and advertise the sale of HIV self-testing kits in England, Scotland and Wales. As of April 2014 we are not aware of any HIV self-test kits that have been CE marked and can be placed on the UK or EU market. This is expected to change in 2014/15.

This document provides important information for people thinking about buying a self-test kit or getting an HIV test.

The intended audience is:

- individuals considering purchasing an HIV self-test kit for personal use
- professional audiences; including clinicians, other healthcare workers, and those working or volunteering for non-governmental organisations involved in HIV prevention

Frequently asked questions

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1. Why should I have an HIV test?

If you are at-risk for HIV infection you should have an HIV test, and if you are at high HIV risk you should have repeat HIV tests regularly. Should you catch HIV, early diagnosis prolongs your life through highly effective treatment and your sexual partners can be protected.

2. Who should have an HIV test?

Taking an HIV test in the only way to find out if you have HIV. If you have HIV, early diagnosis will mean that your treatment will have better outcomes, and the risk of passing the infection on to others will be reduced. If you think you may have been at risk, have an HIV test. Get tested regularly for HIV if you are one of those most-at-risk:

- **men who have sex with men** are advised to have an HIV test and Sexually Transmitted Infection (STI) screen at least annually, and every three months if having unprotected sex with new or casual partners
- **black African men and women** are advised to have an HIV test, and a regular HIVtest and STI screen if having unprotected sex with new or casual partners

Always use a condom correctly and consistently, and until all partners have had a sexual health screen. Do not make decisions to engage in sex without a condom, based on the perceived HIV status of a sexual partner. Sex without a condom with partners believed to be of the same HIV status **is unsafe**. For the person with HIV, there is a high risk of acquiring other STIs and hepatitis. For the HIV negative person there is a high risk of HIV transmission (a fifth of HIV positive people are unaware of their infection) as well as acquiring STIs and hepatitis.

3. Where can I get an HIV test?

It is very easy to get an HIV test throughout the UK. You can:

- **ask your doctor**. An HIV test involves having blood taken, or sometimes even a finger prick. Most general practitioner doctors (GPs) are able to arrange to have blood taken and sent to a laboratory for an HIV test, and to get the result back within two to three days. There is no need for a lengthy discussion about HIV testing

- **go to a sexual health or genitourinary medicine (GUM) clinic**. You don't need a referral from your GP and you can go to a clinic anywhere. Sexual health clinics will not share your testing information with other NHS services. Selected clinics may offer "fast-track" testing while you wait, together with a follow-up blood specimen to investigate any immediate results that need more information
- **use an HIV testing service in a non-clinical venue** provided by HIV charities that offer a free, confidential and open-access service
- **request a self-sampling kit online**. There are a number of self-sampling HIV test services available in the UK. You take the specimen yourself (either a finger-prick or a mouth-swab) and return it to a laboratory. After some days you will receive a result from the service, advising you what to do next

4. Will I have to pay for an HIV test?

Attending a GP or sexual health service to have a test for HIV (or any other sexually transmitted infection; STI) is free of charge in the UK. Whether you are a short-term visitor, a student, a migrant from abroad, or an asylum seeker – **no matter what your residency status** – seeing a GP and having an HIV test is free[1]. Highly effective treatment for HIV is available through the NHS, and is free of charge.

If you wish to take a test for HIV, **click here** to find a clinical service convenient for you.

5. What is HIV self-testing?

Self-testing is when you perform an HIV test on yourself away from a medical setting (eg at home), and see a result immediately.

If this result is reactive (positive) you may have HIV, and you will need to visit a **clinical service**, to confirm whether or not you have HIV. If you are diagnosed HIV positive at the clinical service, you will be referred for HIV care and treatment, which is free to all throughout the UK – no matter what residency status you have.

1As detailed in paragraph 106 of "Sustaining services, ensuring fairness: Government response to the consultation on migrant access and financial contribution to NHS provision in England". Department of Health, 2013. www.gov.uk/government/uploads/system/uploads/attachment_data/file/268630/Sustaining_services__ensuring_fairness_-_Government_response_to_consultation.pdf

6. Should I use an HIV self-test?

If you are considering a self-test for HIV, before you test it is important to think about what you will do once you receive the test result; whether it is negative or reactive (positive). If you:

- have thought through what knowing your HIV status will mean to you
- want an immediate test result in the privacy of your home
- are able to obtain a reliable self-testing kit, and
- have read the instructions and are confident you understand how to follow them and interpret the results

Then doing a self-test for HIV will provide you with information about your HIV status.

Self-testing for HIV is different from consulting a healthcare worker who can advise you about testing, provide additional support and help you access laboratory tests of the highest quality.

7. How do I get a self-test kit for HIV?

Self-test kits cannot be sold within the UK or the EU unless they have been CE marked by the manufacturer according to specified safety, quality and performance requirements. As of April 2014 we are not aware of any HIV self-test kits that have been CE marked and can be placed on the UK or EU market. This is expected to change in 2014/15.

If you would like to be tested for HIV then please **click here** to find a clinical or self-sampling service that is convenient for you.

8. How do I know I am buying a reliable self-test kit for HIV?

Whether buying from the high street or online, only buy a self-test kit from a source that you trust, and make sure that the test has a CE mark. To CE mark an HIV self-test kit

the manufacturer must meet a number of requirements concerning test performance, labelling and directions for use[2]. When used as intended CE marked self-test kits will work properly and be acceptably safe. It is expected that CE marked kits will be on the market in England later in 2014/15.

So you should check for the CE mark:

However, no self-test kit is 100% reliable, and the CE mark does not guarantee that the test is suitable for your health needs. You should consult your GP or visit a **clinical service** if your concerns or symptoms persist, or if you have any worries about your health.

9. How soon after a risk event can I use an HIV self-test kit?

If you have engaged in high-risk behaviour (that is sex without a condom with a partner who has HIV or whose HIV status is unknown, or injecting drug use with equipment that may have been used by someone else) within the past three months, some HIV self-test kits may not detect HIV infection. Instead we recommend that you attend a clinic to take a highest quality HIV test – **click here** to find a clinic.

The period of time between becoming infected with HIV and the infection being detectable by a test is referred to as the “window period”. If an HIV test is performed during this window period, a person who has recently become infected with HIV may receive a “false negative” test result. Different tests have different window periods. Laboratory HIV tests used as part of clinic services usually have a shorter window period than HIV self-test kits.

2Medical tests are subject to an EU Directive called the In Vitro Diagnostic Medical Devices Directive; and Self-Tests must conform to current guidance. Tests that meet the required standards will be CE marked by the manufacturer on the basis of conformity assessment certification from a notifed body whose number should appear on the label after the CE marking. Notified bodies are independent conformity assessment organisations designated and monitored by the regulatory authorities in EU member states as competent to undertake this function. Further information and advice on buying self-test kits for STDs can be found at www.mhra.gov.uk.

10. Is it difficult to use a self-test for HIV?

Self-testing kits for HIV have been developed to be easy to use. People with no specialist scientific or medical skills should be able to use safely any HIV self-test kit. When performing a self-test for HIV you should follow instructions carefully and completely.

11. What should I do if my HIV self-test result is negative?

If your self-test result is negative, there is no need to perform a confirmation test, unless you have reason to believe you did not follow the test instructions, or you have engaged in high-risk behaviour within the window period of the test.

If you have engaged in high-risk behaviour, then you may also be at risk of other sexually transmitted infections (STIs), or bloodborne viruses such as hepatitis B and C. To access testing for other STIs or bloodborne viruses, and advice on how to reduce your risk of getting HIV, an STI or bloodborne virus in the future, please visit a **sexual health service** or **drug addiction service**.

12. What should I do if my HIV self-test result is reactive?

A test result that is reactive (positive) does not mean that you definitely have HIV. All test results that are reactive need to be confirmed. If your HIV self-test result is reactive, you should attend a **clinical service** that is convenient for you. When you attend the clinical service, it will be helpful if you provide the details about the HIV self-test kit that you used. The easiest way for you to do this is to take the kit and its packaging with you.

The clinical service will then perform a further HIV test. If you have HIV, appropriate care and treatment will be made available to you. Highly effective treatment for HIV is available through the NHS, and is free of charge.

13. Can I use an HIV self-test on other people?

Self test kits are intended for personal individual use and should not be used on other people. It is illegal to perform a test on another person without their consent, and the person should not be forced or pressurised to test.

Any medical test (such as a self-test for HIV) should be done with the informed consent of the person being tested. The person should have a clear understanding of the available facts and what the test result will mean in the future (informed), and should have agreed (consented) to take the test.

14. How does self-testing for HIV differ from self-sampling?

Self-sampling HIV test kits are available in the UK. The person who is testing takes a sample (saliva or blood from a finger prick), and then sends it to a laboratory for testing. Results are then given by the service, advising you what to do next.
Self-sampling has been shown to be effective at diagnosing people with HIV who were unaware they were infected. The success of self-sampling, away from clinical settings, suggests there may be a demand for HIV self-testing.

Self-testing kits for HIV are not the same as self-sampling kits. No HIV self-test kits are currently approved for sale in the UK. With HIV self-test kits, an individual takes a sample, tests it themselves using the kit, and obtains their result immediately. There is no need to send the sample to a laboratory, and you read the result yourself.

15. What types of HIV tests do clinical services use?

All clinics will use 4th generation laboratory tests. These are the recommended tests for routine clinical use in the UK [2, 3], and are the most up to date and accurate. To find details of an HIV testing facility offering 4th generation tests please **click here**.

Although HIV self-test kits may be convenient, most self-test kits for HIV are 3rd generation, which are not as reliable as 4th generation tests. The window period of a 3rd generation test is longer than the 4th generation tests available at clinics. This means that a person who has recently acquired HIV could test positive with a 4th generation test, but negative with a 3rd generation test.

16. Can I use an HIV self-test kit to test for other sexually transmitted infections?

No. It is important to understand that self-test kits for HIV only test for HIV infection. Other STIs such as syphilis, gonorrhoea, herpes and chlamydia cannot be identified using an HIV test. If you have engaged in high-risk behaviour, such as sex without a condom, you may also be at risk of other STIs. If you are at risk of STIs, it is recommended that you have a full sexual health screen, at a sexual health service according to your risk profile (detailed below). To access testing for other STIs, and advice on reduction of high-risk behaviours, visit a **sexual health service.**

17. How can I reduce my risk of getting or transmitting HIV and other STIs?

You can reduce your risk of acquiring HIV if you:

- always use a condom correctly and consistently, and until all partners have had a negative sexual health screen
- reduce the number of sexual partners and avoid overlapping sexual relationships
- have an HIV test if you think you may have been at risk. Early HIV diagnosis prolongs your life through treatment and protects your sexual partners
- get tested regularly for HIV if you are one of those most at risk:
  - men who have sex with men should have an HIV test and STI screen at least annually, and every three months if having unprotected sex with new or casual partners
  - black African men and women should have an HIV test and a regular HIV and STI screen if having unprotected sex with new or casual partners
  - if you often find yourself in need of an HIV test (after possible exposure events) you should visit a **clinical service**. These services will offer you advice on how to reduce your chances of contracting HIV and help avoid risks in the future

18. Can I use an HIV self-test to decide whether or not to use a condom?

Do not use self-testing for HIV to make decisions about any behaviour that may put you or your partner at increased risk of HIV infection. The window period of all HIV tests means that you cannot know with complete certainty whether or not a partner has HIV. Sex without a condom also puts you at risk of contracting other STIs. The risk of HIV transmission is greater if either partner has another STI. It is not always possible to tell if you or your partner has an STI – many do not have symptoms. For people who are HIV negative, there is a high risk of HIV acquisition (a fifth of HIV positive people in the UK are unaware of their infection) as well as other STIs, hepatitis B or C. For people who have HIV, there is an increased risk of acquiring other STIs and hepatitis B or C.

19. Why was the ban on selling HIV self-test kits lifted?

There are three main reasons why the ban has been removed:

1. Increased access to HIV testing, treatment and care

Making self-testing available in the UK increases the options for getting an HIV test. One in five people with HIV in the UK do not know that they have HIV. HIV self-testing will not replace clinic-based testing. Instead, self-testing for HIV provides an additional testing method to reach out to those who are uncomfortable or unable to take an HIV test in a clinic [4, 5].

Increased testing means that more people will be aware of their HIV status and start treatment when appropriate. To begin treatment a person with HIV must first be diagnosed. This starts by taking an HIV test.

People with HIV who begin treatment soon after becoming infected can have a near-normal lifespan [6]. Early treatment is better at keeping people with HIV in the best possible health. As well as a benefit to people with HIV, treatment has the additional benefit of making people much less infectious to others, reducing the chance of passing HIV on to sexual partners [7, 8].

2. Regulation of self-test quality

In the UK, medical devices (such as testing kits) must meet specific quality standards. Lifting the ban on HIV self-testing enables properly regulated self-testing kits to be available within the UK. The quality and accuracy of self-testing kits will then be guaranteed.

Illegal self-testing kits are available to purchase over the Internet. These kits do not have to meet the UK standards and regulations. There is no guarantee that non-CE-marked tests will work reliably, and may give you a false result. Non-CE-marked tests kits may come with little or no instructions for use, advice on safer sexual practices, or information on how to get HIV treatment and care [9].

3. Public opinion on self-testing for HIV

In other countries, where self-testing is already available, people have said that they like the increased privacy that self-testing provides, as well as the immediate test results. Self-testing has been shown to be acceptable among those who have never tested for HIV before [4].

20. How will the use of HIV self-test kits be monitored in the UK?

As with any medical device, users of a self-test kit for HIV (including members of the public) should report any “adverse incidents” involving the test kit to the Medicines and Healthcare products Regulatory Agency (MHRA) and the manufacturer or supplier as soon as possible. An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users; for example a misdiagnosis due to a failure of an HIV self-test kit, leading to inappropriate treatment. Please **click here** for details of how to report an adverse incident.

PHE, in collaboration with both the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA), will monitor the outcome of reactive HIV self-tests. Clinicians who provide sexual health services, and who care for people with HIV infection, will be asked to report the confirmed HIV status of patients who have presented for further laboratory tests following a reactive self-test for HIV. All systems, both new and established, collect anonymous data and doctors will not give any personal details to PHE.

How to find a sexual health service

NHS Choices: www.nhs.uk/Service-Search/Sexual-health-services/LocationSearch/1847

NAM: www.aidsmap.com/e-atlas

Terrence Higgins Trust: www.tht.org.uk/sexual-health/Service-finder#open or call THT Direct on 0808 802 1221

How to find a drug addiction service

NHS Choices: www.nhs.uk/Service-Search/Drug-addiction/LocationSearch/1804

How to obtain a self-sampling kit

Two national services offer free self-sampling kits:

- Dean Street at home: http://www.deanstreetathome.com/
- THT self-sampling: www.tht.org.uk/sexual-health/HIV-STIs/HIV-AIDS/HIV-postal-test

A number of local services also offer a free self-sampling service, and self-sampling kits for HIV and other STIs are commercially available.

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