NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

June 23, 2014

New York State Tumor Marker Proficiency Test 5-2014 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from May 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 human serum-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) at

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

Laboratory contacts were sent an email alert indicating the availability of the individual result report. This critique with summary tables and graphs is then sent by a separate email to the same laboratory contacts. It 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.

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

[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.

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 <u>not</u> 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 **<u>average</u> 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 <u>strongly encourage</u> 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 <u>normalized values</u> were calculated for each sample by dividing the individual peer group mean by the median of the means from all peer groups (<u>all method median</u>). 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 <u>target values</u> (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 110 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 89% of the labs. Substantial variation between the peer groups was seen, ranging from 54% to 219% of the all method median.

CA19-9 (Table 2, Figure 2): Results were reported by 69 labs using instruments from seven different manufacturers, but two manufacturers were used by only two labs each, which left five peer groups for grading. Forty-two percent of all reporting labs used Siemens ADVIA-Centaur XP, 22% used either Beckman's Unicel or Access/2, 19% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 7% used the Tosoh ST-AIA method. The CA19-9 concentrations in four of the samples were near or below the lower limit of detection for several methods, making the results non-gradable. Labs that used those methods received an automatic "Pass credit" for those samples. TM271 which was not at the LOD, shows large differences in how each method measured CA19-9, ranging from 84% (Tosoh) to 552% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP averaged almost 2 times higher than the all method median, whereas results from Beckman and Roche were within +/-7% of the all method median. Used by three labs, the Abbott Architect method results averaged 5.5 times higher than the all method median, as shown in Table 2 and Figure 2. As previously seen, there continues to be discordance between the various methods used to measure CA19-9, at least under the conditions of the NYS PT.

The MUC1 breast cancer antigen was measured by 102 labs, with slightly more than half (55%) 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). Four of the samples were at or below the lower limit of detection for several methods, and were thus non-gradable. Labs that used those methods received an automatic "Pass credit" for those samples. TM271 which was not at the LOD, shows that Abbott, Roche, and Siemens Advia were all within +/-6% of the all method median and altogether comprise 70% of the labs measuring CA15-3. In contrast, 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 27% above the median. For TM271, **CA27.29** measurements showed an 18% difference between the ADVIA Centaur XP/CP and the Tosoh methods. In contrast the difference in CA27.29 concentrations in the other samples was much larger. The median CA27.29 measurements averaged 24% higher than the median CA15-3 measurements for sample TM271; furthermore, whereas levels of CA15-3 were close to the lower limit of detection for samples TM272-275, they were significantly higher for CA27.29. We are still investigating what may have caused this discrepancy.

CEA (Table 5, Figure 5): Results were reported by 162 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 45 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 81% of the labs, were within +/-15% of the medians. In contrast, Roche methods were 26% below the median, whereas TOSOH ST-AIA exhibited a high positive bias averaging 45% above the median, which is consistent with what has been seen on previous NYS PT events.

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 96 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 nineteen percent of the total number of labs. Six of the eight methods, used by 75% of the labs, gave results within +/-5% of the all method median, but averaged 13% higher than the assigned targets. Of the remaining two methods, Roche measured 17% higher than the all method median, and 33% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 3% of participants) was the only method with results below the assigned target (-11%) and was 21% 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.

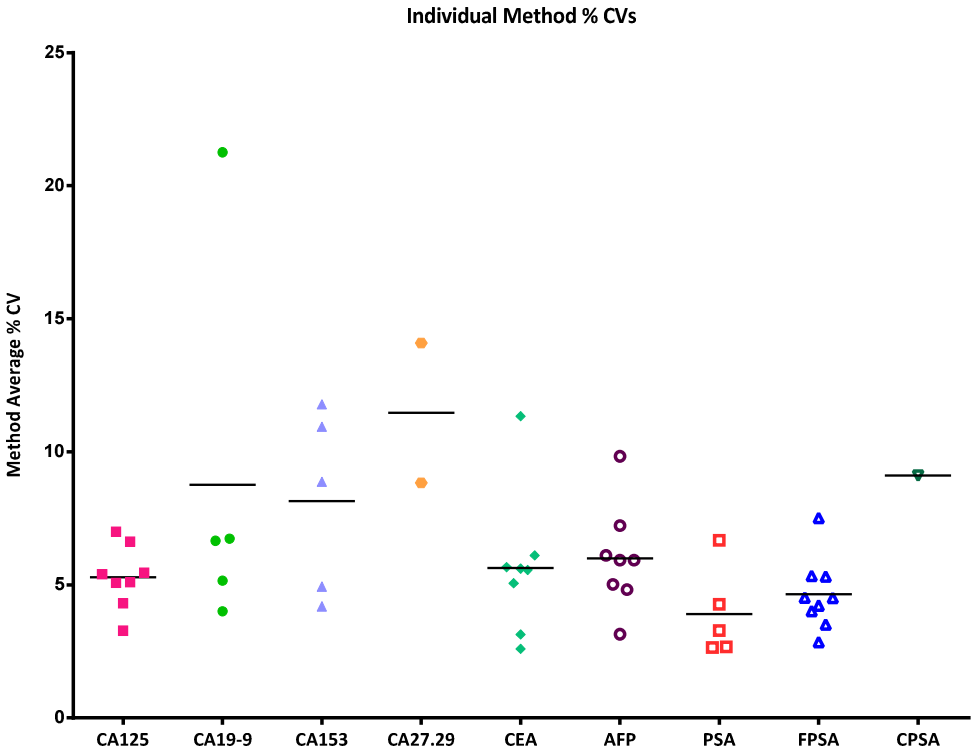
PSA (Table 7, Figure 7): Results were reported by 243 labs using instruments from ten manufacturers, although one instrument was used by only one lab (N=1) and was therefore not included in Table 7. Samples were prepared with varying concentrations of total PSA, but the same proportion of free PSA (20%) to assess if the total PSA level affected the proportion of free PSA. 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). Results from six of the peer groups were within +/-10% of the all method median, and these were between +3% and +15% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 14% above the all method median and 26% above the target (no lab used the WHO calibration), and Siemens Dimension RxL Max/Xpand Plus/EXL was 18% above the all method median and 31% above the assigned targets. In contrast, results from Ortho Clinical Vitros ECi/ECiQ & 5600 were 12% lower than the all method median and 2% lower than the targets.

Free PSA (Table 8, Figure 8): Results were reported by 80 labs using instruments from seven manufacturers which corresponded to five peer groups plus two others with N<3. Two more of the five peer groups comprised less than 10 labs each, and along with the N<3 methods made up 22% of the participants. The remaining three methods were used by 33% of labs for Beckman Unicel/Access calibrated with the Hybritech standards, 30% of labs for Roche Elecsys/E170/Cobas, and 15% 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 (37% higher than the all method medians and 25% higher than the targets), while there were no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. Of the other methods, two (Abbott Architect and Roche Elecsys & Cobas) were within +/-10% of the assigned targets and two (Siemens Immulite 2000 and Siemens Dimension Vista) were 15% and 20% below the assigned targets respectively. Nevertheless, all but Beckman Unicel/Access methods were within 20% 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. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA.

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. Due to the small group size and a couple of outliers, the samples do not show quite as good an agreement within the method as usual, with an average %CV of 9% (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%.



Average %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. 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.

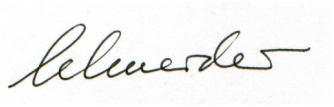
Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

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 date for the remaining 2014 Tumor Marker Proficiency Test event is:

Mail-out date:	**Due date:**
September 9, 2014	September 24, 2014

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: 5-14 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									
TM271	9	27.8	**22.4**	**33.2**	5.4	6.55		1.24	
TM272	10	89.5	**73.4**	**105.6**	16.1	5.51		1.45	
TM273	10	119.0	**97.6**	**140.4**	21.4	5.85		1.44	
TM274	10	68.0	**55.8**	**80.2**	12.2	4.21		1.46	
TM275	10	89.8	**73.6**	**106.0**	16.2	5.19		1.48	
					mean ±SD	5.46	0.86	1.41	0.10
Beckman Unicel & Access/2 BCU/BCX									
TM271	14	23.6	**18.2**	**29.0**	5.4	5.47		1.05	
TM272	14	50.8	**41.7**	**59.9**	9.1	7.70		0.82	
TM273	14	68.3	**56.0**	**80.6**	12.3	7.38		0.83	
TM274	14	37.6	**30.8**	**44.4**	6.8	6.94		0.81	
TM275	14	49.1	**40.3**	**57.9**	8.8	7.49		0.81	
					mean ±SD	7.00	0.90	0.86	0.11
Roche Elecsys & Cobas BME/BMR									
TM271	18	19.7	**14.3**	**25.1**	5.4	3.65		0.88	
TM272	18	66.5	**54.5**	**78.5**	12.0	3.22		1.08	
TM273	18	88.8	**72.8**	**104.8**	16.0	3.33		1.08	
TM274	18	50.2	**41.2**	**59.2**	9.0	3.15		1.08	
TM275	18	65.7	**53.9**	**77.5**	11.8	3.04		1.08	
					mean ±SD	3.28	0.23	1.04	0.09
Siemens Advia Centaur XP & CP COB/COC									
TM271	33	24.2	**18.8**	**29.6**	5.4	5.33		1.08	
TM272	32	56.7	**46.5**	**66.9**	10.2	4.46		0.92	
TM273	33	76.4	**62.6**	**90.2**	13.8	5.63		0.92	
TM274	33	43.0	**35.3**	**50.7**	7.7	4.98		0.92	
TM275	32	56.0	**45.9**	**66.1**	10.1	5.09		0.92	
					mean ±SD	5.10	0.43	0.95	0.07
Siemens Immulite 2000 DPD									
TM271	21	19.5	**14.1**	**24.9**	5.4	7.59		0.87	
TM272	18	29.3	**23.9**	**34.7**	5.4	5.84		0.48	
TM273	18	38.9	**31.9**	**45.9**	7.0	5.91		0.47	
TM274	18	20.6	**15.2**	**26.0**	5.4	7.52		0.44	
TM275	18	28.1	**22.7**	**33.5**	5.4	6.26		0.46	
					mean ±SD	6.63	0.87	0.54	0.18
Siemens Dimension Vista (LOCI) DUV									
TM271	4	21.3	**15.9**	**26.7**	5.4	6.62		0.95	
TM272	4	154.0	**126.3**	**181.7**	27.7	4.86		2.50	
TM273	4	208.8	**171.2**	**246.4**	37.6	6.28		2.53	
TM274	4	115.1	**94.4**	**135.8**	20.7	3.78		2.47	
TM275	4	152.7	**125.2**	**180.2**	27.5	5.46		2.51	
					mean ±SD	5.40	1.14	2.19	0.69
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM271	4	19.9	**14.5**	**25.3**	5.4	0.50		0.89	
TM272	5	55.7	**45.7**	**65.7**	10.0	4.33		0.90	
TM273	5	70.7	**58.0**	**83.4**	12.7	5.57		0.86	
TM274	5	38.7	**31.7**	**45.7**	7.0	10.23		0.83	
TM275	4	51.2	**42.0**	**60.4**	9.2	0.92		0.84	
					mean ±SD	4.31	3.96	0.86	0.03

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Table 1 (cont.): 5-14 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									
TM271	5	28.3	**22.9**	**33.7**	5.4	3.32		1.26	
TM272	5	109.9	**90.1**	**129.7**	19.8	5.61		1.78	
TM273	5	150.1	**123.1**	**177.1**	27.0	4.20		1.82	
TM274	5	81.8	**67.1**	**96.5**	14.7	6.97		1.76	
TM275	5	109.3	**89.6**	**129.0**	19.7	5.30		1.80	
					mean ±SD	5.08	1.39	1.68	0.24

Sample ID	N	All Method Median	Median % CV
TM271	**108**	**22.5**	**5.40**
TM272	**106**	**61.6**	**5.19**
TM273	**107**	**82.6**	**5.74**
TM274	**107**	**46.6**	**5.96**
TM275	**105**	**60.9**	**5.24**
		Average	**5.51**
		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

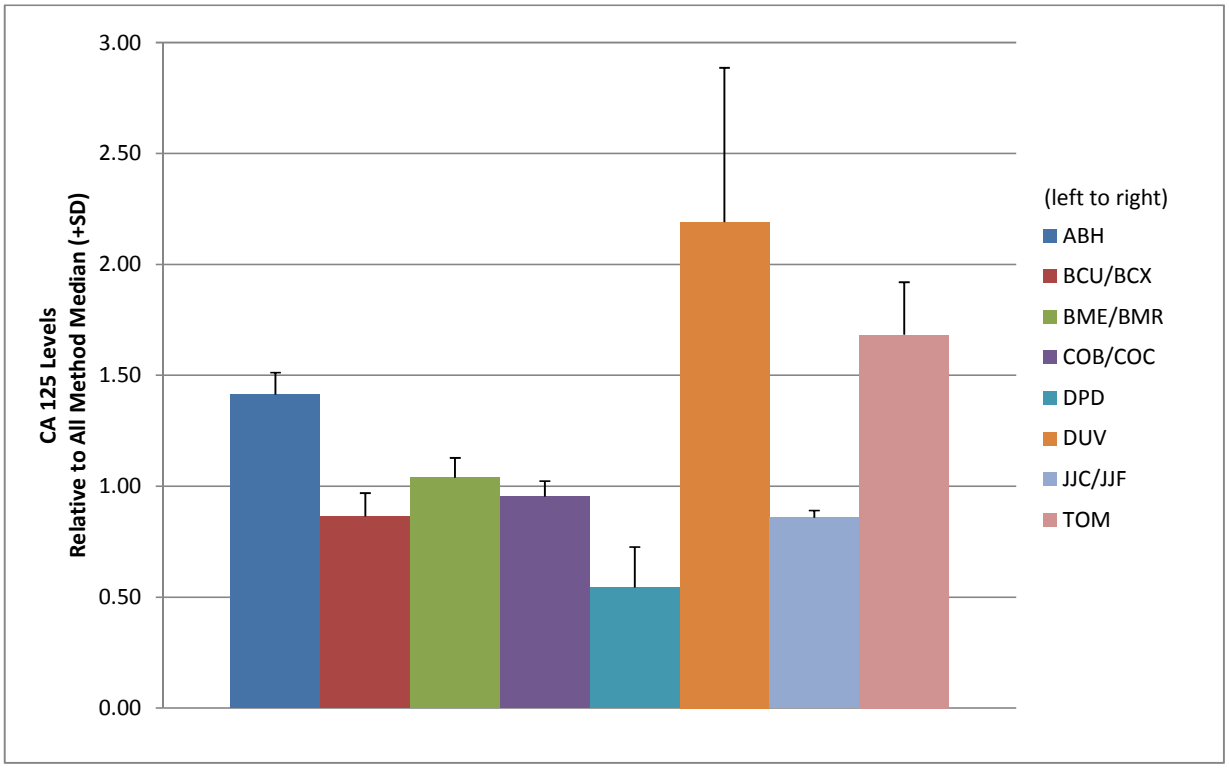

Table 2: 5-14 NYS Tumor Marker PT Summary for CA 19-9

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									
TM271	3	182.1	**149.3**	**214.9**	32.8	6.66		5.52	
TM272	3	NG							
TM273	3	NG							
TM274	3	NG							
TM275	3	NG							
					mean ±SD	6.66	#DIV/0!	5.52	#DIV/0!
Beckman Unicel & Access/2 BCU/BCX									
TM271	15	35.3	**28.9**	**41.7**	6.4	5.16		1.07	
TM272	15	NG							
TM273	15	NG							
TM274	15	NG							
TM275	15	NG							
					mean ±SD	5.16	#DIV/0!	1.07	#DIV/0!
Roche Elecsys & Cobas BME/BMR									
TM271	13	30.7	**25.2**	**36.2**	5.5	4.01		0.93	
TM272	13	NG							
TM273	13	NG							
TM274	13	NG							
TM275	13	NG							
					mean ±SD	4.01	#DIV/0!	0.93	#DIV/0!
Siemens Advia Centaur XP COB									
TM271	29	63.9	**52.4**	**75.4**	11.5	6.74		1.94	
TM272	29	NG							
TM273	29	NG							
TM274	29	NG							
TM275	29	NG							
					mean ±SD	6.74	#DIV/0!	1.94	#DIV/0!
Tosoh AIA TOM									
TM271	5	27.8	**22.8**	**32.8**	5.0	2.48		0.84	
TM272	5	1.8	**0.0**	**5.4**	2.7	18.33			
TM273	5	1.7	**0.0**	**5.3**	2.7	12.94			
TM274	5	1.6	**0.0**	**5.2**	2.6	47.50			
TM275	5	1.6	**0.0**	**5.2**	2.6	25.00			
					mean ±SD	21.25	16.83	0.84	#DIV/0!

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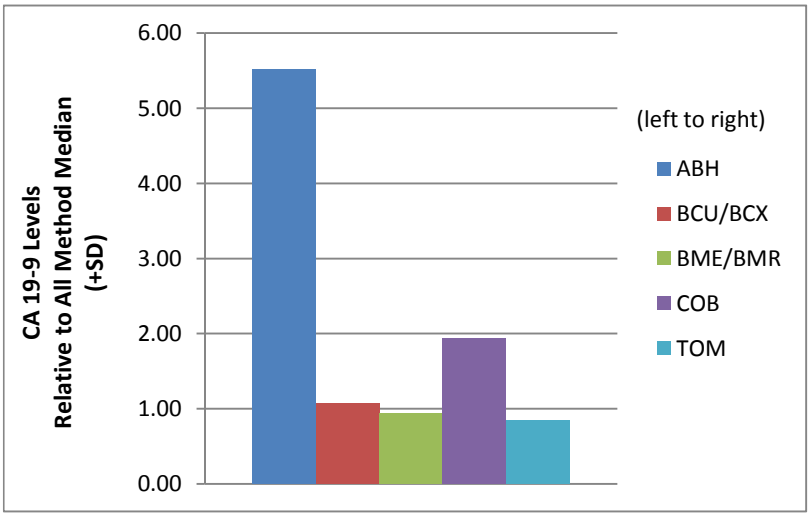
Table 2 (cont.): 5-14 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM271	65	33.0	4.58
TM272	65	1.8	NA
TM273	65	1.7	NA
TM274	65	1.6	NA
TM275	65	1.6	NA

Average*	4.58	*Abbott excluded
Allowable CV %	6.00	
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



Note: Graph is based on data from TM271 only.

Table 3: 5-14 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									
TM271	6	57.0	**38.2**	**75.8**	18.8	5.75		1.06	
TM272	6	1.9	**1.3**	**2.5**	0.6	14.21			
TM273	6	1.9	**1.3**	**2.5**	0.6	13.68			
TM274	6	1.8	**1.2**	**2.4**	0.6	10.56			
TM275	6	1.7	**1.1**	**2.3**	0.6	14.71			
					mean ±SD	11.78	1.87	1.06	#DIV/0!
Beckman Unicel & Access/2 BCU/BCX									
TM271	7	35.9	**24.1**	**47.7**	11.8	9.03		0.67	
TM272	7	2.4	**1.6**	**3.2**	0.8	7.50			
TM273	7	2.3	**1.5**	**3.1**	0.8	10.43			
TM274	7	2.3	**1.5**	**3.1**	0.8	8.70			
TM275	7	2.4	**1.6**	**3.2**	0.8	8.75			
					mean ±SD	8.88	1.05	0.67	#DIV/0!
Roche Elecsys & Cobas BME/BMR									
TM271	14	53.7	**36.0**	**71.4**	17.7	4.19		1.00	
TM272	14	NG							
TM273	14	NG							
TM274	14	NG							
TM275	14	NG							
					mean ±SD	4.19	#DIV/0!	1.00	#DIV/0!
Siemens Advia Centaur XP & CP COB/COC									
TM271	18	53.8	**36.0**	**71.6**	17.8	4.94		1.00	
TM272	18	NG							
TM273	18	NG							
TM274	18	NG							
TM275	18	NG							
					mean ±SD	4.94	#DIV/0!	1.00	#DIV/0!
Siemens Immulite 2000 DPD									
TM271	8	68.4	**45.8**	**91.0**	22.6	3.52		1.27	
TM272	9	4.3	**2.9**	**5.7**	1.4	12.33			
TM273	9	4.3	**2.9**	**5.7**	1.4	10.47			
TM274	9	4.3	**2.9**	**5.7**	1.4	10.00			
TM275	9	4.2	**2.8**	**5.6**	1.4	10.95			
					mean±SD	10.94	1.00	1.27	#DIV/0!

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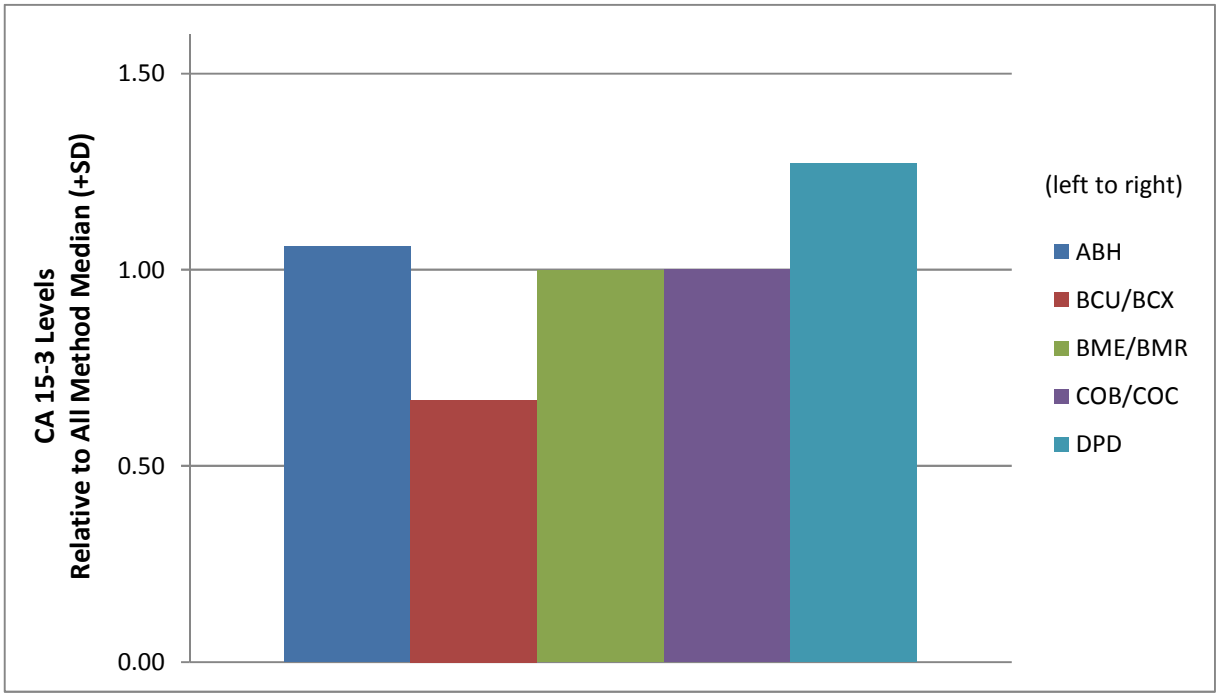
Table 3 (cont.): 5-14 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM271	53	53.8	4.94
TM272	54	2.4	12.33
TM273	54	2.3	10.47
TM274	54	2.3	10.00
TM275	54	2.4	10.95
		Average	9.74
		Allowable CV %	11.0
		Allowable Error (+/-)%	33.0

Note: Higher allowable %CV due to very low levels in samples TM272-TM275.

Figure 3: CA 15-3 Method Comparison



Note: Graph is based on data from TM271 only.

Table 4: 5-14 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									
TM271	40	72.5	**57.3**	**87.7**	15.2	5.75		1.09	
TM272	40	16.0	**8.7**	**23.4**	7.4	15.25			
TM273	40	15.3	**8.0**	**22.7**	7.4	15.03			
TM274	40	15.9	**8.6**	**23.3**	7.4	16.86			
TM275	40	14.9	**7.6**	**22.3**	7.4	17.58			
					mean ±SD	14.09	4.79	1.09	###
Tosoh AIA TOM									
TM271	6	60.7	**48.0**	**73.4**	12.7	6.41		0.91	
TM272	6	60.4	**47.7**	**73.1**	12.7	10.60			
TM273	6	58.4	**46.1**	**70.7**	12.3	12.50			
TM274	6	59.1	**46.7**	**71.5**	12.4	7.97			
TM275	6	59.3	**46.8**	**71.8**	12.5	6.73			
					mean ±SD	8.84	2.63	0.91	###

Sample ID	N	All Method Median		Median % CV
TM271	**46**	**66.6**		**6.08**
TM272	**46**	**NA**		**12.92**
TM273	**46**	**NA**		**13.77**
TM274	**46**	**NA**		**12.41**
TM275	**46**	**NA**		**12.16**
			Average	**11.47**
			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

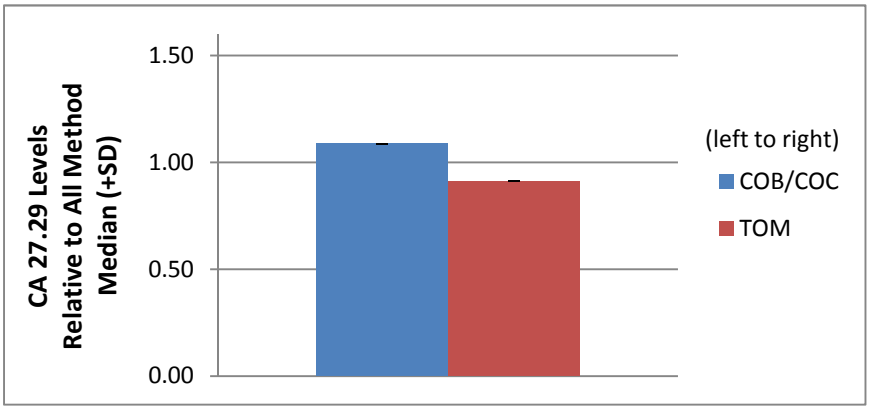


Table 5: 5-14 NYS Tumor Marker PT Summary for CEA

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									
TM271	15	7.1	**5.8**	**8.4**	1.3	6.06		1.03	
TM272	15	12.3	**10.1**	**14.5**	2.2	5.85		1.02	
TM273	15	15.9	**13.0**	**18.8**	2.9	4.78		1.10	
TM274	14	22.3	**18.3**	**26.3**	4.0	4.62		1.09	
TM275	15	36.7	**30.1**	**43.3**	6.6	3.98		1.10	
					mean ±SD	5.06	0.88	1.07	0.04
Beckman Unicel & Access/2 BCU/BCX									
TM271	25	6.6	**5.4**	**7.8**	1.2	5.61		0.96	
TM272	25	10.0	**8.2**	**11.8**	1.8	6.00		0.83	
TM273	25	12.8	**10.5**	**15.1**	2.3	6.33		0.89	
TM274	25	17.9	**14.7**	**21.1**	3.2	5.87		0.87	
TM275	25	28.7	**23.5**	**33.9**	5.2	6.76		0.86	
					mean ±SD	6.11	0.45	0.88	0.05
Roche Elecsys & Cobas BME/BMR									
TM271	23	5.5	**4.5**	**6.5**	1.0	5.64		0.80	
TM272	23	8.5	**7.0**	**10.0**	1.5	5.41		0.71	
TM273	23	10.8	**8.9**	**12.7**	1.9	5.56		0.75	
TM274	23	15.1	**12.4**	**17.8**	2.7	5.56		0.73	
TM275	23	24.3	**19.9**	**28.7**	4.4	5.88		0.73	
					mean ±SD	5.61	0.17	0.74	0.03
Siemens Advia Centaur XP & CP COB/COC									
TM271	45	6.7	**5.5**	**7.9**	1.2	6.57		0.97	
TM272	45	12.6	**10.3**	**14.9**	2.3	5.40		1.05	
TM273	45	16.1	**13.2**	**19.0**	2.9	5.47		1.12	
TM274	45	22.6	**18.5**	**26.7**	4.1	4.87		1.10	
TM275	45	38.6	**31.7**	**45.5**	6.9	5.49		1.16	
					mean ±SD	5.56	0.62	1.08	0.07
Siemens Immulite 2000 DPD									
TM271	11	7.1	**5.8**	**8.4**	1.3	5.35		1.03	
TM272	10	12.9	**10.6**	**15.2**	2.3	7.21		1.07	
TM273	11	16.6	**13.6**	**19.6**	3.0	5.00		1.15	
TM274	11	24.9	**20.4**	**29.4**	4.5	5.14		1.21	
TM275	10	40.9	**33.5**	**48.3**	7.4	5.67		1.23	
					mean ±SD	5.67	0.89	1.14	0.09
Siemens Dimension Vista DUV									
TM271	24	6.3	**5.2**	**7.4**	1.1	3.02		0.91	
TM272	24	9.6	**7.9**	**11.3**	1.7	2.50		0.80	
TM273	24	12.4	**10.2**	**14.6**	2.2	3.95		0.86	
TM274	24	17.5	**14.4**	**20.7**	3.2	3.20		0.85	
TM275	24	28.8	**23.6**	**34.0**	5.2	3.02		0.86	
					mean ±SD	3.14	0.52	0.86	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM271	12	8.4	**6.9**	**9.9**	1.5	13.33		1.22	
TM272	12	11.8	**9.7**	**13.9**	2.1	9.24		0.98	
TM273	12	12.9	**10.6**	**15.2**	2.3	16.67		0.90	
TM274	12	18.8	**15.4**	**22.2**	3.4	12.61		0.91	
TM275	12	30.0	**24.6**	**35.4**	5.4	4.83		0.90	
					mean ±SD	11.34	4.49	0.98	0.14

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Table 5 (cont.): 5-14 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									
TM271	6	9.9	**8.1**	**11.7**	1.8	3.03		1.43	
TM272	6	17.0	**13.9**	**20.1**	3.1	2.41		1.41	
TM273	6	21.9	**18.0**	**25.8**	3.9	2.88		1.52	
TM274	6	30.2	**24.8**	**35.6**	5.4	2.85		1.47	
TM275	6	47.0	**38.5**	**55.5**	8.5	1.83		1.41	
					mean ±SD	2.60	0.49	1.45	0.05

Sample ID	All Method Median	Median % CV
TM271	**6.9**	**5.62**
TM272	**12.1**	**5.63**
TM273	**14.4**	**5.23**
TM274	**20.6**	**5.00**
TM275	**33.4**	**5.16**
	Average	**5.33**
	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

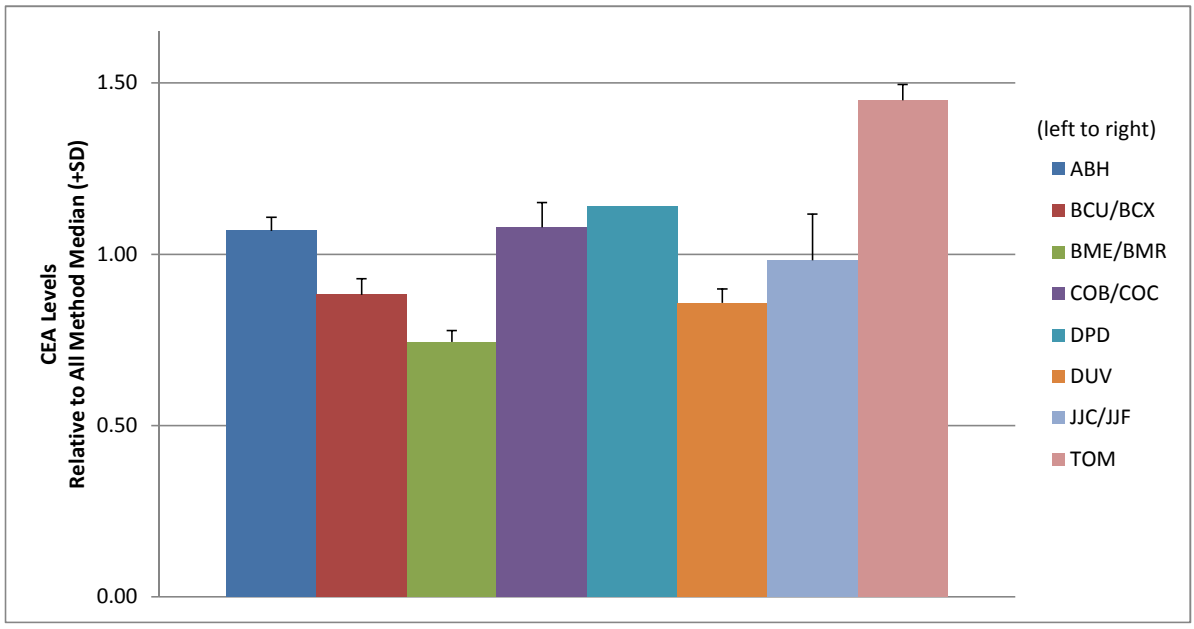

Table 6: 5-14 NYS Tumor Marker PT Summary for AFP

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											
TM271	3	21.4	**17.5**	**25.3**	3.9	2.57		1.03		1.16	
TM272	3	8.5	**7.0**	**10.0**	1.5	3.53		0.99		1.16	
TM273	3	12.9	**10.6**	**15.2**	2.3	2.71		1.02		1.17	
TM274	3	26.3	**21.6**	**31.0**	4.7	4.60		1.02		1.12	
TM275	3	19.1	**15.7**	**22.5**	3.4	2.36		1.01		1.13	
					mean ±SD	3.15	0.92	1.01	0.02	1.15	0.02
Beckman Unicel & Access/2 BCU/BCX											
TM271	19	20.6	**16.9**	**24.3**	3.7	5.49		0.99		1.12	
TM272	19	8.8	**7.2**	**10.4**	1.6	6.70		1.02		1.20	
TM273	19	12.8	**10.5**	**15.1**	2.3	6.64		1.01		1.16	
TM274	19	26.0	**21.3**	**30.7**	4.7	4.88		1.01		1.11	
TM275	19	19.1	**15.7**	**22.5**	3.4	5.92		1.01		1.13	
					mean ±SD	5.93	0.77	1.01	0.01	1.14	0.04
Roche Elecsys & Cobas BME/BMR											
TM271	17	24.5	**20.1**	**28.9**	4.4	4.94		1.18		1.33	
TM272	17	10.0	**8.2**	**11.8**	1.8	4.90		1.16		1.36	
TM273	16	14.7	**12.1**	**17.3**	2.6	3.20		1.16		1.33	
TM274	17	30.3	**24.8**	**35.8**	5.5	7.00		1.17		1.30	
TM275	17	22.2	**18.2**	**26.2**	4.0	5.05		1.17		1.31	
					mean ±SD	5.02	1.35	1.17	0.01	1.33	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM271	25	21.4	**17.5**	**25.3**	3.9	7.66		1.03		1.16	
TM272	25	9.2	**7.5**	**10.9**	1.7	9.24		1.07		1.25	
TM273	25	13.1	**10.7**	**15.5**	2.4	6.95		1.03		1.19	
TM274	25	26.1	**21.4**	**30.8**	4.7	5.79		1.01		1.12	
TM275	25	19.2	**15.7**	**22.7**	3.5	6.51		1.01		1.14	
					mean ±SD	7.23	1.31	1.03	0.02	1.17	0.05
Siemens Immulite 2000 DPD											
TM271	16	20.8	**17.1**	**24.5**	3.7	5.24		1.00		1.13	
TM272	15	8.4	**6.9**	**9.9**	1.5	7.14		0.98		1.15	
TM273	16	12.5	**10.3**	**14.8**	2.3	8.64		0.98		1.13	
TM274	16	25.7	**21.1**	**30.3**	4.6	7.94		0.99		1.10	
TM275	16	17.9	**14.7**	**21.1**	3.2	15.59		0.94		1.06	
					mean±SD	9.83	3.94	0.98	0.02	1.11	0.03
Siemens Dimension Vista DUV											
TM271	7	19.6	**16.1**	**23.1**	3.5	5.71		0.94		1.06	
TM272	7	8.3	**6.8**	**9.8**	1.5	6.27		0.97		1.13	
TM273	7	12.1	**9.9**	**14.3**	2.2	5.62		0.95		1.10	
TM274	7	24.6	**20.2**	**29.0**	4.4	6.42		0.95		1.05	
TM275	7	18.2	**14.9**	**21.5**	3.3	5.60		0.96		1.08	
					mean ±SD	5.93	0.39	0.95	0.01	1.08	0.03
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM271	5	16.1	**13.2**	**19.0**	2.9	6.52		0.78		0.87	
TM272	5	7.1	**5.8**	**8.4**	1.3	7.89		0.83		0.97	
TM273	5	9.8	**8.0**	**11.6**	1.8	5.71		0.77		0.89	
TM274	5	20.1	**16.5**	**23.7**	3.6	5.07		0.78		0.86	
TM275	5	14.7	**12.1**	**17.3**	2.6	5.37		0.78		0.87	
					mean ±SD	6.11	1.13	0.79	0.02	0.89	0.04

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Table 6 (cont.): 5-14 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											
TM271	3	20.7	**17.0**	**24.4**	3.7	3.24		1.00		1.12	
TM272	3	8.7	**7.1**	**10.3**	1.6	4.14		1.01		1.19	
TM273	3	12.6	**10.3**	**14.9**	2.3	5.87		0.99		1.14	
TM274	3	25.5	**20.9**	**30.1**	4.6	4.98		0.99		1.09	
TM275	3	18.8	**15.4**	**22.2**	3.4	5.85		0.99		1.11	
					mean ±SD	4.82	1.14	1.00	0.01	1.13	0.04

Sample ID	All Method Median	IS based Target	SD		Median % CV			All Method Median/ IS Target	
TM271	20.8	18.4	0.82		5.36			1.13	
TM272	8.6	7.3	0.32		6.48			1.17	
TM273	12.7	11.0	0.53		5.79			1.15	
TM274	25.9	23.4	1.39		5.43			1.11	
TM275	19.0	16.9	1.18		5.73			1.12	
				Average	5.76		mean ±SD	1.14	0.03
				Allowable CV %	6.0				
				Allowable Error (+/-)%	18.0				

Figure 6: AFP Method Comparison

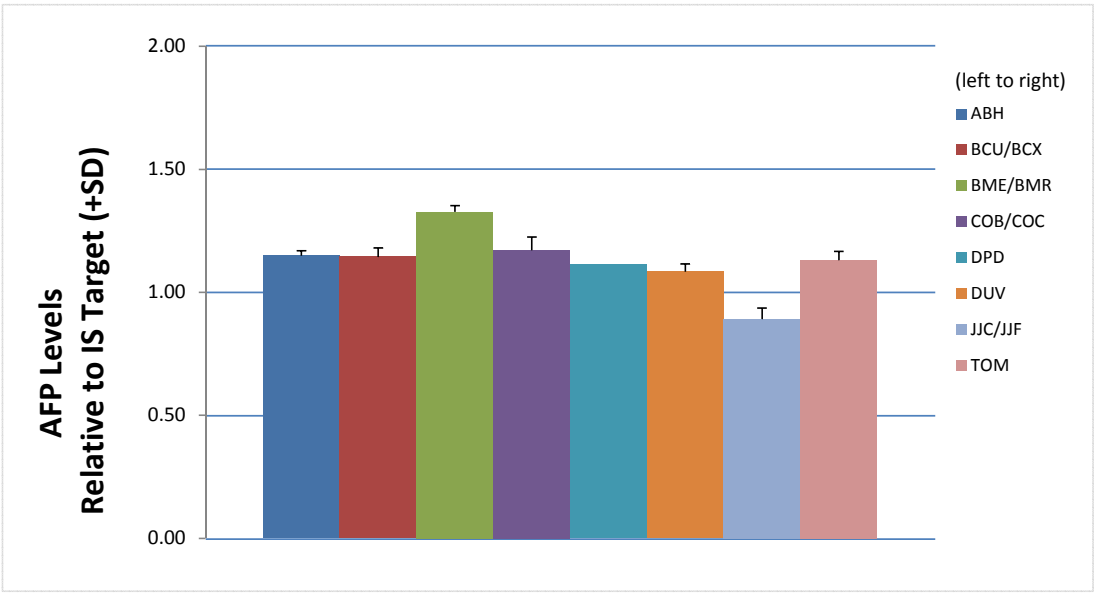

Table 7: 5-14 NYS Tumor Marker PT Summary for PSA

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											
TM271	18	0.89	**0.73**	**1.05**	0.16	7.87		1.00		1.07	
TM272	18	2.45	**2.01**	**2.89**	0.44	6.94		1.04		1.18	
TM273	18	3.92	**3.21**	**4.63**	0.71	8.93		1.05		1.20	
TM274	17	7.74	**6.35**	**9.13**	1.39	7.11		1.05		1.17	
TM275	17	14.61	**11.98**	**17.24**	2.63	6.78		1.03		1.14	
					mean ±SD	7.52	0.89	1.03	0.02	1.15	0.05
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM271	48	0.97	**0.80**	**1.14**	0.17	4.12		1.09		1.17	
TM272	47	2.63	**2.16**	**3.10**	0.47	3.80		1.11		1.26	
TM273	48	4.24	**3.48**	**5.00**	0.76	4.48		1.14		1.29	
TM274	48	8.56	**7.02**	**10.10**	1.54	4.21		1.16		1.30	
TM275	48	16.68	**13.68**	**19.68**	3.00	4.56		1.18		1.30	
					mean ±SD	4.23	0.30	1.14	0.04	1.26	0.06
Roche Elecsys & Cobas BME/BMR											
TM271	41	0.88	**0.72**	**1.04**	0.16	5.68		0.99		1.06	
TM272	41	2.28	**1.87**	**2.69**	0.41	5.26		0.97		1.10	
TM273	41	3.62	**2.97**	**4.27**	0.65	4.97		0.97		1.10	
TM274	41	7.15	**5.86**	**8.44**	1.29	5.03		0.97		1.08	
TM275	41	13.63	**11.18**	**16.08**	2.45	5.58		0.96		1.06	
					mean ±SD	5.31	0.32	0.97	0.01	1.08	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM271	53	0.87	**0.71**	**1.03**	0.16	4.60		0.98		1.05	
TM272	55	2.17	**1.78**	**2.56**	0.39	5.07		0.92		1.04	
TM273	53	3.42	**2.80**	**4.04**	0.62	3.22		0.92		1.04	
TM274	53	6.71	**5.50**	**7.92**	1.21	3.43		0.91		1.02	
TM275	53	12.70	**10.41**	**14.99**	2.29	3.78		0.90		0.99	
					mean ±SD	4.02	0.79	0.92	0.03	1.03	0.02
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM271	14	0.81	**0.66**	**0.96**	0.15	9.88		0.91		0.98	
TM272	13	2.46	**2.02**	**2.90**	0.44	4.47		1.04		1.18	
TM273	14	3.89	**3.19**	**4.59**	0.70	5.14		1.04		1.19	
TM274	11	7.63	**6.26**	**9.00**	1.37	1.57		1.03		1.15	
TM275	13	14.72	**12.07**	**17.37**	2.65	5.64		1.04		1.15	
					mean ±SD	5.34	2.99	1.01	0.06	1.13	0.09
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM271	13	1.01	**0.83**	**1.19**	0.18	3.96		1.13		1.22	
TM272	13	2.76	**2.26**	**3.26**	0.50	3.62		1.17		1.33	
TM273	13	4.39	**3.60**	**5.18**	0.79	4.10		1.18		1.34	
TM274	13	8.90	**7.30**	**10.50**	1.60	2.47		1.20		1.35	
TM275	13	17.03	**13.96**	**20.10**	3.07	3.41		1.20		1.33	
					mean±SD	3.51	0.64	1.18	0.03	1.31	0.05
Siemens Dimension Vista DUV											
TM271	21	0.92	**0.75**	**1.09**	0.17	3.26		1.03		1.11	
TM272	21	2.36	**1.94**	**2.78**	0.42	2.97		1.00		1.13	
TM273	21	3.73	**3.06**	**4.40**	0.67	2.41		1.00		1.14	
TM274	21	7.39	**6.06**	**8.72**	1.33	2.98		1.00		1.12	
TM275	21	14.14	**11.59**	**16.69**	2.55	2.62		1.00		1.10	
					mean ±SD	2.85	0.33	1.01	0.02	1.12	0.01

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Table 7 (cont.): 5-14 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											
TM271	22	0.91	**0.75**	**1.07**	0.16	5.49		1.02		1.10	
TM272	22	2.11	**1.73**	**2.49**	0.38	4.27		0.89		1.01	
TM273	22	3.15	**2.58**	**3.72**	0.57	4.13		0.84		0.96	
TM274	22	6.09	**4.99**	**7.19**	1.10	4.43		0.82		0.92	
TM275	22	11.50	**9.43**	**13.57**	2.07	4.26		0.81		0.90	
					mean ±SD	4.52	0.56	0.88	0.09	0.98	0.08
Tosoh AIA TOM											
TM271	8	0.88	**0.72**	**1.04**	0.16	5.68		0.99		1.06	
TM272	8	2.35	**1.93**	**2.77**	0.42	3.40		1.00		1.13	
TM273	8	3.66	**3.00**	**4.32**	0.66	4.64		0.98		1.12	
TM274	8	7.30	**5.99**	**8.61**	1.31	4.66		0.99		1.10	
TM275	8	13.67	**11.21**	**16.13**	2.46	4.17		0.97		1.07	
					mean ±SD	4.51	0.83	0.98	0.01	1.10	0.03

Sample ID	All Method Median	IS based Target	SD	Median % CV	All Method Median/ IS Target
TM271	**0.89**	**0.83**	**0.04**	**5.49**	**1.07**
TM272	**2.36**	**2.08**	**0.05**	**4.27**	**1.13**
TM273	**3.73**	**3.28**	**0.12**	**4.48**	**1.14**
TM274	**7.39**	**6.61**	**0.26**	**4.21**	**1.12**
TM275	**14.14**	**12.80**	**0.48**	**4.26**	**1.10**
			Average	**4.54**	mean ±SD **1.11** 0.03
			Allowable CV %	**6.00**	
			Allowable Error (+/-)%	**18.0**	

Figure 7: PSA Method Comparison

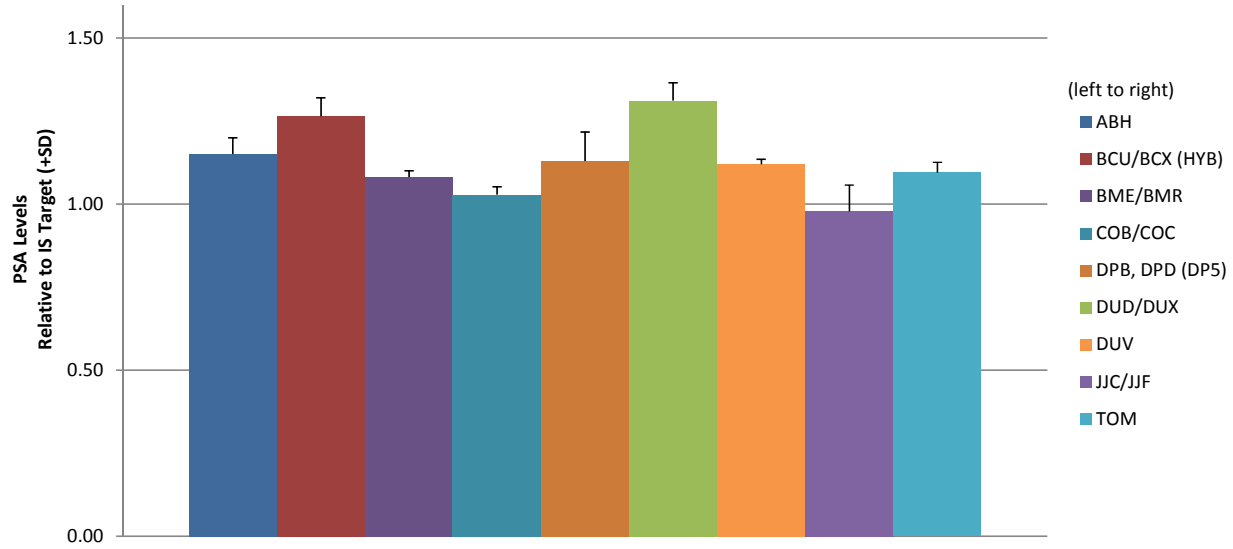

Table 8: 5-14 NYS Tumor Marker PT Summary for Free PSA

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													
TM271	6	0.16	**0.07**	**0.25**	0.09	6.25		1.07		1.02		18.0%	
TM272	6	0.40	**0.31**	**0.49**	0.09	2.50		1.05		0.98		16.3%	
TM273	6	0.62	**0.51**	**0.73**	0.11	3.23		1.03		0.95		15.8%	
TM274	6	1.25	**1.03**	**1.48**	0.23	2.40		1.08		0.95		16.1%	
TM275	6	2.41	**1.98**	**2.84**	0.43	2.07		1.10		0.94		16.5%	
					mean ±SD	3.29	1.71	1.07	0.03	0.97	0.03	16.6%	0.8%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)													
TM271	24	0.20	**0.11**	**0.29**	0.09	5.00		1.33		1.28		20.6%	
TM272	26	0.53	**0.43**	**0.63**	0.10	5.66		1.39		1.30		20.2%	
TM273	26	0.82	**0.67**	**0.97**	0.15	3.66		1.37		1.26		19.3%	
TM274	26	1.61	**1.32**	**1.90**	0.29	3.73		1.39		1.22		18.8%	
TM275	26	3.03	**2.48**	**3.58**	0.55	3.30		1.38		1.18		18.2%	
					mean ±SD	4.27	1.01	1.37	0.02	1.25	0.05	19.4%	1.0%
Roche Elecsys & Cobas BME/BMR													
TM271	17	0.15	**0.06**	**0.24**	0.09	0.00		1.00		0.96		17.0%	
TM272	24	0.38	**0.29**	**0.47**	0.09	2.63		1.00		0.93		16.7%	
TM273	24	0.60	**0.49**	**0.71**	0.11	5.00		1.00		0.92		16.6%	
TM274	24	1.16	**0.95**	**1.37**	0.21	3.45		1.00		0.88		16.2%	
TM275	22	2.19	**1.80**	**2.58**	0.39	2.28		1.00		0.85		16.1%	
					mean ±SD	2.67	1.82	1.00	0.00	0.91	0.04	16.5%	0.4%
Siemens Immulite 2000 DPD													
TM271	12	0.13	**0.04**	**0.22**	0.09	7.69		0.87		0.83		16.0%	
TM272	11	0.35	**0.26**	**0.44**	0.09	8.57		0.92		0.86		14.2%	
TM273	12	0.56	**0.46**	**0.66**	0.10	5.36		0.93		0.86		14.4%	
TM274	12	1.13	**0.93**	**1.33**	0.20	5.31		0.97		0.86		14.8%	
TM275	11	2.17	**1.78**	**2.56**	0.39	6.45		0.99		0.85		14.7%	
					mean ±SD	6.68	1.44	0.94	0.05	0.85	0.01	14.8%	0.7%
Siemens Dimension Vista DUV													
TM271	7	0.13	**0.04**	**0.22**	0.09	0.00		0.87		0.83		14.1%	
TM272	9	0.33	**0.24**	**0.42**	0.09	3.03		0.87		0.81		14.0%	
TM273	9	0.52	**0.43**	**0.61**	0.09	3.85		0.87		0.80		13.9%	
TM274	9	1.05	**0.86**	**1.24**	0.19	3.81		0.91		0.80		14.2%	
TM275	9	1.99	**1.63**	**2.35**	0.36	2.51		0.91		0.77		14.1%	
					mean ±SD	2.64	1.58	0.88	0.02	0.80	0.02	14.1%	0.1%

continued on next page

Table 8 (cont.): 5-14 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	
TM271	66	0.15	0.16	0.003	5.00		0.96		18.8%	
TM272	76	0.38	0.41	0.01	3.03		0.93		19.6%	
TM273	77	0.60	0.65	0.02	3.85		0.92		19.9%	
TM274	77	1.16	1.32	0.04	3.73		0.88		19.9%	
TM275	74	2.19	2.57	0.18	2.51		0.85		20.1%	
				Average	3.62	mean ±SD	0.91	0.04	19.7%	0.5%
				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

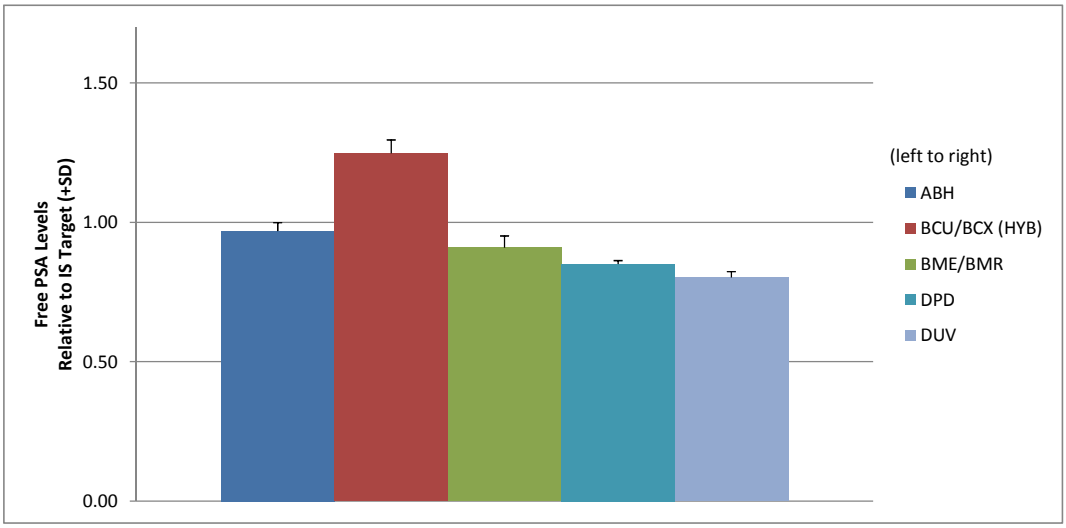

Figure 8B: Calculated % Free PSA Method Comparison

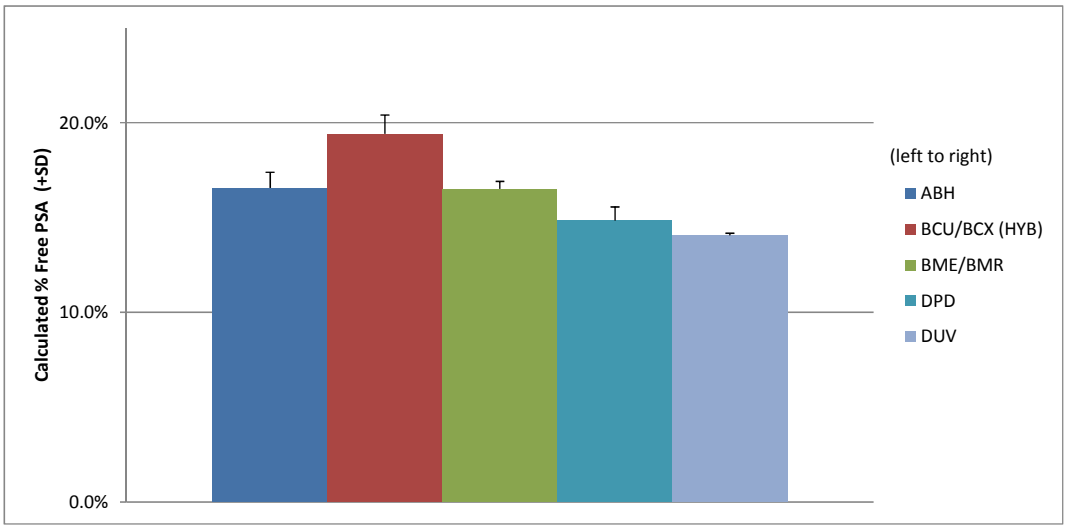

Table 9: 5-14 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM271	9	0.7	**0.6**	**0.8**	0.1	8.45		1.00	
TM272	8	1.8	**1.5**	**2.2**	0.4	9.24		1.00	
TM273	9	2.8	**2.3**	**3.3**	0.5	14.80		1.00	
TM274	9	5.7	**4.7**	**6.8**	1.1	6.97		1.00	
TM275	9	10.8	**8.9**	**12.8**	2.0	6.09		1.00	
					mean ±SD	9.11	3.41	1.00	0.00

Sample ID	All Method Median		Median % CV
TM271	**0.7**		**8.45**
TM272	**1.8**		**9.24**
TM273	**2.8**		**14.80**
TM274	**5.7**		**6.97**
TM275	**10.8**		**6.09**
		Average	**9.11**
		Allowable CV %	**6.0**
		Allowable Error (+/-)%	**18.0**

NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

May 6, 2014

REFRIGERATE SAMPLES UPON ARRIVAL

DO NOT FREEZE

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: **May 21, 2014**

*****IMPORTANT INSTRUCTIONS BELOW—PLEASE READ*****

Samples:
Enclosed are five sealed (5) vials labeled **TM271 to TM275**, each containing proficiency test specimens in a human-derived serum base, sterile filtered and dispensed. All materials used to prepare the samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, universal precautions should be followed when handling samples. Keep refrigerated until use, but do not freeze. Make sure samples are completely mixed before analyzing.

Each vial contains various predetermined amounts of alpha-feto protein (AFP), carcinoembryonic antigen (CEA), cancer antigen 125 (CA125), the breast cancer markers CA15-3 and CA27.29, the GI cancer marker CA19-9 and prostate specific antigen (PSA) in all three currently measured forms, i.e. total PSA, free PSA and complexed PSA (PSA-ACT). Please measure all markers tested in your laboratory.

If your lab measures free and/or complexed PSA measure it in **ALL** of the samples. Please note we can no longer accept results from a second method for any analyte.

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)**. The HCS is a secure website and requires all users to obtain an ID in order to access the HCS and EPTRS application. Questions regarding the entry and submission of proficiency test results or the account application process can be emailed to clepeptrs@health.state.ny.us.

If a test is Temporarily Suspended, choose the appropriate selection from the **Test Status** list on the **Event Menu** page. When temporary suspension of testing is selected, the reason for this suspension must be indicated in the appropriate box at the bottom of the event menu page.
If a test is permanently deleted, select 'test not offered' and also submit the 'delete analyte' form found at: (http://www.wadsworth.org/labcert/TestApproval/forms/DOH3519f.pdf). **Absence of results for any analyte without appropriate notification will result in a failing grade for the missing results.**

The **Event Menu** page also includes a space to enter your lab's upper limit of normal reference range, i.e. cut-off value, for each individual analyte measured. It should indicate the **highest 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.

Please make sure that the **Instrument** and **Reagent** information is current, since the EPTRS Event Menu page is pre-populated from previous entries. It is very important to correctly complete all applicable fields because missing or incorrect entries may result in an inability to move to the next screen or even in test failure if your results get evaluated with the incorrect method group.

We are also asking for the lot numbers of the Reagents and Calibrators used when testing the PT samples. Please enter these on the Event Menu page under the Instrument and Reagent Names.

Results must be reported for all five samples for all analytes you measure, otherwise a zero grade will be given to the missing data. If a result exceeds the **analytical range or is below the method's limit of detection**, indicate this with a greater than (>) or less than (<) sign, respectively, if similar results from patient samples are reported in the same manner. If such samples are routinely diluted and retested, you may do so but be sure to identify the result accordingly in the comments.

The laboratory director or assistant **director with an appropriate CofQ** and **all laboratory personnel analyzing these specimens must sign** the printed electronic summary page. These signatures attest that the proficiency testing samples were analyzed in as close a manner as possible to patient samples, and this signed summary page should be kept on file for review by CLEP surveyors.

Results must be submitted electronically before 11:59 PM on May 21, 2014. It is advisable to submit earlier to allow time to resolve any problem that could occur with result submission. Results not submitted by the due date are categorized as missing with an administrative **failure** and receive a failing grade, even if results were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must **contact the PT section by email as soon as possible before the due date** to see if this can be arranged.

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

For any correspondence regarding the Oncology PT contact us by e-mail at smchale@wadsworth.org 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 remaining 2014 Oncology Tumor Marker Proficiency Test schedule is:

Mail-out date:	Due date:
September 9, 2014	**September 24, 2014**

The above 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						
		TM271	**TM272**	**TM273**	**TM274**	**TM275**
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					

**********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