

August 22, 2008

Dear Colleague:

As Specialty Laboratories continues to enhance our client communication processes, we are pleased to announce that on 09/16/08 we will be offering The Binding Site **Anti-Phospholipid ELISA** assays as a replacement for our laboratory developed tests. The enhanced performance of these assays provides the increased sensitivity and specificity for detection of phospholipid antibodies that will improve the quality of results we may provide.

IgG and IgM Antibodies on the following assays will be affected:

- **Anti-Phosphatidylethanolamine (Anti-PE) [1791]**
- **Anti-Phosphatidic Acid (Anti-PA) [1771]**
- **Anti-Phosphatidylinositol (Anti-PI) [1774]**
- **Anti-Phosphatidylglycerol (Anti-PG) [1775]**
- **Anti-Phosphatidylcholine (Anti-PC) [1751]**

Due to the possible implications of positive results from urinary drug screen testing, effective 9/16/08, *Specialty* will begin to include a reflex confirmation (when appropriate) and discontinue the screen-only assays. We believe this is prudent and will better serve our clients and their patients. The drug screen with confirmation assays are:

- **Drugs of Abuse Urine w/Reflex Confirmation [4129U]**
- **Amphetamine/Methamphetamine Screen Urine w/Reflex Confirmation [4256U]**
- **Barbiturates Screen Urine w/Reflex Confirmation [4121U]**
- **Benzodiazepine Screen Urine w/Reflex Confirmation [4107U]**
- **Cannabinoids Screen Urine w/Reflex Confirmation [4254U]**
- **Cocaine Metabolites Screen Urine w/Reflex Confirmation [4252U]**
- **Methadone Screen Urine w/Reflex Confirmation [4109U]**
- **Opiates Screen Urine w/Reflex Confirmation [4250U]**

We thank you for choosing *Specialty* and look forward to your continued support. For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.

Respectfully Yours,



Christopher Lockhart, M.D.
Laboratory Director

Test Changes:

1846 HER-2/*neu* [IHC], Breast Cancer

Effective	September 16
Component	HER-2/ <i>neu</i>
Reference Range	0, 1+ = Negative Score 0: No staining is observed in invasive tumor cells. Score 1+: Weak incomplete membrane staining in any proportion of invasive tumor cells, or weak complete membrane staining in less than 10% of cells. 2+ = Equivocal Score 2+: Complete membrane staining that is non-uniform or Weak, but with obvious circumferential distribution in at least 10% of cells, or intense, complete membrane staining in 30% or less of tumor cells. 3+ = Positive Score 3+: Uniform, intense, complete membrane staining of > 30% of invasive tumor cells.
Also affected	DOS code 1817, 1818, 1819, 1833, 1839, 1840, 1842, 5846

1771 Phosphatidic Acid IgG, IgM & IgA Autoabs

Effective	September 16
Component	IgG & IgM Autoabs
Reference Range	< 10 U/mL
Assay Category	RUO
Component	IgA Autoabs
Reference Range	< 2.0 Index (no change)
Assay Category	LDT (no change)
Also affected	DOS code 1082, 1776

1751 Phosphatidylcholine IgG, IgM & IgA Autoabs

Effective	September 16
Component	IgG & IgM Autoabs
Reference Range	< 10 U/mL
Assay Category	RUO
Component	IgA Autoabs
Reference Range	< 2.0 Index (no change)
Assay Category	LDT (no change)
Also affected	DOS code 1082, 1776

1791 Phosphatidylethanolamine IgG, IgM & IgA Autoabs

Effective	September 16
Component	IgG & IgM Autoabs
Reference Range	< 10 U/mL
Assay Category	RUO
Component	IgA Autoabs
Reference Range	< 2.0 Index (no change)
Assay Category	LDT (no change)
Also affected	DOS code 1082, 1776

Test Changes: (Cont'd)

1775 Phosphatidylglycerol IgG, IgM & IgA Autoabs

Effective	September 16
Component	IgG & IgM Autoabs
Reference Range	< 10 U/mL
Assay Category	RUO
Component	IgA Autoabs
Reference Range	< 15 U/mL (no change)
Assay Category	LDT (no change)
Also affected	DOS code 1776

1774 Phosphatidylinositol IgG, IgM & IgA Autoabs

Effective	September 16
Component	IgG & IgM Autoabs
Reference Range	< 10 U/mL
Assay Category	RUO
Component	IgA Autoabs
Reference Range	< 15 U/mL (no change)
Assay Category	LDT (no change)
Also affected	DOS code 1776

3521 Vitamin D, 25-Hydroxy (Calcifediol)

Effective	September 16
Component	Vitamin D, 25-hydroxy
Reference Range	30-100 ng/mL
	Deficiency < 10 ng/mL (< 25 nmol/L)
	Insufficiency 10- 30 ng/mL (25- 75 nmol/L)
	Sufficiency 30-100 ng/mL (75-250 nmol/L)
	Toxicity > 100 ng/mL (> 250 nmol/L)
Also affected	DOS code 3525

Discontinued Tests:

Effective Immediately:

PAX2 Allergen - Occupational Mix IgE: PAX2
Replaced by: D71 - *Lepidoglyphus destructor* IgE, D70 - *Acarus siro* IgE, IgE and R1202 Grain Weevil (*Sitophilus granarius*) IgE

Effective August 30, 2008:

4005 Carbohydrate-Deficient Transferrin (CDT) UltraQuant®
Replaced by: S51679 - Carbohydrate Deficient Transferrin, Serum

4020 Motor & Sensory Neuropathy EvaluatR™
Replaced by: 4021 - Motor & Sensory Neuropathy Evaluation and S51679 - Carbohydrate Deficient Transferrin, Serum

4030 Sensory Neuropathy EvaluatR™
Replaced by: 4031 - Sensory Neuropathy Evaluation and S51679 - Carbohydrate Deficient Transferrin, Serum

Effective September 16, 2008:

4125U Drugs of Abuse Screen Urine
Replaced by: 4129U - Drugs of Abuse Urine w/Reflex Confirmation

4106U Amphetamine/Methamphetamine Screen Urine
Replaced by: 4256U - Amphetamine/Methamphetamine Screen Urine w/Reflex Confirmation

4108U Barbiturates Screen Urine
Replaced by: 4121U - Barbiturates Screen Urine w/Reflex Confirmation

4111U Benzodiazepine Screen Urine
Replaced by: 4107U - Benzodiazepine Screen Urine w/Reflex Confirmation

4132U Cannabinoids Screen Urine
Replaced by: 4254U - Cannabinoids Screen Urine w/Reflex Confirmation

4118U Cocaine Metabolites Screen Urine
Replaced by: 4252U - Cocaine Metabolites Screen Urine w/Reflex Confirmation

4113U Methadone Screen Urine
Replaced by: 4109U - Methadone Screen Urine w/Reflex Confirmation

4138U Opiates Screen Urine
Replaced by: 4250U - Opiates Screen Urine w/Reflex Confirmation

Discontinued Tests: (Cont'd)

4117U Phencyclidine (PCP) Screen Urine

Replaced by: 4101U – Phencyclidine (PCP) Screen Urine w/Reflex Confirmation

4149U Propoxyphene Screen Urine

Replaced by: 4127U - Propoxyphene Screen Urine w/Reflex Confirmation