SPECIALTY LABORATORIES
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Test Updates

May 22, 2008

Dear Colleague:

Specialty Laboratories is taking steps to implement the ASCO/CAP Guideline Recommendations to improve the accuracy of human epidermal growth factor receptor 2 (HER-2) testing in invasive breast cancer and its clinical utility as a predictive marker. As you are likely aware, the new CAP Inspection Checklist specifically addresses these recommendations. Our IHC scoring criteria and reference range will change, as noted below. In addition, our HER-2 reports will document the type of fixative used, time/duration of fixation and method of tissue processing. If this information is not already incorporated into the surgical pathology report(s) you send along with the block(s) submitted for testing, we ask that you also begin providing this information for us as soon as possible, in whatever manner is most convenient. Revised Oncology and IHC requisition forms with dedicated areas for these components will be available shortly. In cases where we do not receive this additional information regarding specimen handling, we will report any missing component as "Unknown". We have always required formalin-fixed, paraffin-embedded tissue and believe that most clients utilize processing techniques that are considered "routine", so we do not anticipate a difficult transition.

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:

4128 Lactic Acid Plasma

Effective	Immediately
Collection Instructions	Venous specimens should be collected without the use of a tourniquet or immediately after a tourniquet has been applied. Patient should avoid any exercise of the arm or hand before or during collection of the specimen. Lactate level increases rapidly with physical exercise. Thirty minutes at rest is usually sufficient for lactate to return to pre-exercise level.

5322W Fungus Culture - Whole Blood or Bone Marrow

Effective	Immediately
Specimen/Stability	Whole Blood ACD; Ambient 48 Hours.
Alternate Specimens	Whole Blood SPS; 10.0 mL (5), Ambient 48 Hours(s). Whole Blood Heparin; 10.0 mL (5), Ambient 48 Hours. Bone Marrow ACD; 10.0 mL (5), Ambient 24 hours. Whole Blood Isolator tube; Ambient 48 Hours(s).
Note	Whole Blood SPS is now acceptable.

5322M Fungus Culture & Stain– Miscellaneous

Effective	Immediately
Collection Instructions	Stool is an unacceptable sample type
Also affected	5779M

9430 Cytomegalovirus DNA UltraQuant®

Effective	June 24
Component	Specimen Source – **(ADD)**
Also affected	9430SR

8751 *Mycoplasma pneumoniae IgM Antibodies*

Effective	May 20		
Ref Range	Negative:	<770	Units/mL
	Low Positive:	770-950	Units/mL
	Positive:	>950	Units/mL
Also affected	8741, 2011		

8157 Hypersensitivity Evaluation II

Effective	Immediately
CPT Code	86606, 86744, 86602x3

8156 Hypersensitivity Pneumonitis Evaluation

Effective	Immediately
CPT Code	86744, 86609, 86602x3, 86606, 86001x8

1325 Glomerular Filtration Rate (GFR), Estimated

Effective	June 24
Note	Assay no longer available for pediatric patients (<18Y)

Test Changes: (Cont'd)

5846 HER-2/*neu* [IHC] W/Reflex FISH, Breast Cancer

Effective	June 24
Ref Range	0, 1+ = Negative No staining or weak, incomplete membrane staining of invasive tumor cells. 2+ = Equivocal Non-uniform, intense, complete membrane staining in at least 10% of invasive tumor cells. 3+ = Positive Uniform, intense, complete membrane staining of >30% of invasive tumor cells.
Components	Type of fixation **(ADD)** Reported as "Formalin" or "Unknown" Duration of fixation **(ADD)** Reported as "Number of hours" or "Unknown" Type of tissue processing **(ADD)** Reported as "Routine" or "Unknown" % of tumor cells with complete membrane staining **(ADD)** Resulted as "0-100%."
Also affected	1817, 1818, 1819, 1833, 1839, 1840, 1842, 1846

7482A HIV-1 RNA Quantitation [Real Time PCR] W/RFX GenotypR™ PLUS

Effective	Immediately
Specimen Source	Plasma EDTA; 35 days Frozen.
Alternate Specimens	Plasma ACD; 60 days, Frozen.
Note	PPT tube is no longer acceptable as alternate. **(Removed)**
Collection Instruction	See Specialty's "Guidelines for Shipping Infectious Substances" Sample requirement must be met to prevent a QNS result. If whole blood sample is collected in two PPT tubes (which contain K3 EDTA), the plasma must be physically separated from cells by centrifugation at room temperature for 10 minutes at 1,100xG RCF within 2 hours, followed by transfer of plasma into two plastic daughter vials and frozen within 4 hours. The sample is now considered EDTA plasma and MUST be shipped as indicated below. Plasma EDTA; frozen. Plasma must be separated and frozen within 4 hours of collection to ensure accuracy. Frozen plasma collected in and separated from K3 EDTA tubes is STRONGLY RECOMMENDED and REQUIRED for PPT tubes to assure maximum analytical sensitivity. (See NOTE below referring to freezing of PPT tubes.) Split separated plasma into 2 plastic vials. Ship within 24 hours of collection by overnight courier. Plasma ACD; frozen. Plasma must be separated and frozen within 4 hours of collection to ensure accuracy. Please record time of collection and freezing on container and requisition. Split into 2 plastic vials before freezing. Ship within 24 hours of collection by overnight courier. NOTE that the use of ACD anticoagulated specimens will yield test results that are approximately 15% lower than test results that are obtained from EDTA anticoagulated specimens due to the dilution effect of the 1.5mL of ACD anticoagulant present in the blood collection tube.
Note	Freezing of spun PPT tubes may result in artificially elevated viral RNA levels due to release and consequent amplification of proviral DNA from lysed cells (leakage may occur along the margins of the gel.) The effect is most significant in patients with low or undetectable viral loads. Separation of plasma into separate vials address this concern.

Test Changes: (Cont'd)

3334 Homocysteine UltraQuant®

Effective	Immediately
Method	Chemiluminescent **(Methodology Change)**
Specimen Source	Plasma EDTA; 2 mL(1) Ambient 48 hours, Refrigerated 2 weeks, Frozen 2 Months.
Alternate Specimens	Plasma Heparin; 2 mL (1), Ambient 48 Hours, Refrigerated 2 weeks, Frozen 2 Months. Serum; 2 mL (1), Ambient 48 hours, Refrigerated 2 weeks, Frozen 2 Months.
Collection Instruction	Red top tubes or barrier gel separator tubes: Place the specimen in a refrigerator for 30 minutes after collection. Centrifuge the specimen as soon as possible after complete clot formation has taken place. Transfer the serum into a plastic screw capped vial. EDTA or Heparin tubes: Place the specimen in a refrigerator for 30 minutes after collection centrifuge the specimen as soon as possible and transfer the plasma to a plastic screw capped vial. Longer storage of whole blood samples at room temperature has been found to increase homocysteine concentration in the plasma.
Also affected	5990, 5971, 5973, 4994, 1537