

Medical Device Alert

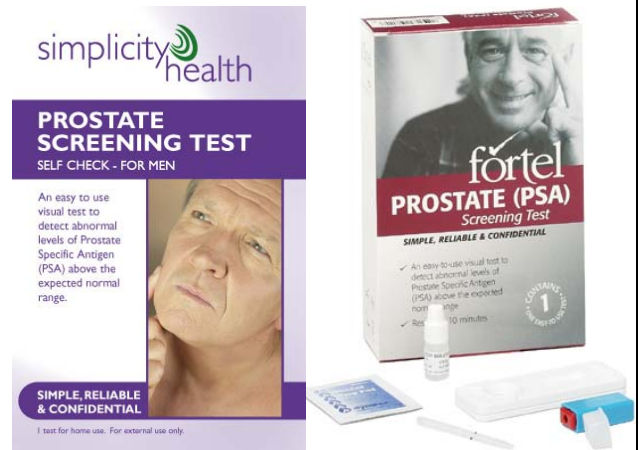
Action

Ref: MDA/2009/069 Issued: 03 November 2009 at 14:30

Device

Home test kits:
Simplicity Health prostate screening
and
Fortel prostate specific antigen test.
Affected lot no. 1012

Manufactured by Biomerica Inc USA.
Distributed in the UK by:
- BHR Pharmaceuticals Ltd
- Simplicity Health Ltd



Problem

Risk of false negative results which could lead to a missed diagnosis of prostate cancer.

Action by

General practitioners.
Pharmacists.

CAS deadlines

Action underway: 17 November 2009
Action complete: 04 January 2010

Action

Consider displaying the safety information sheet (see appendix) to alert potential users.

If a patient presents having used this test, consider the need to further advise and re-test the patient.

Advise users holding kits from the affected lot to discard it.

Contact

UK Supplier
BHR Pharmaceuticals Ltd
Tel: 0870 0349 606
Fax: 0870 0349 607

[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON062530)

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