

November 1, 2006

Dear Colleague:

This client letter details recent changes that have occurred in tests available from *Specialty* as well as a listing of discontinued tests. Please note that Hemoglobin Variants by Electrophoresis as an initial screen is no longer available. We have previously introduced an HPLC methodology for performing the hemoglobin variant screening, which reflexes to electrophoresis and pathologist interpretation as needed, when there is a variant hemoglobin identified. This combined approach is the preferred method for initial evaluation of a suspected hemoglobinopathy. To order, please use test code **4984 Hemoglobin Variant w/reflex to Electrophoresis**. For follow up on patients with known sickle cell disease or other common variant hemoglobins, you may order **4985 Sickle Cell MonitR™** which uses only HPLC to derive % Hgb S, as well as % Hgb A, A2, F and C.

Also of significance are the new reference ranges established for evaluating Heparin therapy. This new understanding of therapeutic performance of anti-Xa drugs can be read in detail on the following pages.

For many of our molecular genetics tests, specimen stability has been changed to 1 week for both ambient and refrigerated whole blood samples.

When submitting patient samples in liquid cytology media for the simultaneous testing of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and human papillomavirus (HPV), please split each specimen into two vials, one for CT/NG and the other for HPV, prior to submission. If only CT and NG are requested (or HPV alone), then one submitted specimen will be sufficient.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.



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

Discontinued and Changed Assays at *Specialty*

Effective date as noted

DISCONTINUED:

S51057 Total Protein/Creatinine Ratio
Effective IMMEDIATELY
Reason Replaced by **1305UR**

S48821 BCL1 DetectR™
Effective IMMEDIATELY
Reason Replaced by **5048**

S40960 Carbamezepine
Effective IMMEDIATELY
Reason Replaced by **4115**

S50869 PCP Confirmation
Effective IMMEDIATELY
Reason Replaced by **4183U**

4987 Hemoglobin Variants by Electrophoresis
Effective IMMEDIATELY
Reason Replaced by **4984**

4977 Hemoglobin Variants by Isoelectric Focusing (IEF)
Effective IMMEDIATELY

Test Changes:

3187 Beta-hCG, Total
Effective IMMEDIATELY
Reason Name Change – (added Total to name)

3522R Folate RBC
Effective IMMEDIATELY
Specimen Whole Blood EDTA Lavender
Alternate Whole Blood EDTA Blue top

5874 Acute Myeloid Leukemia/High Grade Myelodysplasia
Effective IMMEDIATELY
CPT Code 88291, 88237, 88271x12, 88275x8

5878 Myelodysplastic Syndromes (MDS), Low Grade by FISH
Effective IMMEDIATELY
CPT Code 88291, 88237, 88271x6, 88275x5

2927	<i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoea</i>, rRNA								
Effective	IMMEDIATELY								
CPT Code	87800								
3296	Plasminogen Activator Inhibitor-1								
Effective	IMMEDIATELY								
CPT Code	85415								
5779	Fungus Culture: Yeast Screen								
Effective	IMMEDIATELY								
Alternate Specimen	5.0 (3.0)mL Urine, Refrigerated 14 days								
5356	Cystic Fibrosis GenotypR™								
Effective	IMMEDIATELY								
Specimen/Stability	Cells collected in liquid cytology media (LCM, ThinPrep or SurePath) should ship refrigerated within 24 hours. Buccal cells ship refrigerated within 24 hours. Stability, ambient or refrigerated 4 weeks								
5308UR	Phosphorus Urine Random								
Effective	IMMEDIATELY								
Specimen	Urine sample with PH adjusted to <3								
5947	Heparin (Anti-Xa), Low Molecular Weight								
Effective	12-5-2006								
Reference Range	Removed								
Note	Enoxaaparin or nadroparin (twice daily) therapeutic range 0.6 to 1.0 IU/mL								
	Therapeutic ranges vary for other agents and dosing schedules. The measured peak of anti-factor Xa activities varies among individual LMWH preparations given in the same anti-factor Xa dose, due to variations in pharmacokinetics. In order to avoid an increased risk of bleeding, levels of 1.0 IU/mL or greater should be avoided if the appropriateness of the dose is in question in patients with renal impairment or severe obesity.								
	The peak therapeutic anti-factor Xa for once daily administration is less clear, but target therapeutic means are suggested as follows:								
	<table border="0"> <tr> <td>enoxaparin (Levonox)</td> <td>>1.0 IU/mL</td> </tr> <tr> <td>tinzaparin (Novo, Logiparin)</td> <td>0.85 IU/mL</td> </tr> <tr> <td>nadroparin</td> <td>1.3 IU/mL</td> </tr> <tr> <td>dalteparin (Fragmin)</td> <td>1.05 IU/mL</td> </tr> </table>	enoxaparin (Levonox)	>1.0 IU/mL	tinzaparin (Novo, Logiparin)	0.85 IU/mL	nadroparin	1.3 IU/mL	dalteparin (Fragmin)	1.05 IU/mL
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dalteparin (Fragmin)	1.05 IU/mL								
	The target therapeutic mean is measured approximately 4 hrs after administration. (source: Heparin and Low Molecular Weight Heparin. The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy – Chest 2004; 126;188-203).								

3220**Insulin-Like Growth Factor**

Effective	12-5-2006		
Reference Range	Age	Reference Range	Units
	1-7 days	<26	ng/mL
	8-15 days	<41	
	16-364days	25-265	
	1 year	55-327	
	2	51-303	
	3	49-289	
	4	49-283	
	5	50-286	
	6	52-297	
	7	57-316	
	8	64-345	
	9	74-388	
	10	88-452	
	11	111-551	
	12	143-693	
	13	183-850	
	14	220-972	
	15	237-996	
	16	226-903	
	17	193-731	
	18	163-584	
	19	141-483	
	20	127-424	
	21-25 years	116-358	
	26-30	117-329	
	31-35	115-307	
	36-40	109-284	
	41-45	101-267	
	46-50	94-252	
	51-55	87-238	
	56-60	81-225	
	61-65	75-212	
	66-70	69-200	
	71-75	64-188	
	76-80	59-177	
	81-85	55-166	
	>85	40-157	

IGF-I Tanner Stage Ranges

Female		Male	
1	49-342	1	63-279
2	115-428	2	75-420
3	145-760	3	94-765
4	244-787	4	192-861
5	143-859	5	171-814

3178**Growth Hormone Deficiency MonitR™**

Effective	12-5-2006
Reference Range	See ranges in 3220 above

1515**Alpha-1-Antitrypsin GenotypR™**

Effective	IMMEDIATELY
Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week

1518**Alpha-1-Antitrypsin Deficiency Fetal Study**

Effective	IMMEDIATELY
Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week

5358	Cystic Fibrosis GenotypR™ Fetal Study	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
7230	Connexin GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
1705	Narcolepsy EvaluatR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
4562	MTHFR C677T/A1298C GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5290	Familial Mediterranean Fever	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5381	Cytochrome P450 2C9 GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5382	Cytochrome P450 2C19 GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5380	Cytochrome P450 2D6 GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5383	DPD 5-FU GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
1078	Celiac Disease GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
1364	HLA-B*27 GenotypR™	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5363	Fragile X Fetal Study	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week
5206	Ashkenazi Jewish GenotypR™ Panel	Effective	IMMEDIATELY
		Stability	Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Bloom Syndrome: 5216 Carrier, 5217 Diagnostic, 5218 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Canavan Disease: 5226 Carrier, 5227 Diagnostic, 5228 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Familial Dysautonomia: 5236 Carrier, 5237 Diagnostic, 5238 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Fanconi Anemia: 5246 Carrier, 5247 Diagnostic, 5248 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Gaucher Disease: 5256 Carrier, 5257 Diagnostic, 5258 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Mucopolidosis: 5266 Carrier, 5267 Diagnostic, 5268 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Niemann-Pick Disease: 5276 Carrier, 5277 Diagnostic, 5278 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week

Tay-Sachs Disease: 5286 Carrier, 5287 Diagnostic, 5288 Prenatal
Effective IMMEDIATELY
Stability Whole Blood, Ambient 1 Week, Refrigerated 1 Week