SPECIALTY LABORATORIES
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This letter details a number of changes made to provide consistency and continuity in the test listings for our 2004 Directory of Services. Many of the changes, such as clarification of specimen type, are a direct result of our ongoing commitment to providing updated clinical data and in-house analysis on sample stability. The end result will be a decrease in problem specimens and better TAT. This letter mailing was delayed by production difficulties and we regret any inconvenience that the abbreviated written notice may cause. If you would like to receive e-mail notification of test changes as well as new tests and services, you may sign up on our Web site www.specialtylabs.com or contact your *Specialty* Sales Representative.

The new test panels for Breast Cancer and Hepatitis C offer additional ways to reflex test components in response to requests for specific test ordering options from our clients. Similarly, we have created a Rheumatoid Arthritis EvaluatR™ with Cyclic Citrullinated Peptide (CCP) IgG Antibody and Rheumatoid Factor IgG, IgM and IgA Antibodies to aid in differentiating rheumatoid arthritis from other forms of joint disease. These test components are also available individually.

In this issue, we highlight our new Allergen Testing Menu (see attached). Specialty Laboratories offers comprehensive testing for single allergens and mixes utilizing the IMMUNOCAP™ UniCAP1000 advanced system with faster throughput and automated reagent sorting. With the new instrumentation, we now offer nearly 600 IgE-specific single allergens, mixes and panels. We can also provide customized allergen panels to suit the specific needs of our clients. For additional information on allergy testing from *Specialty*, please contact Client Services at 800-421-4449.

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Vice President and Co-Director of Laboratory

New from *Specialty*

Effective Tuesday, January 27 or as noted

1839 Breast Cancer ER, PR, Ki67, HER-2 Reflex to FISH

Component	Method	Reference Range
Estrogen Receptor	IHC	By report
Progesterone Receptor	IHC	By report
HER-2/*neu*	IHC	By report
Ki-67 (MIB-1	IHC	By report

Specimen/Stability	Formalin-fixed, paraffin-embedded Tissue Ambient - 12 Month(s). Use cold pack during summer months.
CPT Code	88342x4
Clinical Utility	ER and PR expression is associated with better prognosis in breast cancer patients. ER expression helps to identify patients likely to benefit from neoadjuvant Tamoxifen aromatase inhibitors. HER-2/*neu* over-expression is associated with poorer prognosis in breast cancer.
Notes	If HER-2/*neu* via IHC is 2+, it will reflex to HER-2/*neu* Gene Amplification [FISH] for an additional fee. If reflexed, add CPT code 83950 and add 3-5 days to the TAT.

4929 Clorazepate (Tranxene®)

Component	Method	Reference Range
Nordiazepam	HPLC	100 - 500 ng/mL

Specimen	2.0 mL serum; Refrigerated, Frozen
Collection Notes	Serum separator tubes are not acceptable; use polypropylene tubes.
CPT Code	80154
Clinical Utility	Orally administered clorazepate is rapidly decarboxylated to its metabolite, nordiazepam. There is essentially no circulating parent drug. Nordiazepam elimination half-life is about 40 to 50 hours. Plasma levels of nordiazepam increase proportionally with Clorazepate dose and show moderate accumulation with repeated administration.

7493 Hepatitis C Virus IgG Abs EIA reflex to RNA Quantitation PCR

Component	Method	Reference Range
HCV IgG Abs	EIA	Nonreactive

Specimen	5 mL Plasma EDTA; Frozen
CPT Code	86803
Collection Notes	1.5 mL Serum -- ambient, refrigerated or frozen is acceptable for antibody testing, but frozen plasma is <u>required</u> for the reflex RNA quantitation by PCR.
Clinical Utility	Assess exposure to hepatitis C virus infection. HCV antibodies are typically not detected until approximately 14 weeks after exposure (or 5 weeks after appearance of the first biochemical marker of illness); absence of these antibodies after this period is strong evidence against HCV infection. Reflex RNA quantitation detects HCV RNA down to 5 IU/mL and up to 10 million IU/mL, provides definitive evidence of infection and establishes a viral load baseline prior to initiation of therapy.
Notes	Reactive results are reflexed to HCV RNA Quantitation by PCR to confirm infection and establish baseline viral load. If reflexed, an additional fee will be charged and turnaround time will be increased.

7489 Hepatitis C Virus RNA Quantitation (PCR) reflex to SubtypR®

Component	Method	Reference Range
Hepatitis C Virus RNA	PCR	<5 IU/mL
Hepatitis C Virus RNA	PCR	<10 copies/mL

Specimen: 5 (2) mL Plasma ACD; Frozen

CPT Code: 87522

Clinical Utility: Quantitates Hepatitis C Virus RNA down to 5 IU/mL to monitor viral load in established Hepatitis C-infected individuals. The upper limit of detection is 10,000,000 IU/mL. Viral loads in excess of 2000 IU/mL are automatically reflexed to a genotype assay to ascertain specific subtype. Clinical outcomes are genotype-dependent and differ with regard to disease severity and responses to (peg)interferon and ribiviran combination therapy. A better long-term response to therapy was observed with genotypes 2a and 2b (52%) and with 3a and 3b (74%) than with types 1a and 1b (29%). Other factors associated with favorable response are low pretreatment viral load and the absence of liver cirrhosis.

Notes: Results >2000 IU/mL are reflexed to HCV SubtypR® for an additional fee.

1013 Rheumatoid Arthritis EvaluatR™

Component	Method	Reference Range
CCP IgG Antibodies	EIA	see below
		Less than 20 Units . Negative
		20 - 39 Units Weak Positive
		40 - 59 Units Moderate Positive
		> or = 60 Units Strong Positive
Rheumatoid Factor IgA Autoabs	EIA	<6 U/mL
Rheumatoid Factor IgG Autoabs	EIA	<6 U/mL
Rheumatoid Factor IgM Autoabs	NEPH	<20 IU/mL

Specimen: 1.0 mL Serum; Refrigerated, Frozen

CPT Code: 83520, 86431 x 3

Clinical Utility: Cyclic Citrullinated Peptide (CCP) IgG Antibody is found in approximately 70% of patients with RA, while only about 2% of random blood donors and disease control subjects are positive. A recent study found citrullinated proteins in the joints of patients with RA, but not in patients with other forms of joint disease.

5703 *Vibrio* Culture

Component	Method	Reference Range
Final Culture	Culture	By report

Specimen: 10 (5.0) mL Fresh, Stool in Carey Blair medium; Refrigerated

CPT Code: 87046

Clinical Utility: The assay isolates and identifies *Vibrio*. The clinical syndromes associated with *Vibrio* species are cholera, gastroenteritis, bacteremia and wound infection.

Notes:
1. Collect specimen early in the clinical course and before the initiation of antimicrobial therapy.
2. Maintaining the moisture content of the specimen is the most important factor in maintaining the viability of *Vibrio*.
3. Provide history of travel or history of consumption of seafood or exposure to seawater. This information will help the laboratory in determining which microbial identification protocol to use.

Test Changes

Effective Tuesday, January 27 or as noted

Test Code	Test Name	Specific Change	Also Affected
3974	Alkaline Phosphatase, Bone Specific	Specimen Serum is the only acceptable specimen type	
7711B	*Borrelia burgdorferi* IgG & IgM Antibodies IB [CDC Criteria] *Effective 12-09-03*	Reference Range No longer reporting the IgM p34 band	7711CB *B. burgdorferi* IgG/IgM CSF, bands 7711SFB *B. burgdorferi* IgG/IgM SynFl, bands 7716B *B. burgdorferi* EIA/IB, bands Reflexes from 8942, 8946, 8956
8955	*Borrelia burgdorferi* C6 Peptide Antibodies AccuQuant® *Effective 02-03-04*	Reference Range <0.80 ug/mL	8955SR *Borrelia burgdorferi* C6 Peptide Antibodies AccuQuant® with Serial Report
3126	Calcitonin *Effective 01-13-04*	Reference Range < 13.0 for both men and women	
3123R	Cholinesterase RBC	Stability Refrigerated - 5 days	
5110	Complete Blood Count & Differential *Effective 12-09-03*	Component Remove the metamyelocytes and bands; Now reporting 5 part differential	
9381	*Coxiella burnetii* IgG, IgM & IgA, Phase 1 & 2	Specimen Serum is the only acceptable specimen type	9371 *Coxiella burnetii* IgG Abs, Phase 1 & 2 9376 *Coxiella burnetii* IgM Abs, Phase 1 & 2
5356	Cystic Fibrosis 70 GenotypR™ Carrier Study	CPT Code 83890, 83901x2, 83892x2, 83896x70, 83912	5358 Cystic Fibrosis GenotypR™ Fetal Study 5357 Cystic Fibrosis GenotypR™ Diagnostic
7851	*Ehrlichia chaffeensis* (HME) IgG & IgM Antibodies	Specimen Serum is the only acceptable specimen type	7848 Ehrlichiosis (HME/HGE) IgG & IgM Abs
2271	Epstein-Barr Virus Nuclear Antigen (EBNA) IgM Antibodies *Effective 12-09-03*	Reference Range Change reference range to: Unit: ISR < 0.91 Not Detected 0.91 - 1.09 Indeterminate > 1.09 Detected	
1398	Glucose-6 Phosphate Dehydrogenase (G-6-PDH)	Stability Refrigerated - 5 days	
7777	Herpesvirus-7, Human IgG & IgM Antibodies	Specimen Serum is the only acceptable specimen type	7775 Herpesvirus-7, Human IgG Antibodies 7778 Herpesvirus-7, Human IgM Antibodies
7784	Herpesvirus-8, Human Antibodies	Specimen Serum is the only acceptable specimen type	
3334	Homocysteine UltraQuant® *Effective 02-03-04*	Reference Range Males: 4.3 - 11.4 umol/L Females: 3.3 - 10.4 umol/L Specimen Heparinized plasma is no longer acceptable. Serum and EDTA plasma are acceptable.	5990 Thrombotic Risk AssessR™ 5971 Thrombotic Risk Evaluation 2 5973 Thrombotic Risk Evaluation 3 4992 Pernicious Anemia AssessR™ 4994 Megaloblastic Anemia AssessR™ 1537 Treatable Ischemia PredictR®
3190	Hydroxyprogesterone, 17 Alpha ** for patients <1 y.o., use test code #S42355*	Reference Range Now includes pediatric reference ranges < 1 year old Not given* Prepubertal <275 ng/dL Male, adult 53 - 357 ng/dL Female, adult 20 - 469 ng/dL Follicular Phase 19 - 182 ng/dL Luteal Phase 22 - 469 ng/dL Oral Contraceptives 18 - 251 ng/dL Post-menopause 20 - 172 ng/dL	

Test Code	Test Name	Specific Change	Also Affected
1145	IgD *Effective 12-09-03*	Reference Range <8.0 mg/dL Stability 2 days refrigerated, 1 month frozen	
2153	*Legionella pneumophila* IgG & IgM Antibodies, Serotypes 1-14	Specimen Serum is the only acceptable specimen type	2156 *L. pneumophila* IgG & IgM Abs 1-6 2154 *L. pneumophila* IgG Abs 1-14 2159 *L. pneumophila* IgM Abs 1-14
3420	Leishmania IgG Antibodies	Specimen Serum is the only acceptable specimen type	
7475	*Mycobacterium tuberculosis* (Direct Test)	Stability Refrigerated only; Frozen not acceptable	
1386	Myeloperoxidase Autoantibodies	Specimen 1 (0.5) mL Serum Serum is only acceptable specimen	
8091	Poliovirus Antibodies	Specimen Serum is the only acceptable specimen type	
1396	Proteinase-3 Autoantibodies	Specimen 1 (0.5) mL Serum Serum is the only acceptable specimen type	
7951	*Rickettsia conorii* IgG & IgM Antibodies	Specimen Serum is the only acceptable specimen type	
1445	*Saccharomyces cerevisiae* IgG & IgA Antibodies DetectR™ *Effective 01-13-04*	Reference Range Negative <20.1 Units Equivocal 20.1 - 24.9 Units Positive => 25 Units	
1331	Tetanus & Diphtheria Toxoid IgG Antibodies	Specimen 2 (1) mL Serum Serum is the only acceptable specimen type	1331P Tetanus & Diphtheria Toxoid IgG Antibodies, Pre/Post Vaccination 1334 Tetanus Toxoid IgG Antibodies 1334P Tetanus Toxoid IgG Abs, Pre/Post
5945	Thrombocytopenia, Heparin-Induced *Effective 01-13-04*	Name Heparin Total Antibodies Method EIA -- PF4 complexed to polyanion	
2261C	Toxoplasma Abs Evaluation CSF *Effective 12-09-03*	Component remove *Toxoplasma* IgA Abs CSF; CPT code 86777 x 1 and 86778	
1030	Transglutaminase IgG & IgA Autoantibodies	Specimen Serum Stability Ambient 7 days, Refrigerated 14 days, Frozen 2 months Serum is the only acceptable specimen type	1029 Transglutaminase IgA Autoantibodies 1027 Transglutaminase IgG Autoantibodies
1215	U1 RNP/snRNP IgG Autoantibodies	Specimen 1 (0.5) mL Serum Serum is only acceptable specimen	
8167	West Nile Virus IgG Antibodies *Effective 01-13-04*	Reference Range >= 1.50 Positive 1.30 -- 1.49 Equivocal <1.30 Negative	8167C West Nile Virus IgG Abs CSF 8169 West Nile Virus IgG & IgM Abs 8169C West Nile Virus IgG & IgM Abs CSF 2772 Meningoencephalomyelitis (MEM) Panel

Discontinued Tests and Evaluations

Effective Tuesday, January 27, 2004 or as noted

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a "replacement", contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to Alternate tests or Sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

Test Code	Test Name	Reason	Alternate or Replacement Tests
3191	17-Alpha-hydroxyprogesterone Pediatric	Included in adult test	3190 Hydroxyprogesterone, 17 Alpha [replacement] or S42355 Hydroxyprogesterone, 17 Alpha Newborn <1yr [sendout]
1837	Breast Cancer ER/PR, HER-2/*neu*, MIB-1 Tissue	Replacing with new panel that reflexes	1839 Breast Cancer ER/PR/Ki67 and HER-2/*neu* Reflex [replacement]
1813	Breast Cancer Profile 2 with MIB-1	Consolidating testing	1839 Breast Cancer ER/PR/Ki67 and HER-2/*neu* Reflex or 1819 Breast Cancer ER/PR/DNA CCA and HER-2/*neu* [altermates]
1838	Breast Cancer ER/PR/MIB-1(Ki67)	Consolidating testing	1839 Breast Cancer ER/PR/Ki67 and HER-2/*neu* Reflex [alternate]
1374	CD4 and CD8 IFN-gamma Producing Cells	Reworking assay	No alternate available
5822	Chromosome Analysis Amniotic Fluid	Revalidating assay	S49666 Chromosome Analysis Amniotic Fluid [sendout]
5818	Chromosome Analysis Products Of Conception/ Skin Biopsies	Revalidating assay	S49665 Chromosome Analysis Tissue [sendout]
5359	Cystic Fibrosis 3199DEL6 Mutation Analysis	This mutation included in CF 70 GenotypR™	5356 Cystic Fibrosis 70 GenotypR™: Carrier Study [alternate]
5814	Cytogenetics, Congenital Disorders	Revalidating assay	S49663 Chromosome Analysis Routine Blood [sendout]
1622	Granulocyte Autoantibodies	Reworking assay	S49640 Granulocyte Autoantibodies [sendout]
1370	HIV-1 ImmunoAssessR™ (CD4+ and CD8+ IFN-gamma cells)	Reworking assay	No alternate available
S49473	HIV-1 p24 Ag for Blood Bank (Abbott)	No longer available	9842 HIV-1 p2 Ag (Beckman Coulter) [alternate]

For additional information please call
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or visit our Web site at www.specialtylabs.com