SPECIALTY LABORATORIES
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March/April, 2005

Dear Colleague:

We are pleased to announce the introduction of testing for 5-Aminolevulinic Acid (5-ALA) in urine. This test as well as Urinary Porphobilinogen (#4169U and #4169UR) are part of our plan to offer more comprehensive laboratory testing services for the diagnosis of porphyrias. This portion of the testing, previously a sendout, is now being offered in-house.

In Endocrinology, for the diagnostic workup of perimenopausal and pubertal conditions in women and for evaluating intersex disorders, gonadal function disorders in cryptorchidism, etc., we now offer Anti-Mullerian Hormone/ Mullerian Inhibiting Substance (AMH/MIS; # 3138).

Error in Directory of Services
A formatting error led to omission of the requirement that specimens be stored and shipped frozen for the Complement tests listed below:

Test code	Test name	Specimen Requirements
1605	Complement C2	1 (0.5) mL Serum; Frozen
1610	Complement C5	1 (0.5) mL Serum; Frozen
1976	Complement C6	1 (0.5) mL Serum; Frozen
1978	Complement C7	1 (0.5) mL Serum; Frozen
1980	Complement C8	1 (0.5) mL Serum; Frozen
1982	Complement C9	1 (0.5) mL Serum; Frozen
1600	Complement Functional Activity CH50	1 (0.8) mL Serum; Frozen
1984	Complement Factor H	1 (0.5) mL Serum; Frozen

Please note that the most up-to-date information on test availability and specimen requirements can be obtained on our Web site at www.specialtylabs.com or by calling Client Services at 800-421-4449.

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

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

New from *Specialty*

Effective Tuesday, April 19, 2005 or as noted

4159U 5-Aminolevulinic Acid, 24-hr Urine (effective 04/19/05)

Component	Method	Reference Range	Units
Aminolevulinic Acid, 24hr	Ion Exchange Chromatography/ Spectroscopy	Less than 7.5	mg/24 hr

Specimen/Stability 2 (1.2) mL 24 hr Urine
Refrigerated – 7 Days, Frozen – 2 Months

Collection Instructions Refrigerate and protect specimen from strong light during 24 hr collection. Wrap aliquot in foil or ship in amber tube refrigerated or frozen. Record total urine volume in mL on both the container and the requisition.

Clinical Utility Elevated urinary levels of 5-Aminolevulinic Acid (ALA) are seen in lead poisoning. Other toxins that lead to elevated 5-ALA levels in urine are alcohol and other heavy metals. Significant elevations are seen also in hereditary tyrosinemia and in the acute neurologic forms of the porphyrias.

Schedule Tuesday, Friday

Turnaround Time 1-4 days

CPT Code 82135

4159UR 5-Aminolevulinic Acid, Random Urine (effective 04/19/05)

Component	Method	Reference Range	Units
Aminolevulinic Acid, random	Ion Exchange Chromatography/ Spectroscopy	Less than 4.5	mg/L

Specimen/Stability 2 (1.2) mL Urine Random
Refrigerated – 7 Days, Frozen – 2 Months

Collection Instructions Collect random urine. Protect specimen from strong light during and following collection. Wrap aliquot in foil or ship in amber tube refrigerated or frozen.

Clinical Utility Elevated urinary levels of 5-Aminolevulinic Acid (ALA) are seen in lead poisoning. Other toxins that lead to elevated 5-ALA levels in urine are alcohol and other heavy metals. Significant elevations are seen also in hereditary tyrosinemia and in the acute neurologic forms of the porphyrias.

Schedule Tuesday, Friday

Turnaround Time 1-4 days

CPT Code 82135

3138 Anti-Mullerian Hormone/Mullerian Inhibiting Substance (effective 04/19/05)

Component	Method	Reference Range	Units
AMH/MIS	EIA	see below	ng/mL
		Males >18 yr 0.40 – 4.60	ng/mL
		Premenopausal Females >18 yr 0.10 – 3.90	ng/mL
		Postmenopausal Females generally <0.05	ng/mL

Specimen/Stability 1 (0.5) mL Serum; Frozen
Frozen – 2 Months

Collection Instructions Separate serum from clot and ship frozen. Frozen SST tubes are not acceptable.

Clinical Utility AMH/MIS may be used in the investigation of ovarian reserve and the perimenopausal transition in women; the detection and onset of puberty in the young; the differential diagnosis of intersex disorders; the diagnosis of cryptorchidism and anorchidism, and the evaluation of male gonadal function in all ages.

Schedule Fridays

Turnaround Time 1-8 days

CPT Code 83516

1732C Kappa Light Chain CSF (effective 04/19/05)

Component	Method	Reference Range	Units
Kappa Light Chain, CSF	Neph	Less than 0.50	mg/L

Specimen/Stability 1 (0.5) mL CSF
Ambient -7 days, Refrigerated – 14 Days, Frozen – 2 Months

Clinical Utility Indicator of intrathecal immunoglobulin synthesis with concomitant kappa free light chain secretion, such as is seen in multiple sclerosis.

Schedule Tuesday, Thursday, Saturday

Turnaround Time 1-4 days

CPT Code 83883

2365 VDRL w/ reflex to *Treponema pallidum* Total Abs FTA (effective 03/11/05)

Component	Method	Reference Range	Units
VDRL	FLO	Nonreactive	

Specimen/Stability 1.5 (0.5) mL Serum
Ambient -48 hours, Refrigerated – 7 Day(s), Frozen – 2 Month(s)

Clinical Utility Screen for syphilis; useful in assessing adequacy of treatment. Biologic false-positives are common in a variety of other infections or rheumatic diseases; thus, positives are reflexed to the more specific *T. pallidum* tests.

Schedule Tuesday, Thursday, Saturday

Turnaround Time 1-4 days

CPT Code 83883

Notes If positive, test is titered to end point. Please supply patient's birth date on *Specialty's* Test Requisition Form for Public Health Department reporting. Diagnostic code required for third party reimbursement. Reactive VDRL results are reflexed to *T. pallidum* IFA testing for an additional fee. If reflexed, add CPT code 86781.

Test Changes

Test Code	Effective Date	Test Name	Specific Change	Also Affected
7589	03/15/05	Adenovirus DNA DetectR™	Alternate Specimen/Stability 5.0 (1.0) mL ACD or EDTA Whole Blood are acceptable alternate specimens Ambient 48 hrs. Do not Freeze.	
3996	04/26/05	Alkaline Phosphatase Isoenzymes	New Component — Reference Range Intestinal % — less than 14% Intestinal U/L — Less than 15 U/L	
5400P	02/22/05	DNA Cell Cycle Analysis, Products Of Conception	Interpretation DNA INDEX — PLOIDY INTERPRETATION 1.0 — DNA Diploid 1.1-1.3 — DNA Aneuploid 1.4-1.6 — DNA Aneuploid (Triploid) 1.7-1.8 — DNA Aneuploid 1.9-2.1 — DNA Aneuploid (Tetraploid) >2.1 — DNA Aneuploid	
4972	04/05/05	Hemoglobin A1c AccuQuant®	Reference Range 4.0 – 6.0 % (reflects ADA recommendations)	4972SR Hemoglobin A1c AccuQuant®, serial reporting
2450	03/15/05	Hepatitis A Virus Total Antibodies	Method MEIA Reference Range Nonreactive Nonreactive Indeterminate Reactive	2460 Hepatitis A Virus Total & IgM Abs 2463 Hepatitis A & B Virus Eval 2464 Hepatitis A, V & C Virus Eval 2477 Hepatitis A Virus Total Abs W/Reflex IgM 7758 Hepatitis A, B & C Virus Post Exposure Panel
2451	03/15/05	Hepatitis A Virus IgM Antibodies	Method MEIA Reference Range Nonreactive Nonreactive Indeterminate Reactive	2460 Hepatitis A Virus Total & IgM Abs 2463 Hepatitis A & B Virus Eval 2464 Hepatitis A, V & C Virus Eval 2477 Hepatitis A Virus Total Abs W/Reflex IgM 7756 Hepatitis A & B Virus Acute Eval 7757 Hepatitis Acute Profile
8324	03/15/05	*Histoplasma* IgG & IgM Abs [EIA]	Interpretation Negative Positive Equivocal	8323 *Histoplasma* IgM Abs 8322 *Histoplasma* IgG Abs

Test Code	Effective Date	Test Name	Specific Change	Also Affected
7480	04/05/05	HIV-1 GenotypR™ PLUS	Reflects changes in Trugene Rules version 9 Component Discontinue Foscarnet Component Names (in same order as current report): Nucleoside and Nucleotide RT Inhibitors zidovudine (AZT) didanosine (ddI) zalcitabine (ddC) lamivudine (3TC)/emtricitabine (FTC) stavudine (d4T) abacavir (ABC) tenofovir (TDF) NonNucleoside RT Inhibitors nevirapine (NVP) delavirdine (DLV) efavirenz (EFV) Protease Inhibitors saquinavir (SQV) indinavir (IDV) ritonavir (RTV) nelfinavir (NFV) amprenavir (APV)/fosamprenavir (FPV) lopinavir + ritonavir (LPV/r) atazanavir (ATV)	7480NY HIV-1 GenotypR™ PLUS New York 7482FPNY HIV-1 RNA Quant by Roche Reflex HIV GenotypR PLUS New York 7484A HIV-1 RNA Quant by Roche Reflex To HIV GenotypR PLUS 7482 HIV-1 RNA UltraQuant [bDNA] w/Rfx HIV GenotypR PLUS 7482SR HIV-1 RNA UltraQuant [bDNA] w/Rfx HIV GenotypR PLUS Serial Reporting 7482A HIV-1 RNA Ultrasensitive By Roche w/Reflex GenotypR PLUS Serial Reporting 7482ASR HIV-1 RNA Ultrasensitive By Roche w/Reflex GenotypR PLUS Serial Reporting
3193	03/10/05	Insulin Free and Bound	Specimen Requirement 2.0 (1.0) mL Serum (to avoid QNS samples)	
3453	04/26/05	Lactate Dehydrogenase Isoenzymes	Reference Range (due to platform change) LD1 16-32% LD2 32-50% LD3 17-27% LD4 6-13% LD5 3-12% Reference ranges for Total LD are not affected. Notes Avoid hemolysis; icteric and lipemic samples are not acceptable.	
4861W	03/15/05	Lead Whole Blood	Collection Instructions Collection material such as alcohol swabs should be lead-free. Use powder-free gloves or rinse the powder off with tap water. For capillary collection, wash hands thoroughly with soap and dry with clean, low-lint towel. Once washed, fingers must not come into contact with any surface, including the other fingers. Clean skin prior to venipuncture with the lead-free alcohol swab. Avoid hemolysis. Avoid worksite collection.	4861CP Lead Capillary 4861X Lead Whole Blood (Priority) 4861I Lead Whole Blood, Industrial – OSHA 4861IX Lead Whole Blood, Industrial – OSHA (Priority) 4863 Lead Whole Blood and Zinc Protoporphyrin 4080W Heavy Metal Screen Whole Blood
3445	04/26/05	Lipoprotein Electrophoresis	Reference Range (due to platform change) Beta Lipoproteins 42.3-69.5% Pre-Beta Lipoproteins 2.0-31.2 % Alpha Lipoproteins 15.1-39.9 % Reference ranges for other panel components are not affected. Stability Ambient - 24 hours; Refrigerated – 3 days	
1648	04/05/05	Lymphocyte Antigen Proliferation Analysis	Reference Range Candida Stimulation Index Greater than 3.0 SI PPD Stimulation Index Greater than 3.0 SI Tetanus Stimulation Index Greater than 3.0 SI	1062 Lymphocyte Antigen & Mitogen Proliferation Analysis 1643 Lymphocyte Antigen Proliferation Analysis, Candida 1644 Lymphocyte Antigen Proliferation Analysis, Tetanus 1645 Lymphocyte Antigen Proliferation Analysis, PPD (Tuberculin)

Test Code	Effective Date	Test Name	Specific Change	Also Affected
1644	04/05/05	Lymphocyte Antigen Proliferation Assays, Tetanus	Name Consistency Lymphocyte Antigen Proliferation Analysis, Tetanus	
1645		Lymphocyte Antigen Proliferation Assays, PPD	Lymphocyte Antigen Proliferation Analysis, PPD	
3941	04/05/05	PTH, Intact Only	Method CEIA Reference Range was 0.7 – 5.6 change to 11.1 – 79.5 Units was pmol/L change to pg/mL	3213 PTH, C Terminal & Intact, Including Ionized & Total Calcium 3944 PTH, Intact, Including Ionized & Total Calcium 3943 PTH, Intact, Including Total Calcium Only 3943SR PTH, Intact, Including Total Calcium Only, Serial Reporting 3942 PTH, ScatterGraph™ (PTH Intact including Total Calcium)

Sendout Changes

Please call Client Services at 800-421-4449 for more information.

Test Name	Old Code	New Code	Sample Requirement Changes	Reference Range Changes
Aminolevulinic Acid 24hr Urine *Effective 05/03/05*	S49272	**4159U**	Aminolevulinic Acid 24hr Urine	No change
Aminolevulinic Acid Random Urine *Effective 05/03/05*	S49306	**4159UR**	Aminolevulinic Acid Random Urine	No change