



LABORATORY UPDATE

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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.

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March 30, 2011

RE: New Report Enhancements – Reissued Clinical Reports

Dear Valued Client:

I would like to share with you enhancements in our ability to communicate with you when it is necessary for the **laboratory** to reissue a report. These enhancements are designed to provide additional categories to facilitate your clinical assessment of the reported change in a Clinical test result.

We are adding four categories to the Clinical test status –

- **“Revised”** will be used when a test **result** value is **changed** and will be indicated on the report with **“=> REVISED: Change in test result(s)”**.
- **“Amended”** will be used when a **client provides a change** to age/DOB or gender that may affect the reference range or flagging (e.g., High, Low) but with no change to the previously reported test results. This change will be indicated on the report with **“=>AMENDED: Report has been updated to reflect patients correct gender or date of birth. Please review results for possible flagging and/or reference range changes.”**
- **“Amended”** will also be used when a client provides additional or changed information such as specimen source that is changed from what was previously reported. There is no change to the interpretation or significance of previously reported test results. This change will be indicated on the report with **“=> AMENDED: Change in client provided information”**.
- **“Addendum”** will be used when new or additional information is added to a previously reported test result without any change to the test result. This addition will be indicated on the report with **“=>ADDENDUM: New or additional information.”**

The test status category listed below will continue to be identified on reports:

“Confirmatory” is used when a **client requests repeat testing** on a previously reported test result(s). If repeat testing confirms the test result this is indicated on the report with **“=> CONFIRMATORY: Client requested repeat testing confirms the previously reported test result(s).”**

An important part of our relationship with you is our steadfast commitment to delivering high quality, innovative laboratory testing, information and services in a timely manner.

We appreciate your support and look forward to continuing to serve all of your laboratory needs.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. G. Schlesinger, MD', with a small flourish at the end.

R. G. Schlesinger, MD
Medical Director, Diagnostic Laboratory of Oklahoma

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

Test Changes

17303 Chlamydia trachomatis, DNA, SDA 17304 Neisseria gonorrhoeae DNA, SDA 17305 Chlamydia trachomatis/Neisseria gonorrhoeae DNA, SDA				
Effective Date:	May 2, 2011			
Specimen Requirements:	Urine, endocervical/urethral swab Vaginal swab is acceptable.			
Collection Instructions:	<ul style="list-style-type: none"> • Urine: Patient should not have urinated for at least 1 hour. Collect the specimen in a sterile, preservative-free collection cup. The patient should collect the first 20-60 mL of voided urine (the first part of the stream – Not Midstream) into a urine collection cup. Urine should be transferred from collection cup to 1 Q^x UPT (Urine Preservative Transport Q^x) within 8 hours of collection provided the urine has been stored at 2-30°C. Discard remaining urine. Urine can be held for up to 24 hours prior to transfer to the Q^xUPT provided that the urine has been stored at 2-8°C. The correct volume of urine has been added when fluid level is in the fill window. This volume corresponds to 2-3 mL of urine. DO NOT overfill or under fill the tube. Invert the Q^x UPT 3-4 times to mix. • Female endocervix: Submit swab in BD Probetec CT/GC Q^x Amplified Assay Collection Kit for Endocervical specimens. • Male urethral: Submit swab in BD Probetec CT/GC Q^x Amplified Assay Collection Kit for Male Urethral specimens. • Vaginal: Submit swab in BD Probetec CT/GC Q^x Amplified DNA Assay collection kit for Vaginal specimens. 			
Rejection Criteria:	Only BD Collection Kits are acceptable. Any other manufacturer's collection transport containers will be rejected. Overfilled or underfilled urine preservative transport (Q^x UPT) will be rejected; BD Probetec Q^x CT/GC Amplified Assay without a swab will be rejected. BD Probetec Q^x CT/GC Amplified Assay collection kit with cleaning swab will be rejected.			
Specimen Stability:		Urine in Q^x UPT	Endocervical or Urethral Swab	Vaginal Swab
	Room temperature:	30 days	30 days	14 days
	Refrigerated:	30 days	30 days	14 days
	Frozen:	6 months	6 months	6 months
Additional Information:	Update specimen requirements, collection instructions, rejection criteria, and stabilities.			

17615 <i>Chlamydia trachomatis</i> DNA, SDA, Pap Vial	
17617 <i>Neisseria gonorrhoeae</i> , DNA, SDA, Pap Vial	
17618 <i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> DNA, SDA, Pap Vial	
Effective Date:	May 2, 2011
Specimen Requirements Collection Instructions:	Liquid Based Cytology: Submit Per manufacturer instructions. For Samples that have the Pap performed outside of Quest Diagnostics: Surepath™ 0.5ml pre-aliquot *of Surepath material** Thinprep® Vial-0.5 ml pre-aliquot* of Preservcyt® material** *Aliquot before performance of liquid based cytology testing **Refer to manufacturer instructions Transfer aliquot to BD ProbeTec Qx CT/GC LBC diluent tube
Rejection Criteria:	Preservcyt or Surepath material previously processed at another facility will not be accepted for CT or NG testing. Add-ons to samples that have already been processed for Surepath or Thinprep will not be accepted.
Specimen Stability:	Liquid Based Cytology: Room Temperature: 30 days Refrigerated: 30 days Frozen: Unacceptable
Additional Information	Update collection instructions, rejection criteria and specimen stability. Additional test codes affected: 17257-SurePath and CT/NG DNA, SDA, Pap Vial 17258-SurePath w/refl HPV and CT/NG DNA, SDA, Pap Vial 17259-SurePath-FP and CT/NG DNA, SDA, Pap Vial 17260-SurePath-FP w/refl HPV and CT/NG DNA, SDA, Pap Vial 18816-SurePath-FPGS and CT/NG DNA,SDA,Pap Vial 18817-SurePath-FPGS w/refl HPV and CT/NG,DNA,SDA Pap Vial 17752-ThinPrep and CT/NG DNA, SDA, Pap Vial 17753-ThinPrep w/refl HPV and CT/NG DNA, SDA, Pap Vial 58355-ThinPrep-TIS and CT/NG DNA, SDA, Pap Vial 58356-ThinPrep-TIS w/refl HPV and CT/NG DNA SDA, Pap Vial

Redirects

Effective May 9, 2011 the following tests previously performed at ViraCor-IBT Laboratories, Inc., will now be performed at Quest Diagnostics Nichols Institute, Valencia. The following information is common for all tests:

CPT Code:	86001
Specimen Requirements:	1 mL serum (0.3 mL min)
Specimen Stability:	Room Temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Range:	< 2.0 mcg/mL
Set Up Schedule:	Sun, Wed, Fri, Same day
Assay Category:	Investigational Use Only
Performing Site:	Quest Diagnostics Nichols Institute, Valencia

Test Code:	Test Name:
38137	Allergen - Almond IgG
38248	Allergen - Banana IgG
38139	Allergen - Barley (Food) IgG
38125	Allergen - Beef IgG
34549	Allergen - Cacao (Chocolate) IgG
38563	Allergen - Cheese, Cheddar Type IgG
38128	Allergen - Chicken Meat IgG
38143	Allergen - Crab IgG
10326	Allergen - Egg (Yolk & White) IgG
11084	Allergen - Gluten IgG
38131	Allergen - Oat IgG
38247	Allergen - Orange IgG
34679	Allergen - Peanut IgG
38116	Allergen - Pork IgG
38126	Allergen - Potato IgG
38135	Allergen - Rice IgG
38130	Allergen - Rye IgG
38108	Allergen - Shrimp IgG
38561	Allergen - Strawberry IgG

QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano, Chantilly and Valencia), Focus Diagnostics, Inc.

New Test Offerings

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

HIV-1 RNA, Qualitative TMA with Reflex to Quantitative Real-Time PCR	
Clinical Significance:	Early detection and treatment monitoring of chronic HIV-1 infection.
Effective Date:	April 11, 2011
Test Code:	18967
CPT Code(s):	87535
Specimen Requirements:	4.6 mL EDTA K2 (lavender-top) plasma submitted in 2 transport containers Collect plasma in EDTA (lavender-top) or a (white-top) PPT Vacutainer™ plasma preparation tube. Separate plasma from the cells by centrifugation within 6 hours after collection. Transfer the plasma to two plastic screw-cap vials and ship frozen.
Rejection Criteria:	Whole blood; unspun PPT (plasma frozen in-situ); Specimen collected using heparin as anticoagulant, leaking, uncapped or broken containers.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 24 hours Refrigerated: 5 days Frozen: 35 days
Reference Ranges:	HIV-1 RNA,QL TMA: Not Detected
Methodology:	Transcription-Mediated Amplification (Reflex Real-Time Polymerase Chain Reaction)
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	If HIV-1 RNA, Qualitative TMA result is Detected, HIV-1 RNA Quantitative, Real-Time PCR will be performed at an additional charge (CPT code: 87536).

SureSwab™, Bacterial Vaginosis/Vaginitis			
<i>Includes: SureSwab™ Bacterial Vaginosis DNA, Quantitative Real-Time PCR; SureSwab™ Trichomonas vaginalis RNA, Qualitative TMA; SureSwab™, Candidiasis, PCR</i>			
Clinical Significance:	To diagnose the causative agent(s) of vaginosis/vaginitis.		
Effective Date:	April 11, 2011		
Test Code:	15509		
CPT Code(s):	87799 (x3), 87512, 87798, 87481 (x4)		
Specimen Requirements:	Vaginal swab in 3 mL Aptima Vaginal Swab collection kit (Orange label) Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.		
Rejection Criteria:	Specimens containing heparin; Leaking samples; Uncapped specimens; Broken container; Non Aptima Vaginal Swab collection kit		
Transport Temperature:	Refrigerated		
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 30 days		
Reference Ranges:	<i>Lactobacillus</i> species:	Accompanies report	Log (cells/mL)
	<i>Atopobium vaginae</i> :	Accompanies report	Log (cells/mL)
	<i>Megasphaera</i> species:	Accompanies report	Log (cells/mL)
	<i>Gardnerella vaginalis</i> :	Accompanies report	Log (cells/mL)
	<i>T vaginalis</i> RNA,QL TMA:	Not Detected	
	<i>C. albicans</i> , DNA:	Not Detected	
	<i>C. glabrata</i> , DNA:	Not Detected	
	<i>C. tropicalis</i> , DNA:	Not Detected	
	<i>C. parapsilosis</i> , DNA:	Not Detected	
Methodology:	Real-Time Polymerase Chain Reaction, Transcription-Mediated Amplification		
Assay Category:	ASR Class 1		
Performing Site:	Quest Diagnostics Nichols Institute		

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.

Magnesium, RBC	
Effective Date:	May 9, 2011
Test Code:	623
Specimen Requirements:	0.5 mL EDTA (lavender-top or dark blue-top tube) packed cells (0.2 mL minimum) EDTA (lavender-top tube) whole blood is acceptable. Sodium Heparin lead-free (tan-top tubes) are no longer acceptable.
Collection Instructions:	Leave packed cells in original collection tube. Patient should refrain from taking vitamins, or mineral herbal supplements for at least one week before sample collection. Do not centrifuge whole blood.
Specimen Stability:	Room temperature and Refrigerated: 7 days Frozen: Unacceptable
Methodology:	Inductively Coupled Plasma-Mass Spectrometry
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Update specimen requirements, collection instructions, method and stability.

Varicella-Zoster Virus Total and IgM Antibody, ACIF/IFA (serum)	
Effective Date:	May 9, 2011
Test Code:	37313
Assay Category:	ASR Class I
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update assay category and always message. This test is used in group code 14525-Encephalitis Antibody Panel (Serum).

Epidermal Antibodies with Reflex to Titers		
Effective Date:	May 16, 2011	
Test Code:	37097	
Specimen Requirements:	0.5 mL serum (minimum 0.1 mL)	
Rejection Criteria:	Gross hemolysis; gross lipemia; gross icterus	
Specimen Stability:	Room temperature: 4 days Refrigerated: 7 days Frozen: 30 days -70 Degrees: Indefinite	
Reference Ranges:	Intercellular Substance Ab: Titer: Basement Membrane Zone Ab: Titer:	Negative <1:10 Negative <1:10
Assay Category:	FDA Approved/Cleared	
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano	
Additional Information:	Update sample volume, reject criteria, stability, reference ranges, and assay category.	

<i>Chlamydophila pneumoniae</i> DNA, Qualitative Real-Time PCR	
Effective Date:	May 16, 2011
Test Code:	16003
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Please provide specimen source. This code is used in group code 17610-Atypical Pneumonia Panel DNA, PCR.

<i>Legionella</i> DNA, Qualitative Real-Time PCR	
Effective Date:	May 16, 2011
Test Code:	15062
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Please provide specimen source. This code is used in group code 17610-Atypical Pneumonia Panel DNA, PCR.

<i>Mycoplasma pneumoniae</i> DNA, Qualitative Real-Time PCR	
Effective Date:	May 16, 2011
Test Code:	15498
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Please provide specimen source. This code is used in group code 17610-Atypical Pneumonia Panel DNA, PCR.

Rhinovirus RNA, RT-PCR	
Effective Date:	May 16, 2011
Test Code:	40035
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Please provide specimen source. This code is used in group code 16473-Respiratory Virus PCR Panel IV.

Discontinued Tests

Genomic Alterations, Postnatal, ClariSure® CGH	
Effective Date:	May 2, 2011
Test Code:	16135
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	This test will be discontinued. The recommended alternative is: 16478- Genomic Alterations, Postnatal, Oligo-SNP Array.

EGFR Pathway (KRAS with Reflex to NRAS, BRAF)	
Effective Date:	May 9, 2011
Test Code:	16819
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	This test will be discontinued. The recommended alternative is 18902 – Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS).