NEW YORK
state department of
HEALTH

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

Sue Kelly
Executive Deputy Commissioner

September 9, 2014

DO NOT FREEZE SAMPLES
REFRIGERATE UPON ARRIVAL

To: Laboratory Director

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

Subject: **Oncology - Soluble Tumor Markers Proficiency Testing**

Due Date: **September 24, 2014**

Samples:
Enclosed are five sealed (5) vials labeled **TM276 to TM280**, each containing proficiency test specimens in a commercially available 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, but 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) as 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 measure it in **ALL** of the samples. We can no longer accept results from a second method for any analyte.

If the proficiency samples are received in a condition unsatisfactory for testing, or are stored incorrectly in your lab, you may request a replacement set before September 17th, 2014. Please contact Susanne McHale at (518) 486-5775 or Helen Ling at (518) 474-0036.

All laboratories must submit their proficiency testing results online through the Electronic Proficiency Testing Reporting System (EPTRS) on the Department's **Health Commerce System (HCS).** It is a secure website requiring users to obtain an ID in order to access the application. To begin, log into the Health Commerce System (HCS) home page: https://commerce.health.state.ny.us . Click on EPTRS under "My Applications"; click on Online Reporting. This will bring you to the "Select Event" page.

Contact the Clinical Laboratory Evaluation Program via clepeptrs@health.state.ny.us if you are unable to access the website or you do not see the "Submit/Attest" button on the Summary Page. Failure to submit test results will result in a score of zero.

Please enter and submit results before 4 PM EST on the due date. It is highly recommended that you log into the system the day that you receive your samples to ensure that your HCS account is still active. If your password has been disabled, then call 1-866-529-1890, option #1. Please note that neither permission nor account issues can be resolved after 5 PM EST.

Although results can still be received into the Health Commerce System until 11:59 PM EST on September 24, 2014, questions can not be answered after 5 PM EST, so it is highly recommended that

you submit results earlier to allow time to resolve any problem that could occur. Results not submitted 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 phone (518) 486-5775 or email (susanne.mchale@health.ny.gov) as soon as possible and **no later than 4 PM EST on the due date** to see if this can be arranged.

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 analyte value** 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. **We are also asking for the Reagents and Calibrators lot numbers used when testing the PT samples. Please enter these under the Instrument and Reagent Names.**

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. It is the responsibility of each laboratory to verify their data and make any necessary changes.

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.

For any correspondence regarding the Oncology PT contact us by e-mail at susanne.mchale@health.ny.gov or:

Tumor Marker Proficiency Testing c/o Susanne McHale
Wadsworth Center, Room E600
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509

The 2015 Oncology Tumor Marker Proficiency Test schedule will be posted at:

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

This document and the worksheet can be found on the website:

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

Additional CLEP reference: http://www.wadsworth.org/labcert/clep/PT/ptindex.html

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

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2014/index.htm

Oncology Soluble Tumor Markers						
		TM276	**TM277**	**TM278**	**TM279**	**TM280**
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					
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					

WORKSHEET

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

REFRIGERATE SAMPLES UPON ARRIVAL

DO NOT FREEZE

FOR LABS TESTING **FREE PSA,** TEST IT FOR **ALL** SAMPLES.

SEE INSTRUCTIONS FOR MORE INFORMATION.

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

WORKSHEET

NEW YORK
state department of
HEALTH

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

Sue Kelly
Executive Deputy Commissioner

October 10, 2014

New York State Soluble Tumor Markers Proficiency Test 9-2014 [1]

Dear Laboratory Director,

This is a summary and critique of the New York State Proficiency Test from September 2014 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

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. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

Your laboratory's individual results, score(s), previous two PT event scores and overall performance status are on a separate report securely posted on the Department's Health Commerce System site under EPTRS (Electronic Proficiency Test Reporting System).

To access the results for your laboratory, please log in to the Electronic Proficiency Test Reporting System homepage at

https://commerce.health.state.ny.us

Click on EPTRS under "My Applications"

Click on Online Reporting

This will bring you to the "Select Event" page

Scroll down and find the current survey in the "Submitted/Closed Events" table and click on "Evaluation" under the "Scored" column.

Laboratory contacts were also sent an email alert indicating the availability of the individual result evaluation report.

This critique with summary tables and graphs is then sent by a separate email to the same laboratory contacts and will also be posted on the Wadsworth website at:

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

Once posted, it can also be accessed through the "Statistical" link from EPTRS.

[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.

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.

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®6 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.

To help you 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.** In general, an acceptable result has a D/Dmax between –1 and +1. Occasionally, however, due to rounding effects, there may be a small discrepancy between the D/Dmax value and the actual scoring, in which case the actual scoring takes precedence. The closer D/Dmax is to zero, the closer your result was to the target. A negative D/Dmax means that your result was below, and a positive value means your result was above the target. No entry in this place means that your result either had a qualifier (< or >) or was not gradable, in which case there will be an NG in the grade column. **Note: If your D/Dmax is not within +/- 0.66 (approximately +/-2 SD), 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 it should. Furthermore, if your **average D/Dmax is greater than +0.5 or smaller than -0.5,** then your results exhibited a substantial high or low bias 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 116 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of the groups included ten or more labs each, together comprising 78% of the labs. The peer group means ranged from 17% below to 47% above the all method median, with Tosoh being the highest. The majority of labs were in peer groups that fell within +/-10% of the all method median target.

CA19-9 (Table 2, Figure 2): Results were reported by 74 labs using instruments from seven different manufacturers, six with N >2 for peer group grading. Forty percent of all reporting labs used Siemens ADVIA-Centaur XP, 23% used either Beckman's Unicel or Access/2, 18% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, 8% used the Tosoh ST-AIA method and 4% used Siemens Dimension Vista. Results from two of the samples (TM277 and TM279) showed a higher variability and therefore were graded on larger allowable error criteria than the other three (see Table 2). In addition, all samples show large differences in how each method measured CA19-9, ranging from 85% (Tosoh) to 542% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP averaged almost 1.8 times higher than the all method median, while results from Beckman, Roche and Tosoh were within +/-15% of the all method median. Used by three labs, the Abbott Architect method results averaged 5.4 times higher than the all method median, as shown in Table 2 and Figure 2. As previously seen, there is discordance between the different 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). Results from two of the samples (TM277 and TM279) showed a higher variability and therefore were graded on larger allowable error criteria than the other three (see Tables 3 & 4). Some methods also exhibited a different relative bias for those two samples when compared to that of the other three samples. Overall, however, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -33% from the all method medians, while Siemens Immulite showed a high bias of 37% above the median. **CA27.29** measurements showed a 20% difference between the ADVIA Centaur XP/CP and the Tosoh methods and the median CA27.29 measurements averaged 24% higher than the median CA15-3 measurements for TM276, 278 and 280, while a much larger difference was seen for the other two samples.

CEA (Table 5, Figure 5): Results were reported by 167 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 7 to 46 labs. Results from the Abbott Architect, Beckman Unicel/Access/2, Siemens Advia Centaur, Siemens Dimension Vista and Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 methods, which altogether accounted for 82% of the labs, were within +/-15% of the medians. Roche methods were 19% below the median, whereas TOSOH ST-AIA exhibited a high positive bias averaging 42% above the median, which is consistent with what has been seen on previous NYS PT events.

Sample pairs TM276 and TM277, and TM278 and TM279, respectively, were matched to have the same concentrations of CEA to assess reproducibility between samples. Overall reproducibility between the sample pairs was very good, ranging from 1.4-6.9%, with an average of only 4% difference between matched samples.

For **AFP, PSA and free PSA,** target values were assigned using traceable International Standards. However, for scoring purposes the results were evaluated based on their respective peer group mean in the same way as all the other analytes. For the purpose of method comparison, the tables show the method bias against both the all method medians and the assigned target values, but the graphs show the performance relative only to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 100 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 20% of the total number of labs. Six of the eight methods, used by 75% of the labs, gave results within +/-10% of the all method median, but averaged 12% higher than the assigned targets. Sample pairs TM276 and TM277, and TM278 and TM279, respectively, were matched to have the same concentrations of AFP to assess reproducibility between samples. Overall reproducibility between sample pairs was good, ranging from 2.4-9.4%, with the average being 5.7%.

Of the remaining two methods, Roche measured 13% higher than the all method median, and 23% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 4% of participants) was the only method with results below the assigned target (-17%) and was also 25% below the all method median. Thus, it appears that most methods somewhat overestimated AFP levels in our samples, a result that is similar to what has been observed in previous NYS PT events for these methods.

PSA (Table 7, Figure 7): Results were reported by 244 labs using instruments from eleven manufacturers, although two instruments were used by only one lab (N=1) and were therefore not included in Table 7. Sample pairs TM276 and TM277, and TM278 and TM279, respectively, were matched to have the same concentrations of total and free PSA to assess reproducibility between samples. While there were substantial differences in total and free PSA measurements between methods, there were only minor differences in the proportion of free PSA between samples (Tables 8 A and B). Furthermore, reproducibility between sample pairs was excellent, ranging from 0.36-4.58%, with the majority less than 2%. Results from six of the peer groups were within +/-10% of the all method median, and these were between +4% and +19% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 12% above the all method median and 26% above the target (no lab used the WHO calibration). In contrast, the Siemens Immulite 1000/2000 was 18% below the all method median and 8% below the assigned targets, and Ortho Clinical Vitros ECi/ECiQ & 5600 results were 8% lower than the all method median but 4% higher than the targets.

Free PSA (Table 8, Figure 8): Results were reported by 86 labs using instruments from seven manufacturers which corresponded to five peer groups plus two others with N<3. In addition, two of the five peer groups comprised less than 10 labs each, and along with the N<3 methods made up 23% of the participants. The remaining three methods were used by 35% of labs for Beckman Unicel/Access calibrated with the Hybritech standards, 26% of labs for Roche Elecsys/E170/Cobas, and 16% for Siemens Immulite 2000. As seen in previous PT events, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (39% higher than the all method

medians and 24% higher than the targets), while there were no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. All of the other methods were within +/-10% of the all method medians, but ranged from -7% to -19% below the assigned targets. All but the Beckman Unicel/Access methods were within 13% of each other, whereas Beckman remains consistently high. We calculated % free PSA for each peer group using their respective average PSA and free PSA levels and the results ranged from 5.7 to 7.9%. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA, but all were within 2.4% of the value calculated from the assigned targets. Furthermore, reproducibility between the sample pairs was excellent, ranging from 0-4.5%.

Please note, labs are required to measure and report **free PSA** for **all proficiency test samples** if free PSA is on their test menu. 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, 9 labs measured **complexed PSA** and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little difference between them. Overall, the samples showed relatively good agreement with an average %CV of 4% (Table 9).

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

While some of the differences between methods 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 S1). We also encourage you to educate your physician clients about this potential problem.

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.

Please be aware that even though the Instrument and Reagent fields will usually be pre-populated in EPTRS based on what was previously entered, it is still necessary to confirm that ALL instruments and reagents have been correctly entered prior to final submission, especially when you changed instruments. That information is critical to evaluate your results within the correct 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.

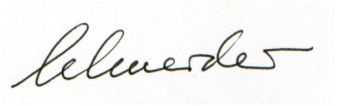
Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

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 kathleen.wagner@health.ny.gov.

The scheduled dates for the 2015 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
January 27, 2015	February 11, 2015
May 5, 2015	May 20, 2015
September 1, 2015	September 16, 2015

If you have any questions or wish to discuss topics alluded to in this critique, contact Susanne McHale at susanne.mchale@health.ny.gov (518) 486-5775, or myself at erasmus.schneider@health.ny.gov or (518) 473-4856.



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

Table 1: 9-14 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 Architect ABH									
TM276	9	33.3	**27.3**	**39.3**	6.0	4.38		1.12	
TM277	9	58.5	**48.0**	**69.0**	10.5	6.07		1.31	
TM278	9	26.3	**20.9**	**31.7**	5.4	4.83		1.14	
TM279	9	42.2	**34.6**	**49.8**	7.6	5.97		1.28	
TM280	9	37.7	**30.9**	**44.5**	6.8	5.86		1.08	
					mean ±SD	5.42	0.77	1.19	0.10
Beckman Unicel & Access/2 BCU/BCX									
TM276	21	33.6	**27.6**	**39.6**	6.0	5.18		1.13	
TM277	21	40.0	**32.8**	**47.2**	7.2	5.08		0.90	
TM278	21	24.8	**19.4**	**30.2**	5.4	4.80		1.08	
TM279	21	29.5	**24.1**	**34.9**	5.4	4.64		0.89	
TM280	21	39.4	**32.3**	**46.5**	7.1	5.13		1.13	
					mean ±SD	4.96	0.23	1.03	0.12
Roche Elecsys & Cobas BME/BMR									
TM276	20	24.5	**19.1**	**29.9**	5.4	3.71		0.83	
TM277	20	40.0	**32.8**	**47.2**	7.2	3.98		0.90	
TM278	20	19.8	**14.4**	**25.2**	5.4	3.38		0.86	
TM279	20	29.8	**24.4**	**35.2**	5.4	4.53		0.90	
TM280	20	28.7	**23.3**	**34.1**	5.4	4.08		0.82	
					mean ±SD	3.94	0.43	0.86	0.04
Siemens Advia Centaur XP & CP COB/COC									
TM276	33	32.7	**26.8**	**38.6**	5.9	3.88		1.10	
TM277	33	48.6	**39.9**	**57.3**	8.7	5.68		1.09	
TM278	33	25.5	**20.1**	**30.9**	5.4	4.90		1.11	
TM279	33	36.1	**29.6**	**42.6**	6.5	5.93		1.09	
TM280	33	38.5	**31.6**	**45.4**	6.9	4.68		1.10	
					mean ±SD	5.01	0.82	1.10	0.01
Siemens Immulite 2000 DPD									
TM276	17	26.6	**21.2**	**32.0**	5.4	5.71		0.90	
TM277	17	40.7	**33.4**	**48.0**	7.3	5.92		0.91	
TM278	17	20.7	**15.3**	**26.1**	5.4	8.94		0.90	
TM279	17	29.9	**24.5**	**35.3**	5.4	6.69		0.91	
TM280	17	32.2	**26.4**	**38.0**	5.8	8.45		0.92	
					mean ±SD	7.14	1.47	0.91	0.01
Siemens Dimension Vista (LOCI) DUV									
TM276	5	23.7	**18.3**	**29.1**	5.4	4.39		0.80	
TM277	5	65.6	**53.8**	**77.4**	11.8	2.16		1.47	
TM278	5	21.3	**15.9**	**26.7**	5.4	5.96		0.92	
TM279	4	49.3	**40.4**	**58.2**	8.9	0.30		1.49	
TM280	5	28.5	**23.1**	**33.9**	5.4	5.26		0.82	
					mean ±SD	3.62	2.34	1.10	0.35
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM276	5	24.7	**19.3**	**30.1**	5.4	6.44		0.83	
TM277	5	37.0	**30.3**	**43.7**	6.7	4.68		0.83	
TM278	5	18.8	**13.4**	**24.2**	5.4	11.60		0.82	
TM279	5	27.6	**22.2**	**33.0**	5.4	7.61		0.84	
TM280	5	29.3	**23.9**	**34.7**	5.4	3.75		0.84	
					mean ±SD	6.81	3.06	0.83	0.01

continued on next page

Table 1 (cont.): 9-14 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	
Tosoh AIA TOM									
TM276	6	39.6	**32.5**	**46.7**	7.1	9.82		1.34	
TM277	6	74.6	**61.2**	**88.0**	13.4	11.58		1.67	
TM278	6	30.6	**25.1**	**36.1**	5.5	8.43		1.33	
TM279	6	56.3	**46.2**	**66.4**	10.1	7.57		1.71	
TM280	6	45.5	**37.3**	**53.7**	8.2	7.05		1.30	
					mean ±SD	8.89	1.83	1.47	0.20

Sample ID	N	All Method Median		Median % CV
TM276	**116**	**29.7**		**4.78**
TM277	**116**	**44.7**		**5.38**
TM278	**116**	**23.1**		**5.43**
TM279	**115**	**33.0**		**5.95**
TM280	**116**	**35.0**		**5.20**
			Average	**5.35**
			Allowable CV %	**6.0**
			Allowable Error if >/= 30 U/ml (+/-) %	**18.0**
			Allowable Error if < 30 U/ml (+/- U/ml)	**5.4**

Figure 1: CA 125 Method Comparison

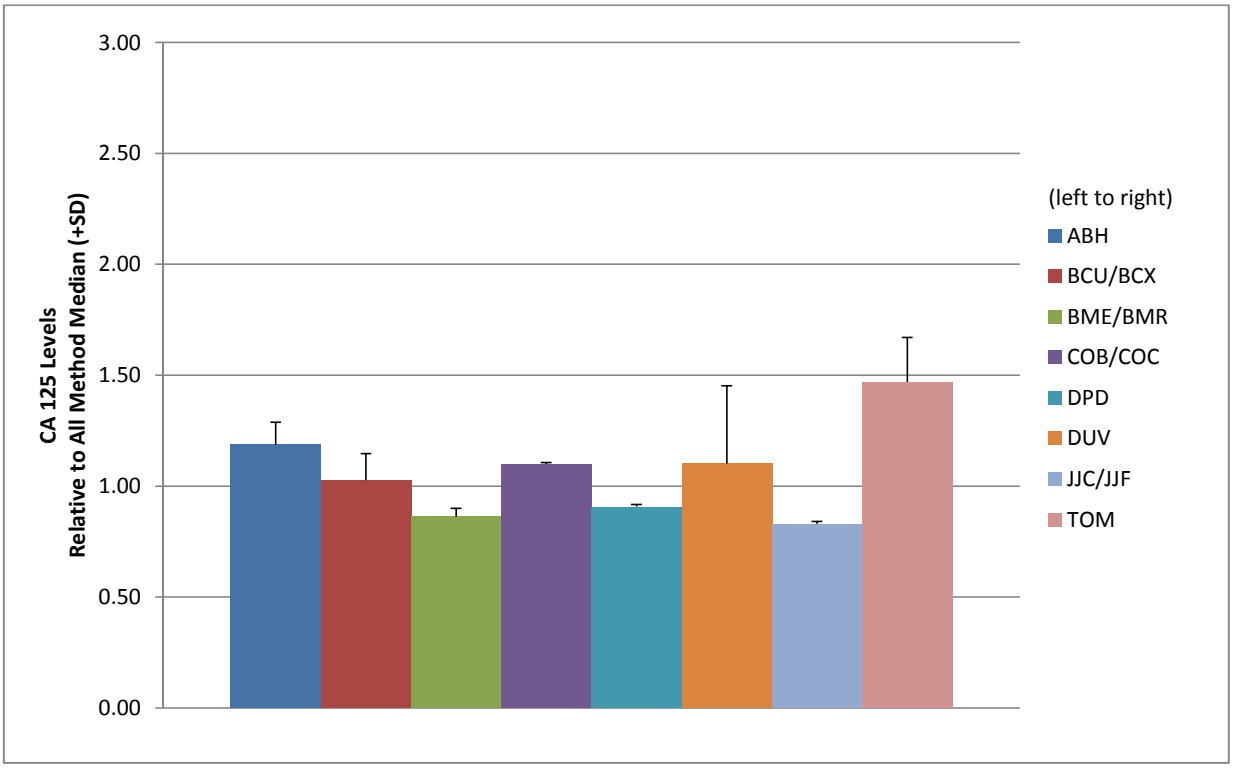


Table 2: 9-14 NYS Tumor Marker PT Summary for CA 19-9

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									
TM276	3	198.6	**162.9**	**234.3**	35.7	5.63		5.67	
TM277	3	142.6	**99.8**	**185.4**	42.8	7.29		5.93	
TM278	3	125.5	**102.9**	**148.1**	22.6	8.17		5.16	
TM279	3	93.4	**65.4**	**121.4**	28.0	10.30		5.05	
TM280	3	167.0	**136.9**	**197.1**	30.1	6.54		5.30	
					mean ±SD	7.59	1.78	5.42	0.37
Beckman Unicel & Access/2 BCU/BCX									
TM276	17	39.8	**32.6**	**47.0**	7.2	4.50		1.14	
TM277	17	26.3	**18.4**	**34.2**	7.9	12.70		1.09	
TM278	17	26.5	**21.7**	**31.3**	4.8	5.40		1.09	
TM279	17	19.1	**13.1**	**25.1**	6.0	9.06		1.03	
TM280	17	35.7	**29.3**	**42.1**	6.4	4.82		1.13	
					mean ±SD	7.29	3.53	1.10	0.04
Roche Elecsys & Cobas BME/BMR									
TM276	13	30.2	**24.8**	**35.6**	5.4	6.16		0.86	
TM277	13	21.8	**15.3**	**28.3**	6.5	10.41		0.91	
TM278	12	21.4	**17.5**	**25.3**	3.9	4.44		0.88	
TM279	13	17.1	**11.1**	**23.1**	6.0	9.12		0.92	
TM280	12	27.3	**22.4**	**32.2**	4.9	2.93		0.87	
					mean ±SD	6.61	3.13	0.89	0.03
Siemens Advia Centaur XP COB									
TM276	30	68.3	**56.0**	**80.6**	12.3	5.53		1.95	
TM277	29	43.1	**30.2**	**56.0**	12.9	10.12		1.79	
TM278	30	44.6	**36.6**	**52.6**	8.0	6.75		1.84	
TM279	30	31.2	**21.8**	**40.6**	9.4	11.47		1.69	
TM280	30	59.8	**49.0**	**70.6**	10.8	5.92		1.90	
					mean ±SD	7.96	2.67	1.83	0.10
Siemens Dimension Vista DUV									
TM276	3	47.0	**38.5**	**55.5**	8.5	1.36		1.34	
TM277	3	29.3	**20.5**	**38.1**	8.8	23.82		1.22	
TM278	3	32.5	**26.7**	**38.4**	5.9	2.31		1.34	
TM279	3	21.5	**15.1**	**28.0**	6.5	17.16		1.16	
TM280	3	42.5	**34.9**	**50.2**	7.7	3.81		1.35	
					mean ±SD	9.69	10.17	1.28	0.09
Tosoh AIA TOM									
TM276	6	25.9	**21.2**	**30.6**	4.7	6.49		0.74	
TM277	6	20.3	**14.2**	**26.4**	6.1	7.73		0.84	
TM278	6	22.1	**18.1**	**26.1**	4.0	5.11		0.91	
TM279	6	17.9	**11.9**	**23.9**	6.0	6.03		0.97	
TM280	6	25.1	**20.6**	**29.6**	4.5	5.58		0.80	
					mean ±SD	6.19	1.00	0.85	0.09

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Table 2 (cont.): 9-14 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM276	69	35.0	5.53
TM277	68	24.1	10.41
TM278	68	24.3	5.11
TM279	69	18.5	9.12
TM280	68	31.5	4.82

Average for TM276, 278 & 280*	5.16	*Abbott excluded
Average for TM277 & 279*	9.77	
Allowable CV % for TM276, 278 & 280	6.0	
Allowable Error if >/= 20 U/ml (+/-) % for TM276, 278 & 280	18.0	
Allowable Error if < 20 U/ml (+/- U/ml) for TM276, 278 & 280	3.6	
Allowable CV % for TM277 & 279 ł	10.0	ł Note: Higher allowable %CV
Allowable Error if >/= 20 U/ml (+/-) % for TM277 & 279 ł	30.0	for samples TM277 & TM279
Allowable Error if < 20 U/ml (+/- U/ml) for TM277 & 279 ł	6.0	due to large variation.

Figure 2: CA 19-9 Method Comparison

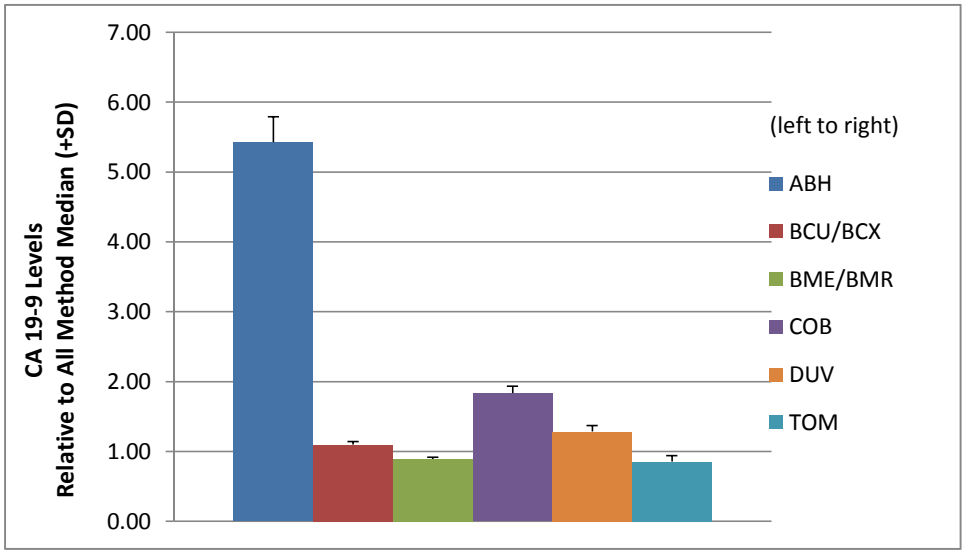

Table 3: 9-14 NYS Tumor Marker PT Summary for CA 15-3

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 Architect ABH									
TM276	6	30.6	**25.1**	**36.1**	5.5	6.67		0.94	
TM277	6	24.5	**9.8**	**39.2**	14.7	11.96		1.53	
TM278	6	50.6	**41.5**	**59.7**	9.1	7.04		0.96	
TM279	6	44.1	**17.6**	**70.6**	26.5	10.57		1.45	
TM280	6	43.2	**35.4**	**51.0**	7.8	6.90		0.95	
					mean ±SD	8.63	2.55	1.17	0.31
Beckman Unicel & Access/2 BCU/BCX									
TM276	9	23.2	**19.0**	**27.4**	4.2	5.60		0.72	
TM277	9	9.5	**3.8**	**15.2**	5.7	25.16		0.59	
TM278	9	37.9	**31.1**	**44.7**	6.8	6.44		0.72	
TM279	9	18.2	**7.3**	**29.1**	10.9	19.01		0.60	
TM280	9	32.3	**26.5**	**38.1**	5.8	4.30		0.71	
					mean ±SD	12.10	9.40	0.67	0.06
Roche Elecsys & Cobas BME/BMR									
TM276	15	33.5	**27.5**	**39.5**	6.0	4.39		1.03	
TM277	15	9.6	**3.8**	**15.4**	5.8	25.31		0.60	
TM278	15	52.8	**43.3**	**62.3**	9.5	4.24		1.00	
TM279	15	20.0	**8.0**	**32.0**	12.0	16.65		0.66	
TM280	15	45.8	**37.6**	**54.0**	8.2	4.96		1.00	
					mean ±SD	11.11	9.52	0.86	0.21
Siemens Advia Centaur XP & CP COB/COC									
TM276	20	32.4	**26.6**	**38.2**	5.8	6.14		1.00	
TM277	20	16.0	**6.4**	**25.6**	9.6	15.63		1.00	
TM278	20	53.3	**43.7**	**62.9**	9.6	7.80		1.01	
TM279	20	30.4	**12.2**	**48.6**	18.2	11.41		1.00	
TM280	20	45.7	**37.5**	**53.9**	8.2	4.73		1.00	
					mean ±SD	9.14	4.40	1.00	0.00
Siemens Immulite 2000 DPD									
TM276	8	46.2	**37.9**	**54.5**	8.3	6.00		1.43	
TM277	8	21.2	**8.5**	**33.9**	12.7	25.61		1.33	
TM278	8	74.6	**61.2**	**88.0**	13.4	7.57		1.41	
TM279	8	39.4	**15.8**	**63.0**	23.6	21.70		1.30	
TM280	8	64.6	**53.0**	**76.2**	11.6	10.31		1.41	
					mean±SD	16.30	8.72	1.37	0.06

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Table 3 (cont.): 9-14 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM276	58	32.4	6.00
TM277	58	16.0	25.16
TM278	58	52.8	7.04
TM279	58	30.4	16.65
TM280	58	45.7	4.96

Average for TM276, 278 & 280	6.00	
Average for TM277 & 279 ł	20.90	
Allowable CV % for TM276, 278 & 280	6.0	
Allowable Error (+/-)% for TM276, 278 & 280	18.0	
Allowable CV % for TM277 & 279 ł	20.0	ł Note: Higher allowable %CV for samples TM277 & TM279 due to large variation.
Allowable Error (+/-)% for TM277 & 279 ł	60.0	

Figure 3: CA 15-3 Method Comparison

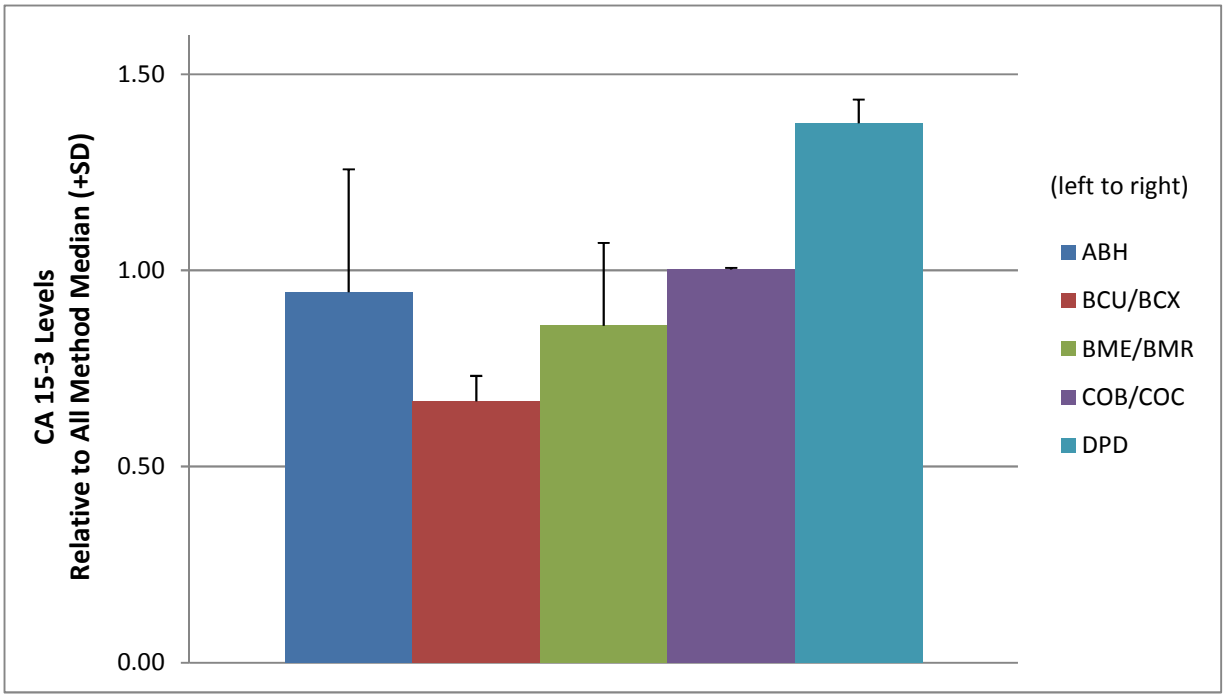

Table 4: 9-14 NYS Tumor Marker PT Summary for CA 27.29

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									
TM276	39	42.5	**32.3**	**52.7**	10.2	11.41		1.08	
TM277	39	24.9	**10.2**	**39.6**	14.7	20.24		0.58	
TM278	39	71.4	**54.3**	**88.5**	17.1	9.05		1.08	
TM279	39	48.6	**28.2**	**69.0**	20.4	13.87		0.67	
TM280	39	62.0	**47.1**	**76.9**	14.9	9.00		1.08	
					mean ±SD	12.71	4.66	0.90	0.25
Tosoh AIA TOM									
TM276	7	36.4	**27.7**	**45.1**	8.7	6.07		0.92	
TM277	7	61.3	**35.6**	**87.0**	25.7	11.17		1.42	
TM278	7	60.8	**46.2**	**75.4**	14.6	7.81		0.92	
TM279	7	96.9	**56.2**	**137.6**	40.7	12.47		1.33	
TM280	7	52.6	**40.0**	**65.2**	12.6	6.16		0.92	
					mean ±SD	8.74	2.93	1.10	0.25

Sample ID	N	All Method Median	Median % CV
TM276	**46**	**39.5**	**8.74**
TM277	**46**	**43.1**	**15.71**
TM278	**46**	**66.1**	**8.43**
TM279	**46**	**72.8**	**13.17**
TM280	**46**	**57.3**	**7.58**

Average for TM276, 278 & 280	**8.25**	
Average for TM277 & 279	**14.44**	
Allowable CV % for TM276, 278 & 280	**8.0**	
Allowable Error if >/= 35 U/ml (+/-) % for TM276, 278 & 280	**24.0**	
Allowable Error if < 35 U/ml (+/- U/ml) for TM276, 278 & 280	**8.4**	
Allowable CV % for TM277 & 279 ł	**14.0**	**ł Note: Higher allowable %CV**
Allowable Error if >/= 35 U/ml (+/-) % for TM277 & 279 ł	**42.0**	**for samples TM277 & TM279**
Allowable Error if < 35 U/ml (+/- U/ml) for TM277 & 279 ł	**14.7**	**due to large variation.**

Figure 4: CA 27.29 Method Comparison

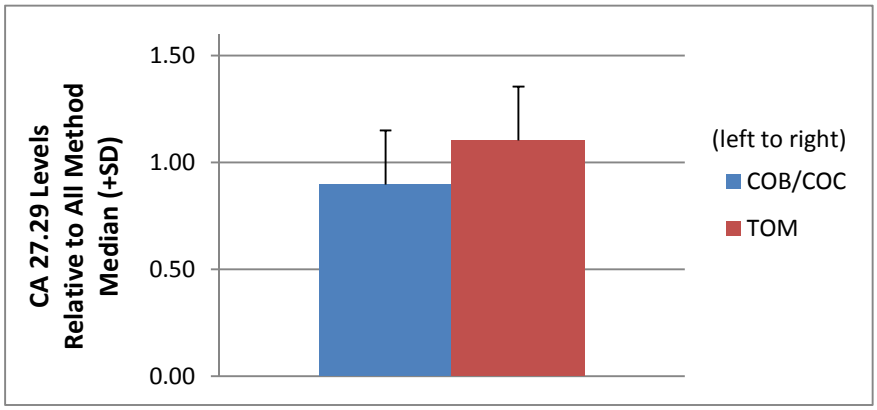

Table 5: 9-14 NYS Tumor Marker PT Summary for CEA

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 Architect ABH									
TM276	14	8.4	**6.9**	**9.9**	1.5	4.64		1.04	
TM277	14	8.7	**7.1**	**10.3**	1.6	4.60		1.09	
TM278	14	13.1	**10.7**	**15.5**	2.4	2.98		1.04	
TM279	14	13.7	**11.2**	**16.2**	2.5	4.16		1.09	
TM280	14	20.1	**16.5**	**23.7**	3.6	4.58		1.06	
					mean ±SD	4.19	0.71	1.07	0.03
Beckman Unicel & Access/2 BCU/BCX									
TM276	29	7.8	**6.4**	**9.2**	1.4	5.13		0.97	
TM277	29	8.0	**6.6**	**9.4**	1.4	4.63		1.01	
TM278	29	12.0	**9.8**	**14.2**	2.2	5.25		0.96	
TM279	28	12.2	**10.0**	**14.4**	2.2	4.43		0.97	
TM280	29	18.0	**14.8**	**21.2**	3.2	5.17		0.95	
					mean ±SD	4.92	0.37	0.97	0.02
Roche Elecsys & Cobas BME/BMR									
TM276	23	6.5	**5.3**	**7.7**	1.2	7.08		0.81	
TM277	23	6.7	**5.5**	**7.9**	1.2	7.01		0.84	
TM278	23	9.9	**8.1**	**11.7**	1.8	7.37		0.79	
TM279	23	10.1	**8.3**	**11.9**	1.8	6.63		0.80	
TM280	22	14.9	**12.2**	**17.6**	2.7	5.44		0.78	
					mean ±SD	6.71	0.76	0.81	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM276	46	7.5	**6.2**	**8.9**	1.4	5.20		0.93	
TM277	45	7.9	**6.5**	**9.3**	1.4	5.95		0.99	
TM278	46	11.8	**9.7**	**13.9**	2.1	5.76		0.94	
TM279	46	12.6	**10.3**	**14.9**	2.3	6.27		1.00	
TM280	46	17.7	**14.5**	**20.9**	3.2	5.71		0.93	
					mean ±SD	5.78	0.39	0.96	0.04
Siemens Immulite 1000/2000 DPB/DPD									
TM276	12	8.4	**6.9**	**9.9**	1.5	7.98		1.04	
TM277	12	8.9	**7.3**	**10.5**	1.6	9.44		1.12	
TM278	12	14.0	**11.5**	**16.5**	2.5	9.57		1.12	
TM279	12	14.7	**12.1**	**17.3**	2.6	10.14		1.17	
TM280	12	20.8	**17.1**	**24.5**	3.7	11.11		1.09	
					mean ±SD	9.65	1.14	1.11	0.05
Siemens Dimension Vista DUV									
TM276	24	7.3	**6.0**	**8.6**	1.3	3.15		0.91	
TM277	24	7.4	**6.1**	**8.7**	1.3	3.51		0.93	
TM278	24	11.3	**9.3**	**13.3**	2.0	2.92		0.90	
TM279	24	11.5	**9.4**	**13.6**	2.1	3.30		0.92	
TM280	24	17.2	**14.1**	**20.3**	3.1	3.31		0.91	
					mean ±SD	3.24	0.22	0.91	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM276	11	8.3	**6.8**	**9.8**	1.5	5.66		1.03	
TM277	12	7.9	**6.5**	**9.3**	1.4	10.63		0.99	
TM278	12	13.4	**11.0**	**15.8**	2.4	8.28		1.07	
TM279	12	12.5	**10.3**	**14.8**	2.3	7.60		1.00	
TM280	12	20.0	**16.4**	**23.6**	3.6	5.30		1.05	
					mean ±SD	7.50	2.16	1.03	0.03

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Table 5 (cont.): 9-14 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	
Tosoh AIA TOM									
TM276	7	11.0	**9.0**	**13.0**	2.0	4.82		1.37	
TM277	7	11.4	**9.3**	**13.5**	2.1	4.65		1.43	
TM278	7	17.9	**14.7**	**21.1**	3.2	3.97		1.43	
TM279	7	18.9	**15.5**	**22.3**	3.4	3.60		1.51	
TM280	7	26.3	**21.6**	**31.0**	4.7	4.11		1.38	
					mean ±SD	4.23	0.50	1.42	0.05

Sample ID	N	All Method Median	Median % CV
TM276	**166**	**8.1**	**5.16**
TM277	**166**	**8.0**	**5.30**
TM278	**167**	**12.6**	**5.51**
TM279	**166**	**12.6**	**5.35**
TM280	**166**	**19.0**	**5.23**
		Average	**5.31**
		Allowable CV %	**6.0**
		Allowable Error if >/= 5 ng/ml (+/-) %	**18.0**
		Allowable Error if < 5 ng/ml (+/- ng/ml)	**0.9**

Figure 5: CEA Method Comparison

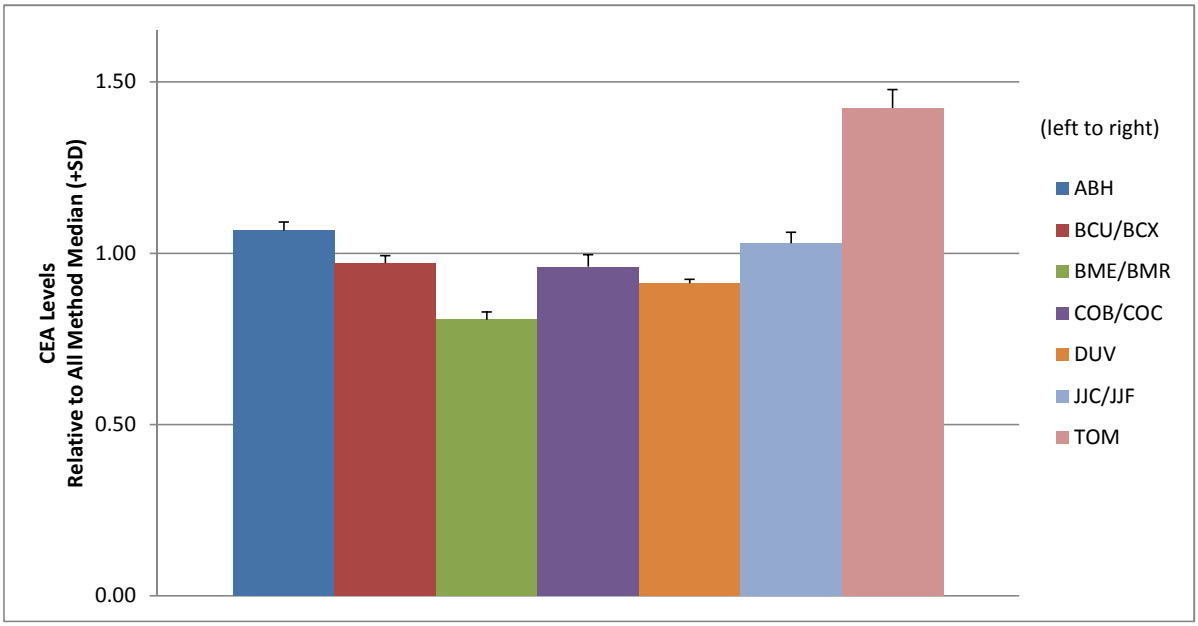

Table 6: 9-14 NYS Tumor Marker PT Summary for AFP

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 Architect ABH											
TM276	4	8.1	**6.6**	**9.6**	1.5	4.20		0.97		1.12	
TM277	4	7.4	**6.1**	**8.7**	1.3	2.30		0.94		1.06	
TM278	4	18.3	**15.0**	**21.6**	3.3	1.91		0.99		1.05	
TM279	4	19.3	**15.8**	**22.8**	3.5	0.52		0.99		1.06	
TM280	4	23.0	**18.9**	**27.1**	4.1	1.48		1.00		1.07	
					mean ±SD	2.08	1.36	0.98	0.03	1.07	0.03
Beckman Unicel & Access/2 BCU/BCX											
TM276	26	8.2	**6.7**	**9.7**	1.5	5.85		0.98		1.13	
TM277	26	7.7	**6.3**	**9.1**	1.4	5.32		0.97		1.10	
TM278	26	18.3	**15.0**	**21.6**	3.3	8.42		0.99		1.05	
TM279	26	19.2	**15.7**	**22.7**	3.5	5.99		0.99		1.06	
TM280	26	22.9	**18.8**	**27.0**	4.1	4.72		1.00		1.06	
					mean ±SD	6.06	1.41	0.99	0.01	1.08	0.03
Roche Elecsys & Cobas BME/BMR											
TM276	16	9.4	**7.7**	**11.1**	1.7	3.72		1.13		1.30	
TM277	16	8.7	**7.1**	**10.3**	1.6	4.48		1.10		1.25	
TM278	16	21.1	**17.3**	**24.9**	3.8	4.64		1.14		1.21	
TM279	16	21.9	**18.0**	**25.8**	3.9	5.94		1.13		1.21	
TM280	16	26.1	**21.4**	**30.8**	4.7	4.52		1.13		1.21	
					mean ±SD	4.66	0.80	1.13	0.02	1.23	0.04
Siemens Advia Centaur XP & CP COB/COC											
TM276	26	8.5	**7.0**	**10.0**	1.5	9.53		1.02		1.17	
TM277	26	8.1	**6.6**	**9.6**	1.5	11.60		1.03		1.16	
TM278	25	18.6	**15.3**	**21.9**	3.3	5.70		1.01		1.07	
TM279	25	19.5	**16.0**	**23.0**	3.5	7.13		1.01		1.07	
TM280	26	23.0	**18.9**	**27.1**	4.1	8.09		1.00		1.07	
					mean ±SD	8.41	2.27	1.01	0.01	1.11	0.05
Siemens Immulite 2000 DPD											
TM276	11	9.0	**7.4**	**10.6**	1.6	6.33		1.08		1.24	
TM277	11	8.3	**6.8**	**9.8**	1.5	6.63		1.05		1.19	
TM278	11	19.6	**16.1**	**23.1**	3.5	5.71		1.06		1.13	
TM279	11	20.5	**16.8**	**24.2**	3.7	6.29		1.06		1.13	
TM280	11	24.7	**20.3**	**29.1**	4.4	6.88		1.07		1.15	
					mean±SD	6.38	0.44	1.06	0.01	1.17	0.05
Siemens Dimension Vista DUV											
TM276	7	8.2	**6.7**	**9.7**	1.5	2.68		0.98		1.13	
TM277	7	7.6	**6.2**	**9.0**	1.4	3.29		0.96		1.09	
TM278	7	18.2	**14.9**	**21.5**	3.3	2.80		0.99		1.05	
TM279	7	19.1	**15.7**	**22.5**	3.4	2.67		0.98		1.05	
TM280	7	22.4	**18.4**	**26.4**	4.0	3.35		0.97		1.04	
					mean ±SD	2.96	0.33	0.98	0.01	1.07	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM276	5	6.7	**5.5**	**7.9**	1.2	2.84		0.80		0.92	
TM277	5	6.1	**5.0**	**7.2**	1.1	3.11		0.77		0.87	
TM278	5	13.6	**11.2**	**16.0**	2.4	4.04		0.74		0.78	
TM279	5	14.1	**11.6**	**16.6**	2.5	3.48		0.73		0.78	
TM280	5	16.6	**13.6**	**19.6**	3.0	3.86		0.72		0.77	
					mean ±SD	3.47	0.50	0.75	0.03	0.83	0.07

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Table 6 (cont.): 9-14 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	
Tosoh AIA TOM											
TM276	4	9.1	**7.5**	**10.7**	1.6	5.49		1.09		1.26	
TM277	4	8.7	**7.1**	**10.3**	1.6	2.07		1.10		1.25	
TM278	4	20.3	**16.6**	**24.0**	3.7	2.76		1.10		1.17	
TM279	4	20.8	**17.1**	**24.5**	3.7	5.48		1.07		1.14	
TM280	4	24.9	**20.4**	**29.4**	4.5	2.13		1.08		1.16	
					mean ±SD	3.59	1.76	1.09	0.01	1.19	0.05

Sample ID	N	All Method Median	IS based Target	SD		Median % CV				All Method Median/ IS Target	
TM276	**99**	8.4	**7.2**	**0.42**		**4.85**				**1.15**	
TM277	**99**	7.9	**7.0**	**0.31**		**3.89**				**1.13**	
TM278	**98**	18.5	**17.4**	**1.24**		**4.34**				**1.06**	
TM279	**98**	19.4	**18.2**	**0.55**		**5.71**				**1.07**	
TM280	**99**	23.0	**21.5**	**0.74**		**4.19**				**1.07**	
					Average	**4.59**		mean ±SD		**1.10**	0.04
					Allowable CV %	**6.0**					
					Allowable Error (+/-)%	**18.0**					

Figure 6: AFP Method Comparison

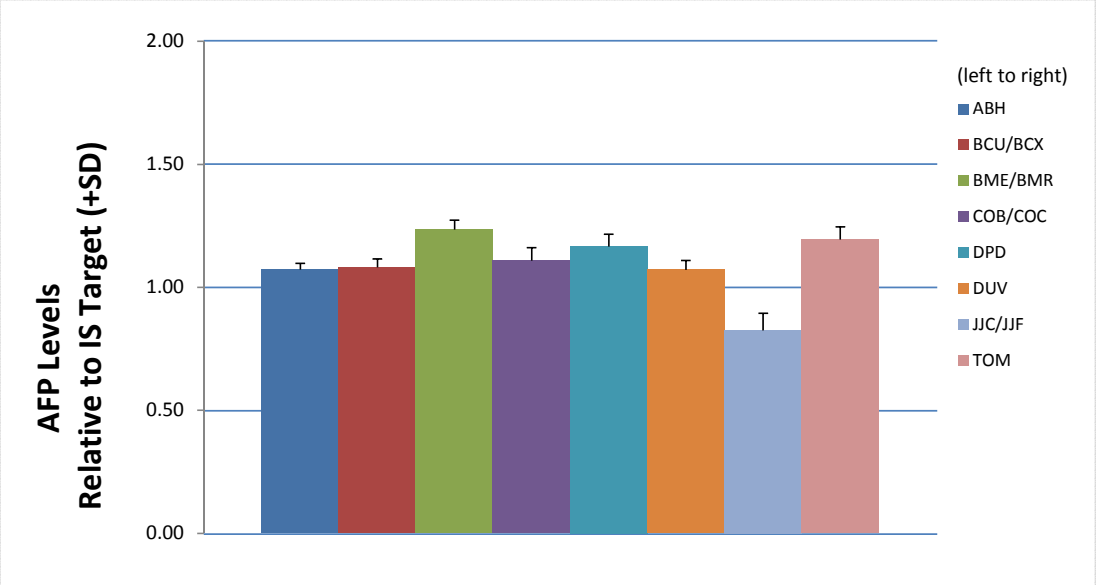

Table 7: 9-14 NYS Tumor Marker PT Summary for PSA

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 Architect ABH											
TM276	18	3.88	**3.18**	**4.58**	0.70	6.70		1.00		1.13	
TM277	18	3.82	**3.13**	**4.51**	0.69	5.50		1.00		1.13	
TM278	18	9.87	**8.09**	**11.65**	1.78	5.17		1.00		1.13	
TM279	18	9.82	**8.05**	**11.59**	1.77	4.58		1.01		1.12	
TM280	18	1.93	**1.58**	**2.28**	0.35	7.25		0.99		1.11	
					mean ±SD	5.84	1.11	1.00	0.00	1.13	0.01
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM276	51	4.32	**3.54**	**5.10**	0.78	4.86		1.11		1.26	
TM277	50	4.27	**3.50**	**5.04**	0.77	3.98		1.12		1.26	
TM278	51	11.10	**9.10**	**13.10**	2.00	5.41		1.12		1.27	
TM279	50	11.14	**9.13**	**13.15**	2.01	5.48		1.14		1.28	
TM280	51	2.16	**1.77**	**2.55**	0.39	5.09		1.11		1.24	
					mean ±SD	4.96	0.60	1.12	0.01	1.26	0.01
Roche Elecsys & Cobas BME/BMR											
TM276	38	3.70	**3.03**	**4.37**	0.67	5.41		0.95		1.08	
TM277	38	3.67	**3.01**	**4.33**	0.66	5.99		0.96		1.09	
TM278	38	9.33	**7.65**	**11.01**	1.68	5.04		0.95		1.07	
TM279	38	9.21	**7.55**	**10.87**	1.66	5.54		0.94		1.05	
TM280	38	1.88	**1.54**	**2.22**	0.34	5.32		0.97		1.08	
					mean ±SD	5.46	0.35	0.95	0.01	1.07	0.01
Siemens Advia Centaur XP & CP COB/COC											
TM276	53	3.49	**2.86**	**4.12**	0.63	5.44		0.90		1.02	
TM277	53	3.42	**2.80**	**4.04**	0.62	4.97		0.90		1.01	
TM278	53	8.63	**7.08**	**10.18**	1.55	5.21		0.87		0.99	
TM279	53	8.56	**7.02**	**10.10**	1.54	5.37		0.88		0.98	
TM280	53	1.80	**1.48**	**2.12**	0.32	4.44		0.93		1.03	
					mean ±SD	5.09	0.40	0.89	0.02	1.01	0.02
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM276	14	3.19	**2.62**	**3.76**	0.57	7.52		0.82		0.93	
TM277	14	3.22	**2.64**	**3.80**	0.58	5.90		0.84		0.95	
TM278	14	7.99	**6.55**	**9.43**	1.44	5.26		0.81		0.92	
TM279	14	8.27	**6.78**	**9.76**	1.49	5.93		0.85		0.95	
TM280	14	1.51	**1.24**	**1.78**	0.27	7.95		0.78		0.87	
					mean ±SD	6.51	1.16	0.82	0.03	0.92	0.03
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM276	16	3.93	**3.22**	**4.64**	0.71	4.58		1.01		1.15	
TM277	16	3.91	**3.21**	**4.61**	0.70	5.37		1.02		1.16	
TM278	16	9.93	**8.14**	**11.72**	1.79	5.04		1.01		1.14	
TM279	16	10.12	**8.30**	**11.94**	1.82	4.84		1.04		1.16	
TM280	16	1.95	**1.60**	**2.30**	0.35	5.13		1.01		1.12	
					mean±SD	4.99	0.30	1.02	0.01	1.15	0.02
Siemens Dimension Vista DUV											
TM276	22	4.00	**3.28**	**4.72**	0.72	2.75		1.03		1.17	
TM277	22	3.87	**3.17**	**4.57**	0.70	2.58		1.01		1.14	
TM278	22	10.01	**8.21**	**11.81**	1.80	2.50		1.01		1.15	
TM279	22	9.75	**8.00**	**11.51**	1.76	2.87		1.00		1.12	
TM280	22	2.02	**1.66**	**2.38**	0.36	2.97		1.04		1.16	
					mean ±SD	2.73	0.20	1.02	0.02	1.15	0.02

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Table 7 (cont.): 9-14 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	
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM276	21	3.65	**2.99**	**4.31**	0.66	4.38		0.94		1.07	
TM277	21	3.49	**2.86**	**4.12**	0.63	4.58		0.91		1.03	
TM278	21	8.85	**7.26**	**10.44**	1.59	4.97		0.90		1.02	
TM279	21	8.51	**6.98**	**10.04**	1.53	4.82		0.87		0.97	
TM280	21	1.94	**1.59**	**2.29**	0.35	4.64		1.00		1.11	
					mean ±SD	4.68	0.23	0.92	0.05	1.04	0.05
Tosoh AIA TOM											
TM276	8	4.10	**3.36**	**4.84**	0.74	5.61		1.06		1.20	
TM277	8	4.05	**3.32**	**4.78**	0.73	6.17		1.06		1.20	
TM278	8	10.19	**8.36**	**12.02**	1.83	4.32		1.03		1.17	
TM279	8	10.14	**8.31**	**11.97**	1.83	4.34		1.04		1.16	
TM280	8	2.10	**1.72**	**2.48**	0.38	5.24		1.08		1.21	
					mean ±SD	5.14	0.81	1.05	0.02	1.19	0.02

Sample ID	N	All Method Median	IS based Target	SD	Median % CV		All Method Median/ IS Target	
TM276	**241**	3.88	3.42	0.05	**5.41**		**1.13**	
TM277	**240**	3.82	3.38	0.19	**5.37**		**1.13**	
TM278	**241**	9.87	8.71	0.27	**5.04**		**1.13**	
TM279	**240**	9.75	8.73	0.29	**4.84**		**1.12**	
TM280	**241**	1.94	1.74	0.06	**5.13**		**1.11**	
				Average	**5.16**	mean ±SD	1.13	0.01
				Allowable CV %	**6.00**			
				Allowable Error (+/-)%	**18.0**			

Figure 7: PSA Method Comparison

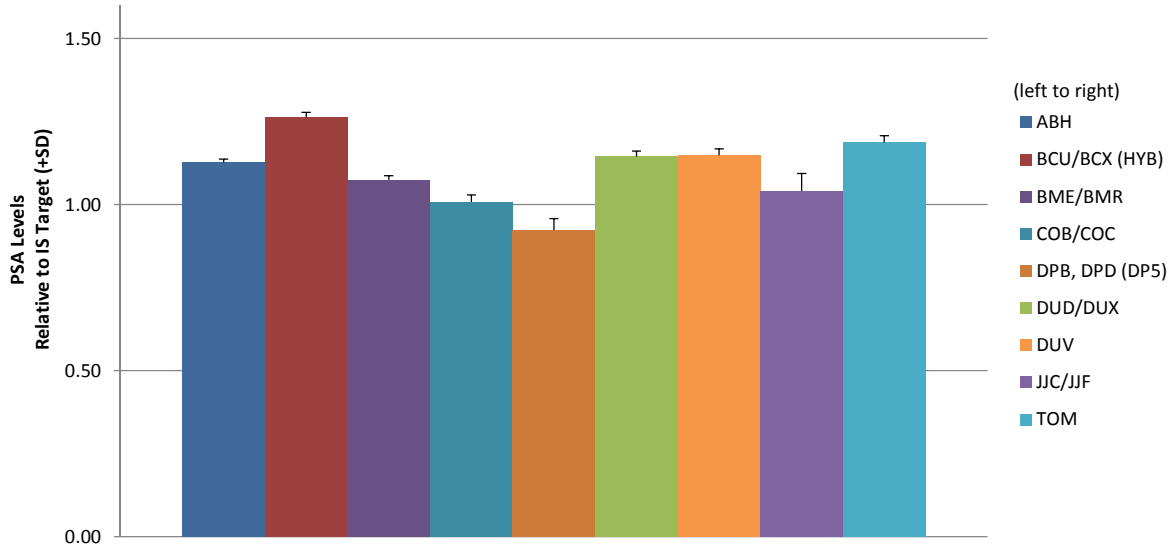

Table 8: 9-14 NYS Tumor Marker PT Summary for Free PSA

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		% free PSA (calculated)	
Abbott Architect ABH													
TM276	7	0.24	**0.15**	**0.33**	0.09	8.33		1.00		0.87		6.2%	
TM277	7	0.25	**0.16**	**0.34**	0.09	4.00		1.00		0.88		6.5%	
TM278	7	0.63	**0.52**	**0.74**	0.11	1.59		1.00		0.91		6.4%	
TM279	7	0.63	**0.52**	**0.74**	0.11	3.17		1.00		0.89		6.4%	
TM280	5	0.12	**0.03**	**0.21**	0.09	0.00		1.00		0.90		6.2%	
					mean ±SD	3.42	3.15	1.00	0.00	0.89	0.02	6.3%	0.1%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)													
TM276	30	0.34	**0.25**	**0.43**	0.09	8.82		1.42		1.23		7.9%	
TM277	30	0.35	**0.26**	**0.44**	0.09	5.71		1.40		1.23		8.2%	
TM278	27	0.82	**0.67**	**0.97**	0.15	3.66		1.30		1.18		7.4%	
TM279	30	0.85	**0.70**	**1.00**	0.15	4.71		1.35		1.20		7.6%	
TM280	30	0.18	**0.09**	**0.27**	0.09	5.56		1.50		1.34		8.3%	
					mean ±SD	5.69	1.93	1.39	0.07	1.24	0.06	7.9%	0.4%
Roche Elecsys & Cobas BME/BMR													
TM276	22	0.26	**0.17**	**0.35**	0.09	7.69		1.08		0.94		7.0%	
TM277	22	0.27	**0.18**	**0.36**	0.09	7.41		1.08		0.95		7.4%	
TM278	22	0.63	**0.52**	**0.74**	0.11	6.35		1.00		0.91		6.8%	
TM279	21	0.63	**0.52**	**0.74**	0.11	4.76		1.00		0.89		6.8%	
TM280	22	0.13	**0.04**	**0.22**	0.09	7.69		1.08		0.97		6.9%	
					mean ±SD	6.78	1.26	1.05	0.05	0.93	0.03	7.0%	0.2%
Siemens Immulite 2000 DPD													
TM276	14	0.23	**0.14**	**0.32**	0.09	8.70		0.96		0.83		7.2%	
TM277	14	0.23	**0.14**	**0.32**	0.09	8.70		0.92		0.81		7.1%	
TM278	14	0.56	**0.46**	**0.66**	0.10	7.14		0.89		0.80		7.0%	
TM279	12	0.58	**0.48**	**0.68**	0.10	3.45		0.92		0.82		7.0%	
TM280	13	0.11	**0.02**	**0.20**	0.09	9.09		0.92		0.82		7.3%	
					mean ±SD	7.41	2.34	0.92	0.02	0.82	0.01	7.1%	0.1%
Siemens Dimension Vista DUV													
TM276	10	0.22	**0.13**	**0.31**	0.09	4.55		0.92		0.79		5.5%	
TM277	10	0.23	**0.14**	**0.32**	0.09	4.35		0.92		0.81		5.9%	
TM278	10	0.57	**0.47**	**0.67**	0.10	3.51		0.90		0.82		5.7%	
TM279	10	0.58	**0.48**	**0.68**	0.10	3.45		0.92		0.82		5.9%	
TM280	8	0.11	**0.02**	**0.20**	0.09	0.00		0.92		0.82		5.4%	
					mean ±SD	3.17	1.84	0.92	0.01	0.81	0.01	5.7%	0.2%

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Table 8 (cont.): 9-14 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV		All Method Median/ IS Target		% free PSA calculated from IS Targets	
TM276	83	0.24	0.28	0.011	8.33		0.87		8.1%	
TM277	83	0.25	0.29	0.01	5.71		0.88		8.4%	
TM278	80	0.63	0.70	0.04	3.66		0.91		8.0%	
TM279	80	0.63	0.71	0.03	3.45		0.89		8.1%	
TM280	78	0.12	0.13	0.01	5.56		0.90		7.7%	
				Average	5.34	mean ±SD	0.89	0.02	8.1%	0.3%
				Allowable CV %	6.0					
				Allowable Error if >/= 0.5 ng/ml (+/-)%	18.0					
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	0.09					

Figure 8A: Free PSA Method Comparison

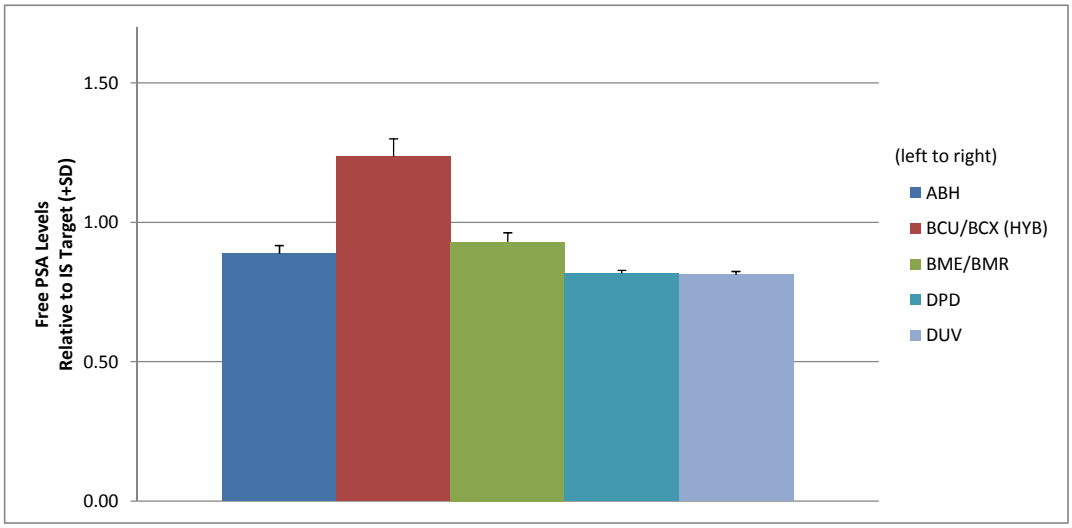

Figure 8B: Calculated % Free PSA Method Comparison

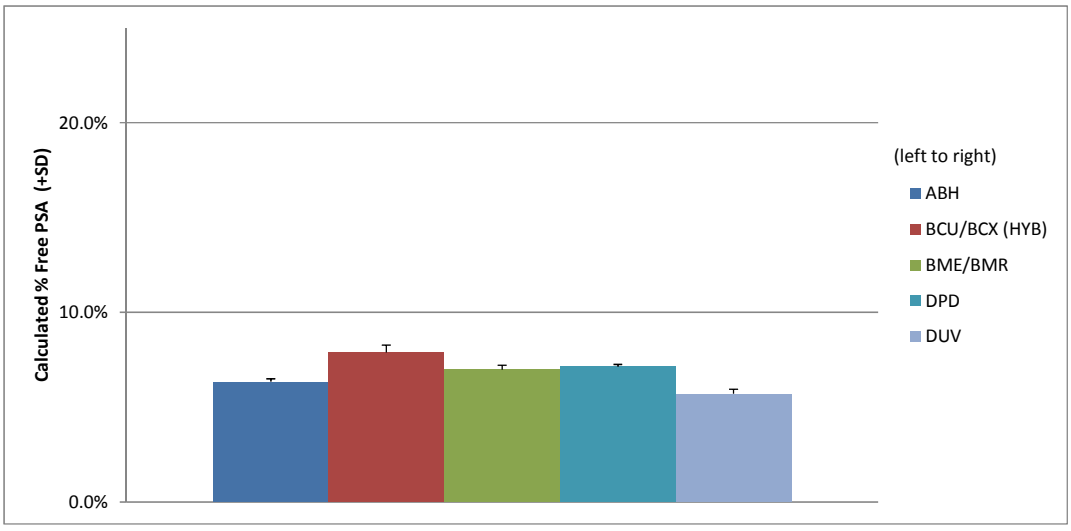

Table 9: 9-14 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM276	9	3.5	**2.8**	**4.1**	0.7	4.34		1.00	
TM277	9	3.3	**2.7**	**3.9**	0.6	3.61		1.00	
TM278	9	8.8	**7.2**	**10.3**	1.6	5.02		1.00	
TM279	9	8.5	**6.9**	**10.0**	1.6	4.14		1.00	
TM280	9	1.8	**1.4**	**2.1**	0.4	2.84		1.00	
					mean ±SD	3.99	0.82	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM276	**9**	**3.5**		**4.34**
TM277	**9**	**3.3**		**3.61**
TM278	**9**	**8.8**		**5.02**
TM279	**9**	**8.5**		**4.14**
TM280	**9**	**1.8**		**2.84**
			Average	**3.99**
			Allowable CV %	**6.0**
			Allowable Error (+/-)%	**18.0**