

February 2004

Dear Colleague:

We are pleased to introduce in this letter the *Histoplasma* DNA UltraQuant[®], which is a new highly sensitive "quantitative" PCR based assay for the detection of *Histoplasma* in urine or plasma. The assay sensitivity is one to two orders of magnitude greater than traditional *Histoplasma* antigen testing and as sensitive as our "qualitative" *Histoplasma* DNA DetectR[™]. We have also enhanced the reporting of DNA ploidy analysis on products of conception to rule out triploidy (partial moles) or aneuploidy (some complete moles). We will shortly incorporate a p57 IHC stain to this panel to enhance the distinction of partial vs. complete molar pregnancies (call for availability of p57). Other changes have been made to streamline and enhance our breast cancer panels to best reflect contemporary oncology practices.

You will soon be receiving our 2004 Directory of Services incorporating many of the changes presented in the last few editions of this letter. If you would like to receive e-mail notification of test changes as well as details on new tests and services, you may sign up on our Web site www.specialtylabs.com or contact your *Specialty* Sales Representative.

You will note in our new Directory that we have established recommended protocols for handling frozen specimens and platelet-poor plasma. These protocols are intended as guidelines for optimum sample stability. The protocols are listed below for easy reference:

STANDARD INSTRUCTIONS FOR STRICT FROZEN SPECIMENS

The tests below require that samples are collected, frozen within one hour and maintained frozen during shipment. Please observe the following standard instructions for strict frozen specimens.

Split into 2 plastic vials and freeze within 1 hour of collection. Ship frozen on dry ice by *Specialty* or overnight courier. Please note any delay in freezing sample on the requisition/order.

PLATELET-POOR PLASMA COLLECTION INSTRUCTIONS

When collecting the sample, please observe the following instructions for collection, processing and shipment:

- Draw a plain red-top tube to remove tissue fluid contamination. Discard this tube.
- Draw blood into a buffered citrate collection tube (light blue top) filled to proper level. Sodium citrate of 105-109 mmol/L, (3.2%) should be used. Use of other anticoagulants is unacceptable.
- The anticoagulant-to-blood ratio should be 1:9; inadequate filling of the collection device will decrease this ratio and may lead to inaccurate results.
- The final citrate concentration in the blood should be adjusted in patients who have hematocrit values >55%. For hematocrits below 20%, no current data are available to support a recommendation for adjusting the citrate concentration.
- The needle gauge could be from 19-22. For pediatric patients a 21-23 gauge needle may be used.
- Invert gently 6 times to mix. Process immediately.
- Centrifuge for 15 min at 2500 x g.
- Remove plasma using a plastic pipette to transfer into a new plastic tube.
- Repeat centrifugation at 2500 x g for 15 minutes to assure complete platelet removal.
- Dispense the plasma into 2 or more plastic tubes using a plastic transfer pipette. Label tubes appropriately.
- Freeze immediately at -70° C.
- Specimen must remain frozen at all times. Ship to *Specialty* within 24 hours on dry ice.
- Specimen should not be submitted if:
 - it is hemolyzed; micro clots are present; the tube is less than 90% filled; or
 - a specimen with hematocrit >55% is collected without anticoagulant adjustment

For additional information on testing or other specimen collection guidelines, 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, March 9, 2004 or as noted

5400P DNA Cell Cycle Analysis, Products of Conception

Component	Method	Reference Range Units
DNA Index	FC	By report
DNA Ploidy	FC	By report
Specimen/Stability	Formalin-fixed, paraffin-embedded Tissue Block; Paraffin Block Ambient – 60 Months; Refrigerated (during summer months)	
Collection Instructions	Ship by overnight courier. Use cold pack during summer months	
Clinical Utility	DNA cell cycle analysis can characterize DNA aneuploid populations in products of conception to rule out DNA triploidy associated with partial hydatidiform moles. Complete moles are typically diploid, but may be tetraploid or aneuploid. S-Phase is not reported in products of conception samples.	
Schedule	Monday-Sunday	
Turnaround Time	2-4 days	
CPT Code	88182	

NOTE: an additional panel with p57 by IHC for partial vs complete mole will be available soon. Contact Anatomic Pathology for test availability.

1833 ER/PR/Ki67/p53 & HER-2 reflex to FISH, Breast Cancer

Component	Method	Reference Range Units
Estrogen Receptor	IHC	By report
Progesterone Receptor	IHC	By report
HER-2/ <i>neu</i>	IHC	By report
Ki-67 (MIB-1)	IHC	By report
p53	IHC	By report
Specimen/Stability	Formalin-fixed, paraffin-embedded Tissue Block; Paraffin Block Ambient – 60 Months; Refrigerated (during summer months)	
Collection Instructions	Ship by overnight courier. Use cold pack during summer months	
Clinical Utility	ER and PR expression are associated with better prognosis in breast cancer patients. ER expression helps to identify patients likely to benefit from neoadjuvant Tamoxifen aromatase inhibitors. HER-2/ <i>neu</i> over-expression is associated with poorer prognosis in breast cancer.	
Schedule	Monday-Sunday	
Turnaround Time	2-4 days	
CPT Code	88342x5	
Notes	If HER-2/ <i>neu</i> via IHC is 2+, it will reflex to HER-2/ <i>neu</i> FISH [gene amplification] for an additional fee. If reflexed, add CPT code 83950 and add 5-7 days to the TAT.	

7588 ***Histoplasma* DNA UltraQuant[®]** (effective 1-21-04)

Component	Method	Reference Range Units
<i>Histoplasma capsulatum</i> DNA	PCR	<200 copies/mL
Specimen Stability	5.0 (1.0) mL Urine or 5.0 (1.) mL ACD/EDTA Plasma Ambient - 4 Day(s), Refrigerated - 4 Day(s), Frozen - 2 Month(s)	
Collection Instructions	For Urine: Collect midstream urine in a sterile container. For Plasma: Collect whole blood, centrifuge within 4 hours, separate plasma from whole blood.	
Clinical Utility	Identifies <i>Histoplasma capsulatum</i> infection. May have additional benefit in monitoring the effectiveness of therapy. Exceeds sensitivity of antigen test	
Schedule	Tuesday, Thursday	
Turnaround Time	1-5 days	
CPT Code	87799	
Notes	Quantitates DNA load down to 200 copies/mL in both urine and plasma. Upper reporting limit is 10,000,000 copies/mL	

Test Changes

Effective Tuesday, March 16, 2004 or as noted

<u>Test Code</u>	<u>Test Name</u>	<u>Specific Change</u>	<u>Also Affected</u>
3143U	Beta-2 Microglobulin Urine	<u>Stability</u> Refrigerated 14 days; Frozen not recommended	4500I Cadmium Exposure OSHA Urine & Whole Blood (specimen 3) 4500URI Cadmium Exposure OSHA Urine (specimen 2)
5400	Breast Cancer DNA Cell Cycle Analysis, Tissue	<u>Test Name</u> DNA Cell Cycle Analysis, Breast Cancer	
1817	Breast Cancer Profile 4 with HER-2/ <i>neu</i> , MIB-1 (Ki-67)	<u>Test Name</u> ER/PR/HER-2/Ki-67/DNA Cell Cycle Analysis, Breast Cancer	
4836	Calcium, Total <i>Effective 3-3-04</i>	<u>Reference Range</u> Male & Female 0-1 years: 7.6-11.0 mg/dL	3213 PTH, C Terminal & Intact, Including Ionized & Total Calcium 3208 PTH, C Terminal, Including Ionized and Total Calcium 3945 PTH, C Terminal, Including Total Calcium Only 3944 PTH, Intact, Including Ionized & Total Calcium 3943 PTH, Intact including Total Calcium 3943SR PTH, Intact including Total Calcium with serial reporting 3942 PTH Scattergraph 5315 Metabolic Panel, Basic 5317 Metabolic Panel, Comprehensive 5314 Renal Function Panel
1600	Complement: CH50 Total Functional Activity, Classic Path	<u>Alternate Specimen</u> Plasma EDTA is no longer acceptable. Serum is the only acceptable specimen.	
3123R	Cholinesterase RBC	<u>Stability</u> Ambient - 72 Hour(s)	
2960	Fecal Leukocytes	<u>Stability</u> Ambient is no longer acceptable. Stool PVA or rectal swab should be refrigerated and shipped on cold pack to arrive within 48 hours of collection.	

5301	Glucose	<u>Alternate Specimen</u> Plasma Fluoridated/Oxalated, Heparinized or EDTA	
3012	HIV-1 Antibodies (IB)	<u>Alternate Specimen</u> PPT tubes; Ambient, Refrigerated, Frozen The tubes need to be spun at the collection site, to avoid hemolysis. The plasma should be removed expeditiously from the cells	3012B HIV-1 Abs + Bands 3012NY HIV-1 Abs New York 3012NYB HIV-1 Abs + Bands New York 3012T HIV-1 Abs IB [Blood Bank] 3012BT HIV-1 Abs by IB + Bands [Blood Bank]
4168	Kidney Stone Risk AssessR™	<u>3 Required Specimens</u> Specimen 1: Urine 24-hour No additive Specimen 2: Urine 24-hour HCl additive Specimen 3: Urine 24-hour NaOH additive	
4866R	Magnesium RBC	<u>Alternate Specimen</u> Whole Blood Heparin Trace Metal	
3878	Pancreatic Elastase 1	<u>Stability</u> Ambient 5 Days, Refrigerated 7 Days, Frozen 1 Year	
8236	Parvovirus B19 IgG & IgM Antibodies	<u>Interpretation</u> Indeterminate is now a result option	
6100	Platelet Glycoprotein (Direct & Indirect) Antibodies	<u>Specimen</u> 40 (20) mL EDTA Whole Blood	6104 Platelet Associated Glycoprotein (Direct) Abs
4141	Risperidone	<u>Stability</u> Ambient 7 Days, Refrigerated 31 Days, Frozen 2 Month(s) <u>Shipping</u> Ship by overnight courier	
7521	Toxoplasma DNA DetectR™	<u>Alternate Specimen Requirements</u> 0.3 (0.1) g Brain biopsy tissue; refrigerated or frozen in sterile saline or RPMA media) <u>Stability</u> Refrigerated 4 days; Frozen 2 months	

Discontinued Tests

Effective Tuesday, March 16, 2004 or as noted

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a "replacement," contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to alternate tests or sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

Test Code	Test Name	Reason	Alternate or Replacement Tests
RC203	Allergen - Ampicillin IgE	CAP not available	C5 Ampicilloyl IgE [replacement]
RC204	Allergen - Amoxicillin IgE	CAP not available	C6 Amoxicilloyl IgE [replacement]
1804	Breast Cancer Profile 1 with ER/PR, DNA Cell Cycle Analysis	Newer panels include HER-2 reflex to FISH and may include Ki67 (or Ki67 and p53) in lieu of DNA CCA	1818 ER/PR/HER-2 rfx FISH/DNA CCA [alternate] 1839 ER/PR/Ki67/HER-2 rfx FISH [alternate] 1833 ER/PR/Ki67/p53 & HER-2 reflex to FISH, Breast Cancer
5297	Glucose 2 hr Post Prandial	Low volume	5301 Glucose [alternate]
5295	Glucose 2 hr Tolerance	Low volume	5301 Glucose [alternate]
5301P	Glucose, Plasma	Plasma alternate specimen	5301 Glucose [replacement]
7445	Osteoporosis COL1A1 GenotypR™	Low volume	None available

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