Laboratory Bulletin

Date: **December 12, 2012**

To: **Physicians, Laboratory Directors and Managers**

From: **Provincial Laboratory for Public Health (ProvLab)**

Re: **Transitioning to the polymerase chain reaction (PCR) for routine cytomegalovirus (CMV) testing in urine samples**

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Key Messages:

It has been known for some time that the polymerase chain reaction (PCR) is a more sensitive method of detecting cytomegalovirus (CMV) in urine than shell-vial culture. The CMV DNA PCR assay has been the method of choice for the screening of CMV congenitally-infected neonates in the first 2-3 weeks of life, in many centres, worldwide.

There will be a brief transitional period when urine samples will be tested by both the current shell-vial culture test, as well as the CMV DNA PCR test. This routine dual testing will be discontinued by **Thursday, 20 December 2012**, after which only the CMV DNA PCR test will be routinely performed on all urines. The shell-vial culture will only be available in special circumstances, e.g., for a repeatedly PCR-inhibitory specimen or as a specific request by the Infectious Diseases team only.

Background:

Cytomegalovirus infections of the developing fetus, *in utero*, at any time during pregnancy, can have serious consequences. In addition, it is known that of all the CMV-congenitally infected, but otherwise apparently normal-looking babies at birth, approximately15% may go on to develop variable degrees of sensorineural deafness and developmental delay. Undiagnosed, asymptomatic congenital CMV infection is also now thought to be one of the main causes of sensorineural hearing loss in young children (1-3).

Why is this important:

- The timely screening of neonatal urines (within 2-3 weeks of birth) for CMV allows the prompt and accurate diagnosis of congenital CMV infection.
- ProvLab will be moving from the existing viral culture method to a PCR-based assay to enhance the sensitivity of this routine testing. If confirmed, these babies can then be followed up, long-term, to carefully monitor their hearing and developmental progress.
- There is a long-term follow-up program for such CMV-infected infants in Alberta.
- The PCR-based assay will also provide a more sensitive detection method for CMV in urine taken from all other patients.
- Users should be aware that asymptomatic CMV shedding can sporadically occur from otherwise immunocompetent individuals, e.g., when they have other concomitant infections or illnesses.

Sample types:

- Primarily urine (at least 0.5 mL in a plain universal container).
- Oral fluids/saliva (a swab in universal transport media) can also be tested, but the validation for these samples is incomplete at present.
- Please ensure the screw caps are well-tightened for these samples, so there is no risk of leakage.

Result reporting:

- Results for testing on urine samples will be reported qualitatively as NEGATIVE or POSITIVE.
- For the oral fluids/saliva samples, the PCR-based assay has not yet been validated for these sample types. The result report will include a comment to this effect.

References:

1. Foulon I, Naessens A, Foulon W, Casteels A, Gordts F. A 10-year prospective study of sensorineural hearing loss in children with congenital cytomegalovirus infection. J Pediatr. 2008 Jul; 153(1):84-8.
2. Grosse SD, Ross DS, Dollard SC. Congenital cytomegalovirus (CMV) infection as a cause of permanent bilateral hearing loss: a quantitative assessment. J Clin Virol. 2008 Feb; 41(2):57-62.
3. Nijman J, van Loon AM, de Vries LS, Koopman-Esseboom C, Groenendaal F, Uiterwaal CS, Verboon-Maciolek MA. Urine viral load and correlation with disease severity in infants with congenital or postnatal cytomegalovirus infection. J Clin Virol. 2012 Jun; 54(2):121-4.

Inquiries and feedback may be directed to:

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This bulletin has been reviewed and approved by:

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