

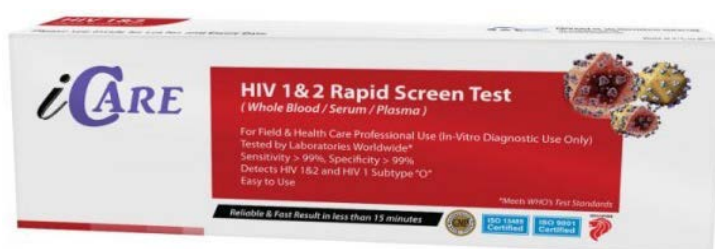
Safety Notice

Medical Devices



IRISH MEDICINES BOARD

Illegal “*iCARE*” self test kits (including HIV self tests)



***iCARE* HIV 1&2 rapid screen test**
***iCARE* Syphilis rapid screen test**
***iCARE* Gonorrhoea rapid screen test**
***iCARE* Chlamydia rapid screen test**

Priority 2 – Warning

IMB Safety Notice: SN2014(25)

Issue Date: 15th May 2014

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Supplied via the following websites: www.hivhometests.co.uk www.testhiv.de www.testhiv.nl www.hiv-zelftest.nl	CP20456

ISSUE

The *iCARE* HIV 1&2, *iCARE* Syphilis, *iCARE* Gonorrhoea and *iCARE* Chlamydia rapid screen self-test kits do not bear the CE mark, as required in Europe. They are being sold illegally. These tests for sexually transmitted infections (STIs) either have no CE mark, have no legal CE mark, or bear a fake CE mark.

ACTION OR RECOMMENDATIONS

The IMB advises the public:

- 1) **Do not buy or use** the *iCARE* HIV 1&2, *iCARE* Syphilis, *iCARE* Gonorrhoea or *iCARE* Chlamydia rapid screen self-test kits sourced either on-line or from any shop / supplier.
- 2) Contact your GP or pharmacist if you have (or think you may have) purchased or used an *iCARE* self-test STI kit. If affected, consider the need to re-test.
- 3) Do not buy medical devices from websites that you have not verified.

The IMB advises that healthcare professionals:

- 1) Notify the IMB of any suspected or confirmed incidents of patients having purchased and/or used *iCARE* HIV 1&2, *iCARE* Syphilis, *iCARE* Gonorrhoea or *iCARE* Chlamydia rapid screen self-test kits.
- 2) Advise affected patients of the need to re-test.

TARGET GROUPS

General public
General Practitioners
STI clinics
Pharmacies
Healthcare professionals who use these devices

Supplies managers
Community clinics
Drug addiction treatment centres
Blood transfusion clinics
Practise nurses

BACKGROUND

As these tests offer no proof that they meet the necessary legal requirements for CE marking, there is no guarantee that they work properly. Therefore someone who is infected with HIV, syphilis, gonorrhoea, or chlamydia may get a false negative test result making them think they are not infected. As a consequence, they may not get the necessary medical help and could unknowingly spread infection. On the other hand, someone who is not infected may get a false positive result telling them they are infected leading to undue stress.

Information / Related Documents:

The websites we know about that sell the illegal HIV and other STI tests are:

www.hivhometests.co.uk;
www.testhiv.de;
www.testhiv.nl;
www.hiv-zelftest.nl.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

The **manufacturer** is thought to be:

Future Ventures Ltd
Chamber of Commerce
10a Seapower Industrial Centre
Kowloon
Hong Kong

IMB CONTACT INFORMATION

Questions about these devices or adverse incidents should be reported to:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6767836
E-mail: medicaldevices@imb.ie
Website: www.imb.ie