# Laboratory Procedure Manual

*Analyte:* *bioMerieux CMV IgG*

*Matrix:* Serum

*Method:* Enzyme-linked fluorescent immunoassay (ELFA)

*Method No:*
*Revised:*

*as performed by:* *Herpes* Diagnostic Laboratory

*contact:* Sheila Dollard, PhD

**Important Information for Users**

The National Center for Infectious Diseases periodically refines these laboratory methods. It is the responsibility of the user to contact the person listed on the title page of each write-up before using the analytical method to find out whether any changes have been made and what revisions, if any, have been incorporated.

## Public Release Data Set Information

This document details the Lab Protocol for testing the items listed in the following table:

| File Name | Variable Name | SAS Label |
|---|---|---|
| CMV_G | LBXCMV | Cytomegalovirus |

## 1. Summary of Test Principle and Clinical Relevance

CMV antigen detects specific antibody in serum. CMV is clinically important in several patient populations.

## 2. Safety Precautions

Treat all blood products as potentially infectious; wear appropriate personal protection equipment. Dispose of all Solid Phase Receptacle (SPR) and test strips in autoclave pans.

## 3. Computerization; Data System Management

CMV IgG ELISA use computer programs designed by Biomerieux. All specimen NHANES numbers were scanned by the barcode reader. The VIDAS instrument read specimen reactivity and assigned numeric values.

## 4. Specimen Collection, Storage, and Handling Procedures; Criteria for Specimen Rejection

Specimens arrived frozen from CASPIR and immediately placed at -20°C. Before testing, the specimens were thawed at 4°C. Specimens were kept at 4°C if further testing was needed, or returned to -20°C if testing was complete. Specimens with excessive microbial contamination were not tested.

## 5. Procedures for Microscopic Examinations; Criteria for Rejection of Inadequately Prepared Slides

Not applicable

## 6. Preparation of Reagents, Calibration (Standards), Controls, and All Other Materials; Equipment and Instrumentation

### a. Reagent Preparation

All reagents including standards and controls were from commercial kits.

### b. Standards Preparation

Not applicable

### c. Preparation of Quality Control Materials

Not applicable

**d. Other Materials**

**e. Instrumentation**

VIDAS (**V**itek **I**mmuno**D**iagnostic **A**ssay **S**ystem), model # v5431, bioMerieux Vitek, Inc., 595 Anglum Drive, Hazelwood, Missouri 63042-2395.

## 7. Calibration and Calibration Verification Procedures

**a. Performance Checks for the Assay**

Kit controls are included with each run and the kit standards are run every 14 days in duplicate, as per manufacturer instructions.

**b. Calibration of Instrument**

Calibration kits were run as recommended plus the instruments received preventative maintenance from company service engineers at least annually.

**c. Instructions for Calibration of Instrument**

Commercial calibration kits were used per manufacturer's instructions annually during preventative maintenance.

## 8. Procedure Operating Instructions; Calculations; Interpretation of Results

VIDAS is a fully automated closed system that performs every step after 100ul of sample has been added. The computer software from the manufacturer interpreted the results.

## 9. Reportable Range of Results

<4AU/ml to 400AU/ml

## 10. Quality Control (QC) Procedures

**a. Blind Quality Controls**

Not applicable

**b. Bench Quality Controls**

Not applicable

## 11. Remedial Action if Calibration or QC Systems Fail to Meet Acceptable Criteria

Testing is repeated if controls and/or standards were out of range.

## 12. Limitations of Method; Interfering Substances and Conditions

**a.** A very recent CMV infection (less than three weeks) may have IgG levels <4AU/ml.

**b.** Rare cross-reactivity can occur with other infectious diseases.

## 13. Reference Ranges (Normal Values)

Reference ranges of positive and negative controls, and standards were established by the MLE (Master Lot Entry) card for each lot. Controls and standards out of range were flagged by the instrument and therefore the results are void and must be repeated.

## 14. Critical Call Results ("Panic Values")

Not applicable

## 15. Specimen Storage and Handling during Testing

Specimens were tested at room temperature and returned to 4°C until further testing. Once all testing was complete, specimens were returned to -20°C.

## 16. Alternate Methods for Performing Test of Stored Specimens if Test System Fails

Alternate method for performing test, not applicable; however, if test system fails, troubleshoot and the run was repeated. If run fails again, a service call was placed. Specimens will remain at 4°C until testing was complete.

## 17. Test Result Reporting System; Protocol for Reporting Critical Calls (If Applicable)

Not applicable

## 18. Transfer or Referral of Specimens; Procedures for Specimen Accountability and Tracking

Specimens have a barcode which was used for tracking during all laboratory testing. For refrigerator and freezer storage, each specimen was accounted for by box number, and cell number. At completion of testing and analysis, all specimens will be returned to CASPIR CDC storage or destroyed.

## 19. Summary Statistics and QC Graphs

Qualitative assays are assays with a positive, negative or indeterminate result. Since the controls do not generate quantitative values, plots are not generated for quality control purposes.

## . References

1. Horodniceanu F., Michelson S. Archives of Virology, 1980,64,287-301.
2. Yolken R.H., Stopa P.J. Journal of Clin. Microbiology, 1980, Vol II, N°6, 546-551.
3. Ahlfors H., Ivarsson S.A., Johnsson T. and Svanberg L. Acta Paediatr Scand 71, 1982, 109-113