



TEST UPDATE

FROM YOUR LABORATORY SERVICES PROVIDER

Chemiluminescent Immunoassay (CLIA) Testing for Select Infectious Disease Serology Assays

Mary Beth Baker, M.S., S.V

On 8/24/07, PAML will be converting infectious disease serology testing for CYTOMEGALOVIRUS IgG & IgM, EPSTEIN BARR VIRUS IgG, IgM, Early Antigen and Nuclear Antigen and TOXOPLAS-MOSIS IgG & IgM, from enzyme-linked immunosorbant (ELISA) or immunofluorescent (IF) technologies to Chemiluminescent Immunoassay (CLIA).

Detection of antibodies to infectious diseases is an important clinical diagnostic tool. To be effective such assays must be highly sensitive, specific, robust and simple. In the evolving arena of antibody testing, chemiluminescent immunoassay (CLIA) technology offers distinct advantages over enzyme-linked immunosorbant (ELISA) or immunofluorescent (IF) technologies. Infectious disease serology testing done by CLIA is more sensitive and less prone to interference and background signal than that done by either ELISA or IF.

Specimen requirements for all of the CLIA assays infectious disease assays included in the accompanying table are identical:

Test Information

DESCRIPTION	See attached
METHOD	Chemiluminescent Immunoassay (CLIA)
ORDER CODE	See attached
CPT CODE	See attached
SAMPLE	Serum SST tube 1.0 mL
SPECIMEN REQUIREMENTS	1 mL serum (SST Tube). Separate serum from cells and place in a separate plastic tube. Store and transport refrigerated. Avoid freeze/thaw cycles.
COMMENTS	Stability: Refrigerated 48 hr, Frozen -20° C 1 month Unacceptable conditions - Plasma or whole blood. Serum samples that are grossly hemolyzed, icteric, lipemic, contain particulate matter or are contaminated.
RANGES	See attached

The biggest change that you will notice in these infectious disease serology reports is the change in reporting units and reference ranges. The units and reference ranges are not consistent among the CLIA assays. Read your reports carefully. Each serological result will include a comment to help interpret the test results. The results of the CLIA assays are qualitative and cannot be interpreted quantitatively nor compared quantitatively to previous ELISA or IFA results.

Quick Facts

CLIA Advantages over ELISA and FA:

- ▶ Increased Sensitivity
- ▶ Less prone to interference and background signal
- ▶ Consistent specimen requirements

Significant Test Changes:

- ▶ New Order Codes
- ▶ New Reporting Units
- ▶ New Reporting Ranges

For more information, please
contact Client Services or
see us on the Web at



Provided for the clients of

PATHOLOGY ASSOCIATES MEDICAL LABORATORIES • PACLAB NETWORK LABORATORIES
TRI-CITIES LABORATORY • TREASURE VALLEY LABORATORY • ALPHA MEDICAL LABORATORY

JUNE 2007

For more information, please contact your local representative.

Table: Summation of the Changes in Order Codes and Reporting Units

ANALYTE	TEST CODES		METHOD	REPORTING UNITS			
				Units	Neg	Equ	Pos
CMV IgG	Old Code:	CMVG;CMV.IGG	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	CMVGL	CLIA	U/mL	<0.60	0.60 - 0.69	≥ 0.70
CMV IgM	Old Code:	CMVM;CMV.IGM	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	CMVML	CLIA	Au/mL	< 30.0	30.0 - 34.9	≥ 35.0
CMV IgG & IgM	Old Code:	CMVGM; CMV.IGG.IGM	ELISA	Refer to the individual test results			
	New Code:	CMVGML	CLIA				
TOXO IgG	Old Code:	TOXOG;TOXO.IGG	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	TOXOGL	CLIA	IU/mL	< 6.0	6.0 - 7.9	≥ 8.0
TOXO IgM	Old Code:	TOXOM;TOXO.IGM	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	TOXOML	CLIA	Au/mL	< 8.0	8.0 - 9.9	≥ 10.0
TOXO IgG & IgM	Old Code:	TOXOGM;TOXO.IGG.IGM	ELISA	Refer to the individual test results			
	New Code:	TOXGML	CLIA				
EBV IgG	Old Code:	EBVG;EBV.IGG	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	EBVGL	CLIA	U/mL	< 18.0	18.0 - 21.9	≥ 22.0
EBV IgM	Old Code:	EBVM;EBV.IGM	ELISA	ISR	< 0.91	0.91-1.09	> 1.09
	New Code:	EBVML	CLIA	U/mL	< 36.0	36.0 - 43.9	≥ 44.0
EBV IgG & IgM	Old Code:	EBVGM;EBV.IGG.IGM	ELISA	Refer to the individual test results			
	New Code:	EBVGML	CLIA				
EBV NA Aby	Old Code:	EBVNA;EBV.NUC	IFA	TITER	<1:10		≥ 1:10
	New Code:	EBVNAL	CLIA	U/mL	<18.0	18.0 - 21.9	≥ 22.0
EBV EA Aby	Old Code:	EBVEA;EBV.EARLY	IFA	TITER	<1:10		≥ 1:10
	New Code:	EBVEAL	CLIA	U/mL	< 9.0	9.0 - 10.9	≥ 11.0
EBV Panel	Old Code:	EBVPAN;EBV.AB	ELISA;IFA	Refer to the individual test results			
	New Code:	EBPANL	CLIA				
TORCH IgG	Old Code:	TORCHG	ELISA	Refer to the individual test results			
	New Code:	TORGL	CLIA & ELISA				
TORCH IgM	Old Code:	TORCHM	ELISA	Refer to the individual test results			
	New Code:	TORML	CLIA & ELISA				
TORCH IgG & IgM	Old Code:	TORCHGM	ELISA	Refer to the individual test results			
	New Code:	TORGML	CLIA & ELISA				

Provided for the clients of

PATHOLOGY ASSOCIATES MEDICAL LABORATORIES • PACLAB NETWORK LABORATORIES
TRI-CITIES LABORATORY • TREASURE VALLEY LABORATORY • ALPHA MEDICAL LABORATORY

JUNE 2007

For more information, please contact your local representative.