

Press release: Regulator seizes almost 10,000 unsafe STI + HIV test kits

Almost 10,000 sexually transmitted infection (STI) and HIV test kits which could give unreliable and false results have been seized by the Medicines and Healthcare products Regulatory Agency (MHRA) since 2015. Today the Agency are warning people to make sure that they are purchasing from safe and legitimate sources and avoid fake STI and HIV test kits which could give unreliable and false results.

Fake test kits could potentially give false negatives and lead to an increase in diseases such as chlamydia, syphilis and gonorrhoea as well as HIV. A false negative test result occurs when the test shows negative and the person is instead positive.

Online marketplaces are a known avenue where potentially unsafe test kits are being sold. While MHRA works with companies to remove these types of products from sale, the next stage of the [#FakeMeds campaign](#) intends to educate people buying STI & HIV test kits online.

Do not use any kit that has not been sealed, that has damaged packaging or is outside of its expiry date.

Make sure that the instructions for use are clear, easy to follow and written in understandable language.

If you have any concerns about the quality of a self-test kit, report it to the MHRA using the [Yellow Card Scheme](#).

Approved self-testing kits carry a CE mark – this shows that they have gone through the proper regulatory processes and, when used in accordance with their instructions, are safe to use. Approved kits should also clearly state they are intended for use as self-tests.

Separate MHRA research has revealed people are prepared to buy risky products over the internet.

25% of young people¹ have bought medical products online in the past 12 months and almost 1 in 10 (9%) admitted to buying products they knew, or strongly suspected, to be falsified.

More than 6 in 10 of those surveyed (63%) bought STI test kits after reading articles about home testing kits on a website, forum or blog and 64% wanted to avoid the embarrassment of buying the kits in a shop or pharmacy.

MHRA's Devices Group Manager, Graeme Tunbridge:

Know what you're buying by purchasing self-test kits and other medical devices from a safe and legitimate provider. Look for the distance selling logo which means that the supplier is registered with the MHRA to sell medicines to the public and has been accredited as a legitimate source. Make sure that the test is easy to use and has clear instructions.

Alternatively, if you are buying a medicine online look for the distance selling logo, which means that the supplier is registered with the MHRA to sell medicines to the public and has been accredited as a legitimate source.

Michael Brady, Medical Director, Terrence Higgins Trust said:

It's great that medical advances now mean there are increasingly more HIV and STI testing options available online. Improving access, choice and convenience of where and how to test are key components of our approach to HIV prevention and tackling STIs.

It is extremely worrying to hear about illegal and fake test kits being advertised online and THT supports the #FakeMeds campaign from the MHRA. We agree that it's really important for people to know that what they're purchasing is safe, effective and will reliably diagnose or exclude STIs and HIV.

Dr Oscar quote:

It is terrifying that there are so many fake and dangerous STI test kits out there, which could cause people to unwittingly spread infections and diseases.

Be safe and make sure you are buying legitimate products.

"If you suspect you may have an STI, please visit your local GP or healthcare professional – it's much better to be safe than sorry."

¹ MHRA qualitative research of 1,009 18-30 year olds.