

July, 2005

Dear Colleague:

Specialty is adding YKL-40 (Human Cartilage Glycoprotein 39) to our impressive menu of tests primarily intended for clinical trials and independent clinical studies. The test has been shown to be useful in assessing tissue damage in rheumatoid arthritis and osteoarthritis; other uses for this test include monitoring and staging certain cancers and liver damage related to cirrhosis. For more information on test availability, please contact Client Services at 800-421-4449.

Other new tests include Histamine testing on plasma or urine (24hr or random) to provide options for evaluating allergic sensitivities and other physiological processes. Previously, it was necessary for the client to request confirmation testing on samples positive for *Chlamydia/Neisseria*. The new test listed in this client letter automatically performs the reflex to confirmatory testing for *C. trachomatis* and/or *N. gonorrhoeae*, if detected, for an additional fee.

New IHC Stains

CDX2 is expressed in the nuclei of intestinal epithelial cells from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas, intestinal metaplasia of the stomach and intestinal-type gastric cancer. It is not expressed in the normal gastric mucosa, mesothelioma, breast, prostate, or lung cancers.

PAX5 is expressed in the nuclei of lymphoid cells of B-cell lineage. The PAX5 gene encodes the B-cell lineage specific activator protein (BSAP) that is expressed at early, but not late stages of B-cell differentiation. PAX5 is expressed in leukemias and lymphomas of B-cell lineage and is seen in the Reed Sternberg cells of Hodgkins disease.

HIV Immunoblot Interpretation

Confirmatory immunoblot testing is more specific than initial EIA screening; however, discrepant EIA results should be followed up or repeated as clinically indicated.

Infrequently Ordered Allergens

A number of allergens that are ordered infrequently will now have an extended turnaround time of 1-14 days. Reagents for these tests may not be immediately available. For a list of these allergens, please contact Client Services or visit our Web site.

HCV

The Centers for Disease Control has recommended a new cut-off for RIBA confirmation of the Abbott AxSYM HCV Antibody assay. If the signal to cut-off ratio (s/co) is >10 [i.e., strongly reactive] RIBA confirmation is not necessary. *Specialty* reports the result as "nonreactive", "indeterminate", "weakly reactive" or "reactive" based on the s/co test result. When we switched the HCV to the AxSYM platform in April, CDC had not made any specific recommendations regarding the cut-off for RIBA confirmation; our internal study indicated an 8.0 cut-off, and we established that value to separate weakly reactive specimens (requiring confirmation) from strongly reactive ones. We will now recommend RIBA confirmation for any indeterminate or weakly reactive HCV antibody tests by MEIA (i.e., those with an s/co greater than 0.8 but less than or equal to 10.0) and use this cut-off for our test in which the immunoassay automatically reflexes to RIBA if indeterminate or weakly reactive (#2445 HCV IgG Reflex to RIBA and 2445B HCV Reflex to RIBA plus bands). None of these changes will affect the current reporting structure of "nonreactive", "indeterminate", "weakly reactive" or "reactive" that our clients see, but interpretive comments will be changed to reflect the CDC recommendations.

For additional information, please contact Client Services at 800-421-4449.



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Vice President and Laboratory Director

New from Specialty

Effective Tuesday, July 19, 2005 or as noted

7440SW *Chlamydia trach*/*Neisseria* rRNA PLUS [TMA] Swab w/Reflex Confirmation (effective 07/19/05)

Component	Method	Reference Range	Units
<i>C. trachomatis</i>	TMA	Not Detected	
<i>N. gonorrhoeae</i>	TMA	Not Detected	
Specimen/Stability	Gen-Probe (Aptima) Swab in media (see Collection Instructions) Ambient - 60 Day(s), Refrigerated - 60 Day(s), Frozen - 3 Month(s)		
Collection Instructions	Swabs with wooden shafts are NOT acceptable. 1. Endocervical swab specimens (Gen-Probe): a. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft). Discard swab. b. Insert specimen collection swab (blue shaft) into endocervical canal. c. Gently rotate swab clockwise for 10-30 seconds in the endocervical canal to ensure adequate sampling. d. Withdraw swab carefully; avoid any contact with vaginal mucosa. e. Immediately place specimen collection swab into transport tube. f. Carefully break swab shaft at scoreline; use care to avoid splashing of contents. g. Re-cap swab specimen transport tube tightly. 2. Male urethral swab specimens (Gen-Probe): a. Patient should not have urinated for at least one hour prior to sample collection. b. Insert specimen collection swab (blue shaft) 2-4 cm into urethra. c. Gently rotate swab clockwise for 2-3 seconds in urethra to ensure adequate sampling. d. Withdraw swab carefully. e. Immediately place specimen collection swab into transport tube. f. Carefully break swab shaft at scoreline; use care to avoid splashing of contents. g. Re-cap swab specimen transport tube tightly. Specimen Transport & Storage (Gen-Probe): After collection, store and transport swab specimen transport tube at 2-30° C. Assay within 60 days of collection. ThinPrep® Pap Test Specimens: Specimens collected using broom-type device and placed in Cytoc PreservCyt® Solution for use in making ThinPrep Pap Test slides can be used for CT/GC testing. Collect specimens in routine manner; 4 mL PreservCyt solution required for CT/GC test. PreservCyt® specimens stable 3 weeks ambient following collection and prior to processing.		
Clinical Utility	The most sensitive and rapid screen for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> .		
Schedule	Sunday-Saturday		
Turnaround Time	1-3 days		
CPT Code	87491, 87591		
Notes	Please supply patient's birth date on Specialty's Test Requisition Form for Public Health Department reporting. Note that this test <u>automatically</u> performs the reflex to confirmatory testing for <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> , if detected, for an additional fee.		

3354P Histamine, Plasma (effective 07/19/05)

Component	Method	Reference Range	Units
Histamine Plasma	EIA	<150	ng/dL
Specimen/Stability	1.0 (0.3) mL Plasma EDTA; Frozen only Frozen - 2 Month(s)		
Collection Instructions	Collect plasma using EDTA, chill immediately on ice. Carefully aspirate the upper 2/3 of plasma. Hemolyzed samples must not be used. Split into 2 plastic vials before freezing. Ship by overnight courier.		
Clinical Utility	Histamine is useful to assess the occurrence of flushing. Histamine functions as a potent mediator of numerous physiological and pathophysiological processes. Histamine has been clearly implicated as a primary mediator of "acute phase" allergic reactions. Elevated histamine levels are found in cases of mastocytoma, chronic myeloid leukemia (CML) and polycythaemia vera. The uncontrolled histamine release following the consumption of different foods may cause a dangerous histamine situation, especially in persons with allergies. Toxic side effects include circulatory disorders, headaches and gastrointestinal pains, and may lead to chronic intoxication and liver damage.		
Schedule	Thursday		
Turnaround Time	1-8 days		
CPT Code	83088		

3354U Histamine, Urine with Creatinine (effective 07/19/05)

Component	Method	Reference Range	Units
Histamine/Creatinine Ratio	EIA/CALC		<60ug/g of Creatinine
Specimen/Stability	1.0 (0.3) mL Random or 24hr Urine; Frozen only Frozen - 2 Month(s)		
Collection Instructions	Collect urine in plastic container; do not use glass. Freeze random urine or well-mixed aliquot of 24-hr urine in plastic container.		
Clinical Utility	Histamine is useful to assess the occurrence of flushing. Histamine functions as a potent mediator of numerous physiological and pathophysiological processes. Histamine has been clearly implicated as a primary mediator of "acute phase" allergic reactions. Elevated histamine levels are found in cases of mastocytoma, chronic myeloid leukemia (CML) and polycythaemia vera. The uncontrolled histamine release following the consumption of different foods may cause a dangerous histamine situation, especially in persons with allergies. Toxic side effects include circulatory disorders, headaches and gastrointestinal pains, and may lead to chronic intoxication and liver damage.		
Schedule	Thursday		
Turnaround Time	1-8 days		
CPT Code	83088		

Immunohistochemistry Stains (effective immediately)

IHC201	CDX2
IHC202	PAX5
Specimen Req	Formalin-fixed, paraffin-embedded tissue; Ambient; unstained, positively charged slides (4) are also acceptable.
Clinical Utility	IHC stains are useful for identification of antigens present in paraffin-embedded tissues. Properly selected panels may aid in the identification of tumor type and subclassification. Additional markers may be useful in assessing proliferation (Ki67) or prognosis (e.g., bcl-2 or HER-2/ <i>neu</i>) in selected tumor types.
Collection Notes	Shipping on cold pack is recommended during the warm weather months. Ship by overnight courier to <i>Specialty</i> .
Schedule	Monday-Sunday
Turnaround Time	1-4 days
CPT Code	88342 times the number of antibodies selected
Notes	Diagnostic code required for third party reimbursement. Please send copy of pathology report and other applicable tests.
Order Codes	1857 IHC Stain & Diagnostic Interpretation: Pathologist Chooses 1-3 Stains 1859 IHC Stain & Diagnostic Interpretation: Pathologist Chooses 1-6 Stains 1854 IHC Stain & Interpretation: Client Chooses Stains 1856 IHC Stain Only: Client Chooses Stains

4104U LSD (Lysergic Acid Diethylamide) Urine (effective 07/19/05)

Component	Method	Reference Range	Units
LSD Urine	LC/MS-MS	<0.1	ng/mL
2-oxo-3-hydroxy-LSD Urine	LC/MS-MS	<0.1	ng/mL
Specimen/Stability	10 (5.0) mL Urine; Ambient, Refrigerated or Frozen Ambient - 7 days, Refrigerated - 7 days, Frozen - 2 months		
Schedule	Thursday		
Turnaround Time	1-8 days		
Clinical Utility	Used for diagnosis and treatment of LSD use or overdose. After ingestion, the concentration of LSD in urine falls to <1 ng/mL within a few hours. LSD is detectable in urine for several days to 2 weeks. 2-oxo-3hydroxy-LSD (O-H-LSD) has been identified as an LSD metabolite present at severalfold higher concentrations than LSD in human urine. This assay can serve as both a screen and confirmatory assay at the same time.		
CPT Code	82542		

3137 YKL-40 (Human Cartilage Glycoprotein 39) (effective 07/19/05)

Component	Method	Reference Range	Units
YKL-40	EIA	24.0-125.0	ng/mL
Specimen/Stability	0.5 mL Serum, Refrigerated or Frozen Refrigerated - 7 days, Frozen - 2 months		
Collection Instructions	Draw enough blood in a red top evacuated tube to deliver sufficient serum volume (usually 2.5 times the amount requested) Allow to clot at ambient temperature at least one hour then separate serum by centrifugation. Transfer the serum into plastic vials for transport under refrigerated or frozen conditions. Serum specimens shipped frozen in SST tubes will be rejected.		
Schedule	Wednesday		
Turnaround Time	1-8 days		
Clinical Utility	YKL-40, also known as Human Cartilage Glycoprotein 39, is produced by chondrocytes, synovial cells, activated macrophages and neutrophils and is involved in tissue remodeling. It has been used as a marker of joint destruction activity in rheumatoid arthritis and osteoarthritis, liver fibrosis in alcoholic cirrhosis and survival following recurring breast cancer or colorectal cancer.		
CPT Code	83520		
Notes	By special arrangement; requires a minimum of 5 specimens. Contact Clinical Trials or Client Services for more information.		

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
5900	06-28-05	Activated Protein C Resistance	<u>Stability</u> Citrated Plasma Frozen - 14 days	5901 Activated Protein C Resistance reflex to Factor V GenotypR™
4859	06-28-05	Copper Liver	<u>Alternate Specimens</u> Tissue Sterile Container	
4313	06/15/05	Cyclosporine A Whole Blood [HPLC]	<u>Name</u> Cyclosporine A Whole Blood [LC/MS-MS] <u>Method</u> LC/MS-MS <u>Specimen Requirement</u> Reduced to 4.0 (2.0) mL	
3354	07/19/05	Histamine	<u>Name and Test Code</u> 3354W Histamine Whole Blood <u>Method</u> EIA <u>TAT</u> 1-8 days <u>Specimen Volume/Collection Instructions</u> Reduced to 1.0 (0.3) mL Heparinized Whole Blood Collect blood in heparinized tube and split into 2 plastic vials before freezing. Do not use EDTA. Do not use glass tubes. <u>Reference Range</u> 210-1500 nmol/L	
3536	06-28-05	Iron Liver	<u>Alternate Specimens</u> Tissue Sterile Container	
1760	07-19-05	Kappa/Lambda Light-Chain Free Serum	<u>Reference Range and Units</u> Kappa Light-Chain Free 0.33-1.94 mg/dL Lambda Light-Chain Free 0.57-2.63 mg/dL Kappa/Lambda Ratio 0.26-1.65 (unchanged)	
1062	06/17/05	Lymphocyte Antigen & Mitogen Proliferation Analysis	<u>Specimen Requirement</u> 30 (20) mL Whole Blood ACD For infants, 15 mL whole blood ACD is sufficient.	

Test Code	Effective Date	Test Name	Specific Change	Also Affected
1060	06/17/05	Lymphocyte Mitogen Proliferation Analysis	<u>Specimen Requirement</u> 20 mL Whole Blood ACD For infants, 10 mL whole blood ACD is sufficient.	
3206	07-19-05	Prolactin	<u>Stability</u> Ambient is no longer acceptable; Refrigerated stability is 2 days, Frozen (preferred) stability is 2 months	2017 Infertility: Endocrine Evaluation (Male)
3226	07-19-05	Thyroxine (T4)	<u>Stability</u> Ambient is no longer acceptable; Refrigerated stability is 4 days, Frozen (preferred) stability is 2 months	3230 Thyroxine, Free Index 3954 Thyroxine Free, Direct Dialysis
3228	07-19-05	Thyroxine (T4) Free	<u>Stability</u> Ambient is no longer acceptable; Refrigerated stability is 4 days, Frozen (preferred) stability is 2 months	3954 Thyroxine, Free Index
5702	06-28-05	<i>Yersinia</i> Culture	<u>Specimen/Stability</u> Frozen stool is no longer an acceptable specimen type. Stool in Cary-Blair media Ambient (72hr) [preferred] or Refrigerated (48hr) are acceptable as are Stool Ambient (24hr) or Stool Refrigerated (48hr)	

Sendout Changes

Discontinue Sendout S49702 and use #4104U LSD (Lysergic Acid Diethylamide) Urine
 Discontinue Sendout S49043 and use #3354P Histamine, Plasma
 Discontinue Sendout S48718 and use #3354U Histamine, Urine
 Discontinue Sendout S48719 and use #3354U Histamine, Urine

Please call Client Services at 800-421-4449 or visit our website at www.specialtylabs.com for more information.