



**PATHOLOGY ASSOCIATES  
MEDICAL LABORATORIES**

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# TEST ALERT

Number 256, September 5, 2003

The following tables reflect revisions only; other existing data remain unchanged.

<b>Test Method</b> <b>GA Workpar / SQ Code</b> <b>CPT Code(s)</b>	<b>Specimen Requirements</b>	<b>Reference Ranges</b>	<b>Comments</b> <b>Effective Date</b>
BCR/ABL T(9;22) BY RT-PCR RT-PCR BCR922 / BCR922 83891, 83902, 83898, 83894, 83912 (ARUP)	5 mL EDTA whole blood (lavender top tube). Store and transport refrigerated. This specimen must reach ARUP Laboratory within 48 hours of collection.	BCR/ABL t(9;22) Negative: bcr/abl fusion transcript is not detected. Positive (major): Major bcr/abl fusion transcript is detected. Positive (minor): Minor bcr/abl fusion transcript is detected. Patient RNA was isolated, reverse transcribed (RT) into cDNA and subjected to PCR amplification using oligonucleotide primers specific for the bcr gene on chromosome 9. These primer sets are designed to detect two gene fusion products: p210 and p190. An additional RT-PCR amplification directed at human c-abl gene segment was performed as a control for sample cDNA quality. Each assay included a positive control reaction using cDNA from a cell line with a known t(9;22) translocation and a negative control reaction using cDNA from a cell line with no evidence of a t(9;22) translocation. PCR products were analyzed by electrophoresis and UV transillumination of ethidium bromide stained gels. Positive and negative control reactions gave appropriate results. Results of this test must always be interpreted in the context of morphologic and other relevant data and should not be used alone for a diagnosis of malignancy. This test is not intended to detect minimal residual disease. The performance characteristics of this test were validated by ARUP Labs, Inc. The US Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under CLIA and by all states to perform high-complexity testing. This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.	NEW PROCEDURE Min. amt: 1 mL. Other acceptable specimens: ACD A, heparinized, or sodium citrate whole blood (yellow, green, or blue top tube) or 3 mL bone marrow. Unacceptable conditions: samples not received in performing lab within 48 hours of collection. Stability: 1 hour at room temperature, 48 hours refrigerated, unacceptable frozen. Effective 9-23-03.
CA19-9 CA19-9 / CA199			This is now an FDA-approved assay. Effective immediately.

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CARDIAC RISK ASSESSMENT BATTERY Hexokinase, FPIA, Enzymatic, Neph CRABAT / CRABAT 80061, 83090, 86141, 82947	5 mL serum (SST or red top tube) and 1 mL EDTA plasma (lavender top tube). Patient should be fasting 12-14 hours. Put EDTA tube on ice immediately after drawing and separate from plasma within 6 hours. Separate serum from cells and put in separate tube. Store and transport all tubes refrigerated.	<p>Cholesterol</p> <table border="0"> <tr> <td>LT 200</td> <td>mg/dL</td> <td>Desirable</td> </tr> <tr> <td>200-239</td> <td></td> <td>Borderline high</td> </tr> <tr> <td>240 or more</td> <td></td> <td>High</td> </tr> </table> <p>Triglycerides</p> <table border="0"> <tr> <td>LT 150</td> <td>mg/dL</td> <td>Normal</td> </tr> <tr> <td>150-199</td> <td></td> <td>Borderline high</td> </tr> <tr> <td>200-499</td> <td></td> <td>High</td> </tr> <tr> <td>500 or more</td> <td></td> <td>Very high</td> </tr> </table> <p>HDL</p> <table border="0"> <tr> <td>LT 40</td> <td>mg/dL</td> <td>Low</td> </tr> <tr> <td>40-59</td> <td></td> <td>Within normal limits</td> </tr> <tr> <td>60 or more</td> <td></td> <td>High</td> </tr> </table> <p>HDL cholesterol greater or equal to 60 mg/dL is considered to be a "negative" risk factor, serving to remove one risk factor from the total count.</p> <p>LDL (calc)</p> <table border="0"> <tr> <td>LT 100</td> <td>mg/dL</td> <td>Optimal</td> </tr> <tr> <td>100-129</td> <td></td> <td>Near or above optimal</td> </tr> <tr> <td>130-159</td> <td></td> <td>Borderline high</td> </tr> <tr> <td>160-189</td> <td></td> <td>High</td> </tr> <tr> <td>190 or more</td> <td></td> <td>Very high</td> </tr> </table> <p>To calculate 10-year cardiac risk for the patient, go to <a href="http://www.paml.com">http://www.paml.com</a>, click on <i>testing</i>, then on <i>ranges/algorithms</i>, and then on <i>lipid results</i>.</p> <p>LDL/HDL Ratio No longer applicable or reported.</p> <p>CHO/HDL Ratio No longer applicable or reported.</p> <p>High-Sensitivity CRP</p> <table border="0"> <tr> <td>Low risk</td> <td>LT 1.0</td> <td>mg/L</td> </tr> <tr> <td>Average risk</td> <td>1.0-3.0</td> <td></td> </tr> <tr> <td>High risk</td> <td>GT 3.0</td> <td></td> </tr> </table> <p>Relative risk categories follow the recommendations of the American Heart Association and the CDC. Measurement of hsCRP should be done twice (averaging results), optimally two weeks apart, in metabolically stable patients. If the hsCRP level is GT 10 mg/L, the test should be repeated and the patient examined for non-cardiovascular sources of inflammation, such as infection.</p> <p>Homocysteine, Cardiac Risk 4.0-12.0 <math>\mu</math>mol/L</p> <p>Glucose</p> <table border="0"> <tr> <td>0-28 days</td> <td>28-62</td> <td>mg/dL</td> </tr> <tr> <td>Adult</td> <td>65-109</td> <td></td> </tr> <tr> <td>Pregnant female</td> <td>65-94</td> <td></td> </tr> </table> <p><i>ADA diagnostic categories for non-pregnant adults:</i></p> <p>Impaired fasting glucose: 110-125 mg/dL.</p> <p>A fasting glucose result of 126 mg/dL or greater indicates diabetes if the abnormality is confirmed on a subsequent day.</p> <p>A random glucose result of GT 200 mg/dL indicates diabetes if the abnormality is confirmed on a subsequent day.</p>	LT 200	mg/dL	Desirable	200-239		Borderline high	240 or more		High	LT 150	mg/dL	Normal	150-199		Borderline high	200-499		High	500 or more		Very high	LT 40	mg/dL	Low	40-59		Within normal limits	60 or more		High	LT 100	mg/dL	Optimal	100-129		Near or above optimal	130-159		Borderline high	160-189		High	190 or more		Very high	Low risk	LT 1.0	mg/L	Average risk	1.0-3.0		High risk	GT 3.0		0-28 days	28-62	mg/dL	Adult	65-109		Pregnant female	65-94		NEW PROCEDURE Min. amt: 2.5 mL serum, 0.5 mL EDTA plasma. Unacceptable conditions: frozen specimens. Stability: 1 week refrigerated. Effective 9-23-03.
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CHLAMYDIA ELISA ELISA CHLAM.SCR.EIA / CHLE	Female endocervical, male urethral, or ocular specimens. Collect swab and put in MicroTrak II (Syva) chlamydia EIA transport media or M4. Store and transport refrigerated. Do not freeze. Indicate the source of the specimen on the request. Positive ELISA tests are confirmed for <i>Chlamydia trachomatis</i> by DFA.		M4 transport media is available from the PAML Supply Dept. Unacceptable conditions: other transport media, wooden swabs, or frozen. Stability: 7 days at room temperature, 7 days refrigerated, unacceptable frozen. Effective 9-15-03.
COXSACKIE B VIRUS AB COX B / COXB		Source Coxsackie B, (Type 1) LT 1:10 No antibody detected. Coxsackie B, (Type 2) LT 1:10 No antibody detected. Coxsackie B, (Type 3) LT 1:10 No antibody detected. Coxsackie B, (Type 4) LT 1:10 No antibody detected. Coxsackie B, (Type 5) LT 1:10 No antibody detected. Coxsackie B, (Type 6) LT 1:10 No antibody detected. Interpretation Single positive antibody titers of greater than or equal to 1:80 may indicate past or current infection. Seroconversion or an increase in titers between acute and convalescent sera of at least four-fold is considered strong evidence of current or recent infection. The clinical significance and criteria for interpretation of results from CSF have not been established.	Stability: 2 hours at room temperature, 2 weeks refrigerated, 1 year frozen. Effective 9-15-03.
CYTOMEGALOVIRUS BY PCR CMVPCR / CMVPCR		The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.	Unacceptable conditions: non-sterile or leaking containers, heparinized, frozen, hemolyzed, or clotted whole blood or bone marrow samples. Effective 9-15-03.
DIPHTHERIA TOXOID IGG AB DIPHG / DIPHG	2 mL serum (red top tube). Separate serum from cells and put in separate plastic tube. Store and transport refrigerated.		Min. amt: 1 mL. Stability: 7 days at room temperature, 14 days refrigerated, 2 months frozen. Effective immediately.

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ECHOVIRUS AB ECHO / ECHO		Echovirus Ab Type 6 LT 1:10 Echovirus Ab Type 7 LT 1:10 Echovirus Ab Type 9 LT 1:10 Echovirus Ab Type 11 LT 1:10 Echovirus Ab Type 30 LT 1:10  Interpretation Single positive antibody titers of greater than 1:80 may indicate past or current infection. Seroconversion or an increase in titers between acute and convalescent sera of at least four-fold is considered strong evidence of current or recent infection.  CSF can be tested. However, the clinical significance and criteria for interpretation of results have not been established.	Stability: 2 days at room temperature, 2 weeks refrigerated, 1 year frozen. Effective 9-15-03.
GAD65 ANTIBODY ASSAY GAD65 / GAD65	1 mL serum (red top tube). Separate serum from cells and put in separate plastic tube. Store and transport refrigerated.		CSF is no longer acceptable. Effective 9-16-03.
HEPATITIS D VIRUS ANTIBODY, TOTAL EIA HEPDAB / HEPDAB 86692 (Focus)	1 mL serum (red top tube). Separate serum from cells and put in separate plastic tube. Store and transport refrigerated.	Negative Interpretive Criteria Negative – Antibody not detected.  Equivocal – Submission of a second specimen (collected 3-4 weeks after initial specimen) is suggested if clinically warranted.  Positive – Antibody detected.  Hepatitis D virus (HDV) infection occurs in association with HBV infection. A positive result for HDV total antibody may indicate either acute or chronic HDV infection. HDV antibodies appear transiently during acute infection, and typically disappear with resolution of the infection. In contrast, HDV antibodies usually persist in chronic infection. Measurement of HDV IgM may help distinguish acute from chronic infection.  This assay was performed using a kit labeled " For research use only" by the manufacturer. The kit's performance characteristics have been established and validated by Focus Technologies for in-vitro diagnostic use.	NEW PROCEDURE Min. amt: 0.5 mL. Effective 9-23-03.
HEPATITIS DELTA ANTIBODY HEP-DEL / HDAB	This workpar is being discontinued.	Use the workpar HEPDAB to order this test.	Effective 9-23-03.
HERPES SIMPLEX VIRUS BY PCR HSVPCR / HSVPCR		The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.	Unacceptable conditions: unsterile or leaking containers, heparinized or hemolyzed samples. Stability: 30 minutes at room temperature (except tissue), 24 hours refrigerated (except tissue), 3 months frozen. Effective 9-15-03.

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PARVOVIRUS, HUMAN, DNA BY PCR HPVPCR / HPVPCR			Unacceptable conditions: Non-sterile or leaking containers; heparinized, hemolyzed, frozen, or clotted whole blood or bone marrow; tissues in formalin or other preservatives. Effective 9-15-03.
PNEUMOCOCCAL ANTIBODY PANEL Fluoroimmunoassay PNEIBT / PNEIBT		"See separate report."  This test has not been approved or cleared by the FDA. It was developed and validated by IBT Reference Lab.	New procedure originally published in Test Alert 255 with an effective date of 9-10-03.
POLIO VIRUS AB POLIO.AB / POLIOV	1 mL serum (red top tube). Separate serum from cells ASAP and put in separate plastic tube. Store and transport refrigerated. Paired sera are advised. Please indicate source.		Min. amt: 0.5 mL. Stability: 2 days at room temperature, 3 weeks refrigerated, 1 year frozen. Effective 9-15-03.
RENIN ACTIVITY [ARUP] RENARU / RENARU	2 mL frozen EDTA plasma.		Changes in volumes and stability only. All other information remains unchanged. Min. amt: 1.2 mL. Stability: 6 hours at room temperature, unstable refrigerated, 1 month frozen. Effective 9-15-03.
VARICELLA-ZOSTER VIRUS BY PCR VZVPCR / VZVPCR	Indicate source.	The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.	Unacceptable conditions: non-sterile or leaking containers and heparinized or hemolyzed samples. Effective 9-15-03.
ZINC, URINE (QUANTITATIVE) ZINCUQ / ZINCUQ		Collection Period (h) Volume (mL) Zinc, Urine Not established $\mu\text{g/dL}$ Zinc, Urine 150-1200 $\mu\text{g/d}$ Creatinine, Ur M 0-2 yrs Not established mg/d 3-8 yrs 140-700 9-12 yrs 300-1300 13-17 yrs 500-2300 18-50 yrs 1000-2500 51-80 yrs 800-2100 GT 80 yrs 600-2000 F 0-2 yrs Not established 3-8 yrs 140-700 9-12 yrs 300-1300 13-17 yrs 400-1600 18-50 yrs 700-1600 51-80 yrs 500-1400 GT 80 yrs 400-1300 Zinc, Ur 10-700 $\mu\text{g/gCr}$	Effective 9-15-03.

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ACETYLCHOLINE RECEPTOR AB PANEL ACHRPN / ACHRPN ACETYLCHOLINE RECEPTOR BINDING AB AR-AB / ACETYL ACETYLCHOLINE RECEPTOR BLOCKING AB AR.AB.BLOCK / ARAB ACETYLCHOLINE RECEPTOR MODULATING AB ACHRMO / ACHRMO C1 ESTERASE INHIBITOR (TOTAL) C-1 EST / C1EST H. INFLUENZA TYPE B AB (IGG) H.INFB.AB / HFLUBG LYME (B. BURGDORFERI) AB, CSF LYMECF / LYMECF PNEUMOCOCCAL AB, IGG PNEUAB / PNEUAB		The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.	Compliance statement added. Effective 9-15-03.
LYSOZYME MUR / LYSOZ		This test uses a kit designated by the manufacturer as "for research use, not for clinical use." The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.	Compliance statement added. Effective 9-15-03.
TOXOCARA AB, IGG TOXC / TOXC		Analyte Specific Reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration approval. This test was developed and its performance characteristics determined by ARUP Laboratories, Inc. It has not been approved by the U.S. Food and Drug Administration. This test should not be regarded as investigational or for research use.	Compliance statement added. Effective 9-15-03.