

New Procedures

Several new procedures have been made available since the last issue of *LabHorizons* was published. For a complete file of LabCorp's published clinical assays, keep back issues of *LabHorizons* together with your copy of the *Directory of Services and Interpretive Guide*. Now you can access the electronic *Directory* at www.LabCorp.com; just click on the "Directory of Services" button.

Cytochrome P450 2D6/2C19 Genotyping and Phenotyping 511316

CPT 83891; 83901(x2); 83894; 83892(x29); 83896(x29); 83903; 83912

Related Information

Cytochrome P450 2C9 Genotyping

Cytochrome P450 2D6 Genotyping

Synonyms AmpliChip™, DME genotyping

Specimen Whole blood

Volume 7 mL

Minimum Volume 3 mL

Container Lavender-stopper (EDTA) tube

Storage Instructions Maintain at room temperature or refrigerate

Causes for Rejection Hemolyzed specimen; quantity not sufficient for analysis

Use The Roche AmpliChip CYP540 test is intended to identify a patient's CYP2D6 and CYP2C19 genotype from genomic DNA. Information about CYP2D6 and CYP2C19 genotype may be used as an aid to clinicians in determining therapeutic strategy and treatment does for therapeutics that are metabolized by the CYP2D6 or CYP2C19 gene product.

Limitations The metabolism of drugs is also influenced by ethnicity, diet, and other medications. All factors should be considered prior to initiating new therapy.

Methodology Polymerase chain reaction (PCR), gel electrophoresis, microarray (hybridization)

Human Immunodeficiency Virus 1 (HIV-1) Antibody With Reflex to Nucleic Acid Testing 083850

CPT 86701 (If reflex testing is performed, additional charges may occur, represented by CPT codes 87535, 86689)

Synonyms HIV-1 Ab Reflex NAT; NAA HIV Ab Reflex; NAT HIV Ab Reflex; NGI HIV Ab Reflex

Test Includes HIV-1 antibody, EIA; reflex to NAT; HIV-1 antibody-OD ratio; HIV-1 antibody, qualitative

Specimen Plasma

Volume 5 mL

Minimum Volume 3 mL

Container Plasma preparation tube (PPT) is required to perform pooled nucleic acid testing.

Collection Specimen should be collected in a plasma preparation tube (PPT). Centrifuge specimen within six hours of collection. Forward original tube to the test facility; do **not** pour off.

Storage Instructions Refrigerate.

Causes for Rejection Hemolysis; lipemia; gross bacterial contamination; heparinized plasma

Use Detects antibodies by specific immune binding and subsequent color development

Limitations The presence of HIV RNA in an HIV antibody-negative sample may be due to the presence of acute HIV infection prior to seroconversion. Repeat HIV antibody and Western blot confirmatory testing from a newly collected sample is needed to confirm the diagnosis of HIV. In a recent study, the interval from nucleic acid detection to first antibody reactivity ranged from 6 to 42 days with median interval of 11.5 days. The nucleic acid test has been FDA-approved for the screening of plasma products but is not approved for HIV clinical diagnostics. The result should not be used as a definitive diagnosis of HIV infection without confirmation by HIV antibody and Western blot from a subsequent blood collection.

Methodology Enzyme immunoassay (EIA); recombinant HIV antigen; Western blot; RNA detection by polymerase chain reaction

Lipoprotein-associated Phospholipase A₂ 141275

CPT 83520

Specimen Plasma

Volume 0.3 mL

Minimum Volume 0.2 mL (**Note:** This volume does **not** allow for repeat testing.)

Container Lavender-stopper (EDTA plasma) tube

Collection Prepare the samples using a standard plasma separation procedure. Separate the plasma from cells and transfer to a plastic transport tube.

Storage Instructions Plasma may be stored for up to four hours prior to separation from cells. After processing, the sample is stable for three days at 2°C to 8°C or frozen for longer storage.

Patient Preparation No special preparations are necessary.

Causes for Rejection Non-EDTA plasma sample received; sample received on cells.

Use The PLAC test is an enzyme immunoassay for the quantitative determination of Lp-PLA₂ (lipoprotein-associated phospholipase A₂) in human plasma, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease and ischemic stroke associated with atherosclerosis.

Limitations This test does not replace blood lipids or any other traditional risk factors identified for coronary heart disease and should be used in conjunction with clinical findings and other diagnostic tests.

Methodology Enzyme immunoassay (EIA)

References

Caslake MJ, Packard CJ, Suckling KE, Holmes SD, Chamberlain P, Macphee CH. Lipoprotein-associated phospholipase A(2), platelet-activating factor acetylhydrolase: A potential new risk factor for coronary artery disease. *Atherosclerosis*. 2000 Jun; 150(2):413-419.

Kudo I, Murakami M. Phospholipase A2 enzymes. *Prostaglandins Other Lipid Mediat*. 2002 Aug; 68-69:3-58.

Hakkinen T, Luoma JS, Hiltunen MO, et al. Lipoprotein-associated phospholipase A(2), platelet-activating factor acetylhydrolase, is expressed by macrophages in human and rabbit atherosclerotic lesions. *Arterioscler Thromb Vasc Biol*. 1999 Dec; 19(12):2909-2917.

Chisolm GM, Steinberg D. The oxidative modification hypothesis of atherogenesis: An overview. *Free Radic Biol Med*. 2000 Jun 15; 28(12):1815-1826.

Witztum JL. The oxidation hypothesis of atherosclerosis. *Lancet*. 1994 Sep 17; 344(8925):793-795.

MacPhee CH, Moores KE, Boyd HF, et al. Lipoprotein-associated phospholipase A2, platelet-activating factor acetylhydrolase, generates two bioactive products during the oxidation of low-density lipoprotein: use of a novel inhibitor. *Biochem J*. 1999 Mar 1; 338(Pt2):479-487.

Macphee CH. Lipoprotein-associated phospholipase A2: A potential new risk factor for coronary artery disease and a therapeutic target. *Curr Opin Pharmacol*. 2001 Apr; 1(2):121-125.

Suckling KE, Macphee CH. Lipoprotein-associated phospholipase A2: A target directed at the atherosclerotic plaque. *Expert Opin Ther Targets*. 2002 Jun; 6(3): 309-314.

Dada N, Kim NW, Wolfert RL. Lp-PLA2: An emerging biomarker of coronary heart disease. *Expert Rev Mol Diagn*. 2002 Jan; 2(1):17-22.

Packard CJ, O'Reilly DS, Caslake MJ, et al. Lipoprotein-associated phospholipase A2 as an independent predictor of coronary heart disease. West of Scotland Coronary Prevention Study Group. *N Engl J Med*. 2000 Oct 19; 343(16):1148-1155.

Blake GJ, Dada N, Fox JC, Manson JE, Ridker PM. A prospective evaluation of lipoprotein-associated phospholipase A(2) levels and the risk of

future cardiovascular events in women. *J Am Coll Cardiol*. 2001 Nov 1; 38(5):1302-1306.

Ballantyne CM, Hoogeveen RC, Bang H, et al. Lipoprotein-associated phospholipase A2, high-sensitivity C-reactive protein, and risk for incident coronary heart disease in middle aged men and women in the Atherosclerosis Risk in Communities (ARIC) study. *Circulation*. 2004 Feb 24; 109(7):837-842.

American Heart Association. *Heart Disease and Stroke Statistics—2005 Update*. Dallas, Texas: American Heart Association; 2005.

Ballantyne CM, Hoogeveen RC, et al. *Circulation*. 2004; (110): Supp III:641.

diaDexus. *LpPLA2 Assay*. South San Francisco, Calif: diaDexus; 2005. Package Insert.

ZAP-70 in B-CLL 489000

CPT 88184; 88185(x2); 88187

Special Instructions Draw specimen so it will arrive in the laboratory Monday through Friday and within 24 hours of collection. Indicate date and time of collection on the test request form.

Specimen Peripheral blood (preferred) or bone marrow

Volume Peripheral blood: 7 mL whole blood in green-stopper (sodium heparin) tube and one lavender-stopper (EDTA) tube. Store and ship at room temperature. **Bone marrow:** 2 mL to 3 mL of marrow in green-stopper (sodium heparin) tube. Ship at room temperature.

Container Peripheral blood: Green-stopper (sodium heparin) tube and one lavender-stopper (EDTA) tube; **Bone marrow:** Green-stopper (sodium heparin) tube

Storage Instructions Store and ship according to specimen type received.

Use Expression of the ZAP-70 protein correlates with disease stage in chronic lymphocytic leukemia (CLL) and may serve as a prognostic marker in B-CLL.

Methodology Flow cytometry

Announcements

New and Revised CPT Codes

The list below includes new and revised CPT code(s) for 2005. This list consists of routine tests only. It does not include any custom panels created for individual clients. Please contact your local LabCorp account manager if you have questions.

Note: The CPT codes listed here are in accordance with the current edition of *Current Procedural Terminology*, a publication of the American Medical Association. CPT codes are provided for the convenience of our clients; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and should not be used without confirming with the applicable payor that their use is appropriate in each case.

Number	Test Name
333561	Ashkenazi Jewish Carrier Profile
512145	Bloom Syndrome, DNA Analysis
511147	Canavan Disease, DNA Analysis
511352	Familial Dysautonomia, DNA Analysis
511212	Fanconi Anemia Type C, DNA Analysis
511048	Gaucher Disease, DNA Analysis
512020	Jewish Heritage Profile
511386	Mucopolipidosis Type IV Mutation Detection
511329	Niemann-Pick Disease, DNA Analysis
510404	Tay-Sachs Disease, DNA Analysis

CPT Code(s)
83891(x2); 83901; 83892; 83896(x31); 83912(x3); 83080
83891; 83901; 83892; 83896; 83912
83891; 83901; 83892; 83896(x4); 83912
83891; 83901; 83892; 83896(x2); 83912
83891; 83901; 83892; 83896(x2); 83912
83891; 83901; 83892; 83896(x8); 83912
83891(x2); 83901(x2); 83892(x36); 83912(x3); 83894
83891; 83901; 83892; 83896(x2); 83912
83891; 83901; 83892; 83896(x4); 83912
83891; 83901; 83892; 83896(x7); 83912

Reflex Testing After Antibody Screen Positives to be Billed

An Antibody Screen (006015) is often ordered to detect atypical IgG antibodies (and occasionally IgM antibodies) prior to transfusion or during pregnancy. Antibodies detected by the screen are subsequently identified, and a titer is performed if the antibody identified is considered to be clinically significant during pregnancy. Effective **February 1, 2006**, LabCorp will charge for the additional identifi-

cation testing when the results of an antibody screen are positive. The additional fee will also be charged when the additional testing is performed in conjunction with antibody screening tests performed as components of profiles or test combinations. If there are any questions, please contact your LabCorp representative.

ICD-9-CM Diagnosis Codes: October 1, 2005 Changes

Grace Periods Eliminated

Reminder: The Centers for Medicare and Medicaid Services (CMS) eliminated the 90-day grace period for submitting discontinued ICD-9-CM diagnosis codes, effective **October 1, 2004**. Previously, a 90-day grace period from October 1 through December 31 had been permitted for transition to the updated ICD-9-CM diagnosis codes. Other health care payors followed Medicare's lead.

The Health Insurance Portability and Accountability Act (HIPAA) transaction and code set rule requires use of the medical code set that

is valid at the time the service is provided. ICD-9-CM diagnosis codes and HCPCS codes are each considered a medical code set.

ICD-9-CM Diagnosis Code Updates

The following list of ICD-9-CM diagnosis codes are invalid after September 30, 2005. These codes must be at a higher level of specificity to be valid codes as of October 1, 2005. Please consult the Web site indicated below for a complete list of new diagnosis codes, invalid diagnosis codes, and revised diagnosis code titles.
http://www.cms.hhs.gov/manuals/pm_trans/R591CP.pdf

Code	Description	Code	Description
276.5	Volume Depletion	996.4	Mechanical Complication of Internal Orthopedic Device, Implant, and Graft
287.3	Primary Thrombocytopenia	V12.6	Diseases of the Respiratory System
567.2	Other Suppurative Peritonitis	V17.8	Other Musculoskeletal Diseases
567.8	Other Specified Peritonitis	V26.3	Genetic Counseling and Testing
585	Chronic Renal Failure	V58.1	Chemotherapy
599.6	Urinary Obstruction, Unspecified	V64.0	Vaccination not Carried Out Because of Contradiction
770.1	Meconium Aspiration Syndrome		
799.0	Asphyxia		

Important Customer Service Telephone/Fax Numbers

Department	Voice Extension (Dial 800-222-7566 and follow prompts.)	Fax Number
Client Billing	6-5282	877-867-8266
Client Credit and Collections	None	336-436-4155
Client Field Services	6-5287	336-436-1016
CPT Coding	6-8400	336-436-1048
Credit Refunds	6-7932	336-436-4036
Customer Service	6-3506	336-436-0609
Managed Care Billing	None	336-436-1019
Medicaid Billing	6-6997	336-436-4067
Medicare Billing	6-6999	866-827-8047
Patient Collections	6-6060	866-227-2939
Patient Customer Service	6-6060	866-227-2939
Patient Special Operations	6-7200	336-513-6714

Updates to the *Directory of Services and Interpretive Guide*

Test Name	Number	Field/Change
Alkaline Phosphatase Isoenzymes	001612	Reference Interval Liver: 26% to 86%; Bone: 11% to 68%; Intestine: 0% to 16%
Beta-Galactosidase Deficiency, Leukocytes	402370	Synonyms Galactosialidosis, MPS IVb; Morquio B Disease Use Diagnose patients with beta-galactosidase deficiency, Morquio disease type B (MPS IVb), and combined beta-galactosidase/neuraminidase deficiency (galactosialidosis)
Bile Acids	010330	Reference Interval 4.5 - 24.6 mcmol/L
Bloom Syndrome, DNA Analysis	512145	Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
Canavan Disease, DNA Analysis	511147	Limitations This test detects approximately 98% of mutations responsible for Canavan disease in Ashkenazi Jews, and ~60% of mutations in non-Jewish Caucasians. Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis of four aspartoacylase gene mutations
Chlamydia/Gonococcus, DNA Probe With Confirmation	164160	Synonyms Chlamydia/Gonococcus by DNA Probe (With Confirmation, at additional charge) Special Instructions Specify specimen source. Specimen Gen-Probe PACE swab—endocervical or male urethral specimens only.
Familial Dysautonomia, DNA Analysis	511352	Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
Fanconi Anemia (Type C), DNA Analysis	511212	Synonyms Jewish Heritage; IVS+4 A.T Mutation; 322delG Mutation Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
Fragile X Syndrome, Chromosome and DNA Analysis	510115	Methodology Polymerase chain reaction (PCR) followed by agarose gel and capillary electrophoresis, and, if required, Southern blot hybridization; Cytogenetic studies
Gaucher Disease, DNA Analysis	511048	Limitations To determine affected status, biochemical testing is recommended. This assay detects approximately 97% of the mutations responsible for Gaucher disease type I and 50% to 60% of types II and III (childhood and juvenile onset) in the Ashkenazi Jewish population; 75% of mutations in non-Jewish Caucasians are also detected. This test is not appropriate for determining affected status for childhood-/juvenile-onset disease. Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
Hepatitis Profile XI (HBV Vaccine Follow-up Profile)	265389	Specimen Serum or plasma (heparinized or EDTA) Container Serum gel-barrier tube, red-stopper tube, lavender-stopper (EDTA plasma) tube, or green-stopper (heparinized plasma) tube Collection If tube other than serum gel-barrier tube is used, transfer separated serum or plasma to a plastic transport tube. Causes for Rejection Hemolysis Methodology Immunochemiluminometric assay (ICMA))
Lactate Dehydrogenase (LD) Isoenzymes	001842	Reference Interval Total: 100-250 IU/L LD1: 16% to 35% LD2: 24% to 41% LD3: 16% to 27% LD4: 5% to 14% LD5: 5% to 24%
Mucopolipidosis Type IV Mutation Detection	511386	Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
Niemann-Pick Disease, DNA Analysis	511329	Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis
5' Nucleotidase	001701	Reference Interval 0 - 10 IU/L
Progesterone	004317	Collection If a red-stopper tube is used, transfer separated serum to a plastic transport tube.
Tay-Sachs Disease, DNA Analysis	510404	Limitations Greater than 95% of the mutant alleles in persons with Ashkenazi Jewish heritage are detected, 80% of mutations in persons with French-Canadian ancestry, and 25% of mutations in non-Jewish Caucasians are also detected. Methodology Polymerase chain reaction (PCR), primer extension, and flow-sorted bead array analysis

Note: For the most up-to-date test information, please consult the electronic *Directory of Services and Interpretive Guide* (e-DoS) at www.LabCorp.com.

