NEW YORK STATE OF OPPORTUNITY. Department of Health

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SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

May 5, 2015

DO NOT FREEZE SAMPLES

REFRIGERATE UPON ARRIVAL

To: Laboratory Director

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

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

Due Date: **May 20, 2015**

Samples:
Enclosed are five sealed (5) vials labeled **TM286 to TM290**, each containing proficiency test specimens in a serum based matrix, sterile filtered and dispensed. All materials used to prepare the samples were tested and found to be negative for HBV, HCV and HIV, but universal precautions should be followed when handling samples. Keep refrigerated until use, but do not freeze. Make sure samples are completely mixed before analyzing.

If the proficiency samples are received in a condition unsatisfactory for testing, or are stored incorrectly in your lab, you may request a replacement set before May 13th, 2015. Please contact Susanne McHale at (518) 486-5775 or Helen Ling at (518) 474-0036.

Each vial contains various predetermined amounts of alpha-feto protein (AFP), carcinoembryonic antigen (CEA), cancer antigen 125 (CA125), the breast cancer markers CA15-3 and CA27.29, the GI cancer marker CA19-9 and prostate specific antigen (PSA) as total PSA, free PSA and complexed PSA (PSA-ACT). Please measure all markers tested in your laboratory. If your lab measures free and/or complexed PSA measure it in **ALL** of the samples. We can no longer accept results from a second method for any analyte.

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),** which is a secure website requiring users to obtain an ID in order to access the application. To begin, log into the Health Commerce System (HCS) home page: https://commerce.health.state.ny.us. Click on EPTRS under "My Applications"; click on Online Reporting. This will bring you to the "Select Event" page.

Contact the Clinical Laboratory Evaluation Program via clepeptrs@health.state.ny.us or (518) 486-5410 or (518) 485-5378 if you are unable to access the website or you do not see the "Submit/Attest" button on the Summary Page. Failure to submit test results will result in a score of zero.

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

It is also recommended that you enter your results before 4 pm EST on the due date. **Although results can be received into the Health Commerce System until 11:59 PM EST on May 20, 2015, help may not be available after 4 PM EST** should you encounter technical problems. Results not submitted are categorized as missing, leading to an administrative **failure** and a failing grade, even if they were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must contact the PT section by phone (518) 486-5775 or email (susanne.mchale@health.ny.gov) as soon as possible but **no later than 4 PM EST on the due date** to see if this can be arranged.

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

The **Event Menu** page also includes a space to enter your lab's upper limit of normal reference range, i.e. cut-off value, for each individual analyte measured. It should indicate the **highest analyte value** that would be **considered NORMAL** as reported back to a physician. Please enter this value with the same precision as you report your results for that analyte. **We are also asking for the Reagents and Calibrators lot numbers used when testing the PT samples. Please enter these under the Instrument and Reagent Names.**

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

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

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

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

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

The remaining 2015 Oncology Tumor Marker Proficiency Test schedule is posted at:
http://www.wadsworth.org/labcert/clep/PT/ptindex.html

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

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

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June 5, 2015

New York State Soluble Tumor Markers Proficiency Test 5-2015 [1]

Dear Laboratory Director,

This is a summary and critique of the New York State Proficiency Test from May 2015 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

Laboratories were challenged with five (5) different coded specimens prepared by Wadsworth Center personnel. Purified analyte preparations were added in varying concentrations to a serum-based matrix, then sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

Your laboratory's individual results, score(s), previous two PT event scores and overall performance status are on a separate report securely posted on the Department's Health Commerce System site under EPTRS (Electronic Proficiency Test Reporting System). To access the results for your laboratory, please log in to the Electronic Proficiency Test Reporting System homepage at:

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

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

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

Scroll down or filter by year under "Submitted/Closed Events" to find the correct survey and click on **Evaluation** in the Scored column.

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

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

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

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

[1] The use of brand and/or trade names in this report does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health.

Please **review, print and sign** your score report within two weeks of notification of release and keep it in your files. You will need it for your next laboratory survey to demonstrate successful participation in the NYS PT program.

For grading purposes, all results were evaluated based on their respective peer group mean. This mean was determined with the robust regression followed by outlier identification (ROUT) statistical method, as implemented in GraphPad's Prism®6 software (Harvey J Motulsky and Ronald E Brown, "Detecting outliers when fitting data with nonlinear regression – a new method based on robust nonlinear regression and the false discovery rate," BMC Bioinformatics 7:123 (2006). Available at: http://www.biomedcentral.com/1471-2105/7/123). This method identifies outliers through robust statistical analysis with a nonlinear curve fit of the data, thus removing points that can skew calculations of the mean. For our purposes, the target is the mean determined from the best fit values derived from that analysis while the standard deviation (SD) was calculated by multiplying the standard error of the mean for each individual peer group with the square root of the number of labs in that peer group. Except for AFP, the allowable error and range were determined from the average of the median %CV's for each sample across all methods (see summary tables); allowances for increased scatter at low concentrations were made for some analytes. For AFP only, the allowable error and range were +/- 3SD from your peer group mean. Please note that, unless indicated otherwise, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, except where the linear regression line between the results from two instruments showed a significant ($p<0.01$) deviation from identity.

To help you compare your results to those of your peer group, we have calculated a D/Dmax value and displayed it on your individual report card next to the range for each sample. D/Dmax is a measure of how much your result (x) deviates from your peer group target, **D/Dmax=(x-target)/(maximum allowable error)**, with D being the difference of your result from the target, and Dmax being the **maximal allowable error for your peer group.** In general, an acceptable result has a D/Dmax between –1 and +1. Occasionally, however, due to rounding effects, there may be a small discrepancy between the D/Dmax value and the actual scoring, in which case the actual scoring takes precedence. The closer D/Dmax is to zero, the closer your result was to the target. A negative D/Dmax means that your result was below, and a positive value means your result was above the target. No entry in this place means that your result either had a qualifier (< or >) or was not gradable, in which case there will be an NG in the grade column. **Note: If your D/Dmax is not within +/- 0.66 (approximately +/-2 SD), especially for more than one or two samples, you should carefully check your result(s) since this indicates that they are significantly different from the mean(s) of your peer group.** While this could be an isolated incident, it could also potentially indicate that your assay may not be performing as it should. Furthermore, if your **average D/Dmax is greater than +0.5 or smaller than -0.5,** then your results exhibited a substantial high or low bias compared to the rest of your peer group, suggesting a potentially significant systematic error with your assay. Possible causes could include a calibration drift, reagents that are close to their expiration date, or subtle malfunction of your instrument. We strongly encourage you to take a close look at the run in question as well as others performed around that time and/or with the same reagent lots, and to evaluate if patient results might have been similarly affected.

For all analytes, summary tables give the targets and acceptable ranges for each sample and peer group (if N >2). We also present graphical comparisons of the results among the different peer groups. In order to compare results between peer groups more easily, average normalized values were calculated for each sample by dividing the individual peer group mean by the median of the means from all peer groups (all method median). The all method medians are used instead of the all lab means to reduce the bias towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, we calculated these values relative to the assigned target values (see below) as well as the all method median. Keep in mind when comparing methods that in some of the peer groups the number of results (N) was small. However, the fact that the relative performance for almost all methods has been very constant over the last several years indicates that the results shown reflect the true behavior of each method compared to its peers, at least under the conditions of the NYS Sera and Soluble Tumor Markers Proficiency Test.

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 118 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 86% of the labs. The peer group means ranged from 35% below to 34% above the all method median, with Ortho Clinical Diagnostics being the lowest and Tosoh being the highest. Forty-two percent of labs were in the two peer groups that fell at or within +/-10% of the all method median. Overall the different methods used to measure CA125 are not well harmonized, and the reference range cut-off value of 35 U/ml may not apply across the board. Indeed, different laboratories reported different reference ranges, suggesting that individual laboratories determine their own reference ranges based on their own patient populations. Consequently, baseline levels for serial measurements should be redetermined if there is a change in the method or instrument used.

CA19-9 (Table 2, Figure 2): Results were reported by 77 labs using instruments from seven different manufacturers, five with N >2 for peer group grading. Forty-three percent of all reporting labs used Siemens ADVIA Centaur XP, 23% used either Beckman's Unicel or Access/2, 17% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, 8% used the Tosoh ST-AIA method and 4% used Siemens Dimension Vista. For illustrative purposes, Abbott was included on Table 2 and Figure 2, but values were not used for calculation of the all method median because the Abbott Architect method results averaged 4.9 times higher than the all method median. Excluding Abbott, only Siemens ADVIA Centaur XP was more than 15% different from the median (+89%), suggesting that there is at least some harmonization between manufacturers.

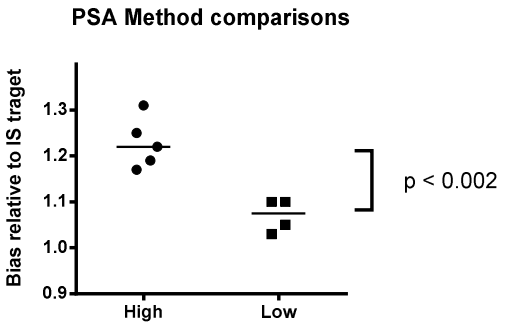
The MUC1 breast cancer antigen was measured by 110 labs, with slightly more than half (56%) using an instrument from one of six manufacturers (five with N>2) to measure **CA15-3** (Table 3, Figure 3) and the remainder using an instrument from one of two manufacturers to measure **CA27.29** (Table 4, Figure 4). While four of the six methods for CA15-3 were within +/-5% of the all method median, the Beckman Unicel/Access results still exhibited a notable negative bias, averaging -36% from the all method medians, whereas Siemens Immulite was 16% above the median. **CA27.29** measurements showed a 24% difference between the ADVIA Centaur XP/CP and the Tosoh methods which is more discordant than in past PT

events, and the median CA27.29 measurements averaged 7% higher than the median CA15-3 measurements in this event. Siemens Immulite 2000 for CA15-3 and Siemens ADVIA Centaur XP/CP for CA27.29 showed larger inter-laboratory variation than other methods as shown by their higher %CV values averaging 12.74% and 8.68% respectively.

CEA (Table 5, Figure 5): Results were reported by 166 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 7 to 48 labs. Results from the Abbott Architect, Beckman Unicel/Access/2, Roche Elecsys & Cobas, Siemens ADVIA Centaur and Siemens Dimension Vista which altogether accounted for 83% of the labs, were within +/-15% of the medians. In contrast, results from the Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 instruments were 31% below the median, whereas Tosoh AIA exhibited a high positive bias averaging 69% 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 means. For the purpose of method comparison, the tables show the method bias against both the all method medians and the assigned target values, but the graphs show the performance relative only to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 103 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to 20% of the total number of labs. Six of the eight methods, used by 90% of the labs, gave results within +/-10% of the all method median, but averaged 12% higher than the assigned targets. Of the remaining two methods, Tosoh measured 13% higher than the all method median, and 25% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants) was the only method with a bias below the assigned target at -8%, and was the lowest overall method with a bias of 17% below the all method median. Most methods somewhat overestimated AFP levels in our samples, but the overall difference in measurements between most methods is less than 15%, which is a result similar to what has been observed in previous NYS PT events.



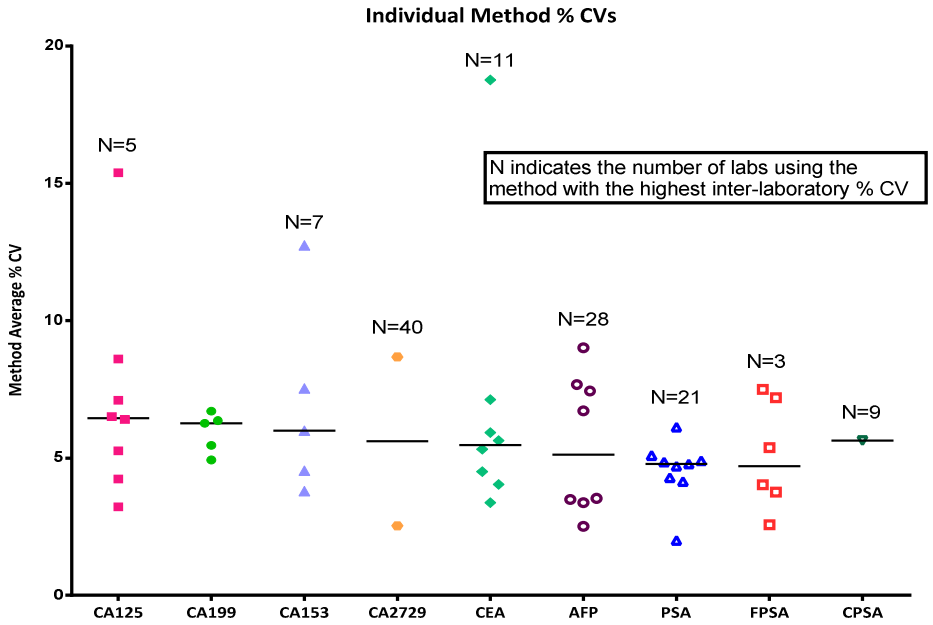
PSA (Table 7, Figure 7): Results were reported by 251 labs using instruments from nine manufacturers. There was a clear separation into a high and low group that were statistically significantly different ($p < 0.002$). The low group contained Roche, Siemens ADVIA Centaur, Siemens Immulite, and Ortho Clinical, whereas the high group contained Abbott, Beckman, Siemens Dimension (RxL Max Xpand Plus, EXL), Siemens Dimension Vista, and Tosoh. Results from the low group were 7% (95% CI, 1.3-12.7%) above the target, and those from the high group were 22.8% (95% CI, 16.0-29.6%) above the target. These results suggest that there is still a difference in how the different methods are calibrated.

Free PSA (Table 8, Figure 8): Results were reported by 89 labs using instruments from seven manufacturers which corresponded to five peer groups plus two others with N<3. In addition, two of the five peer groups comprised less than 10 labs each, and along with the N<3 methods made up 20% of the participants. The remaining three methods were used by 75% of labs with 34% Beckman Unicel/Access calibrated with the Hybritech standards, 24% Roche Elecsys/E170/Cobas, and 18% Siemens Immulite 2000. Results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (36% higher than the all method medians and 56% higher than the targets), while there are no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. All of the other methods were within +/-10% of the all method medians, but ranged from 3% to 23% above the assigned targets. All but the Beckman Unicel/Access methods were within 17% of each other, whereas Beckman remains consistently high. We calculated % free PSA for each peer group using their respective average PSA and free PSA levels and the results ranged from 10.1 to 13.9%. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA, but all were on average 2.3% of the value calculated from the assigned targets, differences that likely are not clinically significant.

Please note, labs are required to measure and report **free PSA** for **all proficiency test samples** if free PSA is on their test menu. We understand that this may in some cases be a deviation from a lab's policy in dealing with free PSA and could mean that PT samples are not treated exactly like patient samples.

Finally, 9 labs measured **complexed PSA** and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little difference between them and good inter-laboratory agreement indicated by an average %CV of 5.6% (Table 9).

In conclusion, substantial differences remain between the results obtained with various methods or instruments for some analytes. Furthermore, not all methods appear equally reproducible as indicated by the spread of the average within-method %CVs (see graph below). Most %CVs are <10% but there are some notable outliers, which could at least in part be caused by the low number of labs using that particular method.



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

While some of the differences between methods may be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We make every effort to minimize the differences that can be attributed to the sample composition and suggest that despite the somewhat artificial nature of the PT samples, the differences between the results obtained by various methods might also be reflected in patient serum samples. Therefore, we encourage labs and physicians to use caution when comparing the results from the same patient measured with different methods on different instruments, since clearly not all methods are equal. For this reason, **we require that the method used be clearly indicated on the patient report** (Oncology Standard OC S1). We also encourage you to educate your physician clients about this potential problem.

We would like to reiterate the following cautionary notes regarding the interpretation of the results from this proficiency test: 1) since some of the assays were done by a small number of labs, the results might be skewed due to a lack of statistical power; 2) it is difficult to make accurate comparisons of results when the % CVs are large; and finally 3) the analyses for PT purposes are done with artificially prepared mixtures of proteins, which may or may not accurately reflect patient derived samples.

Please be aware that even though the Instrument and Reagent fields will usually be pre-populated in EPTRS based on what was previously entered, it is still necessary to confirm that ALL instruments and reagents have been correctly entered prior to final submission, especially when you changed instruments. That information is critical to evaluate your results within the correct peer group or it could (and has) lead to failure if the two peer groups are substantially different. Furthermore, make sure to only select a qualifier (< or >) when your result is below or above your quantifiable range or you may end up with a technical failure. No changes can be made for incorrect or missing information after the submission deadline.

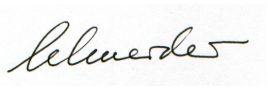
Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

Please note that questions regarding the electronic proficiency testing reporting system (EPTRS) account application process and the entry and submission of proficiency test results can be directed to clepeptrs@health.state.ny.us .

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

Mail-out date:	**Due date:**
September 1, 2015	September 16, 2015

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



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

Table 1: 5-15 NYS Tumor Marker PT Summary for CA 125

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect ABH									
TM286	11	16.8	**11.4**	**22.2**	5.4	7.08		1.25	
TM287	11	25.3	**19.9**	**30.7**	5.4	7.11		1.23	
TM288	11	45.6	**37.4**	**53.8**	8.2	6.73		1.19	
TM289	11	29.2	**23.8**	**34.6**	5.4	7.19		1.22	
TM290	11	33.3	**27.3**	**39.3**	6.0	7.36		1.19	
					mean ±SD	7.10	0.23	1.22	0.03
Beckman Unicel & Access/2 BCU/BCX									
TM286	23	14.9	**9.5**	**20.3**	5.4	4.36		1.11	
TM287	23	24.0	**18.6**	**29.4**	5.4	6.13		1.17	
TM288	23	45.5	**37.3**	**53.7**	8.2	4.66		1.19	
TM289	23	28.4	**23.0**	**33.8**	5.4	6.37		1.19	
TM290	23	32.8	**26.9**	**38.7**	5.9	4.79		1.18	
					mean ±SD	5.26	0.92	1.17	0.03
Roche Elecsys & Cobas BME/BMR									
TM286	19	12.5	**7.1**	**17.9**	5.4	4.16		0.93	
TM287	18	18.4	**13.0**	**23.8**	5.4	2.66		0.90	
TM288	18	32.5	**26.7**	**38.4**	5.9	3.69		0.85	
TM289	18	21.4	**16.0**	**26.8**	5.4	2.99		0.90	
TM290	18	24.6	**19.2**	**30.0**	5.4	2.60		0.88	
					mean ±SD	3.22	0.68	0.89	0.03
Siemens Advia Centaur XP & CP COB/COC									
TM286	36	14.3	**8.9**	**19.7**	5.4	8.46		1.07	
TM287	36	22.6	**17.2**	**28.0**	5.4	5.62		1.10	
TM288	36	41.3	**33.9**	**48.7**	7.4	5.59		1.08	
TM289	36	26.2	**20.8**	**31.6**	5.4	6.41		1.10	
TM290	36	30.6	**25.1**	**36.1**	5.5	5.92		1.10	
					mean ±SD	6.40	1.20	1.09	0.01
Siemens Immulite 2000 DPB/DPD									
TM286	13	12.0	**6.6**	**17.4**	5.4	5.50		0.90	
TM287	13	17.8	**12.4**	**23.2**	5.4	6.46		0.87	
TM288	13	35.2	**28.9**	**41.5**	6.3	6.48		0.92	
TM289	13	21.6	**16.2**	**27.0**	5.4	7.22		0.90	
TM290	13	25.2	**19.8**	**30.6**	5.4	6.90		0.90	
					mean ±SD	6.51	0.65	0.90	0.02
Siemens Dimension Vista (LOCI) DUV									
TM286	5	11.3	**5.9**	**16.7**	5.4	11.15		0.84	
TM287	5	16.6	**11.2**	**22.0**	5.4	7.71		0.81	
TM288	5	26.6	**21.2**	**32.0**	5.4	7.97		0.70	
TM289	5	19.1	**13.7**	**24.5**	5.4	7.59		0.80	
TM290	5	20.5	**15.1**	**25.9**	5.4	8.59		0.73	
					mean ±SD	8.60	1.48	0.78	0.06
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM286	4	7.1	**1.7**	**12.5**	5.4	14.08		0.53	
TM287	5	11.5	**6.1**	**16.9**	5.4	20.78		0.56	
TM288	5	27.5	**22.1**	**32.9**	5.4	10.15		0.72	
TM289	5	16.1	**10.7**	**21.5**	5.4	15.03		0.67	
TM290	5	17.6	**12.2**	**23.0**	5.4	16.88		0.63	
					mean ±SD	15.38	3.89	0.65	0.07

continued on next page

Table 1 (cont.): 5-15 NYS Tumor Marker PT Summary for CA 125

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Tosoh AIA TOM									
TM286	6	17.6	**12.2**	**23.0**	5.4	6.53		1.31	
TM287	6	28.2	**22.8**	**33.6**	5.4	3.26		1.38	
TM288	6	50.6	**41.5**	**59.7**	9.1	3.06		1.32	
TM289	6	32.1	**26.3**	**37.9**	5.8	4.83		1.34	
TM290	6	36.9	**30.3**	**43.5**	6.6	3.44		1.32	
					mean ±SD	4.23	1.47	1.34	0.02

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM286	**117**	**13.4**	**6.81**	**4.16**	**14.08**
TM287	**117**	**20.5**	**6.28**	**2.66**	**20.78**
TM288	**117**	**38.3**	**6.16**	**3.06**	**10.15**
TM289	**117**	**23.9**	**6.80**	**2.99**	**15.03**
TM290	**117**	**27.9**	**6.48**	**2.60**	**16.88**
		Average	**6.51**		
		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

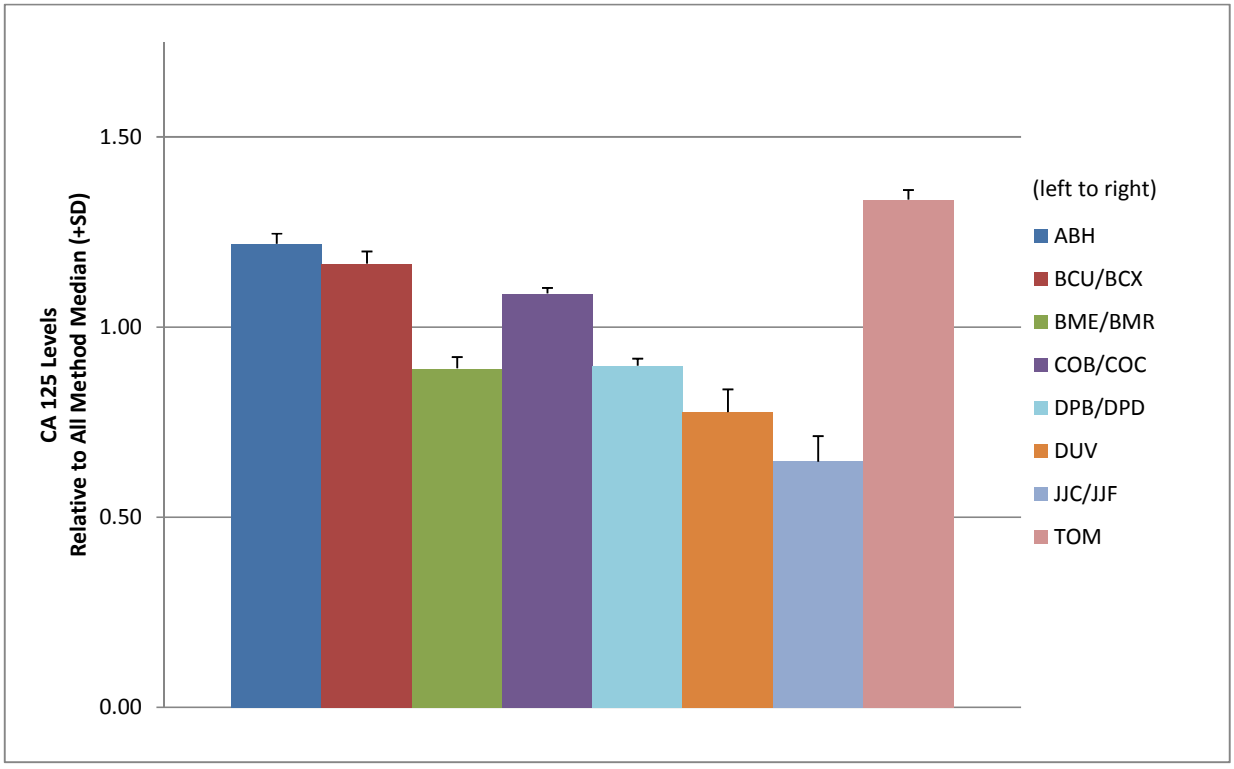


Table 2: 5-15 NYS Tumor Marker PT Summary for CA 19-9

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect ABH									
TM286	2	76.5	**62.7**	**90.3**	13.8	7.58		4.45	
TM287	2	239.0	**196.0**	**282.0**	43.0	10.77		5.25	
TM288	2	164.5	**134.9**	**194.1**	29.6	10.02		5.02	
TM289	2	130.3	**106.8**	**153.8**	23.5	12.70		5.07	
TM290	2	146.3	**120.0**	**172.6**	26.3	10.83		4.89	
					mean ±SD	10.38	1.85	4.94	0.30
Beckman Unicel & Access/2 BCU/BCX									
TM286	18	15.6	**12.0**	**19.2**	3.6	6.28		0.91	
TM287	18	45.5	**37.3**	**53.7**	8.2	4.97		1.00	
TM288	18	32.8	**26.9**	**38.7**	5.9	5.64		1.00	
TM289	18	25.3	**20.7**	**29.9**	4.6	5.57		0.98	
TM290	18	29.9	**24.5**	**35.3**	5.4	4.82		1.00	
					mean ±SD	5.46	0.59	0.98	0.04
Roche Elecsys & Cobas BME/BMR									
TM286	12	16.2	**12.6**	**19.8**	3.6	4.32		0.94	
TM287	13	38.6	**31.7**	**45.5**	6.9	11.89		0.85	
TM288	13	29.9	**24.5**	**35.3**	5.4	4.85		0.91	
TM289	12	24.8	**20.3**	**29.3**	4.5	5.16		0.96	
TM290	12	27.5	**22.6**	**32.5**	5.0	5.05		0.92	
					mean ±SD	6.26	3.17	0.92	0.04
Siemens Advia Centaur XP COB									
TM286	33	32.3	**26.5**	**38.1**	5.8	7.12		1.88	
TM287	33	86.9	**71.3**	**102.5**	15.6	7.42		1.91	
TM288	32	62.6	**51.3**	**73.9**	11.3	5.35		1.91	
TM289	32	48.3	**39.6**	**57.0**	8.7	5.65		1.88	
TM290	33	55.3	**45.3**	**65.3**	10.0	6.26		1.85	
					mean ±SD	6.36	0.90	1.89	0.03
Siemens Dimension Vista DUV									
TM286	3	17.2	**13.6**	**20.8**	3.6	6.51		1.00	
TM287	3	52.7	**43.2**	**62.2**	9.5	5.83		1.16	
TM288	3	38.2	**31.3**	**45.1**	6.9	7.70		1.16	
TM289	3	31.7	**26.0**	**37.4**	5.7	5.17		1.23	
TM290	3	35.0	**28.7**	**41.3**	6.3	8.29		1.17	
					mean ±SD	6.70	1.29	1.15	0.09
Tosoh AIA TOM									
TM286	6	18.0	**14.4**	**21.6**	3.6	6.39		1.05	
TM287	6	34.4	**28.2**	**40.6**	6.2	3.75		0.76	
TM288	6	28.4	**23.3**	**33.5**	5.1	6.30		0.87	
TM289	6	25.7	**21.1**	**30.3**	4.6	2.76		1.00	
TM290	6	26.9	**22.1**	**31.7**	4.8	5.43		0.90	
					mean ±SD	4.93	1.61	0.91	0.11

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Table 2 (cont.): 5-15 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM286	72	17.2	6.39	4.32	7.12
TM287	73	45.5	5.83	3.75	11.89
TM288	72	32.8	5.64	4.85	7.70
TM289	71	25.7	5.17	2.76	5.65
TM290	72	29.9	5.43	4.82	8.29

Average	5.69
Allowable CV %	6.0
Allowable Error if >/= 20 U/ml (+/-) %	18.0
Allowable Error if < 20 U/ml (+/- U/ml)	3.6

*Abbott excluded from all calculations

Figure 2: CA 19-9 Method Comparison

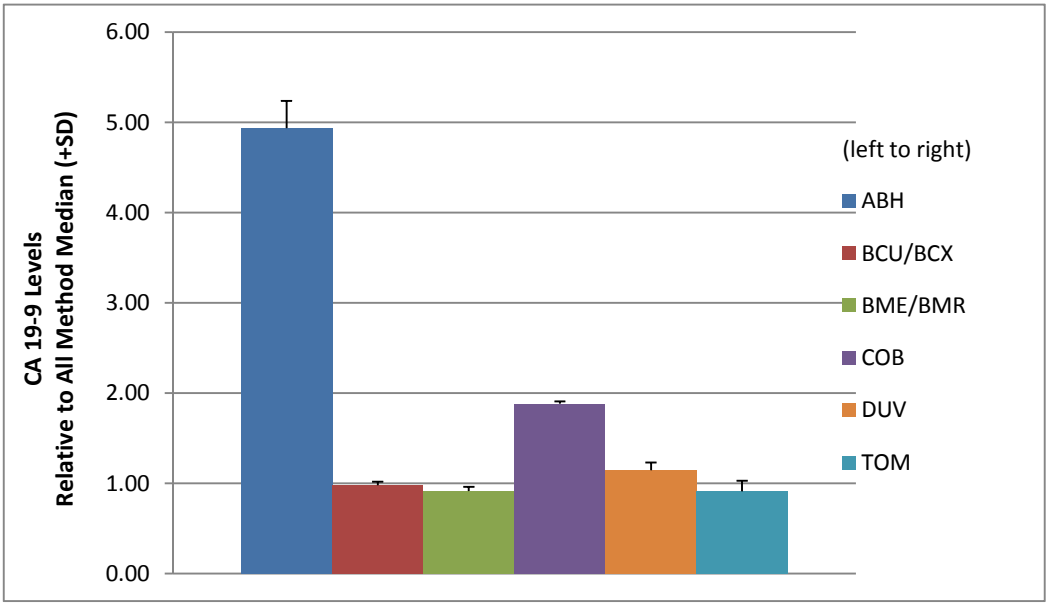

Table 3: 5-15 NYS Tumor Marker PT Summary for CA 15-3

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect ABH									
TM286	5	18.9	**15.5**	**22.3**	3.4	4.97		0.93	
TM287	5	41.8	**34.3**	**49.3**	7.5	3.01		0.95	
TM288	5	30.2	**24.8**	**35.6**	5.4	5.23		0.92	
TM289	5	46.8	**38.4**	**55.2**	8.4	2.52		0.92	
TM290	5	36.0	**29.5**	**42.5**	6.5	3.22		0.92	
					mean ±SD	3.79	1.19	0.93	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM286	10	13.2	**10.8**	**15.6**	2.4	6.14		0.65	
TM287	10	28.1	**23.0**	**33.2**	5.1	7.19		0.64	
TM288	10	21.5	**17.6**	**25.4**	3.9	6.65		0.66	
TM289	10	32.7	**26.8**	**38.6**	5.9	3.88		0.65	
TM290	10	24.7	**20.3**	**29.1**	4.4	6.15		0.63	
					mean ±SD	6.00	1.26	0.64	0.01
Roche Elecsys & Cobas BME/BMR									
TM286	13	20.3	**16.6**	**24.0**	3.7	4.33		1.00	
TM287	13	44.0	**36.1**	**51.9**	7.9	4.48		1.00	
TM288	13	32.8	**26.9**	**38.7**	5.9	4.21		1.00	
TM289	13	50.6	**41.5**	**59.7**	9.1	4.68		1.00	
TM290	13	39.3	**32.2**	**46.4**	7.1	4.99		1.00	
					mean ±SD	4.54	0.31	1.00	0.00
Siemens Advia Centaur XP & CP COB/COC									
TM286	23	20.3	**16.6**	**24.0**	3.7	8.03		1.00	
TM287	23	44.8	**36.7**	**52.9**	8.1	7.41		1.02	
TM288	23	33.1	**27.1**	**39.1**	6.0	7.43		1.01	
TM289	23	51.2	**42.0**	**60.4**	9.2	7.07		1.01	
TM290	23	39.4	**32.3**	**46.5**	7.1	7.69		1.00	
					mean ±SD	7.53	0.36	1.01	0.01
Siemens Immulite 2000 DPD									
TM286	7	22.1	**18.1**	**26.1**	4.0	9.82		1.09	
TM287	7	52.2	**42.8**	**61.6**	9.4	12.59		1.19	
TM288	7	39.1	**32.1**	**46.1**	7.0	15.91		1.19	
TM289	7	59.9	**49.1**	**70.7**	10.8	14.37		1.18	
TM290	7	46.0	**37.7**	**54.3**	8.3	8.09		1.17	
					mean±SD	12.74	3.39	1.16	0.01

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

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM286	58	20.3		6.14	4.33	9.82
TM287	58	44.0		7.19	3.01	12.59
TM288	58	32.8		6.65	4.21	15.91
TM289	58	50.6		4.68	2.52	14.37
TM290	58	39.3		6.15	3.22	8.09
			Average	6.16		
			Allowable CV %	6.0		
			Allowable Error (+/-) %	18.0		

Figure 3: CA 15-3 Method Comparison

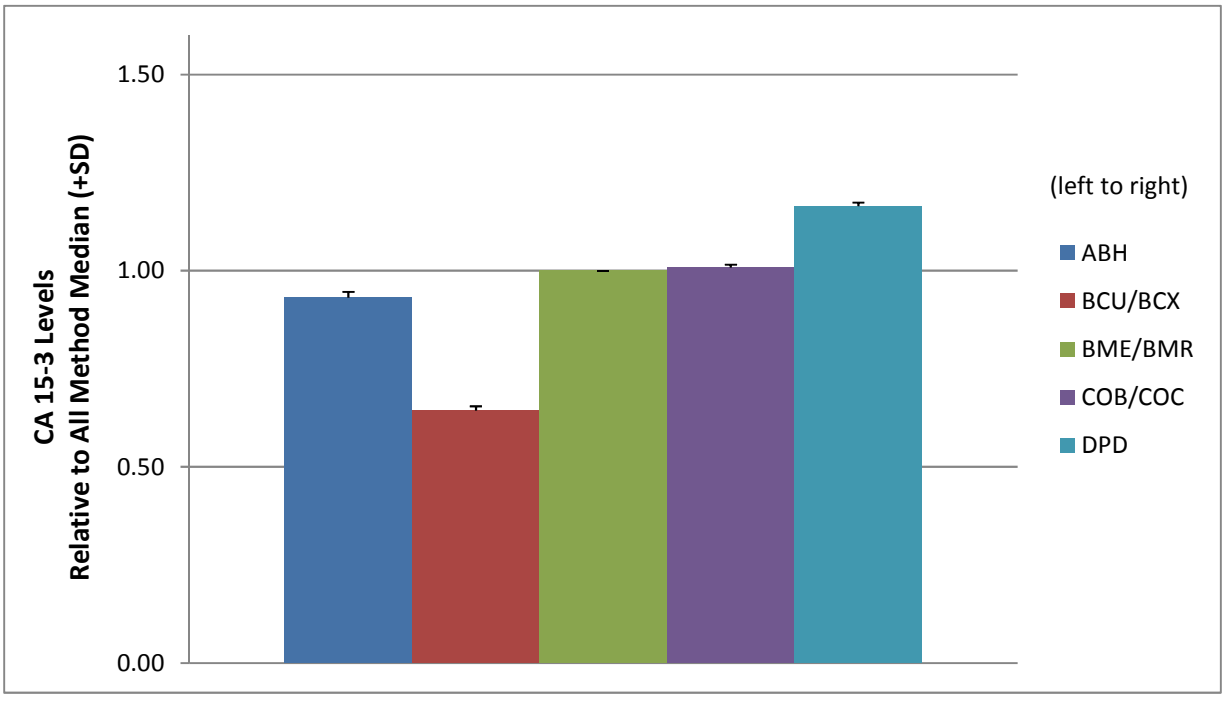

Table 4: 5-15 NYS Tumor Marker PT Summary for CA 27.29

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Siemens Advia Centaur XP & CP COB/COC									
TM286	40	19.8	**12.5**	**27.2**	7.4	14.09		1.02	
TM287	40	56.9	**45.0**	**68.8**	11.9	6.34		1.16	
TM288	40	38.6	**30.5**	**46.7**	8.1	9.35		1.11	
TM289	40	66.2	**52.3**	**80.1**	13.9	5.91		1.17	
TM290	40	49.7	**39.3**	**60.1**	10.4	7.73		1.15	
					mean ±SD	8.68	3.31	1.12	0.06
Tosoh AIA TOM									
TM286	7	19.2	**11.9**	**26.6**	7.4	2.55		0.98	
TM287	7	40.9	**32.3**	**49.5**	8.6	1.98		0.84	
TM288	7	31.1	**23.8**	**38.5**	7.4	2.15		0.89	
TM289	7	47.1	**37.2**	**57.0**	9.9	2.29		0.83	
TM290	7	36.9	**29.2**	**44.6**	7.7	3.69		0.85	
					mean ±SD	2.53	0.68	0.88	0.06

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM286	**47**	**19.5**	**8.32**	**2.55**	**14.09**
TM287	**47**	**48.9**	**4.16**	**1.98**	**6.34**
TM288	**47**	**34.9**	**5.75**	**2.15**	**9.35**
TM289	**47**	**56.7**	**4.10**	**2.29**	**5.91**
TM290	**47**	**43.3**	**5.71**	**3.69**	**7.73**
			Average	**5.61**	

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

Figure 4: CA 27.29 Method Comparison

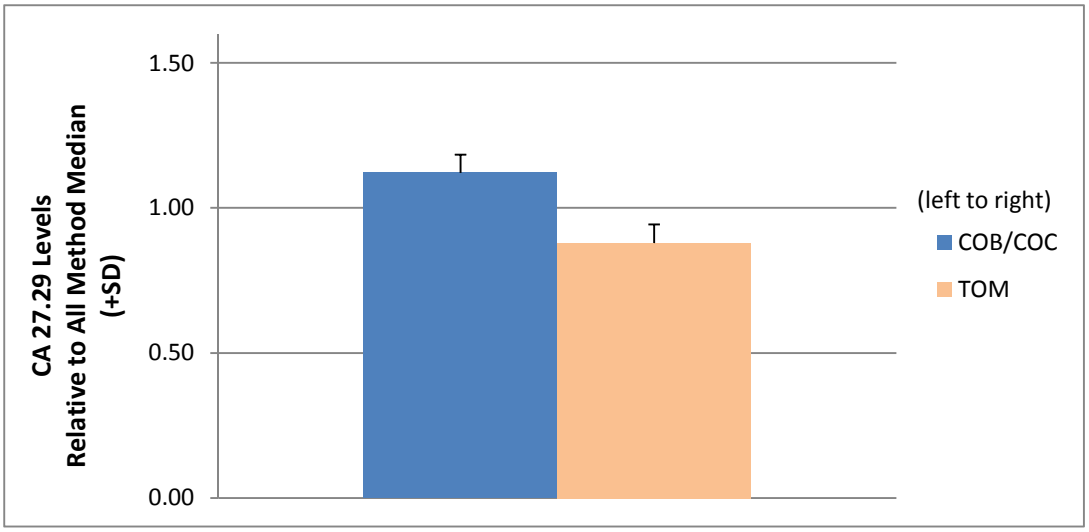

Table 5: 5-15 NYS Tumor Marker PT Summary for CEA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect ABH									
TM286	15	4.2	**3.3**	**5.1**	0.9	9.76		1.18	
TM287	15	11.1	**9.1**	**13.1**	2.0	5.41		1.17	
TM288	15	7.6	**6.2**	**9.0**	1.4	5.26		1.13	
TM289	15	26.8	**22.0**	**31.6**	4.8	4.03		1.14	
TM290	15	18.9	**15.5**	**22.3**	3.4	5.13		1.15	
					mean ±SD	5.92	2.22	1.15	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM286	31	3.4	**2.5**	**4.3**	0.9	8.24		0.96	
TM287	31	9.6	**7.9**	**11.3**	1.7	6.56		1.02	
TM288	31	6.8	**5.6**	**8.0**	1.2	7.21		1.01	
TM289	31	22.5	**18.5**	**26.6**	4.1	6.58		0.95	
TM290	31	16.2	**13.3**	**19.1**	2.9	7.04		0.98	
					mean ±SD	7.12	0.68	0.98	0.03
Roche Elecsys & Cobas BME/BMR									
TM286	19	3.7	**2.8**	**4.6**	0.9	3.78		1.04	
TM287	20	9.1	**7.5**	**10.7**	1.6	4.62		0.96	
TM288	21	6.7	**5.5**	**7.9**	1.2	4.63		0.99	
TM289	20	20.8	**17.1**	**24.5**	3.7	4.57		0.88	
TM290	20	15.2	**12.5**	**17.9**	2.7	4.93		0.92	
					mean ±SD	4.51	0.43	0.96	0.06
Siemens Advia Centaur XP & CP COB/COC									
TM286	47	3.4	**2.5**	**4.3**	0.9	5.00		0.96	
TM287	48	9.3	**7.6**	**11.0**	1.7	6.02		0.98	
TM288	48	6.4	**5.2**	**7.6**	1.2	6.56		0.95	
TM289	48	23.2	**19.0**	**27.4**	4.2	4.83		0.98	
TM290	48	16.7	**13.7**	**19.7**	3.0	5.75		1.02	
					mean ±SD	5.63	0.72	0.98	0.03
Siemens Immulite 1000/2000 DPB/DPD									
TM286	10	3.9	**3.0**	**4.8**	0.9	6.41		1.10	
TM287	10	11.2	**9.2**	**13.2**	2.0	5.45		1.19	
TM288	10	7.6	**6.2**	**9.0**	1.4	3.95		1.13	
TM289	10	29.0	**23.8**	**34.2**	5.2	4.59		1.23	
TM290	10	20.7	**17.0**	**24.4**	3.7	6.23		1.26	
					mean ±SD	5.32	1.06	1.18	0.07
Siemens Dimension Vista DUV									
TM286	23	3.3	**2.4**	**4.2**	0.9	3.64		0.93	
TM287	22	9.2	**7.5**	**10.9**	1.7	3.04		0.97	
TM288	23	6.5	**5.3**	**7.7**	1.2	3.08		0.96	
TM289	23	22.4	**18.4**	**26.4**	4.0	3.04		0.95	
TM290	23	16.1	**13.2**	**19.0**	2.9	4.04		0.98	
					mean ±SD	3.37	0.45	0.96	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM286	11	1.4	**0.5**	**2.3**	0.9	37.86		0.39	
TM287	11	6.7	**5.5**	**7.9**	1.2	18.06		0.71	
TM288	11	3.1	**2.2**	**4.0**	0.9	26.77		0.46	
TM289	11	24.0	**19.7**	**28.3**	4.3	4.17		1.02	
TM290	11	14.4	**11.8**	**17.0**	2.6	6.94		0.88	
					mean ±SD	18.76	13.98	0.69	0.27

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Table 5 (cont.): 5-15 NYS Tumor Marker PT Summary for CEA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Tosoh AIA TOM									
TM286	7	6.5	**5.3**	**7.7**	1.2	3.38		1.83	
TM287	7	15.5	**12.7**	**18.3**	2.8	3.94		1.64	
TM288	7	11.3	**9.3**	**13.3**	2.0	5.22		1.67	
TM289	7	38.1	**31.2**	**45.0**	6.9	3.88		1.61	
TM290	7	27.8	**22.8**	**32.8**	5.0	3.78		1.69	
					mean ±SD	4.04	0.69	1.69	0.08

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM286	**163**	**3.6**	**5.71**	**3.38**	**37.86**
TM287	**164**	**9.5**	**5.43**	**3.04**	**18.06**
TM288	**166**	**6.8**	**5.24**	**3.08**	**26.77**
TM289	**165**	**23.6**	**4.37**	**3.04**	**6.58**
TM290	**165**	**16.5**	**5.44**	**3.78**	**7.04**

Average	**5.24**
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

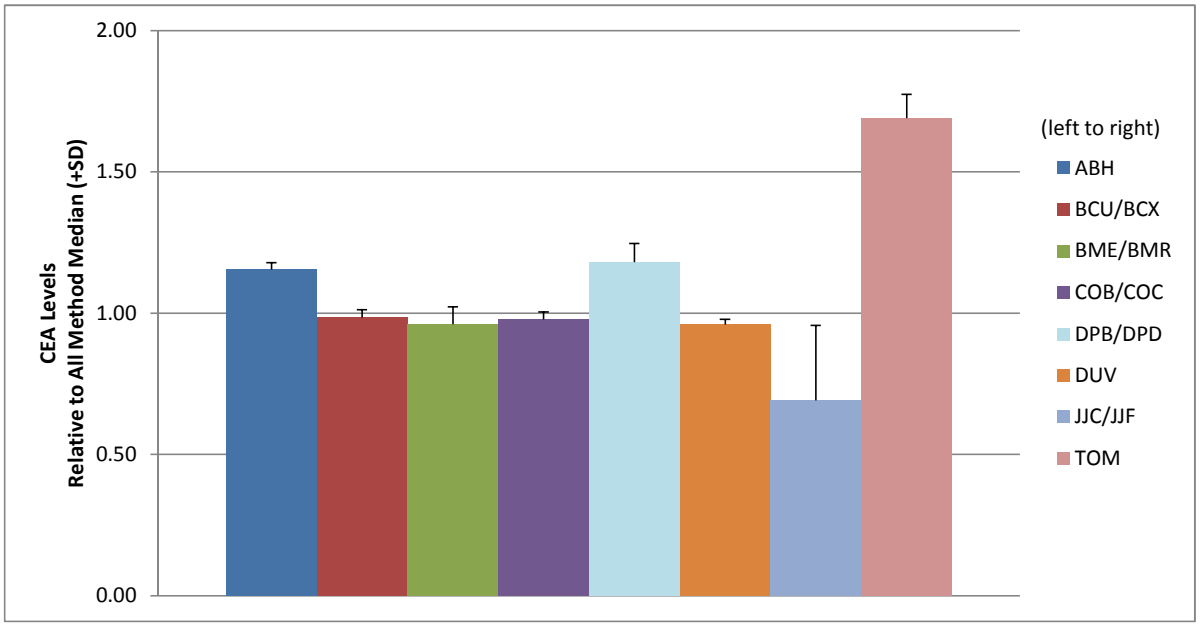

Table 6: 5-15 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit Based on 3SD	Upper Limit Based on 3SD	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott Architect ABH											
TM286	5	5.6	**4.9**	**6.3**	0.7	4.11		0.97		1.10	
TM287	5	9.9	**9.1**	**10.7**	0.8	2.73		0.99		1.09	
TM288	5	20.2	**18.3**	**22.2**	2.0	3.22		0.99		1.07	
TM289	5	7.8	**6.8**	**8.8**	1.0	4.23		0.97		1.06	
TM290	5	29.2	**27.0**	**31.5**	2.3	2.57		1.01		1.09	
					mean ±SD	3.37	0.77	0.98	0.02	1.08	0.01
Beckman Unicel & Access/2 BCU/BCX											
TM286	27	5.7	**4.4**	**7.0**	1.3	7.54		0.98		1.12	
TM287	27	9.9	**7.9**	**11.9**	2.0	6.77		0.99		1.09	
TM288	27	20.3	**16.3**	**24.3**	4.0	6.55		0.99		1.08	
TM289	27	8.0	**6.3**	**9.7**	1.7	7.00		0.99		1.09	
TM290	27	28.9	**24.0**	**33.9**	5.0	5.71		0.99		1.08	
					mean ±SD	6.71	0.67	0.99	0.01	1.09	0.02
Roche Elecsys & Cobas BME/BMR											
TM286	15	6.4	**5.6**	**7.2**	0.8	4.06		1.10		1.26	
TM287	14	11.0	**10.3**	**11.7**	0.7	2.18		1.09		1.21	
TM288	15	22.3	**20.5**	**24.1**	1.8	2.74		1.09		1.18	
TM289	15	8.9	**7.6**	**10.2**	1.3	4.94		1.11		1.21	
TM290	15	31.9	**28.5**	**35.3**	3.4	3.51		1.10		1.19	
					mean ±SD	3.49	1.09	1.10	0.01	1.21	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM286	28	6.8	**4.6**	**9.0**	2.2	10.88		1.17		1.34	
TM287	29	10.5	**8.2**	**12.8**	2.3	7.33		1.04		1.16	
TM288	29	20.7	**15.7**	**25.7**	5.0	8.07		1.01		1.10	
TM289	29	8.5	**5.4**	**11.6**	3.1	12.24		1.06		1.16	
TM290	29	29.0	**23.3**	**34.7**	5.7	6.55		1.00		1.08	
					mean ±SD	9.01	2.43	1.06	0.07	1.17	0.10
Siemens Immulite 1000 & 2000 DPB/DPD											
TM286	11	5.9	**4.6**	**7.2**	1.3	7.29		1.02		1.16	
TM287	11	10.2	**8.0**	**12.5**	2.3	7.35		1.01		1.12	
TM288	11	20.9	**16.4**	**25.4**	4.5	7.18		1.02		1.11	
TM289	11	8.1	**6.3**	**9.9**	1.8	7.28		1.01		1.10	
TM290	11	29.1	**21.0**	**37.2**	8.1	9.31		1.00		1.08	
					mean ±SD	7.68	0.91	1.01	0.01	1.12	0.03
Siemens Dimension Vista DUV											
TM286	6	5.7	**5.2**	**6.2**	0.5	2.81		0.98		1.12	
TM287	6	9.7	**8.9**	**10.5**	0.8	2.68		0.97		1.07	
TM288	6	19.8	**18.5**	**21.2**	1.4	2.27		0.97		1.05	
TM289	6	7.9	**7.4**	**8.4**	0.5	2.15		0.98		1.08	
TM290	6	27.8	**25.6**	**30.0**	2.2	2.66		0.96		1.03	
					mean ±SD	2.51	0.28	0.97	0.01	1.07	0.03
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM286	6	5.1	**4.3**	**5.9**	0.8	5.29		0.88		1.00	
TM287	6	8.1	**7.2**	**9.0**	0.9	3.58		0.81		0.89	
TM288	6	16.6	**15.2**	**18.0**	1.4	2.89		0.81		0.88	
TM289	6	6.8	**6.1**	**7.5**	0.7	3.38		0.84		0.93	
TM290	6	23.8	**22.0**	**25.6**	1.8	2.48		0.82		0.89	
					mean ±SD	3.53	1.08	0.83	0.03	0.92	0.05

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Table 6 (cont.): 5-15 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit Based on 3SD	Upper Limit Based on 3SD	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Tosoh AIA TOM											
TM286	4	6.8	**3.7**	**10.0**	3.2	15.44		1.17		1.34	
TM287	4	11.4	**8.6**	**14.2**	2.8	8.16		1.13		1.25	
TM288	4	22.6	**21.4**	**23.8**	1.2	1.77		1.10		1.20	
TM289	4	9.3	**6.9**	**11.7**	2.4	8.49		1.16		1.27	
TM290	4	31.7	**28.6**	**34.9**	3.2	3.31		1.09		1.18	
					mean ±SD	7.44	5.36	1.13	0.03	1.25	0.06

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max %CV		All Method Median/ IS Target	
TM286	**102**	**5.8**	**5.1**	**0.41**		**6.29**	**2.81**	**15.44**		**1.14**	
TM287	**102**	**10.1**	**9.1**	**0.54**		**5.17**	**2.18**	**8.16**		**1.11**	
TM288	**103**	**20.5**	**18.8**	**1.16**		**3.05**	**1.77**	**8.07**		**1.09**	
TM289	**103**	**8.1**	**7.3**	**0.54**		**5.97**	**2.15**	**12.24**		**1.10**	
TM290	**103**	**29.1**	**26.9**	**0.64**		**3.41**	**2.48**	**9.31**		**1.08**	
					Average	**4.78**			mean ±SD	**1.10**	0.02

Allowable Error = +/-3SD

Figure 6: AFP Method Comparison

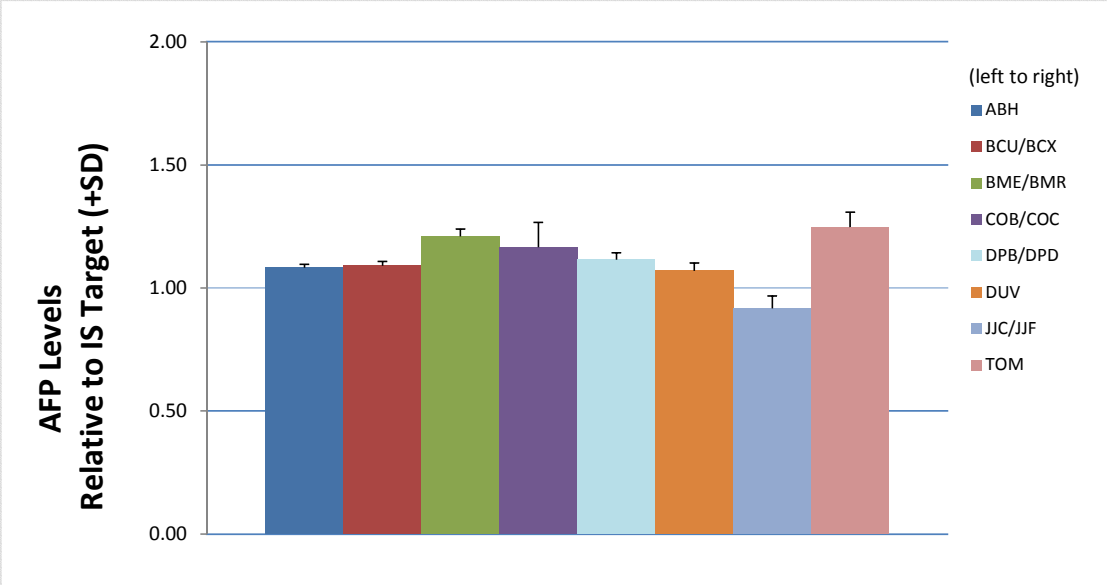

Table 7: 5-15 NYS Tumor Marker PT Summary for PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott Architect ABH											
TM286	20	1.79	**1.47**	**2.11**	0.32	5.59		1.02		1.22	
TM287	20	3.59	**2.94**	**4.24**	0.65	5.57		1.03		1.25	
TM288	20	17.64	**14.46**	**20.82**	3.18	3.80		1.05		1.16	
TM289	20	8.98	**7.36**	**10.60**	1.62	5.01		1.05		1.22	
TM290	20	5.83	**4.78**	**6.88**	1.05	4.29		1.05		1.23	
					mean ±SD	4.85	0.79	1.04	0.01	1.22	0.03
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM286	53	1.87	**1.53**	**2.21**	0.34	4.81		1.07		1.27	
TM287	53	3.77	**3.09**	**4.45**	0.68	5.31		1.09		1.31	
TM288	54	19.84	**16.27**	**23.41**	3.57	6.00		1.18		1.31	
TM289	51	9.72	**7.97**	**11.47**	1.75	4.53		1.14		1.32	
TM290	52	6.25	**5.13**	**7.38**	1.13	4.80		1.12		1.32	
					mean ±SD	5.09	0.58	1.12	0.04	1.31	0.02
Roche Elecsys & Cobas BME/BMR											
TM286	37	1.65	**1.35**	**1.95**	0.30	4.24		0.94		1.12	
TM287	37	3.22	**2.64**	**3.80**	0.58	4.35		0.93		1.12	
TM288	37	16.25	**13.33**	**19.18**	2.93	4.25		0.96		1.07	
TM289	37	8.06	**6.61**	**9.51**	1.45	4.22		0.94		1.09	
TM290	37	5.27	**4.32**	**6.22**	0.95	4.36		0.95		1.11	
					mean ±SD	4.28	0.07	0.94	0.01	1.10	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM286	52	1.57	**1.29**	**1.85**	0.28	5.10		0.90		1.07	
TM287	52	3.02	**2.48**	**3.56**	0.54	3.31		0.87		1.05	
TM288	53	15.18	**12.45**	**17.91**	2.73	5.34		0.90		1.00	
TM289	54	7.51	**6.16**	**8.86**	1.35	5.06		0.88		1.02	
TM290	53	4.92	**4.03**	**5.81**	0.89	5.69		0.88		1.04	
					mean ±SD	4.90	0.92	0.89	0.01	1.03	0.03
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM286	17	1.60	**1.31**	**1.89**	0.29	4.38		0.91		1.09	
TM287	17	3.22	**2.64**	**3.80**	0.58	5.59		0.93		1.12	
TM288	16	16.16	**13.25**	**19.07**	2.91	4.64		0.96		1.07	
TM289	16	8.19	**6.72**	**9.66**	1.47	4.88		0.96		1.11	
TM290	17	5.39	**4.42**	**6.36**	0.97	4.45		0.97		1.14	
					mean ±SD	4.79	0.49	0.95	0.02	1.10	0.03
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM286	15	1.85	**1.52**	**2.18**	0.33	5.41		1.06		1.26	
TM287	15	3.64	**2.98**	**4.30**	0.66	4.67		1.05		1.26	
TM288	15	18.41	**15.10**	**21.72**	3.31	4.24		1.09		1.21	
TM289	15	9.09	**7.45**	**10.73**	1.64	4.84		1.06		1.23	
TM290	15	5.96	**4.89**	**7.03**	1.07	4.36		1.07		1.26	
					mean±SD	4.70	0.46	1.07	0.02	1.25	0.02
Siemens Dimension Vista DUV											
TM286	23	1.77	**1.45**	**2.09**	0.32	2.26		1.01		1.20	
TM287	23	3.48	**2.85**	**4.11**	0.63	2.30		1.00		1.21	
TM288	23	17.57	**14.41**	**20.73**	3.16	1.88		1.04		1.16	
TM289	23	8.80	**7.22**	**10.38**	1.58	1.82		1.03		1.19	
TM290	23	5.69	**4.67**	**6.71**	1.02	1.76		1.02		1.20	
					mean ±SD	2.00	0.26	1.02	0.01	1.19	0.02

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Table 7 (cont.): 5-15 NYS Tumor Marker PT Summary for PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM286	21	1.56	**1.28**	**1.84**	0.28	8.97		0.89		1.06	
TM287	21	3.14	**2.57**	**3.71**	0.57	6.69		0.90		1.09	
TM288	21	15.50	**12.71**	**18.29**	2.79	4.84		0.92		1.02	
TM289	21	7.70	**6.31**	**9.09**	1.39	4.68		0.90		1.04	
TM290	21	5.00	**4.10**	**5.90**	0.90	5.40		0.90		1.06	
					mean ±SD	6.12	1.78	0.90	0.01	1.05	0.03
Tosoh AIA TOM											
TM286	8	1.75	**1.44**	**2.07**	0.32	4.00		1.00		1.19	
TM287	8	3.47	**2.85**	**4.09**	0.62	3.46		1.00		1.20	
TM288	8	16.88	**13.84**	**19.92**	3.04	4.50		1.00		1.11	
TM289	8	8.55	**7.01**	**10.09**	1.54	4.09		1.00		1.16	
TM290	8	5.57	**4.57**	**6.57**	1.00	4.67		1.00		1.18	
					mean ±SD	4.14	0.47	1.00	0.00	1.17	0.04

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max % CV		All Method Median/ IS Target	
TM286	**246**	**1.75**	**1.47**	**0.05**		**4.81**	**2.26**	**8.97**		**1.19**	
TM287	**246**	**3.47**	**2.88**	**0.08**		**4.67**	**2.30**	**6.69**		**1.20**	
TM288	**247**	**16.88**	**15.16**	**0.62**		**4.50**	**1.88**	**6.00**		**1.11**	
TM289	**245**	**8.55**	**7.39**	**0.33**		**4.68**	**1.82**	**5.06**		**1.16**	
TM290	**246**	**5.57**	**4.73**	**0.25**		**4.45**	**1.76**	**5.69**		**1.18**	
					Average	**4.62**			mean ±SD	**1.17**	0.04
					Allowable CV %	**6.00**					
					Allowable Error (+/-)%	**18.0**					

Figure 7: PSA Method Comparison

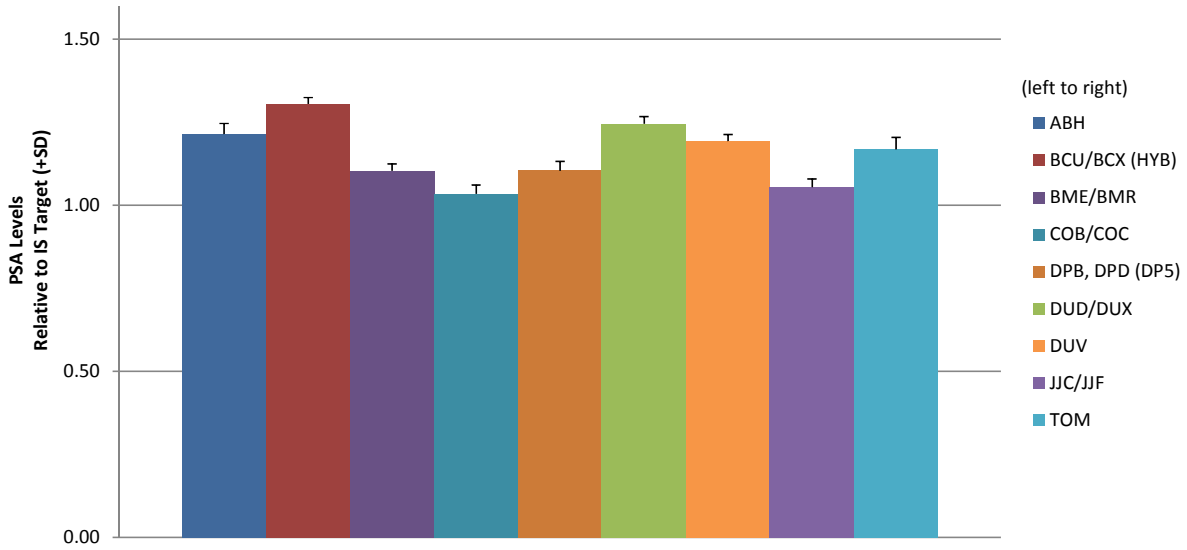

Table 8: 5-15 NYS Tumor Marker PT Summary for Free PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target		% free PSA (calculated)	
Abbott Architect ABH													
TM286	7	0.21	**0.12**	**0.30**	0.09	4.76		1.05		1.25		11.7%	
TM287	7	0.42	**0.33**	**0.51**	0.09	3.33		1.05		1.23		11.7%	
TM288	7	2.17	**1.78**	**2.56**	0.39	3.64		1.11		1.25		12.3%	
TM289	7	1.03	**0.84**	**1.22**	0.19	3.50		1.08		1.23		11.5%	
TM290	7	0.68	**0.56**	**0.80**	0.12	3.53		1.06		1.19		11.7%	
					mean ±SD	3.75	0.58	1.07	0.03	1.23	0.02	11.8%	0.3%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)													
TM286	29	0.28	**0.19**	**0.37**	0.09	5.71		1.40		1.66		15.0%	
TM287	29	0.54	**0.44**	**0.64**	0.10	6.11		1.35		1.58		14.3%	
TM288	30	2.56	**2.10**	**3.02**	0.46	4.92		1.31		1.48		12.9%	
TM289	29	1.28	**1.05**	**1.51**	0.23	5.00		1.35		1.52		13.2%	
TM290	29	0.88	**0.72**	**1.04**	0.16	5.11		1.38		1.54		14.1%	
					mean ±SD	5.37	0.52	1.36	0.03	1.56	0.07	13.9%	0.9%
Roche Elecsys & Cobas BME/BMR													
TM286	19	0.20	**0.11**	**0.29**	0.09	3.50		1.00		1.19		12.1%	
TM287	21	0.40	**0.31**	**0.49**	0.09	3.50		1.00		1.17		12.4%	
TM288	21	1.95	**1.60**	**2.30**	0.35	4.31		1.00		1.12		12.0%	
TM289	21	0.95	**0.78**	**1.12**	0.17	4.00		1.00		1.13		11.8%	
TM290	21	0.64	**0.52**	**0.76**	0.12	4.84		1.00		1.12		12.1%	
					mean ±SD	4.03	0.57	1.00	0.00	1.15	0.03	12.1%	0.2%
Siemens Immulite 2000 DPD													
TM286	15	0.18	**0.09**	**0.27**	0.09	8.33		0.90		1.07		11.3%	
TM287	16	0.36	**0.27**	**0.45**	0.09	6.11		0.90		1.05		11.2%	
TM288	15	1.78	**1.46**	**2.10**	0.32	8.76		0.91		1.03		11.0%	
TM289	14	0.86	**0.71**	**1.01**	0.15	6.63		0.91		1.02		10.5%	
TM290	16	0.57	**0.47**	**0.67**	0.10	6.14		0.89		1.00		10.6%	
					mean ±SD	7.20	1.26	0.90	0.01	1.03	0.03	10.9%	0.3%
Siemens Dimension Vista DUD/DUX													
TM286	3	0.19	**0.10**	**0.28**	0.09	10.53		0.95		1.13		10.3%	
TM287	3	0.38	**0.29**	**0.47**	0.09	5.26		0.95		1.11		10.4%	
TM288	3	1.88	**1.54**	**2.22**	0.34	2.13		0.96		1.08		10.2%	
TM289	3	0.90	**0.74**	**1.06**	0.16	5.56		0.95		1.07		9.9%	
TM290	3	0.57	**0.47**	**0.67**	0.10	14.04		0.89		1.00		9.6%	
					mean ±SD	7.50	4.73	0.94	0.03	1.08	0.05	10.1%	0.3%
Siemens Dimension Vista DUV													
TM286	7	0.18	**0.09**	**0.27**	0.09	0.00		0.90		1.07		10.2%	
TM287	9	0.36	**0.27**	**0.45**	0.09	6.39		0.90		1.05		10.3%	
TM288	10	1.83	**1.50**	**2.16**	0.33	2.46		0.94		1.06		10.4%	
TM289	10	0.89	**0.73**	**1.05**	0.16	2.02		0.94		1.06		10.1%	
TM290	10	0.60	**0.49**	**0.71**	0.11	2.00		0.94		1.05		10.5%	
					mean ±SD	2.57	2.34	0.92	0.02	1.06	0.01	10.3%	0.2%

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Table 8 (cont.): 5-15 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD		Median % CV	All Method Median/ IS Target		% free PSA calculated from IS Targets		Measured %fPSA
TM286	77	0.20	0.17	0.009		4.76	1.19		11.5%		11.8%
TM287	82	0.40	0.34	0.02		6.11	1.17		11.9%		11.7%
TM288	83	1.95	1.73	0.17		4.31	1.12		11.4%		11.5%
TM289	81	0.95	0.84	0.06		4.00	1.13		11.4%		11.2%
TM290	83	0.64	0.57	0.04		4.84	1.12		12.1%		11.4%
							mean	±SD	mean	±SD	mean
					Average	4.80	1.15	0.03	11.6%	0.003	11.5%
					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

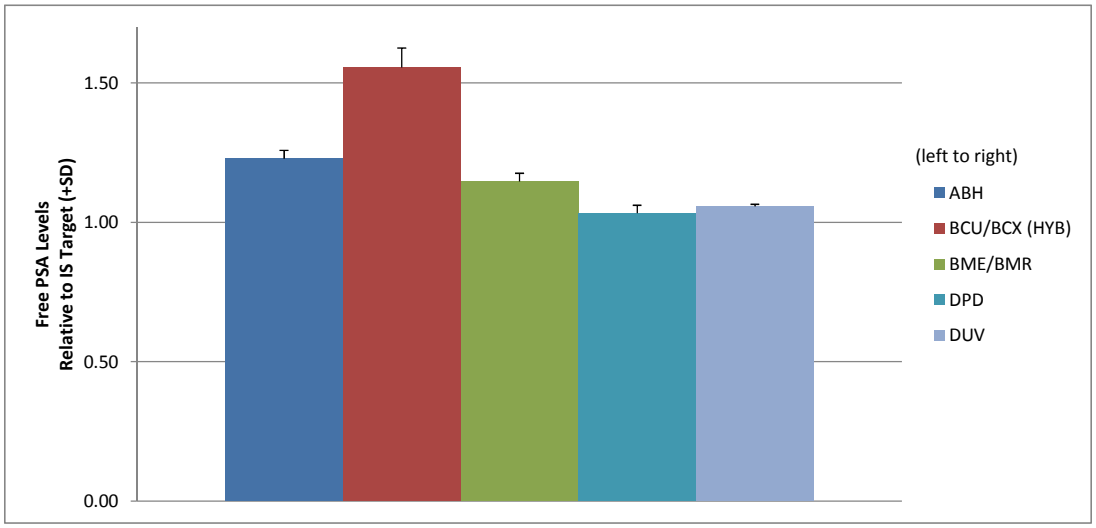

Figure 8B: Calculated % Free PSA Method Comparison

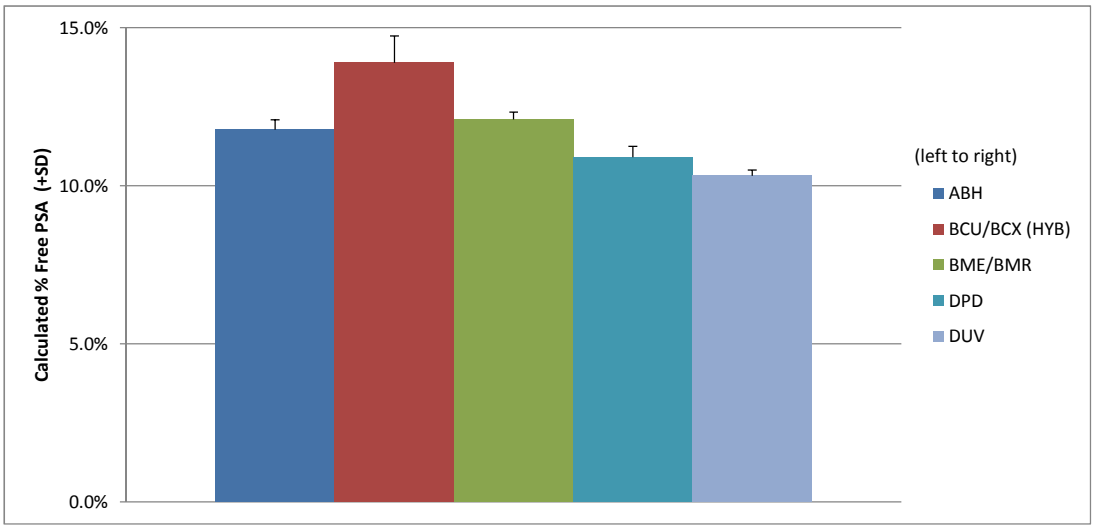

Table 9: 5-15 NYS Tumor Marker PT Summary for Complexed PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Siemens Advia Centaur XP & CP COB/COC									
TM286	9	1.5	**1.2**	**1.7**	0.3	6.80		1.00	
TM287	9	2.9	**2.4**	**3.4**	0.5	5.48		1.00	
TM288	9	14.7	**12.1**	**17.4**	2.7	4.76		1.00	
TM289	9	7.4	**6.0**	**8.7**	1.4	5.43		1.00	
TM290	9	4.7	**3.9**	**5.6**	0.9	5.70		1.00	
					mean ±SD	5.63	0.74	1.00	0.00

Sample ID	All Method Median		Median % CV
TM286	**1.5**		**6.80**
TM287	**2.9**		**5.48**
TM288	**14.7**		**4.76**
TM289	**7.4**		**5.43**
TM290	**4.7**		**5.70**
		Average	**5.63**
		Allowable CV %	**6.0**
		Allowable Error (+/-)%	**18.0**

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

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2015/index.htm

		TM286	TM287	TM288	TM289	TM290
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