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October 7, 2015

New York State Soluble Tumor Markers Proficiency Test 9-2015 [1]

Dear Laboratory Director,

This is a summary and critique of the New York State Proficiency Test from Sept 2015 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 in varying concentrations to a serum-based matrix, then 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

Under "My Applications" click on **EPTRS**

Click on **Online Reporting** which will bring you to the "Select Event" page

Scroll down or filter by year under "Submitted/Closed Events" to find the correct survey and click on **Evaluation** in 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 sent by a separate email to the laboratory contacts and will also be posted on the public Wadsworth website at:

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

Once posted, it can also be accessed by clicking the **Statistical** link from the "Select Event" webpage.

[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 within two weeks of notification of release 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. Except for AFP, the allowable error and range were determined from the average of the median %CVs for each sample across all methods (see summary tables); allowances for increased scatter at low concentrations were made for some analytes. For AFP only, the allowable error and range were +/- 3SD from your peer group mean. 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 on your individual report card 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 Sera and Soluble Tumor Markers Proficiency Test.

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 113 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 86% of the labs. The peer group means ranged from 46% below to 30% above the all method median, with Ortho Clinical Diagnostics being the lowest and Tosoh being the highest. Seventy-six percent of labs were in the four peer groups that fell at or within +/-10% of the all method median. The different methods used to measure CA125 are still not very well harmonized, and the reference range cut-off value of 35 U/ml may not apply across the board. Indeed, different laboratories reported cut-off values ranging from 16.3 to 36.0 U/ml suggesting that individual laboratories determine their own reference ranges based on their own patient populations. However an individual lab's reference range does not necessarily correspond to the lab's method's relative performance in the NYS PT. Consequently, baseline levels for serial measurements should be redetermined if there is a change in the method or instrument used.

CA19-9 (Table 2, Figure 2): Results were reported by 73 labs using instruments from seven different manufacturers, four with N >2 for peer group grading. Forty percent of all reporting labs used Siemens ADVIA Centaur XP, 27% used either Beckman's Unicel or Access/2, 16% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, 8% used the Tosoh ST-AIA method and 3% used Siemens Dimension Vista. For illustrative purposes, Abbott was included on Table 2 and Figure 2, but values were not used for calculation of the all method median because the Abbott Architect method results averaged 4.8 times higher than the all method median. Excluding Abbott, only Siemens ADVIA Centaur XP was more than 10% different from the median (+94%), suggesting that there is at least some harmonization between manufacturers.

The MUC1 breast cancer antigen was measured by 104 labs, with slightly more than half (56%) using an instrument from one of six manufacturers (one with N=1) 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). Of the five methods used by more than 2 labs for CA15-3, three were within +/-5% of the all method median, whereas the Beckman Unicel/Access results exhibited a notable negative bias, averaging -30% from the all method medians and Siemens Immulite averaging 32% 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 showed a 7-32% concentration dependent positive bias compared to the median CA15-3 measurements. Furthermore, the methods used to measure CA27.29 seemed less reproducible than those used or CA15-3, as shown by the somewhat higher %CVs.

CEA (Table 5, Figure 5): Results were reported by 164 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 7 to 43 labs. Results from the Abbott Architect, Beckman Unicel/Access/2, Roche Elecsys & Cobas, Siemens ADVIA Centaur and Siemens Dimension Vista which altogether accounted for 82% of the labs, were within +/-15% of the medians. In contrast, results from the Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 instruments were 28% below the median, whereas Tosoh AIA exhibited a high positive bias averaging 67% above the median, which is consistent with what has been seen in previous NYS PT events. Furthermore, the average %CV for the Ortho Clinical instruments was 3-5 times higher than those for the other methods suggesting poor reproducibility.

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 means. 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 101 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 22% of the total number of labs. Five of the eight methods, used by 36% of the labs, gave results within +/-10% of the all method median, but averaged 7% higher than the assigned targets. Of the remaining methods, Beckman measured 12% lower than the all method median, and 4% lower than the targets, whereas the Siemens Advia Centaur peer group (used by 25% of participants) was 15% above the all method median and 26% higher than the target. Siemens Immulite was 12% and 22% above the median and target, respectively. Most methods somewhat overestimated AFP levels in our samples, but the overall difference in measurements between most methods is less than 15%, which is a result similar to what has been observed in previous NYS PT events.

PSA (Table 7, Figure 7): Results were reported by 242 labs using instruments from nine manufacturers. Results from two methods, Beckman Unicel/Access and Siemens Dimension (RxL Max Xpand Plus, EXL), were clearly higher than those from the others at 27% and 25% above the target, respectively. In contrast, results from the rest of the methods ranged from 1% (Siemens Advia Centaur XP & CP) to 17% (Abbott Architect and Siemens Dimension Vista) above the target. These results suggest that there is still a difference in how the different methods are calibrated.

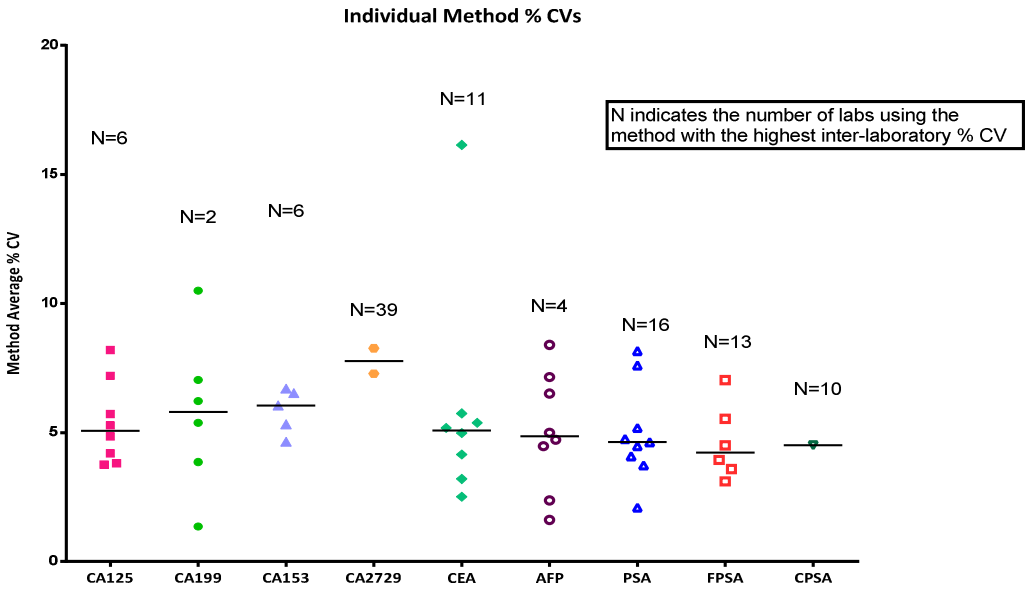
Free PSA (Table 8, Figure 8): Results were reported by 85 labs using instruments from seven manufacturers which corresponded to six peer groups plus one with N<3. In addition, three of the six peer

groups comprised less than 10 labs each, and along with the N<3 method made up 25% of the participants. The remaining three methods were used by 75% of labs with 35% Beckman Unicel/Access calibrated with the Hybritech standards, 25% Roche Elecsys/E170/Cobas, and 15% Siemens Immulite 2000. Results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (33% higher than the all method medians and 53% higher than the targets), while there were no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. Abbott Architect was 14% above the all method median and 31% above the assigned targets, while all of the other methods were within +/-10% of the all method medians, but ranged from 3% to 23% above the assigned targets. We calculated % free PSA for each peer group using their respective average PSA and free PSA levels. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA, but all were on average within 2.4% of the value calculated from the assigned targets, differences that likely are not clinically significant.

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 and good inter-laboratory agreement indicated by an average %CV of 4.5% (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 (see graph below). Most %CVs are <10% but there are some notable outliers, which could at least in part be caused by the low number of labs using that particular method.



Median %CV distribution for each analyte, with individual symbols representing separate peer groups.

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 or it could (and has) lead to failure if the two peer groups are substantially different. Furthermore, make sure to only select a qualifier (< or >) when your result is below or above your quantifiable range or you may end up with a technical failure. No changes can be made for incorrect or missing information after the submission deadline.

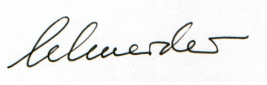
Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

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 .

For those labs that elected to receive the NYS PT next year, the scheduled dates for the 2016 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
January 26, 2016	February 10, 2016
May 3, 2016	May 18, 2016
August 30, 2016	September 14, 2016

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: 9-15 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									
TM291	11	38.7	**31.7**	**45.7**	7.0	3.88		1.26	
TM292	11	26.3	**20.9**	**31.7**	5.4	3.12		1.27	
TM293	11	28.8	**23.4**	**34.2**	5.4	5.90		1.25	
TM294	11	55.1	**45.2**	**65.0**	9.9	3.92		1.27	
TM295	11	32.5	**26.7**	**38.4**	5.9	2.00		1.29	
					mean ±SD	3.76	1.43	1.27	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM291	25	34.4	**28.2**	**40.6**	6.2	5.55		1.12	
TM292	25	22.7	**17.3**	**28.1**	5.4	5.59		1.10	
TM293	25	23.1	**17.7**	**28.5**	5.4	6.45		1.00	
TM294	23	50.2	**41.2**	**59.2**	9.0	3.63		1.15	
TM295	25	27.2	**21.8**	**32.6**	5.4	5.18		1.08	
					mean ±SD	5.28	1.04	1.09	0.06
Roche Elecsys & Cobas BME/BMR									
TM291	17	26.4	**21.0**	**31.8**	5.4	4.20		0.86	
TM292	16	19.0	**13.6**	**24.4**	5.4	3.95		0.92	
TM293	17	21.2	**15.8**	**26.6**	5.4	3.58		0.92	
TM294	17	37.8	**31.0**	**44.6**	6.8	3.73		0.87	
TM295	17	23.1	**17.7**	**28.5**	5.4	3.59		0.92	
					mean ±SD	3.81	0.26	0.90	0.03
Siemens Advia Centaur XP & CP COB/COC									
TM291	31	32.7	**26.8**	**38.6**	5.9	5.05		1.07	
TM292	31	22.4	**17.0**	**27.8**	5.4	6.12		1.08	
TM293	31	24.2	**18.8**	**29.6**	5.4	5.21		1.05	
TM294	31	47.6	**39.0**	**56.2**	8.6	5.82		1.09	
TM295	31	27.6	**22.2**	**33.0**	5.4	6.41		1.10	
					mean ±SD	5.72	0.58	1.08	0.02
Siemens Immulite 2000 DPB/DPD									
TM291	13	28.6	**23.2**	**34.0**	5.4	6.75		0.93	
TM292	13	18.4	**13.0**	**23.8**	5.4	6.63		0.89	
TM293	13	19.7	**14.3**	**25.1**	5.4	7.61		0.86	
TM294	13	39.4	**32.3**	**46.5**	7.1	8.17		0.91	
TM295	13	22.9	**17.5**	**28.3**	5.4	6.86		0.91	
					mean ±SD	7.20	0.66	0.90	0.03
Siemens Dimension Vista (LOCI) DUV									
TM291	4	24.7	**19.3**	**30.1**	5.4	4.66		0.81	
TM292	4	18.9	**13.5**	**24.3**	5.4	4.02		0.91	
TM293	4	22.9	**17.5**	**28.3**	5.4	4.10		1.00	
TM294	4	35.4	**29.0**	**41.8**	6.4	3.87		0.81	
TM295	4	22.9	**17.5**	**28.3**	5.4	4.28		0.91	
					mean ±SD	4.19	0.30	0.89	0.08
Ortho Clinical Diag Vitros ECi/ECiQ & 5600 JJC/JJF									
TM291	6	18.3	**12.9**	**23.7**	5.4	6.61		0.60	
TM292	6	9.4	**4.0**	**14.8**	5.4	9.68		0.45	
TM293	6	11.0	**5.6**	**16.4**	5.4	9.73		0.48	
TM294	6	31.3	**25.7**	**36.9**	5.6	7.48		0.72	
TM295	6	13.2	**7.8**	**18.6**	5.4	7.50		0.52	
					mean ±SD	8.20	1.42	0.54	0.12

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Table 1 (cont.): 9-15 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									
TM291	6	38.7	**31.7**	**45.7**	7.0	3.54		1.26	
TM292	6	26.6	**21.2**	**32.0**	5.4	5.11		1.29	
TM293	6	30.1	**24.7**	**35.5**	5.4	5.28		1.31	
TM294	6	57.4	**47.1**	**67.7**	10.3	5.26		1.32	
TM295	6	33.5	**27.5**	**39.5**	6.0	5.07		1.33	
					mean ±SD	4.85	0.74	1.30	0.03

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM291	**113**	**30.7**	**4.85**	**3.54**	**6.75**
TM292	**112**	**20.7**	**5.35**	**3.12**	**9.68**
TM293	**113**	**23.0**	**5.59**	**3.58**	**9.73**
TM294	**111**	**43.5**	**4.59**	**3.63**	**8.17**
TM295	**113**	**25.2**	**5.13**	**2.00**	**7.50**
		Average	**5.10**		
		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

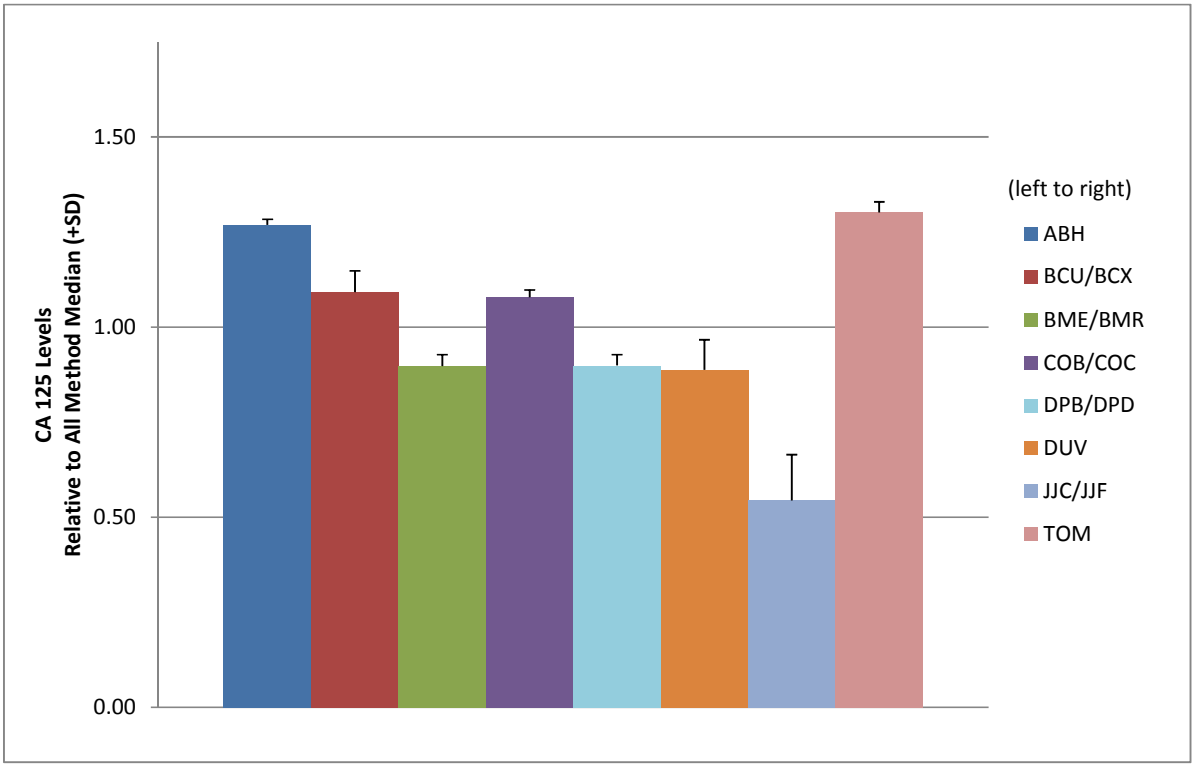

Table 2: 9-15 NYS Tumor Marker PT Summary for CA 19-9

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									
TM291	2	78.0	**64.0**	**92.0**	14.0	14.59		4.26	
TM292	2	250.3	**205.2**	**295.4**	45.1	8.11		5.44	
TM293	2	107.1	**87.8**	**126.4**	19.3	11.95		4.00	
TM294	2	182.4	**149.6**	**215.2**	32.8	11.01		5.17	
TM295	2	128.7	**105.5**	**151.9**	23.2	6.87		4.88	
					mean ±SD	10.50	3.08	4.75	0.61
Beckman Unicel & Access/2 BCU/BCX									
TM291	20	16.8	**13.2**	**20.4**	3.6	8.81		0.92	
TM292	20	46.0	**37.7**	**54.3**	8.3	6.46		1.00	
TM293	20	22.7	**18.6**	**26.8**	4.1	8.15		0.85	
TM294	20	35.3	**28.9**	**41.7**	6.4	5.64		1.00	
TM295	20	25.9	**21.2**	**30.6**	4.7	6.14		0.98	
					mean ±SD	7.04	1.37	0.95	0.07
Roche Elecsys & Cobas BME/BMR									
TM291	12	17.2	**13.6**	**20.8**	3.6	4.77		0.94	
TM292	12	40.4	**33.1**	**47.7**	7.3	3.04		0.88	
TM293	12	23.1	**18.9**	**27.3**	4.2	3.72		0.86	
TM294	12	31.8	**26.1**	**37.5**	5.7	3.40		0.90	
TM295	12	24.6	**20.2**	**29.0**	4.4	4.39		0.93	
					mean ±SD	3.86	0.71	0.90	0.03
Siemens Advia Centaur XP COB									
TM291	29	34.7	**28.5**	**40.9**	6.2	5.07		1.90	
TM292	29	97.9	**80.3**	**115.5**	17.6	6.08		2.13	
TM293	29	45.9	**37.6**	**54.2**	8.3	7.12		1.71	
TM294	29	70.5	**57.8**	**83.2**	12.7	7.02		2.00	
TM295	29	52.0	**42.6**	**61.4**	9.4	5.79		1.97	
					mean ±SD	6.22	0.86	1.94	0.15
Siemens Dimension Vista DUV									
TM291	2	18.3	**14.7**	**21.9**	3.6	1.91		1.00	
TM292	2	52.3	**42.9**	**61.7**	9.4	2.98		1.14	
TM293	2	26.8	**22.0**	**31.6**	4.8	1.04		1.00	
TM294	2	41.2	**33.8**	**48.6**	7.4	0.17		1.17	
TM295	2	29.4	**24.1**	**34.7**	5.3	0.71		1.11	
					mean ±SD	1.36	1.10	1.08	0.08
Tosoh AIA TOM									
TM291	6	20.2	**16.6**	**23.8**	3.6	3.61		1.10	
TM292	6	36.3	**29.8**	**42.8**	6.5	3.86		0.79	
TM293	6	29.2	**23.9**	**34.5**	5.3	8.25		1.09	
TM294	6	32.0	**26.2**	**37.8**	5.8	5.69		0.91	
TM295	6	26.4	**21.6**	**31.2**	4.8	5.49		1.00	
					mean ±SD	5.38	1.86	0.98	0.13

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Table 2 (cont.): 9-15 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM291	71	18.3	4.77	1.91	8.81
TM292	71	46.0	3.86	2.98	6.46
TM293	71	26.8	7.12	1.04	8.25
TM294	71	35.3	5.64	0.17	7.02
TM295	71	26.4	5.49	0.71	6.14
			Average*	5.38	

*Abbott excluded from all calculations

Allowable CV %	6.0
Allowable Error if >/= 20 U/ml (+/-) %	18.0
Allowable Error if < 20 U/ml (+/- U/ml)	3.6

Figure 2: CA 19-9 Method Comparison

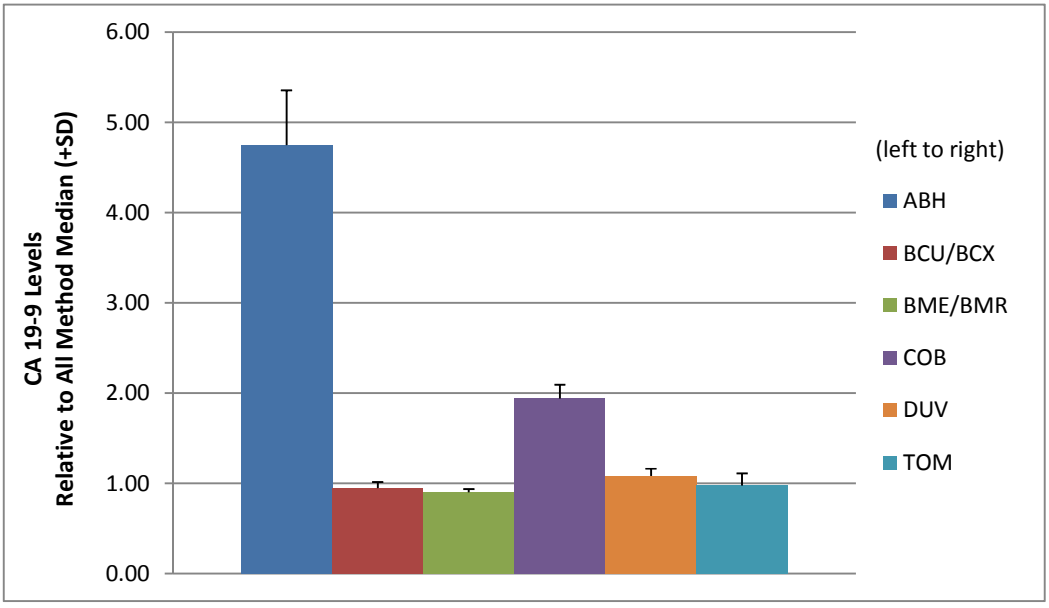

Table 3: 9-15 NYS Tumor Marker PT Summary for CA 15-3

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									
TM291	5	18.3	**15.0**	**21.6**	3.3	5.25		0.97	
TM292	5	23.8	**19.5**	**28.1**	4.3	6.30		0.97	
TM293	5	55.1	**45.2**	**65.0**	9.9	7.68		0.97	
TM294	5	39.9	**32.7**	**47.1**	7.2	5.61		0.99	
TM295	5	34.6	**28.4**	**40.8**	6.2	5.43		0.97	
					mean ±SD	6.05	1.02	0.98	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM291	12	13.1	**10.7**	**15.5**	2.4	5.04		0.69	
TM292	12	17.3	**14.2**	**20.4**	3.1	6.76		0.71	
TM293	12	39.0	**32.0**	**46.0**	7.0	3.13		0.69	
TM294	12	28.2	**23.1**	**33.3**	5.1	4.11		0.70	
TM295	12	24.6	**20.2**	**29.0**	4.4	4.19		0.69	
					mean ±SD	4.65	1.36	0.70	0.01
Roche Elecsys & Cobas BME/BMR									
TM291	13	19.9	**16.3**	**23.5**	3.6	5.78		1.05	
TM292	13	25.7	**21.1**	**30.3**	4.6	5.49		1.05	
TM293	12	59.5	**48.8**	**70.2**	10.7	3.70		1.05	
TM294	13	42.4	**34.8**	**50.0**	7.6	5.64		1.05	
TM295	13	37.4	**30.7**	**44.1**	6.7	5.99		1.05	
					mean ±SD	5.32	0.92	1.05	0.00
Siemens Advia Centaur XP & CP COB/COC									
TM291	20	18.9	**15.5**	**22.3**	3.4	5.82		1.00	
TM292	20	24.5	**20.1**	**28.9**	4.4	5.39		1.00	
TM293	20	56.7	**46.5**	**66.9**	10.2	6.17		1.00	
TM294	20	40.2	**33.0**	**47.4**	7.2	9.30		1.00	
TM295	20	35.5	**29.1**	**41.9**	6.4	5.94		1.00	
					mean ±SD	6.53	1.58	1.00	0.00
Siemens Immulite 2000 DPD									
TM291	6	24.4	**20.0**	**28.8**	4.4	5.90		1.29	
TM292	6	31.8	**26.1**	**37.5**	5.7	3.71		1.30	
TM293	6	76.8	**63.0**	**90.6**	13.8	9.77		1.35	
TM294	6	53.8	**44.1**	**63.5**	9.7	8.38		1.34	
TM295	6	47.4	**38.9**	**55.9**	8.5	4.94		1.34	
					mean±SD	6.70	2.84	1.32	0.02

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

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM291	56	18.9		5.78	5.04	5.90
TM292	56	24.5		5.49	3.71	6.76
TM293	55	56.7		6.17	3.13	9.77
TM294	56	40.2		5.64	4.11	9.30
TM295	56	35.5		5.43	4.19	5.99
			Average	5.70		
			Allowable CV %	6.0		
			Allowable Error (+/-) %	18.0		

Figure 3: CA 15-3 Method Comparison

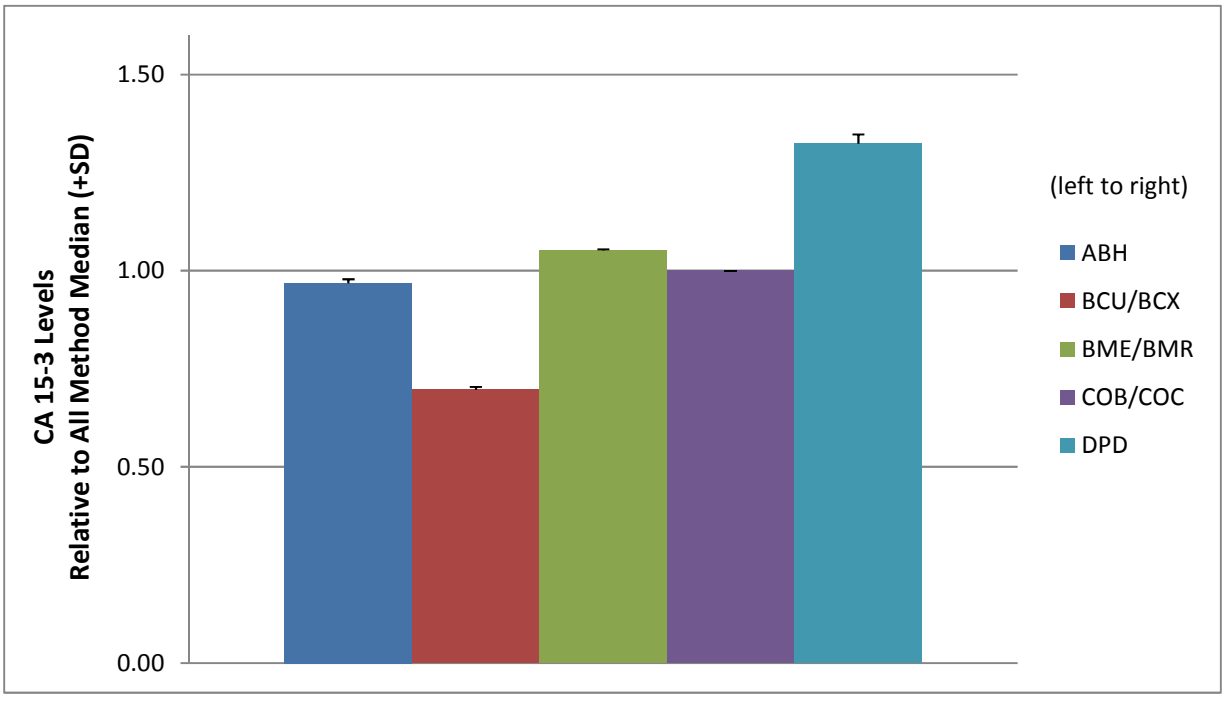

Table 4: 9-15 NYS Tumor Marker PT Summary for CA 27.29

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									
TM291	39	20.1	**12.8**	**27.5**	7.4	13.58		0.99	
TM292	38	30.2	**22.9**	**37.6**	7.4	9.01		1.06	
TM293	39	87.1	**68.8**	**105.4**	18.3	5.37		1.16	
TM294	39	59.7	**47.2**	**72.2**	12.5	6.18		1.13	
TM295	39	50.3	**39.7**	**60.9**	10.6	7.16		1.14	
					mean ±SD	8.26	3.27	1.10	0.07
Tosoh AIA TOM									
TM291	7	20.7	**13.4**	**28.1**	7.4	9.18		1.01	
TM292	7	26.8	**19.5**	**34.2**	7.4	7.13		0.94	
TM293	7	62.5	**49.4**	**75.6**	13.1	5.41		0.84	
TM294	7	46.0	**36.3**	**55.7**	9.7	8.70		0.87	
TM295	7	38.2	**30.2**	**46.2**	8.0	5.99		0.86	
					mean ±SD	7.28	1.64	0.90	0.07

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM291	**46**	**20.4**		**11.38**	**9.18**	**13.58**
TM292	**45**	**28.5**		**8.07**	**7.13**	**9.01**
TM293	**46**	**74.8**		**5.39**	**5.37**	**5.41**
TM294	**46**	**52.9**		**7.44**	**6.18**	**8.70**
TM295	**46**	**44.3**		**6.58**	**5.99**	**7.16**
			Average	**7.77**		

Allowable CV %	**7.0**
Allowable Error if >/= 35 U/ml (+/-) %	**21.0**
Allowable Error if < 35 U/ml (+/- U/ml)	**7.35**

Figure 4: CA 27.29 Method Comparison

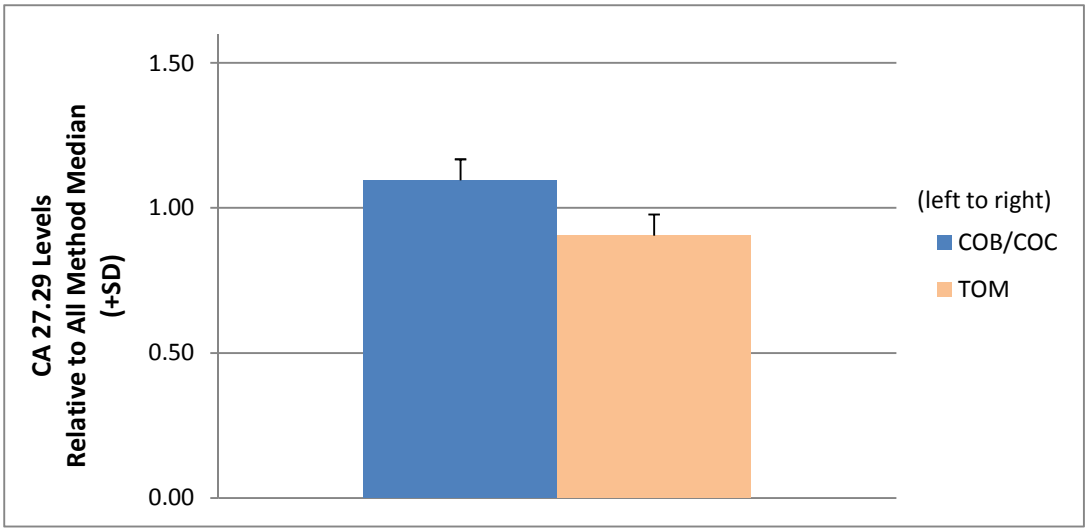

Table 5: 9-15 NYS Tumor Marker PT Summary for CEA

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									
TM291	15	9.5	**7.8**	**11.2**	1.7	5.26		1.14	
TM292	15	8.6	**7.1**	**10.1**	1.5	5.47		1.12	
TM293	15	17.1	**14.0**	**20.2**	3.1	5.79		1.11	
TM294	15	15.4	**12.6**	**18.2**	2.8	3.51		1.12	
TM295	15	9.4	**7.7**	**11.1**	1.7	4.89		1.13	
					mean ±SD	4.98	0.89	1.13	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM291	32	8.2	**6.7**	**9.7**	1.5	5.12		0.99	
TM292	32	7.8	**6.4**	**9.2**	1.4	6.15		1.02	
TM293	32	15.0	**12.3**	**17.7**	2.7	5.73		0.98	
TM294	32	13.7	**11.2**	**16.2**	2.5	4.31		1.00	
TM295	32	8.3	**6.8**	**9.8**	1.5	4.58		0.99	
					mean ±SD	5.18	0.77	1.00	0.02
Roche Elecsys & Cobas BME/BMR									
TM291	20	7.8	**6.4**	**9.2**	1.4	3.97		0.94	
TM292	20	7.5	**6.2**	**8.9**	1.4	4.40		0.98	
TM293	20	13.2	**10.8**	**15.6**	2.4	4.32		0.86	
TM294	20	12.3	**10.1**	**14.5**	2.2	3.66		0.89	
TM295	20	7.7	**6.3**	**9.1**	1.4	4.42		0.92	
					mean ±SD	4.15	0.33	0.92	0.05
Siemens Advia Centaur XP & CP COB/COC									
TM291	43	8.4	**6.9**	**9.9**	1.5	5.24		1.01	
TM292	43	7.4	**6.1**	**8.7**	1.3	5.54		0.97	
TM293	43	15.7	**12.9**	**18.5**	2.8	5.16		1.02	
TM294	43	13.8	**11.3**	**16.3**	2.5	4.86		1.00	
TM295	43	8.4	**6.9**	**9.9**	1.5	6.07		1.01	
					mean ±SD	5.37	0.46	1.00	0.02
Siemens Immulite 1000/2000 DPB/DPD									
TM291	11	10.0	**8.2**	**11.8**	1.8	7.10		1.20	
TM292	11	8.8	**7.2**	**10.4**	1.6	5.34		1.15	
TM293	11	19.4	**15.9**	**22.9**	3.5	5.05		1.26	
TM294	11	16.7	**13.7**	**19.7**	3.0	3.83		1.21	
TM295	11	9.9	**8.1**	**11.7**	1.8	7.37		1.19	
					mean ±SD	5.74	1.48	1.20	0.04
Siemens Dimension Vista DUV									
TM291	25	8.0	**6.6**	**9.4**	1.4	2.25		0.96	
TM292	25	7.5	**6.2**	**8.9**	1.4	2.93		0.98	
TM293	24	14.4	**11.8**	**17.0**	2.6	2.08		0.94	
TM294	25	13.1	**10.7**	**15.5**	2.4	2.67		0.95	
TM295	24	8.0	**6.6**	**9.4**	1.4	2.63		0.96	
					mean ±SD	2.51	0.34	0.96	0.02
Ortho Clinical Diag Vitros ECi/ECiQ & 5600 JJC/JJF									
TM291	11	5.6	**4.6**	**6.6**	1.0	20.36		0.67	
TM292	11	4.9	**4.0**	**5.8**	0.9	19.39		0.64	
TM293	11	12.9	**10.6**	**15.2**	2.3	8.76		0.84	
TM294	11	11.3	**9.3**	**13.3**	2.0	13.54		0.82	
TM295	11	5.3	**4.3**	**6.3**	1.0	18.68		0.63	
					mean ±SD	16.14	4.90	0.72	0.10

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Table 5 (cont.): 9-15 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									
TM291	7	14.5	**11.9**	**17.1**	2.6	2.76		1.75	
TM292	7	12.4	**10.2**	**14.6**	2.2	2.58		1.62	
TM293	7	25.1	**20.6**	**29.6**	4.5	3.19		1.64	
TM294	7	22.5	**18.5**	**26.6**	4.1	4.27		1.64	
TM295	7	14.4	**11.8**	**17.0**	2.6	3.19		1.72	
					mean ±SD	3.20	0.66	1.67	0.06

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM291	**164**	**8.3**	**5.18**	**2.25**	**20.36**
TM292	**164**	**7.7**	**5.40**	**2.58**	**19.39**
TM293	**163**	**15.4**	**5.11**	**2.08**	**8.76**
TM294	**164**	**13.8**	**4.05**	**2.67**	**13.54**
TM295	**163**	**8.4**	**4.74**	**2.63**	**18.68**

Average	**4.89**
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

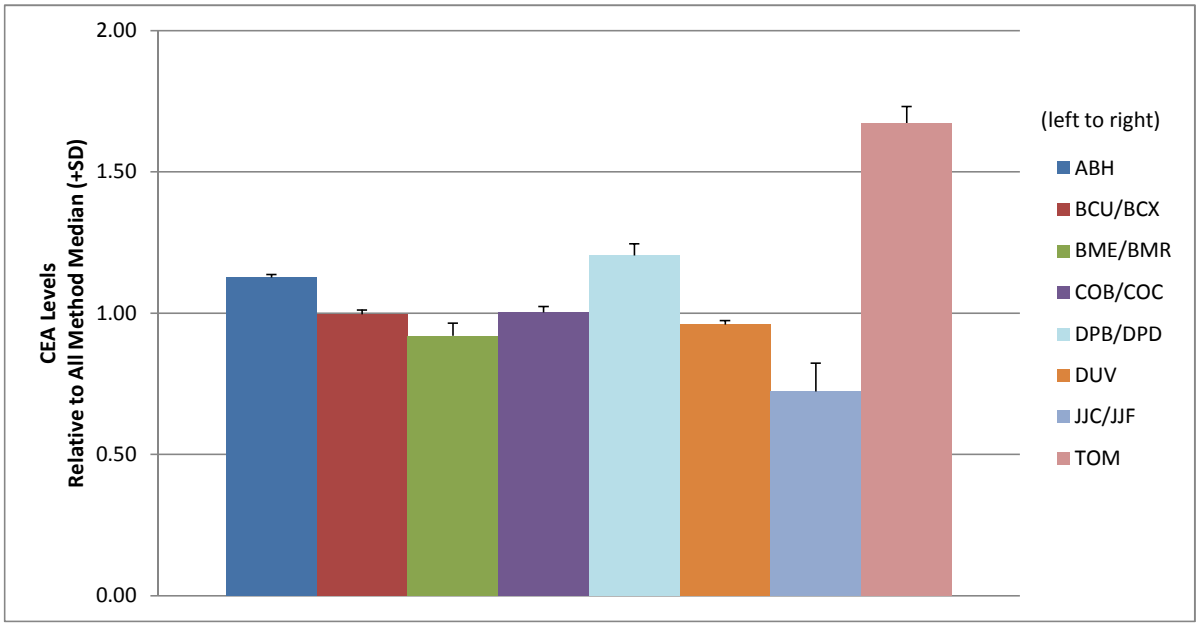

Table 6: 9-15 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit Based on 3SD	Upper Limit Based on 3SD	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott Architect ABH											
TM291	5	6.2	**5.4**	**7.0**	0.8	4.19		0.92		1.06	
TM292	5	11.4	**10.9**	**11.9**	0.5	1.58		0.93		0.99	
TM293	5	16.9	**15.6**	**18.2**	1.3	2.60		0.95		0.99	
TM294	5	9.2	**8.8**	**9.6**	0.4	1.41		0.94		1.04	
TM295	5	21.9	**20.6**	**23.3**	1.4	2.05		0.94		1.03	
					mean ±SD	2.37	1.12	0.94	0.01	1.02	0.03
Beckman Unicel & Access/2 BCU/BCX											
TM291	27	5.8	**4.8**	**6.8**	1.0	5.69		0.86		0.99	
TM292	27	10.6	**9.0**	**12.2**	1.6	4.91		0.87		0.92	
TM293	27	15.5	**13.4**	**17.6**	2.1	4.58		0.87		0.91	
TM294	27	8.7	**7.2**	**10.2**	1.5	5.63		0.89		0.98	
TM295	26	20.7	**18.1**	**23.3**	2.6	4.15		0.89		0.97	
					mean ±SD	4.99	0.67	0.88	0.01	0.96	0.04
Roche Elecsys & Cobas BME/BMR											
TM291	16	7.0	**5.0**	**9.0**	2.0	9.71		1.04		1.20	
TM292	16	12.9	**10.6**	**15.2**	2.3	6.05		1.05		1.12	
TM293	16	19.0	**15.2**	**22.8**	3.8	6.74		1.07		1.12	
TM294	16	10.4	**8.2**	**12.6**	2.2	6.92		1.06		1.17	
TM295	16	25.1	**20.3**	**29.9**	4.8	6.33		1.08		1.18	
					mean ±SD	7.15	1.47	1.06	0.02	1.16	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM291	25	7.9	**5.6**	**10.2**	2.3	9.62		1.17		1.35	
TM292	25	14.0	**11.2**	**16.8**	2.8	6.71		1.14		1.22	
TM293	24	20.5	**17.9**	**23.1**	2.6	4.20		1.15		1.21	
TM294	25	11.2	**8.6**	**13.8**	2.6	7.86		1.14		1.27	
TM295	24	27.0	**23.6**	**30.4**	3.4	4.15		1.16		1.26	
					mean ±SD	6.51	2.37	1.15	0.01	1.26	0.06
Siemens Immulite 1000 & 2000 DPB/DPD											
TM291	11	7.2	**6.5**	**8.0**	0.8	3.47		1.07		1.23	
TM292	11	13.6	**12.0**	**15.3**	1.7	4.04		1.11		1.19	
TM293	11	20.9	**18.5**	**23.3**	2.4	3.88		1.18		1.23	
TM294	11	10.8	**9.2**	**12.4**	1.6	5.00		1.10		1.22	
TM295	11	26.5	**21.8**	**31.2**	4.7	5.96		1.14		1.24	
					mean ±SD	4.47	1.00	1.12	0.04	1.22	0.02
Siemens Dimension Vista DUV											
TM291	5	6.0	**5.8**	**6.2**	0.2	1.00		0.89		1.02	
TM292	7	10.9	**10.3**	**11.5**	0.6	1.93		0.89		0.95	
TM293	7	16.2	**15.4**	**17.0**	0.8	1.67		0.91		0.95	
TM294	7	8.8	**8.2**	**9.4**	0.6	2.39		0.90		0.99	
TM295	7	21.2	**20.5**	**21.9**	0.7	1.13		0.91		0.99	
					mean ±SD	1.62	0.57	0.90	0.01	0.98	0.03
Ortho Clinical Diag Vitros ECi/ECiQ & 5600 JJC/JJF											
TM291	6	6.7	**5.6**	**7.8**	1.1	5.52		0.99		1.14	
TM292	6	11.8	**10.4**	**13.2**	1.4	4.07		0.96		1.03	
TM293	6	17.3	**14.7**	**19.9**	2.6	5.09		0.97		1.02	
TM294	6	9.4	**8.3**	**10.5**	1.1	4.04		0.96		1.06	
TM295	6	22.9	**19.5**	**26.3**	3.4	4.89		0.98		1.07	
					mean ±SD	4.72	0.65	0.97	0.01	1.07	0.05

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Table 6 (cont.): 9-15 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit Based on 3SD	Upper Limit Based on 3SD	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Tosoh AIA TOM											
TM291	4	6.8	**4.5**	**9.1**	2.3	11.18		1.01		1.16	
TM292	4	12.7	**9.0**	**16.5**	3.8	9.84		1.04		1.11	
TM293	4	18.2	**14.2**	**22.2**	4.0	7.36		1.03		1.07	
TM294	4	10.2	**7.8**	**12.6**	2.4	7.94		1.04		1.15	
TM295	4	23.6	**19.6**	**27.6**	4.0	5.68		1.02		1.11	
					mean ±SD	8.40	2.15	1.03	0.01	1.12	0.04

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max %CV		All Method Median/ IS Target	
TM291	**99**	**6.8**	**5.9**	**0.50**		**5.61**	**1.00**	**11.18**		**1.15**	
TM292	**101**	**12.3**	**11.5**	**0.93**		**4.49**	**1.58**	**9.84**		**1.07**	
TM293	**100**	**17.8**	**17.0**	**1.38**		**4.39**	**1.67**	**7.36**		**1.04**	
TM294	**101**	**9.8**	**8.9**	**0.41**		**5.32**	**1.41**	**7.94**		**1.11**	
TM295	**99**	**23.3**	**21.3**	**2.67**		**4.52**	**1.13**	**6.33**		**1.09**	
					Average	**4.86**			mean ±SD	**1.09**	0.04

Allowable Error = +/-3SD

Figure 6: AFP Method Comparison

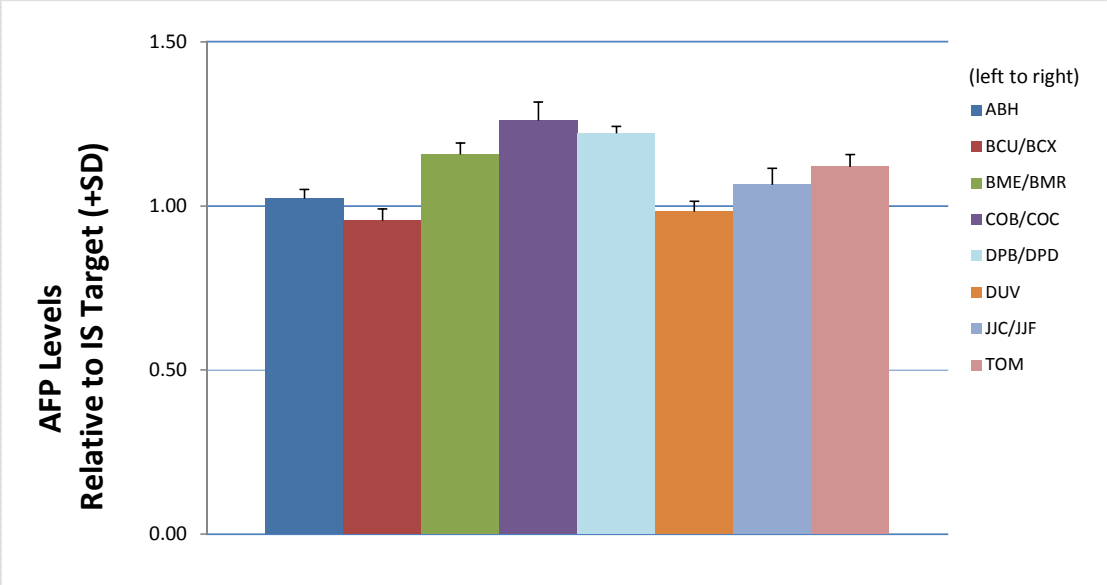

Table 7: 9-15 NYS Tumor Marker PT Summary for PSA

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											
TM291	20	18.01	**14.77**	**21.25**	3.24	4.78		1.07		1.18	
TM292	20	2.25	**1.85**	**2.66**	0.41	3.11		1.01		1.17	
TM293	20	6.15	**5.04**	**7.26**	1.11	5.53		1.03		1.16	
TM294	20	8.49	**6.96**	**10.02**	1.53	5.42		1.04		1.17	
TM295	20	4.07	**3.34**	**4.80**	0.73	4.91		1.02		1.15	
					mean ±SD	4.75	0.97	1.04	0.02	1.17	0.01
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM291	53	19.62	**16.09**	**23.15**	3.53	5.40		1.17		1.28	
TM292	52	2.43	**1.99**	**2.87**	0.44	3.29		1.09		1.27	
TM293	53	6.70	**5.49**	**7.91**	1.21	6.72		1.12		1.27	
TM294	53	9.28	**7.61**	**10.95**	1.67	5.28		1.14		1.28	
TM295	53	4.41	**3.62**	**5.20**	0.79	5.22		1.10		1.25	
					mean ±SD	5.18	1.22	1.13	0.03	1.27	0.01
Roche Elecsys & Cobas BME/BMR											
TM291	35	16.78	**13.76**	**19.80**	3.02	4.77		1.00		1.10	
TM292	35	2.22	**1.82**	**2.62**	0.40	4.50		1.00		1.16	
TM293	35	5.90	**4.84**	**6.96**	1.06	4.41		0.99		1.12	
TM294	35	8.05	**6.60**	**9.50**	1.45	4.72		0.99		1.11	
TM295	35	4.00	**3.28**	**4.72**	0.72	4.75		1.00		1.13	
					mean ±SD	4.63	0.16	1.00	0.01	1.12	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM291	49	15.15	**12.42**	**17.88**	2.73	3.89		0.90		0.99	
TM292	47	2.03	**1.66**	**2.40**	0.37	3.45		0.91		1.06	
TM293	49	5.30	**4.35**	**6.25**	0.95	4.53		0.89		1.00	
TM294	49	7.29	**5.98**	**8.60**	1.31	2.88		0.89		1.00	
TM295	49	3.58	**2.94**	**4.22**	0.64	3.91		0.90		1.01	
					mean ±SD	3.73	0.61	0.90	0.01	1.01	0.03
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM291	16	16.11	**13.21**	**19.01**	2.90	7.32		0.96		1.05	
TM292	16	2.07	**1.70**	**2.44**	0.37	9.66		0.93		1.08	
TM293	16	5.77	**4.73**	**6.81**	1.04	8.67		0.97		1.09	
TM294	16	7.95	**6.52**	**9.38**	1.43	7.80		0.98		1.09	
TM295	16	3.80	**3.12**	**4.48**	0.68	7.37		0.95		1.07	
					mean ±SD	8.16	1.00	0.96	0.02	1.08	0.02
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM291	15	19.28	**15.81**	**22.75**	3.47	4.93		1.15		1.26	
TM292	15	2.40	**1.97**	**2.83**	0.43	4.17		1.08		1.25	
TM293	15	6.64	**5.44**	**7.84**	1.20	4.82		1.11		1.26	
TM294	15	9.21	**7.55**	**10.87**	1.66	4.34		1.13		1.27	
TM295	15	4.32	**3.54**	**5.10**	0.78	4.17		1.08		1.22	
					mean±SD	4.48	0.36	1.11	0.03	1.25	0.02
Siemens Dimension Vista DUV											
TM291	24	17.77	**14.57**	**20.97**	3.20	2.42		1.06		1.16	
TM292	24	2.28	**1.87**	**2.69**	0.41	2.19		1.03		1.19	
TM293	24	6.22	**5.10**	**7.34**	1.12	2.09		1.04		1.18	
TM294	23	8.43	**6.91**	**9.95**	1.52	2.02		1.03		1.16	
TM295	24	4.04	**3.31**	**4.77**	0.73	1.73		1.01		1.14	
					mean ±SD	2.09	0.25	1.03	0.02	1.17	0.02

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Table 7 (cont.): 9-15 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											
TM291	21	16.21	**13.29**	**19.13**	2.92	7.16		0.97		1.06	
TM292	21	2.10	**1.72**	**2.48**	0.38	10.00		0.95		1.09	
TM293	21	5.68	**4.66**	**6.70**	1.02	7.39		0.95		1.07	
TM294	21	7.69	**6.31**	**9.07**	1.38	7.02		0.94		1.06	
TM295	21	3.72	**3.05**	**4.39**	0.67	6.45		0.93		1.05	
					mean ±SD	7.60	1.38	0.95	0.01	1.07	0.02
Tosoh AIA TOM											
TM291	9	16.73	**13.72**	**19.74**	3.01	3.77		1.00		1.09	
TM292	9	2.22	**1.82**	**2.62**	0.40	4.05		1.00		1.16	
TM293	9	5.96	**4.89**	**7.03**	1.07	4.03		1.00		1.13	
TM294	9	8.15	**6.68**	**9.62**	1.47	4.42		1.00		1.12	
TM295	9	3.89	**3.19**	**4.59**	0.70	4.11		0.97		1.10	
					mean ±SD	4.08	0.23	0.99	0.01	1.12	0.02

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max % CV		All Method Median/ IS Target	
TM291	**242**	**16.78**	15.28	0.51		**4.78**	**2.42**	**7.32**		**1.10**	
TM292	**239**	**2.22**	1.92	0.07		**4.05**	**2.19**	**10.00**		**1.16**	
TM293	**242**	**5.96**	5.29	0.21		**4.82**	**2.09**	**8.67**		**1.13**	
TM294	**241**	**8.15**	7.27	0.17		**4.72**	**2.02**	**7.80**		**1.12**	
TM295	**242**	**4.00**	3.54	0.13		**4.75**	**1.73**	**7.37**		**1.13**	
					Average	**4.62**			mean ±SD	**1.13**	0.02
					Allowable CV %	**6.00**					
					Allowable Error (+/-)%	**18.0**					

Figure 7: PSA Method Comparison

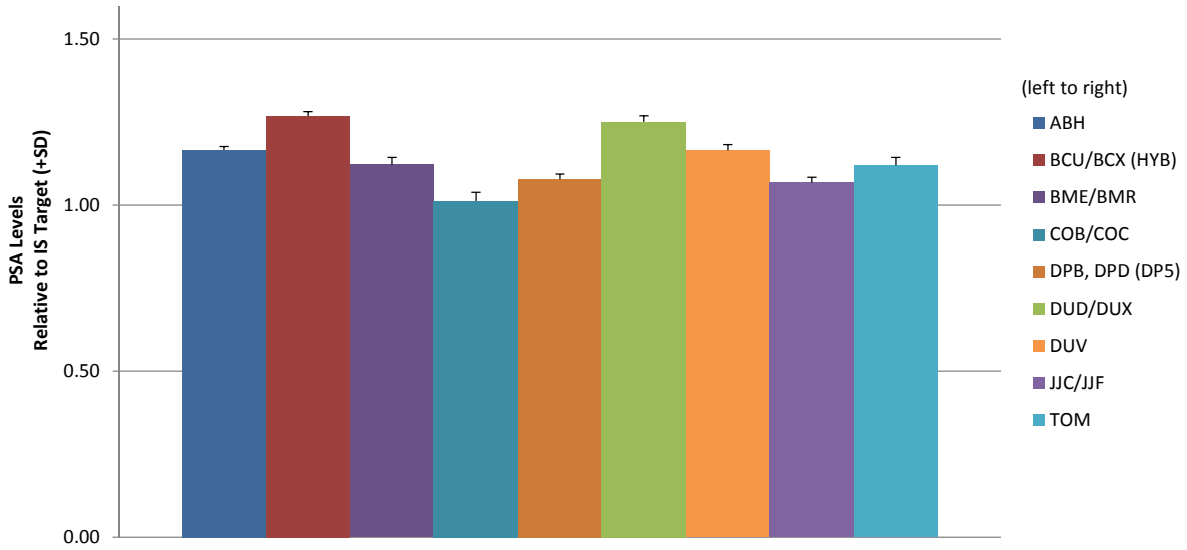

Table 8: 9-15 NYS Tumor Marker PT Summary for Free PSA

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													
TM291	7	2.13	**1.75**	**2.51**	0.38	7.46		1.15		1.31		11.8%	
TM292	7	0.56	**0.46**	**0.66**	0.10	3.93		1.12		1.32		24.9%	
TM293	7	0.69	**0.57**	**0.81**	0.12	5.36		1.13		1.28		11.2%	
TM294	7	0.98	**0.80**	**1.16**	0.18	5.00		1.14		1.31		11.5%	
TM295	7	1.22	**1.00**	**1.44**	0.22	5.90		1.15		1.32		30.0%	
					mean ±SD	5.53	1.30	1.14	0.01	1.31	0.02	17.9%	8.9%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)													
TM291	30	2.44	**2.00**	**2.88**	0.44	3.93		1.32		1.50		12.4%	
TM292	30	0.68	**0.56**	**0.80**	0.12	5.74		1.36		1.60		28.0%	
TM293	30	0.82	**0.67**	**0.97**	0.15	3.90		1.34		1.52		12.2%	
TM294	30	1.13	**0.93**	**1.33**	0.20	4.60		1.31		1.51		12.2%	
TM295	30	1.41	**1.16**	**1.66**	0.25	4.33		1.33		1.53		32.0%	
					mean ±SD	4.50	0.75	1.33	0.02	1.53	0.04	19.4%	9.8%
Roche Elecsys & Cobas BME/BMR													
TM291	21	1.85	**1.52**	**2.18**	0.33	4.05		1.00		1.14		11.0%	
TM292	21	0.50	**0.41**	**0.59**	0.09	2.80		1.00		1.18		22.5%	
TM293	21	0.61	**0.50**	**0.72**	0.11	3.61		1.00		1.13		10.3%	
TM294	21	0.86	**0.71**	**1.01**	0.15	3.60		1.00		1.15		10.7%	
TM295	21	1.06	**0.87**	**1.25**	0.19	3.87		1.00		1.15		26.5%	
					mean ±SD	3.59	0.48	1.00	0.00	1.15	0.02	16.2%	7.7%
Siemens Immulite 2000 DPD													
TM291	13	1.75	**1.44**	**2.07**	0.32	4.00		0.95		1.08		10.9%	
TM292	12	0.46	**0.37**	**0.55**	0.09	11.74		0.92		1.08		22.2%	
TM293	13	0.55	**0.45**	**0.65**	0.10	6.91		0.90		1.02		9.5%	
TM294	13	0.76	**0.62**	**0.90**	0.14	6.84		0.88		1.01		9.6%	
TM295	13	0.99	**0.81**	**1.17**	0.18	5.66		0.93		1.07		26.1%	
					mean ±SD	7.03	2.89	0.92	0.02	1.05	0.03	15.6%	7.9%
Siemens Dimension Vista DUD/DUX													
TM291	4	1.90	**1.56**	**2.24**	0.34	4.21		1.03		1.17		9.9%	
TM292	4	0.49	**0.40**	**0.58**	0.09	4.08		0.98		1.15		20.4%	
TM293	4	0.59	**0.48**	**0.70**	0.11	1.69		0.97		1.10		8.9%	
TM294	4	0.85	**0.70**	**1.00**	0.15	5.88		0.99		1.13		9.2%	
TM295	4	1.05	**0.86**	**1.24**	0.19	3.81		0.99		1.14		24.3%	
					mean ±SD	3.94	1.49	0.99	0.02	1.14	0.03	14.5%	7.3%
Siemens Dimension Vista DUV													
TM291	9	1.72	**1.41**	**2.03**	0.31	2.15		0.93		1.06		9.7%	
TM292	9	0.45	**0.36**	**0.54**	0.09	5.78		0.90		1.06		19.7%	
TM293	9	0.56	**0.46**	**0.66**	0.10	3.93		0.92		1.04		9.0%	
TM294	9	0.78	**0.64**	**0.92**	0.14	1.67		0.91		1.04		9.3%	
TM295	9	0.99	**0.81**	**1.17**	0.18	2.02		0.93		1.07		24.5%	
					mean ±SD	3.11	1.73	0.92	0.01	1.05	0.01	14.4%	7.2%

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Table 8 (cont.): 9-15 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		Measured %fPSA
TM291	84	1.85	1.63	0.05		4.00	1.14		10.6%		10.9%
TM292	83	0.50	0.42	0.03		5.74	1.18		22.1%		23.0%
TM293	84	0.61	0.54	0.04		3.93	1.13		10.2%		10.2%
TM294	84	0.86	0.75	0.05		4.60	1.15		10.3%		10.4%
TM295	84	1.06	0.92	0.05		4.33	1.15		26.1%		27.2%
							mean	±SD	mean	±SD	
					Average	4.52	1.15	0.02	15.9%	0.077	
					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 8: Free PSA Method Comparison

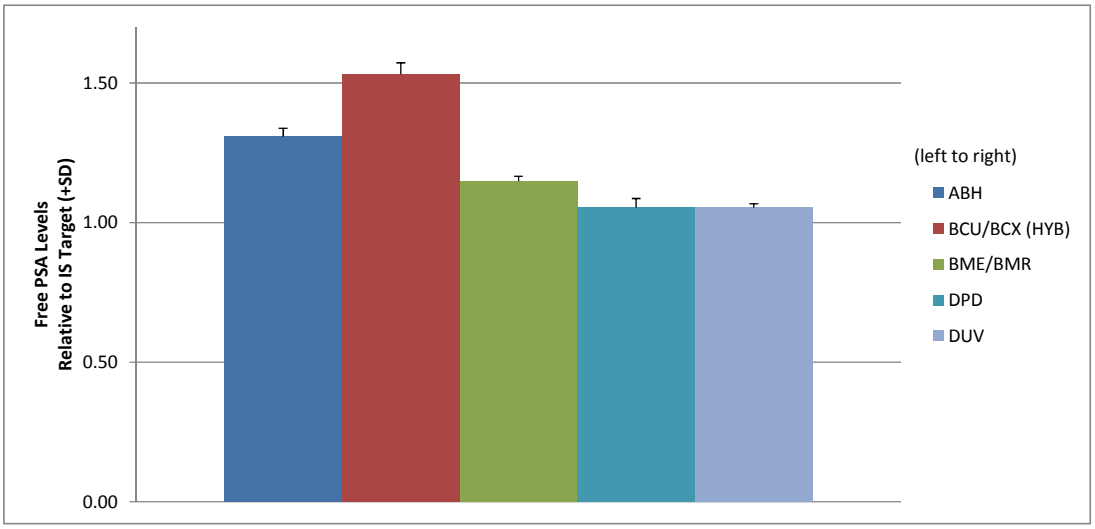

Table 9: 9-15 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM291	9	14.0	**11.5**	**16.5**	2.5	1.57		1.00	
TM292	7	1.6	**1.3**	**1.9**	0.3	5.00		1.00	
TM293	10	5.0	**4.1**	**5.8**	0.9	5.66		1.00	
TM294	10	6.8	**5.6**	**8.0**	1.2	5.00		1.00	
TM295	10	2.6	**2.2**	**3.1**	0.5	5.32		1.00	
					mean ±SD	4.51	1.66	1.00	0.00

Sample ID	All Method Median		Median % CV
TM291	**14.0**		**1.57**
TM292	**1.6**		**5.00**
TM293	**5.0**		**5.66**
TM294	**6.8**		**5.00**
TM295	**2.6**		**5.32**
		Average	**4.51**
		Allowable CV %	**6.0**
		Allowable Error (+/-)%	**18.0**