



# SPECIALTY LABORATORIES

2211 Michigan Avenue  
Santa Monica, CA 90404

800-421-4449

## New from *Specialty*

effective April 29, 2003 or as noted

### 1450 Fecal Lactoferrin

Component	Method	Reference Range
Fecal Lactoferrin	EIA	Negative
Specimen Requirement	1 gram Stool; Refrigerated or Frozen Collect approximately 1 gram of formed stool in a clean, leakproof plastic container.	
CPT Code	83516	
Clinical Utility	The Fecal Lactoferrin test is for the qualitative detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The test can be used as a diagnostic aid to help identify patients with active, inflammatory bowel disease (IBD) and rule out those with active, irritable bowel syndrome (IBS), which is noninflammatory.	
Notes	Specimens that have been collected or stored in 10% Formalin, SAF, or PVA fixatives are not acceptable. Use of Carey-Blair transport medium is not acceptable.	

### 3878 Pancreatic Elastase 1

Component	Method	Reference Range
Pancreatic Elastase 1	EIA	Reference Interval: Normal:> 200 ug E1 / g stool  Moderate to mild exocrine pancreatic insufficiency:100 - 200 ug E1 / g stool  Severe exocrine pancreatic insufficiency:< 100 ug E1 / g stool
Specimen Requirement	1 gram Stool; Refrigerated or Frozen Collect approximately 1 gram of formed stool in a clean, leakproof plastic container.	
CPT Code	83516	
Clinical Utility	The Pancreatic Elastase 1 test quantifies E1 in stool allowing the diagnosis or exclusion of pancreatic exocrine insufficiency, which can be caused by chronic pancreatitis, cystic fibrosis, pancreatic tumor, cholelithiasis or diabetes mellitus.	
Notes	Specimens that have been collected or stored in 10% Formalin, SAF, or PVA fixatives are not acceptable. Use of Carey-Blair transport medium is not acceptable.	

## Test Changes

effective April 29, 2003 or as noted

Test Code	Test Name	Reason for Change	Specific Change	Also Affected
3974	Alkaline Phosphatase, Bone Specific	Additional specimen types	<u>Specimen</u> Acceptable Alternate Specimens: EDTA or Heparin Plasma	
9521	Arbovirus IgG Antibodies	Avoid possible interference due to anticoagulant	<u>Specimen</u> Serum is only acceptable sample. Plasma is not acceptable.	8931 Western Equine Encephalitis Total Abs 8936 Eastern Equine Encephalitis Total Abs 8921 St. Louis Encephalitis Total Abs

				8926 California-La Crosse Encephalitis Total Antibodies
8226	Arbovirus IgM Antibodies	Avoid possible interference due to anticoagulant	<u>Specimen</u> Serum only acceptable sample. Plasma is not acceptable.	8176 California-La Crosse Encephalitis IgM Antibodies 8191 Western Equine Encephalitis IgM Abs 8181 Eastern Equine Encephalitis IgM Abs 8186 St. Louis Encephalitis IgM Abs
3258	Carcinoembryonic Antigen (CEA)	Extend specimen stability	<u>Stability</u> Ambient - 5 days, Refrigerated - 14 days, Frozen - 2 months.	3258SR Carcinoembryonic Ag Serial Rpt
2927	<i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i> , rRNA	Clarify stability	<u>Stability</u> Ambient - 7 days, Refrigerated - 7 days, Frozen - 1 month	2925 <i>Chlamydia trachomatis</i> Detection [rRNA] 2930 <i>Neisseria gonorrhoeae</i> Antigen Detection [rRNA]
9436	Cytomegalovirus IgG & IgM Antibodies	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	9431 Cytomegalovirus IgG Antibodies 2231 Cytomegalovirus IgM Antibodies
3146	Dehydroepiandrosterone (DHEA)	Updated assay validation	<u>Reference Range</u> Adult: 140-850 ng/dL Prepubertal: 30-350 ng/dL.	
1210	Extractable Nuclear Antigen (ENA) IgG Autoantibodies	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 days, Frozen - 2 months	1235 Scl-70 IgG Autoantibodies 1215 U1 RNP/snRNP IgG Autoantibodies 1220 SM (Smith) IgG Autoantibodies
3352	HDL Cholesterol	Extend specimen stability	<u>Stability</u> Ambient - 48 hours, Refrigerated - 14 days, Frozen - 3 months	1538 Cardiovascular Disease Risk AssessR™ 3454 Cholesterol Evaluation
2451	Hepatitis A Virus IgM Antibodies	Clarify specimen stability	<u>Stability</u> Refrigerated - 48 hours, Frozen - 2 months	2460 Hepatitis A Virus Total & IgM Abs 7756 Hepatitis A & B Virus Acute Eval 2463 Hepatitis A & B Virus Evaluation 2464 Hepatitis A, B & C Virus Evaluation 7757 Hepatitis Acute Profile
8051	Herpes Simplex Virus 1/2 IgG & IgM Antibodies	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	9446 HSV 1 & 2 IgG Antibodies 9451 HSV SeroDx® Type 1 Antibodies 9461 HSV SeroDx® Type 2 Antibodies 9471 HSV 1 & 2 IgM Antibodies
1350	HLA: B27 Typing	Clarify method	<u>Interpretation</u> Methodology is FC. LMC is used to confirm inconclusive or borderline results at no additional charge.	
1822	Human Papillomavirus GenotypR™	Differentiate HPV tests offered by Specialty	<u>Name</u> Human Papillomavirus High & Low Risk DetectR™	1824 Human Papillomavirus reflex to High & Low Risk DetectR™
1143	Humoral Immune Evaluation (Pneumo 12)	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	1143P Humoral Immune Evaluation (Pneumo 12), Pre/Post Vaccination 1086/P Humoral Immune Evaluation Plus <i>H. influenzae B</i> / Pre/Post Vaccination 1415/P Diphtheria Toxoid IgG Antibodies / Pre/Post Vaccination 1146 Humoral Immune Evaluation + Pneumo 12 & <i>H. influenzae B</i> 1043/P Humoral Immune Evaluation/ Pre/Post Vaccination 1148/P Humoral Immune Status Survey (Pneumo 12) / Pre/Post Vaccination 1048/P Humoral Immune Status Survey (Pneumo 4) / Pre/Post Vaccination

1143	Humoral Immune Evaluation, <i>continued</i>			1340 Immune Status Panel - DPT 1331/P Tetanus & Diphtheria Toxoid IgG Antibodies / Pre/Post Vaccination 2386/P <i>Streptococcus pneumoniae</i> IgG Antibodies, 12 Serotypes / Pre/Post Vaccination 2370/P <i>Streptococcus pneumoniae</i> IgG Antibodies, 4 Serotypes / Pre/Post Vaccination 2384/P <i>Streptococcus pneumoniae</i> IgG Antibodies, 7 Serotypes [Heptavalent] / Pre/Post Vaccination
3860	Neuron-Specific Enolase	Clarify specimen stability	<u>Stability</u> Ambient - 2 days, Refrigerated - 7 days, Frozen - 2 months	3860C Neuron-Specific Enolase CSF 3254 Small-Cell Carcinoma Monitor,
9620	NMP22® Bladder Tumor Marker	Clarify specimen requirement	<u>Specimen</u> An NMP22® Urine Collection Kit is available from <i>Specialty</i> . Do not use other methods for collecting urine samples.	
2361	Ova & Parasite: Routine Exam	Identify acceptable specimen types	<u>Specimen</u> URINE is acceptable alternate specimen for suspected <i>Schistosoma haematobium</i> <u>Collection</u> 15mL in sterile cup container without preservatives collected preferably at mid-day. Ship ambient within 1 day of collection.	
2361	Ova & Parasite: Routine Exam	Identify acceptable specimen types	<u>Specimen</u> Sputum is acceptable alternate specimen. <u>Collection</u> Submit 3-4 mL sputum in 10% formalin and PVA. Ship ambient or refrigerated within 7 days of collection.	2362 Ova & Parasite: Comprehensive Exam with <i>Coccidia</i> Evaluation 2363 Ova & Parasite: <i>Coccidia</i>
4874R	Potassium, RBC	Updated assay validation	<u>Reference Range</u> 55 - 85 mmol/L	
3546 3547	PSA (Prostate-Specific Antigen) Prostate-Specific Antigen, Free & Total	Clarify method	<u>Method</u> ICMA	3545 PSA (Prostate-Specific Antigen), Total reflex to Free 3546SR Prostate-Specific Antigen with serial reporting 3547SR Prostate-Specific Antigen, Free & Total with serial reporting 3546F Prostate-Specific Antigen Fluid
5697	Respiratory Syncytial Virus Antigen Detection	Implementation of new kit	<u>Method</u> Immunochromatography <u>Stability</u> Frozen - 7 days	
9421	Rubella IgG & IgM Antibodies	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	9416 Rubella IgG Antibodies 2475 Rubella IgM Antibodies
1007	SS-A & SS-B IgG Autoantibodies	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	1204 SS-A IgG Antibodies 1205 SS-B IgG Antibodies
9901	TORCH IgG & IgM Antibodies Evaluation	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen - 2 month(s)	9911 TORCH IgG Antibodies Evaluation 2231 TORCH IgM Antibodies Evaluation Panel

2261	<i>Toxoplasma</i> Antibody Evaluation	Extend specimen stability	<u>Stability</u> Ambient - 7 day(s), Refrigerated - 14 day(s), Frozen – 2 month(s)	8972 <i>Toxoplasma</i> Encephalitis AccuDx® 9426 <i>Toxoplasma</i> IgG Antibodies 8970 <i>Toxoplasma</i> IgG Antibody Index 7675 <i>Toxoplasma</i> IgM Antibodies
3520	Vitamin D, 1, 25-Dihydroxy (Calcifidol)	Implementation of new kit	<u>Reference Range</u> 25.1-66.1 pg/mL <u>Method</u> RIA <u>Specimen</u> Serum Alternate: EDTA plasma Heparin plasma is not acceptable.	3523 Vitamin D, 1, 25-Dihydroxy & 25-Hydroxy

## Late-Breaking News

call Client Services for more information

### Cadmium Sample Collection

For test codes S49616 and S49608, Cadmium Exposure Survey, a special collection kit will be required to ensure accurate sample stability. The kit is available from Client Supply. Please contact Send Outs directly at (800)421-7110, X2551 with questions.

### CDC Licensure Renewal

*Specialty* has received a renewal license from the Centers for Disease Control. The new permit number is 2003-02-079; expiration date is 2/14/04.

### CPT Code Changes Recommended:

<u>Test Code</u>	<u>Test Name</u>	<u>Change from</u>	<u>Change to</u>	<u>Reason for Change</u>
1821	Human Papillomavirus High Risk DetectR™	87620	87621	Review by expert
1822	Human Papillomavirus High & Low Risk DetectR™	87621	87621x2	Review by expert
7533	Brain Natriuretic Protein (BNP) EvaluatR™	83520	83880	2003 coding change

### Cystic Fibrosis Testing (test codes 5356, 5357, 5358)

When samples are positive for the I148T mutation, the client will be contacted to determine need for an add-on test to assess whether the 3199del6 mutation is also present. The I148T mutation alone may not be pathogenic; whereas, the I148T + 3199del6 is implicated in cystic fibrosis.

### Directory of Services Correction

The reference range listing in the 2003 Directory of Services for 1331 Tetanus and Diphtheria Toxoid IgG Antibodies is incorrect. The ranges should be:

- Diphtheria Toxoid IgG Abs >0.10 IU/mL
- Tetanus Toxoid IgG Abs >0.15 IU/mL

### Drug Levels Method Change

Please note that we have upgraded the tests listed below from HPLC to Liquid Chromatography/Tandem Mass Spectrometry. This method is more reliable for measuring drug levels in the presence of potentially interfering substances. Reference ranges and CPT codes are unchanged.

- 4964 Clozapine & Norclozapine
- 4912 Alprazolam
- 4918 Clonazepam

### Sendout Test Changes:

We have negotiated improved pricing for tests sent to Focus Technologies; new prices went into effect April 1, 2003. The following sendout tests are being switched to Focus for improved turnaround time and sample stability.

<u>Name of Test</u>	<u>Current SO Code</u>	<u>New SO Code</u>
Parainfluenza Virus Ab	S49872	S50343
<i>Yersinia</i> Antibodies	S50024	S50344
<i>Toxocara</i> Antibodies	S49820	S50345
Hantavirus IgG, IgM	S49874	S50346
RSV Antibodies	S49853	S50347
Coxsackie B Virus Abs	S48735	S50348

### Specimen Identification Labels

We now provide labels to identify the type of specimen you are sending to *Specialty*. This will enable us to accession and process your request(s) without any delay for verification of correct specimen. Contact Client Services for more information or to place an order.

## Discontinued Tests and Evaluations

effective April 29, 2003 or as noted

The following test(s) are no longer available routinely from *Specialty*. Whenever possible, replacement or 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 your Sales Representative if you have any questions.

Test Code	Test Name	Reason	Alternate or Replacement Tests
3109NY	Alpha-Fetoprotein Tumor Marker New York	Special New York code no longer needed	3109 Alpha-Fetoprotein Tumor Marker [Replacement]
3121NY	CA 125 New York	Special New York code no longer needed	3121 CA 125 [Replacement]
3119NY	CA 15-3 New York	Special New York code no longer needed	3119 CA 15-3 [Replacement]
3120NY	CA 19-9 New York	Special New York code no longer needed	3120 CA 19-9 [Replacement]
3134NY	CA27.29 New York	Special New York code no longer needed	3134 CA 27.29 [Replacement]
3258NY	Carcinoembryonic Antigen New York	Special New York code no longer needed	3258 Carcinoembryonic Antigen [Replacement]
1372	HIV-1 gag- and pol-Specific CD8/A2 T-Lymphocyte Quant	Assay was designed as reflex on A2 positive samples for HIV-1	1370 HIV-1 ImmunoassessR™ [Alternate]
3019B	HIV-1/HIV-2 Antibodies reflex to Immunoblot + bands	Low volume	9915B HIV-1/HIV-2 Antibodies [EIA] reflex to IB + bands [Replacement]
3547NY	Prostate-Specific Antigen, Free & Total New York	Special New York code no longer needed	3547 PSA (Prostate-Specific Antigen), Free & Total [Replacement]
3546NY	PSA (Prostate-Specific Antigen New York)	Special New York code no longer needed	3546 PSA (Prostate-Specific Antigen) [Replacement]



Michael C. Dugan, M.D.  
Vice President and Co-Director of Laboratory

**For additional information please call  
Client Services at 800-421-4449  
or visit our Web site at [www.specialtylabs.com](http://www.specialtylabs.com)**