



Australian Government
Department of Health and Ageing

MEDIA STATEMENT

11th May 2009

SELF-TEST BOWEL CANCER KITS – IMPORTANT NOTICE FOR USERS

The Department of Health and Ageing will start contacting participants in the National Bowel Cancer Screening Program from this week to invite people to re-take the test, after quality issues were identified during an investigation of the test kits.

The Department has recently observed that the level of positive results in tests performed since 1 December 2008 is lower than expected. The Department has reviewed the reliability of the test kits under certain conditions.

108,000 people have undertaken tests since this time and have returned a negative result and will be asked to repeat the test with a new kit. The Department will write to all 475,000 people who have received the test kits since 1 December 2008, although many have not yet used the test and returned it for assessment.

It is expected it will take no longer than two weeks to contact all affected people. New test kits will then be issued as they become available in coming weeks.

People who have used the screening kit and have received a positive result are not affected. Anyone with a positive result should, if they have not already done so, see their doctor to arrange further investigation.

The Department is in urgent discussions with Dorevitch Pathology, the supplier of the test kits, to verify the cause of the problem and ensure that new, reliable tests are available as soon as possible. The test kits are manufactured by Japan-based Fujirebio Diagnostics, imported into Australia by Siemens Medical Healthcare Diagnostics, and supplied to the Department by Dorevitch Pathology. Preliminary investigations indicate that recent changes to the kit contents by Fujirebio may be the cause of the test result discrepancies.

The Department is seeking advice to determine the legal and financial liability of the supplier resulting from this investigation and the re-testing.

The Australian Government is taking a safety-first approach to this issue to protect the integrity of the National Bowel Cancer Screening Program. Our highest priority is the well-being of the program participants.

The Australian public can have full confidence in the program. This is a case where the Department has identified a problem early, and is taking all necessary steps to remedy the problem.

The kits were provided as part of the National Bowel Cancer Screening program to screen all 50, 55 and 65-year-olds.

The Department will contact all people who received kits since 1 December to advise of new test options.

People who received kits prior to 1 December 2008 are not affected even if they returned the samples after this date.

While people are waiting for retesting, they should contact their doctor if they are concerned or are experiencing any of the following symptoms – bleeding from the rectum, signs of blood in faeces, notable change in the frequency and consistency of bowel movements, abdominal pain, or unexpected tiredness.

For further information on screening status, members of the public who have received test kits since 1 December 2008 should contact Dorevitch Pathology on 1 300 738 365.

Information about re-testing options is available at www.health.gov.au

Background

Changes in test results under the National Bowel Cancer Screening Program were discovered when routine evaluation of the data from upgraded self-test kits began to show a noticeable decline in the rate of positive results – signs of possible cancer.

The inclusion in July 2008 of 50 year old Australians in the screening test was anticipated to reflect a lower positive incidence across the data. This was initially thought to be a reason for the recent decline in positive results.

However, as more kits were introduced, the positive rate fell further, with the March figures showing a marked decline. Extensive testing is being carried out to identify potential causes.

New kits will be sent to all affected people as soon as testing confirms the efficacy and reliability of the new kits. This may take some time, possibly several weeks, before testing is complete and supply is available.

The Faecal Occult Blood Test kit used by the Department of Health and Ageing is manufactured by Japan-based Fujirebio Diagnostics and imported into Australia by Siemens Medical Solutions Diagnostics. The kit is supplied to the Department by Dorevitch Pathology.

Bowel cancer claims more than 80 Australian lives each week. Australia has one of the highest incidences of bowel cancer in the world.

Early screening for bowel cancer has the potential to prevent as many as 2000 deaths every year.

The free tests are offered to all Australians who turn 50, 55 or 65 years of age between 2008 and 2010. The program in its current phase – to include people turning 50 years of age – began on 1 July 2008.

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