NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

**********PLEASE NOTE**********

This document and the worksheet can now 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

DATE: **May 10, 2011**

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

DUE DATE: May 25th, 2011

PLEASE READ-INFORMATION IS IMPORTANT

Samples:
There are five sealed (5) vials labeled **TM226 to TM230**, each containing diagnostic specimens for proficiency testing. 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 analyze for all of those markers tested in your laboratory the same way as you would with a patient sample. If your lab is also measuring free and/or complexed PSA in addition to total PSA, you are also required to measure those forms of PSA in **ALL** of the samples provided. All materials used to prepare the enclosed samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, it is recommended that universal precautions be used for handling samples. Samples are in a human-derived serum base, sterile filtered and dispensed. Please keep **refrigerated** until use, but **do not freeze**. Before analyzing make sure samples are completely mixed.

Reporting of results: Results must be submitted electronically before 11:59 PM of May 25th, 2011. Please submit a little earlier if possible to allow time to resolve any problem you might have with result submission. Please also read the enclosed bulletin with important updates regarding the electronic proficiency testing reporting system.

All laboratories must submit their proficiency testing results over the internet through the 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 directed to clepeptrs@health.state.ny.us.

Results **not submitted by the due date** will be categorized as missing with an administrative **failure** and will receive a failing grade, even if the 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 routinely measure, otherwise a zero grade will be given to the missing data. Please enter your results in the spaces provided on the electronic PT form. If a result exceeds your analytical range, indicate this with a "less than (<)" or "greater than (>)" sign if similar results from patient samples are reported in the same manner. If such samples are routinely retested after dilution, you may do so provided that the result is identified accordingly. Select the instrument and reagent/kit used for each analyte using the drop-down menus provided. **Please check that the information is current**, since the EPTRS form is pre-populated from previous entries. It is very important to correctly complete all applicable fields as **missing or incorrect entries may result in an inability to move to the next screen, or possibly in test failure. If your lab has temporarily or permanently stopped testing for an analyte** choose the appropriate selection from the test status list on the event menu page. When temporary suspension of testing is selected, the reason for this suspension must be listed on the report form. When a test is deleted, you should select 'test deleted' and also submit a 'delete analyte' form as required by the CLEP office (http://www.wadsworth.org/labcert/clep/Administrative/chngaddanalyte.pdf). **Absence of results for any analyte without appropriate notification will result in a failing grade for the missing results.**

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 the individual analytes measured. There is also a space to interpret whether an individual sample result is abnormal or normal with respect to this cut-off. If you use tables, such as age-specific reference ranges or risk probabilities, to evaluate whether a sample is normal, please indicate this in the comment section and include additional specific information if possible.

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker.

PSA

IMPORTANT NOTE: Labs are **no longer required to calculate % free PSA**. However, labs **are required to measure and report results for free PSA for all samples** if they measure this analyte as part of their regular test menu. There is also a question at the bottom of the free PSA requesting additional information regarding when you would normally calculate % free PSA. Please choose the appropriate drop-down menu selection according to your laboratory's policy. We are no longer asking for the specific PSA range used to determine measuring free PSA or calculating the % free PSA at this time.

Note: For those cases where a lab measures total PSA by a second method in order to use these PSA results in conjunction with free PSA results, there is a place on the form to enter the data from these secondary measurements of PSA.

The laboratory director or the assistant director who must hold a CQ in Oncology-Sera and Soluble Tumor Markers and all laboratory personnel analyzing these specimens **must sign the printed electronic summary** page in the space for attestations. These signatures attest that the proficiency testing samples were analyzed in the same manner as patient samples, and **this signed summary page should be kept on file** for review by surveyors.

Please check your electronic report carefully since missing or incorrect information, especially for instrument and reagent codes, can result in a PT failure. For any correspondence regarding the PT, please address mail to:

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

If you do not receive the samples in satisfactory condition call Ms. McHale at 486-5775 or Ms. Ling at 474-0036.
The next Oncology Tumor Marker Proficiency Test mail-out for **2011** is scheduled as follows:

Mail-out date:	Due date:
September 13, 2011	**September 27, 2011 (PLEASE NOT E THIS IS A TUESDAY)**

NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

New York State Tumor Marker Proficiency Test 5/2011 Evaluation [1]

July 11, 2011

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from May 10, 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 in a series of two-fold dilutions 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 result and score 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 at 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 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 error)**, with D being the difference of your result from the target, and Dmax being the **maximal allowable error for your peer**

[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.

group. Thus, D/Dmax needs to be between –1 and +1 for a result to be considered correct. **Note: If your D/Dmax is not within +/- 0.66, especially for more than one or two samples, you should carefully check your result(s) since this indicates that they are substantially 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 **average 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 strongly encourage 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 normalized values were calculated for each sample by dividing its mean by the median of the means from all peer groups (all method median). The all method medians are used instead of the all lab means to reduce the weight towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, we calculated those values relative to the assigned target values (see below) as well as the all method median. The method comparisons are shown in the right hand graphs under the corresponding analyte table, with the error bars representing the standard deviation. Specifically for this PT event, the five samples were prepared as a series of two-fold dilutions, which allowed us to evaluate the linearity of the methods. The results of this analysis are shown in the graphs on the left at the bottom of each table. For all analytes, all methods exhibited acceptable proportionality with no major deviations from linearity observed. When comparing methods, keep in mind 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:

CA125 (Table 1): Results were reported by 112 labs using 13 different methods or instruments. Combining results from different instruments made by the same manufacturer and/or brand resulted in eight peer groups. Of the eight peer groups, five included ten or more labs each and together comprised over three quarters of the labs. Five peer groups reported results within +/-15% of the all method medians. Of the other three groups, one reported comparatively low results averaging 21% below the medians (Siemens Immulite 2500, used by only 4% of labs), while another was an average of 23% above the median (Abbott AxSYM/Architect, used by 11% of labs). TOSOH ST-AIA (used by six labs representing about 5% of the participants) once again gave the highest results that were on average 35% above the all method medians. Overall, however, the large majority of labs agreed reasonably well on how CA125 was measured in these samples.

CA19-9 (Table 2): Results were reported by 62 labs using nine methods. The only combined results from different instruments (made by the same manufacturer and/or brand) were from Beckman's Unicel and Access instruments. This resulted in eight peer groups total, two of which comprised only one lab each and were therefore not gradable and were also not included in the calculation of the all method medians, but are shown for comparison on the bar graph. Forty-eight percent of all reporting labs used Siemens ADVIA-Centaur, 21% used Beckman Unicel or Access, 13% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 11% used the Tosoh ST-AIA method. The results from the Beckman and Roche instruments were all relatively close to each other and represent the medians. In contrast, measurements by Tosoh ST-AIA were lower by 33%, 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 2.1 and 2.3 times higher, respectively, than the all method medians. As a consequence, the higher measurements from the large number of ADVIA Centaur labs would have caused the average all lab mean to be 58% higher than the median, which is the reason why the all method median is used for calculating the relative bias of each method. 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 and over 8 times higher than the results obtained with the Tosoh ST-AIA. These high measurements by the Abbott Architect are consistent with previous CA19-9 NYS PT results by this method, as well as those obtained in previous corresponding CAP surveys, which have shown it to be at least four-fold higher than the all method medians. Because of that and only being reported by one lab, it was left out of the median and mean calculations. Overall, the results of these different methods indicate there is still substantial discordance between the various methods used to measure CA19-9.

The MUC1 breast cancer antigen was measured by 104 labs, with slightly more than half (54%) using one of ten **CA15-3** methods (Table 3) and the remainder using one of three methods for **CA27.29** (Table 4). Note that the ADVIA Centaur XP and CP instruments were separated, although only two labs reported using the CP instrument and the means of the two CP results were well within the acceptable ranges for the XP instrument. For **CA15-3**, combining results from different instruments made by the same manufacturer and/or brand resulted in seven peer groups, five of which comprised less than ten labs each. The Siemens ADVIA-Centaur method (used by 34% of the labs) did not exhibit the high positive bias that was observed in some previous PT events, and gave results just 9% higher on average than the medians. Also above the all method median were Siemens Immulite 2000/2500 instruments that averaged +17% and the Abbott Architect that was 14% higher than the medians. In contrast, the Abbott AxSYM measurements were 9% lower on average than the all method medians as were Roche Elecsys/Cobas/E170 at -7%, the Vitros ECi/ECiQ results at -17% and most notably, the Beckman Unicel/Access results at 38% lower than the all method medians. Of the methods used for measuring **CA27.29**, the ADVIA Centaur XP and the Tosoh AIA method showed a 13% difference from each other, with the Centaur CP method in between the two. Although the overall median values measured by the CA27.29 methods were slightly higher than CA15-3 in the most concentrated sample (TM 226 by about 4%), they were lower than CA15-3 in the less concentrated samples TM227-TM230, by 1-27%. In conclusions, there are substantial differences in how different manufacturers' instruments measure CA15-3, whereas there seems to be much better concordance between (the fewer) CA27.29 methods.

CEA (Table 5): Results were reported by 168 labs using 15 different methods. After combining results from different instruments made by the same manufacturer and/or brand, ten peer groups remained comprising from 5 to 53 labs. The sole ADVIA Centaur CP result was grouped with the Centaur XP results because it 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 (76%) were fairly consistent, being on average within +/-10% of the medians. Both the two Roche and two Beckman instruments, respectively, were analyzed separately due to significant differences seen between results for at least two of the five samples. On average, the Roche Elecsys/Cobas e411 group was 14% below the all method medians and the E170/Cobas e601 group 19% below, while the Beckman Unicel and Access instruments were 9% and 3% below the medians, respectively. In contrast, and most notably, the Ortho Clinical Diagnostics Vitros ECi/Q & 5600 and the TOSOH ST-AIA methods gave results that averaged 27% and 49% higher than the medians, respectively, indicating consistent differences in how CEA is measured by these instruments. The rest of the instruments, namely the Abbott AxSYM and the various Siemens instruments were essentially identical with 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, both the assigned target values as well as the all method medians were used and are shown in the respective tables.

AFP (Table 6): Results were reported by 100 labs using 13 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, there remained eight peer groups. Four of those were used by less than ten labs each, which

together accounted for twenty percent of the total number of labs. Although AFP has generally shown less discordance between methods than many other tumor marker analytes, two methods (Siemens Immulite and Ortho Clinical Diagnostics Vitros ECi/ECiQ) gave results that were discernibly lower than the rest, whereas Siemens Dimension exhibited a noticeable positive bias. The Vitros method averaged 16% lower than the all method median and 12% lower than the International Standard (IS) target, while the Immulite method averaged 8% lower than the all method median but was within less than 5% of the IS target. In contrast, the Siemens Dimension measured 10% above the all method median and 15% above the IS target on average. The remaining groups were all close to each other, but were on average 6% higher than the IS target. Overall, however, the differences between the various methods were small, indicating good harmonization between the different manufacturers.

PSA (Table 7): Results were reported by 258 labs using 21 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were 12 peer groups, three of which comprised less than ten labs each. The five samples were all prepared with the same proportion of free to ACT-complexed PSA of approximately 14%, but different concentrations of total PSA. In addition to the peer group statistics, the average ratio of the peer group mean/target value is given for each sample to further compare measurement and calibration biases between the different methods. For all methods combined across all five samples there was an average bias of +18% compared to the target values, but there was a clear separation of methods into distinct high and low groups, similar to what was seen in some previous proficiency tests. For comparison, average measured values for each group were graphed against the IS target values for each sample followed by linear regression (Figure 1A). Further discussion of that analysis follows the free PSA section. Overall, the average bias for the high groups was +24%, whereas the average bias for the low group was +3.5%, a difference that was highly significant ($p < 0.0001$). However, the difference between the low groups and the IS target was not significant ($p > 0.05$). The high group comprised seven methods (Abbot AxSYM and Architect, Beckman Unicel and Access with the Hybritech calibration, Siemens Immulite original pack and 3rd generation pack and Siemens Dimension) whose results ranged from 14-35% higher than the targets, whereas the low group comprised five methods (Beckman Unicel/Access with the WHO calibration, Roche Elecsys/Cobas, Siemens ADVIA Centaur XP/CP, Ortho Clinical Diagnostics Vitros (ECi, ECiQ, and 5600) and Tosoh AIA) whose results were just 2-9% higher than the targets. Both the original and 3rd generation Siemens Immulite methods are in the high group, although the results from the 3rd generation assays were between 2.3% to 8.9% lower than those from the original pack. In contrast, there was a clear difference between the Beckman reagents; those calibrated with the original Hybritech standards on average measured 22% and 26% higher than the targets, whereas those calibrated with the international WHO standards measured only 5% higher 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): Results were reported by 83 labs using twelve different methods. After combining results from different instruments made by the same manufacturer and/or brand there were seven peer groups, four of which comprised less than 10 labs each and together were used by less than 20% of the labs. The other three methods were used by 35%, 29% and 19%, respectively. In addition to the peer group statistics, the average ratio of the peer group mean/target value is given to further compare measurement and calibration biases between the different groups. 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 (55% above the targets and 33% higher than the all method medians), while the Beckman Access and Unicel calibrated with the WHO standards were only 16% above the target and right at the all method median, as well as being 33% lower on average than those from the original Hybritech-calibrated Beckman methods. The Siemens Dimension and Abbott Architect were 27% and 28% above the targets, respectively, and were both 10% above the all method medians. Interestingly, the Abbott AxSYM was significantly lower than the Architect, (average p-value = 0.01) with the AxSYM just 10% above the targets. The Roche instruments were grouped together and ran about 14% above target, and the lowest

running method was Siemens Immulite 1000/2000, whose results averaged just 4% above the target. In conclusion, there are substantial differences in how fPSA is measured. Furthermore, not every method that is high for total PSA is also high for fPSA, whereas the two methods that were low for total PSA were also low for fPSA.

High and low group analysis for PSA and free PSA (Figure 1): In order to more easily compare the high and low groups for PSA and free PSA, average measured values for each group were graphed against the IS target values for each sample followed by linear regression (A,C). The slopes between the two groups were found to be significantly different with p-values <0.0001; in contrast, only the low PSA group was not significantly different from the target values (line of identity, p>0.1). Panels B and D represent scatter plots of each method's average bias relative to the respective IS target values. Whereas the mean bias of the high PSA group was significantly different from that of the low group (panel B, p=0.0002), the difference in the mean biases between the two groups for free PSA did not quite reach significance, possibly because of the small number of methods in the high group and their large divergence.

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 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	29	35%
Yes, but only within a specific PSA range	26	31%
No	15	18%
Yes, but only when requested	4	5%
Yes, but only when requested and only within a specific PSA range	9	11%
Other	0	0%
Total	83	100%

Finally, only 8 labs measured **complexed PSA** (Table 9), and all of these used the Siemens ADVIA-Centaur method, with relatively good agreement between the labs as indicated by a %CV of 10.5%.

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 must 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 your results are **submitted**. If results are **saved but not submitted**, they will be graded as an administrative **fail**.

Please be aware that in each subsequent event, fields will 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 entered two PSA tests, the primary PSA test should have been entered on the first PSA line and the secondary assay (for use in conjunction with their free PSA results) on the PSA2 line.

Finally, on both the event menu and the results page, the absence of data in the required fields for **upper limit of normal reference range** (the cut-off level below which a patient result is normal) as well as **sample interpretation** (based on the reference range) should be looked at to ensure accurate reporting during the subsequent event. Furthermore, some labs still appear to be confusing the limits of the normal reference range with the assay's lower or upper limits of detection.

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 scheduled date of the remaining 2011 Tumor Marker Proficiency Test event is:

Mail-out date:
September 13, 2011

Due date:
September 27, 2011
(Please note this is a Tuesday.)

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

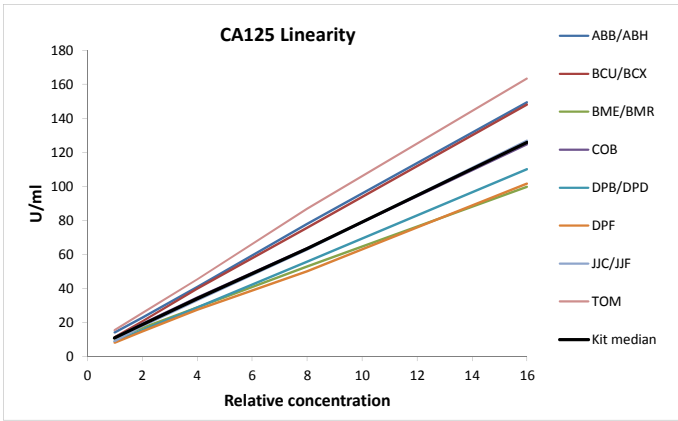
Table 1

5-11 NYS Tumor Marker PT Summary CA125

Instrument/ Sample	Mean= Target	N	SD	%CV	LL	UL	Dmax	Relative Method Bias	
Abbott AxSYM/Architect (ABB/ABH)									
TM226	149.4	12	9.04	6.05	122.5	176.3	26.90	1.19	
TM227	78.0	12	3.34	4.29	64.0	92.0	14.00	1.23	
TM228	40.9	12	2.08	5.08	33.5	48.3	7.40	1.20	
TM229	22.8	12	1.38	6.05	18.7	26.9	4.10	1.23	
TM230	14.1	12	1.41	10.01	10.9	17.3	3.20	1.31	
			mean±SD	6.30	2.20		mean±SD	**1.23**	0.05
Beckman Unicel/Access (BCU/BCX)									
TM226	148.0	14	8.14	5.50	121.4	174.6	26.60	1.18	
TM227	75.6	14	3.42	4.52	62.0	89.2	13.60	1.20	
TM228	39.9	14	2.46	6.18	32.7	47.1	7.20	1.17	
TM229	20.6	14	1.15	5.57	16.9	24.3	3.70	1.11	
TM230	11.4	14	0.80	7.05	8.2	14.6	3.20	1.06	
			mean±SD	5.77	0.93		mean±SD	**1.14**	0.06
Roche Elecsys/Cobas (BME/BMR)									
TM226	99.7	15	4.96	4.97	81.8	117.6	17.90	0.79	
TM227	52.8	15	2.21	4.18	43.3	62.3	9.50	0.84	
TM228	28.9	15	1.71	5.91	23.7	34.1	5.20	0.85	
TM229	16.8	15	1.44	8.55	13.6	20.0	3.20	0.91	
TM230	10.7	15	1.10	10.32	7.5	13.9	3.20	0.99	
			mean±SD	6.79	2.57		mean±SD	**0.87**	0.08
Siemens ADVIA Centaur (COB)									
TM226	124.8	29	5.02	4.03	102.3	147.3	22.50	0.99	
TM227	63.7	30	4.46	7.00	52.2	75.2	11.50	1.01	
TM228	34.7	30	1.70	4.89	28.5	40.9	6.20	1.02	
TM229	19.3	30	1.03	5.35	15.8	22.8	3.50	1.04	
TM230	10.9	30	0.88	8.05	7.7	14.1	3.20	1.01	
			mean±SD	5.86	1.63		mean±SD	**1.01**	0.02
Siemens Immulite 1000/2000 (DPB/DPD)									
TM226	110.1	23	7.39	6.71	90.3	129.9	19.80	0.87	
TM227	55.7	24	3.36	6.04	45.7	65.7	10.00	0.88	
TM228	28.9	24	1.63	5.65	23.7	34.1	5.20	0.85	
TM229	15.6	24	0.94	6.05	12.4	18.8	3.20	0.84	
TM230	8.9	23	0.49	5.53	5.7	12.1	3.20	0.82	
			mean±SD	6.00	0.46		mean±SD	**0.85**	0.02
Siemens Immulite 2500 (DPF)									
TM226	101.6	4	3.99	3.93	83.3	119.9	18.30	0.81	
TM227	50.1	4	1.77	3.54	41.1	59.1	9.00	0.79	
TM228	27.5	4	1.73	6.30	22.6	32.5	4.95	0.81	
TM229	14.7	4	0.88	5.98	11.5	17.9	3.20	0.79	
TM230	8.2	4	0.45	5.54	5.0	11.4	3.20	0.76	
			mean±SD	5.06	1.25		mean±SD	**0.79**	0.02
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)									
TM226	126.8	6	2.40	1.89	104.0	149.6	22.80	1.01	
TM227	62.8	6	2.69	4.29	51.5	74.1	11.30	0.99	
TM228	33.2	6	1.65	4.98	27.2	39.2	6.00	0.98	
TM229	17.9	6	0.86	4.83	14.7	21.1	3.20	0.96	
TM230	9.2	5	1.80	19.66	6.0	12.4	3.20	0.85	
			mean±SD	7.13	7.11		mean±SD	**0.96**	0.06
Tosoh AIA (TOM)									
TM226	163.4	6	15.56	9.53	134.0	192.8	29.40	1.30	
TM227	86.8	6	8.46	9.75	71.2	102.4	15.60	1.37	
TM228	45.3	6	2.78	6.13	37.1	53.5	8.20	1.34	
TM229	25.5	6	2.23	8.76	20.9	30.1	4.60	1.37	
TM230	15.4	6	1.37	8.90	12.2	18.6	3.20	1.43	
			mean±SD	8.61	1.45		mean±SD	**1.36**	0.05

All Methods	All Method Median	Total N	All Method Median %CV	Median LL	Median UL	Median Dmax
TM226	125.8	109	5.24	103.2	148.5	22.65
TM227	63.3	111	4.40	51.9	74.7	11.40
TM228	33.9	111	5.78	27.9	40.1	6.10
TM229	18.6	111	6.01	15.3	22.0	3.35
TM230	10.8	109	8.48	7.6	14.0	3.20
			Average			
			5.98			

Allowable CV
6%
Allowable Error if >18 U/ml (+/-)
18%
Allowable Error if <18 U/ml (+/-)
3.24 U/ml



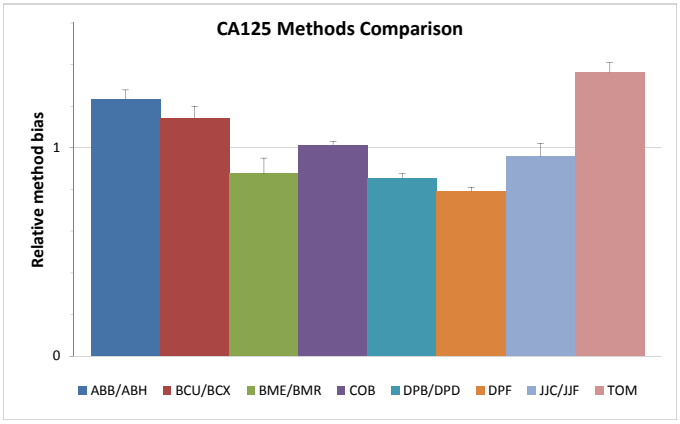
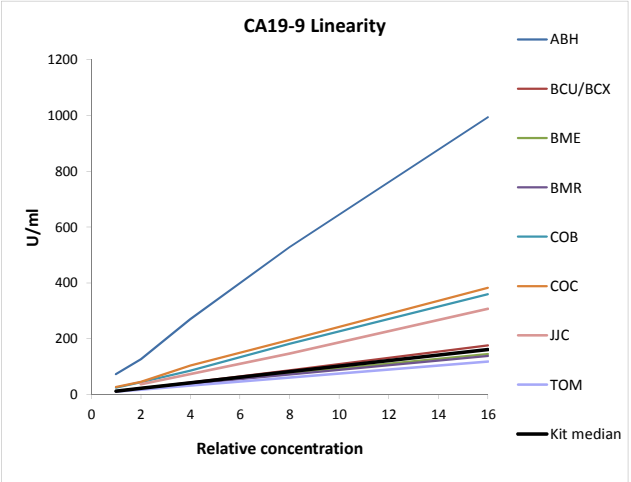


Table 2 **5-11 NYS Tumor Marker PT Summary for CA19-9**

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax	Relative Method Bias	
Abbott Architect (ABH)									
TM226	993.4	1						6.18	
TM227	528.2	1						6.46	
TM228	270.0	1						6.43	
TM229	126.6	1						5.71	
TM230	73.2	1						6.05	
							mean±SD	**6.17**	0.31
Beckman Unicel/Access (BCU/BCX)									
TM226	176.0	13	12.42	7.06	149.6	202.4	26.4	1.10	
TM227	87.1	13	4.68	5.37	74.0	100.2	13.1	1.07	
TM228	43.3	13	3.09	7.14	36.8	49.8	6.5	1.03	
TM229	22.3	13	1.19	5.32	19.0	25.6	3.3	1.01	
TM230	11.4	13	0.79	6.92	9.7	13.1	1.7	0.94	
			mean±SD	6.36	0.93		mean±SD	**1.03**	0.06
Roche Elecsys 2010/Cobas 401 (BME)									
TM226	145.4	2						0.90	
TM227	76.4	2						0.93	
TM228	40.7	2						0.97	
TM229	22.1	2						0.99	
TM230	12.6	2						1.04	
							mean±SD	**0.97**	0.05
Roche E170/Cobas 601 (BMR)									
TM226	138.7	6	3.96	2.85	117.9	159.5	20.8	0.86	
TM227	72.2	6	2.13	2.95	61.4	83.0	10.8	0.88	
TM228	39.1	6	1.17	2.98	33.2	45.0	5.9	0.93	
TM229	20.9	6	0.48	2.31	17.8	24.0	3.1	0.94	
TM230	11.7	6	0.77	6.64	9.9	13.5	1.8	0.96	
			mean±SD	3.55	1.75		mean±SD	**0.92**	0.04
Siemens ADVIA Centaur XP (COB)									
TM226	360.0	30	22.83	6.34	306.0	414.0	54	2.24	
TM227	182.0	29	7.72	4.24	154.7	209.3	27.3	2.23	
TM228	85.5	30	6.11	7.14	72.7	98.3	12.8	2.04	
TM229	44.6	30	2.05	4.60	37.9	51.3	6.7	2.01	
TM230	24.5	30	1.42	5.80	20.8	28.2	3.7	2.02	
			mean±SD	5.63	1.21		mean±SD	**2.11**	0.12
Siemens ADVIA Centaur CP (COC)									
TM226	383.1	3	37.12	9.69	325.6	440.6	57.5	2.38	
TM227	195.8	3	17.39	8.88	166.4	225.2	29.4	2.40	
TM228	103.4	3	14.99	14.50	87.9	118.9	15.5	2.46	
TM229	45.1	3	1.54	3.41	38.3	51.9	6.8	2.03	
TM230	27.2	3	2.65	9.75	23.1	31.3	4.1	2.25	
			mean±SD	9.25	3.94		mean±SD	**2.30**	0.17
Ortho Clinical Diag Vitros (JJC)									
TM226	307.0	1						1.91	
TM227	147.0	1						1.80	
TM228	73.5	1						1.75	
TM229	37.2	1						1.68	
TM230	<37.0	1							
							mean±SD	**1.78**	0.10
Tosoh AIA (TOM)									
TM226	118.2	7	4.72	4.00	100.5	135.9	17.7	0.74	
TM227	60.8	7	2.73	4.49	51.7	69.9	9.1	0.74	
TM228	31.8	7	1.03	3.25	27.0	36.6	4.8	0.76	
TM229	17.5	7	0.50	2.87	14.9	20.1	2.6	0.79	
TM230	10.0	7	0.35	3.53	8.5	11.5	1.5	0.83	
			mean±SD	3.63	0.64		mean±SD	**0.77**	0.04

All Methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax
TM226	160.7	61	5.17	149.6	202.4	26.4
TM227	81.8	60	4.37	74.0	100.2	13.1
TM228	42.0	61	5.19	36.8	49.8	6.5
TM229	22.2	61	3.14	19.0	25.6	3.3
TM230	12.2	61	6.42	9.9	13.5	1.8
			Average 4.86			

Allowable CV 5%
Allowable Error (+/-) 15%



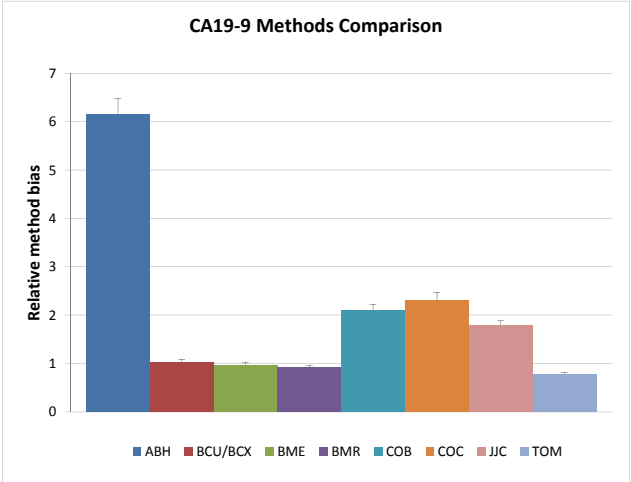
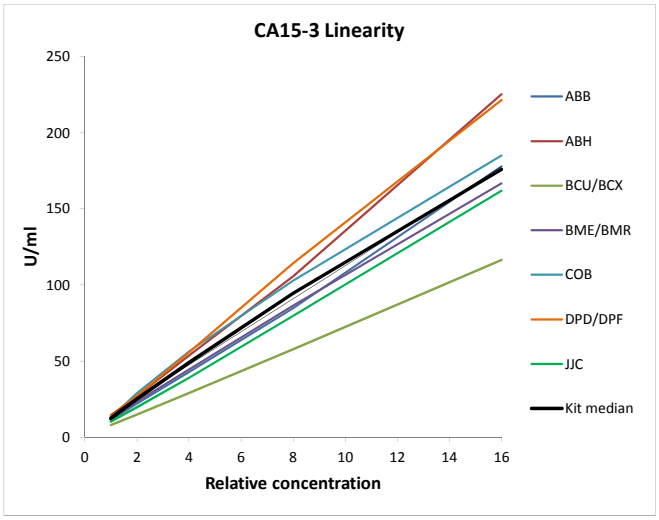


Table 3 **5-11 NYS Tumor Marker PT Summary CA15-3**

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax	Relative Method Bias	
Abbott AxSYM (ABB)									
TM226	177.8	2						1.01	
TM227	84.8	2						0.90	
TM228	42.6	2						0.87	
TM229	22.1	2						0.88	
TM230	11.1	2						0.90	
							mean±SD	**0.91**	0.06
Abbott Architect (ABH)									
TM226	225.3	5	17.31	7.68	180.2	270.4	45.10	1.28	
TM227	105.8	5	5.37	5.07	84.6	127.0	21.20	1.12	
TM228	53.6	5	3.16	5.90	42.9	64.3	10.70	1.10	
TM229	27.0	5	2.00	7.43	21.6	32.4	5.40	1.07	
TM230	13.9	5	1.45	10.49	11.1	16.7	2.80	1.12	
			mean±SD	7.32	2.08		mean±SD	**1.14**	0.08
Beckman Unicel/Access (BCU/BCX)									
TM226	116.5	6	9.70	8.33	93.2	139.8	23.30	0.66	
TM227	57.7	6	2.69	4.67	46.2	69.2	11.50	0.61	
TM228	29.0	6	1.99	6.87	23.2	34.8	5.80	0.59	
TM229	14.9	6	0.50	3.33	11.9	17.9	3.00	0.59	
TM230	7.9	6	0.51	6.47	6.3	9.5	1.60	0.64	
			mean±SD	5.93	1.96		mean±SD	**0.62**	0.03
Roche Elecsys/Cobas (BME/BMR)									
TM226	166.7	9	4.48	2.69	133.4	200.0	33.30	0.95	
TM227	86.3	9	4.54	5.26	69.0	103.6	17.30	0.91	
TM228	44.3	9	1.72	3.88	35.4	53.2	8.90	0.90	
TM229	23.3	9	1.19	5.12	18.6	28.0	4.70	0.93	
TM230	12.0	9	0.42	3.48	9.6	14.4	2.40	0.97	
			mean±SD	4.09	1.10		mean±SD	**0.93**	0.03
Siemens ADVIA Centaur (COB)									
TM226	185.0	19	14.50	7.84	148.0	222.0	37.00	1.05	
TM227	102.7	19	7.65	7.45	82.2	123.2	20.50	1.09	
TM228	56.2	19	3.94	7.02	45.0	67.4	11.20	1.15	
TM229	28.9	19	2.95	10.21	23.1	34.7	5.80	1.15	
TM230	12.7	17	1.31	10.29	10.2	15.2	2.50	1.03	
			mean±SD	8.56	1.57		mean±SD	**1.09**	0.05
Siemens Immulite 200, 2500 (DPD/DPF)									
TM226	221.5	11	17.22	7.77	177.2	265.8	44.30	1.26	
TM227	114.4	11	15.91	13.91	91.5	137.3	22.90	1.21	
TM228	55.6	11	5.85	10.52	44.5	66.7	11.10	1.14	
TM229	27.3	11	2.36	8.64	21.8	32.8	5.50	1.09	
TM230	14.1	11	0.97	6.88	11.3	16.9	2.80	1.14	
			mean±SD	9.54	2.79		mean±SD	**1.17**	0.07
Ortho Clinical Diag Vitros (JJC)									
TM226	161.8	4	2.22	1.37	129.4	194.2	32.40	0.92	
TM227	79.6	4	1.98	2.49	63.7	95.5	15.90	0.84	
TM228	38.8	4	0.89	2.29	31.0	46.6	7.80	0.79	
TM229	19.8	4	0.70	3.54	15.8	23.8	4.00	0.79	
TM230	10.2	4	0.39	3.78	8.2	12.2	2.00	0.83	
			mean±SD	2.69	0.98		mean±SD	**0.83**	0.05

All Methods	All Method Median	Total N	All Method Median %CV	Median LL	Median UL	Median Dmax
TM226	175.9	56	7.73	140.7	211.0	35.15
TM227	94.5	56	5.17	75.6	113.4	18.90
TM228	49.0	56	6.39	39.2	58.8	9.80
TM229	25.2	56	6.28	20.1	30.2	5.05
TM230	12.4	54	6.67	9.9	14.8	2.45
			Average			
			6.45			

Allowable CV
6.7%
Allowable Error (+/-)
20%



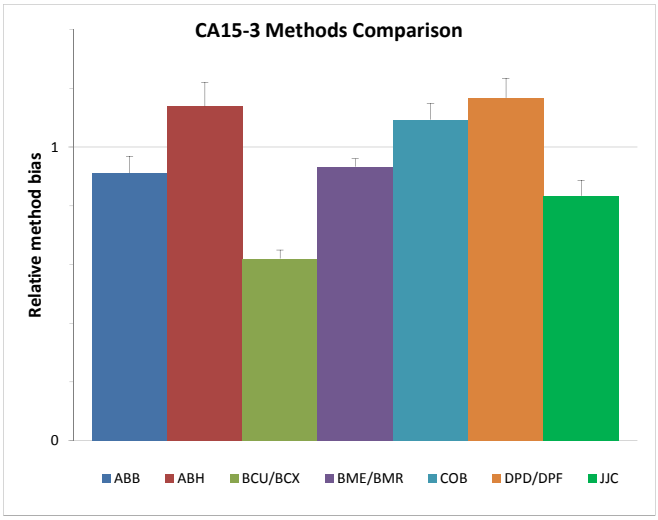


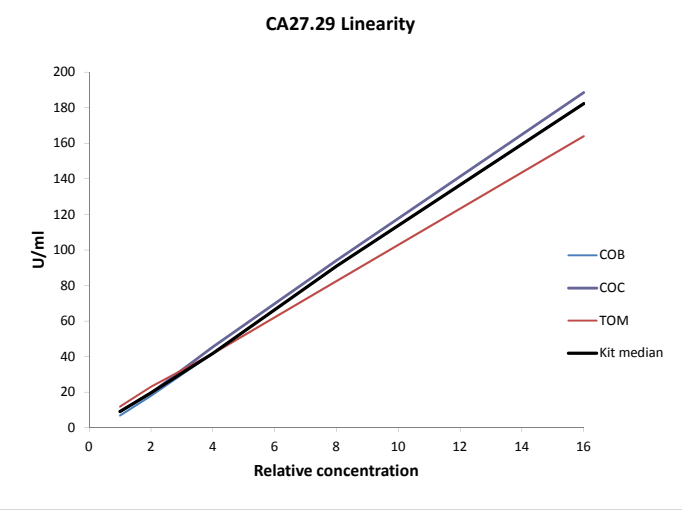
Table 4

5-11 NYS Tumor Marker PT Summary for CA27.29

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax	Relative Method Bias	
Siemens ADVIA Centaur XP (COB)									
TM226	182.2	37	9.51	5.22	149.4	215.0	32.80	1.00	
TM227	90.9	38	5.73	6.30	74.5	107.3	16.40	1.00	
TM228	41.7	38	4.67	11.19	34.2	49.2	7.50	1.00	
TM229	17.6	38	2.87	16.26	10.4	24.8	7.20	0.90	
TM230	6.8	38	3.08	45.60	0.0	14.0	7.00	0.75	
			mean±SD	16.91	16.62		mean±SD	**0.93**	0.11
Siemens ADVIA Centaur CP (COC)									
TM226	188.5	2						1.03	
TM227	94.0	2						1.03	
TM228	45.4	2						1.09	
TM229	19.5	2						1.00	
TM230	9.1	2						1.00	
							mean±SD	**1.03**	0.04
Tosoh AIA (TOM)									
TM226	164.0	8	10.15	6.19	134.5	193.5	29.50	0.90	
TM227	82.4	8	3.57	4.33	67.6	97.2	14.80	0.91	
TM228	41.5	7	0.81	1.96	34.0	49.0	7.50	0.99	
TM229	23.0	8	3.36	14.61	15.8	30.2	7.20	1.18	
TM230	11.8	8	0.82	6.94	4.6	19.0	7.20	1.30	
			mean±SD	6.81	4.77		mean±SD	**1.06**	0.18

All methods	All Method median	Total N	All Method Median %CV	Median LL	Median UL	Median Dmax
TM226	182.2	47	5.22	141.95	204.25	31.15
TM227	90.9	48	6.30	71.05	102.25	15.60
TM228	41.7	47	11.19	34.10	49.10	7.50
TM229	19.5	48	16.26	13.10	27.50	7.20
TM230	9.1	48	45.60	2.30	16.50	7.10
			Average			
			7.57			

Allowable CV if >40 U/ml
6%
Allowable Error if >40 U/ml (+/-)
18%
Allowable Errror if < 40 U/ml (+/-)
7.2 U/ml



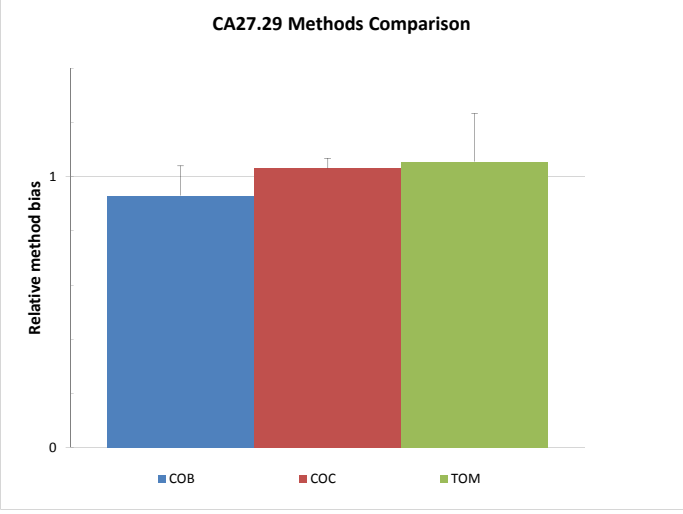


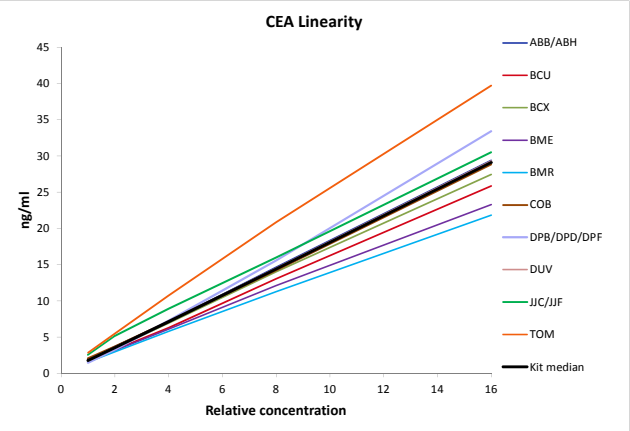
Table 5

5-11 NYS Tumor Marker PT Summary for CEA

Instrument/ Sample	Mean=Target	N	SD	%CV		LL	UL	Dmax	Relative Method Bias	
Abbott AxSYM/Architect (ABB/ABH)										
TM226	29.4	18	1.99	6.76		24.1	34.7	5.3	1.01	
TM227	14.7	18	0.93	6.37		12.1	17.3	2.6	1.02	
TM228	7.1	18	0.49	6.92		5.8	8.4	1.3	1.00	
TM229	3.7	18	0.21	5.67		3.0	4.4	0.7	1.03	
TM230	1.9	18	0.14	7.51		1.2	2.6	0.7	1.04	
			mean±SD	6.65	0.68			mean±SD	**1.02**	0.02
Beckman Unicel (BCU)										
TM226	25.9	17	1.62	6.26		21.2	30.6	4.7	0.89	
TM227	13.0	17	0.90	6.88		10.7	15.3	2.3	0.91	
TM228	6.3	17	0.35	5.63		5.2	7.4	1.1	0.88	
TM229	3.3	17	0.21	6.46		2.6	4.0	0.7	0.92	
TM230	1.7	17	0.09	5.71		1.0	2.4	0.7	0.92	
			mean±SD	6.19	0.53			mean±SD	**0.90**	0.02
Beckman Access (BCX)										
TM226	27.4	9	0.72	2.64		22.5	32.3	4.9	0.94	
TM227	14.0	9	0.44	3.14		11.5	16.5	2.5	0.98	
TM228	7.0	9	0.36	5.18		5.7	8.3	1.3	0.98	
TM229	3.5	9	0.16	4.60		2.8	4.2	0.7	0.98	
TM230	1.8	9	0.10	5.66		1.1	2.5	0.7	0.98	
			mean±SD	4.24	1.30			mean±SD	**0.97**	0.02
Roche Elecsys/Cobas 401 (BME)										
TM226	23.3	5	1.02	4.37		19.1	27.5	4.2	0.80	
TM227	12.1	5	0.48	3.97		9.9	14.3	2.2	0.84	
TM228	6.1	5	0.28	4.64		5.0	7.2	1.1	0.86	
TM229	3.2	5	0.24	7.51		2.5	3.9	0.7	0.89	
TM230	1.6	5	0.14	8.84		0.9	2.3	0.7	0.89	
			mean±SD	5.86	2.17			mean±SD	**0.86**	0.04
Roche E170/Cobas 601 (BMR)										
TM226	21.8	18	0.92	4.19		17.9	25.7	3.9	0.75	
TM227	11.3	18	0.40	3.55		9.3	13.3	2	0.78	
TM228	5.8	18	0.26	4.47		4.8	6.8	1	0.82	
TM229	3.0	18	0.16	5.48		2.3	3.7	0.7	0.84	
TM230	1.6	18	0.15	9.61		0.9	2.3	0.7	0.87	
			mean±SD	5.46	2.42			mean±SD	**0.81**	0.05
Siemens ADVIA Centaur (COB/COC)										
TM226	28.8	53	1.54	5.34		23.6	34.0	5.2	0.99	
TM227	14.2	53	0.75	5.25		11.6	16.8	2.6	0.99	
TM228	7.1	53	0.39	5.43		5.8	8.4	1.3	1.00	
TM229	3.7	53	0.22	5.89		3.0	4.4	0.7	1.05	
TM230	2.1	53	0.17	8.07		1.4	2.8	0.7	1.15	
			mean±SD	6.00	1.18			mean±SD	**1.04**	0.07
Siemens Immulite 1000, 2000, 2500 (DPB/DPD/DPF)										
TM226	33.4	19	1.82	5.45		27.4	39.4	6	1.15	
TM227	15.6	19	0.66	4.25		12.8	18.4	2.8	1.08	
TM228	7.3	19	0.62	8.55		6.0	8.6	1.3	1.02	
TM229	3.3	19	0.30	9.00		2.6	4.0	0.7	0.93	
TM230	1.5	19	0.23	15.23		0.8	2.2	0.7	0.83	
			mean±SD	8.50	4.27			mean±SD	**1.00**	0.12
Siemens Dimension (DUV)										
TM226	29.3	11	0.96	3.29		24.0	34.6	5.3	1.01	
TM227	14.5	11	0.54	3.70		11.9	17.1	2.6	1.01	
TM228	7.2	11	0.26	3.65		5.9	8.5	1.3	1.01	
TM229	3.6	11	0.15	4.07		3.0	4.2	0.6	1.02	
TM230	1.8	11	0.09	5.03		1.1	2.5	0.7	1.02	
			mean±SD	3.95	0.67			mean±SD	**1.01**	0.00
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)										
TM226	30.8	11	2.17	7.05		25.3	36.3	5.5	1.06	
TM227	15.8	11	0.69	4.39		13.0	18.6	2.8	1.10	
TM228	9.0	11	0.92	10.24		7.4	10.6	1.6	1.26	
TM229	5.3	11	0.81	15.11		4.3	6.3	1	1.49	
TM230	2.6	11	1.02	39.61		1.9	3.3	0.7	1.43	
			mean±SD	15.28	14.17			mean±SD	**1.27**	0.19
Tosoh AIA (TOM)										
TM226	39.7	7	0.85	2.14		32.6	46.8	7.1	1.37	
TM227	20.9	7	0.71	3.38		17.1	24.7	3.8	1.45	
TM228	10.8	7	0.37	3.43		8.9	12.7	1.9	1.51	
TM229	5.5	7	0.24	4.45		4.5	6.5	1	1.54	
TM230	2.8	7	0.11	3.99		2.1	3.5	0.7	1.58	
			mean±SD	3.48	0.87			mean±SD	**1.49**	0.08

All Methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax
TM226	29.1	168	4.85	23.8	34.3	5.25
TM227	14.4	168	4.11	11.8	17.0	2.6
TM228	7.1	168	5.30	5.8	8.4	1.3
TM229	3.6	168	5.78	2.9	4.2	0.7
TM230	1.8	168	7.79	1.1	2.5	0.7
			5.93			
			Average			
			5.57			

Allowable CV if > 3.5 ng/ml	
6%	
Allowable Error if > 3.5 ng/ml (+/-)	
18%	
Allowable Error if < 3.5 ng/ml (+/-)	
0.7	ng/ml



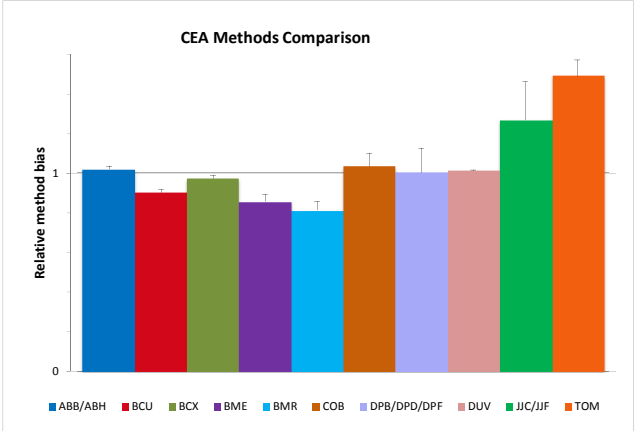


Table 6

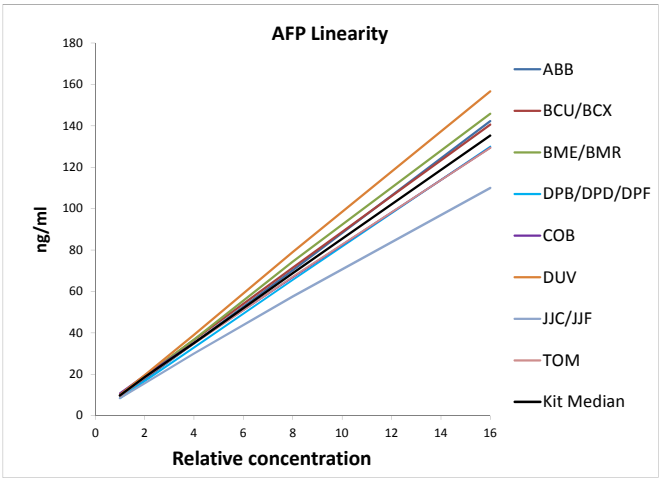
5-11 NYS Tumor Marker PT Summary for AFP

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median		Bias relative to IS target	
Abbott AxSYM (ABB)											
TM226	142.3	8	9.64	6.78	116.7	167.9	25.60	1.05		1.06	
TM227	70.4	8	5.96	8.47	57.7	83.1	12.70	1.02		1.04	
TM228	35.0	8	2.97	8.48	28.7	41.3	6.30	1.00		1.03	
TM229	17.6	8	1.51	8.59	14.4	20.8	3.20	0.95		1.02	
TM230	9.6	8	0.70	7.27	7.9	11.3	1.70	0.98		1.06	
			mean±SD	7.92	0.84		mean±SD	**1.00**	0.04	**1.04**	0.02
Beckman Unicel/Access (BCU/BCX)											
TM226	140.7	18	10.08	7.16	115.4	166.0	25.30	1.04		1.05	
TM227	71.5	18	6.48	9.06	58.6	84.4	12.90	1.04		1.06	
TM228	36.6	18	2.27	6.21	30.0	43.2	6.60	1.04		1.08	
TM229	18.9	17	0.85	4.50	15.5	22.3	3.40	1.02		1.09	
TM230	10.0	18	0.61	6.17	8.2	11.8	1.80	1.02		1.11	
			mean±SD	6.62	1.67		mean±SD	**1.03**	0.01	**1.08**	0.02
Roche Elecsys/Cobas (BME/BMR)											
TM226	145.9	15	10.84	7.43	119.6	172.2	26.30	1.08		1.09	
TM227	74.5	15	5.60	7.52	61.1	87.9	13.40	1.08		1.10	
TM228	36.8	15	3.52	9.58	30.2	43.4	6.60	1.05		1.08	
TM229	19.1	15	1.38	7.21	15.7	22.5	3.40	1.03		1.11	
TM230	10.0	15	0.68	6.79	8.2	11.8	1.80	1.02		1.11	
			mean±SD	7.71	1.08		mean±SD	**1.05**	0.03	**1.10**	0.01
Siemens ADVIA Centaur (COB)											
TM226	129.5	25	7.07	5.46	106.2	152.8	23.30	0.96		0.97	
TM227	66.9	25	4.24	6.34	54.9	78.9	12.00	0.97		0.99	
TM228	35.3	25	2.26	6.41	28.9	41.7	6.40	1.00		1.04	
TM229	19.4	25	1.43	7.38	15.9	22.9	3.50	1.04		1.12	
TM230	10.8	25	0.89	8.26	8.9	12.7	1.90	1.10		1.20	
			mean±SD	6.77	1.08		mean±SD	**1.01**	0.06	**1.06**	0.09
Siemens Immulite 1000, 2000, 2500 (DPB/DPD/DPF)											
TM226	130.0	22	5.38	4.14	106.6	153.4	23.40	0.96		0.97	
TM227	65.8	22	3.06	4.65	54.0	77.6	11.80	0.96		0.97	
TM228	33.0	22	1.22	3.69	27.1	38.9	5.90	0.94		0.97	
TM229	16.7	22	0.76	4.54	13.7	19.7	3.00	0.90		0.97	
TM230	8.5	22	0.27	3.18	7.0	10.0	1.50	0.87		0.95	
			mean±SD	4.04	0.61		mean±SD	**0.92**	0.04	**0.97**	0.01
Siemes Dimension (DUV)											
TM226	156.8	4	1.80	1.15	128.6	185.0	28.20	1.16		1.17	
TM227	79.1	4	1.12	1.41	64.9	93.3	14.20	1.15		1.17	
TM228	39.1	4	0.53	1.35	32.1	46.1	7.00	1.11		1.15	
TM229	19.7	4	0.24	1.24	16.2	23.2	3.50	1.06		1.14	
TM230	10.2	4	0.26	2.57	8.4	12.0	1.80	1.04		1.14	
			mean±SD	1.55	0.58		mean±SD	**1.10**	0.05	**1.15**	0.02
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)											
TM226	110.0	4	6.93	6.30	90.2	129.8	19.80	0.81		0.82	
TM227	57.7	4	2.92	5.05	47.3	68.1	10.40	0.84		0.86	
TM228	30.0	4	1.69	5.63	24.6	35.4	5.40	0.85		0.88	
TM229	15.7	4	0.68	4.35	12.9	18.5	2.80	0.84		0.90	
TM230	8.4	4	0.34	4.04	6.9	9.9	1.50	0.86		0.94	
			mean±SD	5.07	0.92		mean±SD	**0.84**	0.02	**0.88**	0.04
Tosoh AIA (TOM)											
TM226	129.3	4	1.12	0.87	106.0	152.6	23.30	0.96		0.97	
TM227	67.2	4	1.94	2.89	55.1	79.3	12.10	0.98		1.00	
TM228	34.8	4	1.02	2.94	28.5	41.1	6.30	0.99		1.02	
TM229	18.3	4	0.38	2.06	15.0	21.6	3.30	0.98		1.06	
TM230	9.7	4	0.21	2.16	8.0	11.4	1.70	0.98		1.07	
			mean±SD	2.18	0.84		mean±SD	**0.98**	0.01	**1.02**	0.04

All Methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	Method median/ IS Target	
TM226	135.4	100	5.88	111.0	159.7	24.35	1.01	
TM227	68.8	100	5.70	56.4	81.2	12.40	1.02	
TM228	35.2	100	5.92	28.8	41.5	6.35	1.03	
TM229	18.6	99	4.52	15.3	22.0	3.35	1.08	
TM230	9.9	100	5.10	8.1	11.6	1.75	1.09	
			Average				**1.05**	0.03
			5.42					

Allowable CV
6%
Allowable Error (+/-)
18%

IS targets	SD	%CV
133.8	9.94	7.4%
67.5	4.71	7.0%
34.0	1.69	5.0%
17.3	0.35	2.0%
9.0	0.47	5.2%



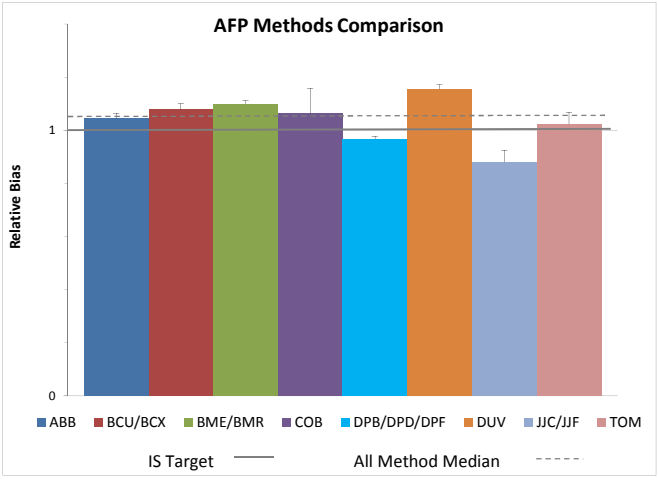


Table 7

5-11 NYS Tumor Marker PT Summary for PSA

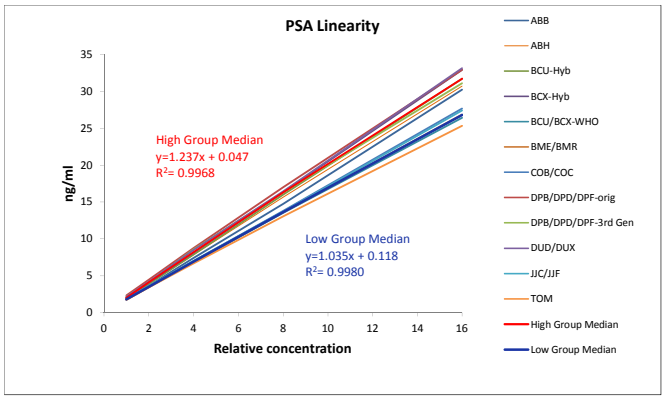
Instrument/ Sample	Mean=Target	N	SD	%CV		LL	UL	Dmax	Bias relative to all method median		Bias relative to IS target	
Abbott AxSYM (ABB)												
TM226	30.3	12	2.23	7.36		25.8	34.8	4.5	0.99		1.18	
TM227	14.8	12	0.80	5.44		12.6	17.0	2.2	0.97		1.14	
TM228	7.4	12	0.52	6.98		6.3	8.5	1.1	0.97		1.13	
TM229	3.7	12	0.17	4.75		3.1	4.3	0.6	0.97		1.12	
TM230	1.9	12	0.10	5.36		1.6	2.2	0.3	0.96		1.15	
			mean±SD	5.98	1.13			mean±SD	**0.97**	0.01	**1.14**	0.02
Abbott Architect (ABH)												
TM226	30.7	11	1.33	4.35		26.1	35.3	4.6	1.01		1.20	
TM227	15.6	11	0.84	5.35		13.3	17.9	2.3	1.03		1.20	
TM228	7.9	11	0.35	4.42		6.7	9.1	1.2	1.03		1.20	
TM229	3.9	11	0.20	5.17		3.3	4.5	0.6	1.03		1.20	
TM230	1.9	11	0.10	5.30		1.6	2.2	0.3	1.00		1.20	
			mean±SD	4.92	0.49			mean±SD	**1.02**	0.02	**1.20**	0.00
Beckman Unicel-Hybritech calibration (BCU-Hyb)												
TM226	31.7	22	1.89	5.97		26.9	36.5	4.8	1.04		1.24	
TM227	16.0	21	0.81	5.07		13.6	18.4	2.4	1.05		1.23	
TM228	7.9	22	0.40	5.11		6.7	9.1	1.2	1.04		1.21	
TM229	3.9	22	0.21	5.50		3.3	4.5	0.6	1.03		1.20	
TM230	2.0	22	0.09	4.68		1.7	2.3	0.3	1.01		1.21	
			mean±SD	5.27	0.49			mean±SD	**1.03**	0.02	**1.22**	0.02
Beckman Access-Hybritech calibration (BCX-Hyb)												
TM226	32.9	27	1.82	5.52		28.0	37.8	4.9	1.08		1.28	
TM227	16.4	27	0.77	4.70		13.9	18.9	2.5	1.08		1.26	
TM228	8.2	27	0.42	5.14		7.0	9.4	1.2	1.07		1.25	
TM229	4.1	27	0.19	4.76		3.5	4.7	0.6	1.08		1.25	
TM230	2.0	27	0.10	4.91		1.7	2.3	0.3	1.04		1.25	
			mean±SD	5.01	0.33			mean±SD	**1.07**	0.02	**1.26**	0.01
Beckman Unicel/Access WHO calibration (BCU/BCX-WHO)												
TM226	26.4	4	4.43	16.76		22.4	30.4	4	0.87		1.03	
TM227	13.5	4	1.75	12.91		11.5	15.5	2	0.89		1.04	
TM228	6.9	4	0.97	14.13		5.9	7.9	1	0.90		1.05	
TM229	3.5	4	0.43	12.52		3.0	4.0	0.5	0.92		1.07	
TM230	1.8	4	0.17	9.90		1.5	2.1	0.3	0.90		1.08	
			mean±SD	13.24	2.50			mean±SD	**0.90**	0.02	**1.05**	0.02
Roche Elecsys/Cobas (BME/BMR)												
TM226	26.8	37	0.90	3.34		22.8	30.8	4	0.88		1.04	
TM227	13.6	39	0.48	3.55		11.6	15.6	2	0.90		1.05	
TM228	6.9	36	0.17	2.44		5.9	7.9	1	0.90		1.05	
TM229	3.5	38	0.14	4.00		3.0	4.0	0.5	0.92		1.07	
TM230	1.8	39	0.08	4.37		1.5	2.1	0.3	0.91		1.09	
			mean±SD	3.54	0.74			mean±SD	**0.90**	0.02	**1.06**	0.02
Siemens ADVIA Centaur XP & CP (COB/COC)												
TM226	27.7	62	1.68	6.07		23.5	31.9	4.2	0.91		1.08	
TM227	13.8	62	1.09	7.88		11.7	15.9	2.1	0.91		1.06	
TM228	7.0	62	0.39	5.55		6.0	8.1	1.05	0.91		1.06	
TM229	3.5	62	0.21	6.02		3.0	4.0	0.5	0.94		1.09	
TM230	1.8	62	0.10	5.33		1.5	2.1	0.3	0.94		1.13	
			mean±SD	6.17	1.01			mean±SD	**0.92**	0.02	**1.08**	0.03
Siemens Immulite 1000, 2000, 2500 with original PSA pack (DPB/DPD/DPF-orig)												
TM226	32.9	24	1.94	5.89		28.0	37.8	4.9	1.08		1.28	
TM227	17.0	26	1.06	6.21		14.5	19.6	2.55	1.12		1.31	
TM228	8.8	26	0.63	7.23		7.5	10.1	1.3	1.15		1.34	
TM229	4.5	26	0.28	6.18		3.8	5.2	0.7	1.18		1.37	
TM230	2.3	26	0.24	10.43		2.0	2.6	0.3	1.20		1.44	
			mean±SD	7.19	1.88			mean±SD	**1.15**	0.05	**1.35**	0.06
Siemens Immulite 1000, 2000, 2500 with 3rd generation PSA pack (DPB/DPD/DPF-3rd gen)												
TM226	31.1	4	0.85	2.72		26.4	35.8	4.7	1.02		1.21	
TM227	16.3	5	1.00	6.15		13.9	18.7	2.4	1.07		1.26	
TM228	8.6	5	1.43	16.70		7.3	9.9	1.3	1.13		1.31	
TM229	4.1	5	0.24	5.79		3.5	4.7	0.6	1.09		1.26	
TM230	2.1	5	0.17	7.82		1.8	2.4	0.3	1.11		1.32	
			mean±SD	7.84	5.28			mean±SD	**1.08**	0.04	**1.27**	0.04
Siemens Dimension EXL, RxL Max, Xpand Plus (DUD/DUX)												
TM226	33.1	22	1.76	5.32		28.1	38.1	5	1.09		1.29	
TM227	16.5	22	0.71	4.32		14.0	19.0	2.5	1.08		1.27	
TM228	8.5	22	0.40	4.69		7.2	9.8	1.3	1.11		1.30	
TM229	4.2	22	0.17	3.99		3.6	4.8	0.6	1.11		1.29	
TM230	2.1	22	0.10	4.71		1.8	2.4	0.3	1.11		1.33	
			mean±SD	4.61	0.50			mean±SD	**1.10**	0.01	**1.29**	0.02
Ortho Clinical Diag Vitros ECi/ECiQ, 5600 (JJC/JJF)												
TM226	27.4	17	1.03	3.74		23.3	31.5	4.1	0.90		1.07	
TM227	13.7	17	0.53	3.85		11.6	15.8	2.1	0.90		1.05	
TM228	7.0	17	0.33	4.76		6.0	8.1	1.05	0.92		1.07	
TM229	3.6	16	0.13	3.66		3.1	4.1	0.5	0.95		1.10	
TM230	1.9	17	0.15	7.80		1.6	2.2	0.3	0.97		1.16	
			mean±SD	4.76	1.75			mean±SD	**0.93**	0.03	**1.09**	0.04
Tosoh AIA (TOM)												
TM226	25.3	9	1.11	4.37		21.5	29.1	3.8	0.83		0.99	
TM227	13.0	9	0.51	3.91		11.1	15.0	1.95	0.86		1.00	
TM228	6.7	9	0.28	4.19		5.7	7.7	1	0.87		1.02	
TM229	3.4	9	0.12	3.60		2.9	3.9	0.5	0.90		1.04	
TM230	1.7	9	0.08	4.84		1.4	2.0	0.3	0.89		1.06	
			mean±SD	4.18	0.47			mean±SD	**0.87**	0.03	**1.02**	0.03

All methods	All Method Median	Total N	All Method Median % CV	Median LL	Median UL	Median Dmax	Method median/ IS Target	
TM226	30.5	251	5.42	26.0	35.1	4.55	1.19	
TM227	15.2	255	5.21	13.0	17.5	2.25	1.17	
TM228	7.7	253	5.12	6.5	8.8	1.15	1.17	
TM229	3.8	254	4.97	3.2	4.4	0.6	1.16	
TM230	1.9	256	5.32	1.6	2.2	0.3	1.20	
			Average				**1.18**	0.02

High Group Median	Low Group Median
31.7	26.8
16.3	13.6
8.2	6.9
4.1	3.5
2.0	1.8

Allowable CV
5%
Allowable Error (+/-)
15%

IS targets	SD	%CV
25.7	0.93	3.6%
13.0	0.53	4.1%
6.5	0.29	4.4%
3.3	0.11	3.5%
1.6	0.07	4.1%



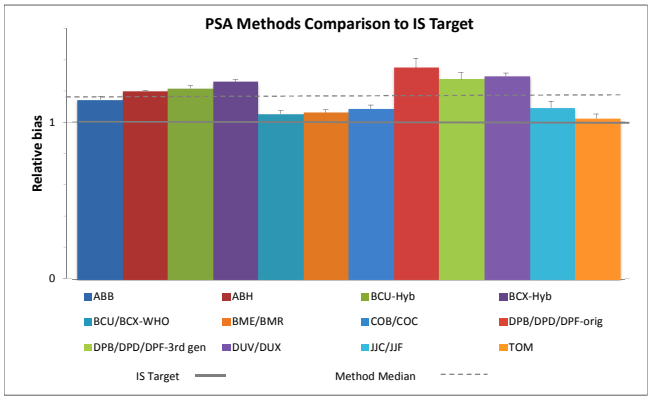


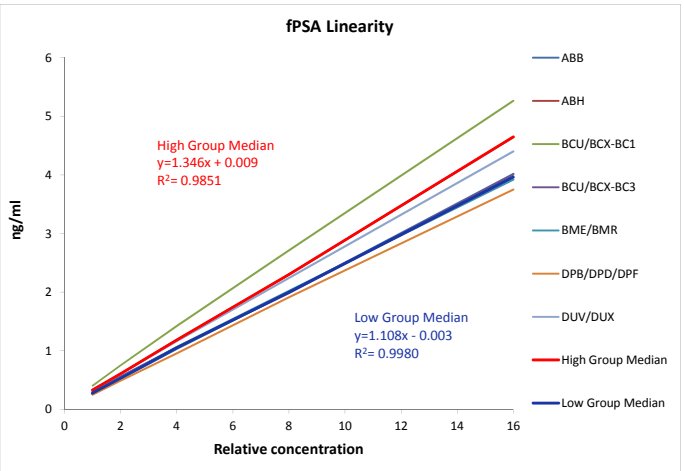
Table 8 **5-11 NYS Tumor Marker PT Summary for fPSA**

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax	Bias relative to all method median		Bias relative to IS target	
Abbott AxSYM (ABB)											
TM226	4.02	3	0.108	2.69	3.42	4.62	0.6	1.00		1.14	
TM227	2.00	3	0.111	5.57	1.70	2.30	0.3	0.99		1.11	
TM228	1.03	3	0.032	3.11	0.88	1.18	0.15	0.97		1.10	
TM229	0.52	3	0.012	2.23	0.37	0.67	0.15	0.91		1.08	
TM230	0.26	3	0.006	2.25	0.11	0.41	0.15	0.86		1.06	
			mean±SD	3.17	1.39		mean±SD	**0.95**	0.06	**1.10**	0.03
Abbott Architect (ABH)											
TM226	4.65	3	0.193	4.15	3.95	5.35	0.7	1.16		1.31	
TM227	2.30	3	0.118	5.13	1.96	2.65	0.345	1.14		1.28	
TM228	1.18	3	0.015	1.29	1.00	1.36	0.18	1.11		1.25	
TM229	0.61	3	0.006	0.95	0.46	0.76	0.15	1.07		1.27	
TM230	0.31	3	0.006	1.88	0.16	0.46	0.15	1.02		1.26	
			mean±SD	2.68	1.85		mean±SD	**1.10**	0.05	**1.28**	0.02
Beckman Unicel/Access-Hybritech calibration (BCU/BCX-Hyb)											
TM226	5.27	29	0.300	5.69	4.48	6.06	0.79	1.31		1.49	
TM227	2.71	29	0.131	4.84	2.30	3.12	0.41	1.34		1.51	
TM228	1.42	29	0.063	4.46	1.21	1.63	0.21	1.34		1.51	
TM229	0.75	29	0.050	6.62	0.60	0.90	0.15	1.33		1.58	
TM230	0.40	29	0.026	6.40	0.25	0.55	0.15	1.34		1.66	
			mean±SD	5.60	0.94		mean±SD	**1.33**	0.01	**1.55**	0.07
Beckman Unicel/Access-WHO calibration (BCU/BCX-WHO)											
TM226	4.01	2						1.00		1.13	
TM227	1.99	2						0.98		1.11	
TM228	1.06	2						1.00		1.12	
TM229	0.57	2						1.00		1.19	
TM230	0.30	2						1.00		1.24	
							mean±SD	**1.00**	0.01	**1.16**	0.05
Roche Elecsys/Cobas (BME/BMR)											
TM226	3.92	24	0.157	4.00	3.33	4.51	0.59	0.98		1.11	
TM227	2.02	24	0.082	4.07	1.72	2.32	0.3	1.00		1.13	
TM228	1.06	23	0.037	3.51	0.90	1.22	0.16	1.00		1.13	
TM229	0.54	24	0.031	5.85	0.39	0.69	0.15	0.95		1.13	
TM230	0.29	23	0.011	3.86	0.14	0.44	0.15	0.96		1.19	
			mean±SD	4.26	0.92		mean±SD	**0.98**	0.02	**1.14**	0.03
Siemens Immulite 1000, 2000, 2500 (DPB/DPD/DPF)											
TM226	3.75	16	0.271	7.22	3.19	4.31	0.56	0.93		1.06	
TM227	1.91	16	0.134	7.04	1.62	2.20	0.29	0.94		1.06	
TM228	0.95	16	0.088	9.26	0.80	1.10	0.15	0.90		1.01	
TM229	0.49	16	0.044	9.09	0.34	0.64	0.15	0.87		1.03	
TM230	0.25	16	0.034	13.43	0.10	0.40	0.15	0.84		1.04	
			mean±SD	9.21	2.58		mean±SD	**0.90**	0.04	**1.04**	0.02
Siemens Dimension EXL, RxL Max, Xpand Plus (DUD/DUX)											
TM226	4.41	6	0.122	2.77	3.75	5.07	0.66	1.10		1.25	
TM227	2.24	6	0.186	8.31	1.90	2.58	0.34	1.11		1.25	
TM228	1.16	6	0.116	9.96	0.99	1.33	0.17	1.10		1.23	
TM229	0.61	6	0.037	6.14	0.46	0.76	0.15	1.07		1.27	
TM230	0.33	6	0.016	4.90	0.18	0.48	0.15	1.11		1.37	
			mean±SD	6.42	2.82		mean±SD	**1.10**	0.01	**1.27**	0.06

All methods	All Method Median	Total N	All Method Median %CV	Median LL	Median UL	Median Dmax			All Method Median/ IS Target	
TM226	4.02	83	4.00	3.59	4.85	0.630			1.14	
TM227	2.02	83	5.57	1.81	2.45	0.320			1.13	
TM228	1.06	82	3.51	0.95	1.28	0.165			1.13	
TM229	0.57	83	5.85	0.43	0.73	0.150			1.19	
TM230	0.30	82	4.71	0.15	0.45	0.150			1.24	
			Average					mean±SD	**1.16**	0.05
	High Group Median	Low Group Median	4.73							

4.65	3.97	Allowable CV
2.30	2.00	5%
1.18	1.05	Allowable Error if > or = 1ng/ml (+/-)
0.61	0.53	15%
0.33	0.28	Allowable Error if <1ng/ml (+/-)
		0.15 ng/ml

IS Targets	SD	%CV
3.54	0.25	7.2%
1.79	0.12	6.8%
0.94	0.04	4.6%
0.48	0.03	5.3%
0.24	0.01	3.2%



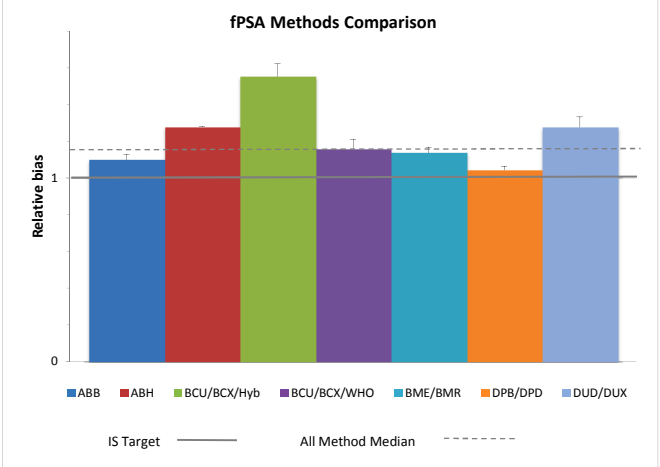
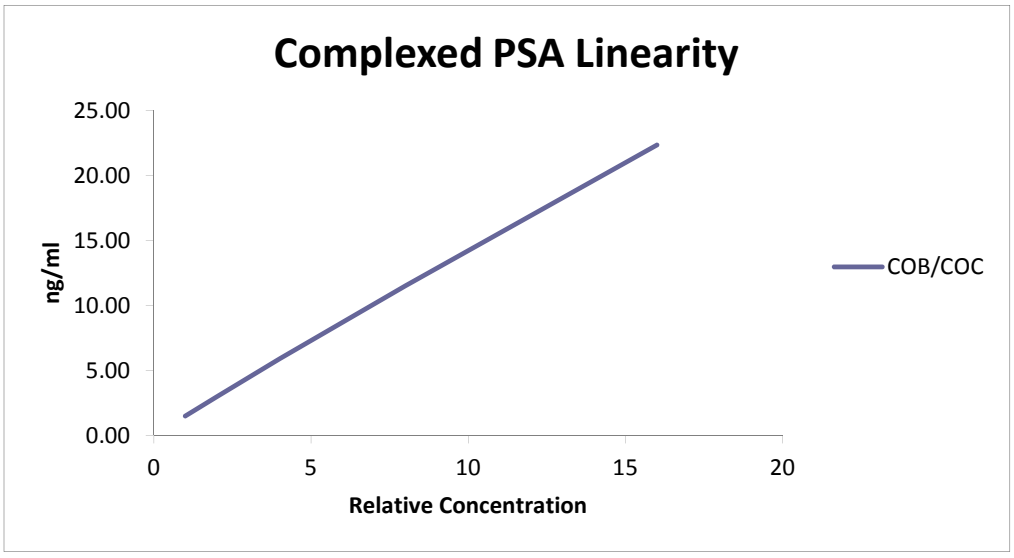


Table 9 **5-11 NYS Tumor Marker PT Summary Complexed PSA**

Instrument/ Sample	Mean=Target	N	SD	%CV	LL	UL	Dmax
Siemens ADVIA Centaur XP & CP (COB/COC)							
TM226	22.4	8	0.74	3.32	20.0	24.7	2.35
TM227	11.5	8	0.51	4.39	10.3	12.7	1.21
TM228	5.9	8	0.16	2.63	5.3	6.5	0.62
TM229	3.0	8	0.07	2.38	2.7	3.3	0.31
TM230	1.5	8	0.05	3.56	1.3	1.7	0.16

Average CV
3.26
Allowable Cv
3.5%
Allowable Error (+/-)
11%



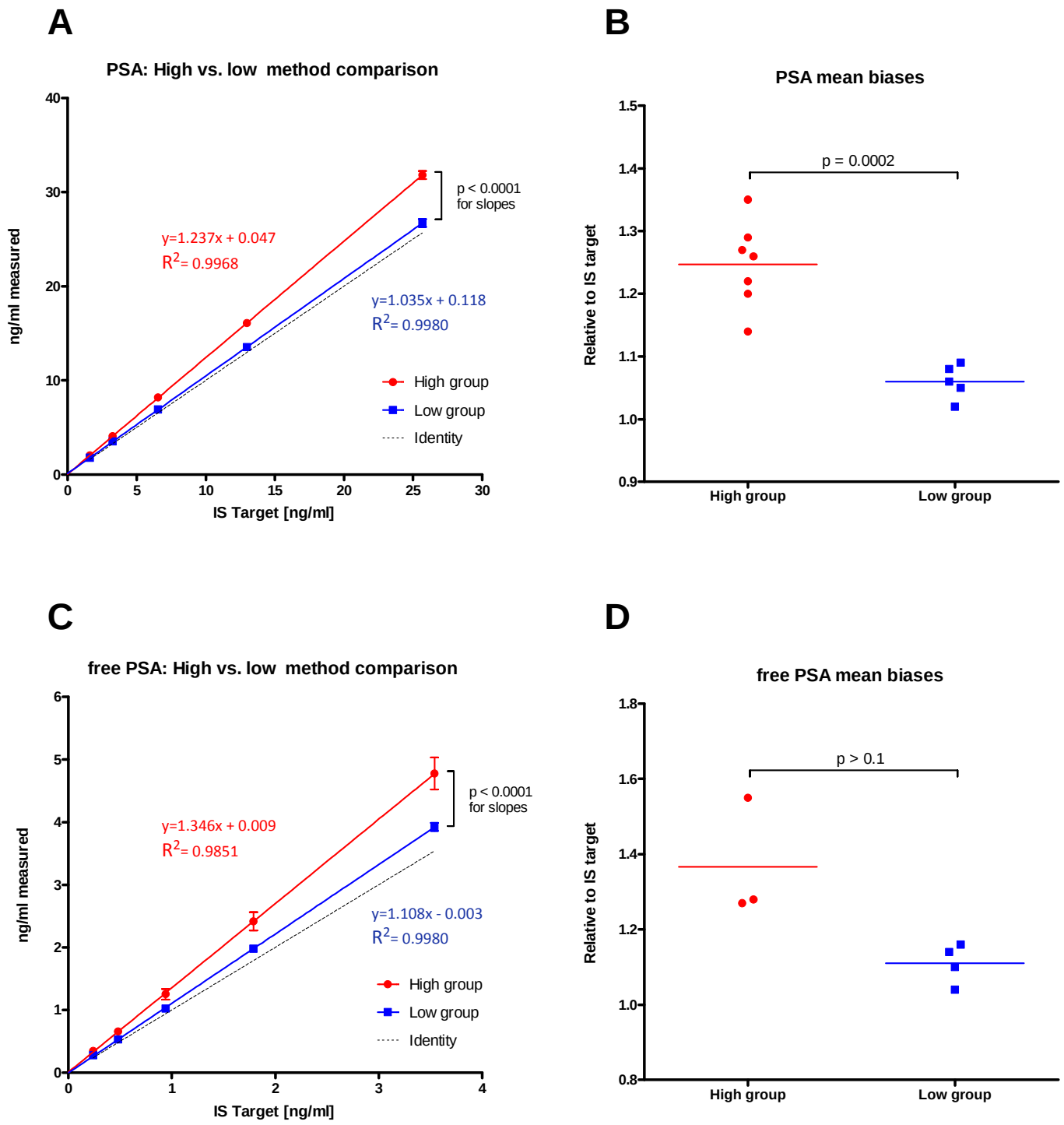


Figure 1: Grouped methods comparison for PSA (A,B) and free PSA (C,D).
Panels A, C: average measured values for PSA (A) and free PSA (C) for the high and low groups were graphed against the respective IS target values for each sample followed by linear regression. Error bars represent the standard errors of the mean and are shown unless smaller than the symbols. Panels B, D: scatter plots of each method's average bias relative to the respective IS target values. Individual points represent the means from individual methods, the lines represent the means of each group.

**********PLEASE NOTE**********

INSTRUCTIONS CAN NOW BE FOUND AT
http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm

Oncology Soluble Tumor Markers
Worksheet Only - Do Not Mail

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker						
		TM226	TM227	TM228	TM229	TM230
AFP (ng/ml)	>/<					
	Result					
	Interpretation					
CA 125 (U/ml)	>/<					
	Result					
	Interpretation					
CA 15-3 (U/ml)	>/<					
	Result					
	Interpretation					
CA 19-9 (U/ml)	>/<					
	Result					
	Interpretation					
CA 27.29 (U/ml)	>/<					
	Result					
	Interpretation					
CEA (ng/ml)	>/<					
	Result					
	Interpretation					
PSA (Total) (ng/ml)	>/<					
	Result					
	Interpretation					

Oncology Soluble Tumor Markers
Worksheet Only - Do Not Mail

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker						
		TM226	TM227	TM228	TM229	TM230
Complexed PSA (ng/ml)	>/<					
	Result					
	Interpretation					
PSA (Total) for a 2nd method used in conjunction with free PSA (ng/mL)	>/<					
	Result					
	Interpretation					
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

****