



LABORATORY UPDATE

www.dlolar.com

Routine Testing

Newest Urine Collection Cup 3

Test Changes

- Bilirubin, Direct, Neonatal - Update reference range 4
- Bilirubin, Total, Neonatal - Update reference range..... 4
- Creatinine w/eGFR - Update rejection criteria and reference range..... 5
- Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgM) – Update test name and units of measure. 6
- Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgG) - Update test name and units of measure. 6
- Epstein-Barr Virus Antibody Panel - Update test name, units of measure, and minimum volume requirements. 6
- Epstein-Barr Virus Nuclear Antigen (EBNA) Antibody (IgG) - Update test name and units of measure. 7
- Epstein-Barr Virus, Early Antigen D Antibody (IgG) - Update test name and units of measure. 7
- HIV-1 Antibody, HIV-1, Western Blot – Update collection instructions..... 7
- HIV Antibodies, HIV-1/-2, EIA, with Reflexes – Update reflexing description..... 8



The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

**Quest Diagnostics Nichols Institute (San Juan Capistrano and Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

- BK Virus DNA, Qualitative Real-Time PCR, Urine 8
- BK Virus DNA, Quantitative Real-Time PCR, Urine 9
- UGT1A1 Genotyping..... 9

Test Changes

- HIV Antibodies, HIV-1/HIV-2, Western Blot/Immunoblot - Update specimen volume and report structure to add new reporting analytes.....10
- HIV-2 Antibody, Immunoblot - Update test and result name, specimen volume and methodology.10
- HIV Antibodies, HIV-1/HIV-2, EIA with Reflex to HIV-1, Western Blot - Update report structure to add new reporting analytes, update sample volume.11
- HIV-2 Antibody, EIA with Reflex to Immunoblot - Update test name and sample volume.....11
- HIV Antibody, HIV-1, Western Blot w/rfl to HIV-2, EIA w/rfl to Immunoblot - Update test name, methodology and report structure to add reporting analytes.12

Discontinued Tests

- Hepatitis B Surface Antigen12

DLO is pleased to inform you of the following new and updated laboratory testing information:

Newest Urine Collection Cup

Effective immediately, a new, improved urine collection cup is available to clients as well as to our Patient Service Centers. This cup is only used to collect the primary sample and urine must be transferred to the appropriate tube with preservative prior to submission to the laboratory for testing. Other cups such as green top screw cap cups should not be used to transport urine specimens. They do not contain a preservative and are designed only for body fluids and some tissues for culture. The new cup has been tested and shown to be essentially sterile when used properly, and is made from non-bacteriostatic polystyrene plastic that will not leak when warm specimen comes in contact with the cup. In addition, the new cups have a spout that greatly eases the transfer of specimen into a urinalysis transport tube.

If the cup has to be transported for a short distance from the bathroom to the collection station, there is a plastic lid molded to fit the cup that may be used to prevent any spills from occurring. *When placing the lid on the cup, the cup should be held near the top at the rim, where the cup is strongest.*



Through this voice of the customer initiative, we have improved the quality and ease of specimen collection. Please contact your Sales/Service Representative should you have any questions.

The supply order number for the new cup is: 136802

The supply order number for the cup lid is: 136948

Test Changes

Bilirubin, Direct, Neonatal	
Clinical Significance:	Elevated in jaundice of the newborn and obstructive jaundice.
Effective Date:	March 9, 2009
Test Code:	34162
Reference Range:	Direct Bilirubin: < or = 0.3 mg/dL
Additional Information:	Update reference range. These changes also apply to test code 6631 - Bilirubin, Total and Direct, Neonatal.

Bilirubin, Total, Neonatal			
Clinical Significance:	Elevated in jaundice of the newborn and obstructive jaundice.		
Effective Date:	March 9, 2009		
Test Code:	20381		
Reference Range:	Total Bilirubin:	1 day:	< or = 5.1 mg/dL
		2 days:	< or = 7.2 mg/dL
		3-5 days:	< or = 10.3 mg/dL
		6-7 days:	< or = 8.4 mg/dL
		8-9 days:	< or = 6.5 mg/dL
		10-11 days:	< or = 4.6 mg/dL
		12-13 days:	< or = 2.7 mg/dL
		14 days - 9 years:	0.2 - 0.8 mg/dL
		10 yrs - 19 years:	0.2 - 1.1 mg/dL
	> or = 20 years:	0.2 - 1.2 mg/dL	
	Indirect Bilirubin:	1 day:	< or = 5.1 mg/dL
		2 days:	< or = 7.2 mg/dL
		3-5 days:	< or = 10.3 mg/dL
		6-7 days:	< or = 8.4 mg/dL
		8-9 days:	< or = 6.5 mg/dL
		10-11 days:	< or = 4.6 mg/dL
		12-13 days:	< or = 2.7 mg/dL
		14 days - 9 years:	0.2 - 0.8 mg/dL
10 yrs - 19 years:		0.2 - 1.1 mg/dL	
> or = 20 years:	0.2 - 1.2 mg/dL		
Additional Information:	Update reference range. These changes also apply to test codes 6631 - Bilirubin, Total and Direct, Neonatal; 10231 - Comprehensive Metabolic Panel; 287 - Bilirubin, Total; 10256 - Hepatic Function Panel; 7286 - Bilirubin, Fractionated.		

Creatinine w/ eGFR			
Clinical Significance:	Serum creatinine is useful in the evaluation of kidney function and in monitoring renal dialysis. A serum creatinine result within the reference range does not rule out renal function impairment: serum creatinine is not sensitive to early renal damage since it varies with age, gender and ethnic background. The impact of these variables can be reduced by an estimation of the glomerular filtration rate using an equation that includes serum creatinine, age and gender.		
Effective Date:	March 9, 2009		
Test Code:	375		
Rejection Criteria:	Grossly Icteric		
Reference Range:		Males	Females
	0 - 2 days	0.79 - 1.58 mg/dL	0.79 - 1.58 mg/dL
	3 - 5 days	0.46 - 1.23 mg/dL	0.46 - 1.23 mg/dL
	6 - 7 days	0.37 - 1.05 mg/dL	0.37 - 1.05 mg/dL
	8 days - 30 days	0.35 - 0.92 mg/dL	0.35 - 0.92 mg/dL
	31 days - 11 months	0.27 - 0.72 mg/dL	0.27 - 0.72 mg/dL
	1 - 3 years	0.30 - 0.70 mg/dL	0.30 - 0.70 mg/dL
	4 - 6 years	0.29 - 0.68 mg/dL	0.29 - 0.68 mg/dL
	7 - 9 years	0.38 - 0.73 mg/dL	0.38 - 0.73 mg/dL
	10 - 12 years	0.42 - 0.78 mg/dL	0.42 - 0.78 mg/dL
	13 - 15 years	0.54 - 0.95 mg/dL	0.54 - 0.95 mg/dL
	16 - 17 years	0.70 - 1.16 mg/dL	0.51 - 1.00 mg/dL
	18 - 19 years	0.67 - 1.26 mg/dL	0.48 - 1.01 mg/dL
	20 - 29 years	0.80 - 1.30 mg/dL	0.57 - 1.03 mg/dL
	30 - 39 years	0.79 - 1.33 mg/dL	0.58 - 1.06 mg/dL
	40 - 49 years	0.78 - 1.34 mg/dL	0.59 - 1.07 mg/dL
	50 - 59 years	0.76 - 1.46 mg/dL	0.60 - 1.10 mg/dL
	60 - 69 years	0.76 - 1.46 mg/dL	0.60 - 1.18 mg/dL
	> 69 years	0.67 - 1.54 mg/dL	0.63 - 1.22 mg/dL
	eGFR African American	> OR = 60	mL/min/1.73m ²
	eGFR Non-African American	> OR = 60	mL/min/1.73m ²
Methodology:	Spectrophotometry		
FDA Status:	FDA Approved/Cleared		
Additional Information:	Update rejection criteria and reference range. These changes apply to the following test codes: 10165 – Basic Metabolic Panel w/eGFR; 10231 – Comprehensive Metabolic Panel w/eGFR; 10314 – Renal Function Panel w/eGFR; 7943 – Creatinine Clearance w/ eGFR		

Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgM)				
Clinical Significance:	Primary infection by EBV causes infectious mononucleosis, usually a self-limiting disease in children and young adults. Infection with EBV can cause lymphoproliferative disorders including tumors. VCA-IgM typically appears approximately 4-6 weeks after initial infection and declines to undetectable in 1 month in young children and up to 3 months in others.			
Effective Date:	March 9, 2009			
<i>Former Test Name:</i>	<i>Epstein-Barr Virus Antibody (IgM) to Viral Capsid Antigen (VCA-IgM)</i>			
Test Code:	8426			
Reference Ranges:	EBV VCA Ab (IgM):	< or = 0.90 0.91-1.09 > or = 1.10	Negative Equivocal Positive	Index Index Index
Additional Information:	Update test name and units of measure.			

Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgG)				
Clinical Significance:	Primary infection by EBV causes infectious mononucleosis, usually a self-limiting disease in children and young adults. Infection with EBV can cause lymphoproliferative disorders including tumors. VCA-IgG appears approximately 10 weeks after initial infection and persists for life. Absence of VCA-IgG typically indicates the patient is susceptible to infection.			
Effective Date:	March 9, 2009			
<i>Former Test Name:</i>	<i>Epstein-Barr Virus Antibody (IgG) to Viral Capsid Antigen (VCA-IgG)</i>			
Test Code:	8474			
Reference Ranges:	EBV VCA Ab (IgG):	< or =0.90 0.91-1.09 > or =1.10	Negative Equivocal Positive	Index Index Index
Additional Information:	Update test name and units of measure.			

Epstein-Barr Virus Antibody Panel				
Clinical Significance:	Primary infection by EBV causes infectious mononucleosis, usually a self-limiting disease in children and young adults. Infection with EBV can cause lymphoproliferative disorders including tumors. VCA-IgG appears approximately 10 weeks after initial infection and persists for life. VCA-IgM typically appears approximately 4-6 weeks after initial infection and declines to undetectable in 1 month in young children and up to 3 months in others.			
Effective Date:	March 9, 2009			
<i>Former Test Name:</i>	<i>Epstein-Barr Virus Panel</i>			
Test Code:	6421			
Specimen Requirements:	1 mL serum (minimum 0.6 mL)			
Reference Ranges:	EBV Capsid IgM:	< or =0.90 0.91-1.09 >or =1.10	Negative Equivocal Positive	Index Index Index
	EBV Capsid IgG:	< or =0.90 0.91-1.09 > or =1.10	Negative Equivocal Positive	Index Index Index
	EBNA IgG:	< or =0.90 0.91-1.09 > or =1.10	Negative Equivocal Positive	Index Index Index
Additional Information:	Update test name, units of measure, and minimum volume requirements.			

Epstein-Barr Virus Nuclear Antigen (EBNA) Antibody (IgG)				
Clinical Significance:	Primary infection by EBV causes infectious mononucleosis, usually a self-limiting disease in children and young adults. Infection with EBV can cause lymphoproliferative disorders including tumors. EBNA is detected during convalescence and high titers persist for life. VCA-IgM positivity in the absence of EBNA suggests the patient has a recent, active infection.			
Effective Date:	March 9, 2009			
<i>Former Test Name:</i>	<i>Epstein-Barr Virus Antibody to Nuclear Antigen (EBNA)(IgG)</i>			
Test Code:	8564			
Reference Ranges:	EBV EBNA Ab (IgG):	< or =0.90 0.91-1.09 > or =1.10	Negative Equivocal Positive	Index Index Index
Additional Information:	Update test name and units of measure.			

Epstein-Barr Virus, Early Antigen D Antibody (IgG)				
Clinical Significance:	Primary infection by EBV causes infectious mononucleosis, usually a self-limiting disease in children and young adults. Infection with EBV can cause lymphoproliferative disorders including tumors. Early Antigen D Antibody appears approximately 1 month after infection and typically is transient lasting only 1-2 months. Persistently elevated levels suggest reactivation or persistence of EBV infection.			
Effective Date:	March 9, 2009			
<i>Former Test Name:</i>	<i>Epstein-Barr Virus, Antibody to Early Antigen D (IgG)</i>			
Test Code:	15447			
Reference Ranges:	EBV EA-D Ab (IgG):	< or =0.90 0.91-1.09 > or =1.10	Negative Equivocal Positive	Index Index Index
Additional Information:	Update test name and units of measure.			

HIV-1 Antibody, HIV-1, Western Blot	
Clinical Significance:	HIV-1 is the virus that causes Acquired Immunodeficiency Syndrome (AIDS). Western blot with an EIA-positivity has combined specificity of greater than 99.9%. Western blot results may be indeterminate with early HIV-1 infection and in patients with autoimmune disease and women who are pregnant.
Effective Date:	March 9, 2009
Test Code:	5233
Specimen Requirements:	1 mL serum To protect patient confidentiality, we recommend identifying specimens by using a code number in place of patient's name on the specimen vial and the test request form. Tube must be labeled with patient identified and submitted only for HIV testing. HIV-1 Western Blot requires the original tube for testing.
Additional Information:	Update collection instructions.

HIV Antibodies, HIV-1/-2, EIA, with Reflexes	
Clinical Significance:	The combination HIV-1/HIV-2 includes detection of subtypes of HIV-1 not included in HIV-1 alone. Repeatedly positive results are confirmed by the highly specific western blot.
Effective Date:	March 9, 2009
Test Code:	19728
Additional Information:	<p>Update reflexing description.</p> <p>Reflex criteria: If HIV 1/2 Antibody screen is repeatedly reactive, HIV-1 Antibody, Western Blot will be performed at an additional charge (CPT: 86689).</p> <p>If HIV-1 Antibody, Western Blot is negative or indeterminate, HIV-2 Antibody, EIA will be performed at an additional charge (CPT: 86702).</p> <p>If HIV-2 Antibody, EIA is reactive, HIV-2 Antibody, Immunoblot will be performed at an additional charge (CPT: 86689).</p>

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

The following tests will be available through Quest Diagnostics Nichols Institute on the dates indicated below.

BK Virus DNA, Qualitative Real-Time PCR, Urine	
Clinical Significance:	This test is used to determine the presence of BK Virus DNA in patient's specimens. Detection of the virus in these specimens may be indicative of an active infection, as PCR detects the presence of the virus, and not the host's reaction to the virus. Polyomavirus BK DNA detection in urine or plasma is associated with an increased risk of graft rejection in renal recipients.
Effective Date:	February 9, 2009
Test Code:	16553
CPT Code:	87798
Specimen Requirements:	0.7 mL random urine (sterile, leak-proof container)
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	Not detected
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly and Focus Diagnostics, Inc.

BK Virus DNA, Quantitative Real-Time PCR, Urine	
Clinical Significance:	This test is used to determine the presence of BK Virus DNA in patient's specimens. Detection of the virus in these specimens may be indicative of an active infection, as PCR detects the presence of the virus, and not the host's reaction to the virus. Polyomavirus BK DNA detection in urine or plasma is associated with an increased risk of graft rejection in renal recipients. Quantitative testing may indicate change in risk over time. This is a quantitative molecular test, with a linear range of 500-39,000,000 copies/mL.
Effective Date:	February 9, 2009
Test Code:	16581
CPT Code:	87799
Specimen Requirements:	0.7 mL random urine (sterile, leak-proof container)
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	< 500 copies/mL
Methodology:	Real-Time Polymerase Chain Reaction
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly and Focus Diagnostics, Inc.

UGT1A1 Genotyping	
Clinical Significance:	Uridine diphosphate glucuronosyltransferase 1A1 (UGT1A1) is primarily responsible for the glucuronidation and detoxification of SN-38, the active metabolite of irinotecan (Camptosar), used in the treatment of colorectal cancer. The TA-7 variant referred to as UGT1A1*28, is associated with reduced SN-38 glucuronidation and increased toxicity. Individuals homozygous for the UGT1A1*28 (TA-7) allele have Gilbert syndrome which is a mild form of hyperbilirubinemia.
Effective Date:	Available now
Test Code:	16521
CPT Code:	83891, 83892 (x4), 83896 (x4), 83908 (x4), 83912
Specimen Requirements:	5 mL EDTA (lavender-top tube) whole blood
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 8 days Frozen: 14 days
Reference Ranges:	Accompanies report
Methodology:	Invader Assay, Signal Amplification
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

HIV Antibodies, HIV-1/HIV-2, Western Blot/Immunoblot			
Clinical Significance:	HIV-1 is the virus that causes Acquired Immunodeficiency Syndrome (AIDS). Western blot and EIA-positivity have a combined specificity of greater than 99.9%. Western blot results may be indeterminate with early HIV-1 infection and in patients with autoimmune disease and women who are pregnant. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Western blot is useful to confirm repeatedly reactive EIA results.		
Effective Date:	March 23, 2009		
Test Code:	10110		
Specimen Requirements:	2 mL serum (minimum 1 mL)		
Reference Ranges:	HIV-1 AB, WESTERN BLOT	Interpretation p18 p24 p31 p40 gp41 p51 p55 p65 gp120 gp160 HIV 2 Antibody, Immunoblot	Negative Per report Per report Per report Per report Per report Per report Per report Per report Per report Per report Negative
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano		
Additional Information:	Update specimen volume and report structure to add new reporting analytes.		

HIV-2 Antibody, Immunoblot	
Clinical Significance:	HIV-2 is closely related to HIV-1 regarding nucleic acid sequence and clinical disease. HIV-2 is endemic to West Africa with nearly all cases in the United States identified in citizens or travelers from West Africa. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Western blot is useful to confirm repeatedly reactive EIA results.
Effective Date:	March 23, 2009
Test Code:	34313
Specimen Requirements:	1 mL serum (minimum 0.5 mL) To protect patient confidentiality, we recommend identifying specimens by using a code number in place of patient's name on the specimen vial and the test request form.
Methodology:	Immunoblot
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test and result name, specimen volume and methodology.

HIV Antibodies, HIV-1/HIV-2, EIA with Reflex to HIV-1, Western Blot			
Clinical Significance:	The combination HIV-1/HIV-2 includes detection of subtypes of HIV-1 not included in HIV-1, EIA alone. HIV-2 is closely related to HIV-1 regarding nucleic acid sequence and clinical disease. HIV-2 is endemic to West Africa with nearly all cases in the United States identified in citizens or travelers from West Africa. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Western blot is useful to confirm repeatedly reactive EIA results.		
Effective Date:	March 23, 2009		
Test Code:	37694		
Specimen Requirements:	2 mL serum (minimum 0.5 mL)		
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days To protect patient confidentiality, we recommend identifying specimens by using a code number in place of patient's name on the specimen vial and the test request form.		
Reference Ranges:	HIV 1/2 Ab Screen, EIA		Non reactive
	HIV-1 AB, WESTERN BLOT	Interpretation	Negative
		P18	Per report
		P24	Per report
		P31	Per report
		P40	Per report
		GP41	Per report
		P51	Per report
		P55	Per report
		P65	Per report
		GP120	Per report
		GP160	Per report
Methodology:	Immunoassay		
Performing Site:	Quest Diagnostics Nichols Institute		
Additional Information:	If HIV-1/HIV-2 EIA Antibody screen is reactive, then HIV-1 Antibody Western Blot will be performed at an additional charge (CPT: 86689). Update report structure to add new reporting analytes, update sample volume.		

HIV-2 Antibody, EIA with Reflex to Immunoblot	
Clinical Significance:	HIV-2 is closely related to HIV-1 regarding nucleic acid sequence and clinical disease. HIV-2 is endemic to West Africa with nearly all cases in the United States identified in citizens or travelers from West Africa. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Immunoblot is useful to confirm repeatedly reactive EIA results.
Effective Date:	March 23, 2009
Test Code:	37363
Specimen Requirements:	1 mL serum (minimum 0.5 mL) To protect patient confidentiality, we recommend identifying specimens by using a code number in place of patient's name on the specimen vial and the test request form. Tube must be labeled with patient identifier and submitted only for HIV testing. HIV-1 Western Blot requires the original tube for testing.
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update test name, sample volume and collection instructions.

HIV Antibody, HIV-1, Western Blot w/rfl to HIV-2, EIA w/rfl to Immunoblot			
Clinical Significance:	HIV-1 is the virus that causes Acquired Immunodeficiency Syndrome (AIDS). Western blot and EIA-positivity have a combined specificity of greater than 99.9%. Western blot results may be indeterminate with early HIV-1 infection and in patients with autoimmune disease and women who are pregnant. Rarely, HIV-1 Western blot indeterminate results may be due to HIV-2 infection in a patient who has been exposed to HIV-2. The Western blot is useful to confirm repeatedly reactive EIA results.		
Effective Date:	March 23, 2009		
Test Code:	37708		
Reference Ranges:	HIV-1 Ab, Western Blot	Interpretation	Negative
		p18	Per report
		p24	Per report
		p31	Per report
		p40	Per report
		gp41	Per report
		p51	Per report
		p55	Per report
		p65	Per report
		gp120	Per report
		gp160	Per report
		HIV 2 Antibody, EIA	Nonreactive
		HIV 2 Antibody, Immunoblot	Negative
Methodology:	Western blot, Immunoassay, Immunoblot		
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano		
Additional Information:	If the Western blot is negative or indeterminate, an HIV-2 ELISA will be performed at an additional charge. If the HIV-2 ELISA is repeatedly reactive, an HIV-2 Immunoblot will be performed at an additional charge. Update test name, methodology and report structure to add reporting analytes.		

Discontinued Tests

Hepatitis B Surface Antigen	
Effective Date:	March 16, 2009
Test Code:	37567
Additional Information:	This test will be discontinued. The recommended alternative is: 498-Hepatitis B Surface Antigen with Reflex Confirmation.