

Medical Device Alert

Action

Ref: MDA/2009/070 Issued: 05 November 2009 at 11:00

Device

Urine test strips.

Uritest 13G manufactured by URIT Medical Electronic.

Distributed in the UK by Econo-Med Ltd.

All batches.



Problem

Potential for misdiagnosis due to poor analytical precision and sensitivity when testing for low levels of microalbumin and creatinine in urine.

Risk of poor impregnation of the microalbumin and creatinine test pads by the sample, due to their position at the top on the strip.

No instructions for use are provided by the company to aid visual interpretation of the test.

Action by

Healthcare personnel using, supervising, quality assuring or distributing this device.

Healthcare personnel treating patients based on results from these kits.

Action

Do not use the test strip for the determination of microalbumin or creatinine.

For other parameters make sure all test pads are fully immersed into the sample, because the length of the strip can exceed that of the urine sample pots commonly used in the UK.

Only use strips with the appropriate analyser, Uritest-500C or Uritest-50, as per instructions.

CAS deadlines

Action underway: 25 November 2009
Action complete: 25 January 2010

Contact

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Link to full Medical Device Alert

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON062575>