NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Acting Commissioner

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

New mailout date: February 3, 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**

New Due Date: **February 18, 2015**

Samples:
Enclosed are five sealed (5) vials labeled **TM281 to TM285**, each containing proficiency test specimens in a protein 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 February 11th, 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 February 18, 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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March 20, 2015

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

Dear Laboratory Director,

This is a summary and critique of the New York State Proficiency Test from January/February 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 to a protein-based matrix, sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

Your laboratory's individual results, score(s), previous two PT event scores and overall performance status are on a separate report securely posted on the Department's Health Commerce System site under EPTRS (Electronic Proficiency Test Reporting System).

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

Click on EPTRS under "My Applications"

Click on Online Reporting

This will bring you to the "Select Event" page

Scroll down and find the current survey in the "Submitted/Closed Events" table and click on "Evaluation" under the "Scored" column.

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

[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.

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

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

Once posted, it can also be accessed through the "Statistical" link from EPTRS.

Please **review, print and sign** your score report 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 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 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 88% of the labs. The peer group means ranged from 20% below to 33% above the all method median, with Tosoh being the highest. Forty-one percent of labs were in the two peer groups that fell at or within +/-10% of the all method median target.

CA19-9 (Table 2, Figure 2): Results were reported by 71 labs using instruments from seven different manufacturers, six with N >2 for peer group grading. Forty-one percent of all reporting labs used Siemens ADVIA-Centaur XP, 24% 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. As previously seen, there are large differences in how each method measured CA19-9, ranging from 65% (Tosoh) to 506% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP averaged almost 1.7 times higher than the all method median, while results from Beckman, and Roche were within +/-10% of the all method median. Used by three labs, the Abbott Architect method results averaged 5.1 times higher than the all method median, as shown in Table 2 and Figure 2. These results show there continues to be discordance between the different methods used to measure CA19-9, at least under the conditions of the NYS PT.

The MUC1 breast cancer antigen was measured by 102 labs, with slightly more than half (56%) 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). Overall, the Beckman Unicel/Access CA15-3 results exhibited a notable negative bias, averaging -28% from the all method medians, while Siemens Immulite showed a high bias of 41% above the median. In contrast, **CA27.29** measurements showed only a 4% difference between the ADVIA Centaur XP/CP and the Tosoh methods but the median CA27.29 measurements averaged 22% higher than the median CA15-3 measurements. Furthermore, the inter-laboratory variation for CA27.29 was substantially larger than for CA15-3, as shown by the higher %CV values for CA27.29.

CEA (Table 5, Figure 5): Results were reported by 164 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 7 to 45 labs. Results from the Abbott Architect, Beckman Unicel/Access/2, Siemens Advia Centaur, Siemens Dimension Vista and Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 methods, which altogether accounted for 83% of the labs, were within +/-15% of the medians. Roche methods were 21% below the median, whereas TOSOH ST-AIA exhibited a high positive bias averaging 41% 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 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 21% of the total number of labs. Six of the eight methods, used by 83% of the labs, gave results within +/-10% of the all method median, and averaged 11% higher than the assigned targets. Of the remaining two methods, Tosoh measured 11% higher than the all method median, and 22% 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 (-17%) and was also 25% below the all method median. Thus, 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.

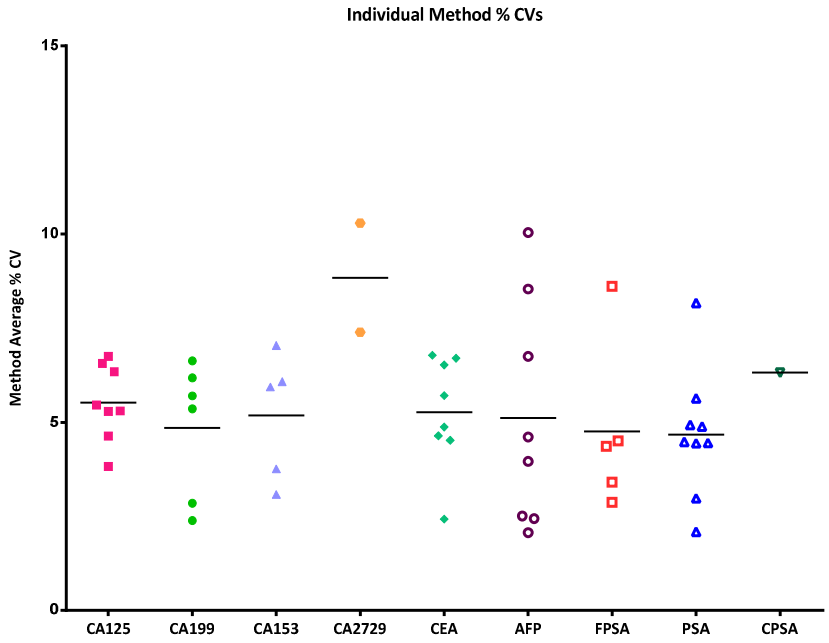
PSA (Table 7, Figure 7): Results were reported by 247 labs using instruments from eleven manufacturers, although two instruments were used by only one lab (N=1) and were therefore not included in Table 7. While there were substantial differences in total and free PSA measurements between methods, there were only minor differences in the proportion of free PSA between samples (Tables 8 A and B). Results from six of the peer groups were within +/-10% of the all method median, and these were between +7% and +19% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 13% above the all method median and 30% above the target (no lab used the WHO calibration). In contrast, the Siemens Immulite 1000/2000 was 19% below the all method median and 7% below the assigned targets, and Advia Centaur results were 11% lower than the all method median but 2% higher than the targets.

Free PSA (Table 8, Figure 8): Results were reported by 84 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 21% of the participants. The remaining three methods were used by 79% of labs with 36% Beckman Unicel/Access calibrated with the Hybritech standards, 25% of labs for Roche Elecsys/E170/Cobas, and 18% for Siemens Immulite 2000. Results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (33% higher than the all method medians and 54% higher than the targets), while there were 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% above to 10% below the assigned targets. All but the Beckman Unicel/Access methods were within 13% 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 8.8 to 9.1%. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA, but all were within 2.6% of the value calculated from the assigned targets.

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. Overall, the samples showed relatively good agreement with an average %CV of 6% (Table 9). On average, cPSA values were 12% lower than measured total PSA levels, which is slightly larger than would be expected from the %fPSA.

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 most are <10%.



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

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

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

Please be aware that even though the Instrument and Reagent fields will usually be pre-populated in EPTRS based on what was previously entered, it is still necessary to confirm that ALL instruments and reagents have been correctly entered prior to final submission, especially when you changed instruments. That information is critical to evaluate your results within the correct peer group. There have been instances where individual labs either **selected a qualifier (< or >) inadvertently or chose an incorrect instrument or reagent** while scrolling through the electronic reporting page lists. This can result in a **technical failure** for results evaluated outside of the correct peer group or an **administrative failure** for incorrect methodology. No changes can be made for incorrect or missing information after the submission deadline.

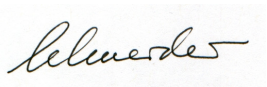
Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

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

The scheduled dates for the remaining 2015 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
May 5, 2015	May 20, 2015
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: 1-15 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									
TM281	10	50.0	**41.0**	**59.0**	9.0	5.98		1.10	
TM282	10	30.5	**25.0**	**36.0**	5.5	6.00		1.17	
TM283	10	17.2	**11.8**	**22.6**	5.4	7.27		1.17	
TM284	10	44.2	**36.2**	**52.2**	8.0	6.40		1.14	
TM285	10	32.6	**26.7**	**38.5**	5.9	7.15		1.14	
					mean ±SD	6.56	0.62	1.14	0.03
Beckman Unicel & Access/2 BCU/BCX									
TM281	23	53.2	**43.6**	**62.8**	9.6	5.51		1.17	
TM282	23	28.2	**22.8**	**33.6**	5.4	5.43		1.08	
TM283	23	15.8	**10.4**	**21.2**	5.4	5.76		1.07	
TM284	23	45.0	**36.9**	**53.1**	8.1	4.87		1.16	
TM285	23	33.2	**27.2**	**39.2**	6.0	4.88		1.16	
					mean ±SD	5.29	0.40	1.13	0.05
Roche Elecsys & Cobas BME/BMR									
TM281	18	36.3	**29.8**	**42.8**	6.5	5.21		0.80	
TM282	18	22.3	**16.9**	**27.7**	5.4	4.98		0.86	
TM283	19	12.4	**7.0**	**17.8**	5.4	5.08		0.84	
TM284	19	31.9	**26.2**	**37.6**	5.7	5.05		0.82	
TM285	19	23.4	**18.0**	**28.8**	5.4	6.20		0.82	
					mean ±SD	5.30	0.51	0.83	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM281	32	49.3	**40.4**	**58.2**	8.9	4.14		1.09	
TM282	32	28.3	**22.9**	**33.7**	5.4	4.38		1.09	
TM283	32	15.7	**10.3**	**21.1**	5.4	5.73		1.07	
TM284	32	42.3	**34.7**	**49.9**	7.6	4.44		1.09	
TM285	32	31.5	**25.8**	**37.2**	5.7	4.44		1.10	
					mean ±SD	4.63	0.63	1.09	0.01
Siemens Immulite 2000 DPB/DPD									
TM281	14	41.3	**33.9**	**48.7**	7.4	5.13		0.91	
TM282	14	23.8	**18.4**	**29.2**	5.4	7.23		0.92	
TM283	14	12.8	**7.4**	**18.2**	5.4	5.23		0.87	
TM284	14	35.2	**28.9**	**41.5**	6.3	6.82		0.91	
TM285	14	25.9	**20.5**	**31.3**	5.4	7.30		0.90	
					mean ±SD	6.34	1.07	0.90	0.02
Siemens Dimension Vista (LOCI) DUV									
TM281	4	30.6	**25.1**	**36.1**	5.5	4.74		0.68	
TM282	4	23.4	**18.0**	**28.8**	5.4	5.34		0.90	
TM283	4	13.7	**8.3**	**19.1**	5.4	6.06		0.93	
TM284	4	29.6	**24.2**	**35.0**	5.4	6.76		0.76	
TM285	4	20.9	**15.5**	**26.3**	5.4	4.40		0.73	
					mean ±SD	5.46	0.96	0.80	0.11
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM281	5	41.3	**33.9**	**48.7**	7.4	3.63		0.91	
TM282	5	22.5	**17.1**	**27.9**	5.4	4.27		0.87	
TM283	5	11.1	**5.7**	**16.5**	5.4	5.05		0.76	
TM284	5	34.0	**27.9**	**40.1**	6.1	2.50		0.88	
TM285	5	24.9	**19.5**	**30.3**	5.4	3.69		0.87	
					mean ±SD	3.83	0.93	0.84	0.06

continued on next page

Table 1 (cont.): 1-15 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									
TM281	6	57.5	**47.2**	**67.9**	10.4	6.26		1.27	
TM282	6	35.1	**28.8**	**41.4**	6.3	6.30		1.35	
TM283	6	19.9	**14.5**	**25.3**	5.4	5.78		1.35	
TM284	6	52.2	**42.8**	**61.6**	9.4	9.18		1.35	
TM285	6	37.5	**30.8**	**44.3**	6.8	6.21		1.31	
					mean ±SD	6.75	1.38	1.33	0.04

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM281	**111**	**45.3**	**5.25**	**3.63**	**6.26**
TM282	**111**	**26.0**	**5.38**	**4.27**	**7.20**
TM283	**112**	**14.7**	**5.75**	**5.05**	**7.27**
TM284	**112**	**38.8**	**5.21**	**2.50**	**9.18**
TM285	**112**	**28.7**	**5.54**	**3.69**	**7.15**

Average	**5.42**
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

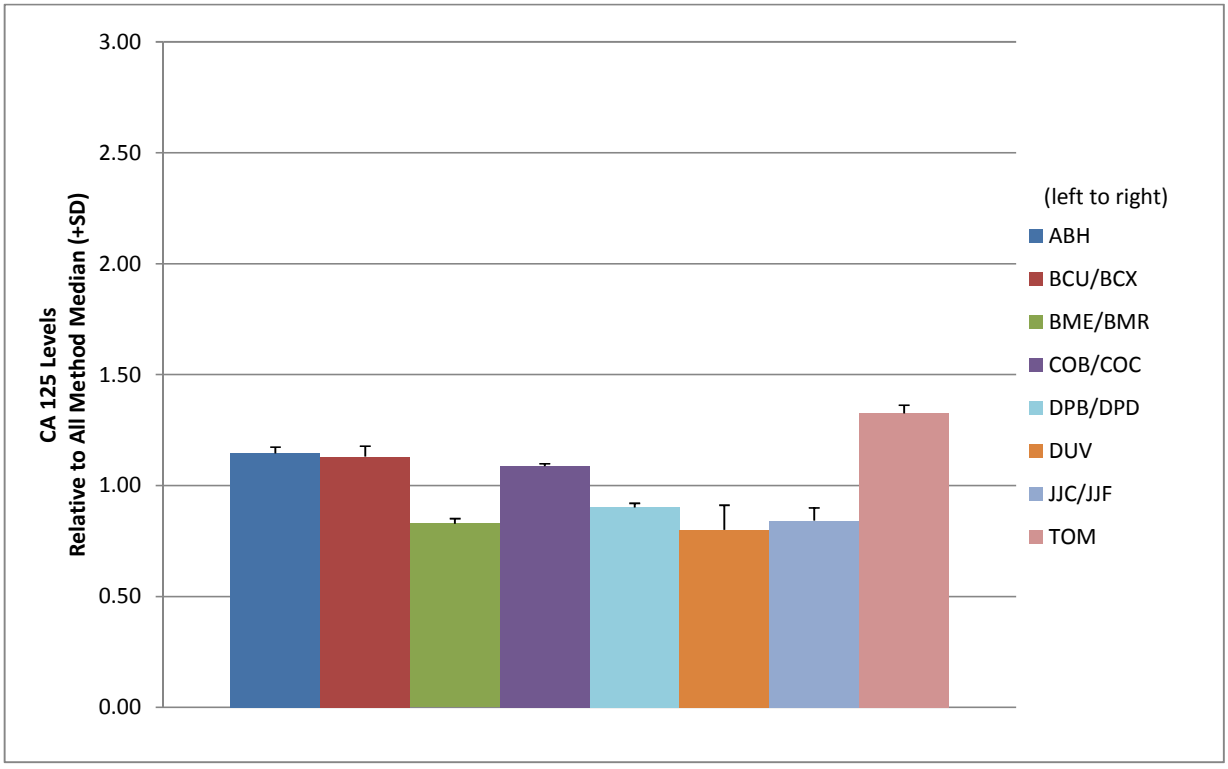


Table 2: 1-15 NYS Tumor Marker PT Summary for CA 19-9

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									
TM281	3	112.2	**92.0**	**132.4**	20.2	5.80		5.22	
TM282	3	232.2	**190.4**	**274.0**	41.8	5.64		5.22	
TM283	3	147.7	**121.1**	**174.3**	26.6	6.40		5.01	
TM284	3	388.9	**318.9**	**458.9**	70.0	3.31		4.81	
TM285	3	163.7	**134.2**	**193.2**	29.5	7.34		5.05	
					mean ±SD	5.70	1.49	5.06	0.17
Beckman Unicel & Access/2 BCU/BCX									
TM281	17	21.5	**17.6**	**25.4**	3.9	5.91		1.00	
TM282	17	44.5	**36.5**	**52.5**	8.0	5.51		1.00	
TM283	17	29.5	**24.2**	**34.8**	5.3	4.78		1.00	
TM284	17	80.8	**66.3**	**95.3**	14.5	4.79		1.00	
TM285	16	32.4	**26.6**	**38.2**	5.8	5.80		1.00	
					mean ±SD	5.36	0.54	1.00	0.00
Roche Elecsys & Cobas BME/BMR									
TM281	12	17.6	**14.0**	**21.2**	3.6	4.26		0.82	
TM282	12	34.7	**28.5**	**40.9**	6.2	1.87		0.78	
TM283	12	23.5	**19.3**	**27.7**	4.2	2.60		0.80	
TM284	12	58.1	**47.6**	**68.6**	10.5	2.20		0.72	
TM285	12	25.0	**20.5**	**29.5**	4.5	3.32		0.77	
					mean ±SD	2.85	0.96	0.78	0.04
Siemens Advia Centaur XP COB									
TM281	29	36.2	**29.7**	**42.7**	6.5	6.22		1.68	
TM282	29	75.4	**61.8**	**89.0**	13.6	6.86		1.69	
TM283	29	47.6	**39.0**	**56.2**	8.6	4.92		1.61	
TM284	29	148.2	**121.5**	**174.9**	26.7	6.40		1.83	
TM285	29	52.3	**42.9**	**61.7**	9.4	6.50		1.61	
					mean ±SD	6.18	0.74	1.69	0.09
Siemens Dimension Vista DUV									
TM281	3	23.2	**19.0**	**27.4**	4.2	2.37		1.08	
TM282	3	49.3	**40.4**	**58.2**	8.9	2.74		1.11	
TM283	3	32.3	**26.5**	**38.1**	5.8	2.69		1.09	
TM284	3	84.4	**69.2**	**99.6**	15.2	3.09		1.04	
TM285	3	33.7	**27.6**	**39.8**	6.1	1.07		1.04	
					mean ±SD	2.39	0.78	1.07	0.03
Tosoh AIA TOM									
TM281	6	14.7	**11.1**	**18.3**	3.6	9.86		0.68	
TM282	6	31.1	**25.5**	**36.7**	5.6	5.02		0.70	
TM283	6	20.1	**16.5**	**23.7**	3.6	7.11		0.68	
TM284	6	44.2	**36.2**	**52.2**	8.0	4.10		0.55	
TM285	6	20.0	**16.4**	**23.6**	3.6	7.05		0.62	
					mean ±SD	6.63	2.23	0.65	0.06

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Table 2 (cont.): 1-15 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM281	67	21.5	5.91	2.37	9.86
TM282	67	44.5	5.02	1.87	6.86
TM283	67	29.5	4.78	2.60	7.11
TM284	67	80.8	4.10	2.20	6.40
TM285	66	32.4	5.80	1.07	7.05
			Average 5.12	*Abbott excluded	

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

Figure 2: CA 19-9 Method Comparison

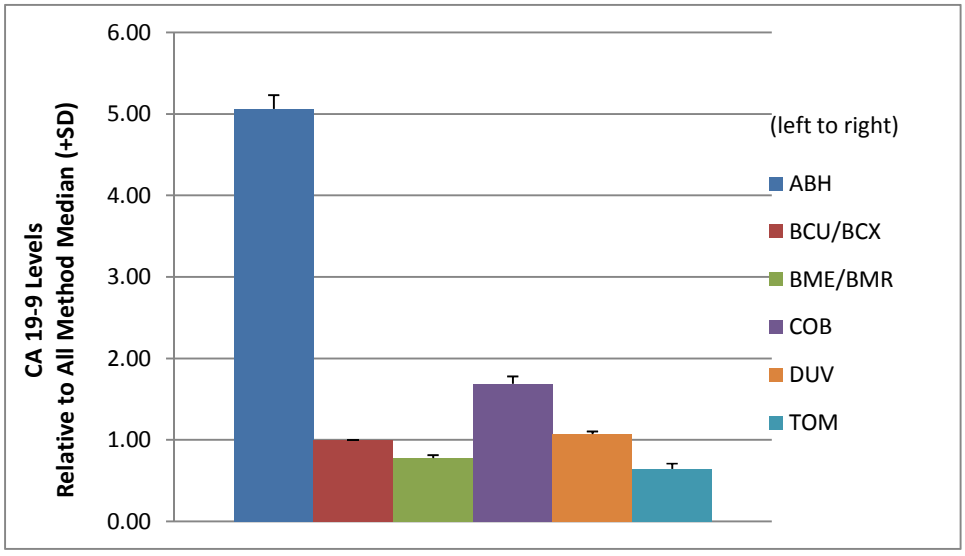

Table 3: 1-15 NYS Tumor Marker PT Summary for CA 15-3

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									
TM281	5	23.1	**18.9**	**27.3**	4.2	3.29		0.95	
TM282	5	67.3	**55.2**	**79.4**	12.1	1.60		0.96	
TM283	5	38.5	**31.6**	**45.4**	6.9	2.94		0.94	
TM284	5	51.1	**41.9**	**60.3**	9.2	4.81		0.96	
TM285	5	27.8	**22.8**	**32.8**	5.0	2.73		0.96	
					mean ±SD	3.08	1.33	0.96	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM281	9	17.3	**14.2**	**20.4**	3.1	4.34		0.71	
TM282	9	51.5	**42.2**	**60.8**	9.3	6.68		0.74	
TM283	9	28.7	**23.5**	**33.9**	5.2	7.25		0.70	
TM284	9	37.7	**30.9**	**44.5**	6.8	6.02		0.71	
TM285	9	20.6	**16.9**	**24.3**	3.7	6.12		0.71	
					mean ±SD	6.08	1.09	0.72	0.01
Roche Elecsys & Cobas BME/BMR									
TM281	14	24.6	**20.2**	**29.0**	4.4	4.67		1.02	
TM282	14	69.8	**57.2**	**82.4**	12.6	3.19		1.00	
TM283	14	40.8	**33.5**	**48.1**	7.3	3.95		1.00	
TM284	14	53.2	**43.6**	**62.8**	9.6	3.98		1.00	
TM285	14	29.0	**23.8**	**34.2**	5.2	3.00		1.00	
					mean ±SD	3.76	0.67	1.00	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM281	20	24.2	**19.8**	**28.6**	4.4	5.99		1.00	
TM282	20	70.4	**57.7**	**83.1**	12.7	8.04		1.01	
TM283	20	40.8	**33.5**	**48.1**	7.3	5.83		1.00	
TM284	20	54.0	**44.3**	**63.7**	9.7	7.04		1.02	
TM285	20	28.9	**23.7**	**34.1**	5.2	8.30		1.00	
					mean ±SD	7.04	1.14	1.00	0.01
Siemens Immulite 2000 DPD									
TM281	7	33.4	**27.4**	**39.4**	6.0	6.50		1.38	
TM282	7	103.4	**84.8**	**122.0**	18.6	6.35		1.48	
TM283	7	57.7	**47.3**	**68.1**	10.4	3.69		1.41	
TM284	7	74.7	**61.3**	**88.1**	13.4	6.76		1.40	
TM285	7	39.2	**32.1**	**46.3**	7.1	6.94		1.36	
					mean±SD	5.94	1.52	1.41	0.05

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

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM281	55	24.2		4.67	3.29	6.50
TM282	55	69.8		6.35	1.60	8.04
TM283	55	40.8		3.95	2.94	7.25
TM284	55	53.2		6.02	3.98	7.04
TM285	55	28.9		6.12	2.73	8.30
			Average	5.42		
			Allowable CV %	6.0		
			Allowable Error (+/-) %	18.0		

Figure 3: CA 15-3 Method Comparison

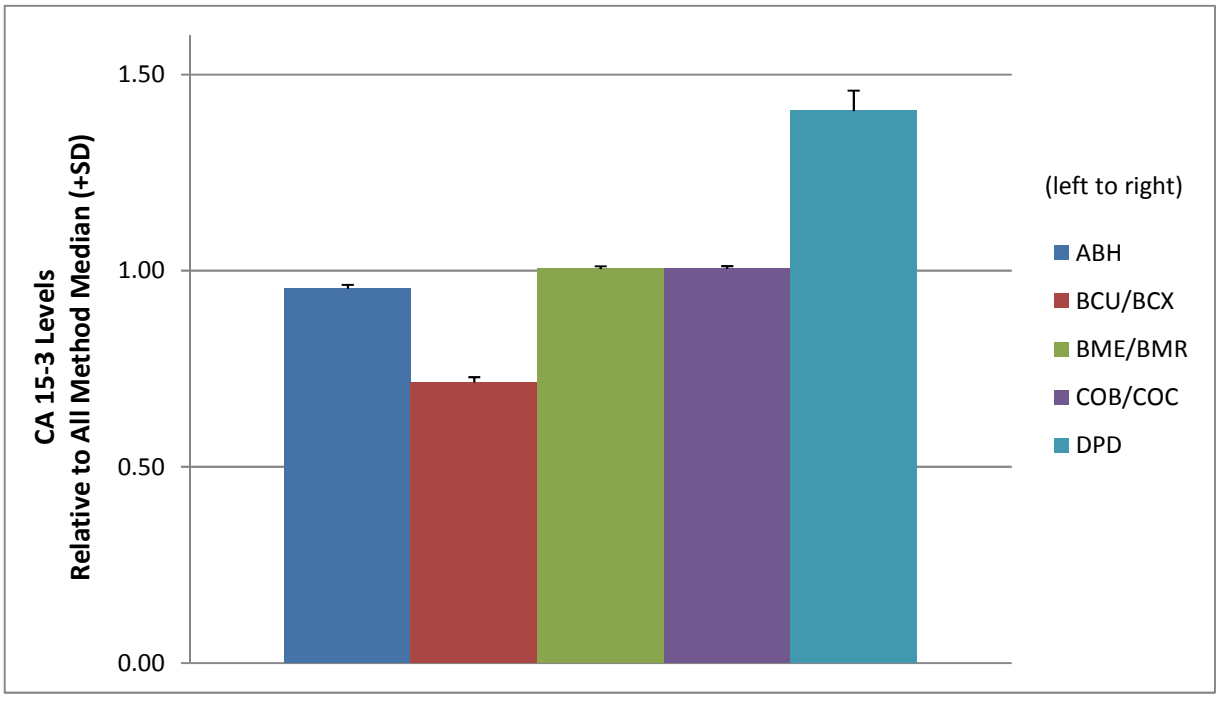

Table 4: 1-15 NYS Tumor Marker PT Summary for CA 27.29

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									
TM281	38	27.8	**19.4**	**36.2**	8.4	13.06		0.98	
TM282	38	90.9	**69.1**	**112.7**	21.8	8.98		1.05	
TM283	38	51.3	**39.0**	**63.6**	12.3	11.13		1.01	
TM284	38	70.4	**53.5**	**87.3**	16.9	7.87		1.06	
TM285	38	35.0	**26.6**	**43.4**	8.4	10.40		1.00	
					mean ±SD	10.29	2.00	1.02	0.04
Tosoh AIA TOM									
TM281	7	29.2	**20.8**	**37.6**	8.4	8.42		1.02	
TM282	7	81.9	**62.2**	**101.6**	19.7	6.69		0.95	
TM283	7	50.0	**38.0**	**62.0**	12.0	6.42		0.99	
TM284	7	62.4	**47.4**	**77.4**	15.0	9.55		0.94	
TM285	7	34.9	**26.5**	**43.3**	8.4	5.87		1.00	
					mean ±SD	7.39	1.54	0.98	0.04

Sample ID	N	All Method Median		Median % CV	Min %CV	Max %CV
TM281	**45**	**28.5**		**10.74**	**8.42**	**13.06**
TM282	**45**	**86.4**		**7.83**	**6.69**	**8.98**
TM283	**45**	**50.7**		**8.78**	**6.42**	**11.13**
TM284	**45**	**66.4**		**8.71**	**7.87**	**9.55**
TM285	**45**	**35.0**		**8.14**	**5.87**	**10.40**
			Average	**8.84**		
			Allowable CV %	**8.0**		
			Allowable Error if >/= 35 U/ml (+/-) %	**24.0**		
			Allowable Error if < 35 U/ml (+/- U/ml)	**8.4**		

Figure 4: CA 27.29 Method Comparison

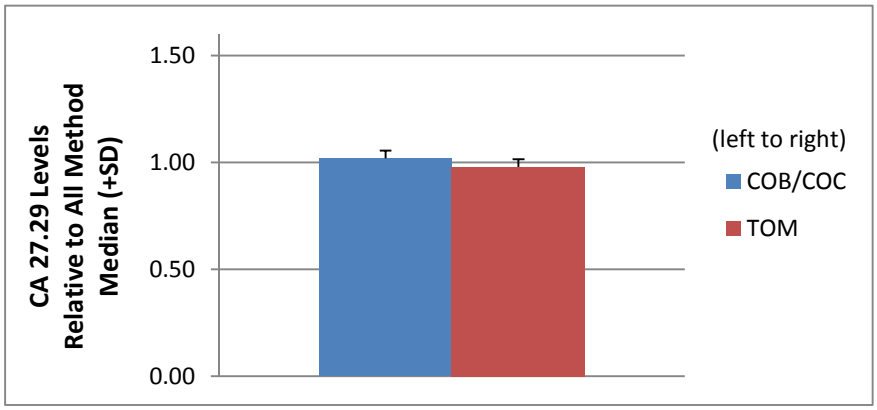

Table 5: 1-15 NYS Tumor Marker PT Summary for CEA

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									
TM281	15	4.4	**3.5**	**5.3**	0.9	5.45		1.01	
TM282	15	10.7	**8.8**	**12.6**	1.9	3.55		1.02	
TM283	15	10.8	**8.9**	**12.7**	1.9	3.89		1.03	
TM284	15	21.6	**17.7**	**25.5**	3.9	4.26		1.04	
TM285	15	9.7	**8.0**	**11.4**	1.7	5.46		1.02	
					mean ±SD	4.52	0.89	1.02	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM281	31	4.3	**3.4**	**5.2**	0.9	7.44		0.99	
TM282	31	10.2	**8.4**	**12.0**	1.8	6.57		0.97	
TM283	31	10.0	**8.2**	**11.8**	1.8	6.20		0.95	
TM284	31	19.6	**16.1**	**23.1**	3.5	6.02		0.95	
TM285	31	9.1	**7.5**	**10.7**	1.6	6.37		0.95	
					mean ±SD	6.52	0.55	0.96	0.02
Roche Elecsys & Cobas BME/BMR									
TM281	21	3.4	**2.5**	**4.3**	0.9	6.18		0.78	
TM282	21	8.1	**6.6**	**9.6**	1.5	4.94		0.77	
TM283	20	8.2	**6.7**	**9.7**	1.5	4.27		0.78	
TM284	21	16.4	**13.4**	**19.4**	3.0	4.82		0.79	
TM285	20	7.7	**6.3**	**9.1**	1.4	4.16		0.81	
					mean ±SD	4.87	0.80	0.79	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM281	45	4.2	**3.3**	**5.1**	0.9	6.43		0.97	
TM282	45	10.5	**8.6**	**12.4**	1.9	5.62		1.00	
TM283	45	10.3	**8.4**	**12.2**	1.9	6.21		0.98	
TM284	45	19.8	**16.2**	**23.4**	3.6	4.14		0.96	
TM285	45	9.4	**7.7**	**11.1**	1.7	6.17		0.98	
					mean ±SD	5.71	0.93	0.98	0.02
Siemens Immulite 1000/2000 DPB/DPD									
TM281	10	4.7	**3.8**	**5.6**	0.9	9.15		1.08	
TM282	10	12.2	**10.0**	**14.4**	2.2	7.62		1.16	
TM283	10	12.2	**10.0**	**14.4**	2.2	3.69		1.16	
TM284	10	24.5	**20.1**	**28.9**	4.4	5.06		1.18	
TM285	10	10.8	**8.9**	**12.7**	1.9	7.96		1.13	
					mean ±SD	6.70	2.25	1.14	0.04
Siemens Dimension Vista DUV									
TM281	23	4.0	**3.1**	**4.9**	0.9	2.50		0.92	
TM282	22	9.6	**7.9**	**11.3**	1.7	2.29		0.91	
TM283	22	9.6	**7.9**	**11.3**	1.7	2.60		0.91	
TM284	22	19.5	**16.0**	**23.0**	3.5	2.36		0.94	
TM285	23	8.8	**7.2**	**10.4**	1.6	2.39		0.92	
					mean ±SD	2.43	0.12	0.92	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM281	12	5.0	**4.1**	**5.9**	0.9	12.40		1.15	
TM282	12	10.5	**8.6**	**12.4**	1.9	5.62		1.00	
TM283	12	10.7	**8.8**	**12.6**	1.9	5.14		1.02	
TM284	12	21.7	**17.8**	**25.6**	3.9	4.42		1.05	
TM285	11	10.3	**8.4**	**12.2**	1.9	6.31		1.08	
					mean ±SD	6.78	3.22	1.06	0.06

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Table 5 (cont.): 1-15 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									
TM281	7	6.2	**5.1**	**7.3**	1.1	2.90		1.43	
TM282	7	15.0	**12.3**	**17.7**	2.7	3.93		1.43	
TM283	7	14.8	**12.1**	**17.5**	2.7	5.88		1.41	
TM284	7	28.6	**23.5**	**33.7**	5.1	5.42		1.38	
TM285	7	13.6	**11.2**	**16.0**	2.4	5.07		1.42	
					mean ±SD	4.64	1.21	1.41	0.02

Sample ID	N	All Method Median	Median % CV	Min %CV	Max %CV
TM281	**164**	**4.4**	**6.30**	**2.50**	**12.40**
TM282	**163**	**10.5**	**5.28**	**2.29**	**7.62**
TM283	**162**	**10.5**	**4.70**	**2.60**	**6.21**
TM284	**163**	**20.7**	**4.62**	**2.36**	**6.02**
TM285	**162**	**9.6**	**5.82**	**2.39**	**7.96**

Average	**5.34**
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

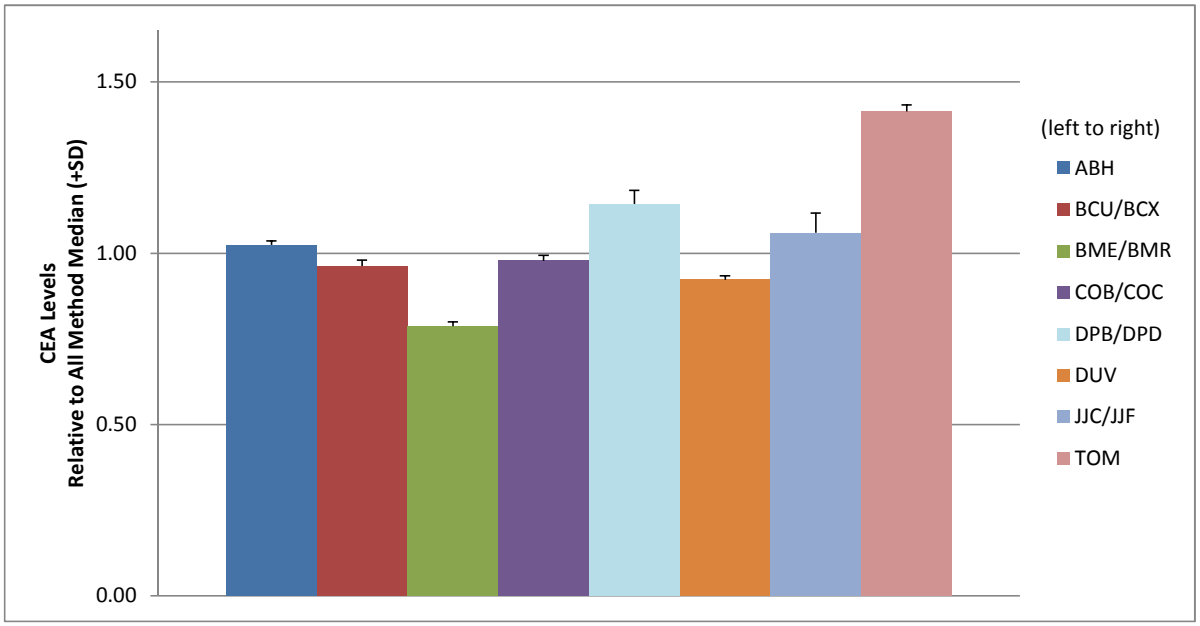

Table 6: 1-15 NYS Tumor Marker PT Summary for AFP

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											
TM281	5	10.6	**10.0**	**11.2**	0.6	1.79		0.98		1.11	
TM282	5	21.8	**20.1**	**23.5**	1.7	2.66		1.00		1.11	
TM283	5	5.3	**5.0**	**5.6**	0.3	2.08		0.97		1.04	
TM284	5	33.4	**32.3**	**34.5**	1.1	1.08		1.01		1.13	
TM285	5	14.1	**12.2**	**16.1**	2.0	4.61		1.00		1.11	
					mean ±SD	2.44	1.34	0.99	0.02	1.10	0.04
Beckman Unicel & Access/2 BCU/BCX											
TM281	27	10.6	**8.4**	**12.8**	2.2	6.89		0.98		1.11	
TM282	27	21.6	**17.0**	**26.2**	4.6	7.04		1.00		1.10	
TM283	27	5.4	**4.4**	**6.4**	1.0	6.30		0.99		1.05	
TM284	26	32.6	**26.6**	**38.6**	6.0	6.10		0.99		1.10	
TM285	27	14.1	**11.0**	**17.3**	3.2	7.45		1.00		1.11	
					mean ±SD	6.75	0.55	0.99	0.01	1.09	0.02
Roche Elecsys & Cobas BME/BMR											
TM281	14	11.4	**9.9**	**12.9**	1.5	4.39		1.06		1.19	
TM282	14	23.7	**20.6**	**26.8**	3.1	4.35		1.09		1.21	
TM283	15	6.0	**5.0**	**7.0**	1.0	5.50		1.10		1.17	
TM284	15	36.4	**31.9**	**40.9**	4.5	4.09		1.10		1.23	
TM285	15	15.5	**13.3**	**17.7**	2.2	4.71		1.10		1.22	
					mean ±SD	4.61	0.55	1.09	0.02	1.20	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM281	27	11.0	**7.6**	**14.4**	3.4	10.18		1.02		1.15	
TM282	27	21.0	**16.3**	**25.7**	4.7	7.52		0.97		1.07	
TM283	27	5.5	**2.7**	**8.3**	2.8	16.91		1.01		1.07	
TM284	27	32.1	**25.1**	**39.2**	7.1	7.32		0.97		1.09	
TM285	27	14.2	**10.7**	**17.7**	3.5	8.24		1.00		1.12	
					mean ±SD	10.04	4.01	0.99	0.02	1.10	0.03
Siemens Immulite 1000 & 2000 DPB/DPD											
TM281	11	11.0	**8.1**	**13.9**	2.9	8.73		1.02		1.15	
TM282	11	23.0	**17.6**	**28.4**	5.4	7.78		1.06		1.17	
TM283	11	5.5	**3.9**	**7.1**	1.6	9.64		1.01		1.07	
TM284	11	34.5	**26.5**	**42.5**	8.0	7.74		1.05		1.17	
TM285	11	14.6	**10.7**	**18.5**	3.9	8.84		1.03		1.15	
					mean ±SD	8.54	0.80	1.03	0.02	1.14	0.04
Siemens Dimension Vista DUV											
TM281	6	10.1	**9.4**	**10.8**	0.7	2.38		0.94		1.05	
TM282	6	20.6	**19.4**	**21.8**	1.2	1.89		0.95		1.05	
TM283	6	5.2	**4.8**	**5.6**	0.4	2.31		0.95		1.02	
TM284	6	31.7	**30.4**	**33.0**	1.3	1.39		0.96		1.07	
TM285	6	13.7	**12.7**	**14.7**	1.0	2.41		0.97		1.08	
					mean ±SD	2.07	0.44	0.95	0.01	1.05	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM281	6	8.3	**7.3**	**9.3**	1.0	3.86		0.77		0.87	
TM282	6	15.5	**13.6**	**17.4**	1.9	4.00		0.71		0.79	
TM283	6	4.5	**3.8**	**5.2**	0.7	5.33		0.83		0.88	
TM284	6	23.5	**20.9**	**26.1**	2.6	3.70		0.71		0.80	
TM285	6	10.6	**9.7**	**11.5**	0.9	2.92		0.75		0.83	
					mean ±SD	3.96	0.87	0.75	0.05	0.83	0.04

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Table 6 (cont.): 1-15 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											
TM281	4	11.8	**10.7**	**12.9**	1.1	3.05		1.09		1.23	
TM282	4	23.8	**22.5**	**25.1**	1.3	1.81		1.10		1.21	
TM283	4	6.1	**5.6**	**6.6**	0.5	2.95		1.12		1.19	
TM284	4	36.1	**32.2**	**40.0**	3.9	3.60		1.09		1.22	
TM285	4	16.0	**15.5**	**16.5**	0.5	1.13		1.13		1.26	
					mean ±SD	2.51	1.01	1.11	0.02	1.22	0.02

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max %CV		All Method Median/ IS Target	
TM281	**99**	**10.8**	**9.6**	**1.05**		**4.12**	**1.79**	**10.18**		**1.13**	
TM282	**99**	**21.7**	**19.7**	**0.86**		**4.17**	**1.81**	**8.17**		**1.10**	
TM283	**100**	**5.5**	**5.1**	**1.13**		**5.42**	**2.08**	**16.91**		**1.06**	
TM284	**99**	**33.0**	**29.5**	**2.39**		**3.90**	**1.08**	**8.05**		**1.12**	
TM285	**100**	**14.2**	**12.7**	**1.62**		**4.66**	**1.13**	**9.32**		**1.11**	
					Average	**4.45**			mean ±SD	**1.10**	0.02

Allowable Error = +/-3SD

Figure 6: AFP Method Comparison

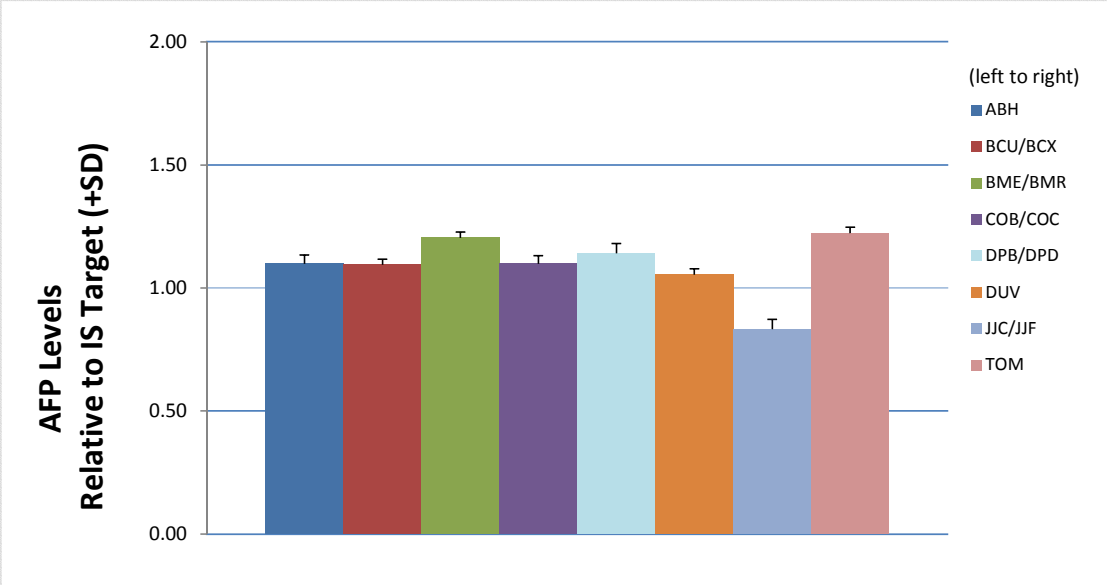

Table 7: 1-15 NYS Tumor Marker PT Summary for PSA

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											
TM281	18	3.44	**2.82**	**4.06**	0.62	4.36		1.04		1.21	
TM282	18	1.72	**1.41**	**2.03**	0.31	4.65		1.04		1.16	
TM283	18	17.18	**14.09**	**20.27**	3.09	4.83		1.06		1.19	
TM284	18	5.27	**4.32**	**6.22**	0.95	4.36		1.01		1.19	
TM285	18	8.53	**6.99**	**10.07**	1.54	3.99		1.01		1.19	
					mean ±SD	4.44	0.32	1.03	0.02	1.19	0.02
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM281	52	3.71	**3.04**	**4.38**	0.67	5.12		1.12		1.30	
TM282	52	1.82	**1.49**	**2.15**	0.33	4.95		1.10		1.23	
TM283	52	19.06	**15.63**	**22.49**	3.43	5.14		1.18		1.32	
TM284	52	5.84	**4.79**	**6.89**	1.05	5.14		1.12		1.32	
TM285	52	9.55	**7.83**	**11.27**	1.72	4.29		1.13		1.33	
					mean ±SD	4.93	0.36	1.13	0.03	1.30	0.04
Roche Elecsys & Cobas BME/BMR											
TM281	35	3.15	**2.58**	**3.72**	0.57	4.76		0.95		1.11	
TM282	36	1.60	**1.31**	**1.89**	0.29	6.88		0.97		1.08	
TM283	38	15.70	**12.87**	**18.53**	2.83	6.82		0.97		1.09	
TM284	36	4.90	**4.02**	**5.78**	0.88	4.49		0.94		1.10	
TM285	37	8.02	**6.58**	**9.46**	1.44	5.24		0.95		1.12	
					mean ±SD	5.64	1.14	0.96	0.01	1.10	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM281	52	2.97	**2.44**	**3.50**	0.53	4.04		0.90		1.04	
TM282	53	1.51	**1.24**	**1.78**	0.27	4.64		0.92		1.02	
TM283	53	14.43	**11.83**	**17.03**	2.60	5.20		0.89		1.00	
TM284	53	4.56	**3.74**	**5.38**	0.82	4.17		0.88		1.03	
TM285	53	7.35	**6.03**	**8.67**	1.32	4.22		0.87		1.03	
					mean ±SD	4.45	0.47	0.89	0.02	1.02	0.02
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)											
TM281	17	2.70	**2.21**	**3.19**	0.49	9.63		0.82		0.95	
TM282	17	1.32	**1.08**	**1.56**	0.24	9.85		0.80		0.89	
TM283	17	13.51	**11.08**	**15.94**	2.43	8.29		0.84		0.94	
TM284	17	4.18	**3.43**	**4.93**	0.75	5.98		0.80		0.94	
TM285	17	6.74	**5.53**	**7.95**	1.21	7.12		0.80		0.94	
					mean ±SD	8.17	1.65	0.81	0.02	0.93	0.02
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM281	14	3.30	**2.71**	**3.89**	0.59	4.24		1.00		1.16	
TM282	14	1.65	**1.35**	**1.95**	0.30	4.85		1.00		1.11	
TM283	14	16.71	**13.70**	**19.72**	3.01	3.59		1.04		1.16	
TM284	14	5.20	**4.26**	**6.14**	0.94	5.00		1.00		1.17	
TM285	14	8.48	**6.95**	**10.01**	1.53	4.72		1.00		1.18	
					mean±SD	4.48	0.57	1.01	0.02	1.16	0.03
Siemens Dimension Vista DUV											
TM281	22	3.43	**2.81**	**4.05**	0.62	2.33		1.04		1.20	
TM282	22	1.72	**1.41**	**2.03**	0.31	2.33		1.04		1.16	
TM283	22	17.14	**14.05**	**20.23**	3.09	2.22		1.06		1.19	
TM284	21	5.35	**4.39**	**6.31**	0.96	2.06		1.03		1.20	
TM285	20	8.67	**7.11**	**10.23**	1.56	1.50		1.03		1.21	
					mean ±SD	2.09	0.35	1.04	0.01	1.19	0.02

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Table 7 (cont.): 1-15 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											
TM281	20	3.12	**2.56**	**3.68**	0.56	5.13		0.95		1.09	
TM282	21	1.64	**1.34**	**1.94**	0.30	5.49		0.99		1.11	
TM283	21	14.94	**12.25**	**17.63**	2.69	4.75		0.93		1.03	
TM284	21	4.70	**3.85**	**5.55**	0.85	4.04		0.90		1.06	
TM285	21	7.56	**6.20**	**8.92**	1.36	5.03		0.90		1.05	
					mean ±SD	4.89	0.54	0.93	0.04	1.07	0.03
Tosoh AIA TOM											
TM281	8	3.36	**2.76**	**3.96**	0.60	2.38		1.02		1.18	
TM282	8	1.69	**1.39**	**1.99**	0.30	2.96		1.02		1.14	
TM283	8	16.14	**13.23**	**19.05**	2.91	3.66		1.00		1.12	
TM284	8	5.21	**4.27**	**6.15**	0.94	3.65		1.00		1.17	
TM285	8	8.44	**6.92**	**9.96**	1.52	2.25		1.00		1.18	
					mean ±SD	2.98	0.67	1.01	0.01	1.16	0.03

Sample ID	N	All Method Median	IS based Target	SD		Median % CV	Min %CV	Max % CV		All Method Median/ IS Target	
TM281	**238**	**3.30**	**2.85**	**0.14**		**4.36**	**2.33**	**9.63**		**1.16**	
TM282	**241**	**1.65**	**1.48**	**0.08**		**4.85**	**2.33**	**9.85**		**1.11**	
TM283	**243**	**16.14**	**14.44**	**0.90**		**4.83**	**2.22**	**8.29**		**1.12**	
TM284	**240**	**5.20**	**4.44**	**0.22**		**4.36**	**2.06**	**5.98**		**1.17**	
TM285	**240**	**8.44**	**7.17**	**0.39**		**4.29**	**1.50**	**7.12**		**1.18**	
					Average	**4.54**			mean ±SD	**1.15**	0.03
					Allowable CV %	**6.00**					
					Allowable Error (+/-)%	**18.0**					

Figure 7: PSA Method Comparison

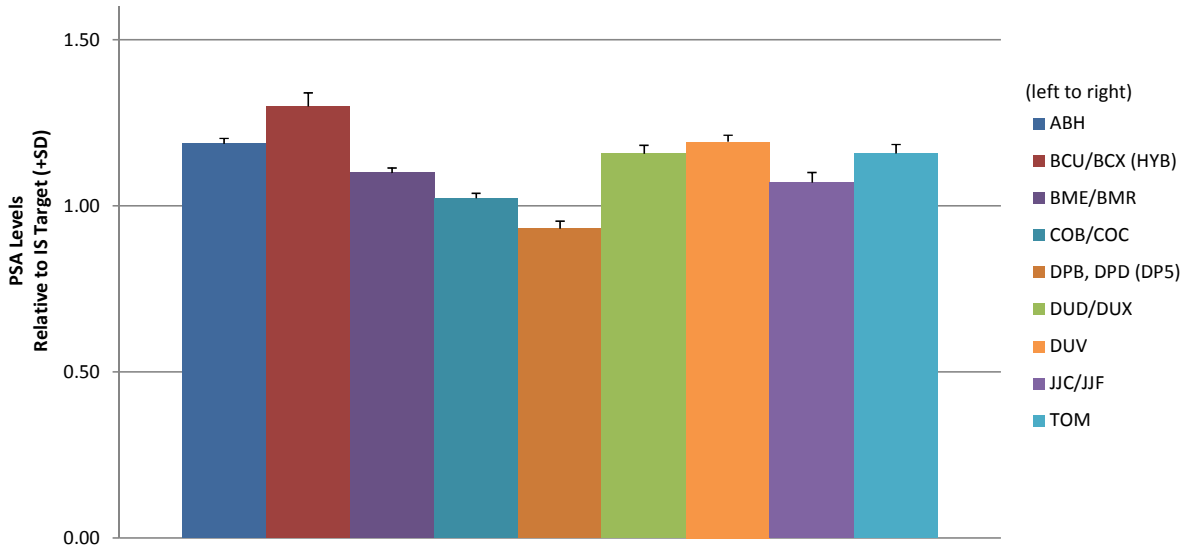

Table 8: 1-15 NYS Tumor Marker PT Summary for Free PSA

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													
TM281	6	0.30	**0.21**	**0.39**	0.09	1.67		1.03		1.21		8.7%	
TM282	6	0.14	**0.05**	**0.23**	0.09	0.00		1.00		1.21		8.1%	
TM283	6	1.47	**1.21**	**1.73**	0.26	3.47		1.04		1.18		8.6%	
TM284	6	0.45	**0.36**	**0.54**	0.09	3.33		1.05		1.21		8.5%	
TM285	6	0.74	**0.61**	**0.87**	0.13	4.86		1.03		1.17		8.7%	
					mean ±SD	2.67	1.87	1.03	0.02	1.20	0.02	8.5%	0.2%
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)													
TM281	29	0.39	**0.30**	**0.48**	0.09	5.64		1.34		1.57		10.5%	
TM282	29	0.19	**0.10**	**0.28**	0.09	6.32		1.36		1.64		10.4%	
TM283	30	1.79	**1.47**	**2.11**	0.32	4.41		1.27		1.44		9.4%	
TM284	29	0.58	**0.48**	**0.68**	0.10	3.97		1.35		1.56		9.9%	
TM285	29	0.94	**0.77**	**1.11**	0.17	4.36		1.31		1.48		9.8%	
					mean ±SD	4.94	0.99	1.33	0.04	1.54	0.08	10.0%	0.5%
Roche Elecsys & Cobas BME/BMR													
TM281	17	0.29	**0.20**	**0.38**	0.09	2.41		1.00		1.17		9.2%	
TM282	18	0.15	**0.06**	**0.24**	0.09	5.33		1.07		1.29		9.4%	
TM283	21	1.41	**1.16**	**1.66**	0.25	4.33		1.00		1.13		9.0%	
TM284	21	0.43	**0.34**	**0.52**	0.09	5.35		1.00		1.15		8.8%	
TM285	19	0.72	**0.59**	**0.85**	0.13	2.36		1.00		1.13		9.0%	
					mean ±SD	3.96	1.49	1.01	0.03	1.18	0.07	9.1%	0.2%
Siemens Immulite 2000 DPD													
TM281	15	0.26	**0.17**	**0.35**	0.09	10.38		0.90		1.05		9.6%	
TM282	14	0.12	**0.03**	**0.21**	0.09	10.83		0.86		1.03		9.1%	
TM283	15	1.31	**1.07**	**1.55**	0.24	6.26		0.93		1.05		9.7%	
TM284	15	0.39	**0.30**	**0.48**	0.09	8.46		0.91		1.05		9.3%	
TM285	15	0.64	**0.52**	**0.76**	0.12	9.84		0.89		1.01		9.5%	
					mean ±SD	9.16	1.85	0.90	0.03	1.04	0.02	9.4%	0.2%
Siemens Dimension Vista DUV													
TM281	8	0.26	**0.17**	**0.35**	0.09	1.92		0.90		1.05		7.6%	
TM282	9	0.12	**0.03**	**0.21**	0.09	7.50		0.86		1.03		7.0%	
TM283	9	1.28	**1.05**	**1.51**	0.23	2.89		0.91		1.03		7.5%	
TM284	8	0.39	**0.30**	**0.48**	0.09	1.54		0.91		1.05		7.3%	
TM285	8	0.66	**0.54**	**0.78**	0.12	3.64		0.92		1.04		7.6%	
					mean ±SD	3.50	2.38	0.90	0.02	1.04	0.01	7.4%	0.3%

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Table 8 (cont.): 1-15 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
TM281	75	0.29	0.25	0.030		2.41	1.17		8.7%		8.8%
TM282	76	0.14	0.12	0.01		6.32	1.21		7.8%		8.5%
TM283	81	1.41	1.24	0.16		4.33	1.13		8.6%		8.7%
TM284	79	0.43	0.37	0.05		3.97	1.15		8.4%		8.3%
TM285	77	0.72	0.63	0.10		4.36	1.13		8.8%		8.5%
							mean	±SD	mean	±SD	mean
					Average	4.28	1.16	0.03	8.5%	0.004	8.53%
					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

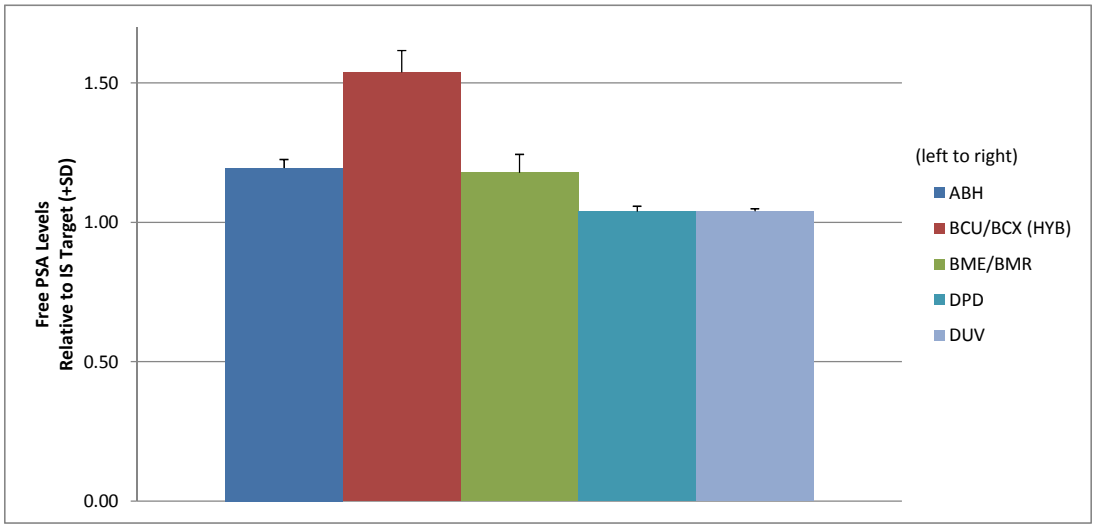

Figure 8B: Calculated % Free PSA Method Comparison

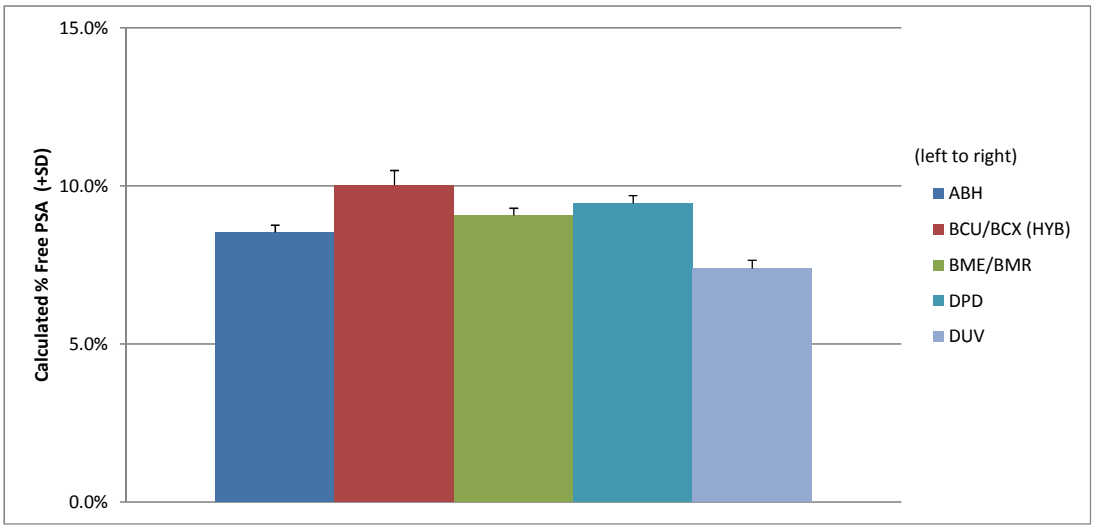

Table 9: 1-15 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM281	7	2.9	**2.4**	**3.4**	0.5	7.24		1.00	
TM282	7	1.5	**1.2**	**1.7**	0.3	5.44		1.00	
TM283	7	14.3	**11.7**	**16.8**	2.6	6.10		1.00	
TM284	7	4.5	**3.7**	**5.3**	0.8	5.56		1.00	
TM285	7	7.2	**5.9**	**8.5**	1.3	7.25		1.00	
					mean ±SD	6.32	0.88	1.00	0.00

Sample ID	All Method Median		Median % CV
TM281	**2.9**		**7.24**
TM282	**1.5**		**5.44**
TM283	**14.3**		**6.10**
TM284	**4.5**		**5.56**
TM285	**7.2**		**7.25**
		Average	**6.32**
		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

		TM281	TM282	TM283	TM284	TM285
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