



SPECIALTY LABORATORIES

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Santa Monica, CA 90404

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Coming SOON... Coronavirus (SARS) RNA by PCR

Specialty has a TaqMan assay for the detection of the SARS coronavirus directly from patient respiratory specimens and serum in final validation stages. Call Client Services or check our Website for test availability and shipping instructions.

New from *Specialty*

effective June 3, 2003 or as noted

5701 Aerobic Stool Culture, Routine

Component	Method	Reference Range
Organism/Pathogen	CULTURE	Not detected
Specimen Requirement	2.0 (1.0) grams Stool; Ambient, Refrigerated	
Collection Instructions	Collect 1-2 g fresh stool specimen after onset of symptoms. Preserve in enteric transport media (Cary Blair) immediately. Rectal swabs from infants and patients with active diarrhea are acceptable. Ship stool in Cary Blair on cold pack.	
CPT Code	87045, 87046	
Clinical Utility	Determine the etiologic agent of infectious diarrhea or food poisoning.	
Notes	<p>1. Submit a minimum of three stool specimens collected one per day for three days. A single stool specimen may not exclude bacterial pathogens as a cause of diarrhea. Patients who develop diarrhea while hospitalized and more than 72 hours after admission should be tested for <i>Clostridium difficile</i> by detection of either Toxin A or Toxin B testing or both.</p> <p>2. This assay is for the screening of <i>Salmonella</i>, <i>Shigella</i>, and <i>Campylobacter</i>. Culture includes the identification of the predominant organism or pathogen. If isolated, susceptibility testing will be performed and a fee will be charged. Call Client Services for details.</p>	

8452 *Echinococcus* IgG Antibodies

Component	Method	Reference Range
<i>Echinococcus</i> IgG	EIA	Not detected
Specimen Requirement	1.0 mL Serum; Ambient – 48 hr, Refrigerated – 2 wk, Frozen – 1 mo	
CPT Code	86682	
Clinical Utility	The <i>Echinococcus</i> IgG assay is an important component for the diagnosis of Hydatid disease caused by ingestion of viable parasite eggs since there is no fecal shedding in infected individuals. Increasing antibody levels are indicative of recent or current infection. Cross-reactivity may occur with cysticercosis-positive sera. Patients with collagen vascular diseases, hepatic cirrhosis, and other parasitic diseases such as schistosomiasis may also demonstrate false-positive reactions with this test.	

8442 *Entamoeba histolytica* IgG Antibodies

Component	Method	Reference Range
<i>E. histolytica</i> IgG	EIA	Not detected
Specimen Requirement	1.0 mL Serum; Refrigerated – 1 wk, Frozen – 2 mo	
Collection Instructions	Ship refrigerated or frozen.	
CPT Code	86753	
Clinical Utility	Detects specific antibodies against <i>Entamoeba histolytica</i> in suspected cases of amebiasis. Results should be interpreted in the context of clinical findings and other diagnostic results.	

8324 Histoplasma IgG & IgM Antibodies

Component	Method	Reference Range
<i>Histoplasma</i> IgG	EIA	Not detected
<i>Histoplasma</i> IgM	EIA	Not detected
Specimen Requirement	1.0 mL Serum; Ambient – 48 hr, Refrigerated – 2 wk, Frozen – 1 mo	
CPT Code	86698x2	
Clinical Utility	The <i>Histoplasma</i> IgG and IgM assays are both sensitive and specific for the detection of antibodies against <i>Histoplasma capsulatum</i> in serum or plasma. A positive IgM result is indicative of current infection. A single positive IgG result with a negative IgM indicates a recent or past infection.	

7484A HIV Roche reflex Ultrasensitive and/or reflex GenotypR™ PLUS

Component	Method	Reference Range
HIV-1 RNA (log 10)	CALC	< 2.6 log 10
HIV-1 RNA Quant	PCR	< 400 copies/mL
Specimen Requirement	5.0 (3.0) mL Plasma; Frozen	
Collection Instructions	See <i>Specialty's</i> "Guidelines for Shipping Infectious Substances". Sample requirement must be met to prevent a QNS result. Plasma must be separated and frozen within 4 hours of collection to ensure accuracy. Please record time of collection and freezing on container and requisition. Plasma is recommended for maximum analytical sensitivity. Split into 2 plastic vials before freezing.	
CPT Code	87536	
Notes	If greater than or equal to 400 copies/mL, the assay will reflex directly to the HIV GenotypR™ Plus. Values less than 400 copies/mL are reflexed to an Ultrasensitive PCR assay that further quantifies down to 50 copies/mL. If greater than or equal to 200 copies/mL, this assay will then reflex to the HIV GenotypR™ PLUS. If reflexed to GenotypR PLUS™, add CPT code 87901; an additional fee will be charged.	

5360 M. avium Complex (MAC) Culture Identification (DNA Probe test)

Component	Method	Reference Range
<i>M. avium</i> complex	DNA PROBE	By report
Specimen Requirement	3 mL Slant or Broth; Ambient	
Collection Instructions	Specimen also accepted: BROTH (growth in 7H9 broth, BACTEC 12b, and MGIT). On the outer container affix a label "Etiologic Agent/Biomedical Material." Ship specimen to <i>Specialty</i> by overnight courier (following courier regulations) at ambient temperature.	
Clinical Utility	Rapid DNA probe test that utilizes the technique of nucleic hybridization for the identification of <i>M. avium</i> complex (MAC complex) isolated from culture.	
Notes	<ol style="list-style-type: none"> 1. Send PURE culture only. If the specimen submitted is mixed, there will be separate charges for each organism that requires <i>Mycobacterium</i> identification. 2. There may be a delay in turn around time if the specimen submitted is mixed with non-acid fast bacteria or the broth has insufficient organism mass to perform DNA probe. 3. If MAC is identified, susceptibility testing will be done at client's request for an additional charge. Call Client Services for details. 	

5632 M. tuberculosis Complex Culture Identification (DNA Probe test)

Component	Method	Reference Range
<i>M. tuberculosis</i> complex	DNA PROBE	By report
Specimen Requirement	3 mL (broth), Slant or Broth; Ambient	
Collection Instructions	Specimens also accepted: BROTH (growth in 7H9 broth, BACTEC 12b, and MGIT). On the outer container affix a label "Etiologic Agent/Biomedical Material." Ship specimen to <i>Specialty</i> by overnight courier (following courier regulations) at ambient temperature.	
Clinical Utility	Rapid DNA probe test which utilizes the technique of nucleic hybridization for the identification of <i>M. tuberculosis</i> complex (TB complex) isolated from culture.	
Notes	1. Send PURE culture only. If the specimen submitted is mixed, there will be separate charges for each organism that requires <i>Mycobacterium</i> identification. 2. There may be a delay in turn around time if the specimen submitted is mixed with non-acid fast bacteria or the broth has insufficient organism mass to perform DNA probe. 3. If <i>M. tuberculosis</i> is identified, assay will automatically reflex to susceptibility testing at an additional charge. Call Client Services for details.	

Test Changes

effective June 3, 2003 or as noted

Test Code	Test Name	Reason for Change	Specific Change	Also Affected
3131	Adenosine Deaminase	Revalidation	<u>Reference Range</u> Serum 0 - 10 U/L CSF 0 - 10 U/L Pleural transudate 0 - 6.7 U/L Pleural exudate 1.6 - 9.2 U/L	
5700	Aerobic Bacterial Culture: Stool Comprehensive, reflex to Susceptibility	Schedule times, collection instructions, notes	<u>Collection Instructions</u> Collect 1-2 grams of fresh stool specimen after onset of symptoms. Preserve in enteric transport media (Cary Blair) immediately. Rectal swabs from infants and patients with active diarrhea are acceptable. <u>Stability</u> Ambient-Refrigerated 48 hours	
4912	Alprazolam	New Method combines 5 analytes for greater efficiency.	<u>Method</u> LC-MS-MS	
3258	Carcinoembryonic Antigen (CEA)	Recent in-house study extended ambient stability.	<u>Stability</u> Ambient - 5 days, Refrigerated - 7 days, Frozen - 2Months	3258SR Carcinoembryonic Antigen with serial reporting 3258C Carcinoembryonic Antigen CSF 3258F Carcinoembryonic Antigen Fluid
3371	Cardiolipin IgG, IgM & IgA Autoantibodies [EIA]	Revised update of reference ranges	<u>Reference Range</u> IgG Autoantibodies < 11 GPL U/mL: Negative 11 - 19 GPL U/mL: Indeterminate 20 - 80 GPL U/mL: Low-Medium Positive >80 GPL U/mL: Strong Positive <u>Reference Range</u> IgM Autoantibodies <10 MPL U/mL: Negative 10 - 19 MPL U/mL: Indeterminate 20 - 80 MPL U/mL: Low-Medium Positive >80 MPL U/mL: Strong Positive	3372 Cardiolipin IgG Autoantibodies 3373 Cardiolipin IgM Autoantibodies [EIA] 5963 Lupus Anticoagulant: Screen 1 1081 Antiphospholipid Syndrome EvaluatR™ 1082 Antiphospholipid Syndrome Evaluation, Expanded 1776 Antiphospholipid Evaluation 1080S Antiphospholipid Syndrome Evaluation without LA 5976 Lupus Anticoagulant: Screen 2

Test Code	Test Name	Reason for Change	Specific Change	Also Affected
9026	Cold Agglutinins	Refrigerated/frozen specimens are also acceptable.	<u>Stability</u> Serum Ambient - 5 day(s), Refrigerated - 14 days(s) Frozen - 30 days(s) <u>Collection Instructions</u> Clot blood at 37°C for 30 min. Centrifuge and separate. Once separated from clot, serum may be sent ambient, refrigerated, or frozen.	
3129U	Cortisol, Free 24 hour UltraQuant®	Extend stability and clarify collection instructions	<u>Collection Instructions</u> Acetic, boric, and hydrochloric acid are all acceptable additives. Add 10 mL of 50% acetic acid or 5 g of boric acid or 0.5 mL of 6N hydrochloric acid (HCl) at the start of a 24 hour collection to achieve a pH between 2.0 and 4.0. Measure the total volume, mix the specimen and transfer the aliquot to a clean, leakproof screw cap tube. Record the total volume on specimen container and requisition form. <u>Stability</u> Ambient - 2 days, Refrigerated - 7 days, Frozen - 2 weeks. Ship refrigerated or frozen.	
3154	Estrone	Addition of Alternate Specimen	<u>Specimen</u> EDTA plasma is an acceptable specimen.	
5363	Fragile X DNA Analysis, Prenatal	Correction of CPT codes	<u>CPT Code</u> 2 digestions and 2 gels PCR: 88390, 83894, 83898, 83912 Southern Analysis if needed: 88390, 83892 X 2, 83894 X 2, 83896, 83897, 83898, 83912	
2462	Hepatitis B Virus e Antigen/ Antibody Evaluation	Update specimen	<u>Specimen</u> Serum; Plasma ACD, Heparinized or EDTA Ambient-14 Day(s), Refrigerated-31 Day(s), Frozen-2 Month(s)	
7576	Hepatitis C Virus RNA UltraQuant®	Manufacturer's change of lower limit of sensitivity.	<u>Reference Range</u> <615 IU/mL <u>Notes</u> Criteria for reflex to TMA now <615 IU/mL on all HCV UltraQuant® assays.	7578 Hepatitis C Virus RNA UltraQuant® reflex to SubtypR® 7576SR Hepatitis C Virus RNA UltraQuant® [bDNA] with serial reporting 7476SR Hepatitis C Virus RNA AccuQuant® bDNA reflex to SubtypR® with serial reporting 7486 Hepatitis C Virus RNA AccuQuant® 7476 Hepatitis C Virus RNA AccuQuant® [bDNA] Reflex SubtypR® 7486SR Hepatitis C Virus RNA AccuQuant® [bDNA] with serial reporting 5906 Hepatitis Autoimmune EvaluatR™ PLUS 7578SR Hepatitis C Virus RNA [bDNA] with serial reporting reflex to HCV
2427	Herpes Simplex Virus Culture reflex to Typing		<u>Reflex Protocol:</u> Reflex Positive HSV culture to typing from culture rather than DFA.	

Test Code	Test Name	Reason for Change	Specific Change	Also Affected
9874	HIV-1 RNA UltraQuant®	Extended upper limits of reporting to improve the monitoring of elevated viral loads.	<u>Component</u> The upper limit of detection of 500,000 copies/mL will be removed. Specimens greater than 500,000 copies/mL will be run on dilution.	9874SR HIV-1 RNA UltraQuant® [bDNA] with serial reporting 9878 HIV-1 RNA UltraQuant® reflex to HIV-1 PhenoScript™ 9872 HIV-1 RNA UltraQuant® & CD4 Cell Count 9872SR HIV-1 RNA UltraQuant® [bDNA] & CD4 Cell Count with serial reporting 7482 HIV-1 RNA UltraQuant® reflex to HIV GenotypR™ PLUS (RTI+PI) 7482SR HIV-1 RNA UltraQuant® [bDNA] reflex to HIV GenotypR™ PLUS with serial reporting
7780C	HTLV I/II Antibodies Immunoblot + CSF	Updated specimen	<u>Specimen</u> 3.0 (2.0) mL CSF	7780CB HTLV I/II Antibodies Immunoblot bands CSF
1760	Kappa/Lambda Light-Chain Free (Serum)	Updated reference range due to improved kit	<u>Reference Range</u> Kappa (serum) mg/L (3.30-19.40) Lambda (serum) mg/L (5.71-26.30) Kappa/Lambda Ratio (0.26-1.65)	
2422	<i>Legionella pneumophila</i> Antigen Detection	Add specimen types	<u>Specimens</u> Sputum smear/slides/container Transtracheal Aspirate smear/slides/container Bronchial Wash smear/slides/container Lung Tissue smear/slides/container Pleural Fluid, smear/slides/container Sterile Container	
4872U	Manganese 24 hour Urine	Reactivation; reference range update	<u>Collection Instructions</u> Avoid worksite collection. Collect urine in an acid washed plastic container available through <i>Specialty</i> . Acidify with hydrochloric, acetic or nitric acid (1 mL of concentrated acid for each 100 mL urine) before or after collection. Send acidified aliquot in a <i>Specialty</i> transfer tube. <u>Reference Range</u> <5 ug/24 hr for 4872U <u>Stability</u> Ambient - 1 month, Refrigerated - 2 months, Frozen - 2 months	
4872UR	Manganese Urine Random	Reactivation; reference range update	<u>Reference Range</u> <5 ug/g creatinine for 4872UR	
4872R	Manganese RBC	Reactivation	<u>Collection Instructions</u> Avoid worksite collection. <u>Reference Range</u> 10 - 60 ug/L <u>Stability</u> Refrigerated - 3 days	4165 Minerals Analysis
4872	Manganese Serum	Reactivation	<u>Collection Instructions</u> Carefully clean skin prior to venipuncture. Avoid hemolysis. Avoid worksite collection.	
4872W	Manganese Whole Blood	Reactivation	<u>Collection Instructions</u> Carefully clean skin prior to venipuncture. Avoid hemolysis. Avoid worksite collection.	
3990	PTH-Related Protein	Patient distribution validation	<u>Reference Range</u> < 1.4 pmol/L	

Test Code	Test Name	Reason for Change	Specific Change	Also Affected
F90G	RAST-Malt IgE	Reactivation	<u>Name</u> Allergen - Malt IgE	
3286W	Serotonin (Hydroxytryptamine, 5-) Whole Blood	Reactivation; Updated methodology	<u>Reference Range</u> 50 - 200 ng/mL	
1110	Thyroglobulin Autoantibodies	New platform	<u>Reference Range</u> < 60 U/mL <u>Method</u> ICMA	1016 Thyroid Autoantibodies 3060 Thyroid Antibodies Evaluation 3251 Thyroglobulin Evaluation
3062	Thyroid Peroxidase Autoantibodies	New platform	<u>Reference Range</u> <60 U/mL	1016 Thyroid Autoantibodies 3060 Thyroid Antibodies Evaluation 1000 ANALyzer® 1005 ANALyzer® without ANA 1006 ANALyzer® without Rheum Factor
5200	Urinalysis	Expand collection instructions	<u>Collection Instructions</u> If no preservation tablet is available, ship urine sample refrigerated for overnight delivery.	

Late-Breaking News

call Client Services for more information

- The following statement will appear on all HIV antibody and antigen assay reports: "This information is protected by some state laws and in such cases, cannot be further disclosed without the patient's specific written consent, or as otherwise permitted by law."
- For HIV RNA Quantitation assays that reflex to Ultrasensitive testing (9874A and 9874ASR), we will report "reflexed to Ultrasensitive" rather than the test's lower limit of detection. A specific result will be reported on the Ultrasensitive report that follows.
- Please note when sending paraffin block encased specimens for immunohistochemical analysis that *Specialty* will perform testing and charge for each specimen received. If you have multiple sections from the same site, please select and send only the sample(s) that you want tested. If you have questions, please contact our AP/Oncology Department at 888-567-5225.
- The following tests that were not available to New York clients are now available from *Specialty*.
4125 Drugs Of Abuse Screen Serum; discontinue sendout S49323NYDrug Screen Serum - New York [1864]
4125U Drugs Of Abuse Screen Urine; discontinue sendout S49312NY Drug Screen Urine New York [1868]
- *Specialty* will soon be incorporating changes to our DRVVT testing for Lupus Anticoagulant (test code 1911). The test will reflex from a positive DRVVT screen to mixing studies and confirmation. This change will affect DRVVT testing in all panels for lupus anticoagulant. *Specialty* offers a number of individual assays and panels for identifying the heterogeneous group of antibodies considered lupus anticoagulants in order to complement the tests available from our hospital clients.

Discontinued Tests and Evaluations

effective June 3, 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
5732	HIV-1 Proviral DNA AccuQuant®	Low volume	9885 HIV-1 DNA DetectR™ [alternate]

Discontinued Tests and Evaluations

Specialty has changed reporting and/or received approval for a number of tests so that separate New York (NY) codes are no longer necessary. New York clients can use the same test number without the NY to order the tests indicated below:

9884NYP	HIV-1 RNA Quant by Roche New York Prognostic	9874ANY	HIV-1 RNA Quant by Roche Reflex Ultrasensitive New York
9884NYPS	HIV-1 RNA Quant by Roche New York Prognostic with serial reporting	7487NY	HIV-1 RNA UltraQuant® [BDNA] New York
7482NY	HIV-1 RNA Quant by Roche reflex to GenotypR™ PLUS	7482ANY	HIV-1 RNA Ultrasensitive by Roche reflex to GenotypR™ PLUS NY
7482NYS	HIV-1 RNA Quant by Roche reflex to GenotypR™ PLUS ser rept (NY)		

The following tests and panels were placed on hold last year and are being discontinued at this time. Wherever *Specialty* offers an alternate test we have indicated the recommended test below. Sendout tests are already in place for these assays

1413	Acetylcholine Receptor Modulating Autoabs	1410 ACHR Binding Abs; [alternate]	4915	Isoniazid
		1412 ACHR Blocking Abs [alternate]	7546	<i>Leptospira</i> IgG Abs
2501	Adenovirus Antibodies		2398	<i>Leptospira</i> Culture & Darkfield Microscopy
2501C	Adenovirus Antibodies CSF		3978	Leukocyte Alkaline Phosphatase Stain
1514	Alpha-1-Antitrypsin Phenotyping	1515 Alpha-1-Antitrypsin GenotypR™ [alternate]	8841	<i>Listeria monocytogenes</i> Antibodies
3106	Androstenediol Glucuronide		8841C	<i>Listeria monocytogenes</i> Antibodies CSF
8886	<i>Campylobacter jejuni</i> Total Antibodies [CF]		4871UR	Lithium Urine Random
8866	<i>C. jejuni</i> Total Antibodies [EIA]		4103U	Lysergic Acid Diethylamide (LSD) Screen Urine
4116	Carbamazepine, Free		2516	<i>Neisseria gonorrhoeae</i> Antibodies
2401	<i>Chlamydia pneumoniae</i> Culture		2621	Parainfluenza Virus Types 1-3 Antibodies
2631	<i>Chlamydia</i> spp. Total Antibodies		1257	PM-Scl Autoantibodies
9166	<i>Coccidioides</i> Total Antibodies		7528	Pro-ANP DetectR™ for Congestive Heart Failure
8321	<i>Coccidioides</i> IgG Abs		2646	Respiratory Syncytial Virus Total Antibodies
8316	<i>Coccidioides</i> IgM Abs		4919	Rifampin
1486	Complement Split Product C3a		4152	Salicylate
9099	<i>Cryptococcus</i> Abs		3222	Somatostatin
9099C	<i>Cryptococcus</i> Antibodies CSF		9636	<i>Streptococcus pneumoniae</i> Antigen
1139	Cystatin C		9636C	<i>Streptococcus pneumoniae</i> Antigen CSF
4120	Digitoxin		9636U	<i>Streptococcus pneumoniae</i> Antigen Urine
4122	Digoxin		8566	<i>Strongyloides</i> IgG Abs
8171	<i>Francisella tularensis</i> IgG, IgM, IgA Abs		7565	<i>Treponema pallidum</i> IgG & IgM Antibodies
8166	<i>Francisella tularensis</i> Total Antibodies [Agglutinins]		7561	<i>Treponema pallidum</i> IgG Antibodies
9606	<i>Haemophilus influenzae</i> B Antigen		7561C	<i>Treponema pallidum</i> IgG Antibodies CSF
2468	Hepatitis G Virus RNA DetectR™		9386	<i>Trichinella</i> IgG Antibodies
1431	IgA Fibronectin Aggregates & Serum IgA			
2586	Influenza Virus Antibodies, Type A	8516 Influenza Virus A & B IgG, IgM & IgA Abs [alternate]		
2591	Influenza Virus Antibodies, Type B	8516 Influenza Virus A & B IgG, IgM & IgA Abs [alternate]		
2741	Influenza Virus Antibodies, Types A & B	8516 Influenza Virus A & B IgG, IgM & IgA Abs [alternate]		



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