

Table of Contents

Announcements.....	4
New Test Offerings	5
Anidulafungin, HPLC	5
Capreomycin, HPLC.....	5
Test Changes	6
HLA-B27 Antigen.....	6
Luteinizing Hormone.....	6
ERCC1, IHC with Interpretation	6
ERCC1, IHC without Interpretation	7
C3a desArg Fragment	7
IGF Binding Protein-1 (IGFBP-1)	7
Annexin V Antibodies (IgG, IgM).....	7
von Willebrand Factor Antigen	8
Neopterin	8
Mycobacteria Identification.....	8
Acyclovir, HPLC.....	8
Amprenavir, HPLC.....	8
Fluconazole, HPLC.....	9
Ganciclovir, HPLC	9
Indinavir, HPLC	9
Kaletra™, HPLC	9
Nelfinavir, HPLC	9
Nevirapine, HPLC.....	10
Saquinavir, HPLC	10
Streptomycin, HPLC	10
Redirects	11
Inhibin B.....	11

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.

Discontinued Tests.....	12
B-Cell Gene Rearrangement, Quantitative PCR, Cell-based.....	12
B-Cell Gene Rearrangement, Quantitative PCR, Plasma-based, Leumeta®.....	12
T-Cell Receptor (TCR) Gene Rearrangement, Quantitative PCR, Cell-based	12
T-Cell Receptor (TCR) Gene Rearrangement, Quantitative PCR, Leumeta®.....	12
Lyme Disease (Borrelia burgdorferi) DNA Qualitative Real-Time PCR, Blood	12
Lyme Disease (B burgdorferi) QL DNA Real-Time PCR, CSF or Synovial Fluid.....	13
Lyme Disease (Borrelia burgdorferi) DNA Qualitative Real-Time PCR, Urine.....	13

Summary of Test Changes

Test Name	Test Code(s)	Performing Site	Test Code	Test Name	Specimen Requirements	Transport Temperature	Shipping Temperature	Specimen Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Reject Criteria	Other (see listing)
HLA-B27 Antigen	528				x					x				
Luteinizing Hormone	615									x				
ERCC1, IHC with Interpretation	16979													x
ERCC1, IHC without Interpretation	16988													x
C3a desArg Fragment	17689				x			x						
IGF Binding Protein-1 (IGFBP-1)	36590									x				
Annexin V Antibodies (IgG, IgM)	11266							x						x
von Willebrand Factor Antigen	4919								x					
Neopterin	34890									x				
Mycobacteria Identification	11137													x
Acyclovir, HPLC	8398									x			x	
Amprenavir, HPLC	10577									x			x	
Fluconazole, HPLC	34882									x			x	
Ganciclovir, HPLC	15472									x			x	
Indinavir, HPLC	10930									x			x	
Kaletra™, HPLC	15531									x			x	
Nelfinavir, HPLC	10578									x			x	
Nevirapine, HPLC	10576									x			x	
Saquinavir, HPLC	10585									x			x	
Streptomycin, HPLC	30303									x			x	
Sulfamethoxazole, HPLC	16990									x			x	

Announcements

PROFICIENCY TEST REMINDER: PLEASE ENSURE THAT YOU DO NOT SEND YOUR PROFICIENCY TEST (PT) SAMPLES TO DLO FOR TESTING, EVEN IF YOU SEND SUCH TESTING TO DLO FOR YOUR PATIENT TESTING.

Federal regulations prohibit the referral, or communication, of proficiency test material or data during an active survey; even if it is inadvertent. Unintentional referral of proficiency testing can occur if you have automated systems that generate a referral for reflexive testing OR if you store your proficiency testing samples in DLO specimen transport bags or in areas where our couriers' pick-up samples from your laboratory. If DLO receives proficiency test samples from another laboratory we are obligated by law to notify the federal government. Review the brochure identified below to identify ways to prevent inadvertent proficiency test referrals.

The Center for Medicare and Medicaid Services (CMS) - Clinical laboratory Improvement Amendments (CLIA) Program has made available on the CMS website an informative brochure should you require additional information. <http://www.cms.gov/CLIA/downloads/CLIAbrochure8.pdf>

CLIENT QUALITY CONCERNS: As always, please contact your local DLO laboratory or salesperson if you have any concerns or comments, including concerns about laboratory performance or quality. If you do not have the number you may use the "Contact Us" link on the DLO web site for the number to customer service and they will connect you with the appropriate person. In addition, if you are not satisfied with our response, you may contact CMS; see instructions on the CLIA web site <http://www.cms.gov/CLIA/downloads/CLIAbrochure9.pdf>.

New Test Offerings

The following tests will be available through DLO on the dates indicated below.

Anidulafungin, HPLC	
Clinical Significance:	Anidulafungin is an antifungal of the echinocandin class of antifungals, targeting susceptible strains of <i>Candida</i> . The mechanism of action for anidulafungin is to inhibit the synthesis of (1,3)B-D-glucan, an essential compound in the structure of fungal cell walls and one that is not present in mammalian cells. Measurement of serum anidulafungin levels may be helpful to optimize drug dosing regimens, particularly where there is non-compliance, concern about drug interactions, pharmacokinetic variability, or suspected toxicity.
Effective Date:	September 26, 2011
Test Code:	90088
CPT Code(s):	80299
Specimen Requirements:	2 mL red-top (no gel) serum
Rejection Criteria:	(SST®); other body fluids including plasma
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days
Reference Ranges:	<0.1 mcg/mL
Methodology:	High Performance Liquid Chromatography
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.

Capreomycin, HPLC	
Effective Date:	September 26, 2011
Clinical Significance:	Capreomycin is commonly used in the treatment of tuberculosis, but may induce hearing loss as a result of its toxicity. Measurement of serum capreomycin levels may be helpful to optimize drug dosing regimens, particularly where there is non-compliance, concern about drug interactions, pharmacokinetic variability, or suspected toxicity.
Test Code:	90277
CPT Code(s):	80299
Specimen Requirements:	2 mL red-top (no gel) serum
Rejection Criteria:	(SST®); other body fluids including plasma
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days
Reference Ranges:	<0.1 mcg/mL
Methodology:	High Performance Liquid Chromatography
Assay Category:	Laboratory Developed Test
Performing Site:	Focus Diagnostics, Inc.

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the information that is changing appears in this update. *Former test codes and test names have been italicized.*

HLA-B27 Antigen	
Effective Date:	September 12, 2011
Test Code:	528
Specimen Requirements:	5 mL whole blood collected in sodium heparin (green-top) tube
Reference Ranges:	Negative

Luteinizing Hormone		
Effective Date:	September 12, 2011	
Test Code:	615	
Reference Ranges:	Male and Female <18 yrs	LH reference ranges established on post-pubertal patient population. Reference range not established for pre-pubertal patients using this assay. For pre-pubertal patients, the Quest Diagnostics Nichols Institute LH, Pediatrics assay is recommended (order code 36086).
	Male: 18-59 yrs	1.5 – 9.3 mIU/mL
	> or = 60 yrs	1.6 - 15.2 mIU/mL
	Female: Follicular Phase	1.9 – 12.5 mIU/mL
	Mid-Cycle Peak	8.7 – 76.3 mIU/mL
	Luteal Phase	0.5 – 16.9 mIU/mL
	Postmenopausal	10.0 – 54.7 mIU/mL
Additional Information:	This change also affects: <ul style="list-style-type: none"> • 30953 – LH, 2 specimens • 30954 – LH, 3 specimens • 30955 – LH, 4 specimens • 4571 – LH, 5 specimens • 34434 – LH, 6 specimens • 34435 – LH, 7 specimens • 34436 – LH, 8 specimens • 34437 – LH, 9 specimens. • 7137 – FSH and LH • 16992 - OVA1(TM)(Includes FSH and LH) 	

ERCC1, IHC with Interpretation	
Effective Date:	September 12, 2011
Test Code:	16979
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

ERCC1, IHC without Interpretation	
Effective Date:	September 12, 2011
Test Code:	16988
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

C3a desArg Fragment	
Effective Date:	September 19, 2011
Test Code:	17689
Specimen Requirements:	1 mL EDTA (lavender-top) plasma in each of 2 tubes (minimum: 0.5 mL in each of 2 tubes)
Specimen Stability:	Frozen: 21 days
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

IGF Binding Protein-1 (IGFBP-1)					
Effective Date:	September 19, 2011				
Test Code:	36590				
Reference Ranges:	<table border="1"> <tr> <td>Adults:</td> <td>5- 34 ng/mL</td> </tr> <tr> <td>Pediatrics:</td> <td> 5-9 years 15-95 ng/mL 10-14 years 8-64 ng/mL 15-18 years 5-40 ng/mL </td> </tr> </table>	Adults:	5- 34 ng/mL	Pediatrics:	5-9 years 15-95 ng/mL 10-14 years 8-64 ng/mL 15-18 years 5-40 ng/mL
Adults:	5- 34 ng/mL				
Pediatrics:	5-9 years 15-95 ng/mL 10-14 years 8-64 ng/mL 15-18 years 5-40 ng/mL				
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano				

Annexin V Antibodies (IgG, IgM)	
Effective Date:	September 19, 2011
Test Code:	11266
Collection Instruction:	Platelet-poor plasma: Centrifuge light blue-top tube 15 minutes at approx. 1500g within 60 minutes of collection. Using pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/ mcl). Freeze immediately and ship on dry ice.
Specimen Stability:	Room temperature: 24 hours
Assay Category:	Research Use Only
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

von Willebrand Factor Antigen	
Effective Date:	September 19, 2011
Test Code:	4919
Units of Measure:	%
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano and Chantilly
Additional Information:	Please note this test is included in the following group codes: <ul style="list-style-type: none"> • 15540-von Willebrand Comprehensive Panel 2 • 19790-von Willebrand Comprehensive Panel • 19649 - Menorrhagia Screen

Neopterin	
Effective Date:	September 19, 2011
Test Code:	34890
Reference Ranges:	<15 nmol/L
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Mycobacteria Identification	
Effective Date:	September 19, 2011
Test Code:	11137
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	The following result code will be removed from this test code: 85995939 Identification by HPLC.

Acyclovir, HPLC	
Effective Date:	September 26, 2011
Test Code:	8398
<i>Former Test Name:</i>	<i>Antiviral Serum Level, Acyclovir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Amprenavir, HPLC	
Effective Date:	September 26, 2011
Test Code:	10577
<i>Former Test Name:</i>	<i>Antiretroviral Level, Amprenavir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Fluconazole, HPLC	
Effective Date:	September 26, 2011
Test Code:	34882
<i>Former Test Name:</i>	<i>Antifungal Serum Level, Fluconazole, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 1.0 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Ganciclovir, HPLC	
Effective Date:	September 26, 2011
Test Code:	15472
<i>Former Test Name:</i>	<i>Antiviral Serum Level, Ganciclovir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Indinavir, HPLC	
Effective Date:	September 26, 2011
Test Code:	10930
<i>Former Test Name:</i>	<i>Antiretroviral Level, Indinavir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.2 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Kaletra™, HPLC	
Effective Date:	September 26, 2011
Test Code:	15531
<i>Former Test Name:</i>	<i>Antiretroviral Level, Kaletra™, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.2 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Nelfinavir, HPLC	
Effective Date:	September 26, 2011
Test Code:	10578
<i>Former Test Name:</i>	<i>Antiretroviral Level, Nelfinavir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Nevirapine, HPLC	
Effective Date:	September 26, 2011
Test Code:	10576
<i>Former Test Name:</i>	<i>Antiretroviral Level, Nevirapine, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Saquinavir, HPLC	
Effective Date:	September 26, 2011
Test Code:	10585
<i>Former Test Name:</i>	<i>Antiretroviral Level, Saquinavir, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 0.1 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Streptomycin, HPLC	
Effective Date:	September 26, 2011
Test Code:	30303
<i>Former Test Name:</i>	<i>Antimicrobial Serum Level, Streptomycin, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 1.0 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Sulfamethoxazole, HPLC	
Effective Date:	September 26, 2011
Test Code:	16990
<i>Former Test Name:</i>	<i>Antimicrobial Level, Sulfamethoxazole, HPLC</i>
Rejection Criteria:	Serum Separator Tube (SST®); other body fluids including plasma
Reference Ranges:	< 5.0 mcg/mL
Performing Site:	Focus Diagnostics, Inc.

Redirects

Effective September 19, 2011, the following test previously performed at Quest Diagnostics Nichols Institute San Juan Capistrano will now be performed at Quest Diagnostics Nichols Institute, Valencia.

Inhibin B			
Effective Date:	September 19, 2011		
Test Code:	34445		
Reject Criteria	Hemolyzed, icteric and lipemic samples		
Transport Temperature	Frozen		
Specimen Stability:	Room temperature: 48 hours		
Reference Ranges:	(Age):	Male	Female
	5-9.9 years	21 - 166 pg/mL	< or = 18 pg/mL
	10-13.9 years	41 – 328 pg/mL	< or = 86 pg/mL
	14-17.9 years	135 – 368 pg/mL	< or = 123 pg/mL
	>18 years:	47 - 308 pg/mL	
	Females:		
	Pre-menopausal:	<153 pg/mL	
	Post-menopausal:	<10 pg/mL	
Performing Site:	Quest Diagnostics Nichols Institute, Valencia		

Discontinued Tests

B-Cell Gene Rearrangement, Quantitative PCR, Cell-based	
Effective Date:	September 19, 2011
Test Code:	16005
Additional Information:	The recommended alternative is: 14868 - B-Cell Gene Rearrangement, Qualitative PCR, Cell-based performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

B-Cell Gene Rearrangement, Quantitative PCR, Plasma-based, Leumeta®	
Effective Date:	September 19, 2011
Test Code:	16118
Additional Information:	The recommended alternative is: 16119 -B-Cell Gene Rearrangement, Qualitative PCR, Plasma-based, Leumeta® performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

T-Cell Receptor (TCR) Gene Rearrangement, Quantitative PCR, Cell-based	
Effective Date:	September 19, 2011
Test Code:	16025
Additional Information:	The recommended alternative is: 15930 -T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

T-Cell Receptor (TCR) Gene Rearrangement, Quantitative PCR, Leumeta®	
Effective Date:	September 19, 2011
Test Code:	17861
Additional Information:	The recommended alternative is 17862 -T-Cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Leumeta® performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

Lyme Disease (<i>Borrelia burgdorferi</i>) DNA Qualitative Real-Time PCR, Blood	
Effective Date:	September 19, 2011
Test Code:	34287
Additional Information:	The recommended alternative is: 15777- Lyme Disease (<i>Borrelia</i> spp) DNA, Qualitative Real-Time PCR, Blood, performed at Focus Diagnostics, Inc.

Lyme Disease (B burgdorferi) QL DNA Real-Time PCR, CSF or Synovial Fluid	
Effective Date:	September 19, 2011
Test Code:	30297
Additional Information:	The recommended alternative is: 15564- Lyme Disease (<i>Borrelia</i> spp) DNA, Qual Real-Time PCR, Synovial Fluid/CSF, performed at Focus Diagnostics, Inc.

Lyme Disease (Borrelia burgdorferi) DNA Qualitative Real-Time PCR, Urine	
Effective Date:	September 19, 2011
Test Code:	36181
Additional Information:	The recommended alternative is: 15868- Lyme Disease (<i>Borrelia</i> spp) DNA, Qualitative Real-Time PCR, Urine, performed at Focus Diagnostics, Inc.