



Lab Alert

Date: August 31, 2011

From: Regional Pathology Services

Subject: Changes for Molecular, Infectious Disease testing

Starting September 8th, 2011 specimen requirements for the following tests will require plasma yielded from an EDTA (Lavender) tube. Plasma must be separated from blood within 48 hours of collection. Label samples with patient's name, date of birth, and indicate "plasma" when applicable. Stability: refrigerated: one week; frozen plasma is acceptable.

Note: All client fees remain unchanged.

EBV DNA Detection cpt code updates: Qualitative 87798

Quantitative 87799

The following whole blood molecular tests

will change to EDTA Plasma as of 8 September 2011.

LIS Code	Test Name	Minimum Volume of plasma:	Only acceptable specimen as of 9/8/2011:
ADVBL	Adenovirus DNA/Blood	1 ml	EDTA Plasma
BKDB	BK DNA Quant/Blood	1 ml	EDTA Plasma
CMVQB	CMV DNA detect/Quant Blood	1 ml	EDTA Plasma
EBVQ	EBV DNA detect/Quant Blood	1 ml	EDTA Plasma
HHV6B	HHV-6 DNA detect/Blood	1 ml	EDTA Plasma
HHV8B	HHV-8 DNA detect Blood	1 ml	EDTA Plasma
HSVBL	HSV DNA detect/Blood	1 ml	EDTA Plasma
HVMPB	Herpes Virus Panel, Blood	1 ml	EDTA Plasma
JCB	JC DNA Detect, Blood	1 ml	EDTA Plasma
PARDB	Parvovirus DNA, Blood	1 ml	EDTA Plasma

VZVB	VZV DNA Detect/Blood	1 ml	EDTA Plasma
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- Molecular can no longer accept whole blood for these tests.
- 1 mL minimum of EDTA plasma (*please call for pediatric/NICU patients*).
- EDTA tubes must be spun, aliquoted and stored at 4°C within 48 hours of being collected.
- If there are multiple molecular tests, one aliquoted tube is acceptable (1 mL minimum).
- No changes will occur to body fluids. They must remain unspun and refrigerated.
- State source on lab order and specimen tube ie: “source; plasma” If source is not stated Regional Pathology Services will call clients to ascertain the source.

RE: EBV DNA Detection and Quantitation Assay: New Test and Specimen Source Change

Starting September 8, 2011 a new assay (FOCUS ASR) will be employed for EBV DNA detection and viral load quantitation. The previous test targeted the bamH1-K rightward (BKRF-1) open reading frame encoding EBNA-1. This new test targets the LMP2A gene of EBV and more accurately detects and quantifies virus in our patient population.

The specimen source for the previous test was whole blood. The specimen source for the new test will be plasma. As a result of this change, viral loads will be significantly lower and more specific for an active viral infection. In healthy individuals, EBV DNA is usually not measurable in plasma, whereas it is frequently amplifiable from whole blood because the viral genome is retained after primary infection in about 0.0001% of circulating leukocytes.

Plasma must be separated from blood within 48 hours of collection to minimize the potential for a falsely elevated viral load values due to release of viral genomes emanating from rupture of leukocytes during storage.

Below are examples of differences observed between the previous whole blood test and the new test with plasma as the specimen source:

	Previous test; whole blood	New test; plasma
Patient A	7290 copy/mL	Negative, EBV virus not detected, <300 copy/mL plasma
Patient B	25,000 copy/mL	Positive <500 copy/mL
Patient C	155,000 copy/mL	3,554 copy/mL

If you have questions or concerns about this change please contact Cathy Gebhart (phone 559-7660, e-mail cgebhart@unmc.edu).

Test Code	EBVQB
Test Name	Epstein Barr Virus (EBV) DNA Detection & Quantitation
Reference Interval:	Negative, EBV virus not detected, <300 copy/mL plasma
Lower Limit of Quantitation:	500 EBV copy/mL plasma
Upper Limit of Quantitation:	50,000,000 EBV copy/mL plasma

RE: CMV DNA Detection and Quantitation Assay: Recalibration and Specimen Source Change

Starting September 8, 2011 a new CMV standard (W.H.O. International Standard for Nucleic Acid Amplification Techniques, 1st International Standard, NIBSC number: 09/162) will be employed for the CMV DNA detection and viral load quantitation assay. The International Standard will allow for comparison of results across laboratories.

The specimen source for the previous test was whole blood. The specimen source for the new test will be plasma. As a result, viral load values and viral kinetics will be different and must be considered when monitoring patient results during the conversion between specimen sources. Detection of CMV in plasma is more specific for an active viral infection.

Plasma must be separated from blood within 48 hours of collection to minimize the potential for a falsely elevated viral load values due to release of viral genomes due to breakdown of leukocytes during storage.

Below are examples of differences observed between the previous whole blood test and the newly calibrated test with plasma as the specimen source:

	Previous test; whole blood	Newly calibrated test; plasma
Patient A	1,200 copy/mL	3,674 IU/mL
Patient B	4,200 copy/mL	17,831 IU/mL
Patient C	63,000 copy/mL	247,690 IU/mL

If you have questions or concerns about this change please contact Cathy Gebhart (phone 559-7660, e-mail cgebhart@unmc.edu).

Test Code	CMVQB
Test Name	Cytomegalovirus (CMV) DNA Detection & Quantitation
Reference Interval:	Negative, CMV virus not detected, <176 IU/mL plasma
Lower Limit of Quantitation:	290 CMV IU/mL plasma
Upper Limit of Quantitation:	2,900,000 CMV IU/mL plasma

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