

Questions and Answers

Pregnancy test kits: Cleaview HCG

Lot Number HG0050

What is wrong with the pregnancy test kit?

MHRA has been informed of a patient who received negative test results when tested with lot HG0050 of this kit. A test with another lot of the same product gave a positive result. The pregnancy was confirmed by ultrasound.

The manufacturer has recalled this batch of product

The manufacturer has determined that this problem was caused by a single manufacturing fault that was not detected by routine quality control checks.

This test is intended for professional use only. It is not intended for direct sale to members of the public.

What action is MHRA/Department of Health taking?

The Medicines and Healthcare products Regulatory Agency has published the manufacturer's recall letters on its website and has published a Medical Device Alert to the health service advising users to stop using this kit and to develop a policy to review high risk patients.

How many of these kits have been sold?

The UK manufacturer informed MHRA that around 80,000 test kits from lot HG0050 were distributed in Europe in March and April 2007, and the manufacturer has estimated that around 100 test kits were affected by the manufacturing fault.

What is a pregnancy test?

A pregnancy test kit measures the level of a hormone called HCG (human chorionic gonadotrophin) which rises during pregnancy.

Why are pregnancy test performed?

They may be performed for a variety of reasons such as:

- To confirm pregnancy
- To exclude pregnancy before giving treatment/drugs/x-rays
- To help diagnose or exclude ectopic pregnancy (An ectopic pregnancy is a form of pregnancy in which a fertilized egg settles and grows outside of the womb. This can lead to internal bleeding).

Which pregnancy tests are affected?

The MHRA Medical Device Alert is only about Clearview HCG lot HG0050, which is intended to be used only by healthcare professionals. Pregnancy test kits that are sold for use at home are not affected.

How many batches of the Clearview pregnancy test kit are affected by this problem?

The manufacturer has determined that only one lot of this kit is affected by the manufacturing problem (lot number HG0050). Products from this lot are labelled as Clearview HCG.

Are home tests affected?

Clearview pregnancy test kit is intended for use in hospitals and not sold over the counter for home use. MHRA is not aware of problems with any other pregnancy test kits (Unipath's Clearblue pregnancy test kit which is intended for use at home is not affected by this recall).

How many hospitals are affected?

MHRA does not have a complete list of the recipients of this lot as some product was distributed direct by Unipath and some was distributed by third parties.

The MHRA Device Alert has been sent to all NHS primary care and acute trusts and to hospitals in the independent sector.

I recently had a negative pregnancy test result from testing done in a hospital/clinic/GP surgery before they decided that a course of treatment was appropriate. What should I do?

If your test result was negative and you are concerned that you may be pregnant, you should make an appointment to discuss these matters with your doctor, walk-in centre, sexual health clinic, family planning clinic or pharmacist.

Are any other pregnancy test kits affected by this problem?

The MHRA is not aware of any other pregnancy test kits that are affected by this problem.

What can we use instead?

There are a variety of alternative pregnancy test kits available.

I have recently bought a pregnancy test kit for use at home. Could the result have been wrong?

The recalled devices are not sold in retail pharmacies. However, no pregnancy test is 100% accurate. An indication of the accuracy may be found in the instructions for use. MHRA is not aware of any problems with other pregnancy test kits.

I did a pregnancy test at home recently and I believe the result was wrong. What should I do?

The recalled devices are not sold in retail pharmacies. However, no pregnancy test is 100% accurate. An indication of accuracy may be found in the instructions for use.

- If you have concerns about your health, contact your GP.

- If you have concerns about the accuracy of a test kit result this can be reported to MHRA. Details of how to do this are on the MHRA website <http://www.mhra.gov.uk>

If I have had a pregnancy test recently and the result was negative, how can I tell if this was correct?

The recalled devices are not sold in retail pharmacies. If you are concerned that you may be pregnant it may be helpful to have another pregnancy test carried out. Some pharmacies offer a pregnancy testing service, and pregnancy tests for use at home can be obtained through your GP, Family Planning Clinic, pharmacies and supermarkets.

I am a health care professional and have recently sent samples for laboratory pregnancy testing. How can I tell if this testing might be affected by this problem?

Contact the laboratory to check which test kit they used.

What is the Medicines and Healthcare products Regulatory Agency?

The Medicines and Healthcare products Regulatory Agency is an Executive Agency of the Department of Health with responsibility for safeguarding public health and patient safety by ensuring that medicines, healthcare products and medical devices meet the appropriate standards of safety, quality and performance.

How are pregnancy test kits regulated?

Since the 7 December 2003 the Medical Devices Regulations have applied. All test kits have to meet the requirements of these regulations and bear the CE mark.

Was this pregnancy test kit regulated?

The Clearview pregnancy test carries the CE mark under the Medical Devices Regulations. The CE mark represents that manufacturer's declaration that the device meets all of the relevant Essential Requirements for safety and performance.