NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

March 10, 2014

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

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from January 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. Analyte levels were pre-assayed and stability tested in our laboratory. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

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)

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:

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 113 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 72% of the labs. There was a separation of groups into high and low clusters with the same bias as seen in the past; the "low" cluster ranged from 11% to 15% below the all method median and contained Roche Cobas, Siemens Immulite 2000, Siemens Dimension Vista and Ortho Clinical instruments, while the "high" cluster was more diverse, ranging from 8% to 31% above the all method median with the Tosoh instrument being the highest. The other "high" instruments were from Abbott, Beckman and Siemens Advia Centaur.

CA19-9 (Table 2, Figure 2): Results were reported by 72 labs using instruments from seven different manufacturers, but due to two having N=1, five peer groups remained for grading. Forty-three percent of all reporting labs used Siemens ADVIA-Centaur XP, 21% used either Beckman's Unicel or Access/2, 18% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 7% used the Tosoh ST-AIA method. As seen with previous PT events, there remain large differences in how each method measured CA19-9, ranging from 80% (Tosoh) to 531% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP were on average 2 times higher than the all method median, whereas results from Beckman and Roche were within +/-6% of the all method median. Used by three labs, the Abbott Architect method results averaged 5.3 times higher than the all method median as shown in Table 2 and Figure 2 and displayed a rather large variation between those labs. 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 105 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). Abbott, Roche, Siemens Advia, Siemens Immulite and Ortho Clinical (with only one lab reporting) were all within +/-10% of the all method median and altogether comprise 84% of the labs measuring CA15-3. In contrast, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -32% from the all method medians, which is similar to previous NYS PT events. **CA27.29** measurements showed a 8% difference between the ADVIA Centaur XP/CP and the Tosoh methods and the median CA27.29 measurements averaged 14% higher than the median CA15-3 measurements.

CEA (Table 5, Figure 5): Results were reported by 169 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 49 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 75% of the labs, were within +/-10% of the medians. In contrast, Roche methods were 18% 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 graphical figures show the performance relative only to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 101 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to nineteen percent of the total number of labs. Six of the eight methods, used by 75% of the labs, gave results within +/-3% of the all method median, but averaged 13% higher than the assigned targets. Of the remaining two methods, Roche measured 20% higher than the all method median, and 36% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants) was the only method with results below the assigned target (-8%) and was 19% 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 252 labs using instruments from nine peer groups. One of the peer groups comprised only seven members, but made up only 3% of the labs. Samples were prepared with varying concentrations of total PSA, but the same proportion of free PSA (10%) to assess if the total PSA level affected the proportion of free PSA. While there were substantial differences in PSA measurements between methods, there was no recognizable difference in the proportions of free PSA, which is similar to previous NYS PT events. Also, no clear separation into statistically significantly different high and low clusters of methods was seen. Results from five of the peer groups were within +/-10% of the all method median, and between +9% and +21% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 14% above the all method median and 29% above the target (no lab used the WHO calibration), and Siemens Dimension RxL Max/Xpand Plus/EXL was 15% above the all method median and 30% above the assigned targets. In contrast, results from Ortho Clinical Vitros ECi/ECiQ & 5600 were 24% lower than the all method median and 13% lower than the targets. Siemens Immulite 2000 with the original PSA pack was exactly at the assigned target and 12% lower than the all method median.

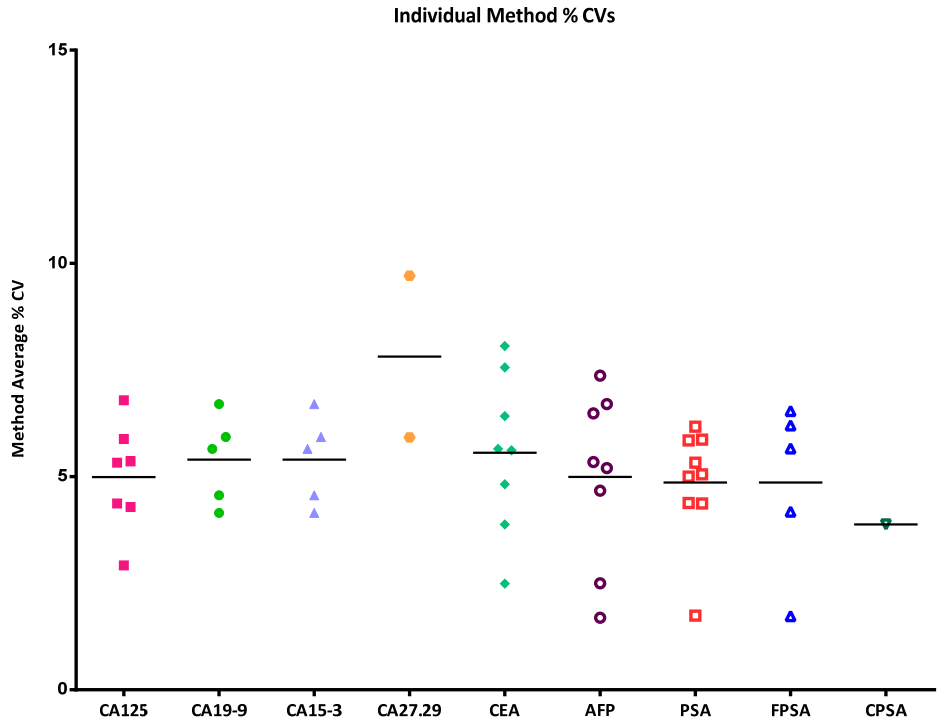
Free PSA (Table 8, Figure 8): Results were reported by 84 labs using instruments from six manufacturers which corresponded to five peer groups plus three others with N<3. Two of the five peer groups comprised less than 10 labs each and along with the N<3 methods, made up 17% of the participants. The remaining three methods were used by 31% of labs each for Beckman Unicel/Access calibrated with the Hybritech standards and Roche Elecsys/E170/Cobas, and 18% for Siemens Immulite 1000/2000. 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 (35% higher than the all method medians and 24% higher than the targets), while there were no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. Of the other methods, two (Abbott Architect and Roche

Elecsys & Cobas) were within +/-10% of the assigned targets and two (Siemens Immulite and Siemens Dimension Vista) were 14% and 16% below the assigned targets respectively. Nevertheless, all but Beckman Unicel/Access methods were within 10% of each other, whereas Beckman remains consistently high.

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, 11 labs measured **complexed PSA** and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little difference between them. Overall, the samples showed relatively good agreement with an average %CV of 4% (Table 9).

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



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 1b). 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. 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.

The PSA for a 2nd method analyte option allows labs to enter results from a second PSA assay if a different method for total PSA is used in conjunction with their free PSA measurements**.** If only one PSA test was done, then results should **only** be entered in the first PSA (Total) entry line. Note: As per new guidelines from CMS, measuring and reporting results from a second instrument will no longer be allowed in future PT events

Please note that questions regarding the electronic proficiency testing reporting system (EPTRS) account application process and the entry and submission of proficiency test results can be directed to clepeptrs@health.state.ny.us, or directly to Kathi Wagner at (518) 402-4266 or by e-mail at klw05@health.state.ny.us.

The scheduled dates for the remaining 2014 Tumor Marker Proficiency Test event are:

Mail-out date:	**Due date:**
May 6, 2014	May 21, 2014
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 smchale@wadsworth.org (518) 486-5775, or myself at schneid@wadsworth.org or (518) 474-2088.

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

Table 1: 1-14 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									
TM266	10	22.2	**16.8**	**27.6**	5.4	6.08		1.27	
TM267	10	32.0	**26.2**	**37.8**	5.8	3.28		1.24	
TM268	10	68.8	**56.4**	**81.2**	12.4	6.57		1.21	
TM269	10	65.6	**53.8**	**77.4**	11.8	5.98		1.24	
TM270	10	42.9	**35.2**	**50.6**	7.7	4.73		1.24	
					mean ±SD	5.33	1.33	1.24	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM266	15	20.0	**14.6**	**25.4**	5.4	6.35		1.15	
TM267	15	30.4	**24.9**	**35.9**	5.5	7.89		1.18	
TM268	15	68.7	**56.3**	**81.1**	12.4	5.95		1.21	
TM269	15	61.1	**50.1**	**72.1**	11.0	7.20		1.15	
TM270	15	39.9	**32.7**	**47.1**	7.2	6.54		1.15	
					mean ±SD	6.79	0.77	1.17	0.03
Roche Elecsys & Cobas BME/BMR									
TM266	17	15.3	**9.9**	**20.7**	5.4	5.03		0.88	
TM267	17	22.4	**17.0**	**27.8**	5.4	4.46		0.87	
TM268	17	47.2	**38.7**	**55.7**	8.5	4.07		0.83	
TM269	17	45.8	**37.6**	**54.0**	8.2	3.65		0.86	
TM270	17	29.8	**24.4**	**35.2**	5.4	4.26		0.86	
					mean ±SD	4.29	0.51	0.86	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM266	34	19.0	**13.6**	**24.4**	5.4	6.68		1.09	
TM267	34	28.6	**23.2**	**34.0**	5.4	5.35		1.11	
TM268	34	60.7	**49.8**	**71.6**	10.9	5.24		1.07	
TM269	35	56.9	**46.7**	**67.1**	10.2	4.55		1.07	
TM270	35	37.3	**30.6**	**44.0**	6.7	4.99		1.08	
					mean ±SD	5.36	0.80	1.08	0.02
Siemens Immulite 2000 DPD									
TM266	21	15.5	**10.1**	**20.9**	5.4	4.32		0.89	
TM267	22	23.0	**17.6**	**28.4**	5.4	7.35		0.89	
TM268	21	50.3	**41.2**	**59.4**	9.1	6.18		0.89	
TM269	22	47.4	**38.9**	**55.9**	8.5	6.65		0.89	
TM270	22	31.6	**25.9**	**37.3**	5.7	4.91		0.91	
					mean ±SD	5.88	1.25	0.89	0.01
Siemens Diag Dimension Vista (LOCI) DUV									
TM266	3	15.9	**10.5**	**21.3**	5.4	5.09		0.91	
TM267	3	21.4	**16.0**	**26.8**	5.4	0.79		0.83	
TM268	3	43.7	**35.8**	**51.6**	7.9	3.57		0.77	
TM269	3	46.5	**38.1**	**54.9**	8.4	0.86		0.88	
TM270	3	30.6	**25.1**	**36.1**	5.5	4.28		0.88	
						2.92	1.99	0.85	0.06
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM266	5	11.9	**6.5**	**17.3**	5.4	7.23		0.68	
TM267	5	19.2	**13.8**	**24.6**	5.4	6.04		0.74	
TM268	5	52.9	**43.4**	**62.4**	9.5	4.05		0.93	
TM269	5	49.2	**40.3**	**58.1**	8.9	4.02		0.93	
TM270	5	31.9	**26.2**	**37.6**	5.7	3.42		0.92	
					mean ±SD	4.95	1.61	0.88	0.09

continued on next page

Table 1 (cont.): 1-14 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									
TM266	5	22.0	**16.6**	**27.4**	5.4	3.27		1.26	
TM267	5	33.3	**27.3**	**39.3**	6.0	2.49		1.29	
TM268	5	74.5	**61.1**	**87.9**	13.4	4.13		1.31	
TM269	5	71.1	**58.3**	**83.9**	12.8	5.02		1.34	
TM270	5	46.1	**37.8**	**54.4**	8.3	6.92		1.33	
					mean ±SD	4.37	1.71	1.31	0.03

Sample ID	N	All Method Median		Median % CV
TM266	**110**	**17.5**		**5.59**
TM267	**111**	**25.8**		**4.91**
TM268	**110**	**56.8**		**4.69**
TM269	**112**	**53.1**		**4.79**
TM270	**112**	**34.6**		**4.82**
			Average	**4.96**
			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

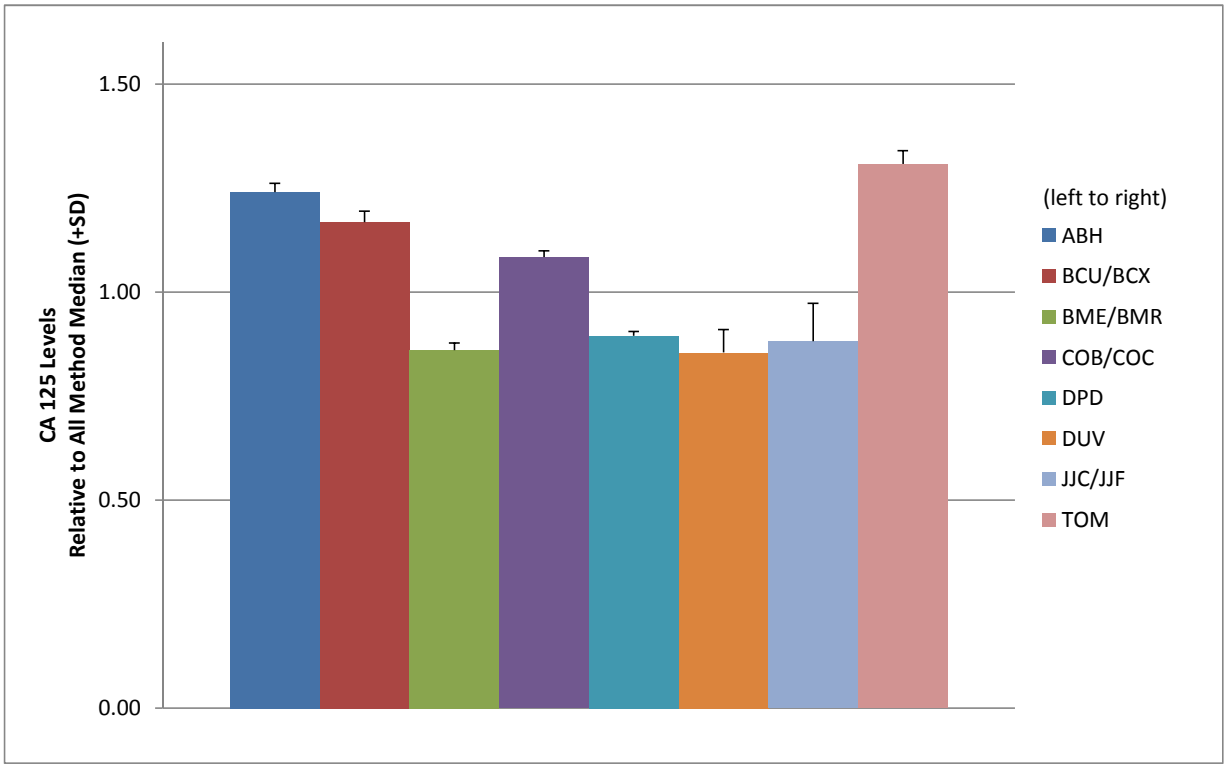


Table 2: 1-14 NYS Tumor Marker PT Summary for CA 19-9

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									
TM266	3	458.7	**376.1**	**541.3**	82.6	2.67		5.79	
TM267	3	80.1	**65.7**	**94.5**	14.4	1.99		4.98	
TM268	3	365.6	**299.8**	**431.4**	65.8	6.58		5.85	
TM269	3	136.2	**111.7**	**160.7**	24.5	4.74		4.53	
TM270	3	229.9	**188.5**	**271.3**	41.4	4.44		5.42	
					mean ±SD	4.08	1.82	5.31	0.56
Beckman Unicel & Access/2 BCU/BCX									
TM266	15	86.3	**70.8**	**101.8**	15.5	6.12		1.09	
TM267	15	16.1	**12.5**	**19.7**	3.6	5.90		1.00	
TM268	15	67.8	**55.6**	**80.0**	12.2	5.34		1.09	
TM269	15	29.2	**23.9**	**34.5**	5.3	5.55		0.97	
TM270	15	45.2	**37.1**	**53.3**	8.1	4.31		1.06	
					mean ±SD	5.44	0.70	1.04	0.05
Roche Elecsys & Cobas BME/BMR									
TM266	13	72.1	**59.1**	**85.1**	13.0	4.52		0.91	
TM267	13	16.1	**12.5**	**19.7**	3.6	4.91		1.00	
TM268	13	57.1	**46.8**	**67.4**	10.3	4.45		0.91	
TM269	13	28.6	**23.5**	**33.7**	5.1	3.64		0.95	
TM270	13	39.7	**32.6**	**46.8**	7.1	4.18		0.94	
					mean ±SD	4.34	0.47	0.94	0.04
Siemens Advia Centaur XP COB									
TM266	31	173.8	**142.5**	**205.1**	31.3	5.05		2.19	
TM267	31	31.0	**25.4**	**36.6**	5.6	6.65		1.93	
TM268	31	135.7	**111.3**	**160.1**	24.4	6.34		2.17	
TM269	31	53.0	**43.5**	**62.5**	9.5	6.43		1.76	
TM270	31	84.8	**69.5**	**100.1**	15.3	7.16		2.00	
					mean ±SD	6.32	0.78	2.01	0.18
Tosoh AIA TOM									
TM266	5	50.6	**41.5**	**59.7**	9.1	2.98		0.64	
TM267	5	14.2	**10.6**	**17.8**	3.6	4.44		0.88	
TM268	5	41.4	**33.9**	**48.9**	7.5	2.44		0.66	
TM269	5	30.9	**25.3**	**36.5**	5.6	5.34		1.03	
TM270	5	33.9	**27.8**	**40.0**	6.1	8.64		0.80	
					mean ±SD	4.77	2.45	0.80	0.16

continued on next page

Table 2 (cont.): 1-14 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM266	67	79.2	4.78
TM267	67	16.1	5.40
TM268	67	62.5	4.89
TM269	67	30.1	5.44
TM270	67	42.5	5.74
		Average*	5.25
		Allowable CV %	6.00
		Allowable Error if >/= 20 U/ml (+/-) %	18.0
		Allowable Error if < 20 U/ml (+/- U/ml)	3.6

*Abbott excluded

Figure 2: CA 19-9 Method Comparison

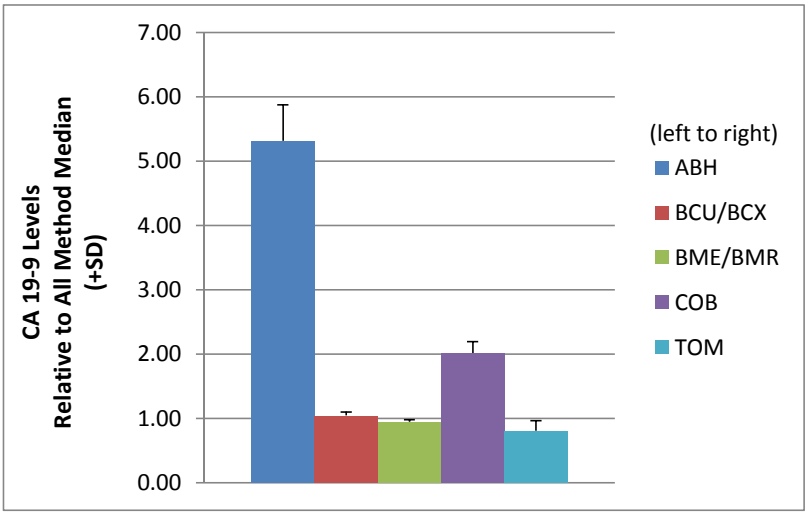


Table 3: 1-14 NYS Tumor Marker PT Summary for CA 15-3

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									
TM266	6	24.1	**19.8**	**28.4**	4.3	4.94		0.99	
TM267	6	23.7	**19.4**	**28.0**	4.3	5.44		0.97	
TM268	5	38.4	**31.5**	**45.3**	6.9	0.94		0.99	
TM269	6	97.7	**80.1**	**115.3**	17.6	7.88		1.03	
TM270	6	54.5	**44.7**	**64.3**	9.8	3.60		1.01	
					mean ±SD	4.56	2.93	1.00	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM266	7	16.7	**13.7**	**19.7**	3.0	5.75		0.69	
TM267	7	16.9	**13.9**	**19.9**	3.0	6.75		0.69	
TM268	7	26.6	**21.8**	**31.4**	4.8	7.52		0.69	
TM269	7	63.1	**51.7**	**74.5**	11.4	4.56		0.66	
TM270	7	36.1	**29.6**	**42.6**	6.5	5.10		0.67	
					mean ±SD	5.93	1.20	0.68	0.01
Roche Elecsys & Cobas BME/BMR									
TM266	14	23.9	**19.6**	**28.2**	4.3	5.36		0.98	
TM267	13	23.4	**19.2**	**27.6**	4.2	3.12		0.96	
TM268	13	37.5	**30.8**	**44.3**	6.8	2.83		0.97	
TM269	14	88.5	**72.6**	**104.4**	15.9	4.38		0.93	
TM270	14	51.6	**42.3**	**60.9**	9.3	5.08		0.95	
					mean ±SD	4.15	1.14	0.96	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM266	20	24.6	**20.2**	**29.0**	4.4	4.96		1.01	
TM267	19	25.0	**20.5**	**29.5**	4.5	4.48		1.03	
TM268	20	38.9	**31.9**	**45.9**	7.0	6.35		1.01	
TM269	20	92.3	**75.7**	**108.9**	16.6	6.32		0.97	
TM270	20	53.9	**44.2**	**63.6**	9.7	6.14		0.99	
					mean ±SD	5.65	0.87	1.00	0.02
Siemens Immulite 2000 DPD									
TM266	9	29.8	**24.4**	**35.2**	5.4	5.07		1.22	
TM267	9	29.5	**24.2**	**34.8**	5.3	8.20		1.21	
TM268	9	46.7	**38.3**	**55.1**	8.4	7.28		1.21	
TM269	9	113.8	**93.3**	**134.3**	20.5	6.04		1.20	
TM270	9	65.8	**54.0**	**77.6**	11.8	5.27		1.21	
					mean ±SD		1.30	1.21	0.01

continued on next page

Table 3 (cont.): 1-14 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM266	56	24.1	5.07
TM267	54	23.7	5.44
TM268	54	38.4	6.35
TM269	56	92.3	6.04
TM270	56	53.9	5.10
		Average	5.60
		Allowable CV %	6.00
		Allowable Error (+/-)%	18.0

Figure 3: CA 15-3 Method Comparison

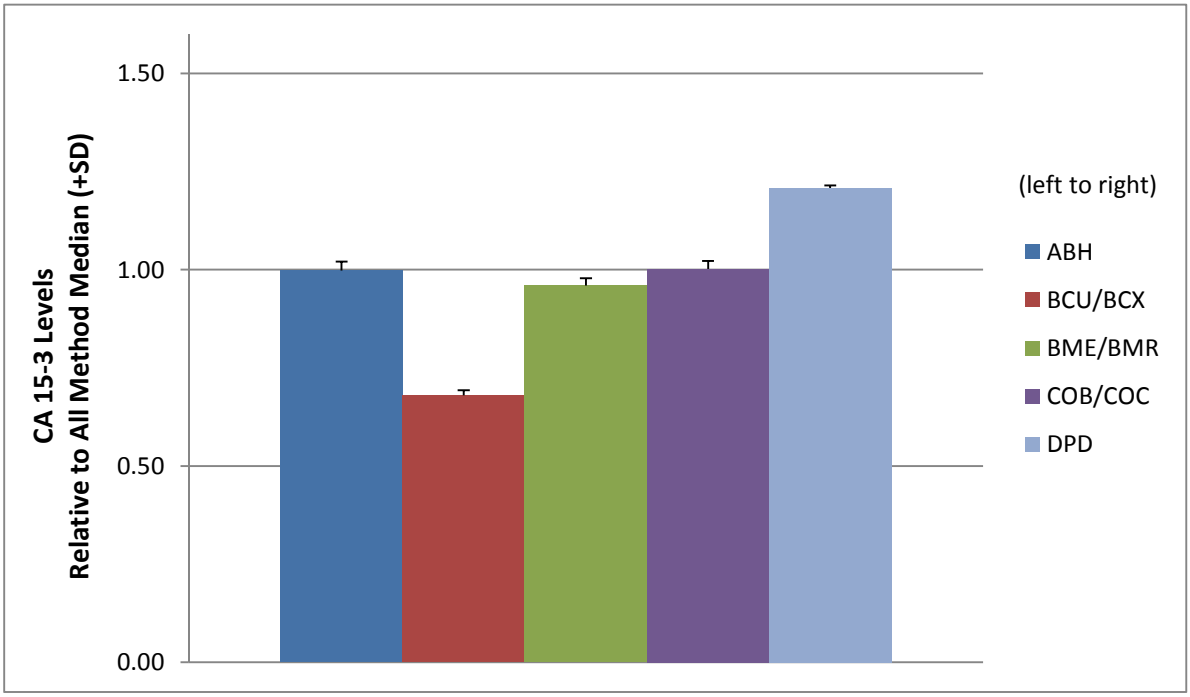


Table 4: 1-14 NYS Tumor Marker PT Summary for CA 27.29

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									
TM266	41	25.7	**18.4**	**33.1**	7.4	12.65		0.99	
TM267	40	25.5	**18.2**	**32.9**	7.4	12.24		1.01	
TM268	41	46.6	**36.8**	**56.4**	9.8	9.85		1.04	
TM269	41	124.7	**98.5**	**150.9**	26.2	6.05		1.09	
TM270	41	68.8	**54.4**	**83.2**	14.4	7.76		1.09	
					mean ±SD	9.71	2.84	1.04	0.04
Tosoh AIA TOM									
TM266	6	26.1	**18.8**	**33.5**	7.4	6.55		1.01	
TM267	6	25.0	**17.7**	**32.4**	7.4	8.52		0.99	
TM268	6	43.4	**34.3**	**52.5**	9.1	4.59		0.96	
TM269	6	103.6	**81.8**	**125.4**	21.8	5.78		0.91	
TM270	6	58.0	**45.8**	**70.2**	12.2	4.16		0.91	
					mean ±SD	5.92	1.74	0.96	0.04

Sample ID	N	All Method Median	Median % CV
TM266	**47**	**25.9**	**9.60**
TM267	**46**	**25.3**	**10.38**
TM268	**47**	**45.0**	**7.22**
TM269	**47**	**114.2**	**5.91**
TM270	**47**	**63.4**	**5.96**
		Average	**7.81**
		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

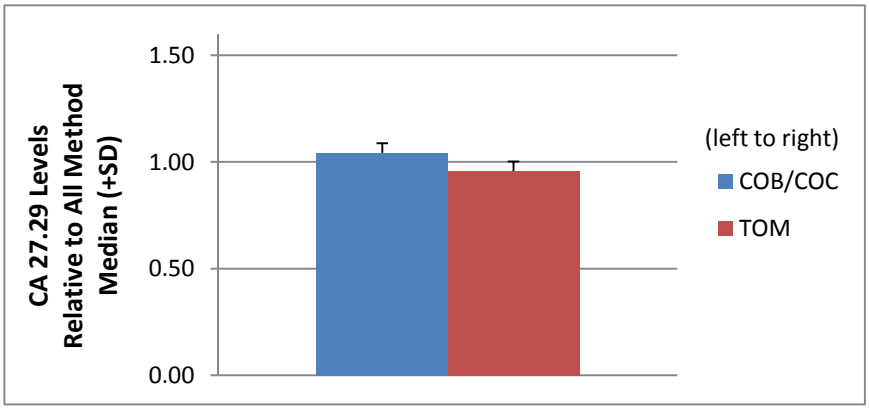


Table 5: 1-14 NYS Tumor Marker PT Summary for CEA

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									
TM266	15	38.3	**31.4**	**45.2**	6.9	4.20		1.02	
TM267	15	3.1	**2.2**	**4.0**	0.9	7.10		1.00	
TM268	15	8.2	**6.7**	**9.7**	1.5	5.37		0.99	
TM269	15	18.9	**15.5**	**22.3**	3.4	3.60		1.03	
TM270	15	10.4	**8.5**	**12.3**	1.9	3.85		1.02	
						4.82	1.44	1.01	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM266	26	35.6	**29.2**	**42.0**	6.4	7.81		0.95	
TM267	26	3.1	**2.2**	**4.0**	0.9	8.06		1.00	
TM268	26	8.3	**6.8**	**9.8**	1.5	6.75		1.01	
TM269	26	17.4	**14.3**	**20.5**	3.1	7.59		0.95	
TM270	26	10.0	**8.2**	**11.8**	1.8	7.60		0.98	
					mean ±SD	7.56	0.49	0.98	0.03
Roche Elecsys & Cobas BME/BMR									
TM266	22	29.9	**24.5**	**35.3**	5.4	4.05		0.80	
TM267	22	2.7	**1.8**	**3.6**	0.9	8.15		0.87	
TM268	22	7.1	**5.8**	**8.4**	1.3	5.35		0.86	
TM269	21	14.1	**11.6**	**16.6**	2.5	5.18		0.77	
TM270	21	8.3	**6.8**	**9.8**	1.5	5.54		0.81	
					mean ±SD	5.65	1.51	0.82	0.04
Siemens Advia Centaur XP & CP COB/COC									
TM266	49	36.8	**30.2**	**43.4**	6.6	6.49		0.98	
TM267	48	3.2	**2.3**	**4.1**	0.9	5.63		1.03	
TM268	49	7.7	**6.3**	**9.1**	1.4	4.94		0.93	
TM269	49	17.9	**14.7**	**21.1**	3.2	5.64		0.97	
TM270	49	10.0	**8.2**	**11.8**	1.8	5.40		0.98	
					mean ±SD	5.62	0.57	0.98	0.04
Siemens Immulite 2000 DPD									
TM266	14	45.1	**37.0**	**53.2**	8.1	7.32		1.20	
TM267	14	3.2	**2.3**	**4.1**	0.9	6.88		1.03	
TM268	14	8.5	**7.0**	**10.0**	1.5	5.47		1.04	
TM269	14	21.4	**17.5**	**25.3**	3.9	7.12		1.17	
TM270	14	11.1	**9.1**	**13.1**	2.0	5.32		1.09	
						6.42	0.95	1.11	0.08
Siemens Dimension Vista DUV									
TM266	24	36.1	**29.6**	**42.6**	6.5	3.46		0.96	
TM267	24	3.0	**2.1**	**3.9**	0.9	4.67		0.97	
TM268	24	8.0	**6.6**	**9.4**	1.4	3.63		0.97	
TM269	24	17.0	**13.9**	**20.1**	3.1	3.82		0.92	
TM270	24	9.7	**8.0**	**11.4**	1.7	3.81		0.95	
					mean ±SD	3.88	0.47	0.95	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM266	12	41.7	**34.2**	**49.2**	7.5	3.67		1.11	
TM267	11	1.8	**0.9**	**2.7**	0.9	20.00		0.58	
TM268	12	10.4	**8.5**	**12.3**	1.9	7.69		1.26	
TM269	12	20.8	**17.1**	**24.5**	3.7	3.13		1.13	
TM270	12	12.4	**10.2**	**14.6**	2.2	5.81		1.22	
					mean ±SD	8.06	6.92	1.06	0.27

continued on next page

Table 5 (cont.): 1-14 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									
TM266	6	51.8	**42.5**	**61.1**	9.3	1.49		1.38	
TM267	6	4.9	**4.0**	**5.8**	0.9	3.67		1.58	
TM268	6	11.0	**9.0**	**13.0**	2.0	2.09		1.33	
TM269	6	27.3	**22.4**	**32.2**	4.9	2.01		1.48	
TM270	6	14.8	**12.1**	**17.5**	2.7	3.18		1.45	
					mean ±SD	2.49	0.90	1.45	0.10

Sample ID	N	All Method Median		Median % CV
TM266	**169**	**37.6**		**4.13**
TM267	**167**	**3.1**		**6.99**
TM268	**169**	**8.3**		**5.36**
TM269	**168**	**18.4**		**4.50**
TM270	**168**	**10.2**		**5.27**
			Average	**5.25**
			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

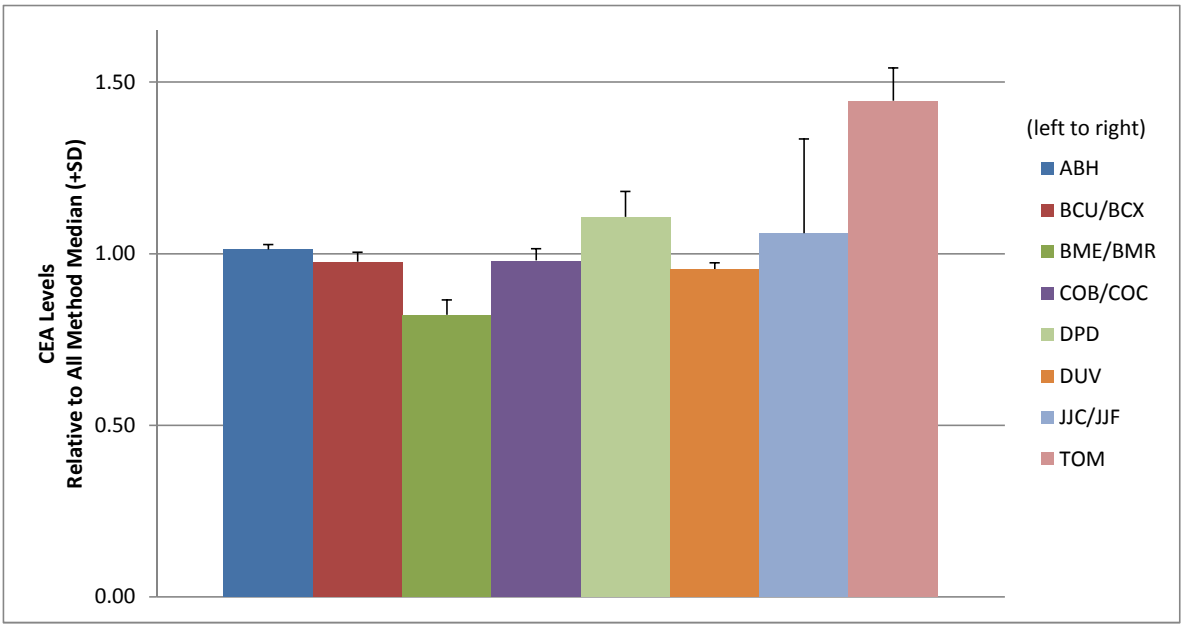


Table 6: 1-14 NYS Tumor Marker PT Summary for AFP

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											
TM266	3	5.6	**4.6**	**6.6**	1.0	8.39		0.93		1.10	
TM267	3	16.6	**13.6**	**19.6**	3.0	2.95		0.99		1.07	
TM268	3	10.7	**8.8**	**12.6**	1.9	4.21		0.97		1.14	
TM269	3	21.4	**17.5**	**25.3**	3.9	4.72		1.01		1.14	
TM270	3	27.7	**22.7**	**32.7**	5.0	3.10		1.05		1.16	
					mean ±SD	4.67	2.21	0.99	0.04	1.12	0.04
Beckman Unicel & Access/2 BCU/BCX											
TM266	20	6.1	**5.0**	**7.2**	1.1	8.36		1.02		1.20	
TM267	20	16.9	**13.9**	**19.9**	3.0	6.39		1.01		1.08	
TM268	20	11.2	**9.2**	**13.2**	2.0	7.59		1.02		1.19	
TM269	20	21.4	**17.5**	**25.3**	3.9	6.64		1.01		1.14	
TM270	20	27.6	**22.6**	**32.6**	5.0	7.86		1.04		1.15	
					mean ±SD	7.37	0.83	1.02	0.01	1.15	0.05
Roche Elecsys & Cobas BME/BMR											
TM266	18	7.3	**6.0**	**8.6**	1.3	7.26		1.22		1.43	
TM267	17	20.0	**16.4**	**23.6**	3.6	6.00		1.20		1.28	
TM268	18	13.0	**10.7**	**15.3**	2.3	6.85		1.18		1.38	
TM269	18	25.4	**20.8**	**30.0**	4.6	6.97		1.20		1.36	
TM270	18	32.3	**26.5**	**38.1**	5.8	6.44		1.22		1.35	
					mean ±SD	6.70	0.49	1.20	0.02	1.36	0.05
Siemens Advia Centaur XP & CP COB/COC											
TM266	27	6.6	**5.4**	**7.8**	1.2	8.33		1.10		1.30	
TM267	27	17.6	**14.4**	**20.8**	3.2	5.40		1.05		1.13	
TM268	27	11.1	**9.1**	**13.1**	2.0	7.57		1.01		1.18	
TM269	27	20.6	**16.9**	**24.3**	3.7	4.95		0.97		1.10	
TM270	27	26.4	**21.6**	**31.2**	4.8	6.17		1.00		1.10	
					mean ±SD	6.48	1.43	1.03	0.05	1.16	0.08
Siemens Immulite 2000 DPD											
TM266	16	5.9	**4.8**	**7.0**	1.1	6.44		0.98		1.16	
TM267	16	16.8	**13.8**	**19.8**	3.0	6.61		1.01		1.08	
TM268	16	10.9	**8.9**	**12.9**	2.0	4.77		0.99		1.16	
TM269	16	21.4	**17.5**	**25.3**	3.9	4.63		1.01		1.14	
TM270	16	26.6	**21.8**	**31.4**	4.8	5.34		1.00		1.11	
					mean±SD	5.34	0.92	1.00	0.01	1.13	0.03
Siemens Dimension Vista DUV											
TM266	7	5.9	**4.8**	**7.0**	1.1	2.88		0.98		1.16	
TM267	7	16.2	**13.3**	**19.1**	2.9	2.72		0.97		1.04	
TM268	7	10.9	**8.9**	**12.9**	2.0	2.39		0.99		1.16	
TM269	7	21.0	**17.2**	**24.8**	3.8	2.14		0.99		1.12	
TM270	7	26.4	**21.6**	**31.2**	4.8	2.39		1.00		1.10	
					mean ±SD	2.50	0.29	0.99	0.01	1.12	0.05
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM266	6	5.0	**4.1**	**5.9**	0.9	6.60		0.83		0.98	
TM267	6	13.4	**11.0**	**15.8**	2.4	4.48		0.80		0.86	
TM268	6	9.0	**7.4**	**10.6**	1.6	5.33		0.82		0.96	
TM269	6	16.9	**13.9**	**19.9**	3.0	3.91		0.80		0.90	
TM270	6	21.7	**17.8**	**25.6**	3.9	5.67		0.82		0.91	
					mean ±SD	5.20	1.05	0.81	0.01	0.92	0.05

continued on next page

Table 6 (cont.): 1-14 NYS Tumor Marker PT Summary for AFP

Tosoh AIA TOM											
TM266	3	6.1	**5.0**	**7.2**	1.1	2.46		1.02		1.20	
TM267	3	16.4	**13.4**	**19.4**	3.0	0.37		0.98		1.05	
TM268	3	11.4	**9.3**	**13.5**	2.1	1.49		1.04		1.21	
TM269	3	21.1	**17.3**	**24.9**	3.8	1.09		0.99		1.13	
TM270	3	26.4	**21.6**	**31.2**	4.8	3.07		1.00		1.10	
					mean ±SD	1.69	1.08	1.00	0.02	1.14	0.07

Sample ID	N	All Method Median	IS based Target	SD		Median % CV			All Method Median/ IS Target	
TM266	**100**	**6.0**	**5.1**	**0.36**		**6.93**			**1.18**	
TM267	**99**	**16.7**	**15.6**	**1.08**		**4.94**			**1.07**	
TM268	**100**	**11.0**	**9.4**	**0.45**		**5.05**			**1.17**	
TM269	**100**	**21.3**	**18.7**	**1.19**		**4.67**			**1.14**	
TM270	**100**	**26.5**	**23.9**	**0.95**		**5.50**			**1.11**	
					Average	**5.42**		mean ±SD	**1.13**	0.04
					Allowable CV %	**6.0**				
					Allowable Error (+/-)%	**18.0**				

Figure 6: AFP Method Comparison

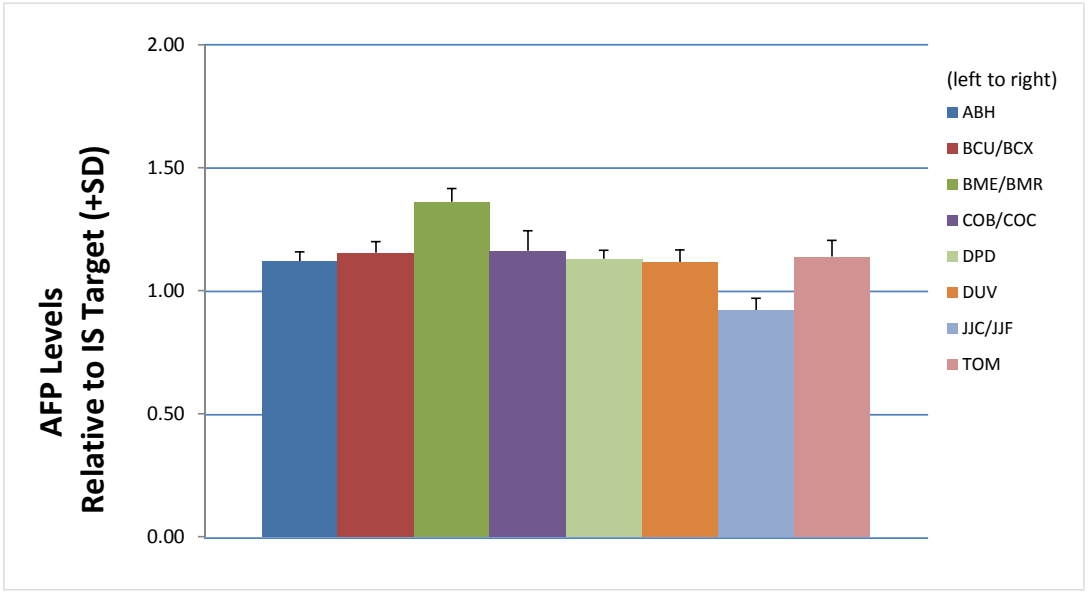


Table 7: 1-14 NYS Tumor Marker PT Summary for PSA

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											
TM266	15	2.0	**1.6**	**2.4**	0.4	4.00		1.00		1.18	
TM267	16	4.1	**3.4**	**4.8**	0.7	4.39		1.05		1.21	
TM268	16	10.3	**8.4**	**12.2**	1.9	3.69		1.06		1.20	
TM269	16	8.1	**6.6**	**9.6**	1.5	5.19		1.05		1.19	
TM270	16	19.8	**16.2**	**23.4**	3.6	4.65		1.05		1.15	
					mean ±SD	4.38	0.58	1.04	0.02	1.18	0.02
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM266	49	2.2	**1.8**	**2.6**	0.4	5.91		1.10		1.29	
TM267	49	4.4	**3.6**	**5.2**	0.8	5.91		1.13		1.29	
TM268	49	11.1	**9.1**	**13.1**	2.0	4.68		1.14		1.29	
TM269	49	8.9	**7.3**	**10.5**	1.6	5.06		1.16		1.31	
TM270	49	22.1	**18.1**	**26.1**	4.0	5.11		1.18		1.28	
					mean ±SD	5.33	0.55	1.14	0.03	1.29	0.01
Roche Elecsys & Cobas BME/BMR											
TM266	42	2.0	**1.6**	**2.4**	0.4	5.00		1.00		1.18	
TM267	42	3.9	**3.2**	**4.6**	0.7	5.38		1.00		1.15	
TM268	39	9.7	**8.0**	**11.4**	1.7	3.71		1.00		1.13	
TM269	38	7.7	**6.3**	**9.1**	1.4	3.51		1.00		1.13	
TM270	40	18.8	**15.4**	**22.2**	3.4	4.26		1.00		1.09	
					mean ±SD	4.37	0.81	1.00	0.00	1.14	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM266	60	1.9	**1.6**	**2.2**	0.3	5.26		0.95		1.12	
TM267	59	3.8	**3.1**	**4.5**	0.7	4.47		0.97		1.12	
TM268	59	9.3	**7.6**	**11.0**	1.7	4.95		0.96		1.08	
TM269	60	7.5	**6.2**	**8.9**	1.4	5.33		0.97		1.10	
TM270	60	18.3	**15.0**	**21.6**	3.3	5.25		0.97		1.06	
					mean ±SD	5.05	0.36	0.97	0.01	1.10	0.02
Siemens Immulite 2000 - Original Pack DPD (DP5)											
TM266	18	1.7	**1.4**	**2.0**	0.3	5.88		0.85		1.00	
TM267	18	3.5	**2.9**	**4.1**	0.6	3.71		0.90		1.03	
TM268	18	8.5	**7.0**	**10.0**	1.5	7.06		0.88		0.99	
TM269	18	6.8	**5.6**	**8.0**	1.2	6.76		0.88		1.00	
TM270	18	16.6	**13.6**	**19.6**	3.0	5.84		0.88		0.97	
					mean ±SD	5.85	1.31	0.88	0.02	1.00	0.02
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM266	13	2.3	**1.9**	**2.7**	0.4	5.65		1.15		1.35	
TM267	13	4.4	**3.6**	**5.2**	0.8	5.23		1.13		1.29	
TM268	13	11.1	**9.1**	**13.1**	2.0	4.68		1.14		1.29	
TM269	13	8.8	**7.2**	**10.4**	1.6	4.20		1.14		1.29	
TM270	13	22.2	**18.2**	**26.2**	4.0	5.23		1.18		1.29	
					mean±SD	5.00	0.56	1.15	0.02	1.30	0.03
Siemens Dimension Vista DUV											
TM266	17	2.1	**1.7**	**2.5**	0.4	0.00		1.05		1.24	
TM267	21	4.2	**3.4**	**5.0**	0.8	1.90		1.08		1.24	
TM268	21	10.4	**8.5**	**12.3**	1.9	2.40		1.07		1.21	
TM269	21	8.2	**6.7**	**9.7**	1.5	2.44		1.06		1.21	
TM270	21	20.4	**16.7**	**24.1**	3.7	1.96		1.09		1.19	
					mean ±SD	1.74	1.00	1.07	0.01	1.21	0.02

continued on next page

Table 7 (cont.): 1-14 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											
TM266	22	1.5	**1.2**	**1.8**	0.3	8.67		0.75		0.88	
TM267	22	3.0	**2.5**	**3.5**	0.5	6.33		0.77		0.88	
TM268	22	7.4	**6.1**	**8.7**	1.3	5.41		0.76		0.86	
TM269	22	5.9	**4.8**	**7.0**	1.1	5.59		0.77		0.87	
TM270	22	14.6	**12.0**	**17.2**	2.6	4.86		0.78		0.85	
					mean ±SD	6.17	1.49	0.76	0.01	0.87	0.01
Tosoh AIA TOM											
TM266	7	1.9	**1.6**	**2.2**	0.3	6.84		0.95		1.12	
TM267	7	3.8	**3.1**	**4.5**	0.7	6.32		0.97		1.12	
TM268	7	9.3	**7.6**	**11.0**	1.7	5.48		0.96		1.08	
TM269	7	7.4	**6.1**	**8.7**	1.3	5.95		0.96		1.09	
TM270	7	17.9	**14.7**	**21.1**	3.2	4.75		0.95		1.04	
					mean ±SD	5.87	0.80	0.96	0.01	1.09	0.03

Sample ID	N	All Method Median	IS based Target	SD		Median % CV			All Method Median/ IS Target	
TM266	**243**	**2.0**	**1.7**	**0.07**		**5.65**			**1.18**	
TM267	**247**	**3.9**	**3.4**	**0.17**		**5.23**			**1.15**	
TM268	**244**	**9.7**	**8.6**	**0.28**		**4.68**			**1.13**	
TM269	**244**	**7.7**	**6.8**	**0.34**		**5.19**			**1.13**	
TM270	**246**	**18.8**	**17.2**	**0.58**		**4.86**			**1.09**	
					Average	**5.12**		mean ±SD	**1.14**	0.03
					Allowable CV %	**6.0**				
					Allowable Error (+/-)%	**18.0**				

Figure 7: PSA Method Comparison

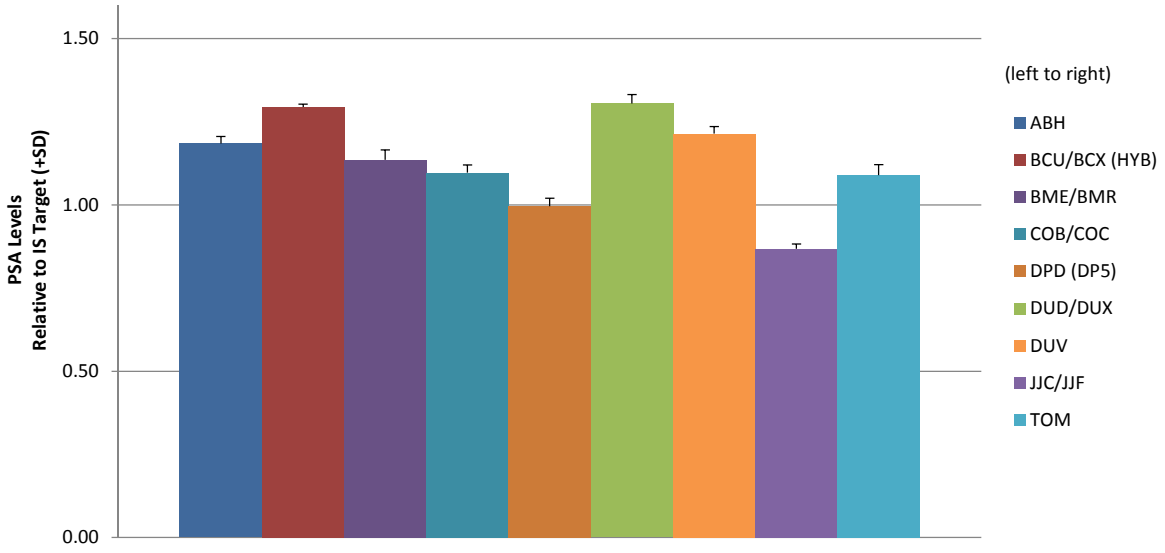


Table 8: 1-14 NYS Tumor Marker PT Summary for Free PSA

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	
Abbott Architect ABH											
TM266	5	0.17	**0.08**	**0.26**	0.09	5.88		1.00		0.97	
TM267	5	0.35	**0.26**	**0.44**	0.09	8.57		1.06		0.98	
TM268	5	0.86	**0.71**	**1.01**	0.15	4.65		1.08		0.97	
TM269	5	0.67	**0.55**	**0.79**	0.12	4.48		1.08		0.98	
TM270	5	1.70	**1.39**	**2.01**	0.31	4.71		1.10		0.99	
						5.66	1.72	1.06	0.04	0.98	0.01
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM266	26	0.22	**0.13**	**0.31**	0.09	9.09		1.29		1.25	
TM267	26	0.46	**0.37**	**0.55**	0.09	6.52		1.39		1.28	
TM268	26	1.07	**0.88**	**1.26**	0.19	4.67		1.34		1.21	
TM269	26	0.85	**0.70**	**1.00**	0.15	5.88		1.37		1.24	
TM270	26	2.06	**1.69**	**2.43**	0.37	4.85		1.34		1.20	
					mean ±SD	6.20	1.78	1.35	0.04	1.24	0.03
Roche Elecsys & Cobas BME/BMR											
TM266	22	0.17	**0.08**	**0.26**	0.09	5.88		1.00		0.97	
TM267	26	0.33	**0.24**	**0.42**	0.09	6.06		1.00		0.92	
TM268	25	0.80	**0.66**	**0.94**	0.14	2.50		1.00		0.90	
TM269	26	0.62	**0.51**	**0.73**	0.11	3.23		1.00		0.90	
TM270	26	1.54	**1.26**	**1.82**	0.28	3.25		1.00		0.89	
					mean ±SD	4.18	1.66	1.00	0.00	0.92	0.03
Siemens Immulite 2000 DPD											
TM266	15	0.16	**0.07**	**0.25**	0.09	6.25		0.94		0.91	
TM267	15	0.31	**0.22**	**0.40**	0.09	6.45		0.94		0.86	
TM268	15	0.75	**0.62**	**0.89**	0.14	8.00		0.94		0.85	
TM269	15	0.58	**0.48**	**0.68**	0.10	5.17		0.94		0.84	
TM270	15	1.47	**1.21**	**1.73**	0.26	6.80		0.95		0.85	
					mean ±SD	6.54	1.02	0.94	0.01	0.86	0.03
Siemens Dimension Vista DUV											
TM266	7	0.15	**0.06**	**0.24**	0.09	0.00		0.88		0.85	
TM267	9	0.30	**0.21**	**0.39**	0.09	0.00		0.91		0.84	
TM268	9	0.73	**0.60**	**0.86**	0.13	4.11		0.91		0.82	
TM269	8	0.57	**0.47**	**0.67**	0.10	1.75		0.92		0.83	
TM270	8	1.43	**1.17**	**1.69**	0.26	2.80		0.93		0.83	
					mean ±SD	1.73	1.79	0.91	0.02	0.84	0.01

continued on next page

Table 8 (cont.): 1-14 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
TM266	75	0.17	0.18	0.01	5.88	0.97
TM267	81	0.33	0.36	0.01	6.45	0.92
TM268	80	0.80	0.88	0.05	4.65	0.90
TM269	80	0.62	0.69	0.03	4.48	0.90
TM270	80	1.54	1.72	0.12	4.71	0.89
				Average	5.23	mean ±SD 0.92 0.03
				Allowable CV %	6.0	
				Allowable Error if >/= 0.5 ng/ml (+/-)%	18.0	
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	0.09	

Figure 8: Free PSA Method Comparison

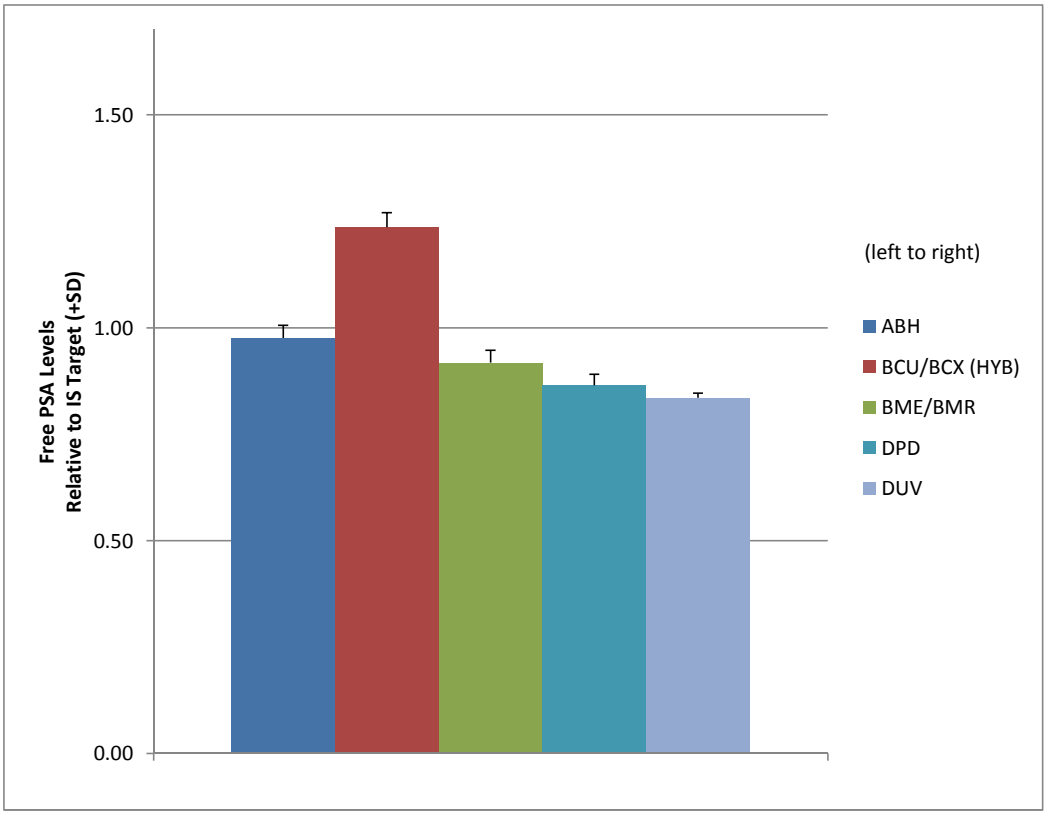


Table 9: 1-14 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM266	11	1.7	**1.4**	**2.1**	0.4	4.02		1.00	
TM267	11	3.4	**2.8**	**4.1**	0.7	4.65		1.00	
TM268	11	8.7	**7.1**	**10.2**	1.6	3.46		1.00	
TM269	11	7.0	**5.7**	**8.2**	1.3	4.03		1.00	
TM270	11	17.0	**13.9**	**20.1**	3.1	3.24		1.00	
					mean ±SD	3.88	0.56	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM266	**11**	**1.7**		**4.02**
TM267	**11**	**3.4**		**4.65**
TM268	**11**	**8.7**		**3.46**
TM269	**11**	**7.0**		**4.03**
TM270	**11**	**17.0**		**3.24**
			Average	**3.88**
			Allowable CV %	**6.0**
			Allowable Error (+/-)%	**18.0**

NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

January 28, 2014

IMPORTANT INSTRUCTIONS—PLEASE READ

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: **February 12, 2014**

Samples:
Enclosed are five sealed (5) vials labeled **TM266 to TM270**, 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. If your lab measures total PSA by a **second method** in conjunction with free PSA, you will receive TWO sets of samples, which must be accessioned and tested separately and reported without inter-method comparison. You may enter those results in the corresponding fields of PSA for a 2nd method on the EPTRS entry webpage.

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 result** measurement

that would be **considered NORMAL** as reported back to a physician. Please enter this value with the same precision as you report your results for that analyte.

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

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

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

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

Results must be submitted electronically before 11:59 PM on February 12, 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 2014 Oncology Tumor Marker Proficiency Test schedule is:

Mail-out date:	Due date:
January 28, 2014	**February 12, 2014**
May 6, 2014	**May 21, 2014**
September 9, 2014	**September 24, 2014**

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

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

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

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						
		TM266	**TM267**	**TM268**	**TM269**	**TM270**
AFP (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 125 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 15-3 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 19-9 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 27.29 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CEA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) **for a 2nd method used in conjunction with free PSA (ng/mL)** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Free PSA (ng/ml) **If test offered, measure and report for all samples** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Complexed PSA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					

WORKSHEET

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

REFRIGERATE SAMPLES UPON ARRIVAL

DO NOT FREEZE

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

SEE INSTRUCTIONS FOR MORE INFORMATION.

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

WORKSHEET