ADDENDUM XIV

INTERPRETATION OF VIRAL ANTIBODY TITERS

IgM specific testing is available to determine a current infection with Toxoplasmosis, Herpes, CMV or Varicella. To determine a current infection for all other viruses, acute and convalescent specimens should be sent. An acute specimen should be drawn at the onset of symptoms with a convalescent specimen drawn 2-3 weeks later. A fourfold or greater increase in antibody titer indicates a probable current infection. Use the following guidelines to interpret viral antibody titers when a single serum specimen is tested. The computer code is indicated in parenthesis.

1. CMV IgG (CMVG)

- Negative: Negative for CMV IgG Antibodies. A negative result is presumed not yet infected with CMV and susceptible to primary infections.
- Equivocal: A new specimen should be sent in 2 weeks.
- Positive: Positive for CMV IgG antibodies and indicates past or current infection.

For diagnostic purposes, Anti-CMV IgG results should be used in conjunction with patient history and other CMV markers (e.g. anti-CMV IgM) for diagnosis of past or present infection.

Results are obtained using the Vidas CMV IgG Assay.

3. Herpes IgM (HERME)

Negative: No detectable antibody.
Equivocal: Sample tested equivocal twice.
Positive: A positive result can occur during primary or recurrent infection.
Limitations: The performance of this assay has not been established on individuals less than 1 year of age.

4. HSV 2 IgG Type Specific with RFLX (HSV2G)

Sample results in the Equivocal or Low Positive index range will be reflexed to HSV 2 IgG Supplemental testing per CDC Guidelines.

2. CMV IgM (CMVM)

- Negative: No detectable IgM antibody to CMV.
- Equivocal: A new specimen should be sent in two weeks.
- Positive: Positive for IgM Antibodies to CMV. Patient is presumed to be experiencing a recent infection (primary, reactivation or reinfection).

Results are obtained using the VIDAS CMV IgM antibody Assay.

Limitations: A diagnosis of an unsuspected primary CMV infection should not be based solely upon a positive result. IgM antibody to CMV can be produced as a result of reactivated infection or reinfection.

5. Measles IgG (MEAS)

- Negative: Indicates undetectable measles virus IgG antibody. Could be susceptible to measles infection.
- Equivocal: Sample tested equivocal twice. Consider potentially susceptible to primary infection.
- Positive: Indicates prior exposure to measles virus or a convalescent stage of infection.

ADDENDUM XIV (CONTINUED)

6. Mumps (MUMPS)

- Negative: Indicates undetectable mumps virus IgG antibody. Could be susceptible to mumps infection.
- Equivocal: Sample tested equivocal twice. Consider potentially susceptible to primary infection.
- Positive: Indicates prior exposure to mumps virus or a convalescent stage of infection.

7. Rubella Antibody IgG (RUB)

- Negative: Presumes that immunity to rubella virus has not been acquired
- Equivocal: Sample tested equivocal twice. Consider potentially susceptible to primary infection.
- Positive: Indicates prior exposure to rubella virus or a convalescent stage of infection.

8. Toxo IgG (TOXOG)**

- <4.0 Negative. Negative for IgG antibody to T. gondii.
- 4-7.9: Equivocal. Specimen may contain low levels of IgG. A second specimen should be tested.
- 28: Positive. Toxo IgG antibody results of greater than or equal to 8 IU/mL are positive for IgG Antibody to T. gondii and indicate acute or past infection.

This result was obtained using the VIDAS Toxo-IgG Assay. IgG values obtained with different manufacturers assay methods may not be used interchangeably. The magnitude of the reported IgG levels cannot be correlated to an endpoint titer.

Limitations: Performance has not been established for cord blood, neonatal samples, body fluid or cerebrospinal fluid. Results from immunosuppressed patients must be evaluated with caution.

9. Toxo IgM (TOXOM)**

- Negative: Non-reactive for anti-Toxoplasma gondii IgM antibodies.
- Equivocal: Samples interpreted as equivocal (gray zone) may contain very low levels of IgM. Suggest testing using an alternate method or a second specimen should be obtained and tested.
- Positive: Presumptively reactive for Anti-<u>Toxoplasma gondii</u> IgM antibodies. A diagnosis of acute or recent <u>toxoplasma gondii</u> should not be based on one IgM serology result. It is suggested that this result be confirmed by an alternate method.

Results are obtained using the VIDAS Toxo-IgM Antibody Assay.

- Limitations: Performance has not been established for cord blood, neonatal samples, body fluid or cerebrospinal fluid. Results from immunosuppressed patients must be evaluated with caution.
- **See Addendum IX (General Guidelines for interpretation of Toxoplasma gondii Serology Results)

10. Varicella IgG (VZG)

- Negative: Indicates no detectable VZV IgG antibody but does not rule out acute infection. Could be susceptible to primary VZV infection.
- Equivocal: Sample tested equivocal twice. Consider potentially susceptible to primary infection.
- Positive: Positive indicates presence of detectible VZV IgG antibodies. Generally indicates exposure to the pathogen or administration of specific immune-globulins, but it is not indication of active infection or stage of disease.

11. Varicella IgM (VZME)

- Negative: No detectible antibody.
- Equivocal: Sample tested equivocal twice.
- Positive: A positive result indicates a primary or reactivated infection with VZV. Such individuals are at risk of transmitting VZV infection.
- Limitations: The performance of this assay has not been established on neonates.