

# Memo

**To:** Reference Laboratory Clients

**From:** Allina Medical Laboratories, Reference Laboratory Services

**Date:** March 1, 2012

**Re:** Change in Tumor Marker Test Methodology

Effective March 5<sup>th</sup>, 2012, Allina Medical Laboratories will change the methodology used to perform Tumor Marker testing from the Roche Cobas (ECLIA) instruments to the Abbott Architect instruments. Please note a change in reference range for several tumor markers (included in test information below).

Certain tumor marker tests are repeated over time to monitor disease progression or recurrence. Due to variations in test methods there may be a need to re-establish tumor marker baseline levels on certain patients where the result does not correlate with previous results or the patient's clinical history.

The Tumor Markers affected by the method change and the correlation statistics observed by paired assays between the current and new method are:

**AFP Tumor Marker (AFT):**

New method demonstrated negative bias of 6%  
Current Reference Range:  $\leq 8.6$  ng/mL  
New Reference Range:  $\leq 8.0$  ng/mL  
Statistics: N=38; R= 0.9995; Slope = 0.94

**CarcinoEmbryonic Antigen (CEA):**

New method demonstrated a negative bias of 5%  
Current Reference Range: Smoker:  $\leq 5.5$  ng/mL, Non-smoker:  $\leq 3.8$  ng/mL  
New Reference Range: Smoker:  $\leq 5.0$  ng/mL, Non-smoker:  $\leq 3.0$  ng/mL  
Statistics: N=49; R= 0.9924; Slope = 0.95

**CA 125:**

New method demonstrated a positive bias of 11%  
Current Reference Range:  $\leq 35.0$  U/mL  
New Reference Range:  $\leq 35.0$  U/mL  
Statistics: N=59; R= 0.9989; Slope = 1.109



### **CA 15-3:**

New method demonstrated a negative bias of 14%

Current Reference Range:  $\leq 30.0$  U/mL

New Reference Range:  $\leq 31.3$  U/mL

Statistics: N=60; R= 0.9953; Slope = 0.86

### **PSA Diagnostic & Screen:**

New method demonstrated a negative bias of 2%

Current Reference Range:  $< 4.0$  ng/mL

New Reference Range:  $< 4.0$  ng/mL

Statistics: N=67; R= 0.9888; Slope = 0.98

As with most tumor markers, values vary depending on the methodology and instrumentation used. Because these tumor markers are utilized for monitoring patients, re-baselining may be indicated. Results from two consecutive samples on a given patient, run by two differing methods, cannot be directly compared.

**Re-baselining** would be performed by evaluating two samples collected at a relatively short interval to reestablish a "baseline" on two data points with the new methodology. It is extremely difficult to retrieve patient charts by diagnosis, contact the appropriate patients, and have them be tested by the old and new methodologies in a reasonable time frame. **In order to help facilitate the re-baselining transition, Allina Medical Laboratories will perform a second tumor marker assay by the new method (Abbott) at no charge.**

To order the repeat tumor marker testing, please complete an AML RE-BASELINING OF TUMOR MARKERS requisition and submit the completed requisition, along with a new specimen, to AML for analysis. These requisitions will be supplied for your clinic with pre-printed clinic data for your site, or a generic requisition, needing additional site specific information completed by your staff, will be available on our website at [www.allina.com/medicallaboratories](http://www.allina.com/medicallaboratories). An example of this requisition has been included with this message for your reference.



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