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October 5, 2016

New York State Soluble Tumor Markers Proficiency Test 9-2016 [1]

Dear Laboratory Director,

This is a summary and critique of the New York State Proficiency Test from September 2016 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/regulatory/clep/pt/summaries

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 (N ≥ 3). 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 ≥ 3). 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.

For this PT challenge, samples were prepared as serial 2-fold dilutions in order to assess linearity of the assays. See each analyte's section for information on the linearity. You should also review your own data to determine if they meet the linearity requirements of your method.

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 51 labs using instruments from eight different manufacturers corresponding to seven peer groups with N ≥ 3. The peer group means ranged from 35% below to 22% above the all method median, with Ortho Clinical Diagnostics being the lowest and Tosoh being the highest. Over half (58%) of the labs were in the two peer groups that fell at or within +/-11% 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 35.0 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. Nevertheless, all methods appear essentially linear over a 16-fold concentration range, though with somewhat different slopes. One method, Ortho Clinical, was unable to detect quantifiable amounts of CA125 in the lowest sample (TM306) and had a larger than usual scatter in the sample with the second lowest concentration.

CA19-9 (Table 2, Figure 2): Results were reported by 29 labs using instruments from five different manufacturers, though only three with N ≥ 3 for peer group grading. Forty-five percent of all reporting labs used Siemens ADVIA Centaur XP, 34% used either Beckman's Unicel or Access/2, and 10% used the Tosoh ST-AIA method. Similar to what has been seen in past events, results from the Siemens Advia Centaur method were almost two-fold higher than those from Beckman and Tosoh, and the Abbott Architect method results averaged 5.3 times higher than the all method median (data not shown, used by one lab only). All methods were linear over the 16 X concentration range.

The MUC1 breast cancer antigen was measured by 46 labs, with 61% using an instrument from one of five manufacturers (two with N=2) 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 methods used for CA15-3, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -34% from the all method medians and Siemens Immulite averaged 16% above the median. **CA27.29** measurements showed a 24% difference between the ADVIA Centaur XP/CP and the Tosoh methods, and the median CA27.29 measurements showed a 13-29% concentration dependent positive bias compared to the corresponding median CA15-3 measurements. With regard to linearity, both Siemens Immulite for CA15-3 and Tosoh for CA27.29 showed some overall deviation from linearity, however this may be affected by the small number of labs in each peer group.

CEA (Table 5, Figure 5): Results were reported by 77 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 3 to 20 labs. Tosoh AIA exhibited a high positive bias averaging 63% above the median and Siemens Immulite 2000 exhibited a smaller, though still positive bias of +14%. In contrast, Ortho Clinical Diagnostics Vitros 5600 was 15% below the median, while the rest of the methods were within +/-11% of the medians suggesting some degree of harmonization among the methods. With regard to linearity, Ortho Clinical exhibited some deviation and also a somewhat different concentration dependent response than the other methods.

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 41 labs using instruments from eight different manufacturers corresponding to eight peer groups. However, only two peer groups comprised more than four labs. Three of the eight methods, used by 41% of the labs, gave results within 6% below the target, and averaged 10% lower than the all method median. The remaining five methods averaged 12% above the target (range 6-20%), with the Siemens Centaur method exhibiting the highest positive bias at +20%. 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. All methods exhibited good linearity.

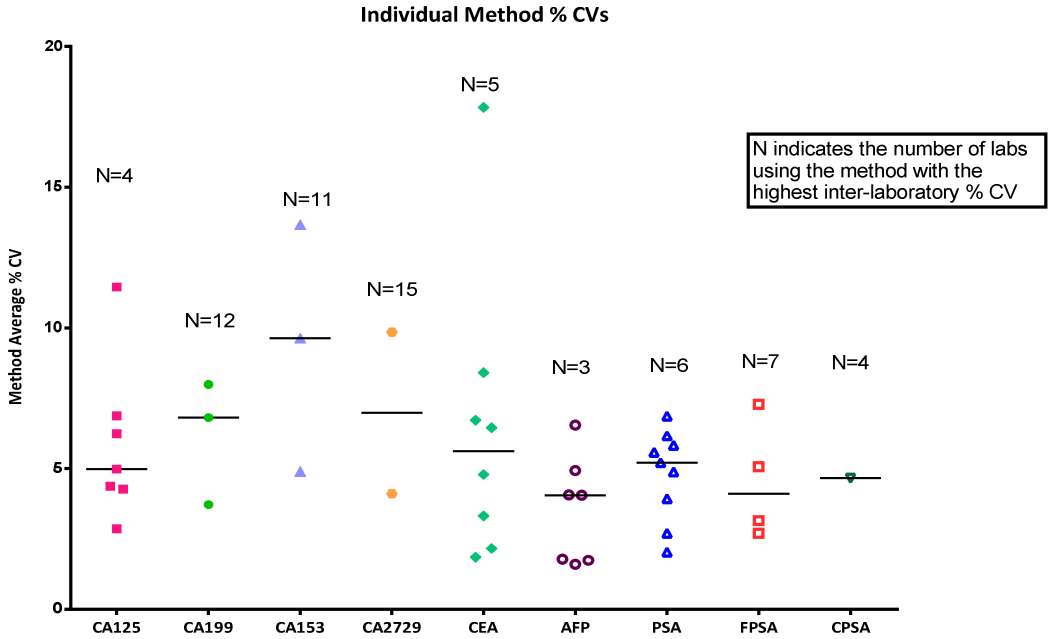
PSA (Table 7, Figure 7): Results were reported by 123 labs using instruments from nine manufacturers. Results from two methods, Beckman Unicel/Access and Siemens Dimension (RxL Max Xpand Plus, EXL), were higher than those from the others at 18% and 20% above the target, respectively. Results from the rest of the methods ranged from 9% below the target (Ortho Clinical Diagnostics Vitros ECiECiQ & 5600) to 14% above the target (Tosoh). These results are consistent with the known difference in calibration between different methods, using either the Hybritech calibrator or the WHO international standard, although the separation into two different groups was not as pronounced as in some previous events. All methods exhibited good linearity.

Free PSA (Table 8, Figure 8): Results were reported by 37 labs using instruments from seven manufacturers, but only four had N ≥ 3. The Beckman Unicel/Access calibrated with the Hybritech standards was the method used by the most labs (45%) and results were distinctly higher than those obtained by the other methods (27% higher than the all method medians and 29% higher than the assigned targets). Abbott Architect was 11% above the all method median and 13% above the assigned targets, the Siemens Immulite averaged 11% lower than the all method medians and10% lower than the assigned targets while the Dimension Vista was 12% below the all method medians and 11% lower than the assigned targets. We calculated % free PSA for each sample using each peer group's respective average PSA and free PSA levels and observed that the differences between methods showed a pattern similar to that of the measured free PSA. All methods showed good linearity.

Please note, labs were 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, only four 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 4.9% (Table 9), and good linearity.

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.

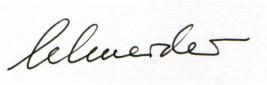
While some of the differences between methods may be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We made every effort to minimize the differences that can be attributed to the sample composition and suggest that

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.

Finally, this shipment was the last proficiency test event in the category Oncology - Soluble Tumor Markers from New York State. After this event, the New York State Clinical Laboratory Evaluation Program will no longer provide proficiency testing in this category. Laboratories holding or applying for a New York State clinical laboratory permit will be required to enroll in a CMS-approved proficiency program for tests offered by the laboratory that are described in 42 CFR 493, subparts H and I. For all other tests that are not described in 42 CFR 493, subparts H and I, laboratories holding or applying for a permit must comply with Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in our Clinical Laboratory Standards of Practice. Laboratories may choose to comply with QA S3 through a proficiency testing program or other process, but must have policies and procedures in place describing the process. Documentation of adherence to this standard, including internal or external proficiency testing results as applicable, will be reviewed during the on-site survey. Please note that the discontinuation of proficiency testing does not change the process for adding or deleting tests and other New York State regulatory requirements including certificates of qualification and permit reapplication.

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
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Table 1: 9-16 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									
TM306	5	15.8	**10.4**	**21.2**	5.4	2.15		1.24	
TM307	5	26.6	**21.2**	**32.0**	5.4	5.71		1.20	
TM308	5	48.4	**39.7**	**57.1**	8.7	2.27		1.20	
TM309	5	92.9	**76.2**	**109.6**	16.7	2.28		1.21	
TM310	5	176.2	**144.5**	**207.9**	31.7	1.87		1.20	
					mean ±SD	2.86	1.60	1.21	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM306	11	12.8	**7.4**	**18.2**	5.4	3.44		1.00	
TM307	11	24.2	**18.8**	**29.6**	5.4	4.59		1.09	
TM308	11	45.5	**37.3**	**53.7**	8.2	5.01		1.13	
TM309	11	90.0	**73.8**	**106.2**	16.2	4.59		1.17	
TM310	11	172.9	**141.8**	**204.0**	31.1	4.24		1.18	
					mean ±SD	4.37	0.59	1.11	0.07
Roche Elecsys & Cobas BME/BMR									
TM306	4	11.7	**6.3**	**17.1**	5.4	10.94		0.92	
TM307	4	19.0	**13.6**	**24.4**	5.4	11.53		0.86	
TM308	4	33.0	**27.1**	**38.9**	5.9	12.00		0.82	
TM309	4	61.5	**50.4**	**72.6**	11.1	11.25		0.80	
TM310	4	117.0	**95.9**	**138.1**	21.1	11.51		0.80	
					mean ±SD	11.45	0.39	0.84	0.05
Siemens Advia Centaur XP & CP COB/COC									
TM306	18	12.7	**7.3**	**18.1**	5.4	6.85		1.00	
TM307	18	22.2	**16.8**	**27.6**	5.4	4.95		1.00	
TM308	18	40.4	**33.1**	**47.7**	7.3	4.50		1.00	
TM309	18	77.0	**63.1**	**90.9**	13.9	3.86		1.00	
TM310	18	146.4	**120.0**	**172.8**	26.4	4.74		1.00	
					mean ±SD	4.98	1.12	1.00	0.00
Siemens Immulite 2000 DPD									
TM306	5	10.6	**5.2**	**16.0**	5.4	3.30		0.83	
TM307	5	17.2	**11.8**	**22.6**	5.4	5.99		0.77	
TM308	5	34.2	**28.0**	**40.4**	6.2	9.65		0.85	
TM309	5	63.5	**52.1**	**74.9**	11.4	5.42		0.82	
TM310	5	127.0	**104.1**	**149.9**	22.9	6.87		0.87	
					mean ±SD	6.24	2.31	0.83	0.03
Ortho Clinical Diag Vitros 5600 JJF									
TM306			**0.0**	**5.5**	2.8				
TM307	3	11.2	**5.8**	**16.6**	5.4	19.38		0.54	
TM308	3	29.3	**23.9**	**34.7**	5.4	3.96		0.79	
TM309	3	67.2	**55.1**	**79.3**	12.1	2.47		0.93	
TM310	3	137.3	**112.6**	**162.0**	24.7	1.68		0.97	
					mean ±SD	6.87	8.39	0.81	0.19
Tosoh AIA TOM									
TM306	4	14.9	**9.5**	**20.3**	5.4	2.28		1.17	
TM307	4	26.6	**21.2**	**32.0**	5.4	4.55		1.20	
TM308	4	49.9	**40.9**	**58.9**	9.0	5.93		1.24	
TM309	4	94.5	**77.5**	**111.5**	17.0	5.90		1.23	
TM310	4	184.8	**151.5**	**218.1**	33.3	2.66		1.26	
					mean ±SD	4.27	1.74	1.22	0.04

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Table 1 (cont.): 9-16 NYS Tumor Marker PT Summary for CA 125

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM306	50	12.8	3.37	2.15	10.94
TM307	50	22.2	5.71	4.55	19.38
TM308	50	40.4	5.01	2.27	12.00
TM309	50	77.0	4.59	2.28	11.25
TM310	47	146.4	4.24	1.68	11.51
		Average	4.58		
		Allowable CV %	6.0		
		Allowable Error if >/= 30 U/ml (+/-) %	18.0		
		Allowable Error if < 30 U/ml (+/- U/ml)	5.4		

Figure 1a: CA 125 Method Comparison

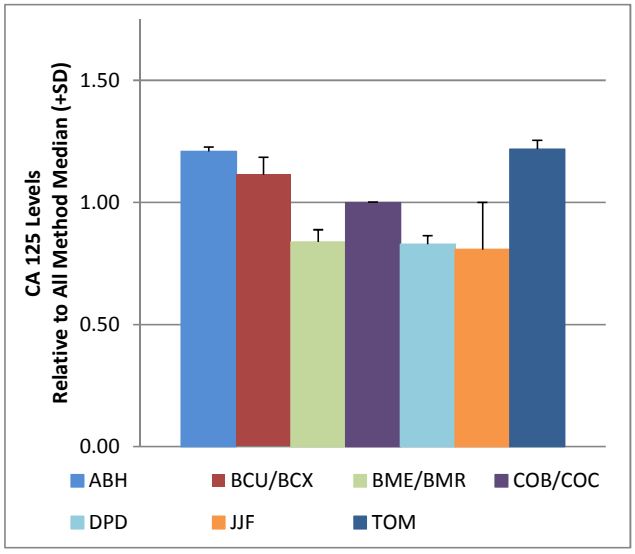

Figure 1b: CA 125 Linearity

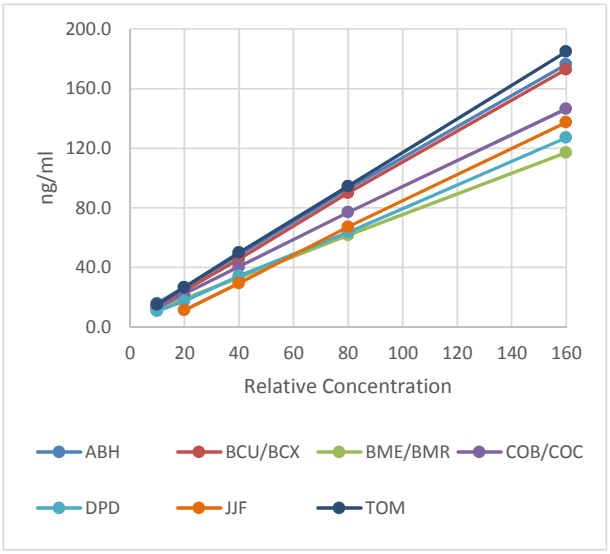

Table 2: 9-16 NYS Tumor Marker PT Summary for CA 19-9

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Beckman Unicel & Access/2 BCU/BCX									
TM306	10	13.9	**10.3**	**17.5**	3.6	7.05		0.81	
TM307	10	24.6	**20.2**	**29.0**	4.4	6.06		1.00	
TM308	9	45.2	**37.1**	**53.3**	8.1	7.32		1.00	
TM309	10	89.2	**73.1**	**105.3**	16.1	6.58		1.00	
TM310	10	174.7	**143.3**	**206.1**	31.4	7.03		1.00	
					mean ±SD	6.81	0.50	0.96	0.09
Siemens Advia Centaur XP COB									
TM306	13	30.8	**25.3**	**36.3**	5.5	8.02		1.79	
TM307	13	50.3	**41.2**	**59.4**	9.1	8.01		2.04	
TM308	13	95.0	**77.9**	**112.1**	17.1	9.32		2.10	
TM309	13	186.6	**153.0**	**220.2**	33.6	6.98		2.09	
TM310	13	358.2	**293.7**	**422.7**	64.5	7.61		2.05	
					mean ±SD	7.99	0.85	2.02	0.13
Tosoh AIA TOM									
TM306	3	17.2	**13.6**	**20.8**	3.6	5.00		1.00	
TM307	3	23.5	**19.3**	**27.7**	4.2	3.57		0.96	
TM308	3	36.2	**29.7**	**42.7**	6.5	4.31		0.80	
TM309	3	59.9	**49.1**	**70.7**	10.8	3.34		0.67	
TM310	3	106.0	**86.9**	**125.1**	19.1	2.37		0.61	
					mean ±SD	3.72	1.00	0.81	0.17

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM306	26	**17.2**	**7.05**	**5.00**	**8.02**
TM307	26	**24.6**	**6.06**	**3.57**	**8.01**
TM308	25	**45.2**	**7.32**	**4.31**	**9.32**
TM309	26	**89.2**	**6.58**	**3.34**	**6.98**
TM310	26	**174.7**	**7.03**	**2.37**	**7.61**
		Average	**6.81**		
		Allowable CV %	**6.0**		
		Allowable Error if >/= 20 U/ml (+/-) %	**18.0**		
		Allowable Error if < 20 U/ml (+/- U/ml)	**3.6**		

Figure 2a: CA 19-9 Method Comparison

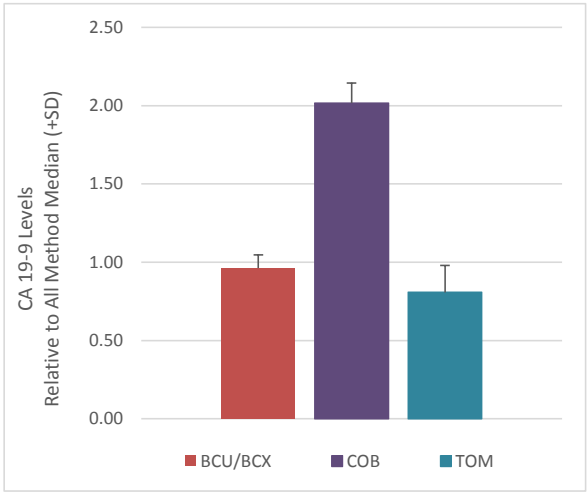

Figure 2b: CA 19-9 Linearity

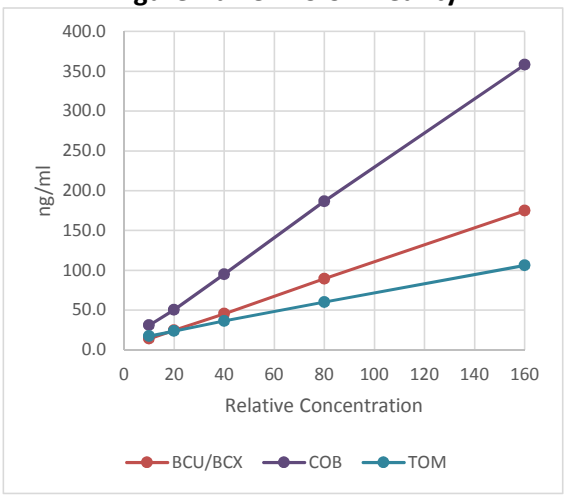

Table 3: 9-16 NYS Tumor Marker PT Summary for CA 15-3

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Beckman Unicel & Access/2 BCU/BCX									
TM306	9	8.7	**7.1**	**10.3**	1.6	4.83		0.64	
TM307	9	16.3	**13.4**	**19.2**	2.9	4.72		0.67	
TM308	9	30.5	**25.0**	**36.0**	5.5	3.28		0.65	
TM309	9	58.6	**48.1**	**69.1**	10.5	6.09		0.65	
TM310	9	117.1	**96.0**	**138.2**	21.1	5.57		0.71	
					mean ±SD	4.90	1.06	0.66	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM306	11	11.1	**9.1**	**13.1**	2.0	12.07		0.82	
TM307	11	21.5	**17.6**	**25.4**	3.9	8.47		0.88	
TM308	11	43.1	**35.3**	**50.9**	7.8	8.98		0.92	
TM309	11	83.5	**68.5**	**98.5**	15.0	8.47		0.93	
TM310	11	160.4	**131.5**	**189.3**	28.9	10.16		0.97	
					mean ±SD	9.63	1.53	0.90	0.06
Siemens Immulite 2000 DPD									
TM306	3	15.1	**12.4**	**17.8**	2.7	15.63		1.12	
TM307	3	26.2	**21.5**	**30.9**	4.7	12.10		1.07	
TM308	3	55.2	**45.3**	**65.1**	9.9	14.26		1.18	
TM309	3	112.7	**92.4**	**133.0**	20.3	12.08		1.26	
TM310	3	194.3	**159.3**	**229.3**	35.0	16.24		1.17	
					mean±SD	13.67	2.00	1.16	0.08

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM306	23	**11.1**	**12.07**	**4.83**	**15.63**
TM307	23	**21.5**	**8.47**	**4.72**	**12.10**
TM308	23	**43.1**	**8.98**	**3.28**	**14.26**
TM309	23	**83.5**	**8.47**	**6.09**	**12.08**
TM310	23	**160.4**	**10.16**	**5.57**	**16.24**
			Average	**9.63**	

Allowable CV %	**6.0**
Allowable Error (+/-) %	**18.0**

Figure 3a: CA 15-3 Method Comparison

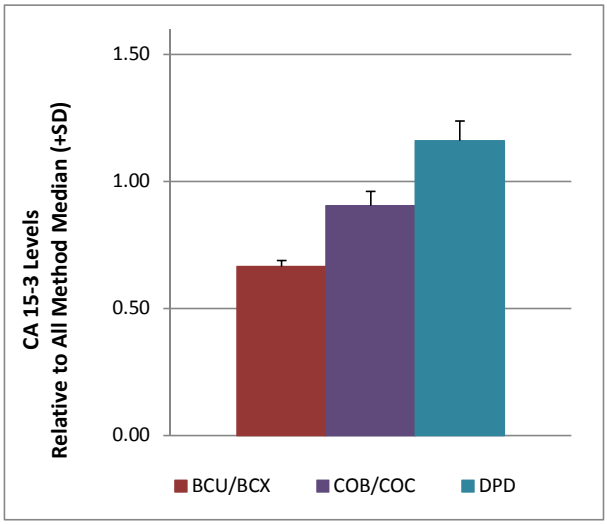

Figure 3b: CA 15-3 Linearity

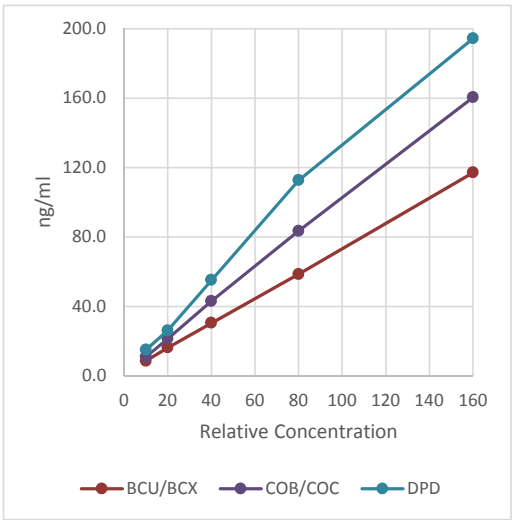

Table 4: 9-16 NYS Tumor Marker PT Summary for CA 27.29

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									
TM306	15	12.0	**4.7**	**19.4**	7.4	20.08		0.96	
TM307	15	27.9	**20.6**	**35.3**	7.4	10.00		1.09	
TM308	15	62.5	**49.4**	**75.6**	13.1	8.30		1.19	
TM309	15	129.2	**102.1**	**156.3**	27.1	5.69		1.20	
TM310	15	244.2	**192.9**	**295.5**	51.3	5.19		1.18	
					mean ±SD	9.85	6.05	1.12	0.10
Tosoh AIA TOM									
TM306	4	13.1	**5.8**	**20.5**	7.4	3.89		1.04	
TM307	4	23.3	**16.0**	**30.7**	7.4	6.09		0.91	
TM308	4	42.6	**33.7**	**51.5**	8.9	4.79		0.81	
TM309	4	86.5	**68.3**	**104.7**	18.2	4.73		0.80	
TM310	4	169.2	**133.7**	**204.7**	35.5	1.02		0.82	
					mean ±SD	4.11	1.89	0.88	0.10

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM306	19	**12.6**		**11.99**	**3.89**	**20.08**
TM307	19	**25.6**		**8.05**	**6.09**	**10.00**
TM308	19	**52.6**		**6.55**	**4.79**	**8.30**
TM309	19	**107.9**		**5.21**	**4.73**	**5.69**
TM310	19	**206.7**		**3.11**	**1.02**	**5.19**
			Average	**6.98**		
			Allowable CV %	**7.0**		
			Allowable Error if >/= 35 U/ml (+/-) %	**21.0**		
			Allowable Error if < 35 U/ml (+/- U/ml)	**7.35**		

Figure 4a: CA 27.29 Method Comparison

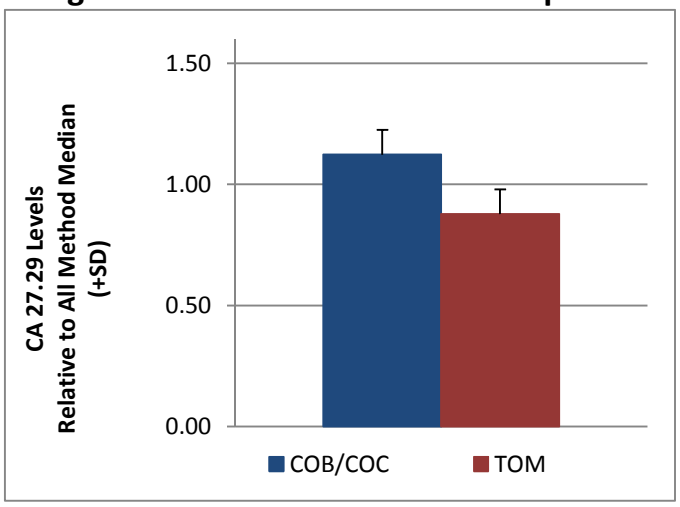

Figure 4b: CA 27.29 Linearity

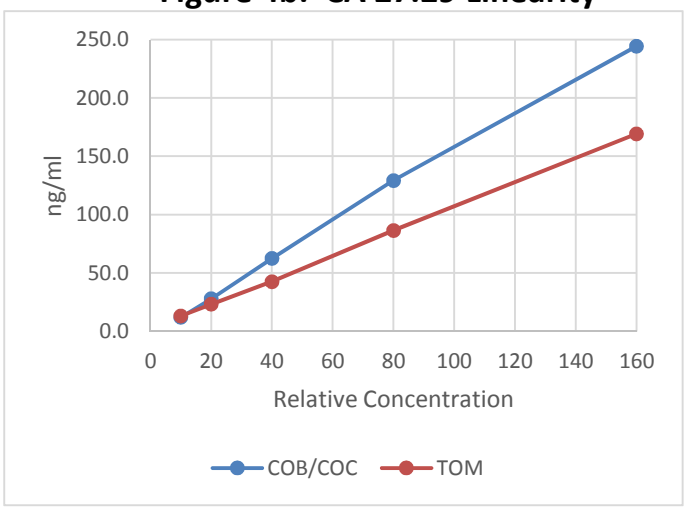

Table 5: 9-16 NYS Tumor Marker PT Summary for CEA

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									
TM306	9	3.3	**2.4**	**4.2**	0.9	3.94		1.14	
TM307	9	5.0	**4.1**	**5.9**	0.9	4.40		1.14	
TM308	9	8.3	**6.8**	**9.8**	1.5	4.58		1.12	
TM309	9	15.3	**12.5**	**18.1**	2.8	5.62		1.07	
TM310	9	29.2	**23.9**	**34.5**	5.3	5.41		1.04	
					mean ±SD	4.79	0.71	1.10	0.04
Beckman Unicel & Access/2 BCU/BCX									
TM306	19	2.8	**1.9**	**3.7**	0.9	5.71		0.97	
TM307	20	4.3	**3.4**	**5.2**	0.9	7.44		0.98	
TM308	20	7.6	**6.2**	**9.0**	1.4	6.32		1.03	
TM309	20	14.1	**11.6**	**16.6**	2.5	5.89		0.99	
TM310	20	27.2	**22.3**	**32.1**	4.9	6.88		0.96	
					mean ±SD	6.45	0.71	0.98	0.03
Roche Elecsys & Cobas BME/BMR									
TM306	4	3.0	**2.1**	**3.9**	0.9	4.00		1.03	
TM307	4	4.5	**3.6**	**5.4**	0.9	3.33		1.02	
TM308	4	7.2	**5.9**	**8.5**	1.3	3.47		0.97	
TM309	4	12.7	**10.4**	**15.0**	2.3	2.60		0.89	
TM310	4	23.3	**19.1**	**27.5**	4.2	3.22		0.83	
					mean ±SD	3.32	0.50	0.95	0.09
Siemens Advia Centaur XP & CP COB/COC									
TM306	18	2.7	**1.8**	**3.6**	0.9	9.63		0.93	
TM307	18	4.2	**3.3**	**5.1**	0.9	6.90		0.95	
TM308	18	7.1	**5.8**	**8.4**	1.3	6.06		0.96	
TM309	18	13.5	**11.1**	**15.9**	2.4	4.81		0.95	
TM310	18	25.8	**21.2**	**30.4**	4.6	6.20		0.91	
					mean ±SD	6.72	1.79	0.94	0.02
Siemens Immulite 2000 DPD									
TM306	3	3.4	**2.5**	**4.3**	0.9	16.18		1.17	
TM307	3	4.8	**3.9**	**5.7**	0.9	9.79		1.09	
TM308	3	8.8	**7.2**	**10.4**	1.6	2.39		1.19	
TM309	3	16.2	**13.3**	**19.1**	2.9	9.57		1.14	
TM310	3	31.5	**25.8**	**37.2**	5.7	4.13		1.12	
					mean ±SD	8.41	5.44	1.14	0.04
Siemens Dimension Vista DUV									
TM306	12	2.5	**1.6**	**3.4**	0.9	2.40		0.86	
TM307	13	4.0	**3.1**	**4.9**	0.9	2.00		0.91	
TM308	13	6.9	**5.7**	**8.1**	1.2	2.46		0.93	
TM309	13	12.6	**10.3**	**14.9**	2.3	2.14		0.88	
TM310	13	24.3	**19.9**	**28.7**	4.4	1.77		0.86	
					mean ±SD	2.16	0.29	0.89	0.03
Ortho Clinical Diag Vitros 5600 JJF									
TM306	6	1.6	**0.7**	**2.5**	0.9	35.63		0.55	
TM307	6	2.9	**2.0**	**3.8**	0.9	25.17		0.66	
TM308	6	7.2	**5.9**	**8.5**	1.3	14.31		0.97	
TM309	6	14.4	**11.8**	**17.0**	2.6	10.56		1.01	
TM310	6	30.2	**24.8**	**35.6**	5.4	3.51		1.07	
					mean ±SD	17.83	12.66	0.85	0.23

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Table 5 (cont.): 9-16 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									
TM306	4	5.3	**4.3**	**6.3**	1.0	1.13		1.83	
TM307	4	7.6	**6.2**	**9.0**	1.4	3.29		1.73	
TM308	4	12.3	**10.1**	**14.5**	2.2	1.38		1.66	
TM309	4	21.6	**17.7**	**25.5**	3.9	2.04		1.52	
TM310	4	39.7	**32.6**	**46.8**	7.1	1.39		1.41	
					mean ±SD	1.85	0.87	1.63	0.17

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM306	75	**2.9**	**4.86**	**1.13**	**35.63**
TM307	77	**4.4**	**5.65**	**2.00**	**25.17**
TM308	77	**7.4**	**4.03**	**1.38**	**14.31**
TM309	77	**14.3**	**5.22**	**2.04**	**10.56**
TM310	77	**28.2**	**3.82**	**1.39**	**6.88**

Average	**4.71**
Allowable CV %	**6.0**
Allowable Error if >/= 5 ng/ml (+/-) %	**18.0**
Allowable Error if < 5 ng/ml (+/- ng/ml)	**0.9**

Figure 5a: CEA Method Comparison

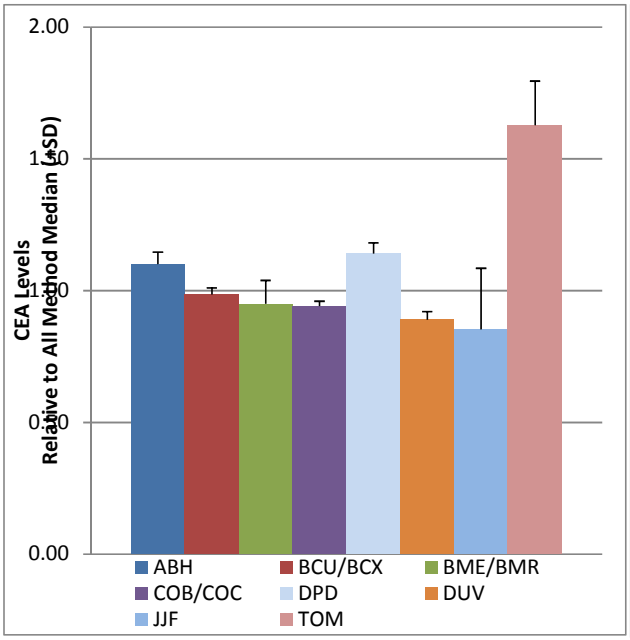

Figure 5a: CEA Linearity

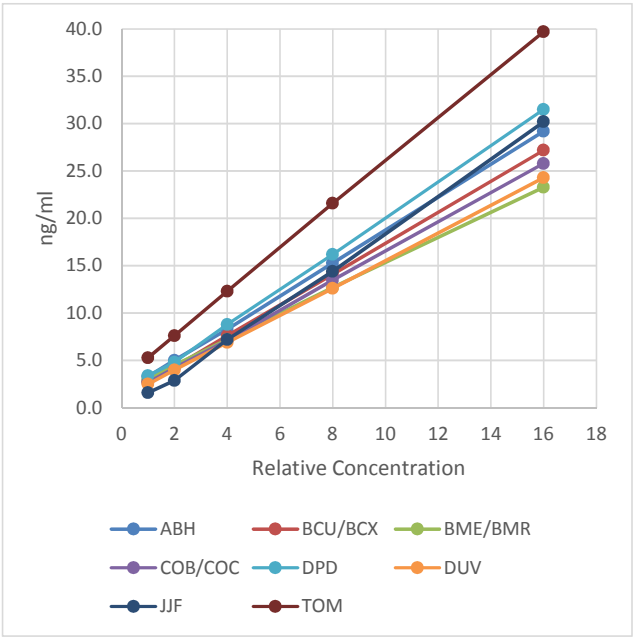

Table 6: 9-16 NYS Tumor Marker PT Summary for AFP

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											
TM306	4	5.7	**5.4**	**6.0**	0.3	1.75		0.89		1.04	
TM307	4	10.5	**10.1**	**10.9**	0.4	1.33		0.90		0.94	
TM308	4	20.7	**20.1**	**21.3**	0.6	0.92		0.92		0.97	
TM309	4	41.5	**37.7**	**45.3**	3.8	3.06		0.95		0.97	
TM310	4	83.7	**79.1**	**88.3**	4.6	1.84		1.00		0.99	
					mean ±SD	1.78	0.80	0.93	0.04	0.98	0.03
Beckman Unicel & Access/2 BCU/BCX											
TM306	10	5.6	**4.9**	**6.3**	0.7	3.93		0.88		1.02	
TM307	10	10.4	**9.0**	**11.8**	1.4	4.42		0.89		0.93	
TM308	10	20.1	**18.1**	**22.1**	2.0	3.38		0.89		0.94	
TM309	10	38.7	**33.8**	**43.6**	4.9	4.19		0.89		0.90	
TM310	10	76.9	**66.8**	**87.0**	10.1	4.38		0.92		0.91	
					mean ±SD	4.06	0.43	0.89	0.02	0.94	0.05
Siemens Advia Centaur XP & CP COB/COC											
TM306	13	8.0	**5.1**	**10.9**	2.9	12.00		1.25		1.45	
TM307	13	13.6	**11.1**	**16.2**	2.6	6.25		1.16		1.22	
TM308	13	25.5	**22.3**	**28.7**	3.2	4.24		1.13		1.20	
TM309	13	46.6	**40.0**	**53.2**	6.6	4.74		1.07		1.09	
TM310	13	88.5	**73.9**	**103.1**	14.6	5.49		1.06		1.04	
					mean ±SD	6.54	3.14	1.13	0.08	1.20	0.16
DPB/DPD											
TM306	3	6.6	**5.4**	**7.8**	1.2	6.06		1.03		1.20	
TM307	3	12.9	**10.2**	**15.6**	2.7	6.98		1.10		1.16	
TM308	3	24.8	**23.2**	**26.4**	1.6	2.14		1.10		1.16	
TM309	3	48.2	**43.1**	**53.3**	5.1	3.55		1.10		1.13	
TM310	3	95.2	**90.8**	**99.6**	4.4	1.53		1.14		1.12	
					mean ±SD	4.05	2.39	1.09	0.04	1.15	0.03
Siemens Dimension Vista DUV											
TM306	3	5.5	**5.3**	**5.7**	0.2	1.09		0.86		1.00	
TM307	3	10.4	**9.5**	**11.3**	0.9	2.98		0.89		0.93	
TM308	3	19.9	**18.9**	**21.0**	1.1	1.76		0.88		0.93	
TM309	3	39.2	**37.6**	**40.9**	1.7	1.40		0.90		0.92	
TM310	3	78.5	**76.6**	**80.4**	1.9	0.79		0.94		0.92	
					mean ±SD	1.60	0.85	0.89	0.03	0.94	0.03
Ortho Clinical Diag Vitros 5600 JJF											
TM306	3	6.6	**6.1**	**7.1**	0.5	2.58		1.03		1.20	
TM307	3	12.0	**11.4**	**12.6**	0.6	1.75		1.03		1.08	
TM308	3	22.6	**21.4**	**23.8**	1.2	1.77		1.00		1.06	
TM309	3	43.7	**42.2**	**45.2**	1.5	1.12		1.00		1.02	
TM310	3	82.0	**78.4**	**85.6**	3.6	1.48		0.98		0.97	
					mean±SD	1.74	0.54	1.01	0.02	1.06	0.09
Tosoh AIA TOM											
TM306	3	6.4	**5.4**	**7.5**	1.1	5.47		1.00		1.16	
TM307	3	11.7	**10.1**	**13.4**	1.7	4.70		1.00		1.05	
TM308	3	22.9	**19.3**	**26.5**	3.6	5.20		1.01		1.07	
TM309	3	44.0	**38.5**	**49.6**	5.6	4.20		1.01		1.03	
TM310	3	86.1	**73.0**	**99.2**	13.1	5.08		1.03		1.01	
					mean ±SD	4.93	0.49	1.01	0.01	1.07	0.06

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Table 6 (cont.): 9-16 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max %CV		All Method Median/ IS Target	
TM306	39	6.4	5.5	0.43		3.93	1.09	12.00		1.16	
TM307	39	11.7	11.1	1.00		4.42	1.33	6.98		1.05	
TM308	39	22.6	21.3	1.89		2.14	0.92	5.20		1.06	
TM309	39	43.7	42.8	2.15		3.55	1.12	4.74		1.02	
TM310	39	83.7	84.9	1.99		1.84	0.79	5.49		0.99	
					Average	3.18			mean ±SD	1.06	0.07

Allowable Error = +/-3SD

Figure 6a: AFP Method Comparison

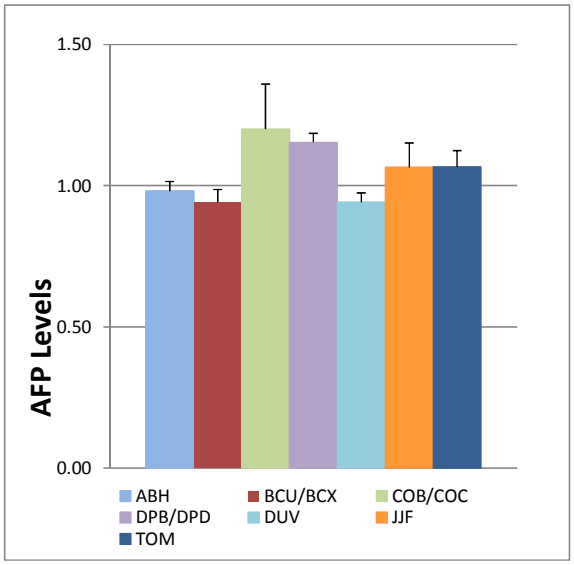

Figure 6b: AFP Linearity

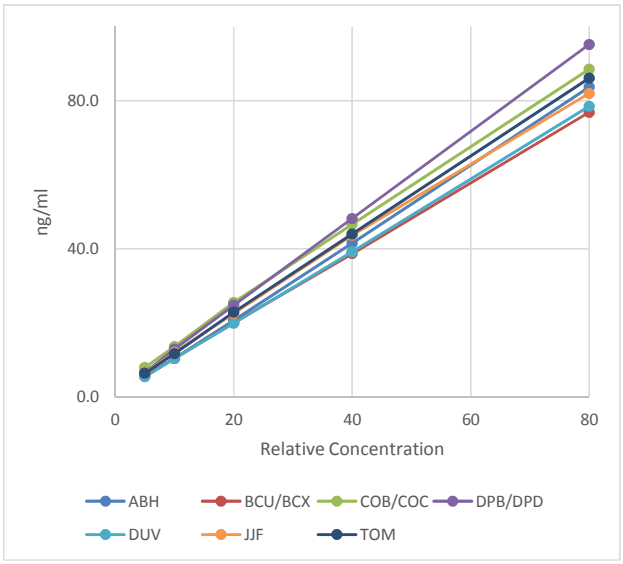

Table 7: 9-16 NYS Tumor Marker PT Summary for PSA

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											
TM306	12	0.90	**0.74**	**1.06**	0.16	4.44		0.99		1.10	
TM307	12	1.79	**1.47**	**2.11**	0.32	5.03		1.00		1.13	
TM308	12	3.50	**2.87**	**4.13**	0.63	4.57		1.00		1.12	
TM309	12	6.95	**5.70**	**8.20**	1.25	6.19		1.00		1.11	
TM310	12	13.78	**11.30**	**16.26**	2.48	5.81		1.00		1.10	
					mean ±SD	5.21	0.76	1.00	0.00	1.11	0.01
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM306	31	0.93	**0.76**	**1.10**	0.17	6.45		1.02		1.13	
TM307	31	1.86	**1.53**	**2.19**	0.33	5.91		1.04		1.18	
TM308	31	3.73	**3.06**	**4.40**	0.67	5.63		1.07		1.19	
TM309	31	7.52	**6.17**	**8.87**	1.35	5.05		1.08		1.20	
TM310	31	15.05	**12.34**	**17.76**	2.71	4.85		1.09		1.20	
					mean ±SD	5.58	0.65	1.06	0.03	1.18	0.03
Roche Elecsys & Cobas BME/BMR											
TM306	10	0.92	**0.75**	**1.09**	0.17	2.17		1.01		1.12	
TM307	9	1.78	**1.46**	**2.10**	0.32	2.25		0.99		1.13	
TM308	10	3.43	**2.81**	**4.05**	0.62	3.21		0.98		1.10	
TM309	10	6.83	**5.60**	**8.06**	1.23	2.78		0.98		1.09	
TM310	10	13.50	**11.07**	**15.93**	2.43	3.11		0.98		1.08	
					mean ±SD	2.70	0.48	0.99	0.01	1.10	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM306	21	0.86	**0.71**	**1.01**	0.15	4.65		0.95		1.05	
TM307	21	1.64	**1.34**	**1.94**	0.30	6.10		0.92		1.04	
TM308	19	3.12	**2.56**	**3.68**	0.56	2.88		0.89		1.00	
TM309	21	6.21	**5.09**	**7.33**	1.12	4.51		0.89		0.99	
TM310	21	12.27	**10.06**	**14.48**	2.21	6.28		0.89		0.98	
					mean ±SD	4.88	1.38	0.91	0.02	1.01	0.03
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM306	6	0.78	**0.64**	**0.92**	0.14	6.41		0.86		0.95	
TM307	6	1.61	**1.32**	**1.90**	0.29	3.73		0.90		1.02	
TM308	6	3.32	**2.72**	**3.92**	0.60	5.12		0.95		1.06	
TM309	6	6.38	**5.23**	**7.53**	1.15	2.35		0.92		1.02	
TM310	6	12.65	**10.37**	**14.93**	2.28	2.06		0.92		1.01	
					mean ±SD	3.93	1.85	0.91	0.03	1.01	0.04
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM306	13	0.98	**0.80**	**1.16**	0.18	6.12		1.08		1.20	
TM307	13	1.89	**1.55**	**2.23**	0.34	6.35		1.06		1.20	
TM308	13	3.77	**3.09**	**4.45**	0.68	5.57		1.08		1.20	
TM309	13	7.52	**6.17**	**8.87**	1.35	6.78		1.08		1.20	
TM310	13	15.00	**12.30**	**17.70**	2.70	6.00		1.09		1.20	
					mean±SD	6.16	0.45	1.08	0.01	1.20	0.00
Siemens Dimension Vista DUV											
TM306	15	0.91	**0.75**	**1.07**	0.16	1.10		1.00		1.11	
TM307	15	1.79	**1.47**	**2.11**	0.32	2.79		1.00		1.13	
TM308	15	3.53	**2.89**	**4.17**	0.64	2.27		1.01		1.13	
TM309	15	6.99	**5.73**	**8.25**	1.26	2.29		1.01		1.12	
TM310	15	13.91	**11.41**	**16.41**	2.50	1.73		1.01		1.11	
					mean ±SD	2.03	0.65	1.00	0.00	1.12	0.01

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Table 7 (cont.): 9-16 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											
TM306	11	0.58	**0.48**	**0.68**	0.10	12.07		0.64		0.71	
TM307	11	1.46	**1.20**	**1.72**	0.26	6.85		0.82		0.92	
TM308	11	3.09	**2.53**	**3.65**	0.56	5.50		0.88		0.99	
TM309	11	5.99	**4.91**	**7.07**	1.08	5.34		0.86		0.96	
TM310	11	12.07	**9.90**	**14.24**	2.17	4.56		0.88		0.96	
					mean ±SD	6.86	3.02	0.81	0.10	0.91	0.11
Tosoh AIA TOM											
TM306	4	0.92	**0.75**	**1.09**	0.17	5.43		1.01		1.12	
TM307	4	1.86	**1.53**	**2.19**	0.33	4.84		1.04		1.18	
TM308	4	3.64	**2.98**	**4.30**	0.66	3.85		1.04		1.16	
TM309	4	7.02	**5.76**	**8.28**	1.26	5.56		1.01		1.12	
TM310	4	14.17	**11.62**	**16.72**	2.55	9.46		1.03		1.13	
					mean ±SD	5.83	2.14	1.03	0.01	1.14	0.03

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max % CV		All Method Median/ IS Target	
TM306	123	**0.91**	**0.82**	**0.06**		**5.43**	**1.10**	**12.07**		**1.11**	
TM307	122	**1.79**	**1.58**	**0.07**		**5.03**	**2.25**	**6.85**		**1.13**	
TM308	121	**3.50**	**3.13**	**0.11**		**4.57**	**2.27**	**5.63**		**1.12**	
TM309	123	**6.95**	**6.25**	**0.28**		**5.05**	**2.29**	**6.78**		**1.11**	
TM310	123	**13.78**	**12.51**	**0.54**		**4.85**	**1.73**	**9.46**		**1.10**	
					Average	**4.99**			mean ±SD	**1.11**	0.01
					Allowable CV %	**6.00**					
					Allowable Error (+/-)%	**18.0**					

Figure 7a: PSA Method Comparison

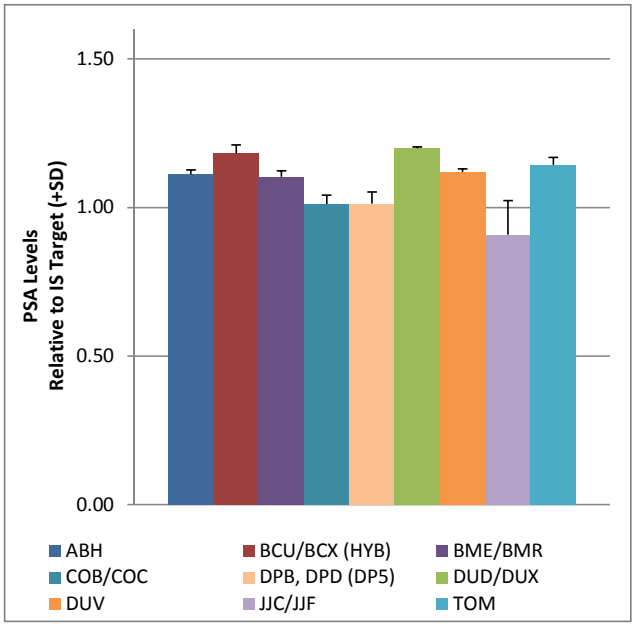

Figure 7b: PSA Linearity

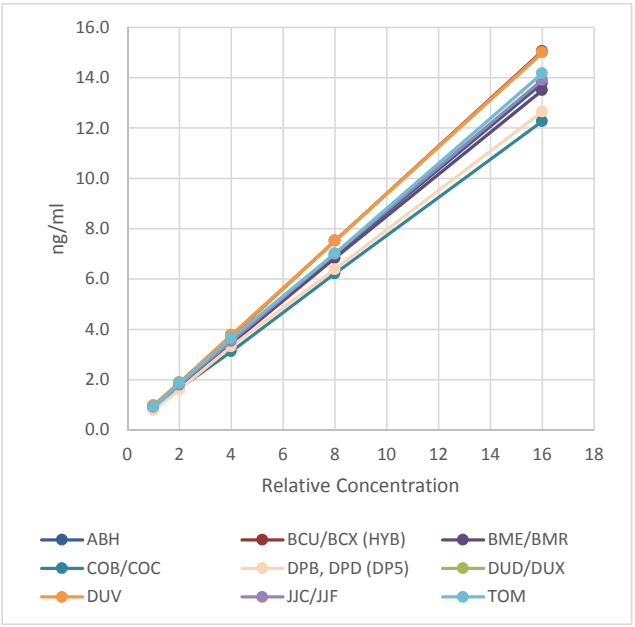

Table 8: 9-16 NYS Tumor Marker PT Summary for Free PSA

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												
TM306	5	0.14	**0.05**	**0.23**	0.09	3.57		1.12		1.19		15.6%
TM307	5	0.27	**0.18**	**0.36**	0.09	2.59		1.10		1.12		15.1%
TM308	5	0.52	**0.43**	**0.61**	0.09	1.54		1.12		1.11		14.9%
TM309	5	0.98	**0.80**	**1.16**	0.18	2.45		1.11		1.10		14.1%
TM310	5	1.92	**1.57**	**2.27**	0.35	3.33		1.12		1.12		13.9%
					mean ±SD	2.70	0.80	1.11	0.01	1.13	0.04	14.7%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)												
TM306	15	0.17	**0.08**	**0.26**	0.09	8.82		1.36		1.44		18.3%
TM307	15	0.32	**0.23**	**0.41**	0.09	5.63		1.31		1.33		17.2%
TM308	15	0.59	**0.48**	**0.70**	0.11	4.41		1.27		1.26		15.8%
TM309	15	1.09	**0.89**	**1.29**	0.20	2.75		1.23		1.22		14.5%
TM310	15	2.04	**1.67**	**2.41**	0.37	3.73		1.19		1.19		13.6%
					mean ±SD	5.07	2.35	1.27	0.07	1.29	0.10	15.9%
Siemens Immulite 2000 DPD												
TM306	7	0.11	**0.02**	**0.20**	0.09	7.27		0.88		0.93		14.1%
TM307	7	0.22	**0.13**	**0.31**	0.09	8.18		0.90		0.92		13.7%
TM308	7	0.41	**0.32**	**0.50**	0.09	8.78		0.88		0.87		12.3%
TM309	7	0.79	**0.65**	**0.93**	0.14	5.44		0.89		0.88		12.4%
TM310	7	1.52	**1.25**	**1.79**	0.27	6.71		0.88		0.89		12.0%
					mean ±SD	7.28	1.30	0.89	0.01	0.90	0.02	12.9%
Siemens Dimension Vista DUV												
TM306	5	0.11	**0.02**	**0.20**	0.09	6.36		0.88		0.93		12.1%
TM307	5	0.21	**0.12**	**0.30**	0.09	3.81		0.86		0.87		11.7%
TM308	5	0.41	**0.32**	**0.50**	0.09	1.71		0.88		0.87		11.6%
TM309	5	0.79	**0.65**	**0.93**	0.14	1.65		0.89		0.88		11.3%
TM310	6	1.49	**1.22**	**1.76**	0.27	2.21		0.87		0.87		10.7%
					mean ±SD	3.15	2.00	0.88	0.01	0.89	0.03	11.5%

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
TM306	32	**0.13**	**0.12**	**0.00**		**6.82**	**1.06**		**14.4%**	**12.0%**
TM307	32	**0.25**	**0.24**	**0.01**		**4.72**	**1.02**		**15.2%**	**11.5%**
TM308	32	**0.47**	**0.47**	**0.02**		**3.06**	**0.99**		**15.0%**	**11.5%**
TM309	32	**0.89**	**0.89**	**0.05**		**2.60**	**0.99**		**14.3%**	**11.4%**
TM310	33	**1.72**	**1.71**	**0.08**		**3.53**	**1.01**		**13.7%**	**12.2%**
							mean	±SD		
					Average	**4.14**	**1.01**	0.03	**14.5%**	

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

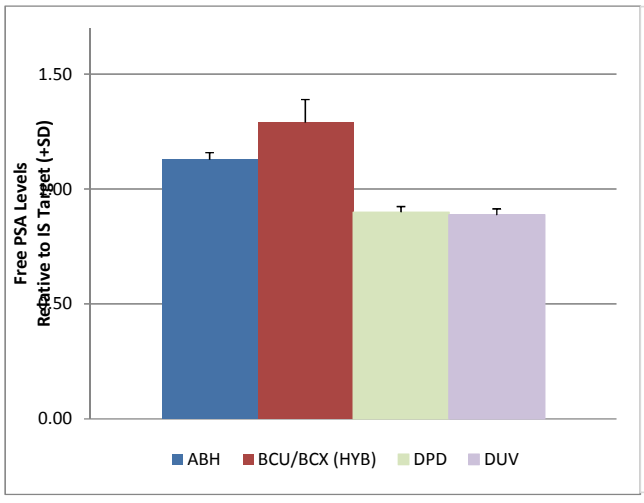

Figure 8b: Free PSA Linearity

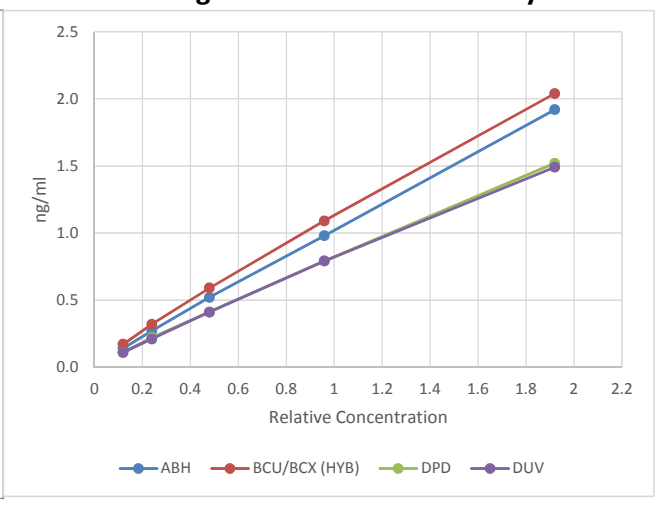

Table 8 (cont.): 9-16 NYS Tumor Marker PT Summary for Free PSA

Figure 8c: Calculated % Free PSA Method Comparison

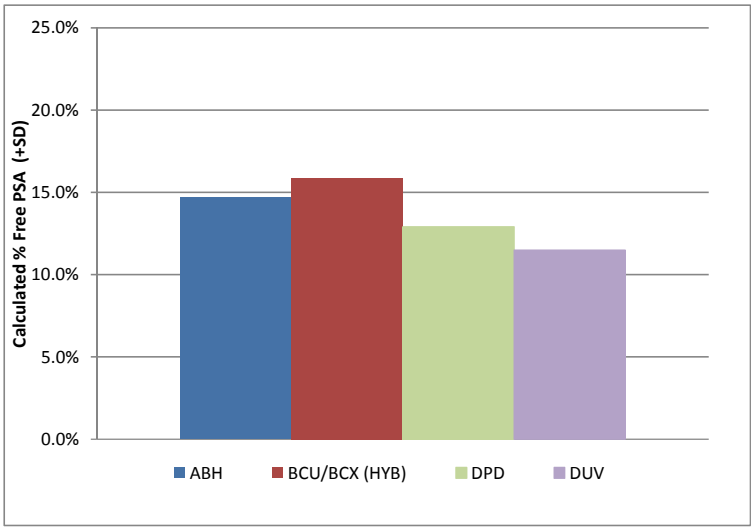

Table 9: 9-16 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM306	4	0.8	**0.6**	**0.9**	0.2	8.00		1.00	
TM307	4	1.4	**1.1**	**1.7**	0.3	5.71		1.00	
TM308	4	2.9	**2.4**	**3.5**	0.6	3.41		1.00	
TM309	4	5.8	**4.7**	**6.8**	1.1	2.26		1.00	
TM310	4	11.5	**9.4**	**13.6**	2.1	3.91		1.00	
					mean ±SD	4.66	2.24	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM306	4	**0.8**		**8.00**
TM307	4	**1.4**		**5.71**
TM308	4	**2.9**		**3.41**
TM309	4	**5.8**		**2.26**
TM310	4	**11.5**		**3.91**
			Average	**4.85**
			Allowable CV %	**6.0**
			Allowable Error (+/-)%	**18.0**

Figure 9: Complexed PSA Method Comparison