NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

September 11, 2012

IMPORTANT INSTRUCTIONS—PLEASE READ

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 26, 2012**

Samples:
Enclosed are five sealed (5) vials labeled **TM246 to TM250**, 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 GI 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, however, labs are no longer required to calculate % free PSA. 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.

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.

If a test is Temporarily Suspended, 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 indicated in the appropriate box at the bottom of the event menu page.

If a test is permanently 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 **Event Menu** page also 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 make sure 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 even in test failure if your results get evaluated with the incorrect method group.

We are also now asking for the Reagent and Calibrator lot numbers for those used when testing the PT samples. Please enter this on the Event Menu page under the Instrument and Reagent Names.

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.

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.

Results must be submitted electronically before 11:59 PM on September 26, 2012. It is advisable to submit earlier to allow time to resolve any problem that could occur with result submission. 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 by email as soon as possible before the due date** to see if this can be arranged.

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

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

The tentative 2013 Oncology Tumor Marker Proficiency Test schedule is:

Mail-out date:	Due date:
January 29, 2013	**February 13, 2013**
May 7, 2013	**May 22, 2013**
September 10, 2013	**September 25, 2013**

Refer to: http://www.wadsworth.org/labcert/clep/PT/ptindex.html

This document and the worksheet can also be found on our website at:

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

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

Sue Kelly
Executive Deputy Commissioner

Date: October 22, 2012

New York State Tumor Marker Proficiency Test 9-2012 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from September 2012 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 (please note the recent change in report format):

Your laboratory's individual results, scores and grade plus scores from the previous two PT events with your overall performance status are displayed on a separate report that has been securely posted on the Department's Health Commerce System site:

https://commerce.health.state.ny.us/doh2/applinks/eptrs/

Laboratory contacts should have already received an email alert indicating the availability of that report.

This critique along with its summary tables and graphs is sent by email to laboratory contacts and will also be posted on our section's website:

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

Additionally, it can be accessed through the "Statistical" link from the Health Commerce site.

Please **review, print 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.

[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.

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 that 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, unless indicated otherwise, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, except where the linear regression line between the results from two instruments showed a significant ($p<0.01$) deviation from identity. 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 next to the range for each sample. 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 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 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 **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 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 all analytes, summary tables give the targets and acceptable ranges for each sample and peer group (if N >2). 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 the individual peer group 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 bias towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, we calculated these values relative to the assigned target values (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:

CA125 (Table 1, Figure 1): Results were reported by 114 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of them included ten or more labs each, together comprising 86% of the labs. Five peer groups, comprising 64% of the labs, gave results within +/-15% of the all method medians. Of the other groups, Siemens Immulite was -16% from the median, while on the other side, Abbott AxSYM and Architect (grouped together) were 18% above the median on average. TOSOH ST-AIA (used by five labs representing about 4% of the participants) was the highest biased method averaging 47% above the all method medians.

CA19-9 (Table 2, Figure 2): Results were reported by 70 labs using instruments from five different manufacturers corresponding to five peer groups. Sample TM247 was a blank for this analyte and therefore was not included in the calculations and was deemed non-gradable on the evaluations; thus, all labs received pass credit (P/C) for this sample. Fifty-one percent of all reporting labs used Siemens ADVIA-Centaur XP, 17% used either Beckman's Unicel or Access/2, 19% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 7% used the Tosoh ST-AIA method. As seen with previous PT's, there were large differences in how each method measured CA19-9, ranging from 64% to 617% of the all method median. Measurements by Tosoh ST-AIA were lower than the medians by an average of 36%, whereas on the opposite side, the results from the Siemens ADVIA-Centaur XP were on average 99% higher than the all method median. Notably, the Abbott Architect method (used by only 2 labs) gave measurements for CA19-9 averaging over six times higher than the all method medians, which has been consistently seen with previous CA19-9 NYS PT results by this method as well as the latest CAP results (TM-B 2012). Looking at the results from all the methods, there continues to be 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 107 labs, with slightly more than half (57%) using an instrument from one of six manufacturers to measure **CA15-3** (Table 3, Figure 3) and the remainder using an instrument from one of two manufacturers to measure **CA27.29** (Table 4, Figure 4). Abbott, Roche, Siemens ADVIA and Ortho Clinical were within +/-10% of the all method median and together comprise 77% of the labs measuring CA15-3. Of the other two, Siemens Immulite 2000 & 2500 systems (used by 16% of labs) averaged +25% compared to the medians, while the Beckman Unicel/Access results exhibited a notable negative bias, averaging -35% from the all method medians. In contrast, **CA27.29** measurements showed only a 12% difference between the ADVIA Centaur XP/CP and the Tosoh methods.

CEA (Table 5, Figure 5): Results were reported by 169 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 50 labs. Overall, the results reported by the majority of the labs (70%) were fairly consistent, being within +/-10% of the medians. There were three exceptions however: the Roche methods averaged 32% below the medians, the Siemens Dimension Vista method measured 17% lower than the medians on average and the TOSOH ST-AIA method exhibited a high positive bias averaging 52% higher than the medians.

For **AFP, PSA and free 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, but the graphs only show the performance relative to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 102 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to twenty-two percent of the total number of labs. Most methods gave results between 0% and +15% of the assigned targets. Abbott AxSYM and Roche groups, however, were 18% and 27% higher, respectively, while the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants) was the lowest with results 11% below the assigned target and 19% below the all method median. These results are similar to what has been observed in previous PT events for these methods.

PSA (Table 7, Figure 7): Results were reported by 259 labs using instruments from eleven different manufacturers comprising eleven peer groups and two additional methods that had results from only one lab each. Three of the peer groups comprised fewer than ten members each, but together made up 7% of the labs. The five samples were all prepared with varied concentrations of total PSA but with the same proportion of 10% free PSA. While there were substantial differences between methods as seen in previous PTs, there was not the clear separation into high and low groups that was observed in past events. Nevertheless and as seen previously, the highest results came from the Beckman Unicel/Access with the Hybritech calibration and Siemens Dimension RxL Max/Xpand Plus/EXL groups, both of which were 26% above the assigned targets; results from the Abbott and Siemens Dimension Vista groups were 18% and 17% above the assigned targets, respectively, whereas results from the Siemens Immulite 3rd Generation Pack and Ortho Clinical Vitros were 8% and 9% **lower** than the assigned targets, respectively. The rest of the methods all fell within 0% and +15% of the assigned targets.

A clear difference is consistently seen between the Beckman groups, as those calibrated using the original Hybritech standard measured on average 26% higher than the targets, while those calibrated with the international WHO standard measured the closest to and essentially at the assigned target levels. This 25% observed 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). In conclusion, the differences seen across methods are significant and mostly consistent with what is seen in patient samples.

Free PSA (Table 8, Figure 8): Results were reported by 85 labs using instruments from six manufacturers corresponding to six peer groups. Three peer groups comprised less than 10 labs each and three other methods had only one or two labs reporting results, altogether making up 19% of the participants. The remaining four methods were used by 31% (Beckman Unicel/Access calibrated with the Hybritech standards), 28% (Roche Elecsys/E170/Cobas) and 25% (Siemens Immulite 1000 and 2000) of labs, respectively. As seen in previous PTs, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained with the rest of the methods (62% above the targets and 39% higher than the all method medians), while there were not enough results from Beckman Access and Unicel calibrated with the WHO standards to allow a comparison to the other methods. The Siemens Dimension RxL Max/Xpand Plus and Abbott Architect results were 24% and 33% above the targets, respectively, and 10% and 15% above the all method medians. The Roche

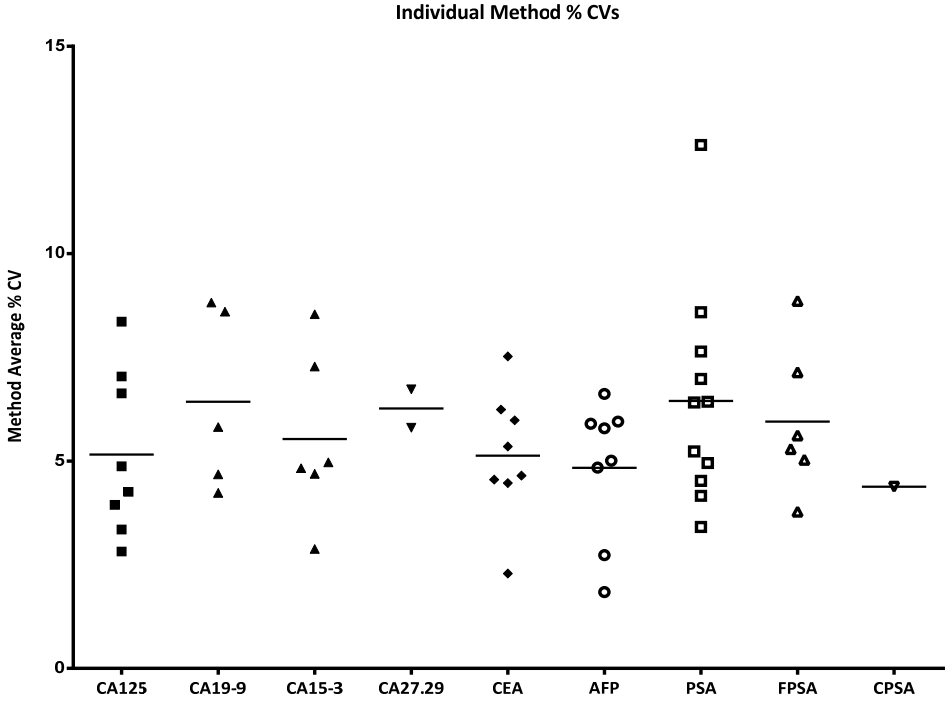
instruments ran an average of 16% above the targets, while Siemens Immulite 1000/2000 and Dimension Vista instruments averaged 9% and 3% above the assigned targets, respectively. In conclusion, there are still substantial differences in how free PSA is measured, and the various methods do not fall into clearly defined high and low groups. Furthermore, not every method that is high for total PSA is also high for free PSA.

The average calculated %free PSA values ranged from a low of 9% with the Siemens Dimension Vista to a high of 13.1% with the Beckman Hybritech methods. However, within one method, the ratios of free to total PSA were relatively constant. As would be expected, a higher % free PSA was derived either from a comparatively lower total or a comparatively higher free PSA measurement. Beckman Access/Unicel showed an inverse relationship between the %free PSA and the total PSA levels, meaning that as the total PSA levels went up from 1.1 to 13.6 ng/ml, the % free PSA values decreased from 14.5 to 12.4%. The other methods had relatively constant % free PSA values across the variable total PSA levels.

Please note, labs are required to measure and report **free PSA** for **all proficiency test samples** if they test for free PSA. 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.

Finally, 12 labs measured **complexed PSA** and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little different between them. Overall, excellent agreement between the labs was seen as evidenced by an average %CV of 4.38% (Table 9). Of note is the observation that calculated % complexed PSA increased with increasing total PSA levels.

In conclusion, there remain substantial differences between the results obtained with various methods or instruments for some of the analytes. Furthermore, not all methods appear equally reproducible as indicated by the spread of the average within method %CVs, though these were in general <10%.



The graph to the left shows the average %CV distribution for each analyte, with individual symbols representing separate peer groups.

While some of these differences may be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We make every effort to minimize the differences that can be attributed to the sample composition and suggest that despite the somewhat artificial nature of the PT samples, the 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 were **submitted**. If results were **saved** but not submitted, they received an administrative **fail**.

Please be aware that in each subsequent PT event the Instrument and Reagent fields will usually be pre-populated based on what was previously entered, but keep in mind it is still necessary to confirm ALL instruments and reagents have been correctly entered. That information is necessary to properly evaluate your results and compare them to those of your peer group. There have been instances where individual labs either **selected a qualifier (< or >) inadvertently or chose an incorrect instrument or reagent** while scrolling through the electronic reporting page lists. This can result in 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 after the submission deadline.

The PSA for a 2nd method analyte option allows labs to enter results from a second PSA assay if a different or additional method for total PSA is used in conjunction with their free PSA measurements**.** If only one PSA test was done, then results should **only** be entered in the first PSA (Total) entry line and "Test Not Offered" should be selected for the PSA for a 2nd method. For labs that enter two PSA tests, the primary PSA method gets entered on the first PSA line and the secondary (used in conjunction with their free PSA results) on the PSA for a 2nd method 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 scheduled dates for the 2013 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
January 29, 2013	February 13, 2013
May 7, 2013	May 22, 2013
September 10, 2013	September 25, 2013

If you have any questions or wish to discuss some of the issues alluded to in this critique, 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: 9-12 NYS Tumor Marker PT Summary for CA 125

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott AxSYM & Architect ABB/ABH									
TM246	12	17.3	**9.8**	**27.9**	9.1	9.71		1.20	
TM247	12	38.7	**31.7**	**53.9**	11.1	9.43		1.16	
TM248	12	51.7	**42.4**	**72.0**	14.8	8.90		1.18	
TM249	11	55.5	**45.5**	**77.3**	15.9	3.62		1.18	
TM250	12	39.4	**32.3**	**54.9**	11.3	10.13		1.17	
					mean ±SD	8.36	2.68	1.18	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM246	11	14.1	**6.6**	**24.1**	8.8	9.36		0.98	
TM247	11	36.7	**30.1**	**51.1**	10.5	7.33		1.10	
TM248	11	47.8	**39.2**	**66.6**	13.7	5.59		1.09	
TM249	11	52.0	**42.6**	**72.5**	14.9	4.27		1.11	
TM250	11	37.2	**30.5**	**51.8**	10.6	6.61		1.10	
					mean ±SD	6.63	1.91	1.08	0.06
Roche Elecsys & Cobas BME/BMR									
TM246	17	14.1	**6.6**	**24.1**	8.8	6.81		0.98	
TM247	16	29.6	**22.1**	**42.4**	10.2	3.11		0.89	
TM248	16	37.8	**31.0**	**52.6**	10.8	2.33		0.86	
TM249	17	39.0	**32.0**	**54.3**	11.2	4.26		0.83	
TM250	16	29.0	**21.5**	**41.7**	10.1	3.21		0.86	
					mean ±SD	3.94	1.74	0.89	0.06
Siemens Advia Centaur XP & CP COB/COC									
TM246	34	14.7	**7.2**	**24.8**	8.8	5.31		1.02	
TM247	35	34.5	**27.0**	**48.0**	10.5	5.74		1.04	
TM248	35	44.6	**36.6**	**62.1**	12.7	4.08		1.02	
TM249	35	47.4	**38.9**	**66.0**	13.5	4.35		1.01	
TM250	35	34.5	**27.0**	**48.0**	10.5	4.87		1.02	
					mean ±SD	4.87	0.68	1.02	0.01
Siemens Immulite 2000 & 2500 DPD									
TM246	23	11.1	**3.6**	**20.6**	8.5	8.74		0.77	
TM247	23	28.1	**20.6**	**40.7**	10.1	5.41		0.85	
TM248	23	37.6	**30.8**	**52.4**	10.8	6.73		0.86	
TM249	23	41.2	**33.8**	**57.3**	11.8	7.04		0.88	
TM250	23	29.0	**21.5**	**41.7**	10.1	7.28		0.86	
					mean ±SD	7.04	1.19	0.84	0.04
Siemens Diag Dimension Vista (LOCI) DUV									
TM246	3	16.2	**8.7**	**26.6**	9.0	1.91		1.13	
TM247	3	30.9	**23.4**	**43.1**	9.8	1.46		0.93	
TM248	3	39.7	**32.6**	**55.2**	11.3	4.33		0.91	
TM249	3	39.6	**32.5**	**55.1**	11.3	4.04		0.85	
TM250	3	29.8	**22.3**	**41.5**	9.6	2.35		0.88	
						2.82	1.29	0.94	0.11
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM246	7	13.2	**5.7**	**23.1**	8.7	4.85		0.92	
TM247	7	32.0	**24.5**	**44.6**	10.1	2.47		0.96	
TM248	7	42.8	**35.1**	**59.6**	12.2	2.71		0.98	
TM249	7	46.3	**38.0**	**64.4**	13.2	3.56		0.99	
TM250	7	33.0	**25.5**	**45.9**	10.2	3.15		0.98	
					mean ±SD	3.35	0.94	0.96	0.03

continued on next page

Table 1 (cont.): 9-12 NYS Tumor Marker PT Summary for CA 125

Tosoh AIA TOM									
TM246	5	21.6	**14.1**	**33.0**	9.5	3.33		1.50	
TM247	5	49.7	**40.8**	**69.1**	14.2	4.29		1.49	
TM248	5	65.1	**53.4**	**90.6**	18.6	5.01		1.49	
TM249	5	67.1	**55.0**	**93.5**	19.2	4.38		1.43	
TM250	5	48.6	**39.9**	**67.6**	13.9	4.28		1.44	
					mean ±SD	4.26	0.60	1.47	0.03

Sample ID	N	All Method Median	Median % CV
TM246	**109**	**14.4**	**6.06**
TM247	**109**	**33.3**	**4.85**
TM248	**109**	**43.7**	**4.67**
TM249	**109**	**46.9**	**4.26**
TM250	**109**	**33.8**	**4.57**
		Average	**4.88**
		Allowable CV %	**6.0**
		Allowable Error if >/= 35 U/ml (+/-) %	**18.0**
		Allowable Error if < 35 U/ml (+/- U/ml)	**7.5**

Figure 1: CA 125 Method Comparison

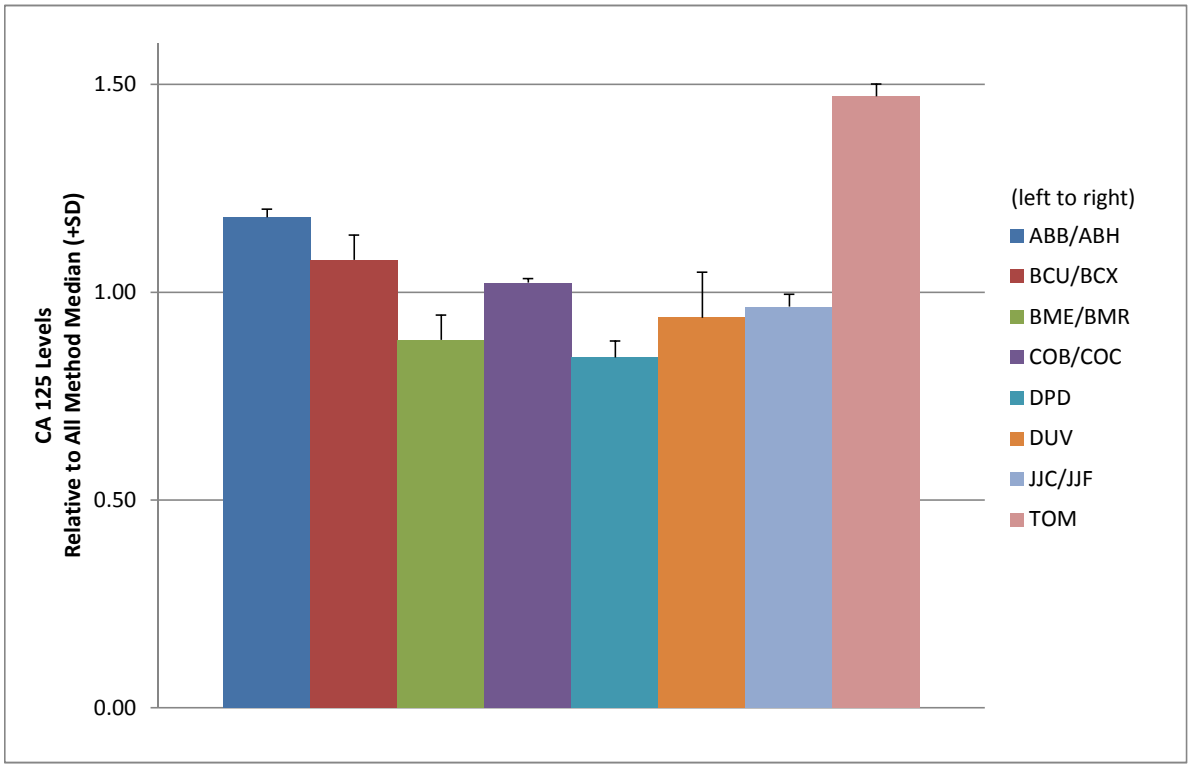


Table 2: 9-12 NYS Tumor Marker PT Summary for CA 19-9

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect ABH									
TM246	2	172.2	**141.2**	**203.2**	31.0	7.72		6.04	
TM247		NG							
TM248	2	342.9	**281.2**	**404.6**	61.7	11.03		5.97	
TM249	2	252.4	**207**	**297.8**	45.4	6.30		6.44	
TM250	2	215.4	**176.6**	**254.2**	38.8	10.24		6.21	
					mean ±SD*	8.82	2.20	6.17	0.21
Beckman Unicel & Access/2 BCU/BCX									
TM246	12	28.5	**23.4**	**33.6**	5.1	6.77		1.00	
TM247		NG							
TM248	12	57.4	**47.1**	**67.7**	10.3	5.85		1.00	
TM249	12	39.2	**32.1**	**46.3**	7.1	5.46		1.00	
TM250	12	34.7	**28.5**	**40.9**	6.2	5.19		1.00	
					mean ±SD*	5.82	0.69	1.00	0.00
Roche Elecsys & Cobas BME/BMR									
TM246	13	23.9	**19.6**	**28.2**	4.3	6.15		0.84	
TM247		NG							
TM248	13	44.6	**36.6**	**52.6**	8.0	7.76		0.78	
TM249	13	31.4	**25.7**	**37.1**	5.7	7.55		0.80	
TM250	13	26.9	**22.1**	**31.7**	4.8	12.94		0.78	
					mean ±SD*	8.60	2.98	0.80	0.03
Siemens Advia Centaur XP COB									
TM246	34	55.7	**45.7**	**65.7**	10.0	4.63		1.95	
TM247		NG							
TM248	34	118.8	**97.4**	**140.2**	21.4	4.19		2.07	
TM249	36	78.0	**64**	**92.0**	14.0	4.97		1.99	
TM250	35	66.9	**54.9**	**78.9**	12.0	4.93		1.93	
					mean ±SD*	4.68	0.36	1.99	0.06
Tosoh AIA TOM									
TM246	5	19.9	**16.3**	**23.5**	3.6	4.97		0.70	
TM247		NG							
TM248	5	35.1	**28.8**	**41.4**	6.3	3.16		0.61	
TM249	5	24.1	**19.8**	**28.4**	4.3	3.65		0.61	
TM250	5	22.2	**18.2**	**26.2**	4.0	5.14		0.64	
					mean ±SD*	4.23	0.97	0.64	0.04

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Table 2 (cont.): 9-12 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM246	66	28.5	6.15
TM247			
TM248	66	57.4	5.85
TM249	68	39.2	5.46
TM250	67	34.7	5.19
		Average*	5.66
		Allowable CV %	6.0
		Allowable Error (+/-)%	18.0

* = TM247 excluded
NG = non-gradable

Figure 2: CA 19-9 Method Comparison

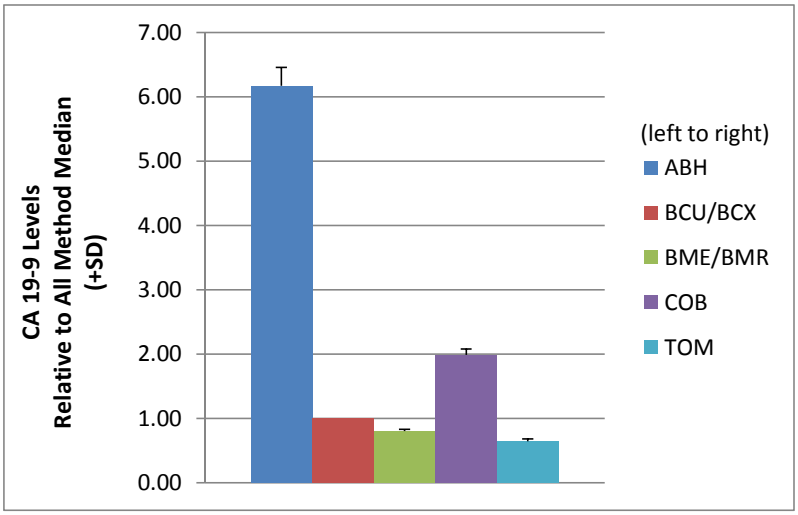

Table 3: 9-12 NYS Tumor Marker PT Summary for CA 15-3

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott AxSYM & Architect ABB/ABH									
TM246	7	67.1	**55.0**	**79.2**	12.1	8.91		0.99	
TM247	7	70.7	**58.0**	**83.4**	12.7	4.07		1.02	
TM248	7	70.4	**57.7**	**83.1**	12.7	4.76		1.01	
TM249	7	33.9	**27.8**	**40.0**	6.1	3.45		1.01	
TM250	7	47.8	**39.2**	**56.4**	8.6	2.95		1.02	
					mean ±SD	4.83	2.38	1.01	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM246	4	43.6	**35.8**	**51.4**	7.8	4.43		0.64	
TM247	4	46.0	**37.7**	**54.3**	8.3	4.20		0.66	
TM248	4	46.4	**38.0**	**54.8**	8.4	5.02		0.66	
TM249	4	21.4	**17.5**	**25.3**	3.9	3.83		0.64	
TM250	4	29.7	**24.4**	**35.0**	5.3	5.99		0.63	
					mean ±SD	4.69	0.85	0.65	0.01
Roche Elecsys & Cobas BME/BMR									
TM246	10	67.2	**55.1**	**79.3**	12.1	2.56		0.99	
TM247	12	67.3	**55.2**	**79.4**	12.1	2.67		0.97	
TM248	11	69.3	**56.8**	**81.8**	12.5	1.92		0.99	
TM249	12	33.0	**27.1**	**38.9**	5.9	3.48		0.99	
TM250	12	46.0	**37.7**	**54.3**	8.3	3.74		0.98	
					mean ±SD	2.88	0.74	0.98	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM246	21	72.1	**59.1**	**85.1**	13.0	6.92		1.06	
TM247	21	73.5	**60.3**	**86.7**	13.2	8.20		1.06	
TM248	21	74.2	**60.8**	**87.6**	13.4	7.53		1.06	
TM249	21	35.3	**28.9**	**41.7**	6.4	6.01		1.06	
TM250	21	49.7	**40.8**	**58.6**	8.9	7.73		1.06	
					mean ±SD	7.28	0.85	1.06	0.00
Siemens Immulite 2000 DPD									
TM246	9	86.8	**71.2**	**102.4**	15.6	4.64		1.27	
TM247	9	87.5	**71.8**	**103.3**	15.8	9.22		1.26	
TM248	9	88.4	**72.5**	**104.3**	15.9	8.30		1.27	
TM249	9	40.8	**33.5**	**48.1**	7.3	9.09		1.22	
TM250	9	56.5	**46.3**	**66.7**	10.2	11.43		1.20	
					mean ±SD	8.54	2.47	1.25	0.03
Ortho Clinical Diag Vitros Eci/ECiQ JJC									
TM246	3	69.0	**56.6**	**81.4**	12.4	0.09		1.01	
TM247	4	67.8	**55.6**	**80.0**	12.2	5.78		0.98	
TM248	4	68.9	**56.5**	**81.3**	12.4	6.34		0.99	
TM249	4	32.0	**26.2**	**37.8**	5.8	6.72		0.96	
TM250	4	45.5	**37.3**	**53.7**	8.2	5.91		0.97	
					mean ±SD	4.97	2.75	0.98	0.02

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Table 3 (cont.): 9-12 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM246	54	68.10	4.53
TM247	57	69.25	4.99
TM248	56	69.85	5.68
TM249	57	33.45	4.92
TM250	57	46.90	5.95
		Average	5.22
		Allowable CV %	6.0
		Allowable Error (+/-)%	18.0

Figure 3: CA 15-3 Method Comparison

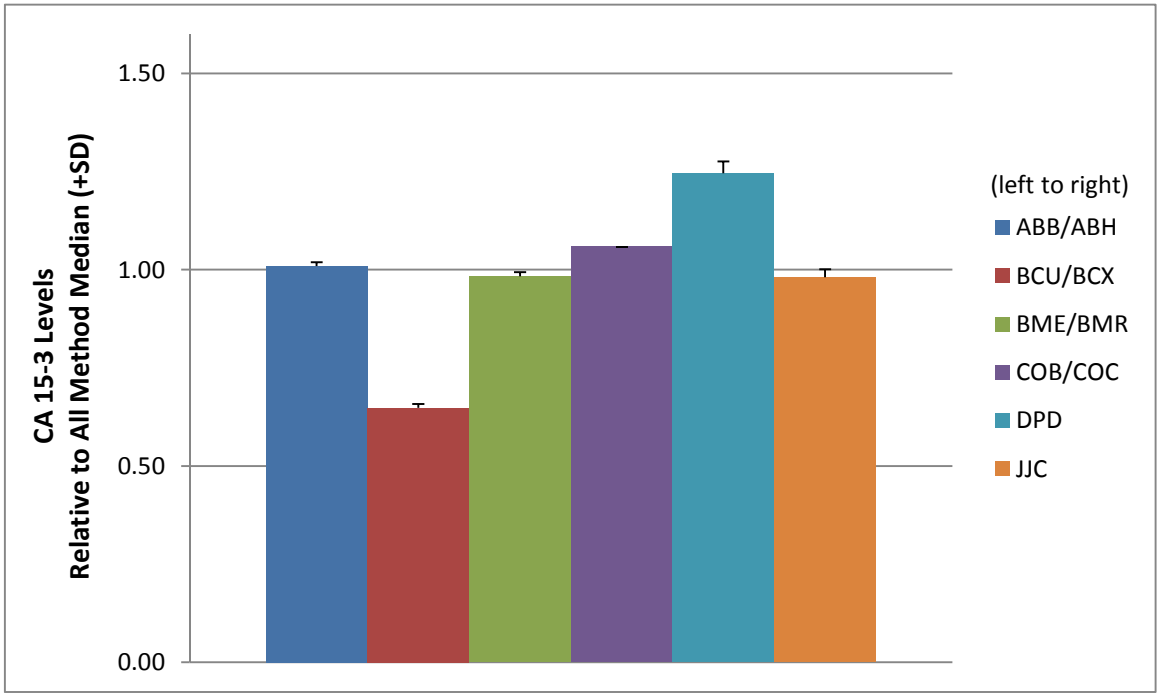

Table 4: 9-12 NYS Tumor Marker PT Summary for CA 27.29

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Siemens Advia Centaur XP & CP COB/COC									
TM246	43	82.5	**65.2**	**99.8**	17.3	4.90		1.09	
TM247	43	85.1	**67.2**	**103.0**	17.9	4.98		1.10	
TM248	42	85.4	**67.5**	**103.3**	17.9	3.99		1.08	
TM249	43	35.4	**28.0**	**42.8**	7.4	8.53		1.00	
TM250	43	55.7	**44.0**	**67.4**	11.7	6.61		1.07	
					mean ±SD	5.80	1.79	1.07	0.04
Tosoh AIA TOM									
TM246	6	69.1	**54.6**	**83.6**	14.5	7.83		0.91	
TM247	6	69.1	**54.6**	**83.6**	14.5	5.98		0.90	
TM248	6	72.3	**57.1**	**87.5**	15.2	7.41		0.92	
TM249	6	35.7	**28.2**	**43.2**	7.5	7.34		1.00	
TM250	6	48.3	**38.2**	**58.4**	10.1	5.07		0.93	
					mean ±SD	6.73	1.16	0.93	0.04

Sample ID	N	All Method Median	Median % CV
TM246	**49**	**75.80**	**6.36**
TM247	**49**	**77.10**	**5.48**
TM248	**48**	**78.85**	**5.70**
TM249	**49**	**35.55**	**7.94**
TM250	**49**	**52.00**	**5.84**
		Average	**6.26**
		Allowable CV %	**7.0**
		Allowable Error if >/= 35 U/ml (+/-) %	**21.0**
		Allowable Error if < 35 U/ml (+/- U/ml)	**7.5**

Figure 4: CA 27.29 Method Comparison

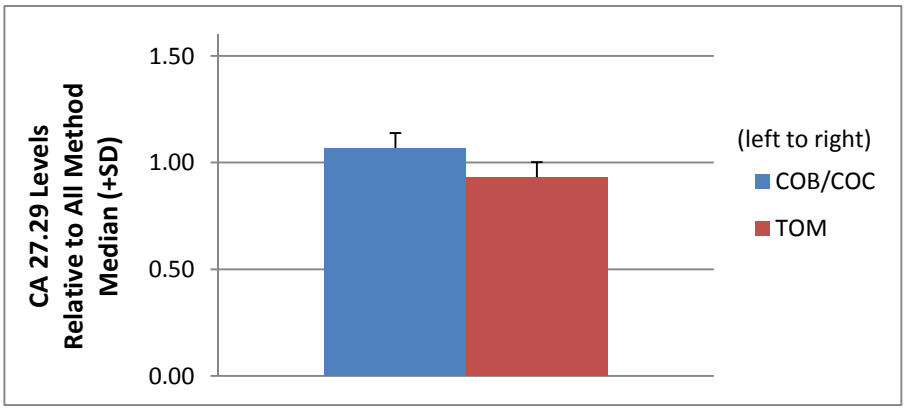

Table 5: 9-12 NYS Tumor Marker PT Summary for CEA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott AxSYM & Architect ABB/ABH									
TM246	15	21.9	**18**	**25.8**	3.9	6.99		1.00	
TM247	15	23.6	**19.4**	**27.8**	4.2	5.42		1.01	
TM248	15	21.3	**17.5**	**25.1**	3.8	7.75		1.00	
TM249	15	11.5	**9.4**	**13.6**	2.1	6.35		0.99	
TM250	15	23.8	**19.5**	**28.1**	4.3	4.71		1.01	
					mean ±SD	6.24	1.21	1.00	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM246	24	21.1	**17.3**	**24.9**	3.8	5.92		0.97	
TM247	23	22.6	**18.5**	**26.7**	4.1	3.10		0.97	
TM248	24	20.4	**16.7**	**24.1**	3.7	5.49		0.96	
TM249	24	11.3	**9.3**	**13.3**	2.0	4.42		0.97	
TM250	24	22.3	**18.3**	**26.3**	4.0	4.30		0.94	
					mean ±SD	4.65	1.11	0.96	0.01
Roche Elecsys & Cobas BME/BMR									
TM246	23	14.5	**11.9**	**17.1**	2.6	5.66		0.66	
TM247	23	15.3	**12.5**	**18.1**	2.8	4.51		0.65	
TM248	23	14.3	**11.7**	**16.9**	2.6	4.55		0.67	
TM249	21	8.2	**6.7**	**9.7**	1.5	3.29		0.71	
TM250	23	16.3	**13.4**	**19.2**	2.9	4.72		0.69	
					mean ±SD	4.55	0.84	0.68	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM246	50	22.0	**18**	**26**	4.0	5.68		1.01	
TM247	50	23.9	**19.6**	**28.2**	4.3	5.73		1.02	
TM248	50	21.2	**17.4**	**25**	3.8	5.57		1.00	
TM249	50	11.8	**9.7**	**13.9**	2.1	4.66		1.02	
TM250	50	23.5	**19.3**	**27.7**	4.2	5.11		0.99	
					mean ±SD	5.35	0.46	1.01	0.01
Siemens Immulite 2000 DPD									
TM246	13	23.8	**19.5**	**28.1**	4.3	8.28		1.09	
TM247	13	24.6	**20.2**	**29**	4.4	7.07		1.05	
TM248	13	22.4	**18.4**	**26.4**	4.0	6.21		1.05	
TM249	13	11.7	**9.6**	**13.8**	2.1	8.55		1.01	
TM250	13	25.4	**20.8**	**30**	4.6	7.48		1.07	
					mean ±SD	7.52	0.94	1.06	0.03
Siemens Dimension Vista DUV									
TM246	22	17.8	**14.6**	**21**	3.2	2.19		0.81	
TM247	21	19.2	**15.7**	**22.7**	3.5	2.03		0.82	
TM248	21	17.4	**14.3**	**20.5**	3.1	2.24		0.82	
TM249	21	9.6	**7.9**	**11.3**	1.7	2.50		0.83	
TM250	21	20.2	**16.6**	**23.8**	3.6	2.48		0.85	
					mean ±SD	2.29	0.20	0.83	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM246	16	21.8	**17.9**	**25.7**	3.9	5.60		1.00	
TM247	16	23.2	**19**	**27.4**	4.2	5.34		0.99	
TM248	16	21.6	**17.7**	**25.5**	3.9	6.30		1.02	
TM249	16	12.7	**10.4**	**15**	2.3	7.17		1.09	
TM250	16	23.9	**19.6**	**28.2**	4.3	5.48		1.01	
					mean ±SD	5.98	0.76	1.02	0.04

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Table 5 (cont.): 9-12 NYS Tumor Marker PT Summary for CEA

Tosoh AIA TOM									
TM246	6	33.4	**27.4**	**39.4**	6.0	3.65		1.53	
TM247	6	36.0	**29.5**	**42.5**	6.5	4.92		1.54	
TM248	6	32.5	**26.7**	**38.4**	5.9	3.54		1.53	
TM249	6	18.0	**14.8**	**21.2**	3.2	5.83		1.55	
TM250	6	34.5	**28.3**	**40.7**	6.2	4.41		1.46	
					mean ±SD	4.47	0.95	1.52	0.04

Sample ID	All Method Median		Median % CV
TM246	**21.9**		**5.67**
TM247	**23.4**		**5.13**
TM248	**21.3**		**5.53**
TM249	**11.6**		**5.25**
TM250	**23.7**		**4.71**
		Average	**5.26**
		Allowable CV %	**6.0**
		Allowable Error (+/-)%	**18.0**

Figure 5: CEA Method Comparison

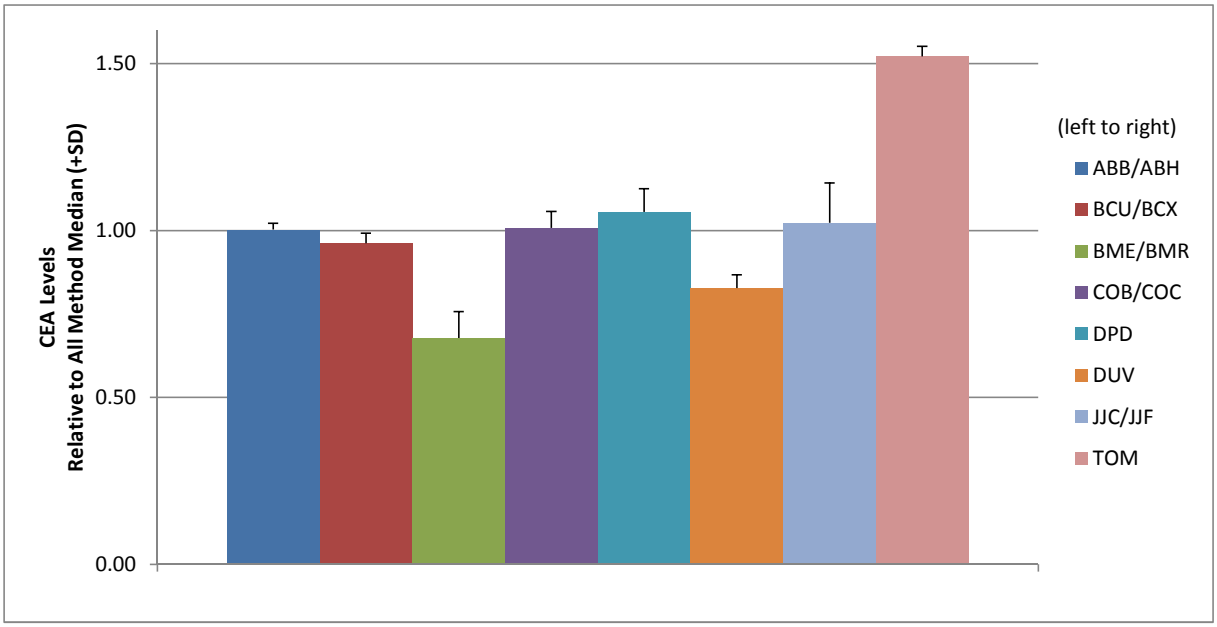

Table 6: 9-12 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott AxSYM ABB											
TM246	8	8.8	**7.2**	**10.4**	1.6	4.43		1.10		1.21	
TM247	8	15.6	**12.8**	**18.4**	2.8	11.79		1.11		1.23	
TM248	7	23.5	**19.3**	**27.7**	4.2	2.43		1.06		1.16	
TM249	8	18.4	**15.1**	**21.7**	3.3	5.65		1.05		1.17	
TM250	8	31.3	**25.7**	**36.9**	5.6	4.66		1.02		1.10	
					mean ±SD	5.79	3.55	1.07	0.04	1.18	0.05
Beckman Unicel & Access/2 BCU/BCX											
TM246	17	7.8	**6.4**	**9.2**	1.4	7.56		0.98		1.08	
TM247	17	13.7	**11.2**	**16.2**	2.5	6.06		0.98		1.08	
TM248	17	21.7	**17.8**	**25.6**	3.9	7.00		0.98		1.07	
TM249	17	17.0	**13.9**	**20.1**	3.1	7.12		0.97		1.08	
TM250	17	29.4	**24.1**	**34.7**	5.3	5.34		0.96		1.03	
					mean ±SD	6.62	0.90	0.97	0.01	1.07	0.02
Roche Elecsys & Cobas BME/BMR											
TM246	16	9.2	**7.5**	**10.9**	1.7	4.78		1.15		1.27	
TM247	15	15.7	**12.9**	**18.5**	2.8	3.89		1.12		1.24	
TM248	16	25.9	**21.2**	**30.6**	4.7	5.25		1.17		1.28	
TM249	16	20.6	**16.9**	**24.3**	3.7	4.81		1.17		1.31	
TM250	16	35.9	**29.4**	**42.4**	6.5	5.46		1.17		1.26	
					mean ±SD	4.84	0.61	1.16	0.02	1.27	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM246	29	8.5	**7.0**	**10.0**	1.5	8.00		1.06		1.17	
TM247	28	14.5	**11.9**	**17.1**	2.6	5.86		1.04		1.14	
TM248	29	22.2	**18.2**	**26.2**	4.0	5.72		1.00		1.10	
TM249	29	17.9	**14.7**	**21.1**	3.2	5.53		1.02		1.14	
TM250	29	31.2	**25.6**	**36.8**	5.6	4.65		1.01		1.10	
					mean ±SD	5.95	1.24	1.03	0.02	1.13	0.03
Siemens Immulite 1000 & 2000 DPB/DPD											
TM246	17	7.9	**6.5**	**9.3**	1.4	6.84		0.99		1.09	
TM247	17	13.9	**11.4**	**16.4**	2.5	5.68		0.99		1.09	
TM248	16	22.2	**18.2**	**26.2**	4.0	4.23		1.00		1.10	
TM249	17	17.7	**14.5**	**20.9**	3.2	7.46		1.01		1.12	
TM250	17	30.9	**25.3**	**36.5**	5.6	5.28		1.00		1.09	
					mean ±SD	5.90	1.28	1.00	0.01	1.10	0.01
Siemens Dimension Vista DUV											
TM246	6	7.2	**5.9**	**8.5**	1.3	3.75		0.90		0.99	
TM247	6	12.6	**10.3**	**14.9**	2.3	2.30		0.90		0.99	
TM248	6	20.2	**16.6**	**23.8**	3.6	2.13		0.91		1.00	
TM249	6	15.9	**13.0**	**18.8**	2.9	2.58		0.90		1.01	
TM250	6	27.9	**22.9**	**32.9**	5.0	2.87		0.91		0.98	
					mean ±SD	2.73	0.64	0.90	0.00	1.00	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM246	6	6.7	**5.5**	**7.9**	1.2	5.82		0.84		0.92	
TM247	6	11.2	**9.2**	**13.2**	2.0	5.00		0.80		0.88	
TM248	6	17.5	**14.4**	**20.7**	3.2	4.80		0.79		0.87	
TM249	6	14.2	**11.6**	**16.8**	2.6	5.00		0.81		0.90	
TM250	6	24.6	**20.2**	**29.0**	4.4	4.43		0.80		0.87	
					mean ±SD	5.01	0.51	0.81	0.02	0.89	0.03
Tosoh AIA TOM											
TM246	3	8.1	**6.6**	**9.6**	1.5	1.48		1.01		1.12	
TM247	3	14.1	**11.6**	**16.6**	2.5	3.55		1.01		1.11	
TM248	3	22.2	**18.2**	**26.2**	4.0	1.71		1.00		1.10	
TM249	3	17.5	**14.4**	**20.7**	3.2	0.97		0.99		1.11	
TM250	3	30.6	**25.1**	**36.1**	5.5	1.50		1.00		1.08	
					mean ±SD	1.84	0.99	1.00	0.01	1.10	0.02

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Table 6 (cont.): 9-12 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD	Median % CV	All Method Median/ IS Target
TM246	102	8.00	7.2	0.49	5.30	1.10
TM247	100	14.00	12.7	0.64	5.34	1.10
TM248	100	22.20	20.2	1.46	4.52	1.10
TM249	102	17.60	15.8	1.08	5.27	1.12
TM250	102	30.75	28.4	1.34	4.66	1.08
				Average	5.02	mean ±SD 1.10 0.01
				Allowable CV %	6.0	
				Allowable Error (+/-)%	18.0	

Figure 6: AFP Method Comparison

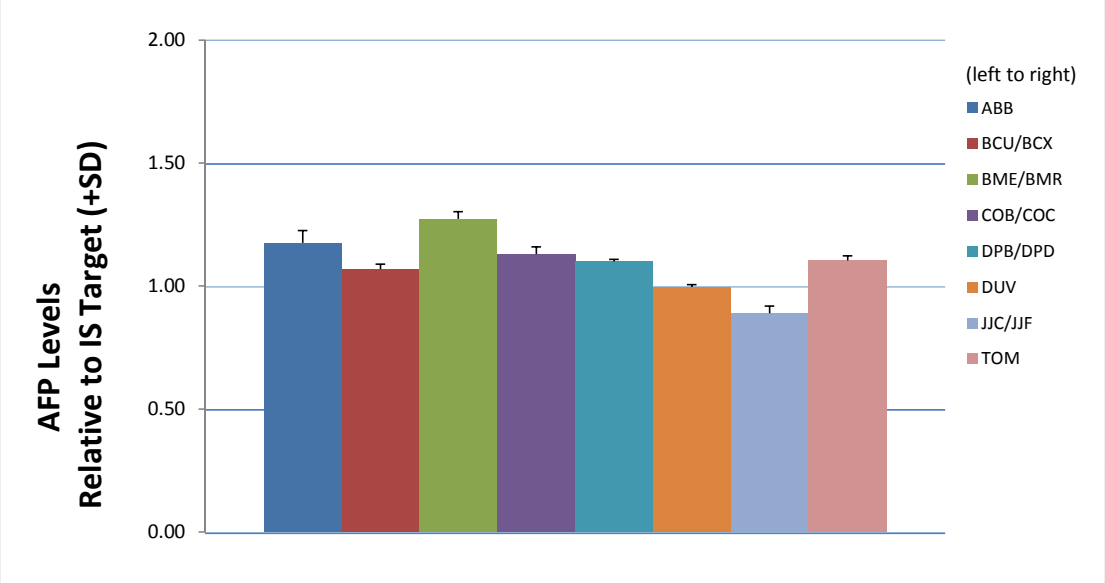

Table 7: 9-12 NYS Tumor Marker PT Summary for PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott AxSYM & Architect ABB/ABH											
TM246	19	1.0	**0.8**	**1.2**	0.2	8.00		1.00		1.11	
TM247	19	2.3	**1.8**	**2.8**	0.5	7.39		1.05		1.21	
TM248	19	4.4	**3.5**	**5.3**	0.9	7.05		1.10		1.22	
TM249	19	7.3	**5.8**	**8.8**	1.5	5.48		1.07		1.20	
TM250	19	12.8	**10.2**	**15.4**	2.6	6.80		1.08		1.17	
					mean ±SD	6.98	1.07	1.06	0.04	1.18	0.04
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM246	49	1.1	**0.9**	**1.3**	0.2	5.45		1.10		1.22	
TM247	49	2.4	**1.9**	**2.9**	0.5	5.00		1.09		1.26	
TM248	49	4.6	**3.7**	**5.5**	0.9	5.22		1.15		1.28	
TM249	49	7.8	**6.2**	**9.4**	1.6	5.26		1.15		1.28	
TM250	49	13.6	**10.9**	**16.3**	2.7	5.00		1.15		1.25	
					mean ±SD	5.23	0.19	1.13	0.03	1.26	0.02
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)											
TM246	3	0.9	**0.7**	**1.1**	0.2	6.67		0.90		1.00	
TM247	3	2.0	**1.6**	**2.4**	0.4	0.00		0.91		1.05	
TM248	3	3.7	**3.0**	**4.4**	0.7	5.68		0.93		1.03	
TM249	3	6.1	**4.9**	**7.3**	1.2	5.74		0.90		1.00	
TM250	3	10.8	**8.6**	**13.0**	2.2	1.94		0.92		0.99	
					mean ±SD	4.52	3.05	0.91	0.01	1.01	0.03
Roche Elecsys & Cobas BME/BMR											
TM246	38	1.0	**0.8**	**1.2**	0.2	5.00		1.00		1.11	
TM247	39	2.1	**1.7**	**2.5**	0.4	3.81		0.95		1.11	
TM248	39	4.0	**3.2**	**4.8**	0.8	3.50		1.00		1.11	
TM249	39	6.7	**5.4**	**8.0**	1.3	4.33		0.99		1.10	
TM250	39	11.7	**9.4**	**14.0**	2.3	3.68		0.99		1.07	
					mean ±SD	4.16	0.66	0.99	0.02	1.10	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM246	60	1.0	**0.8**	**1.2**	0.2	5.00		1.00		1.11	
TM247	59	2.2	**1.8**	**2.6**	0.4	4.55		1.00		1.16	
TM248	60	4.0	**3.2**	**4.8**	0.8	5.25		1.00		1.11	
TM249	60	6.8	**5.4**	**8.2**	1.4	5.00		1.00		1.11	
TM250	60	11.8	**9.4**	**14.2**	2.4	5.34		1.00		1.08	
					mean ±SD	4.95	0.29	1.00	0.00	1.12	0.03
Siemens Immulite 1000 &2000 - Original Pack DPB/DPD (DP5)											
TM246	21	1.0	**0.8**	**1.2**	0.2	8.00		1.00		1.11	
TM247	21	2.2	**1.8**	**2.6**	0.4	8.64		1.00		1.16	
TM248	21	4.1	**3.3**	**4.9**	0.8	8.29		1.03		1.14	
TM249	21	7.1	**5.7**	**8.5**	1.4	9.44		1.04		1.16	
TM250	21	12.3	**9.8**	**14.8**	2.5	10.65		1.04		1.13	
					mean ±SD	8.59	0.62	1.02	0.02	1.14	0.02
Siemens Immulite 1000 & 2000 - 3rd Generation Pack DPB/DPD (DP6)											
TM246	6	0.8	**0.6**	**1.0**	0.2	10.00		0.80		0.89	
TM247	6	1.8	**1.4**	**2.2**	0.4	15.00		0.82		0.95	
TM248	6	3.4	**2.7**	**4.1**	0.7	12.94		0.85		0.94	
TM249	6	5.5	**4.4**	**6.6**	1.1	12.55		0.81		0.90	
TM250	6	9.9	**7.9**	**11.9**	2.0	13.13		0.84		0.91	
					mean ±SD	12.62	2.05	0.82	0.02	0.92	0.03
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM246	12	1.1	**0.9**	**1.3**	0.2	14.55		1.10		1.22	
TM247	12	2.4	**1.9**	**2.9**	0.5	6.25		1.09		1.26	
TM248	12	4.6	**3.7**	**5.5**	0.9	6.74		1.15		1.28	
TM249	12	7.9	**6.3**	**9.5**	1.6	4.68		1.16		1.30	
TM250	12	13.7	**11.0**	**16.4**	2.7	5.99		1.16		1.26	
					mean±SD	7.64	3.93	1.13	0.03	1.26	0.03
Siemens Dimension Vista DUV											
TM246	14	1.0	**0.8**	**1.2**	0.2	3.00		1.00		1.11	
TM247	14	2.3	**1.8**	**2.8**	0.5	3.04		1.05		1.21	
TM248	14	4.3	**3.4**	**5.2**	0.9	4.42		1.08		1.19	
TM249	14	7.2	**5.8**	**8.6**	1.4	3.19		1.06		1.18	
TM250	14	12.5	**10.0**	**15.0**	2.5	2.80		1.06		1.15	
					mean ±SD	3.41	0.67	1.05	0.03	1.17	0.04

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Table 7 (cont.): 9-12 NYS Tumor Marker PT Summary for PSA

Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM246	25	0.9	**0.7**	**1.1**	0.2	6.67		0.90		1.00	
TM247	25	1.8	**1.4**	**2.2**	0.4	6.67		0.82		0.95	
TM248	25	3.2	**2.6**	**3.8**	0.6	6.25		0.80		0.89	
TM249	25	5.3	**4.2**	**6.4**	1.1	6.04		0.78		0.87	
TM250	25	9.0	**7.2**	**10.8**	1.8	6.22		0.76		0.83	
					mean ±SD	6.41	0.31	0.81	0.05	0.91	0.07
Tosoh AIA TOM											
TM246	8	0.9	**0.7**	**1.1**	0.2	6.67		0.90		1.00	
TM247	8	2.1	**1.7**	**2.5**	0.4	7.14		0.95		1.11	
TM248	8	3.9	**3.1**	**4.7**	0.8	5.90		0.98		1.08	
TM249	8	6.5	**5.2**	**7.8**	1.3	6.00		0.96		1.07	
TM250	8	11.1	**8.9**	**13.3**	2.2	5.23		0.94		1.02	
					mean ±SD	6.43	0.59	0.95	0.03	1.05	0.04

Sample ID		**All Method Median**	**IS based Target**	**SD**		**Median % CV**
TM246	255	**1.0**	**0.9**	**0.10**		**6.67**
TM247	255	**2.2**	**1.9**	**0.05**		**6.25**
TM248	256	**4.0**	**3.6**	**0.26**		**5.90**
TM249	256	**6.8**	**6.1**	**0.45**		**5.48**
TM250	256	**11.8**	**10.9**	**0.68**		**5.34**
					Average	**5.93**
					Allowable CV %	**6.66**
					Allowable Error (+/-)%	**20.0**

Figure 7: PSA Method Comparison

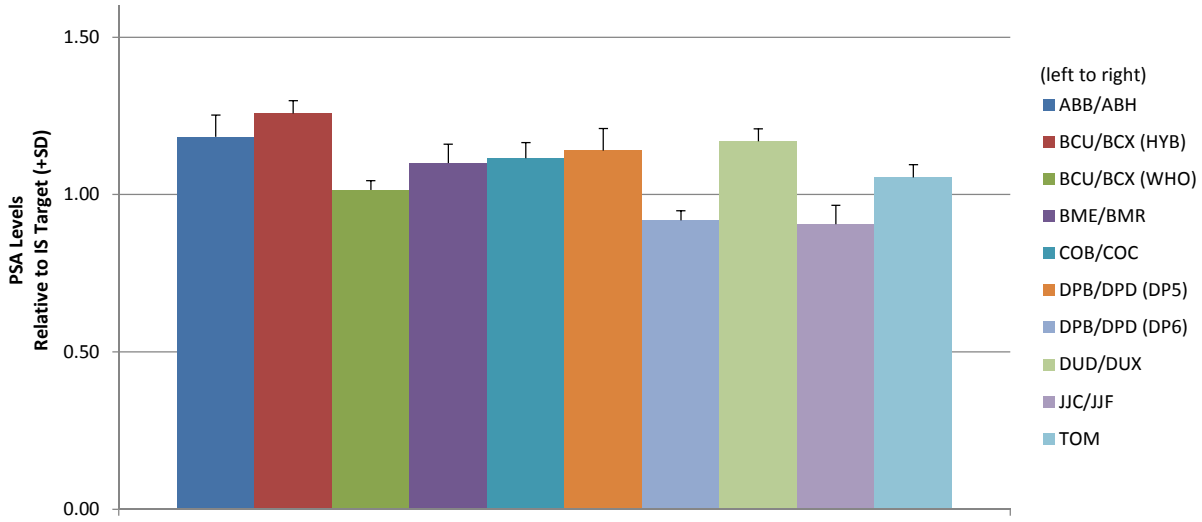

Table 8: 9-12 NYS Tumor Marker PT Summary for Free PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott Architect ABH											
TM246	4	0.12	**0.00**	**0.27**	0.14	8.33		1.09		1.43	
TM247	4	0.26	**0.11**	**0.41**	0.15	3.85		1.18		1.35	
TM248	4	0.50	**0.41**	**0.59**	0.09	2.00		1.16		1.31	
TM249	4	0.84	**0.69**	**0.99**	0.15	1.19		1.15		1.30	
TM250	4	1.41	**1.16**	**1.66**	0.25	3.55		1.15		1.28	
					mean ±SD	3.78	2.77	1.15	0.03	1.33	0.06
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM246	26	0.16	**0.01**	**0.31**	0.15	18.75		1.45		1.90	
TM247	26	0.31	**0.16**	**0.46**	0.15	3.23		1.41		1.61	
TM248	26	0.59	**0.48**	**0.70**	0.11	5.08		1.37		1.55	
TM249	26	0.99	**0.81**	**1.17**	0.18	5.05		1.36		1.53	
TM250	26	1.68	**1.38**	**1.98**	0.30	3.57		1.37		1.53	
					mean ±SD	7.14	6.55	1.39	0.04	1.62	0.16
Roche Elecsys & Cobas BME/BMR											
TM246	24	0.11	**0.00**	**0.26**	0.13	9.09		1.00		1.31	
TM247	24	0.22	**0.07**	**0.37**	0.15	4.55		1.00		1.14	
TM248	24	0.43	**0.28**	**0.58**	0.15	4.65		1.00		1.13	
TM249	24	0.73	**0.60**	**0.86**	0.13	4.11		1.00		1.13	
TM250	24	1.23	**1.01**	**1.45**	0.22	4.07		1.00		1.12	
					mean ±SD	5.29	2.14	1.00	0.00	1.16	0.08
Siemens Immulite 1000 & 2000 DPB/DPD											
TM246	21	0.10	**0.00**	**0.25**	0.13	10.00		0.91		1.19	
TM247	21	0.21	**0.06**	**0.36**	0.15	9.52		0.95		1.09	
TM248	21	0.40	**0.25**	**0.55**	0.15	7.50		0.93		1.05	
TM249	21	0.68	**0.56**	**0.80**	0.12	8.82		0.93		1.05	
TM250	21	1.18	**0.97**	**1.39**	0.21	8.47		0.96		1.07	
					mean ±SD	8.86	0.97	0.94	0.02	1.09	0.06
Siemens Dimension (RxL Max, Xpand Plus) DUD											
TM246	2	NG				90.00	**	2.73		3.56	
TM247	2	NG				8.00		1.14		1.30	
TM248	2	NG				8.70		1.07		1.21	
TM249	2	NG				1.23		1.11		1.25	
TM250	2	NG				4.55		1.07		1.20	
					mean ±SD**	5.62	3.44	1.10	0.73	1.24	0.05
Siemens Dimension Vista DUV											
TM246	4	0.09	**0.00**	**0.24**	0.12	11.11		0.82		1.07	
TM247	6	0.20	**0.05**	**0.35**	0.15	5.00		0.91		1.04	
TM248	6	0.39	**0.24**	**0.54**	0.15	5.13		0.91		1.02	
TM249	6	0.67	**0.55**	**0.79**	0.12	2.99		0.92		1.04	
TM250	6	1.10	**0.90**	**1.30**	0.20	0.91		0.89		1.00	
					mean ±SD	5.03	3.81	0.89	0.04	1.03	0.03

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Table 8 (cont.): 9-12 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV
TM246	81	0.11	0.08	0.00	10.00
TM247	83	0.22	0.19	0.01	4.55
TM248	83	0.43	0.38	0.02	5.08
TM249	83	0.73	0.65	0.04	4.11
TM250	83	1.23	1.10	0.08	3.57
				Average	5.46
				Allowable CV %	6.0
				Allowable Error if >/= 0.5 ng/ml (+/-)%	18.0
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	0.15

** = TM246 excluded from DUD calculation

Figure 8: Free PSA Method Comparison

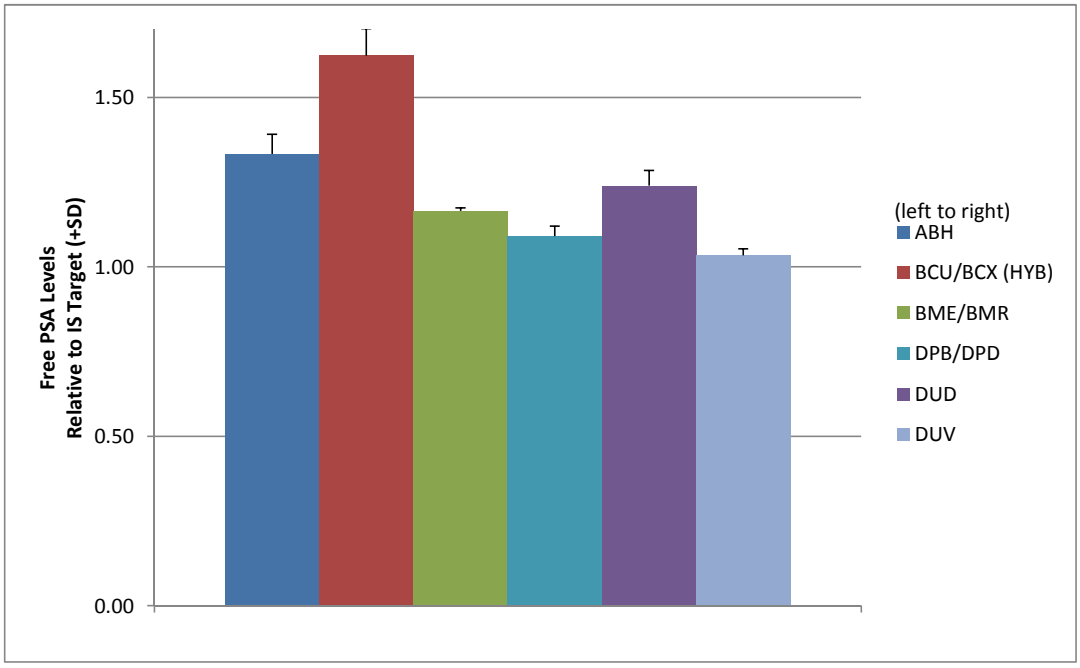

Table 9: 9-12 NYS Tumor Marker PT Summary for Complexed PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Siemens Advia Centaur XP & CP COB/COC									
TM246	12	0.8	**0.7**	**1.0**	0.2	6.02		1.00	
TM247	12	1.9	**1.6**	**2.2**	0.3	4.81		1.00	
TM248	12	3.5	**3.0**	**4.0**	0.5	3.15		1.00	
TM249	12	5.9	**5.0**	**6.8**	0.9	3.55		1.00	
TM250	12	10.3	**8.7**	**11.8**	1.6	3.80		1.00	
					mean ±SD	4.27	1.30	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM246	**12**	**0.8**		**6.02**
TM247	**12**	**1.9**		**4.81**
TM248	**12**	**3.5**		**3.15**
TM249	**12**	**5.9**		**3.55**
TM250	**12**	**10.3**		**3.80**
			Average	**4.27**
			Allowable CV %	**5.0**
			Allowable Error (+/-)%	**15.0**

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

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2012/index.htm

Oncology Soluble Tumor Markers						
		TM246	**TM247**	**TM248**	**TM249**	**TM250**
AFP (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 125 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 15-3 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 19-9 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 27.29 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CEA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) **for a 2nd method used in conjunction with free PSA (ng/mL)** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Free PSA (ng/ml) **If test offered, measure and report for all samples** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Complexed PSA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	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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