



LABORATORY UPDATE

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Routine Testing
Maternal Serum Screening Donor Egg Information Change

Redirects

- Methaqualone, Serum2

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

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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.

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

Maternal Serum Screening Donor Egg Information Change

Effective March 8, 2010, the order entry question “Donor age or date of birth” will be changed. The new verbiage will be: “*Donor Age: Egg Retrieval*” to clarify that we need the age of the egg donor at the time the egg was harvested. Date of birth will no longer be a valid entry. This change affects the following order codes:

5059 – Maternal Serum AFP
7292 - Triple Screen
30294 - Quad Screen
15934 – Penta Screen
16020 – 1 st Trimester Screen hyperGlycosylated hCG
16145 – 1 st Trimester Screen, hCG
16148 – Integrated Screen, Part 1
16150 – Integrated Screen, Part 2
16131 – Sequential Integrated Screen, Part 1
16133 - Sequential Integrated Screen, Part 2
16165 – Serum Integrated Screen, Part 1
16167 – Serum Integrated Screen, Part 2

If you have any questions, please call 866-GENE INFO (866-436-3463).

Redirects

Methaqualone, Serum	
Clinical Significance:	Methaqualone (“quaaludes”) is a central nervous system depressant, with similar effects to barbiturates, and has been prescribed as an anti-anxiety medication or sleep aid. This drug is no longer manufactured or distributed in the United States, and true positive patient samples are uncommon. The detection of methaqualone in serum or urine is useful in the detection of abuse by individuals, resultant treatment for those individuals, and possibly in assisting with criminal prosecution.
Effective Date:	February 8, 2010
Test Code:	645
CPT Code:	82542
Specimen Requirements:	5 mL no additive (red-top tube or royal blue-top tube) serum Acceptable: 5 mL sodium fluoride (gray-top tube) plasma (1.5 mL minimum)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 72 hours Refrigerated: 14 days Frozen: 30 days
Reference Ranges:	None detected
Methodology:	Gas Chromatography, Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	This test, previously performed at National Medical Services, Inc., will now be performed at Quest Diagnostics Nichols Institute, Chantilly.

**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.

Respiratory Virus PCR Panel with 2009 H1N1 <i>Includes: 16046 Adenovirus DNA, QL Real Time PCR; 16807 Influenza A H1N1 (2009) Real Time RT PCR; 16087 Parainfluenza Virus 1,2,3 RNA, QL Real Time PCR; 16047 RSV RNA, QL Real Time PCR</i>	
Clinical Significance:	This panel will aid in the diagnosis of infection by currently circulating respiratory viruses.
Effective Date:	January 11, 2010
Test Code:	16255
CPT Code(s):	87798 (x7)
Specimen Requirements:	Nasopharyngeal, throat swab or nasal swab in 3 mL M4 media or V-C-M medium (green-cap) tube or equivalent (UTM)
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 2 days Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	Not Detected
Methodology:	See individual assays
Assay Category:	Laboratory Developed Test / FDA/EUA (Emergency Use Authorization)
Performing Site:	Focus Diagnostics, Inc.

CAH Panel 6C (Full Screen)

*Includes: Androstenedione, LC/MS/MS * 11-Deoxycortisol, LC/MS/MS, Serum *
Cortisol, Total, LC/MS/MS * DHEA (Dehydroepiandrosterone), Unconjugated, LC/MS/MS *
17-Hydroxypregnenolone, LC/MS/MS * Progesterone, LC/MS/MS *
17-Hydroxyprogesterone, LC/MS/MS * Testosterone, Total, LC/MS/MS*

Clinical Significance:	Useful for diagnosis and differential diagnosis of congenital adrenal hyperplasia (CAH): similar to CAH Panel 6B Comprehensive Screen, but without deoxycorticosterone in order to decrease specimen requirement and allow faster turn around time.
Effective Date:	January 11, 2010
Test Code:	16978
CPT Code(s):	82157, 82634, 82533, 82626, 84143, 84144, 83498, 84403
Specimen Requirements:	4 mL no additive (red-top) serum
Rejection Criteria:	Samples collected in SST tubes.
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 24 hours Refrigerated: 4 days Frozen: 28 days
Reference Ranges:	See individual assays
Methodology:	LC/MS/MS
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

DCP (Des-Gamma-Carboxy-Prothrombin)

Clinical Significance:	The DCP assay is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for progression to hepatocellular carcinoma (HCC) in conjunction with other laboratory findings and clinical assessment.
Effective Date:	February 8, 2010
Test Code:	19982
CPT Code(s):	83951
Specimen Requirements:	1 mL serum
Rejection Criteria:	Lipemic specimens; Hemolysis; Heavy, visible particulate matter
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 48 hours Refrigerated: 7 days Frozen: 21 days
Reference Range:	DCP: < or = 7.5 ng/mL
Methodology:	Immunoassay
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

ERCC1, IHC with Interpretation	
Clinical Significance:	The mammalian ERCC1 (excision repair cross complementing) polypeptide is required for nucleotide excision repair (NER) of damaged DNA. Increased ERCC1 expression has been shown to predict cisplatin resistance and therefore decreased survival in gastric, ovarian, esophageal, colorectal cancers, and NSCLC. This is consistent with the role of ERCC1 in the repair of modified nucleotides, specifically increased removal of cis-platinum-induced DNA adducts.
Effective Date:	January 11, 2010
Test Code:	16979
CPT Code(s):	88342
Specimen Requirements:	Formalin fixed paraffin embedded tissue Pathology report is required.
Rejection Criteria:	Sample other than paraffin block
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze
Reference Range:	Accompanies report
Methodology:	Immunohistochemistry
Assay Category:	Research use only
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

ERCC1, IHC without Interpretation	
Effective Date:	January 11, 2010
Test Code:	16988
CPT Code(s):	88342
Specimen Requirements:	Formalin fixed paraffin embedded tissue Pathology report is required.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze
Reference Range:	Accompanies report
Methodology:	Immunohistochemistry
Assay Category:	Research use only
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Fetomaternal Bleed, Flow Cytometry	
Clinical Significance:	This test quantifies the volume of fetal-maternal hemorrhage (FMH). In Rh positive mothers it is used solely to establish the volume of fetal hemorrhage into the maternal circulation. In Rh negative mothers it is also used to determine if an increased dose of Rh immune globulin (RhIG, anti-D antibody) is necessary. Based on an assumed total maternal circulatory volume of 5,000 mL, the FMH is calculated by multiplying the <u>% Fetal Cells</u> by 50. Please refer to the most current AABB Technical Manual for RhIG dosage information.
Effective Date:	February 8, 2010
Test Code:	16828
CPT Code:	86356
Specimen Requirements:	5 mL EDTA (lavender-top tube) whole blood
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: 24 hours Refrigerated: 4 days Frozen: Unacceptable
Reference Ranges:	Fetal Cells: < or = 0.1%
Methodology:	Flow Cytometry
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

FISH, Multiple Myeloma, IGH/FGFR3, t(4;14)	
Clinical Significance:	The FGFR3/IGH translocation, t(4;14), provides important prognostic information in patients with plasma cell myeloma
Effective Date:	January 11, 2010
Test Code:	16872
CPT Code(s):	88271 (x2), 88275, 88291
Specimen Requirements:	3 mL bone marrow in transport media 1-3 mL bone marrow in transport medium, 5mm X 5mm fresh tumor biopsy in transport medium, paraffin embedded formalin fixed tumor biopsy. Bone marrow in sodium heparin tube (green top) is preferred, dark/royal blue, tan top are acceptable. Ship at room temperature. Bone marrow transport medium is available upon request. In rare cases of plasma cell leukemia, peripheral blood, typically with greater than 20% plasma cells, is an acceptable specimen. For blood sample, please submit 3-5 mL in sodium heparin tube (Green, dark/royal blue or tan top). SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	See Instructions
Reference Range:	Accompanies report
Methodology:	Fluorescence in situ Hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute

FISH, Multiple Myeloma, IGH/MAF, t(14;16)	
Clinical Significance:	Translocation (14;16) (IGH/MAF) provides important prognostic information in patients with plasma cell myeloma
Effective Date:	January 11, 2010
Test Code:	16965
CPT Code(s):	88271 (x2), 88275, 88291
Specimen Requirements:	3 mL bone marrow 1-3 mL bone marrow in transport medium, 5mm X 5mm fresh tumor biopsy in transport medium, paraffin embedded formalin fixed tumor biopsy. Bone marrow in sodium heparin tube (green top) is preferred, dark/royal blue, tan top are acceptable. Ship at room temperature. Bone marrow transport medium is available upon request. In rare cases of plasma cell leukemia, peripheral blood, typically with greater than 20% plasma cells, is an acceptable specimen. For blood sample, please submit 3-5 mL in sodium heparin tube (Green, dark/royal blue or tan top). SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	See Instructions
Reference Range:	Accompanies report
Methodology:	Fluorescence in situ hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute

FISH, Prostate Cancer	
Clinical Significance:	Prostate cancer is the most common malignancy among males in Western countries and the second leading cause of death from cancer in males. If detected early, prostate cancer is often curable.
Effective Date:	February 15, 2010
Test Code:	16076
CPT Code(s):	88365 (x4)
Specimen Requirements:	Paraffin embedded tissue Submit formalin fixed paraffin embedded prostate tissue. DO NOT REJECT. SEND SPECIMEN TO TESTING LABORATORY. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	See Instructions
Methodology:	Fluorescence In Situ Hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Wilms Tumor 1 (WT1) Mutation Analysis	
Clinical Significance:	WT1 mutations occur in up to 15% of patients with AML. Cytogenetically normal acute myeloid leukemia (CN-AML) is the largest subgroup of AML, which represents approximately 45% of adult patients with AML. A WT1 mutation at diagnosis is associated with poor, outcome; it independently predicts a higher risk of relapse when other molecular markers with established prognostic significance and clinical variables are taken into consideration.
Effective Date:	February 8, 2010
Test Code:	16896
CPT Code(s):	83891, 83898 (x6), 83896, 83909, 83894, 83904 (x4), 83912
Specimen Requirements:	6 mL EDTA (lavender-top) whole blood Submission of whole blood (preferred): follow standard whole blood collection procedure. Collect 5-6 mL whole blood samples in an EDTA tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood. Record the draw time; also record sample type on the tube and patient ID on the requisition form. Ship immediately to maintain sample stability.
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: Do Not Freeze
Methodology:	Sequencing and Fragment Analysis
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

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.

Aspirin Resistance (11 Dehydrothromboxane B2)	
Clinical Significance:	Aspirin (which inhibits platelet cyclo-oxygenase) reduces the risk of thrombosis in cardiovascular disease by impairing platelet function. Patients who do not respond to the platelet inhibitory effects of aspirin are designated as "Aspirin Resistant". The measurement of 11-Dehydro Thromboxane B-2 in urine (the principal metabolite of platelet cyclo-oxygenase derived thromboxane B-2) indicates lack of aspirin responsiveness.
Effective Date:	February 15, 2010
Test Code:	16174
Reference Range:	11 Dehydrothromboxane B2: >1500 pg/mg creat
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update units of measure

JAK2 Mutation (V617F) Analysis, Qn, Plasma, Leumeta(R)	
Clinical Significance:	The Jak2 tyrosine kinase (V617F) was detected in most patients (>80%) with polycythemia vera (PV), 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis. The quantitative measurement of V617F may be useful for assessing the correlation of tumor load/phenotype; monitoring/predicting the progression or responses of the disease when MPD patients are under therapy.
Effective Date:	February 15, 2010
Test Code:	16175
Reference Ranges:	JAK2 Mutation,QN,Leumeta: Accompanies report pg/uL Interpretation: Negative
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update units of measure.

Fluorescence in SITU Hybridization Neonatal	
Clinical Significance:	The screening of aneuploidy of newborns for chromosomes 13, 18, 21, X, or Y by interphase FISH is rapid, reliable, and cost-effective. The test is especially suitable for medically urgent cases as a screen, followed by a standard chromosome analysis (Mayo Clin Proc. 1997 Aug;72(8):705-10.).
Effective Date:	February 15, 2010
Test Code:	36053
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update assay category and add ASR always message.

AM=6am-12pm, PM=12pm-6pm, E=6pm-12am, Next Day=12am-6am Pacific Time