

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.

Chronic Myelogenous Leukemia Profile 150410

CPT 88271(x2); 88273; 88275; 88291; 88237; 88264; 88280(x2); 88291

Related Information

- *BCR-ABL1* Transcript Detection for Chronic Myelogenous Leukemia (480475 and 480481)
- Leukemia/Lymphoma Management Test Selection Chart

Synonyms Philadelphia Chromosome

Special Instructions Please direct any questions regarding this test to oncology customer service at 800-533-0567.

Specimen Bone marrow or peripheral blood

Volume If submitting bone marrow: 2 mL in pediatric green-stopper (sodium heparin) tube. If submitting peripheral blood, send 3 mL in pediatric green-stopper (sodium heparin) tube.

Container Pediatric green-stopper (sodium heparin) tube

Collection Submit at room temperature using Leukemia/Lymphoma Specimen Transport Kit (supplied by LabCorp). Specimens should arrive in the laboratory within 48 hours of collection. Indicate date and time of collection on the test request form.

Storage Instructions Maintain specimen at room temperature.

Use Confirm the diagnosis of CML, establish the chronic phase karyotype for comparison with blast crisis alterations, and monitor residual disease.

Methodology Cytogenetics; fluorescence in situ hybridization (FISH)

Hepatitis B Virus (HBV) QuantaSure™ By Real-time PCR With Reflex to HBV Genotype 551550

CPT 87517

Synonyms HBV QuantaSure™; HBV Quantitation; TaqMan™ HBV QuantaSure™

Special Instructions A separate frozen specimen is required for each frozen test ordered. If reflex test is performed, additional charges/CPT code(s) may apply.

Specimen Serum or plasma, frozen

Volume 2 mL

Minimum Volume 1.5 mL

Container Plasma preparation tube (PPT™) or a screw-cap polypropylene frozen transport tube.

Collection Collect whole blood in PPT™, red-stopper tube, gel-barrier tube, yellow-stopper (ACD plasma) tube, or lavender-stopper (EDTA plasma) tube. Do **not** use green-stopper (heparin) tubes. Centrifuge specimen within four hours of collection, remove plasma,

and transfer specimen to a plastic screw-cap transport tube and freeze. Ship frozen on dry ice. If PPT™ is used, do not transfer plasma; centrifuge specimen in a swinging bucket rotor centrifuge and ship frozen on dry ice. To avoid delays in turnaround time when requesting multiple tests on frozen samples, please submit separate frozen specimens for each test requested.

Storage Instructions Freeze

Causes for Rejection Hemolysis; green-stopper (heparin) tube; specimen not frozen; specimen received in "pop-top" or "snap-cap" tube; PPT™ not centrifuged

Use Quantitation of HBV DNA in serum or plasma with reflex to HBV GenoSure™ (genotype) if greater than 1000 copies/mL.

Limitations The HBV QuantaSure assay has a quantitative range of 100 to 5,000,000,000 copies/mL.

Methodology TaqMan™ polymerase chain reaction (PCR) amplification and detection

Streptococcus Group A Direct, DNA Probe 180786

CPT 87650

Synonyms Gen-Probe Group A Streptococcus Direct Test

Specimen Swab of posterior oropharynx, tonsils, or other inflamed area.

Volume One or two swabs

Container Copan Double Dacron Dry Swab in transport tube without medium (red cap).

Storage Instructions Throat swabs are transported to the laboratory at ambient temperature for up to 48 hours after specimen collection. After receipt in the laboratory specimens are stored at 2°C to 8°C and tested within 72 hours.

Causes for Rejection Throat swab that contains visible blood; unlabeled or mislabeled specimen; inappropriate specimen transport device; specimen received after prolonged delay (more than 48 hours); source is not throat.

Use Uses nucleic acid hybridization for the qualitative detection of Group A Streptococcal RNA as an aid in the diagnosis of Group A Streptococcal pharyngitis from throat swabs.

Limitations Blood and potentially other chemiluminescent substances may interfere with this test. A negative test does not exclude the possibility that the numbers of Group A Streptococcal cells may be below the level of detection of the assay. Some strains of *Streptococcus equi* and rare strains of nonhemolytic streptococci that react with Group G antisera may result in a false-positive reaction.

Methodology DNA Probe

References

Gen-Probe. *Group A Streptococcus Direct Test*. San Diego, Calif: Gen-Probe Inc. Package Insert.

VanA and VanB Real-time PCR 138664

CPT 87149

Synonyms VanA PCR; VanA Gene Detection; VanB PCR; VanB Gene Detection

Specimen Culture isolate

Volume 18- to 24-hour culture

Minimum Volume One culture plate or slant tube or bottle

Container Culture plate, slant tube, or bottle

Collection Actively growing isolate (18- to 24-hour) on culture plate, slant tube, or bottle

Storage Instructions Maintain specimen at room temperature.

Causes for Rejection Insufficient growth; leaking or broken plate, tube or bottle; mislabeling

Use Detects presence of VanA and VanB genes (DNA) in clinical isolates

Limitations There must be sufficient growth enterococcus species bacteria in culture for assay to be performed.

Methodology DNA PCR amplification and real-time detection

Announcements



ANA Direct: Improving Patient Care — Follow-up Notice

As reported earlier, on March 21, 2005, LabCorp converted to a technology for antinuclear antibody (ANA) testing that provides more objective, higher quality results than traditional methodologies. The new technology provides a direct measurement of autoantibodies relevant to ANA testing from a single patient sample. The presence of characterized autoantibodies in conjunction with a positive ANA result and symptomatology can have far greater clinical significance than an uncharacterized ANA result alone, thereby positively affecting patient care.

On average, concordance for this improved ANA methodology was 98.4%.¹

On March 21 all requests for IFA test numbers 006254 and 282434, including those contained in client custom panels and profiles, were

converted to the new direct ANA test numbers 164855 and 164962, respectively. Additionally, ANA by IFA with reflex to ENA (282434) will no longer be orderable after that date. CPT coding, pricing, and reimbursement for the new tests are the same as the tests they are replacing, as noted in the table below. To request ANA testing by the IFA methodology after March 21, please order test 164947.

We are confident that the implementation of this direct antinuclear antibody test (ANA Direct or ANA-D) will provide higher quality results for optimal patient management. For more information, please contact your local LabCorp customer service representative and request the *Tech Review* entitled **Direct Antinuclear Antibody: Direct Measurement Improves Patient Care**, which will be available in the second quarter.

Test Name	Current Test N°	New Test N°	CPT Code(s)	2005 NLA
ANA	006254 (IFA)*	164855 (Direct)	86038	\$16.89
ANA (Reflexes to 5 ENAs)	282434 (IFA)**	164962 (Direct)	86038+5 ENAs***	\$16.89 or \$133.89 (w/reflex)
ANA (Reflexes to 9 ENAs)		164863 (Direct)	86038+9 ENAs****	\$16.89 or \$227.63 (w/reflex)
ANA, IFA		164947 (IFA)	86038	\$16.89

*Titer and pattern if positive: Centromere pattern; homogeneous pattern; nucleolar pattern; speckled pattern. **This test will be unavailable after March 21, 2005. ***Reflexes to Anti-ds-DNA Ab, Quantitative; Anti-Smith Ab; RNP Ab; Sjögren's Anti-SS-A; Sjögren's Anti-SS-B. ****Reflexes to Anticentromere B Ab; Anti-ds-DNA Ab, Quantitative; Antihistone Ab; Anti-Jo-1; Antiscleroderma-70 Ab; Anti-Smith Ab; RNP Ab; Sjögren's Anti-

1. Kopnitsky MJ, Connelly M, Amell K, Werst G, Fleming J, Flora B. Qualification of the AtheNA Multi-Lyte ANA test system as a replacement for conventional ANA immunoassay test systems. *Clin Chem.* 2002; 48(6):A149,1-4.



ALERT Notification Policy Enhanced — Follow-up Notice

LabCorp has refined its ALERT results notification protocol to reduce the time physicians spend on unnecessary or redundant telephone calls. Effective April 1, 2005, LabCorp will only call ALERT results that the physician has requested.

In February, all LabCorp clients should have received a packet with additional information, including an ALERT result call designation

form that must be completed and returned to LabCorp if you wish to continue receiving ALERT result telephone calls.

Please contact your LabCorp representative if you have not received your information packet or to request additional information.

Reporting Results of Antibody to Hepatitis C Virus

On April 25, 2005, in accordance with Centers for Disease Control and Prevention (CDC) guidelines for reporting hepatitis C virus (HCV) antibody results,¹ LabCorp will begin reporting a sample/cut-off (s/co) ratio for all HCV antibody results. This ratio provides an assessment of the concentration of the antibody present.

The CDC has further defined an algorithm for testing HCV antibody with confirmation by recombinant immunoblot assay (RIBA) prior to releasing certain positive results. CDC studies have indicated that an s/co ratio >3.7 need not be confirmed by RIBA because the concentration of antibody is sufficiently high that the probability of a false-

positive result is very low. S/co ratios of 1.0 - 3.7 will require confirmation by RIBA to reduce false-positive occurrences.

As a result of CDC guidelines, LabCorp will no longer offer test 140608 (Hepatitis C Virus (HCV) Antibody [without confirmation]). Instead, LabCorp will offer test 143991 (Hepatitis C Virus (HCV) Antibody, Confirmation by RIBA), which will follow the CDC algorithm. Confirmation by RIBA, when indicated, will necessitate an additional charge and will be billed under CPT code 86804. After April 25, clients who order test 140608 will be contacted, informed of the change, and asked to change their order to test 143991.

Test Name	CPT Code(s)	NLA
Hepatitis C Virus (HCV) Antibody, Confirmation by RIBA (Reflex not Performed)	86803	\$19.94
Hepatitis C Virus (HCV) Antibody, Confirmation by RIBA (Reflex Performed)	86803 & 86804	\$21.64 additional

3. Alter MJ, Kuhnert WL, Finelli L. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. *MMWR*. 2003 Feb 7; 52(RR-3):1-15.

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	CPT Code(s)
480228	DNA Ploidy Analysis, Frozen Tissue	88182
551510	Hepatitis B Virus (HBV) DNA, Qualitative, Reflex to HBV QuantaSure™	87516
551550	Hepatitis B Virus (HBV) QuantaSure™ By Real-time PCR with Reflex to HBV Genotype	87517
164897	Herpes Simplex Virus (HSV) Type I-specific Antibodies, IgG	86695
164905	Herpes Simplex Virus (HSV) Types I- and II-specific Antibodies, IgG	86695; 86696
162420	Human T-Cell Lymphotropic Virus I, II (HTLV-I/HTLV-II), DNA by PCR	87798 (x2)
070755	Mephobarbital (Mebaral®), Serum	82205; 80184



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