

May 21, 2007

Dear Colleague:

As part of our continuing efforts to improve testing turnaround times, quality, and service, *Specialty* is making a slight modification to our quantity not sufficient/test not reported (QNS/TNR) notification policy. Effective immediately, upon the first notification we will release the patient report indicating the issue and time / date of notice. Should additional sample be available for completion of testing, please contact Client Relations at 800-421-4449 for assistance.

Please note the expanded age-dependent reference ranges for #3959: Insulin-Like Growth Factor Binding Protein (IGFBP-3). Sex is not a factor with the updated reference ranges, and only the age of the patient is required for proper reporting and interpretation.

Our drugs of abuse tests (DOA) have received numerous updates over the past few months in an effort to produce the most effective and robust platforms available. The two most notable changes for serum tests are that serum is the only acceptable sample (no plasma) and **SST tubes are not acceptable**. Reference ranges have also been carefully scrutinized and revised to address the various scenarios for which DOA testing is used. Please note the reference range reporting change on benzodiazepines enclosed in this update.

Due to serious complications of vitamin B12 deficiency, accurate methods for detection are needed. *Specialty* has adopted Abbot Diagnostics Holotranscobalamin assay for a more accurate assessment of Vitamin B12 status. Vitamin B12 is present in blood bound to two transport proteins, transcobalamine II (TC) and haptocorrin (HC). Only Vitamin B12 bound to transcobalamine II (holoTC) is biologically functional. Measurement of the holo TC fraction affords superior diagnostic sensitivity and allows early identification of patients with Vitamin B12 malabsorption (i.e., low HoloTC levels).

Another notable update involves the Hepatitis B Virus Surface Antigen test(DOS #2454). This test can now be performed on 2.5mL of heparinized plasma, sodium citrate plasma, and EDTA plasma with **same day result reporting**.

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

Sendout Replacements :

S48609 Chromosome Analysis on CVS by culture

Replaced by: 5855 Aneuploidy 13-18-21-X-Y DetectR™

Effective: 6/12/2007

Test Changes :

3310U Hydroxyindoleacetic Acid, 5 (24 hour Urine)

Effective Immediately

Specimen 3.0 (2.0)mL Urine, Ambient 7 days, Refrigerated 14 days,
Frozen 2 months

Also Affected 3310UR

4176 Oxycodone And Metabolite, Serum

Effective Immediately

Specimen 5.0(3.0)mL Serum, Ambient 7 days, Refrigerated 7 days,
Frozen 7 days

Note Serum is the only acceptable sample. SST
tubes are not acceptable.

4176U Oxycodone And Metabolite, Urine

Effective Immediately

Specimen 5.0(3.0)mL Serum, Ambient 7 days, Refrigerated 7 days,
Frozen 7 days

4104U Lysergic Acid Diethylamide (LSD) Urine

Effective Immediately

Specimen 5.0(3.0)mL Serum, Ambient 7 days, Refrigerated 7 days,
Frozen 14 days

4170U Cocaine and Metabolites Confirmation, Urine

Effective Immediately

Specimen 10.0(5.0)mL Serum, Ambient 7 days, Refrigerated 7 days,
Frozen 7 days

Also Affected 4171U, 4172U

5841 UroVysion™

Effective Immediately

Name UroVysion™ (FISH for Bladder Cancer)

3959

Insulin-Like Growth Factor Binding Protein (IGFBP-3)

Effective

May 30, 2007

Ref. Range	AGE	REFERENCE RANGE (mg/L)
	<1 year	0.50- 1.40
	1 year	0.70- 3.60
	2	0.80- 3.90
	3	0.90- 4.30
	4	1.00- 4.70
	5	1.10- 5.20
	6	1.30- 5.60
	7	1.40- 6.10
	8	1.60- 6.50
	9	1.80- 7.10
	10	2.10- 7.70
	11	2.40- 8.40
	12	2.70- 8.90
	13	3.10- 9.50
	14	3.30-10.00
	15	3.50-10.00
	16	3.40- 9.50
	17	3.20- 8.70
	18	3.10- 7.90
	19	2.90- 7.30
	20	2.90- 7.20
	21-25	3.40- 7.80
	26-30	3.50- 7.60
	31-35	3.50- 7.00
	36-40	3.40- 6.70
	41-45	3.30- 6.60
	46-50	3.30- 6.70
	51-55	3.40- 6.80
	56-60	3.40- 6.90
	61-65	3.20- 6.60
	66-70	3.00- 6.20
	71-75	2.80- 5.70
	76-80	2.50- 5.10
	>80	2.20- 4.50

Also Affected

3178

1324F

Protein, Total Fluid

Effective

June 12, 2007

Ref. Range

<2500 mg/dL

4090U Benzodiazepines Confirmation Urine

Effective	June 12, 2007	
Ref. Range	Components	Ref. range ng/mL
	Alpha-Hydroxyalprazolam	<10
	Alpha-Hydroxytriazolam	<10
	Alprazolam	<20
	Chlordiazepoxide	<20
	Diazepam	<20
	Estazolam	<10
	Flurazepam	<10
	Hydroxyethylflurazepam	<20
	Lorazepam	<10
	Midazolam	<20
	Nitrazepam	<20
	Norchlordiazepoxide	<20
	Nordiazepam	<50
	Norfludiazepam	<10
	Oxazepam	<20
	Temazepam	<20
	Triazolam	<10
Also Affected	4107U, 4129U	

1466C IgA CSF

Effective June 12, 2007
 New Dos Code 1506C

1461C IgM CSF

Effective June 12, 2007
 New Dos Code 1508C

4102 Alcohol, Ethyl Serum

Effective June 12, 2007
 Ref. Range see below

< 10 mg/dL (<0.01%) Not detected
 ≥ 80 mg/dL (≥0.08%) Legally intoxicated

	<u>SPORADIC DRINKERS</u>	<u>CHRONIC DRINKERS</u>
200-250 mg/dL (0.20-0.25%)	Alertness lost, becoming lethargic	Effort needed to maintain emotional and motor control
300-350 mg/dL (0.30-0.35%)	Stupor to coma	Drowsy and slow
>500 mg/dL (>0.50%)	Death possible	Coma

4185	Opiates and Metabolites Confirmation Serum
Effective	Immediately
Specimen	5.0(2.5)mL Serum, Ambient 7 days, Refrigerated 14 days Frozen 14 days
Note	Serum is the only acceptable sample. SST tubes are not acceptable
Also Affected	4491, 4493, 4495, 4492, 4496
4170	Cocaine and Metabolites confirmation serum
Effective	Immediately
Specimen	5.0(2.5)mL Serum, Refrigerated 3 days Frozen 7 days
Note	Serum is the only acceptable sample. SST tubes are not acceptable.
Also Affected	4171, 4172
3510	Active B12 HoloTC AssessR™
Effective	Immediately
Method	MEIA
Ref. Range	35-101 pmol/L
Specimen	1.0(0.3)mL Serum, Ambient 3 days, Refrigerated 3 days Frozen 30 days
Clinical Utility	Vitamin B12 is present in blood bound to two transport proteins, transcobalamine II (TC) and haptocorrin (HC). Only Vitamin B12 bound to transcobalamine II (holoTC) is biologically functional. Measurement of the holo TC fraction affords superior diagnostic sensitivity and allows early identification of patients with Vitamin B12 malabsorption (i.e., low HoloTC levels).
Setup	Tuesday, Thursday
Report	Same day
Note	Multiple freeze/thaw cycles should be avoided. Grossly icteric and grossly hemolyzed samples are not acceptable.
9941	<i>Aspergillus</i> Antibodies Panel
Effective	Immediately
Specimen	1.0(0.8)mL Serum, Ambient 7 days, Refrigerated 14 days Frozen 2 months
Also Affects	9941, 9946, 9961
2454	Hepatitis B Virus Surface Antigen
Effective	Immediately
Alt. Specimen	4.0(2.5)mL Plasma(heparinized, sodium citrate, EDTA), Ambient 14 days, Refrigerated 31 days, Frozen 31 days
2417	Acid-fast Bacilli Culture
Effective	Immediately
Alt. Specimen	10(5.0)mL Body Fluid, Ambient 24 hours, Refrigerated 7 days,
Also Affected	2419