NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

September 13, 2011

This document and the worksheet can be found on our website at:
http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm

TO: Laboratory Director

FROM: Erasmus Schneider, Ph.D.
Director, Diagnostic Oncology Section, Clinical Laboratory Evaluation Program

SUBJECT: **ONCOLOGY - SERA AND SOLUBLE TUMOR MARKERS PROFICIENCY TESTING**

DUE DATE: **September 27, 2011 (Please note this is a TUESDAY)**

PLEASE READ-INFORMATION IS IMPORTANT

Samples:
Enclosed are five sealed (5) vials labeled **TM231 to TM235**, each containing proficiency test specimens in a human-derived serum base, sterile filtered and dispensed. All materials used to prepare the samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, universal precautions should be followed when handling samples. Keep **refrigerated** until use, but **do not freeze**. Make sure samples are completely mixed before analyzing.

Each vial contains various predetermined amounts of alpha-feto protein (**AFP**), carcinoembryonic antigen (**CEA**), cancer antigen 125 (**CA125**), the breast cancer markers **CA15-3** and **CA27.29**, the pancreatic cancer marker **CA19-9** and prostate specific antigen (**PSA**) in all three currently measured forms, i.e. **total PSA**, **free PSA** and **complexed PSA** (PSA-ACT). Please measure all markers tested in your laboratory. If your lab measures free and/or complexed PSA in addition to total PSA, you are required to measure it in **ALL** of the samples. Labs are no longer required to calculate % free PSA, but we ask that you choose the appropriate drop-down menu selection indicating your laboratory's policy regarding that calculation. If your lab measures total PSA by a second method in conjunction with free PSA, enter those results in the corresponding fields of PSA for a 2nd method.

Note: The **event menu** page includes a space to enter your lab's **upper limit of normal reference range**, i.e. cut-off value, for each individual analyte measured. It should indicate the highest result measurement that would be considered NORMAL as reported back to a physician. Please enter this value with the same precision as you report your results for that analyte. Please note that we are no longer asking for interpretations with respect to this cut-off.

All laboratories must submit their proficiency testing results through the internet based electronic proficiency testing reporting system (EPTRS) on the Department's Health Commerce System (HCS). The HCS is a secure website and requires all users to obtain an ID in order to access the HCS and EPTRS application. Questions regarding the entry and submission of proficiency test results or the account application process can be emailed to clepeptrs@health.state.ny.us.

Results must be submitted electronically before 11:59 PM on September 27, 2011. Please note this is a Tuesday due to the holiday on Wednesday, and it is advisable to submit earlier to allow time to resolve any problem that may occur with result submission. **(turn over)**

Results not submitted by the due date are categorized as missing with an administrative **failure** and receive a failing grade, even if results were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must **contact the PT section as soon as possible before the due date** to see if this can be arranged.

Results must be reported for all five samples for all analytes you measure, otherwise a zero grade will be given to the missing data. If a result exceeds the **analytical range or is below the method's limit of detection**, indicate this with a greater than (>) or less than (<) sign, respectively, if similar results from patient samples are reported in the same manner. If such samples are routinely diluted and retested, you may do so but be sure to identify the result accordingly in the comments. **Please check that the instrument and reagent information is current**, since the EPTRS Event Menu page is pre-populated from previous entries. It is very important to correctly complete all applicable fields because **missing or incorrect entries may result in an inability to move to the next screen, or possibly in test failure if it causes your results to be evaluated with the wrong peer group.** Choose the appropriate selection from the test status list on the event menu page and indicate if your lab has temporarily suspended or permanently stopped testing for an analyte. When temporary suspension of testing is selected, the reason for this suspension must be indicated in the appropriate box at the bottom of the event menu page. When a test is deleted, select 'test not offered' and also submit the 'delete analyte' form found at: (http://www.wadsworth.org/labcert/TestApproval/forms/DOH3519f.pdf). **Absence of results for any analyte without appropriate notification will result in a failing grade for the missing results.**

The laboratory director or assistant **director with an appropriate CofQ** and all laboratory personnel analyzing these specimens **must sign** the printed electronic summary page. These signatures attest that the proficiency testing samples were analyzed in as close a manner as possible to patient samples, and this signed summary page should be kept on file for review by CLEP surveyors.

For any correspondence regarding the Oncology PT contact:

Tumor Marker Proficiency Testing c/o Susanne McHale
Wadsworth Center, Room E600
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509
or
e-mail: smchale@wadsworth.org

If you do not receive the samples in satisfactory condition call Susanne McHale at (518) 486-5775 or Helen Ling at (518) 474-0036.

The 2012 Oncology Tumor Marker Proficiency Test mail-outs are tentatively scheduled as follows:

Mail-out date:	Due date:
January 24, 2012	**February 8, 2012**
May 8, 2012	**May 23, 2012**
September 11, 2012	**September 26, 2012**

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state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
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November 25, 2011

New York State Tumor Marker Proficiency Test 9/2011 Evaluation [1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from September 13, 2011 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

Samples:

Laboratories were challenged with five (5) different coded specimens prepared by Wadsworth Center personnel. Purified analyte preparations were added to a protein-based matrix, sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. Analyte levels were pre-assayed and stability tested in our laboratory. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

Your laboratory's results, scores and grades are printed on a separate report, together with your grades from the previous two PT events and your overall performance status. Only individual scored reports are mailed, while this critique with summary tables and graphs is sent electronically and also posted on our website at:

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm

Please **review and sign** your score report and keep it in your files. You will need it for your next laboratory survey to demonstrate successful participation in the NYS PT program.

For grading purposes, all results were evaluated based on their respective peer group mean. This mean was determined with the robust regression followed by outlier identification (ROUT) statistical method, as implemented in GraphPad's Prism®5 software (Harvey J Motulsky and Ronald E Brown, "Detecting outliers when fitting data with nonlinear regression – a new method based on robust nonlinear regression and the false discovery rate," BMC Bioinformatics 7:123 (2006). Available: http://www.biomedcentral.com/1471-2105/7/123). This method identifies outliers through robust statistical analysis with a nonlinear curve fit of the data, thus removing points which can skew calculations of the mean. For our purposes, the target is the mean determined from the best fit values derived from that analysis while the standard deviation (SD) was calculated by multiplying the standard error of the mean for each individual peer group with the square root of the number of labs in that peer group. The allowable error and range were determined from the average of the median %CV's for each sample across all methods (see summary tables); allowances for increased scatter at low concentrations were made for some analytes. Please note that, with a few exceptions, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, unless a t-test showed a significant difference between them ($p<0.05$ for at least two of the five samples). In order for you to more easily compare your results to those of your peer group, we have calculated a D/Dmax value and displayed it directly under your individual results. D/Dmax is a measure of how much your result (x) deviates from your peer group target, **D/Dmax=(x-target)/(maximum allowable**

[1] The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

error), with D being the difference of your result from the target, and Dmax being the **maximal allowable error for your peer group.** Thus, D/Dmax needs to be between –1 and +1 for a result to be considered correct. **Note: If your D/Dmax is <u>not</u> within +/- 0.66, especially for more than one or two samples, you should carefully check your result(s) since this indicates that they are significantly different from the mean(s) of your peer group.** While this could be an isolated incident, it could also potentially indicate that your assay may not be performing as well as it should. Furthermore, if your **<u>average</u> D/Dmax is greater than +/- 0.5,** then your results exhibited a substantial high or low bias when compared to the rest of your method peer group, suggesting a potentially significant systematic error with your assay. Possible causes could include a calibration drift, reagents that are close to their expiration date, or subtle malfunction of your instrument. We <u>strongly encourage</u> you to take a close look at the run in question as well as others performed around that time and/or with the same reagent lots, and to evaluate if patient results might have been similarly affected.

For your information, summary tables are included for each analyte showing the targets and upper and lower limits for each sample and peer group. We also present graphical comparisons of the results among the different peer groups. In order to compare results between peer groups more easily, average <u>normalized values</u> were calculated for each sample by dividing its mean by the median of the means from all peer groups (<u>all method median</u>). The all method medians are used instead of the all lab means to reduce the bias towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, we also calculated those values relative to the assigned <u>target values</u> (see below) as well as the all method median. Keep in mind when comparing methods that in some of the peer groups the number of results (N) was small. However, the fact that the relative performance for almost all methods has been very constant over the last several years indicates that the results shown reflect the true behavior of each method compared to its peers, at least under the conditions of the NYS PT.

Discussion:

<u>CA125</u> (Table 1, Figure 1): Results were reported by 115 labs using 13 different methods or instruments. Combining results from different instruments made by the same manufacturer and/or brand resulted in nine peer groups. Of the nine peer groups, four included ten or more labs each and together comprised over 75% of the labs. Five peer groups used by 54% of labs gave results within +/- 15% of the all method medians. Of the other four groups, two (Roche and Siemens Immulite) were below -15% from the median, and two (Abbott Architect and Tosoh) were above +15% from the median. Interestingly, the AxSYM results were significantly (based on t-test analysis) lower than the Architect results and were on average only 3% above the median, compared to 16% of the Architect results. TOSOH ST-AIA (used by six labs representing about 5% of the participants) once again gave the highest results that were on average 32% above the all method medians.

<u>CA19-9</u> (Table 2, Figure 2): Results were reported by 66 labs using ten methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in eight peer groups, three of which comprised only one lab each and therefore were not gradable and not included in the calculation of the all method medians, but are still shown for comparison on the bar graph. Fifty-three percent of all reporting labs used either Siemens ADVIA-Centaur CP or XP, 20% used either Beckman Unicel or Access/2, 14% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 9% used the Tosoh ST-AIA method. Only the Roche and Beckman methods were within +/- 15% of the all method median. Measurements by Tosoh ST-AIA were lower than the medians by an average of 19%, whereas on the opposite side, the results from both of the Siemens ADVIA-Centaur instruments (XP and CP, which were analyzed separately) were on average two times higher than the all method medians. Notable once again is that the Abbott Architect method (used by only 1 lab) gave measurements for CA19-9 averaging six times higher than the all method medians. These high measurements by the Abbott Architect are consistent with previous CA19-9 NYS PT results by this method. Looking at the results from all the methods, it is apparent there is still substantial discordance between the various methods used to measure CA19-9, at least under the conditions of the NYS PT.

The MUC1 breast cancer antigen was measured by 109 labs, with slightly more than half (54%) using one of ten **CA15-3** methods (Table 3, Figure 3) and the remainder using one of three methods for **CA27.29** (Table 4, Figure 4). Note that the ADVIA Centaur XP and CP instruments were combined, since only three labs reported using the CP instrument and the means of the CP results were well within the acceptable ranges for the XP instrument for this and the previous proficiency tests. For **CA15-3**, combining results from different instruments made by the same manufacturer and/or brand resulted in eight peer groups, five of which comprised less than ten labs each. Only two methods (Beckman and Ortho Vitros) gave results that were outside the +/-15% range from the all method median. Notably, the Siemens ADVIA-Centaur method (used by 19% of the labs) did not exhibit the high positive bias that was observed in some previous PT events, and gave results just 7% higher on average than the medians. In contrast, both the Vitros ECi/ECiQ results at -18% and especially, the Beckman Unicel/Access results at -46% from the all method medians, exhibited a strong negative bias. Of the methods used for measuring **CA27.29**, the ADVIA Centaur XP combined with CP and the Tosoh method showed a 10% difference from each other. The overall median values measured by the CA27.29 methods were lower than those for CA15-3 by 13-24%. In conclusion, there are less substantial differences seen between different manufacturers' instruments measurements of CA15-3 than seen in previous events, while there remains good concordance between the CA27.29 methods.

CEA (Table 5, Figure 5): Results were reported by 171 labs using 13 different methods. After combining results from different instruments made by the same manufacturer and/or brand, there remained nine peer groups comprising from 7 to 50 labs. The two ADVIA Centaur CP results were grouped with the Centaur XP results because they fit well with that group, showing no significant difference for this analyte. It remains to be seen whether, when more results are received for the CP instrument, the measurements between the two methods will remain similar. Overall, the results reported by the majority of the labs (74%) were fairly consistent, being within +/-10% of the medians. The two Beckman instruments were analyzed separately due to significant differences seen between results for at least two of the five samples. On average the results from the Beckman Unicel instruments were 10% below those from the Access instruments, though both measured CEA within +/-10% of the all method median. No difference was seen between the Roche Elecsys/Cobas e411 group and the E170/Cobas e601 group so they were combined, and together they averaged 18% below the medians. In contrast, the Ortho Clinical Diagnostics Vitros ECi/Q & 5600 methods gave results that averaged 18% higher than the medians, and notably, the TOSOH ST-AIA measurements averaged 44% higher than the medians.

For **AFP, free PSA and PSA,** target values were assigned using traceable International Standards. However, for grading purposes the results were evaluated and received a passing score if they fell within their peer group-specific acceptable ranges. For the purpose of method comparison, however, the bias against both the assigned target values as well as the all method medians are shown in the respective tables, although the graphs only show the performance relative to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 105 labs using 14 different methods. After combining results from different instruments made by the same manufacturer and/or brand that showed no significant difference by t-test analysis, nine peer groups remained. Five of those were used by less than ten labs each, which together accounted for twenty-two percent of the total number of labs. Although AFP has generally shown less discordance between methods than many other tumor marker analytes, results from the Siemens Immulite 1000 averaged 13% higher and those from the Roche Elecsys/Cobas groups 19% higher than the IS targets. In contrast, the Ortho Vitros methods averaged 23% lower than the IS targets. All the remaining groups were on average within +/- 6% of the IS target, indicating good harmonization between the different manufacturers.

PSA (Table 7, Figures 7A,B): Results were reported by 257 labs using 22 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were 13 peer groups, three of which comprised less than ten labs each and one that comprised only one lab. In order to test the equimolarity of the methods, the five samples were all prepared with the same concentration of total PSA but with varying proportions (1.8-35.7%) of free to ACT-complexed PSA. In general, there was little difference in the amount of PSA measured between the lowest and highest % free PSA samples,

although a slight but consistent trend toward lower PSA level with increasing % free PSA was noticed. However, the decrease amounted to less than 10% and was in most cases statistically not significant. Thus, it appears that all methods are essentially equimolar. In contrast, as usual, there was a clear separation of methods into distinct high and low groups with two methods in between. Overall, the average bias for the high group was +27%, whereas the average bias for the low group was +5%, a difference that was highly significant ($p < 0.01$) (Figure 7B). The high group comprised four methods (Beckman Unicel and Access with the Hybritech calibration, Siemens Immulite with the original PSA pack and Siemens Dimension RxL Max, Xpand Plus, and EXL) whose results ranged from 23-30% higher than the targets, whereas the low group comprised seven methods (Abbot AxSym, Beckman Unicel/Access with the WHO calibration, Roche Elecsys/Cobas, Siemens ADVIA Centaur XP/CP and Dimension Vista, Ortho Vitros ECi, ECiQ, and 5600, and Tosoh AIA) whose results ranged from 1% below to 10% above the targets. The 3rd generation Siemens Immulite and Abbott Architect methods gave the two results in the middle (Fig. 7B). As expected, a clear difference between the Beckman reagents was observed; those calibrated with original Hybritech standards on average measured 23% and 29% higher than the targets, whereas those calibrated with the international WHO standards measured 1% lower than the targets. This difference is consistent with the information Beckman has supplied indicating a 22% difference between the Hybritech and WHO calibrated methods (Access Hybritech PSA Hybritech and WHO Calibration Information #A59476A, 2008). Together, the data suggest that the methods in the high group are calibrated against the original Hybritech standard, whereas the methods in the low group are calibrated against the international WHO standard.

Free PSA (Table 8, Figure 8): Results were reported by 85 labs using thirteen different methods. After combining results from different instruments made by the same manufacturer and/or brand there were nine peer groups, six of which comprised less than 10 labs each and together were used by only 15% of the labs. The other methods were used by 34% (Beckman Unicel/Access calibrated with the Hybritech standards), 28% (Roche Elecsys/E170/Cobas) and 20% (Siemens Immulite 1000 and 2000) of labs, respectively. As seen in the previous PTs, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained with the rest of the methods (53% above the targets and 24% higher than the all method medians), while the Beckman Access and Unicel calibrated with the WHO standards were 18% above the target and 4% below the all method median, as well as being 23% lower on average than those from the original Hybritech-calibrated Beckman methods. The Siemens Dimension and Abbott Architect were 37% and 28% above the targets, respectively, and were 11% and 4% above the all method medians. As seen previously, the Abbott AxSYM was notably lower than the Architect; however, only one lab reported with the AxSYM so no t-test could be performed. The Roche instruments were grouped together and ran about 14% above target, while two of the three Siemens methods, namely Immulite 1000/2000 and Dimension Vista averaged just 2-6% above the target. In conclusion, there are still substantial differences in how free PSA is measured, but in contrast to total PSA, the various methods don't fall into clearly defined high and low groups. Furthermore, not every method that is high for total PSA is also high for free PSA.

Please note, labs are now required to measure and report **free PSA** for **all proficiency test samples** if they test for free PSA, but we are no longer requesting the percent free PSA to be reported since the intention of the proficiency test is to evaluate differences in the analytical measurements from labs and instrument peer groups rather than mathematical calculations. We understand that this may in some cases be a deviation from a lab's policy in dealing with free PSA and could mean that PT samples are not treated exactly like patient samples. However, the ability to accurately measure free PSA is an essential process for a testing laboratory, while calculating % free PSA is a secondary operation usually done by a computer. In addition, some labs do not normally calculate % free PSA at all, but only report free and total PSA values, leaving the calculation of % free PSA to the physician. The question under free PSA regarding lab policy on calculation of % free PSA was included for informational purposes only with the answers as follows:

Does your lab calculate % Free PSA?

Answer	N	% of labs
Yes, always	28	34%
Yes, but only within a specific PSA range	25	30%
No	16	19%
Yes, but only when requested	5	6%
Yes, but only when requested and only within a specific PSA range	8	10%
Other	1	<1%
Total	83	100%

Finally, only 10 labs measured **complexed PSA** and all of these used the Siemens ADVIA-Centaur method, with relatively good agreement between the labs indicated by an average %CV of only 4.5% (Table 9).

In conclusion, the observation has again been made that there are substantial differences between the results obtained with various methods or instruments for many of the analytes. While some of these differences could be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We continue to try to minimize the differences that can be attributed to the sample composition. Nevertheless, despite the somewhat artificial nature of the PT samples, we suggest that differences between the results obtained by various methods might also be reflected in patient serum samples. Therefore, we encourage labs and physicians to use caution when comparing the results from the same patient measured with different methods on different instruments, since clearly not all methods are equal. For this reason, **we require that the method used be clearly indicated on the patient report** (Oncology Standard OC 1b). We also encourage you to educate your physician clients about this potential problem. Furthermore, the comparison of method means to target values set by traceable International Standards for PSA and free PSA clearly shows that not all methods are calibrated equally, as discussed in the respective analyte sections above.

We would like to reiterate the following cautionary notes regarding the interpretation of the results from this proficiency test: 1) since some of the assays were done by a small number of labs, the results might be skewed due to a lack of statistical power; 2) it is difficult to make accurate comparisons of results when the % CVs are large; and finally 3) the analyses for PT purposes are done with artificially prepared mixtures of proteins, which may or may not accurately reflect patient derived samples.

Important Reminder regarding the HCS/EPTRS data submission process: Be sure results are **submitted**. If results were **saved** but not submitted, they will be graded as an administrative **fail**.

Please be aware that in each subsequent event, fields will usually be pre-populated based on what you entered this time or a previous time, but you must **verify that the selected instruments and reagents are correct,** whether pre-populated from the last event or newly entered information. That information must be accurate to properly evaluate your results and compare them to those of your peer group. There are instances where individual labs have either **inadvertently selected a qualifier (< or >) or an incorrect instrument or reagent** when scrolling through the electronic reporting page lists and it has resulted in a failing grade. You are at risk of receiving a **technical failure** for results evaluated outside of the correct peer group or an **administrative failure** for incorrect methodology. No changes can be made for incorrect or missing information once the submission deadline has passed.

The PSA2 option still applies to allow entry of results from a second PSA assay, but only for labs that use a different or additional method for total PSA in conjunction with their free PSA measurements**. If only one PSA test was done, then results should be entered in the first PSA line and "test not offered" selected for PSA2.** For labs that enter two PSA tests, the primary PSA test gets entered on the first PSA line and the secondary assay (for use in conjunction with their free PSA results) on the PSA2 line.

Please note that questions regarding the electronic proficiency testing reporting system (EPTRS) account application process and the entry and submission of proficiency test results can be directed to clepeptrs@health.state.ny.us, or directly to Kathi Wagner at (518) 402-4266 or by e-mail at klw05@health.state.ny.us.

The tentative dates for the 2012 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date**:
January 24, 2012	February 8, 2012
May 8, 2012	May 23, 2012
September 11, 2012	September 26, 2012

If you have any questions or wish to discuss some of the issues alluded to in the PT discussion, you may contact Susanne McHale at (518) 486-5775 or by email at smchale@wadsworth.org, or myself at (518) 474-2088 or by email at schneid@wadsworth.org.

Erasmus Schneider, Ph.D.
Director, Oncology Section
Clinical Laboratory Reference System

Table 1: 9-11 NYS Tumor Marker PT Summary for CA125

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD
Abbott AxSYM (ABB)									
TM231	26.4	6	3.69	14.0	21.6	31.2	4.8	1.02	
TM232	16.3	6	1.94	11.9	13.4	19.2	2.9	0.99	
TM233	33	6	4.5	13.6	27.1	38.9	5.9	1.05	
TM234	46.3	6	4.44	9.6	38	54.6	8.3	1.07	
TM235	18.6	6	3.82	20.5	15.3	21.9	3.3	1.00	
			mean±SD	13.9	4.08			1.03	0.03
Abbott Architect (ABH)									
TM231	30.3	7	1.85	6.1	24.8	35.8	5.5	1.16	
TM232	19.9	7	1.18	5.9	16.3	23.5	3.6	1.20	
TM233	36.1	7	1.75	4.8	29.6	42.6	6.5	1.15	
TM234	48.9	7	2.09	4.3	40.1	57.7	8.8	1.13	
TM235	21.4	7	1.28	6.0	17.5	25.3	3.9	1.16	
			mean±SD	5.4	0.82			1.16	0.03
Beckman Unicel/Access (BCU/BCX)									
TM231	26.3	14	2	7.6	21.6	31	4.7	1.01	
TM232	16.9	14	1.1	6.5	13.9	19.9	3	1.02	
TM233	32.9	14	2.11	6.4	27	38.8	5.9	1.04	
TM234	45.9	14	2.3	5.0	37.6	54.2	8.3	1.06	
TM235	19.3	14	0.97	5.0	15.8	22.8	3.5	1.04	
			mean±SD	6.1	1.10			1.04	0.02
Roche Elecsys/Cobas (BME/BMR)									
TM231	21	15	1.24	5.9	17.2	24.8	3.8	0.81	
TM232	14.1	15	0.85	6.0	11.6	16.6	2.5	0.85	
TM233	24.2	15	1.4	5.8	19.8	28.6	4.4	0.77	
TM234	32.2	15	2.06	6.4	26.4	38	5.8	0.74	
TM235	15.5	14	0.74	4.8	12.7	18.3	2.8	0.84	
			mean±SD	5.8	0.61			0.80	0.04
Siemens ADVIA Centaur Classic and XP (COB)									
TM231	25.7	33	1.47	5.7	21.1	30.3	4.6	0.99	
TM232	16.8	33	1.06	6.3	13.8	19.8	3	1.01	
TM233	30	32	1.87	6.2	24.6	35.4	5.4	0.96	
TM234	40.6	33	2.78	6.8	33.3	47.9	7.3	0.94	
TM235	18.5	32	0.9	4.9	15.2	21.8	3.3	1.00	
			mean±SD	6.0	0.75			0.98	0.03
Siemens Immulite 2000, 2500 (DPD/DPF)									
TM231	20.7	26	1.65	8.0	17	24.4	3.7	0.80	
TM232	12.9	26	0.82	6.4	10.6	15.2	2.3	0.78	
TM233	24.3	26	1.37	5.6	19.9	28.7	4.4	0.77	
TM234	34.5	26	2.36	6.8	28.3	40.7	6.2	0.80	
TM235	14.7	26	0.98	6.7	12.1	17.3	2.6	0.79	
			mean±SD	6.7	0.85			0.79	0.01
Siemens Dimension Vista (DUV)									
TM231	24.4	1						0.94	
TM232	15.6	1						0.94	
TM233	25.4	1						0.81	
TM234	31.1	1						0.72	
TM235	16.6	1						0.90	
			mean±SD					0.86	0.10
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)									
TM231	24.3	7	0.94	3.9	19.9	28.7	4.4	0.94	
TM232	15.3	7	0.8	5.2	12.5	18.1	2.8	0.92	
TM233	29.2	7	0.98	3.4	23.9	34.5	5.3	0.93	
TM234	40.2	7	1.17	2.9	33	47.4	7.2	0.93	
TM235	17.2	7	0.35	2.0	14.1	20.3	3.1	0.93	
			mean±SD	3.5	1.2			0.93	0.01
Tosoh AIA (TOM)									
TM231	34.6	6	2.26	6.5	28.4	40.8	6.2	1.33	
TM232	22.9	6	0.76	3.3	18.8	27	4.1	1.38	
TM233	40.6	5	1.95	4.8	33.3	47.9	7.3	1.29	
TM234	54.9	6	2.89	5.3	45	64.8	9.9	1.27	
TM235	24.5	6	1.28	5.2	20.1	28.9	4.4	1.32	
			mean±SD	5.0	1.2			1.32	0.04

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	
TM231	26.0	114	**6.3**	21.1	30.3	4.6	0.85-1.15
TM232	16.6	114	**6.2**	13.4	19.2	2.9	<0.85, >1.15
TM233	31.5	112	**5.7**	24.6	35.4	5.4	
TM234	43.3	114	**5.8**	33.3	47.9	7.3	
TM235	18.6	112	**5.1**	15.2	21.8	3.3	
			Average 5.8				
			Allowable CV % 6				
			Allowable Error (+/-)% 18				

Figure 1

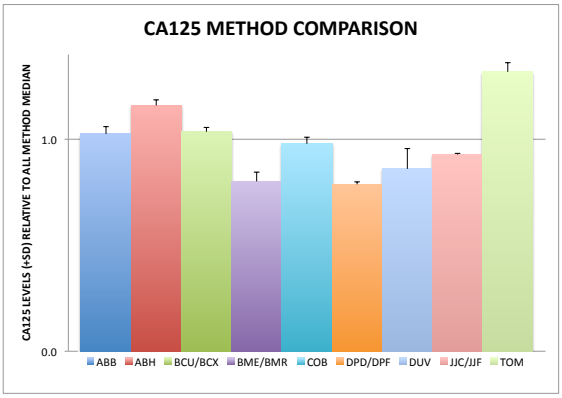

Table 2: 9-11 NYS Tumor Marker PT Summary for CA19.9

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD
Abbott Architect (ABH)									
TM 231	101.2	1						4.65	
TM 232	122.4	1						5.75	
TM 233	171.7	1						6.13	
TM 234	229.1	1						6.05	
TM 235	351.3	1						6.57	
			mean±SD					5.83	0.72
Beckman Unicel/Access (BCU/BCX)									
TM 231	16.6	13	1.4	8.1	14.1	19.1	2.5	0.76	
TM 232	21.1	12	0.9	4.4	17.9	24.3	3.2	0.99	
TM 233	28.0	13	1.8	6.4	23.8	32.2	4.2	1.00	
TM 234	37.9	13	2.5	6.6	32.2	43.6	5.7	1.00	
TM 235	53.5	13	4.7	8.8	45.5	61.5	8.0	1.00	
			mean±SD	6.9	1.7			0.95	0.10
Roche Elecsys/E170/Cobas (BME/BMR)									
TM 231	17.9	9	1.0	5.4	15.2	20.6	2.7	0.82	
TM 232	21.3	9	0.9	4.0	18.1	24.5	3.2	1.00	
TM 233	26.5	9	0.8	3.1	22.5	30.5	4.0	0.95	
TM 234	34.6	9	1.3	3.6	29.4	39.8	5.2	0.91	
TM 235	47.3	9	1.2	2.4	40.2	54.4	7.1	0.88	
			mean±SD	3.7	1.1			0.91	0.07
Siemens ADVIA Centaur CP (COC)									
TM 231	36.1	3	0.7	1.9	30.7	41.5	5.4	1.66	
TM 232	44.1	3	2.0	4.5	37.5	50.7	6.6	2.07	
TM 233	59.4	3	3.5	5.9	50.5	68.3	8.9	2.12	
TM 234	88.3	3	8.8	10.0	75.1	101.5	13.2	2.33	
TM 235	120.2	3	10.2	8.5	102.2	138.2	18.0	2.25	
			mean±SD	6.2	3.2			2.09	0.26
Siemens ADVIA Centaur Classic and XP (COB)									
TM 231	35.7	32	1.9	5.4	30.3	41.1	5.4	1.64	
TM 232	44.2	32	2.4	5.3	37.6	50.8	6.6	2.07	
TM 233	55.2	31	2.2	4.0	46.9	63.5	8.3	1.97	
TM 234	76.6	32	3.8	5.0	65.1	88.1	11.5	2.02	
TM 235	109.8	31	6.1	5.6	93.3	126.3	16.5	2.05	
			mean±SD	5.1	0.6			1.95	0.18
Siemens Dimension Vista (DUV)									
TM 231	22.5	1						1.03	
TM 232	28.8	1						1.35	
TM 233	38.8	1						1.39	
TM 234	53.0	1						1.40	
TM 235	74.5	1						1.39	
			mean±SD					1.31	0.16
Ortho Clinical Diag Vitros ECi (JJC)									
TM 231	26.2	1						1.20	
TM 232	37.4	1						1.76	
TM 233	47.6	1						1.70	
TM 234	65.7	1						1.73	
TM 235	92.3	1						1.73	
			mean±SD					1.62	0.24
Tosoh AIA (TOM)									
TM 231	21.8	6	0.7	3.4	18.5	25.1	3.3	1.00	
TM 232	20.7	6	0.8	3.7	17.6	23.8	3.1	0.97	
TM 233	22.2	5	0.8	3.6	18.9	25.5	3.3	0.79	
TM 234	26.1	6	0.9	3.3	22.2	30.0	3.9	0.69	
TM 235	32.9	6	0.7	2.2	28.0	37.8	4.9	0.62	
			mean±SD	3.2	0.6			0.81	0.17

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	
TM 231	21.8	63	**5.4**	16.9	22.9	3.0	0.85-1.15
TM 232	21.3	62	**4.4**	18.0	24.4	3.2	<0.85, >1.15
TM 233	28.0	61	**4.0**	23.2	31.4	4.1	
TM 234	37.9	63	**5.0**	30.8	41.7	5.5	
TM 235	53.5	62	**5.6**	42.9	58.0	7.6	
			Average 4.9				
			Allowable CV % 5.0				
			Allowable Error (+/-) % 15.0				

Figure 2

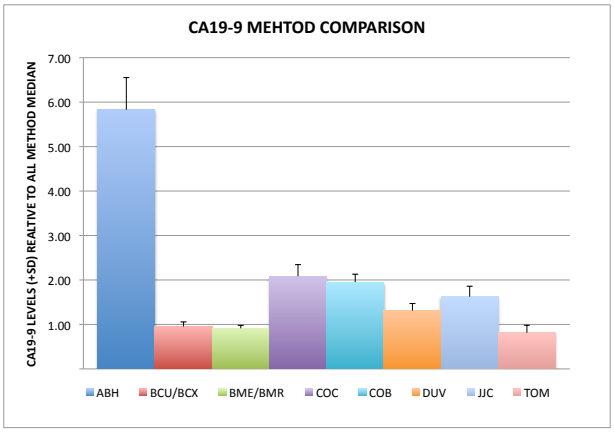

Table 3: 9-11 NYS Tumor Marker PT Summary for CA15-3

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD
Abbott AxSYM (ABB)									
TM231	62.1	1						0.96	
TM232	43.1	1						0.93	
TM233	30.1	1						0.91	
TM234	26.1	1						0.99	
TM235	20.2	1						1.02	
			mean±SD					0.96	0.05
Abbott Architect (ABH)									
TM231	71.3	5	3.6	5.0	57.4	85.2	13.9	1.10	
TM232	50.8	5	2.6	5.1	40.9	60.7	9.9	1.10	
TM233	35.5	5	1.1	3.2	28.6	42.4	6.9	1.07	
TM234	27.9	5	0.4	1.3	22.5	33.3	5.4	1.06	
TM235	21.5	5	1.2	5.5	17.3	25.7	4.2	1.09	
			mean±SD	4.0	1.8			1.08	0.02
Beckman Unicel/Access (BCU/BCX)									
TM231	35.2	5	1.0	2.8	28.3	42.1	6.9	0.55	
TM232	25.5	6	6.2	24.2	20.5	30.5	5.0	0.55	
TM233	17.2	6	2.7	15.8	13.8	20.6	3.4	0.52	
TM234	14.0	6	1.9	13.6	11.3	16.7	2.7	0.53	
TM235	11.3	5	0.3	2.7	9.1	13.5	2.2	0.57	
			mean±SD	11.8	9.2			0.54	0.02
Roche Elecsys/Cobas (BME/BMR)									
TM231	60.2	10	2.9	4.9	48.5	71.9	11.7	0.93	
TM232	42.9	10	2.0	4.7	34.5	51.3	8.4	0.92	
TM233	30.8	10	1.4	4.6	24.8	36.8	6.0	0.93	
TM234	24.8	10	1.3	5.3	20.0	29.6	4.8	0.94	
TM235	18.5	8	0.5	2.6	14.9	22.1	3.6	0.93	
			mean±SD	4.4	1.0			0.93	0.01
Siemens ADVIA Centaur Classic, XP and CP (COB/COC)									
TM231	68.9	21	6.9	10.0	55.5	82.3	13.4	1.07	
TM232	49.9	21	5.3	10.6	40.2	59.6	9.7	1.08	
TM233	35.6	21	2.7	7.6	28.7	42.5	6.9	1.07	
TM234	28.6	21	2.9	10.2	23.0	34.2	5.6	1.08	
TM235	21.0	21	2.2	10.3	16.9	25.1	4.1	1.07	
			mean±SD	9.7	1.2			1.07	0.01
Siemens Immulite 2000, 2500 (DPD/DPF)									
TM231	75.6	11	5.6	7.4	60.9	90.3	14.7	1.17	
TM232	50.7	11	3.7	7.3	40.8	60.6	9.9	1.09	
TM233	36.9	10	3.5	9.4	29.7	44.1	7.2	1.11	
TM234	28.9	11	3.0	10.3	23.3	34.5	5.6	1.10	
TM235	22.1	11	1.6	7.4	17.8	26.4	4.3	1.12	
			mean±SD	8.4	1.4			1.12	0.03
Siemes Dimension Vista (DUV)									
TM231	61.0	1						0.95	
TM232	45.4	1						0.98	
TM233	31.9	1						0.96	
TM234	26.2	1						0.99	
TM235	19.6	1						0.99	
			mean±SD					0.97	0.02
Ortho Clinical Diag Vitros ECi/ECiQ (JJC)									
TM231	54.7	4	3.4	6.1	44.0	65.4	10.7	0.85	
TM232	38.4	4	2.2	5.7	30.9	45.9	7.5	0.83	
TM233	26.3	4	0.9	3.6	21.2	31.4	5.1	0.79	
TM234	21.5	4	0.9	4.0	17.3	25.7	4.2	0.82	
TM235	16.3	4	0.6	3.8	13.1	19.5	3.2	0.83	
			mean±SD	4.7	1.2			0.82	0.02

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	
TM231	64.6	56	**5.60**	52.00	77.10	12.55	0.85-1.15
TM232	46.4	57	**6.51**	37.35	55.45	9.05	<0.85, >1.15
TM233	33.2	56	**6.11**	26.70	39.60	6.45	
TM234	26.4	57	**7.75**	21.25	31.45	5.10	
TM235	19.8	**54**	**4.67**	**15.90**	23.60	3.85	
			Average				
	CA27.29 All Method Median	CA27.29/ CA15-3	**6.13**				
	56.4	0.87	**Allowable CV %**				
	37.8	0.81	**6.50**				
	26.4	0.80	**Allowable Error (+/-) %**				
	20.7	0.79	**19.50**				
	15.0	0.76					

Figure 3

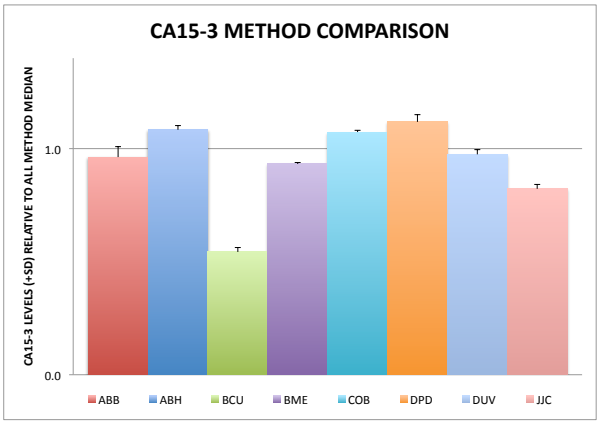

Table 4: 9-11 NYS Tumor Marker PT Summary for CA27.29

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD
Siemens ADVIA Centaur Classic, XP and CP (COB/COC)									
TM 231	57.6	43	4.5	7.8	45.5	69.7	12.1	1.02	
TM 232	37.3	42	3.1	8.4	29.4	45.1	7.8	0.99	
TM 233	23.8	42	2.9	12.3	17.5	30.1	6.3	0.90	
TM 234	18.0	42	2.8	15.4	11.7	24.3	6.3	0.87	
TM 235	11.9	40	2.9	23.9	5.6	18.2	6.3	0.80	
			mean±SD	11.0	3.6			0.95	0.1
Tosoh AIA (TOM)									
TM 231	55.1	7	2.5	4.5	43.5	66.6	11.6	0.98	
TM 232	38.3	7	2.0	5.3	30.2	46.3	8.0	1.01	
TM 233	29.0	7	1.7	5.9	22.7	35.3	6.3	1.10	
TM 234	23.4	7	1.3	5.4	17.1	29.7	6.3	1.13	
TM 235	18.0	7	0.9	5.0	11.7	24.3	6.3	1.20	
			mean±SD	5.2	0.5			1.05	0.1

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax
TM231	56.4	50	**6.1**	44.5	68.2	11.8
TM232	37.8	49	**6.8**	29.8	45.7	7.9
TM233	26.4	49	**9.1**	20.1	32.7	6.3
TM234	20.7	49	**10.4**	14.4	27.0	6.3
TM235	15.0	47	**14.5**	8.6	21.2	6.3

Average
9.4
Allowable CV %
7.0
Allowable Error if >30 U/ml (+/-) %
21.0
Allowable Errror if < 30 U/ml (+/-) U/ml
6.3

Figure 4

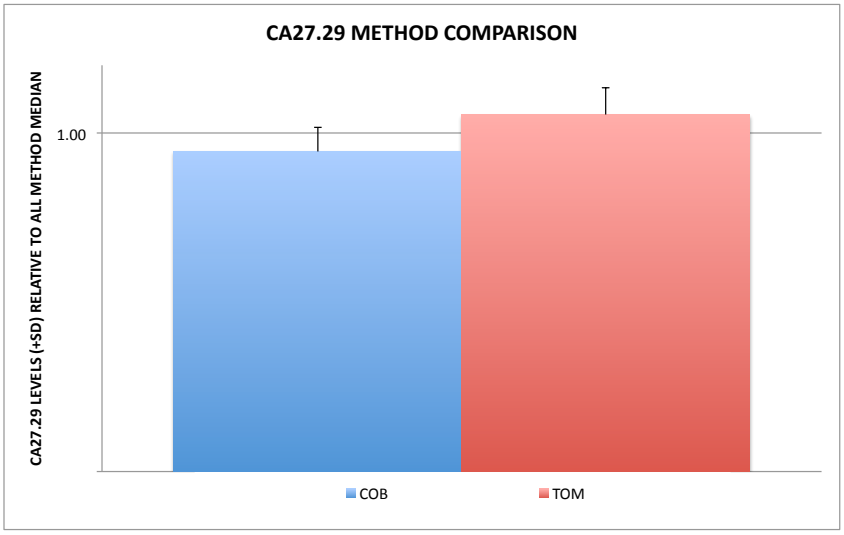

Table 5: 9-11 NYS Tumor Marker PT Summary for CEA

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD
Abbott AxSym (ABB)									
TM 231	4.5	18	0.3	5.8	3.8	5.2	0.7	1.0	
TM 232	6.1	18	0.4	6.4	5.1	7.1	1.0	1.0	
TM 233	8.2	18	0.5	5.6	6.8	9.6	1.4	1.0	
TM 234	12.4	18	0.8	6.4	10.4	14.4	2.0	1.0	
TM 235	4.7	18	0.3	6.6	3.9	5.5	0.8	1.0	
			mean±SD	6.1	0.4			1.02	0.02
Beckman Unicel (BCU)									
TM 231	4.0	17	0.3	7.3	3.3	4.7	0.7	0.9	
TM 232	5.6	17	0.3	5.7	4.7	6.5	0.9	0.9	
TM 233	7.3	17	0.5	6.8	6.1	8.5	1.2	0.9	
TM 234	11.2	17	0.7	6.6	9.4	13.0	1.8	0.9	
TM 235	4.3	17	0.4	8.8	3.6	5.0	0.7	0.9	
			mean±SD	7.1	1.1			0.91	0.02
Beckman Access (BCX)									
TM 231	4.3	10	0.3	6.5	3.6	5.0	0.7	1.0	
TM 232	6.2	11	0.2	3.9	5.2	7.2	1.0	1.0	
TM 233	8.2	11	0.3	3.4	6.8	9.6	1.4	1.0	
TM 234	12.4	11	0.5	4.0	10.4	14.4	2.0	1.0	
TM 235	4.7	11	0.2	4.0	3.9	5.5	0.8	1.0	
			mean±SD	4.4	1.2			1.01	0.02
Roche Elecsys/Cobas/E170 (BME/BMR)									
TM 231	3.6	23	0.2	5.3	3.0	4.2	0.6	0.82	
TM 232	4.9	23	0.2	4.9	4.1	5.7	0.8	0.80	
TM 233	6.6	23	0.3	5.0	5.5	7.7	1.1	0.80	
TM 234	9.7	23	0.4	4.4	8.1	11.3	1.6	0.78	
TM 235	4.0	23	0.2	5.8	3.3	4.7	0.7	0.89	
			mean±SD	5.1	0.5			0.82	0.04
Siemens ADVIA Centaur Classic, XP and CP (COB/COC)									
TM 231	4.4	50	0.2	5.5	3.7	5.1	0.7	1.0	
TM 232	6.1	50	0.4	5.7	5.1	7.1	1.0	1.0	
TM 233	8.3	50	0.5	5.5	6.9	9.7	1.4	1.0	
TM 234	12.6	50	0.6	4.5	10.5	14.7	2.1	1.0	
TM 235	4.4	50	0.3	6.8	3.7	5.1	0.7	1.0	
			mean±SD	5.6	0.8			1.00	0.02
Siemens Immulite 2000 and 2500 (DPD/DPF)									
TM 231	4.1	15	0.4	10.5	3.4	4.8	0.7	0.9	
TM 232	6.1	15	0.6	9.5	5.1	7.1	1.0	1.0	
TM 233	8.4	15	0.7	8.6	7.0	9.8	1.4	1.0	
TM 234	13.3	15	1.0	7.7	11.1	15.5	2.2	1.1	
TM 235	4.1	13	0.2	4.4	3.4	4.8	0.7	0.9	
			mean±SD	8.1	2.3			0.99	0.06
Siemens Dimension Vista (DUV)									
TM 231	4.1	16	0.1	2.0	3.4	4.8	0.7	0.9	
TM 232	6.0	16	0.1	2.3	5.0	7.0	1.0	1.0	
TM 233	8.0	16	0.2	2.6	6.7	9.3	1.3	1.0	
TM 234	12.2	16	0.2	2.0	10.2	14.2	2.0	1.0	
TM 235	4.5	16	0.1	2.2	3.8	5.2	0.7	1.0	
			mean±SD	2.2	0.3			0.98	0.02
Ortho Clinical ECi/ECiQ & 5600 (JJC/JJF)									
TM 231	5.3	12	0.3	6.4	4.4	6.2	0.9	1.2	
TM 232	7.0	12	0.4	5.3	5.8	8.2	1.2	1.1	
TM 233	9.1	12	0.3	3.6	7.6	10.6	1.5	1.1	
TM 234	13.5	14	1.0	7.1	11.3	15.7	2.2	1.1	
TM 235	6.2	14	0.8	13.4	5.2	7.2	1.0	1.4	
			mean±SD	7.2	3.7			1.18	0.11
Tosoh AIA (TOM)									
TM 231	6.4	7	0.2	3.3	5.3	7.5	1.1	1.5	
TM 232	8.9	7	0.4	4.6	7.4	10.4	1.5	1.4	
TM 233	12.1	7	0.5	4.4	10.1	14.1	2.0	1.5	
TM 234	17.9	7	0.7	3.9	14.9	20.9	3.0	1.4	
TM 235	6.2	7	0.3	5.0	5.2	7.2	1.0	1.4	
			mean±SD	4.2	0.7			1.44	0.04

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	
TM231	4.3	168	**5.8**	3.6	5.0	0.7	0.85-1.15
TM232	6.1	169	**5.3**	5.1	7.1	1.0	<0.85, >1.15
TM233	8.2	169	**5.0**	6.8	9.6	1.4	
TM234	12.4	171	**4.5**	10.4	14.4	2.0	
TM235	4.5	169	**5.8**	3.8	5.2	0.7	

Average
5.27
Allowable CV %
5.50
Allowable Error (+/-) %
16.50

Figure 5

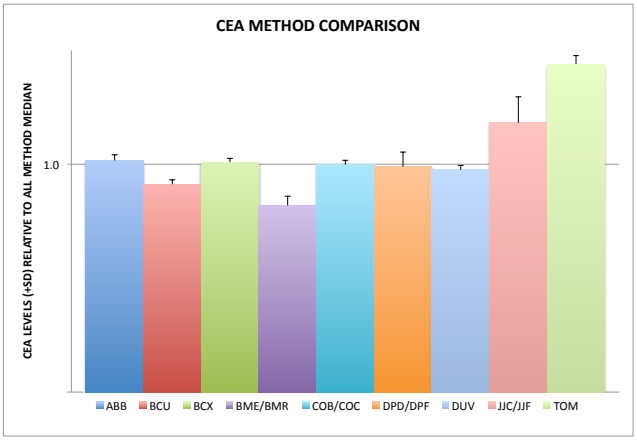

Table 6: 9-11 NYS Tumor Marker PT Summary for AFP

Instrument / Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD	Bias relative to IS target	SD
Abbott AxSYM (ABB)											
TM231	16.2	7	0.93	5.74	13.8	18.6	2.40	1.01		1.05	
TM232	29.8	6	0.73	2.45	25.3	34.3	4.50	0.99		1.00	
TM233	76.3	7	5.08	6.66	64.9	87.7	11.40	1.04		1.04	
TM234	23.2	7	2.27	9.78	19.7	26.7	3.50	1.01		1.06	
TM235	18.3	7	0.82	4.48	15.6	21.0	2.70	1.00		1.06	
			mean±SD	5.82	2.72			**1.01**	0.02	**1.04**	0.03
Beckman Unicel/Access (BCU/BCX)											
TM231	15.6	18	1.10	7.05	13.3	17.9	2.30	0.97		1.01	
TM232	30.0	18	1.76	5.87	25.5	34.5	4.50	1.00		1.01	
TM233	72.3	18	4.79	6.63	61.5	83.1	10.80	0.99		0.98	
TM234	22.3	18	0.95	4.26	19.0	25.6	3.30	0.97		1.02	
TM235	17.5	18	1.06	6.06	14.9	20.1	2.60	0.95		1.01	
			mean±SD	5.97	1.07			**0.98**	0.02	**1.01**	0.01
Roche Elecsys/Cobas (BME/BMR)											
TM231	18.1	16	1.07	5.91	15.4	20.8	2.70	1.13		1.17	
TM232	35.4	16	1.98	5.59	30.1	40.7	5.30	1.18		1.19	
TM233	86.6	16	4.09	4.72	73.6	99.6	13.00	1.19		1.18	
TM234	26.4	16	1.30	4.92	22.4	30.4	4.00	1.14		1.21	
TM235	20.7	16	0.94	4.54	17.6	23.8	3.10	1.13		1.20	
			mean±SD	5.14	0.59			**1.15**	0.03	**1.19**	0.02
Siemens ADVIA Centaur Classic and XP (COB)											
TM231	16.1	27	0.78	4.82	13.7	18.5	2.40	1.00		1.04	
TM232	30.4	28	1.50	4.93	25.8	35.0	4.60	1.01		1.02	
TM233	73.1	28	3.53	4.82	62.1	84.1	11.00	1.00		0.99	
TM234	23.1	28	1.58	6.84	19.6	26.6	3.50	1.00		1.06	
TM235	18.5	28	0.99	5.37	15.7	21.3	2.80	1.01		1.07	
			mean±SD	5.36	0.86			**1.00**	0.01	**1.04**	0.03
Siemens Immulite 1000 (DPB)											
TM231	17.2	1						1.07		1.11	
TM232	33.6	1						1.12		1.13	
TM233	80.8	1						1.11		1.10	
TM234	25.5	1						1.11		1.17	
TM235	19.7	1						1.07		1.14	
			mean±SD					**1.09**	0.02	**1.13**	0.03
Siemens Immulite 2000, 2500 (DPD/DPF)											
TM231	15.2	19	0.85	5.59	12.9	17.5	2.30	0.94		0.98	
TM232	29.9	19	1.17	3.91	25.4	34.4	4.50	0.99		1.00	
TM233	72.3	19	4.00	5.53	61.5	83.1	10.80	0.99		0.98	
TM234	22.1	19	1.25	5.66	18.8	25.4	3.30	0.96		1.01	
TM235	17.2	19	1.29	7.50	14.6	19.8	2.60	0.94		0.99	
			mean±SD	5.64	1.27			**0.97**	0.03	**0.99**	0.01
Siemens Dimension Vista (DUV)											
TM231	14.7	5	0.38	2.59	12.5	16.9	2.20	0.91		0.95	
TM232	28.6	5	0.72	2.52	24.3	32.9	4.30	0.95		0.96	
TM233	70.5	5	1.12	1.59	59.9	81.1	10.60	0.96		0.96	
TM234	21.5	5	0.58	2.70	18.3	24.7	3.20	0.93		0.99	
TM235	16.9	5	0.27	1.60	14.4	19.4	2.50	0.92		0.98	
		7	mean±SD	2.20	0.56			**0.94**	0.02	**0.97**	0.02
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)											
TM231	11.9	6	0.75	6.30	10.1	13.7	1.80	0.74		0.77	
TM232	23.0	6	1.45	6.30	19.6	26.5	3.45	0.77		0.77	
TM233	55.3	6	3.19	5.77	47.0	63.6	8.30	0.76		0.75	
TM234	17.2	6	1.01	5.87	14.6	19.8	2.60	0.75		0.79	
TM235	13.7	6	0.83	6.06	11.6	15.8	2.10	0.75		0.79	
			mean±SD	6.06	0.24			**0.75**	0.01	**0.77**	0.02
Tosoh AIA (TOM)											
TM231	16.5	4	0.24	1.45	14.0	19.0	2.50	**1.02**		1.06	
TM232	31.4	4	0.68	2.17	26.7	36.1	4.70	1.05		1.05	
TM233	74.2	4	2.33	3.14	63.1	85.3	11.10	1.02		1.01	
TM234	24.0	4	0.38	1.58	20.4	27.6	3.60	1.04		1.10	
TM235	18.8	4	0.3	1.60	16.0	21.6	2.80	1.02		1.09	
			mean±SD	1.99	0.70			1.03	0.01	**1.06**	0.04

All methods	All Method Median	Total N
TM231	16.1	103
TM232	30	103
TM233	73.1	104
TM234	23.1	104
TM235	18.3	104

	IS Target	SD
TM231	15.5	0.56
TM232	29.8	1.05
TM233	73.6	2.96
TM234	21.8	0.87
TM235	17.3	0.91

All Method Median % CV	Median LL	Median UL	Median Dmax
5.59	13.30	17.90	2.30
3.91	25.40	34.40	4.50
4.82	61.50	83.10	10.80
4.92	19.00	25.60	3.30
4.54	14.90	20.10	2.60
Average			
4.76			
Allowable CV %			
5.00			
Allowable Error (+/-) %			
15.0			

All Method median/ IS Target	
1.04	
1.01	
0.99	
1.06	
1.06	
1.03	0.03
0.85-1.15	
<0.85, >1.15	

Figure 6

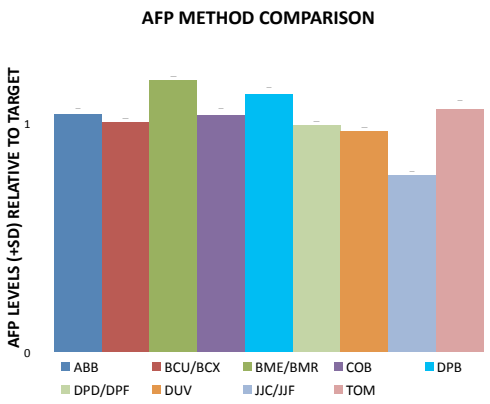

Table 7: 9-11 NYS Tumor Marker PT Summary for PSA

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD	Bias relative to IS target	SD
Abbott AxSym (ABB)											
TM 231	12.4	10	0.5	4.4	10.5	14.3	1.9	0.98		1.19	
TM 232	11.6	10	0.4	3.4	9.9	13.3	1.7	0.97		1.12	
TM 233	11.8	10	0.6	5.1	10.0	13.6	1.8	0.97		1.09	
TM 234	11.3	10	0.4	3.6	9.6	13.0	1.7	0.95		1.05	
TM 235	10.9	10	0.6	5.3	9.3	12.5	1.6	0.95		1.04	
			mean±SD	4.4	0.8			0.97	0.01	1.10	0.06
Abbott Architect (ABH)											
TM 231	13.0	11	0.6	4.2	11.1	15.0	2.0	1.03		1.25	
TM 232	12.2	11	0.5	4.3	10.4	14.0	1.8	1.03		1.17	
TM 233	12.6	11	0.6	4.9	10.7	14.5	1.9	1.04		1.17	
TM 234	12.3	11	0.7	5.4	10.5	14.1	1.8	1.03		1.14	
TM 235	11.5	11	0.5	4.3	9.8	13.2	1.7	1.01		1.10	
			mean±SD	4.6	0.5			1.03	0.01	1.16	0.06
Beckman Access/ Unicel WHO (BC3)											
TM 231	10.6	3	0.4	3.8	9.0	12.2	1.6	0.84		1.02	
TM 232	10.3	3	0.9	8.3	8.8	11.8	1.5	0.87		0.99	
TM 233	10.7	3	0.3	2.3	9.1	12.3	1.6	0.88		0.99	
TM 234	10.6	3	0.7	6.2	9.0	12.2	1.6	0.89		0.98	
TM 235	10.4	3	0.7	6.3	8.8	12.0	1.6	0.91		0.99	
			mean±SD	5.4	2.3			0.88	0.03	0.99	0.01
Beckman Unicel Hybritech (BCU/BC2)											
TM 231	13.1	23	0.5	4.0	11.1	15.1	2.0	1.04		1.26	
TM 232	12.7	22	0.5	4.1	10.8	14.6	1.9	1.07		1.22	
TM 233	13.3	23	0.7	4.9	11.3	15.3	2.0	1.10		1.23	
TM 234	13.3	23	0.7	5.5	11.3	15.3	2.0	1.12		1.23	
TM 235	12.9	23	0.6	4.3	11.0	14.8	1.9	1.13		1.23	
			mean±SD	4.5	0.6			1.09	0.04	1.23	0.01
Beckman Access Hybritech (BCX/BC2)											
TM 231	13.6	29	0.6	4.4	11.6	15.6	2.0	1.08		1.31	
TM 232	13.4	29	0.5	3.9	11.4	15.4	2.0	1.13		1.29	
TM 233	13.8	29	0.5	3.5	11.7	15.9	2.1	1.14		1.28	
TM 234	13.8	29	0.6	4.0	11.7	15.9	2.1	1.17		1.28	
TM 235	13.5	29	0.6	4.7	11.5	15.5	2.0	1.19		1.29	
			mean±SD	4.1	0.5			1.14	0.04	1.29	0.01
Roche Elecsys/E170/Cobas (BME/BMR)											
TM 231	11.1	40	0.5	4.1	9.4	12.8	1.7	0.88		1.07	
TM 232	10.9	38	0.4	3.4	9.3	12.5	1.6	0.92		1.05	
TM 233	11.4	40	0.4	3.9	9.7	13.1	1.7	0.94		1.06	
TM 234	11.4	40	0.5	4.1	9.7	13.1	1.7	0.96		1.06	
TM 235	11.2	40	0.5	4.3	9.5	12.9	1.7	0.98		1.07	
			mean±SD	4.0	0.4			0.94	0.04	1.06	0.01
Siemens ADVIA Centaur Classic , XP and CP (COB/COC)											
TM 231	11.4	61	0.6	5.4	9.7	13.1	1.7	0.90		1.10	
TM 232	11.1	60	0.5	4.4	9.4	12.8	1.7	0.93		1.07	
TM 233	11.6	61	0.6	4.9	9.9	13.3	1.7	0.95		1.07	
TM 234	11.5	61	0.6	4.9	9.8	13.2	1.7	0.97		1.06	
TM 235	11.3	61	0.5	4.5	9.6	13.0	1.7	0.99		1.08	
			mean±SD	4.8	0.4			0.95	0.04	1.08	0.01
Siemens Immulite 1000, 2000 and 2500 original pack (DP5)											
TM 231	14.1	20	1.2	8.4	12.0	16.2	2.1	1.12		1.36	
TM 232	13.6	20	0.9	6.4	11.6	15.6	2.0	1.14		1.31	
TM 233	13.5	20	1.0	7.2	11.5	15.5	2.0	1.11		1.25	
TM 234	13.3	20	1.2	9.3	11.3	15.3	2.0	1.12		1.23	
TM 235	13.0	20	1.2	9.0	11.1	15.0	2.0	1.14		1.24	
			mean±SD	8.1	1.2			1.13	0.01	1.28	0.05
Siemens Immulite 3rd Gen (DP6)											
TM 231	12.9	6	0.5	4.2	11.0	14.8	1.9	1.02		1.24	
TM 232	12.3	6	0.9	7.2	10.5	14.1	1.8	1.04		1.18	
TM 233	12.4	6	1.2	10.0	10.5	14.3	1.9	1.03		1.15	
TM 234	12.2	6	1.0	8.4	10.4	14.0	1.8	1.03		1.13	
TM 235	12.6	5	0.2	1.7	10.7	14.5	1.9	1.11		1.20	
			mean±SD	6.3	3.3			1.04	0.04	1.18	0.04
Siemens Dimension (RxL Max, Xpand Plus) and EXL (DUD/DUX)											
TM 231	14.3	21	0.6	4.0	12.2	16.4	2.1	1.13		1.38	
TM 232	13.4	22	0.8	6.0	11.4	15.4	2.0	1.13		1.29	
TM 233	13.9	22	0.9	6.8	11.8	16.0	2.1	1.15		1.29	
TM 234	13.9	22	1.1	7.8	11.8	16.0	2.1	1.17		1.29	
TM 235	13.3	22	1.0	7.4	11.3	15.3	2.0	1.17		1.27	
			mean±SD	6.4	1.5			1.15	0.02	1.30	0.04
Siemens Dimension Vista (DUV)											
TM 231		1									
TM 232	11.5	1						0.97		1.11	
TM 233	11.6	1						0.96		1.07	
TM 234		1									
TM 235	11.2	1						0.98		1.07	
			mean±SD					0.97	0.01	1.08	0.02
Ortho Clinical Vitros ECi/ECiQ and 5600 (JJC/JJF)											
TM 231	11.1	21	0.5	4.4	9.4	12.8	1.7	0.88		1.07	
TM 232	10.9	22	0.7	6.1	9.3	12.5	1.6	0.91		1.05	
TM 233	11.1	22	0.6	5.0	9.4	12.8	1.7	0.91		1.03	
TM 234	10.8	21	0.4	3.4	9.2	12.4	1.6	0.91		1.00	
TM 235	10.4	22	0.5	4.7	8.8	12.0	1.6	0.91		0.99	
			mean±SD	4.7	1.0			0.90	0.02	1.03	0.03
Tosoh AIA (TOM)											
TM 231	11.1	9	0.5	4.9	9.4	12.8	1.7	0.88		1.07	
TM 232	10.8	9	0.6	5.2	9.2	12.4	1.6	0.91		1.04	
TM 233	11.0	9	0.5	4.8	9.4	12.7	1.7	0.91		1.02	
TM 234	10.9	9	0.6	5.6	9.3	12.5	1.6	0.92		1.01	
TM 235	10.5	9	0.5	4.6	8.9	12.1	1.6	0.92		1.00	
			mean±SD	5.0	0.4			0.91	0.02	1.03	0.03

All methods	All Method Median	Total N
TM231	12.7	254
TM232	11.9	252
TM233	12.1	256
TM234	11.9	255
TM235	11.4	255

	IS Target	SD
TM231	10.4	0.6
TM232	10.4	0.6
TM233	10.8	0.7
TM234	10.8	0.7
TM235	10.5	0.7

All Method Median % CV	Median LL	Median UL	Median Dmax	All Method median/ IS Target
4.3	10.8	14.6	1.9	1.2
4.8	10.2	13.7	1.8	1.1
4.9	10.3	14.0	1.9	1.1
5.5	10.1	13.6	1.8	1.1
4.6	9.7	13.1	1.7	1.1

Average
4.8
Allowable CV %
5.0
Allowable Error (+/-) %
15.0

0.9-1.1
1.1-1.2
>1.2

Figure 7A

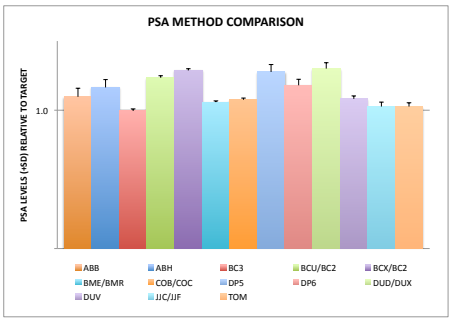

Figure 7B

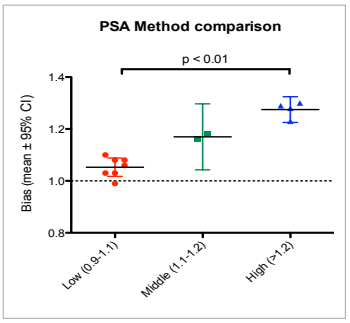

Table 8: 9-11 NYS Tumor Marker PT Summary for Free PSA

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median	SD	Bias relative to IS target	SD
Abbott AxSYM (ABB)											
TM 231	0.21	1						0.92		1.17	
TM 232	1.33	1						0.90		1.09	
TM 233	2.53	1						0.97		1.17	
TM 234	3.26	1						0.88		1.09	
TM 235	4.27	1						0.90		1.14	
			mean±SD					0.91	0.04	1.13	0.04
Abbott Architect (ABH)											
TM 231	0.22	3	0.01	5.37	0.07	0.37	0.15	0.96		1.22	
TM 232	1.54	3	0.06	3.97	1.31	1.77	0.23	1.04		1.26	
TM 233	2.80	3	0.09	3.07	2.38	3.22	0.42	1.08		1.30	
TM 234	4.01	3	0.11	2.75	3.41	4.61	0.60	1.09		1.34	
TM 235	4.92	3	0.14	2.88	4.18	5.66	0.74	1.03		1.31	
			mean±SD	3.61	1.10			1.04	0.05	1.29	0.05
Beckman UnicelAccess Hybritech (BC2)											
TM 231	0.28	28	0.02	6.77	0.13	0.43	0.15	1.23		1.56	
TM 232	1.84	28	0.08	4.51	1.56	2.11	0.28	1.24		1.51	
TM 233	3.28	29	0.15	4.63	2.79	3.77	0.49	1.26		1.52	
TM 234	4.60	29	0.24	5.19	3.91	5.29	0.69	1.25		1.54	
TM 235	5.83	29	0.25	4.36	4.95	6.70	0.87	1.22		1.55	
			mean±SD	5.09	0.99			1.24	0.02	1.54	0.02
Beckman Unicel/Access WHO (BC3)											
TM 231	0.22	2	0.02	9.77				0.96		1.22	
TM 232	1.43	2	0.04	2.94				0.96		1.17	
TM 233	2.43	2	0.04	1.73				0.93		1.13	
TM 234	3.54	2	0.09	2.60				0.96		1.18	
TM 235	4.61	2	0.27	5.84				0.97		1.23	
			mean±SD	4.57	3.29			0.96	0.01	1.19	0.04
Roche Elecsys/E170/Cobas (BME/BMR)											
TM 231	0.23	24	0.02	8.59	0.08	0.38	0.15	1.01		1.28	
TM 232	1.35	24	0.04	3.11	1.15	1.55	0.20	0.91		1.11	
TM 233	2.41	24	0.08	3.16	2.05	2.77	0.36	0.93		1.12	
TM 234	3.34	24	0.09	2.75	2.84	3.85	0.50	0.90		1.12	
TM 235	4.25	24	0.13	2.96	3.61	4.89	0.64	0.89		1.13	
			mean±SD	4.11	2.51			0.93	0.05	1.15	0.07
Siemens Immulite 1000 & 2000 (DPB/DPD)											
TM 231	0.17	17	0.03	15.62	0.02	0.32	0.15	0.75		0.94	
TM 232	1.29	16	0.13	10.39	1.10	1.48	0.19	0.87		1.06	
TM 233	2.34	16	0.16	6.84	1.99	2.69	0.35	0.90		1.09	
TM 234	3.37	16	0.28	8.17	2.86	3.87	0.51	0.91		1.13	
TM 235	4.18	16	0.27	6.44	3.55	4.80	0.63	0.88		1.11	
			mean±SD	9.49	3.76			0.86	0.07	1.07	0.07
Siemens Dimension (RxL Max, Xpand Plus) & EXL (DUD & DUX)											
TM 231	0.31	5	0.03	8.77	0.16	0.46	0.15	1.36		1.72	
TM 232	1.57	5	0.04	2.54	1.34	1.81	0.24	1.06		1.29	
TM 233	2.77	5	0.10	3.72	2.36	3.19	0.42	1.06		1.29	
TM 234	3.85	5	0.05	1.32	3.27	4.43	0.58	1.04		1.29	
TM 235	4.99	5	0.15	2.97	4.24	5.74	0.75	1.05		1.33	
			mean±SD	3.86	2.87			1.11	0.14	1.38	0.19
Siemens Dimension Vista (DUV)											
TM 231	0.24	1						1.05		1.33	
TM 232	1.16	1						0.78		0.95	
TM 233	2.09	1						0.80		0.97	
TM 234	3.10	1						0.84		1.04	
TM 235	3.77	1						0.79		1.00	
			mean±SD					0.85	0.11	1.06	0.16

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	
TM231	0.23	79	**8.59**	0.08	0.38	0.15	0.9-1.1
TM232	1.49	78	**3.11**	1.23	1.66	0.22	1.1-1.2
TM233	2.60	79	**3.16**	2.20	2.98	0.39	>1.2
TM234	3.70	79	**2.75**	3.07	4.15	0.54	
TM235	4.77	79	**2.97**	3.90	5.27	0.69	

	IS Target	SD
TM231	0.18	0.02
TM232	1.22	0.04
TM233	2.15	0.10
TM234	2.99	0.16
TM235	3.75	0.24

Average 4.11

Allowable CV % 5.00

Allowable Error if >1.0 ng/ml (+/-) % 15.00

Allowable Error if <1.0 ng/ml (+/-) ng/ml 0.15

	% free PSA
TM231	1.7%
TM232	11.7%
TM233	19.9%
TM234	27.7%
TM235	35.7%

Figure 8

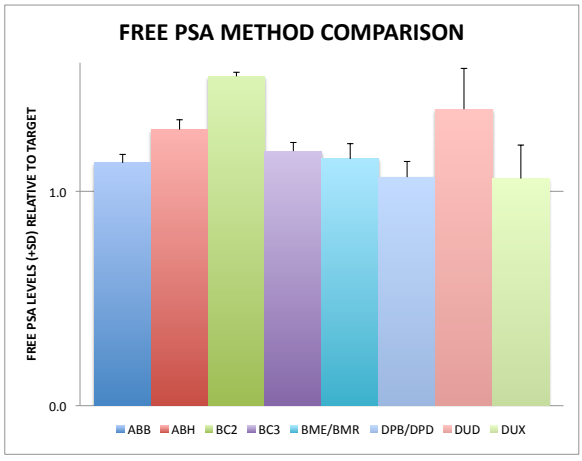

Table 9: 9-11 NYS Tumor Marker PT Summary for complexed PSA

Instrument Reagent/Sample	Target=Mean	N	SD	%CV	LL	UL	Dmax
Siemens Centaur (COB)							
TM231	11.0	10.0	0.5	**4.6**	9.4	12.7	1.7
TM232	9.7	10.0	0.5	**5.2**	8.2	11.2	1.5
TM233	8.9	10.0	0.4	**4.7**	7.6	10.2	1.3
TM234	7.8	10.0	0.3	**4.0**	6.6	9.0	1.2
TM235	6.4	10.0	0.3	**4.0**	5.4	7.4	1.0
			mean±SD	**4.5**	0.5		

All Method Median % CV

4.6

5.2

4.7

4.0

4.0

Average

4.5

Allowable CV %

5.0

Allowable Error (+/-) %

15.0

ONCOLOGY SOLUBLE TUMOR MARKERS
WORKSHEET ONLY---DO NOT MAIL

INSTRUCTIONS CAN BE FOUND AT:

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2011/index.htm

Oncology Soluble Tumor Markers						
		TM231	**TM232**	**TM233**	**TM234**	**TM235**
AFP (ng/ml)	>/<					
	Result					
CA 125 (U/ml)	>/<					
	Result					
CA 15-3 (U/ml)	>/<					
	Result					
CA 19-9 (U/ml)	>/<					
	Result					
CA 27.29 (U/ml)	>/<					
	Result					
CEA (ng/ml)	>/<					
	Result					
PSA (Total) (ng/ml)	>/<					
	Result					
Complexed PSA (ng/ml)	>/<					
	Result					
PSA (Total) for a 2nd method used in conjunction with free PSA (ng/mL)	>/<					
	Result					
Free PSA (ng/ml) If test offered, measure and report for all samples	>/<					
	Result					

**********IMPORTANT!!!!**********

FOR LABS THAT TEST **FREE PSA,** RESULTS MUST NOW BE SUBMITTED FOR **ALL** SAMPLES WHILE **PERCENT** FREE PSA WILL NO LONGER BE REPORTED. SEE INSTRUCTIONS FOR MORE INFORMATION.

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm

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