

# Medical Device Alert

## Action

Ref: MDA/2009/054 Issued: 11 August 2009 at 14:00

### Device

Pregnancy test for professional use.  
Clearview HCG manufactured by  
Unipath Limited.  
Product code 506788 (all lot  
numbers).  
Distributed from January 2008.



### Problem

False positive results may be observed when the test results are interpreted beyond 3 minutes.

### Action by

Healthcare professionals using or distributing this device.

Healthcare personnel treating patients based on results from these kits.

### CAS deadlines

Action underway: 25 August 2009

Action complete: 08 September 2009

### Action

- Ensure that all users read the results at 3 minutes and are aware of the revised instructions for all existing stocks and new products.
- Use a timer, stopwatch or clock as listed in the instructions. Tests read before or after the 3 minute read time should be repeated.
- Consider the need to review previous results.
- Ensure standard operating procedures (SOP) are updated to reflect manufacturer's revised instructions.

### Contact

#### Manufacturer

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### [Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON054493)

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