Cytomegalovirus (CMV) is a common virus that rarely causes noticeable symptoms or significant health problems. However, a new CMV infection may cause serious illness and complications in pregnant women, newborns and people with weakened immune systems.

**SA Pathology uses Siemens test kits to test for CMV infection. A product recall was issued on Wednesday 7 September for test kits used between 17 July 2015 to 24 August 2016.**

**What is CMV?**

Cytomegalovirus (CMV) is a common virus. Fifty per cent people have been infected by young adulthood and up to 85 per cent by 40 years of age.

Peaks of infection occur in children less than 2 years of age, and during adolescence. Once a person becomes infected, the virus remains alive but usually inactive (dormant) within that person’s body for life.

It is rare for a person to get symptoms after the initial infection unless their immune system is weakened by severe illness and treatments (e.g. for cancer).

Reactivation of the virus can occur during pregnancy in women who have had infection previously, with a very small risk of transmission of CMV to the unborn baby.

**Who is at risk?**

If a woman is newly infected with CMV while pregnant, there is a risk that her unborn baby will also become infected (congenital CMV). Infected babies may, but not always, be born with problems.

The highest risk to the unborn baby occurs when a woman who has never had CMV before is infected with the virus for the first time during pregnancy (primary CMV infection) and when infection occurs during the first half of the pregnancy. Infection during one pregnancy does not increase the risk for subsequent pregnancies. However, if primary infection occurs, consideration should be given to waiting for at least 12 months before becoming pregnant again.

**What are the symptoms?**

Infection in children and adults is usually without symptoms. Occasionally, symptoms similar to glandular fever such as fever, sore throat, swollen glands, abdomen pain and jaundice can occur.

**How is CMV diagnosed?**

CMV antibody tests may be ordered when a patient, particularly a pregnant woman, has particular symptoms and will determine whether someone has had a recent CMV infection. Siemens test kits are used by SA Pathology to carry out this test.

**How do I know if I have had a test for CMV?**

Contact your General Practitioner (GP), and they will be able to tell you if you have been tested for CMV.
Frequently Asked Questions

Why were the Siemens test kits recalled?
Siemens identified a problem of increased risk of false-negative patient results due to imprecision of the assay, and has issued an international recall of the product.
The issue affects test kits used by a range of pathology providers internationally and nationally, including SA Pathology, between 17 July 2015 to 24 August 2016.

Why didn’t SA Pathology pick up this issue?
Siemens indicates in its recall notice that the problem was not detectable by normal laboratory quality control processes.

How many tests were conducted over this time?
As a result of the Siemens recall, and advice from the Therapeutic Goods Administration, SA Pathology is currently reviewing 2,076 tests carried out in this period.

What happens to tests that need to be redone?
Siemens has provided guidance on the patients for which retesting should be considered as a precautionary measure.
All affected tests will be repeated, prioritising pregnant women, followed by young children and females aged 12-50 years of age.
SA Pathology has already retested approximately 1,000 tests using existing samples, and all of the re-tests have confirmed the original negative results.

What is the risk from incorrect tests?
The risk of a positive result from the retesting process is estimated to be between 0% and 0.5%.
Samples are currently being re-tested as a precautionary measure, and all tests redone to date have confirmed the original negative result.

What about the accuracy of tests kits now in use?
Siemens claims that the cause of the imprecision has been identified and the current lot number in use is not affected and future lot numbers should not be affected.

Do I need to take any action?
No. If a positive result is returned, your doctor will be contact by SA Pathology.

Who can I contact if I am concerned?
For more information, contact your General Practitioner or phone SA Pathology on 8222 3000

For more information

www.sahealth.sa.gov.au

© Department for Health and Ageing, Government of South Australia. All rights reserved.