NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

May 8, 2012

IMPORTANT INSTRUCTIONS—PLEASE READ

TO: Laboratory Director

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

SUBJECT: **ONCOLOGY - SERA AND SOLUBLE TUMOR MARKERS PROFICIENCY TESTING**

DUE DATE: **May 23, 2012**

Samples:
Enclosed are five sealed (5) vials labeled **TM241 to TM245**, each containing proficiency test specimens in a human-derived serum base, sterile filtered and dispensed. All materials used to prepare the samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, universal precautions should be followed when handling samples. **Keep refrigerated** until use, but **do not freeze**. Make sure samples are completely mixed before analyzing.

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

If your lab measures **free** and/or **complexed PSA** in addition to **total PSA**, you are required to measure it in **ALL** of the samples, however, labs are no longer required to calculate % free PSA. If your lab measures total PSA by a **second method** in conjunction with free PSA, enter those results in the corresponding fields of PSA for a 2nd method.

All laboratories must submit their proficiency testing results through the internet based electronic proficiency testing reporting system (EPTRS) on the Department's Health Commerce System (HCS). The HCS is a secure website and requires all users to obtain an ID in order to access the HCS and EPTRS application. Questions regarding the entry and submission of proficiency test results or the account application process can be emailed to clepeptrs@health.state.ny.us.

The **Event Menu** page includes a space to enter your lab's **upper limit of normal reference range**, i.e. cut-off value, for each individual analyte measured. It should indicate the highest result measurement that would be **considered NORMAL** as reported back to a physician. Please enter this value with the same precision as you report your results for that analyte. Please note that we are no longer asking for interpretations with respect to this cut-off.

Results must be submitted electronically before 11:59 PM on May 23, 2012. It is advisable to submit earlier to allow time to resolve any problem that could occur with result submission.

Results not submitted by the due date are categorized as missing with an administrative **failure** and receive a failing grade, even if results were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must **contact the PT section by email as soon as possible before the due date** to see if this can be arranged.

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. **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 possibly in test failure if it causes your results to be evaluated with the wrong peer group.**

Choose the appropriate selection from the test status list on the event menu page and indicate if your lab has temporarily suspended or permanently stopped testing for an analyte. 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. When a test is 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 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 any correspondence regarding the Oncology PT contact:

Tumor Marker Proficiency Testing c/o Susanne McHale
Wadsworth Center, Room E600
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509
or
e-mail: smchale@wadsworth.org

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

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

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

The remaining 2012 Oncology Tumor Marker Proficiency Test mail-out is scheduled as follows:

Mail-out date:	Due date:
September 11, 2012	**September 26, 2012**

NEW YORK
state department of
HEALTH

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

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June 15, 2012

New York State Tumor Marker Proficiency Test 5-2012 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from May 8, 2012 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

Samples:

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. Analyte levels were pre-assayed and stability tested in our laboratory. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation (please note the recent change in report format):

Your laboratory's individual results, scores and grade plus scores from the previous two PT events with your overall performance status are displayed on a separate report that has been securely posted on the Department's Health Commerce System site:

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

Laboratory contacts should have already received an email alert indicating the availability of that report.

This critique along with its summary tables and graphs is sent by email to laboratory contacts and will also posted on our section's website:

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

Additionally, it can be accessed through the "Statistical" link from the Health Commerce site.

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

[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.

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®5 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. The allowable error and range were determined from the average of the median %CV's for each sample across all methods (see summary tables); allowances for increased scatter at low concentrations were made for some analytes. Please note that, unless indicated otherwise, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, except where the linear regression line between the results from two instruments showed a significant ($p<0.01$) deviation from identity. In order for you to more easily 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.** Thus, D/Dmax needs to be between –1 and +1 for a result to be considered correct. **Note: If your D/Dmax is not within +/- 0.66, 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 well as it should. Furthermore, if your **average D/Dmax is greater than +/- 0.5,** then your results exhibited a substantial high or low bias when 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 >1). 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 117 labs using 14 different methods or instruments. Combining results from different instruments made by the same manufacturer and/or brand resulted in seven peer groups. Of the seven peer groups, five included ten or more labs each and together comprised 89% of the labs. Four peer groups comprising 57% of the labs gave results within +/-15% of the all method medians. Of the other three groups, Roche and Siemens Immulite were -15% and -18% from the median, respectively, while TOSOH ST-AIA (used by five labs only representing about 4% of the participants) gave the highest results averaging 39% above the all method medians.

CA19-9 (Table 2, Figure 2): Results were reported by 69 labs using nine methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in five peer groups. Fifty-two percent of all reporting labs used Siemens ADVIA-Centaur XP, 16% used either Beckman Unicel or Access/2, 19% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 7% used the Tosoh ST-AIA method. Clearly, there were large differences in how each method measured CA19-9, with only the Roche and Beckman methods within +/-15% of the all method median. Measurements by Tosoh ST-AIA were lower than the medians by an average of 36%, whereas on the opposite side, the results from the Siemens ADVIA-Centaur XP were on average almost twice as high as the all method median. Notable once again is that the Abbott Architect method (used by only 2 labs) gave measurements for CA19-9 averaging over five times higher than the all method medians. These high measurements by the Abbott Architect are consistent with previous CA19-9 NYS PT results by this method as well as the latest CAP results (TM-A 2012). Looking at the results from all the methods, there continues to be substantial discordance between the various methods used to measure CA19-9, at least under the conditions of the NYS PT.

The MUC1 breast cancer antigen was measured by 108 labs, with slightly more than half (54%) using one of eleven **CA15-3** methods (Table 3, Figure 3) and the remainder using one of three methods for **CA27.29** (Table 4, Figure 4). For **CA15-3**, combining results from different instruments made by the same manufacturer and/or brand resulted in six peer groups, four of which comprised less than ten labs each. Abbott, Roche and Ortho Clinical were within +/-15% of the all method median. Of the others, Siemens ADVIA-Centaur methods (used by 38% of the labs) exhibited a positive bias of +15%, while Siemens Immulite 2000 & 2500 systems (used by 16% of labs) averaged +21% compared to the median. In contrast, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -37% from the all method medians. Of the methods used for measuring **CA27.29**, the ADVIA Centaur XP combined with CP and the Tosoh method showed only a 6% difference from each other. Interestingly, the reproducibility of the Siemens Advia methods seems strongly dependent on the level of CA27.29 in the samples. The two samples with the lowest concentrations, TM242 and TM244, had % CVs of 16.3% and 11.0%, respectively, which is substantially larger than for the other samples, and also was not observed with the Tosoh method.

CEA (Table 5, Figure 5): Results were reported by 173 labs using 14 different methods. After combining results from different instruments made by the same manufacturer and/or brand, there remained eight peer groups comprising from 6 to 50 labs. Overall, the results reported by the majority of the labs (82%) were fairly consistent, being within +/-10% of the medians. The two exceptions were the Roche methods, which averaged 24% below the medians, and the TOSOH ST-AIA measurements that once again exhibited a high positive bias averaging 50% higher than the medians. Overall, these results are consistent with what has been seen in previous events, but also showed that the majority of the methods are reasonably well harmonized.

For **AFP, PSA and free PSA,** target values were assigned using traceable International Standards. However, for grading purposes the results were evaluated and received a passing score if they fell within their peer group-specific acceptable ranges. For the purpose of method comparison, however, the bias against both the assigned target values as well as the all method medians are shown in the respective tables, but the graphs only show the performance relative to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 103 labs using 12 different methods. After combining results from different instruments made by the same manufacturer and/or brand eight peer groups remained. Four of those comprised less than ten labs each, together making up nineteen percent of the total number of labs. All methods except the Ortho Clinical Diagnostics Vitros peer group (used by 28% of participants) showed results that on average were 15% above the assigned International Standards-based targets, but showed little deviation from each other. The exceptions were the Ortho Vitros peer group (Eci, EciQ and 5600) at -22% from the all method median, and Roche (Elecsys and Cobas) with a positive bias of +15%. These results are similar to what has been observed in previous PT events for these methods.

PSA (Table 7, Figures 7A&B): Results were reported by 259 labs using 21 different methods. After combining results from different instruments made by the same manufacturer and/or brand there remained 11 peer groups, three of which comprised fewer than ten labs each. The five samples were all prepared with varied concentrations of total PSA but with the same proportion of 25% free PSA. As observed in previous PT events, results could be grouped into a low and a high group that were statistically significantly different (P=0.0021) (Figure 7B). The high group comprised Beckman Unicel and Access with the Hybritech calibration; Siemens Immulite instruments using the original PSA pack; Siemens Dimension RxL Max, Xpand Plus, and EXL; and Siemens Immulite Third Generation, though the latter fell in between the low and high groups. Overall, the results for those methods ranged from 19-31% higher than the assigned targets (mean 1.26±0.05). The low group comprised Abbott AxSym and Architect; Beckman Unicel and Access with the WHO calibration; Roche Elecsys and Cobas; Siemens ADVIA Centaur XP/CP; Siemens Dimension Vista; Ortho Vitros ECi, ECiQ, and 5600; and Tosoh AIA with the results ranging from 2% to 13% above the assigned targets (mean 1.09±0.04). There was a clear difference between the Beckman groups as those calibrated using the original Hybritech standard measured on average 27% higher than the targets, while those calibrated with the international WHO standard measured the closest to the target of any method, averaging just 2% above the assigned targets. This represents a 25% difference, but overall is consistent with the information Beckman has supplied indicating a 22% difference between the Hybritech and

WHO calibrated methods (Access Hybritech PSA Hybritech and WHO Calibration Information #A59476A, 2008). In conclusion, although the concordance between the methods within their respective high or low group is excellent (intermethod %CVs <5%), the difference between the high and low groups is significant and consistent with what is seen in patient samples.

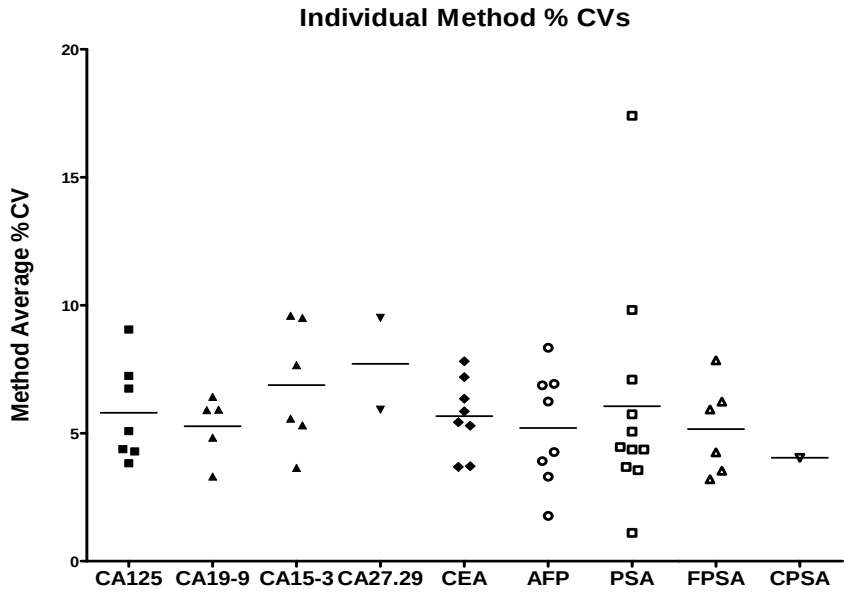
Free PSA (Table 8, Figure 8): Results were reported by 87 labs using eleven different methods. After combining results from different instruments made by the same manufacturer and/or brand there were six peer groups with three comprising less than 10 labs each and together making up only 14% of the participants. The other methods were used by 31% (Beckman Unicel/Access calibrated with the Hybritech standards), 30% (Roche Elecsys/E170/Cobas) and 24% (Siemens Immulite 1000 and 2000) of labs, respectively. As seen in the previous PTs, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained with the rest of the methods (60% above the targets and 35% higher than the all method medians), while there were not enough results from Beckman Access and Unicel calibrated with the WHO standards for a comparison to the other methods. The Siemens Dimension RxL Max, Xpand Plus and Abbott AxSYM/Architect results were 21% and 31% above the targets, respectively, but were only 2% and 11% above the all method medians. As seen previously, the Abbott AxSYM was consistently lower than the Architect; however, not significantly so and therefore the two groups were combined. The Roche instruments were grouped together and ran an average of 16% above target, while Siemens Immulite 1000/2000 and Dimension Vista averaged 11% and 4% above the assigned target, respectively. In conclusion, there are still substantial differences in how free PSA is measured, and the various methods don't fall into clearly defined high and low groups. Furthermore, not every method that is high for total PSA is also high for free PSA. When comparing the calculated %free PSA values they ranged from a low of 19% with the Siemens Immulite and Dimension methods to a high of 29% with the Beckman Hybritech methods. However, within one method, the ratios of free to total PSA were relatively constant. As would be expected, a higher % free PSA was derived either from a comparatively lower total or a higher free PSA measurement. Beckman Access and Unicel methods seemed to show an inverse relationship between the %free PSA and the total PSA levels; the higher the total PSA, the lower the % free PSA values. In contrast, the Siemens Immulite showed higher % free PSA ratios as the total PSA measurement increased, but since the total PSA levels ranged from 0.6ng/ml to about 18.0 ng/mL, the significance of the observed differences in % free PSA is unclear.

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

Finally, only 11 labs measured **complexed PSA** and all of these used either the Siemens ADVIA-Centaur XP or CP, which were combined into one group. Overall, excellent agreement between the labs was evidenced by an average %CV of 3.23% (Table 9).

In conclusion, there remain substantial differences between the results obtained with various methods or instruments for some of the analytes. Furthermore, not all methods appear equally

reproducible as indicated by the spread of the average within method %CVs, though these were in general <10%.



The graph to the left shows the average %CV for each method by analyte.

While some of these differences may be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We make every effort to minimize the differences that can be attributed to the sample composition and suggest that despite the somewhat artificial nature of the PT samples, the differences between the results obtained by various methods might also be reflected in patient serum samples. Therefore, we encourage labs and physicians to use caution when comparing the results from the same patient measured with different methods on different instruments, since clearly not all methods are equal. For this reason, **we require that the method used be clearly indicated on the patient report** (Oncology Standard OC 1b). We also encourage you to educate your physician clients about this potential problem. Furthermore, the comparison of method means to target values set by traceable International Standards for PSA and free PSA clearly shows that not all methods are calibrated equally, as discussed in the respective analyte sections above.

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.

Important Reminder regarding the HCS/EPTRS data submission process: Be sure results were **submitted**. If results were **saved** but not submitted, they received an administrative **fail**.

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

The PSA for a 2nd method analyte option allows labs to enter results from a second PSA assay if a different or additional method for total PSA is used in conjunction with their free PSA measurements**.** If only one PSA test was done, then results should **only** be entered in the first PSA (Total) entry line and "Test Not Offered" should be selected for the PSA for a 2nd method. For labs that enter two PSA tests, the primary PSA method gets entered on the first PSA line and the secondary (used in conjunction with their free PSA results) on the PSA for a 2nd method line.

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

The scheduled date for the remaining 2012 Tumor Marker Proficiency Test event is:

Mail-out date:	**Due date:**
September 11, 2012	September 26, 2012

If you have any questions or wish to discuss some of the issues alluded to in this critique, you may contact Susanne McHale at (518) 486-5775 or by email at smchale@wadsworth.org, or myself at (518) 474-2088 or by email at schneid@wadsworth.org.

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

Table 1: 5-12 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 AxSYM & Architect ABB/ABH									
TM241	14	23.2	**15.7**	**34.9**	9.6	8.97		1.13	
TM242	14	26.2	**18.7**	**38.4**	9.9	10.23		1.12	
TM243	14	48.3	**39.6**	**67.3**	13.8	8.53		1.14	
TM244	14	45.5	**37.3**	**63.4**	13.0	9.34		1.12	
TM245	14	55.5	**45.5**	**77.3**	15.9	8.18		1.12	
					mean ±SD	9.05	0.79	1.13	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM241	11	20.5	**13.0**	**31.7**	9.4	3.32		1.00	
TM242	11	24.5	**17.0**	**36.4**	9.7	5.31		1.05	
TM243	11	45.2	**37.1**	**62.9**	12.9	4.23		1.07	
TM244	11	44.4	**36.4**	**61.8**	12.7	4.68		1.09	
TM245	11	54.9	**45.0**	**76.5**	15.7	3.92		1.11	
					mean ±SD	4.29	0.75	1.06	0.04
Roche Elecsys & Cobas BME/BMR									
TM241	19	17.6	**10.1**	**28.3**	9.1	6.19		0.86	
TM242	19	19.9	**12.4**	**31.0**	9.3	5.53		0.85	
TM243	19	36.3	**29.8**	**50.5**	10.4	5.07		0.86	
TM244	19	34.0	**26.5**	**47.3**	10.4	4.53		0.83	
TM245	19	41.0	**33.6**	**57.1**	11.7	4.07		0.83	
					mean ±SD	5.08	0.83	0.85	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM241	35	20.6	**13.1**	**31.8**	9.4	4.17		1.00	
TM242	35	23.4	**15.9**	**35.1**	9.6	4.10		1.00	
TM243	35	41.6	**34.1**	**57.9**	11.9	5.24		0.99	
TM244	35	40.4	**33.1**	**56.3**	11.6	4.23		0.99	
TM245	35	48.5	**39.8**	**67.5**	13.9	4.16		0.98	
					mean ±SD	4.38	0.48	0.99	0.01
Siemens Immulite 2000 & 2500 DPD/DPF									
TM241	25	16.2	**8.7**	**26.6**	9.0	7.41		0.79	
TM242	23	19.1	**11.6**	**30.0**	9.2	5.81		0.82	
TM243	25	35.0	**28.7**	**48.7**	10.0	7.51		0.83	
TM244	25	34.1	**26.6**	**47.4**	10.4	6.36		0.84	
TM245	25	41.7	**34.2**	**58.1**	11.9	6.67		0.84	
					mean ±SD	6.75	0.72	0.82	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM241	7	18.8	**11.3**	**29.7**	9.2	3.40		0.92	
TM242	7	22.6	**15.1**	**34.2**	9.6	5.09		0.97	
TM243	7	42.2	**34.6**	**58.8**	12.1	2.42		1.00	
TM244	7	40.8	**33.5**	**56.8**	11.7	4.63		1.00	
TM245	7	49.6	**40.7**	**69.0**	14.2	3.59		1.00	
					mean ±SD	3.83	1.06	0.98	0.04
Tosoh AIA TOM									
TM241	5	27.6	**20.1**	**40.1**	10.0	6.99		1.35	
TM242	5	31.7	**24.2**	**44.1**	10.0	6.56		1.35	
TM243	5	62.6	**51.3**	**87.2**	17.9	10.73		1.48	
TM244	5	55.7	**45.7**	**77.5**	15.9	7.34		1.37	
TM245	5	70.2	**57.6**	**97.7**	20.1	4.54		1.42	
					mean ±SD	7.24	2.24	1.39	0.06

continued on next page

Table 1 (cont.): 5-12 NYS Tumor Marker PT Summary for CA 125

Sample ID	N	All Method Median	Median % CV
TM241	116	20.5	6.19
TM242	114	23.4	5.53
TM243	116	42.2	5.24
TM244	116	40.8	4.68
TM245	116	49.6	4.16
		Average	5.16
		Allowable CV %	6.0
		Allowable Error if >/= 35 U/ml (+/-) %	18.0
		Allowable Error if < 35 U/ml (+/- U/ml)	7.5

Figure 1: CA 125 Method Comparison

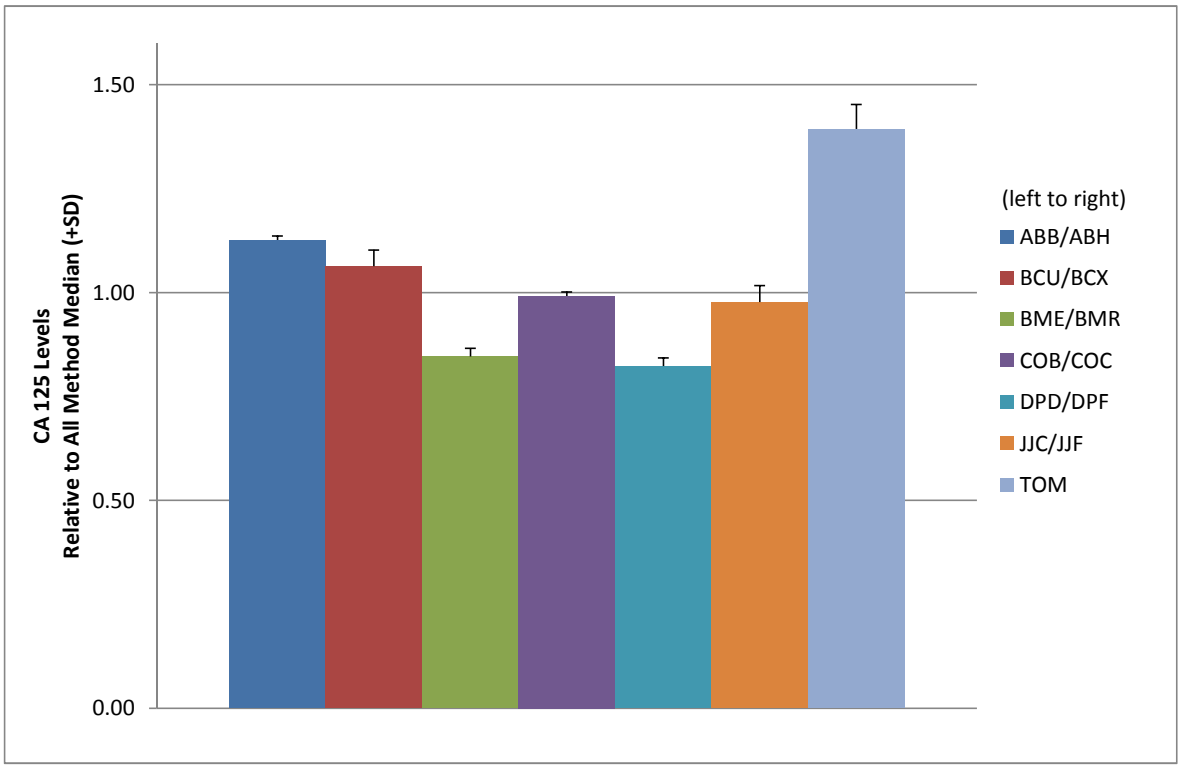


Table 2: 5-12 NYS Tumor Marker PT Summary for CA 19-9

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									
TM241	2	360.0	**295.2**	**424.8**	64.8	2.75		5.82	
TM242	2	239.8	**196.6**	**283.0**	43.2	7.43		5.24	
TM243	2	199.4	**163.5**	**235.3**	35.9	4.43		5.54	
TM244	2	164.3	**134.7**	**193.9**	29.6	2.20		5.69	
TM245	2	99.7	**81.8**	**117.6**	17.9	12.77		5.14	
					mean ±SD	5.92	4.34	5.48	0.29
Beckman Unicel & Access/2 BCU/BCX									
TM241	11	61.9	**50.8**	**73.0**	11.1	5.95		1.00	
TM242	11	45.8	**37.6**	**54.0**	8.2	5.39		1.00	
TM243	11	36	**29.5**	**42.5**	6.5	6.11		1.00	
TM244	11	28.9	**23.7**	**34.1**	5.2	6.96		1.00	
TM245	11	19.4	**15.9**	**22.9**	3.5	7.68		1.00	
					mean ±SD	6.42	0.90	1.00	0.00
Roche Elecsys & Cobas BME/BMR									
TM241	13	52.2	**42.8**	**61.6**	9.4	3.56		0.84	
TM242	13	38.9	**31.9**	**45.9**	7.0	4.60		0.85	
TM243	13	30.7	**25.2**	**36.2**	5.5	4.01		0.85	
TM244	13	25.5	**20.9**	**30.1**	4.6	5.41		0.88	
TM245	13	17.6	**14.4**	**20.8**	3.2	6.59		0.91	
					mean ±SD	4.83	1.20	0.87	0.03
Siemens Advia Centaur XP COB									
TM241	36	130.8	**107.3**	**154.3**	23.5	6.98		2.11	
TM242	36	89.2	**73.1**	**105.3**	16.1	7.54		1.95	
TM243	36	68.3	**56**	**80.6**	12.3	5.14		1.90	
TM244	36	54.5	**44.7**	**64.3**	9.8	4.92		1.89	
TM245	36	37.3	**30.6**	**44.0**	6.7	4.93		1.92	
					mean ±SD	5.90	1.26	1.95	0.09
Tosoh AIA TOM									
TM241	5	43.6	**35.8**	**51.4**	7.8	4.24		0.70	
TM242	5	29.3	**24**	**34.6**	5.3	1.57		0.64	
TM243	5	22.5	**18.5**	**26.6**	4.1	3.87		0.63	
TM244	5	16.9	**13.9**	**19.9**	3.0	4.38		0.58	
TM245	5	12.8	**10.5**	**15.1**	2.3	2.50		0.66	
					mean ±SD	3.31	1.23	0.64	0.04

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Table 2 (cont.): 5-12 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median		Median % CV
TM241	67	61.9		4.24
TM242	67	45.8		5.39
TM243	67	36.0		4.43
TM244	67	28.9		4.92
TM245	67	19.4		6.59
			Average	5.12
			Allowable CV %	6.0
			Allowable Error (+/-)%	18.0

Figure 2: CA 19-9 Method Comparison

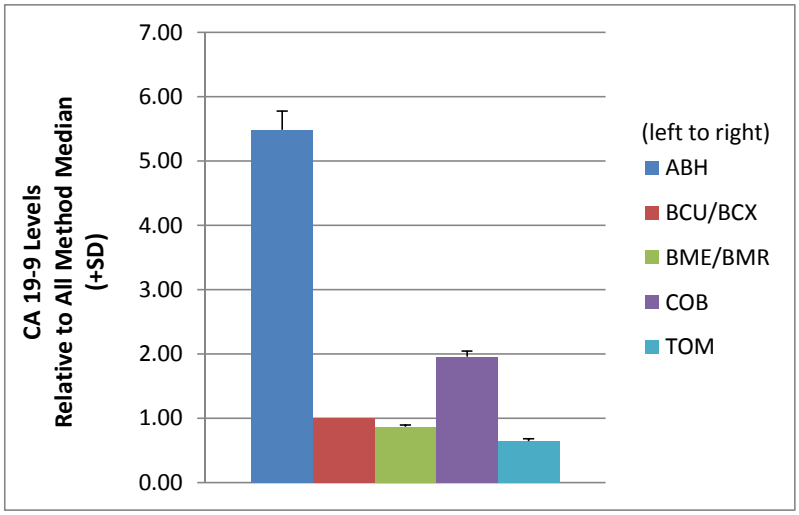

Table 3: 5-12 NYS Tumor Marker PT Summary for CA 15-3

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 AxSYM & Architect ABB/ABH									
TM241	7	78.6	**62.1**	**95.1**	16.5	12.57		1.08	
TM242	7	31.9	**25.2**	**38.6**	6.7	10.31		1.06	
TM243	7	80.8	**63.8**	**97.8**	17.0	9.20		1.02	
TM244	7	33.1	**26.1**	**40.1**	7.0	7.52		1.02	
TM245	7	46.5	**36.7**	**56.3**	9.8	8.37		1.03	
					mean ±SD	9.59	1.96	1.04	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM241	4	43.2	**34.1**	**52.3**	9.1	7.08		0.59	
TM242	4	18.0	**14.2**	**21.8**	3.8	1.72		0.60	
TM243	4	50.3	**39.7**	**60.9**	10.6	3.44		0.63	
TM244	4	21.4	**16.9**	**25.9**	4.5	2.38		0.66	
TM245	4	29.0	**22.9**	**35.1**	6.1	3.62		0.64	
					mean ±SD	3.65	2.07	0.63	0.03
Roche Elecsys & Cobas BME/BMR									
TM241	12	67.5	**53.3**	**81.7**	14.2	5.97		0.92	
TM242	12	28.3	**22.4**	**34.2**	5.9	4.91		0.94	
TM243	12	73.4	**58.0**	**88.8**	15.4	5.23		0.92	
TM244	12	31.5	**24.9**	**38.1**	6.6	4.76		0.98	
TM245	12	43.6	**34.4**	**52.8**	9.2	5.67		0.97	
					mean ±SD	5.31	0.51	0.95	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM241	22	85.7	**67.7**	**103.7**	18.0	8.47		1.17	
TM242	22	35.8	**28.3**	**43.3**	7.5	6.96		1.19	
TM243	22	87.7	**69.3**	**106.1**	18.4	7.66		1.10	
TM244	22	37.5	**29.6**	**45.4**	7.9	8.11		1.16	
TM245	22	51.2	**40.4**	**62.0**	10.8	7.11		1.14	
					mean ±SD	7.66	0.64	1.15	0.03
Siemens Immulite 2000 & 2500 DPD/DPF									
TM241	9	90.1	**71.2**	**109.0**	18.9	12.13		1.23	
TM242	9	35.0	**27.7**	**42.4**	7.4	9.26		1.16	
TM243	9	97.7	**77.2**	**118.2**	20.5	8.50		1.23	
TM244	9	38.9	**30.7**	**47.1**	8.2	8.25		1.20	
TM245	9	54.7	**43.2**	**66.2**	11.5	9.38		1.21	
					mean ±SD	9.50	1.55	1.21	0.03
Ortho Clinical Diag Vitros Eci/ECiQ JJC									
TM241	4	63.3	**50.0**	**76.6**	13.3	4.76		0.87	
TM242	4	24.7	**19.5**	**29.9**	5.2	4.01		0.82	
TM243	4	78.0	**61.6**	**94.4**	16.4	5.60		0.98	
TM244	4	30.4	**24.0**	**36.8**	6.4	7.27		0.94	
TM245	4	43.6	**34.4**	**52.8**	9.2	6.22		0.97	
					mean ±SD	5.57	1.27	0.92	0.07

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Table 3 (cont.): 5-12 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM241	58	73.05	7.78
TM242	58	30.10	5.93
TM243	58	79.40	6.63
TM244	58	32.30	7.40
TM245	58	45.05	6.66
		Average	6.88
		Allowable CV %	7.0
		Allowable Error (+/-)%	21.0

Figure 3: CA 15-3 Method Comparison

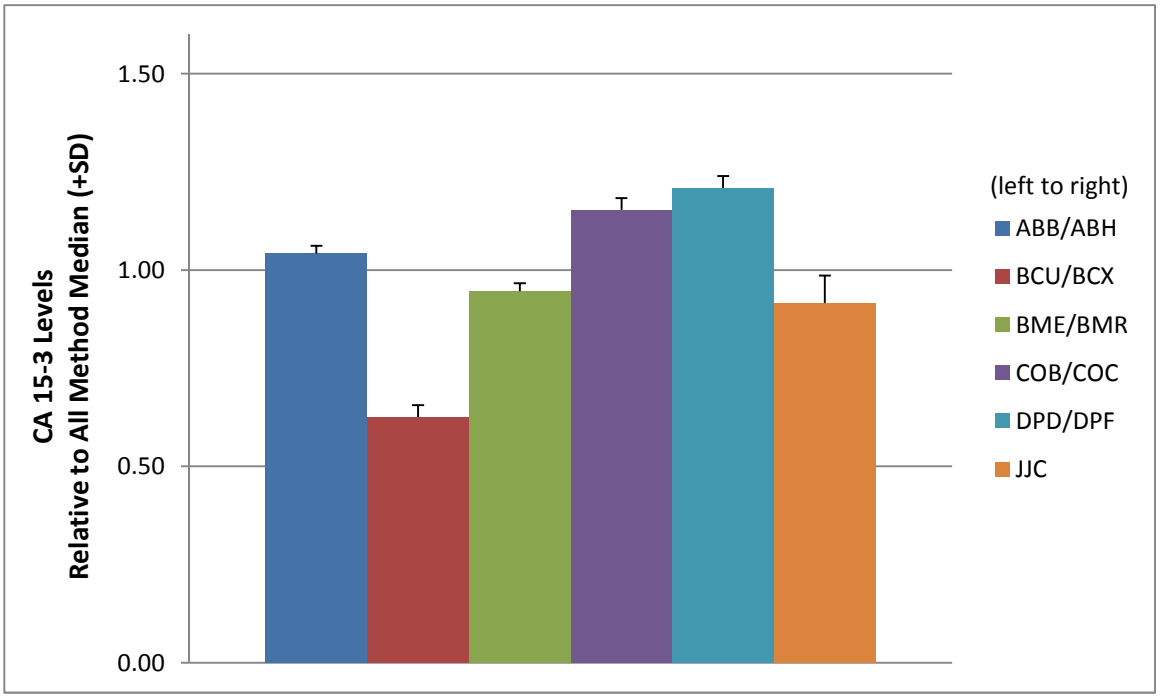

Table 4: 5-12 NYS Tumor Marker PT Summary for CA 27.29

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									
TM241	43	70.5	**55.7**	**85.3**	14.8	6.03		1.04	
TM242	43	22.4	**14.9**	**29.9**	7.5	16.29		0.91	
TM243	43	95.9	**75.8**	**116.0**	20.1	6.19		1.10	
TM244	43	35.1	**27.7**	**42.5**	7.4	11.00		1.02	
TM245	43	54.1	**42.7**	**65.5**	11.4	8.02		1.08	
					mean ±SD	9.51	4.29	1.03	0.07
Tosoh AIA TOM									
TM241	6	65.7	**51.9**	**79.5**	13.8	4.60		0.96	
TM242	6	26.6	**19.1**	**34.1**	7.5	5.75		1.09	
TM243	6	79.1	**62.5**	**95.7**	16.6	6.06		0.90	
TM244	6	34.0	**26.5**	**41.5**	7.5	6.18		0.98	
TM245	6	46.1	**36.4**	**55.8**	9.7	7.01		0.92	
					mean ±SD	5.92	0.87	0.97	0.07

Sample ID	N	All Method Median	Median % CV
TM241	**49**	**68.10**	**5.31**
TM242	**49**	**24.50**	**11.02**
TM243	**49**	**87.50**	**6.12**
TM244	**49**	**34.55**	**8.59**
TM245	**49**	**50.10**	**7.51**
		Average	**7.71**
		Allowable CV %	**7.0**
		Allowable Error if >/= 35 U/ml (+/-) %	**21.0**
		Allowable Error if < 35 U/ml (+/- U/ml)	**7.5**

Figure 4: CA 27.29 Method

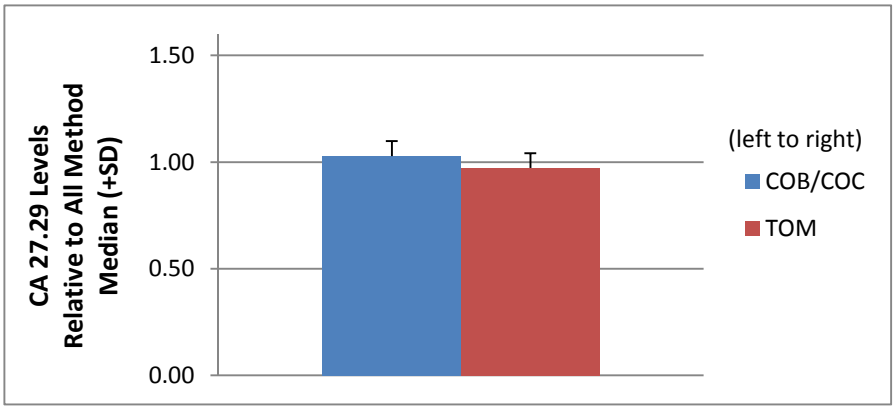

Table 5: 5-12 NYS Tumor Marker PT Summary for CEA

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 AxSYM & Architect ABB/ABH									
TM241	17	6.7	**5.3**	**8.1**	1.4	7.01		1.02	
TM242	17	9.3	**7.3**	**11.3**	2.0	5.38		1.00	
TM243	17	34.3	**27.1**	**41.5**	7.2	6.38		1.00	
TM244	14	30	**23.7**	**36.3**	6.3	3.03		1.00	
TM245	17	22.3	**17.6**	**27**	4.7	4.66		0.97	
					mean ±SD	5.29	1.55	1.00	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM241	24	6.6	**5.2**	**8**	1.4	7.12		1.00	
TM242	24	8.9	**7**	**10.8**	1.9	6.85		0.96	
TM243	25	34.3	**27.1**	**41.5**	7.2	7.70		1.00	
TM244	25	28	**22.1**	**33.9**	5.9	8.00		0.93	
TM245	25	22.5	**17.8**	**27.2**	4.7	6.27		0.98	
					mean ±SD	7.19	0.69	0.97	0.03
Roche Elecsys & Cobas BME/BMR									
TM241	26	5.8	**4.6**	**7**	1.2	5.86		0.88	
TM242	26	7.6	**6**	**9.2**	1.6	7.11		0.82	
TM243	26	23.6	**18.6**	**28.6**	5.0	6.10		0.69	
TM244	26	21.4	**16.9**	**25.9**	4.5	6.12		0.71	
TM245	26	16	**12.6**	**19.4**	3.4	6.56		0.70	
					mean ±SD	6.35	0.49	0.76	0.08
Siemens Advia Centaur XP & CP COB/COC									
TM241	50	6.2	**4.9**	**7.5**	1.3	6.29		0.94	
TM242	50	9.1	**7.2**	**11**	1.9	5.27		0.98	
TM243	50	36.7	**29**	**44.4**	7.7	5.26		1.07	
TM244	50	30	**23.7**	**36.3**	6.3	6.10		1.00	
TM245	50	23.2	**18.3**	**28.1**	4.9	6.34		1.01	
					mean ±SD	5.85	0.54	1.00	0.05
Siemens Immulite 2000 & 2500 DPD/DPF									
TM241	15	6.1	**4.8**	**7.4**	1.3	6.56		0.92	
TM242	15	9.3	**7.3**	**11.3**	2.0	8.92		1.00	
TM243	15	37.8	**29.9**	**45.7**	7.9	7.91		1.10	
TM244	15	32.7	**25.8**	**39.6**	6.9	6.88		1.09	
TM245	15	24.6	**19.4**	**29.8**	5.2	8.78		1.07	
					mean ±SD	7.81	1.08	1.04	0.07
Siemens Dimension Vista DUV									
TM241	18	6.4	**5.1**	**7.7**	1.3	3.59		0.97	
TM242	18	9.2	**7.3**	**11.1**	1.9	4.13		0.99	
TM243	19	31.2	**24.6**	**37.8**	6.6	3.14		0.91	
TM244	19	27.8	**22**	**33.6**	5.8	3.71		0.93	
TM245	19	20.7	**16.4**	**25**	4.3	3.82		0.90	
					mean ±SD	3.68	0.36	0.94	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM241	15	8.3	**6.6**	**10**	1.7	7.35		1.26	
TM242	15	10.8	**8.5**	**13.1**	2.3	6.11		1.16	
TM243	15	34.3	**27.1**	**41.5**	7.2	4.43		1.00	
TM244	15	29.7	**23.5**	**35.9**	6.2	4.38		0.99	
TM245	15	23	**18.2**	**27.8**	4.8	4.87		1.00	
					mean ±SD	5.43	1.28	1.08	0.12

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Table 5 (cont.): 5-12 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									
TM241	6	9.7	**7.7**	**11.7**	2.0	5.36		1.47	
TM242	6	14	**11.1**	**16.9**	2.9	3.50		1.51	
TM243	6	52.8	**41.7**	**63.9**	11.1	2.99		1.54	
TM244	6	43.8	**34.6**	**53**	9.2	2.79		1.46	
TM245	6	34.9	**27.6**	**42.2**	7.3	3.93		1.52	
					mean ±SD	3.71	1.02	1.50	0.03

Sample ID	N	All Method Median	Median % CV
TM241	**171**	**6.6**	**6.56**
TM242	**171**	**9.3**	**6.11**
TM243	**173**	**34.3**	**6.10**
TM244	**170**	**30.0**	**6.10**
TM245	**173**	**23.0**	**6.27**
		Average	**6.23**
		Allowable CV %	**7.0**
		Allowable Error (+/-)%	**21.0**

Figure 5: CEA Method Comparison

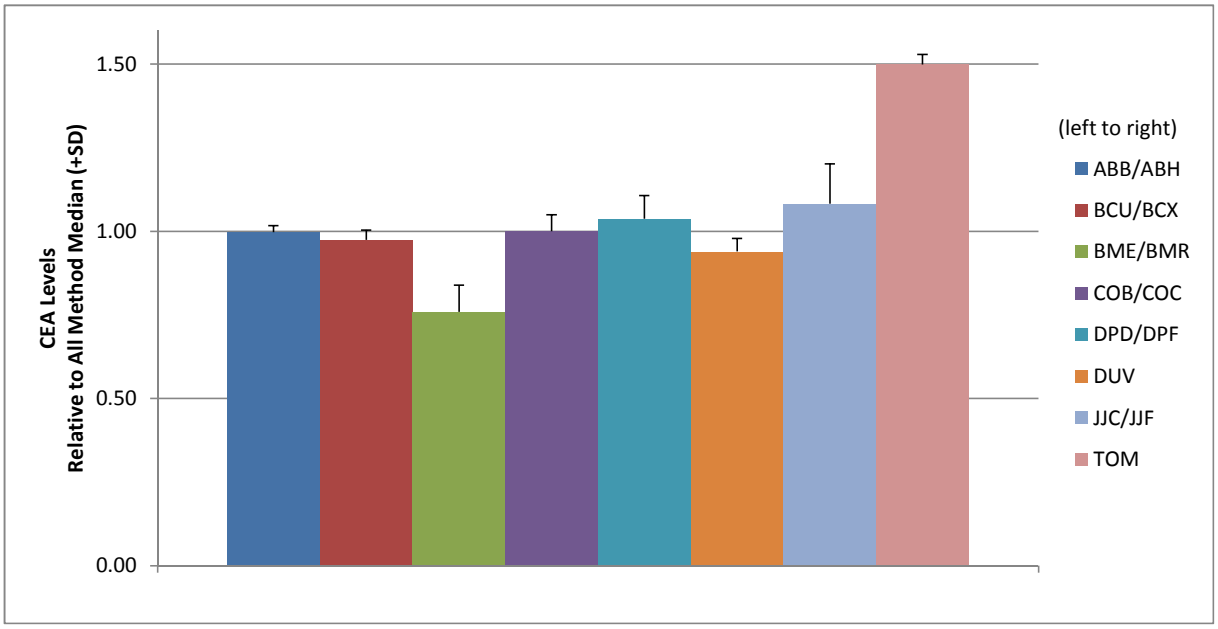

Table 6: 5-12 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott AxSYM ABB											
TM241	8	12.9	**10.6**	**15.2**	2.3	8.76		1.06		1.21	
TM242	8	23.2	**19.0**	**27.4**	4.2	4.70		1.00		1.12	
TM243	8	34.9	**28.6**	**41.2**	6.3	4.07		0.99		1.09	
TM244	8	16.7	**13.7**	**19.7**	3.0	8.80		0.97		1.06	
TM245	8	6.6	**5.4**	**7.8**	1.2	8.03		1.02		1.22	
					mean ±SD	6.87	2.30	1.01	0.04	1.14	0.07
Beckman Unicel & Access/2 BCU/BCX											
TM241	17	12.1	**9.9**	**14.3**	2.2	8.35		1.00		1.13	
TM242	17	22.6	**18.5**	**26.7**	4.1	8.32		0.97		1.09	
TM243	16	35.2	**28.9**	**41.5**	6.3	6.96		1.00		1.10	
TM244	17	17.2	**14.1**	**20.3**	3.1	9.19		0.99		1.10	
TM245	17	6.4	**5.2**	**7.6**	1.2	8.91		0.99		1.19	
					mean ±SD	8.34	0.86	0.99	0.01	1.12	0.04
Roche Elecsys & Cobas BME/BMR											
TM241	17	13.8	**11.3**	**16.3**	2.5	3.70		1.14		1.29	
TM242	17	26.5	**21.7**	**31.3**	4.8	3.96		1.14		1.28	
TM243	17	40.9	**33.5**	**48.3**	7.4	4.33		1.16		1.28	
TM244	17	19.8	**16.2**	**23.4**	3.6	4.09		1.14		1.26	
TM245	17	7.5	**6.2**	**8.9**	1.4	5.20		1.16		1.39	
					mean ±SD	4.26	0.58	1.15	0.01	1.30	0.05
Siemens Advia Centaur XP & CP COB/COC											
TM241	29	12.3	**10.1**	**14.5**	2.2	7.48		1.01		1.15	
TM242	29	23.2	**19.0**	**27.4**	4.2	5.47		1.00		1.12	
TM243	29	35.4	**29.0**	**41.8**	6.4	5.99		1.00		1.10	
TM244	29	18.0	**14.8**	**21.2**	3.2	5.56		1.04		1.15	
TM245	29	7.2	**5.9**	**8.5**	1.3	10.14		1.12		1.34	
					mean ±SD	6.93	1.97	1.03	0.05	1.17	0.09
Siemens Immulite 1000 & 2000 DPB/DPD											
TM241	18	12.0	**9.8**	**14.2**	2.2	6.58		0.99		1.12	
TM242	18	23.4	**19.2**	**27.6**	4.2	6.28		1.01		1.13	
TM243	18	36.5	**29.9**	**43.1**	6.6	4.96		1.03		1.14	
TM244	18	17.4	**14.3**	**20.5**	3.1	6.49		1.01		1.11	
TM245	18	6.4	**5.2**	**7.6**	1.2	6.88		0.99		1.19	
					mean ±SD	6.24	0.75	1.01	0.02	1.14	0.03
Siemens Dimension Vista DUV											
TM241	5	11.4	**9.3**	**13.5**	2.1	3.33		0.94		1.07	
TM242	5	21.8	**17.9**	**25.7**	3.9	4.27		0.94		1.05	
TM243	5	33.6	**27.6**	**39.6**	6.0	3.54		0.95		1.05	
TM244	5	16.3	**13.4**	**19.2**	2.9	3.74		0.94		1.04	
TM245	5	6.0	**4.9**	**7.1**	1.1	4.67		0.93		1.11	
					mean ±SD	3.91	0.55	0.94	0.01	1.06	0.03
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM241	6	9.1	**7.5**	**10.7**	1.6	1.54		0.75		0.85	
TM242	6	17.6	**14.4**	**20.8**	3.2	1.42		0.76		0.85	
TM243	6	27.1	**22.2**	**32.0**	4.9	2.18		0.77		0.85	
TM244	6	13.5	**11.1**	**15.9**	2.4	1.85		0.78		0.86	
TM245	6	5.3	**4.3**	**6.3**	1.0	1.89		0.82		0.98	
					mean ±SD	1.77	0.30	0.78	0.03	0.88	0.06
Tosoh AIA TOM											
TM241	3	12.2	**10.0**	**14.4**	2.2	2.87		1.00		1.14	
TM242	3	23.2	**19.0**	**27.4**	4.2	2.41		1.00		1.12	
TM243	3	36.0	**29.5**	**42.5**	6.5	3.06		1.02		1.12	
TM244	3	17.4	**14.3**	**20.5**	3.1	3.39		1.01		1.11	
TM245	3	6.5	**5.3**	**7.7**	1.2	4.77		1.01		1.21	
					mean ±SD	3.30	0.89	1.01	0.01	1.14	0.04

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Table 6 (cont.): 5-12 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD	Median % CV		All Method Median/ IS Target	
TM241	103	12.15	10.7	0.26	5.14		1.14	
TM242	103	23.20	20.7	0.49	4.48		1.12	
TM243	102	35.30	32.1	1.10	4.20		1.10	
TM244	103	17.30	15.7	0.73	4.82		1.10	
TM245	103	6.45	5.4	0.16	6.04		1.20	
				Average	4.94	mean ±SD	1.13	0.04
				Allowable CV %	6.0			
				Allowable Error (+/-)%	18.0			

Figure 6: AFP Method Comparison

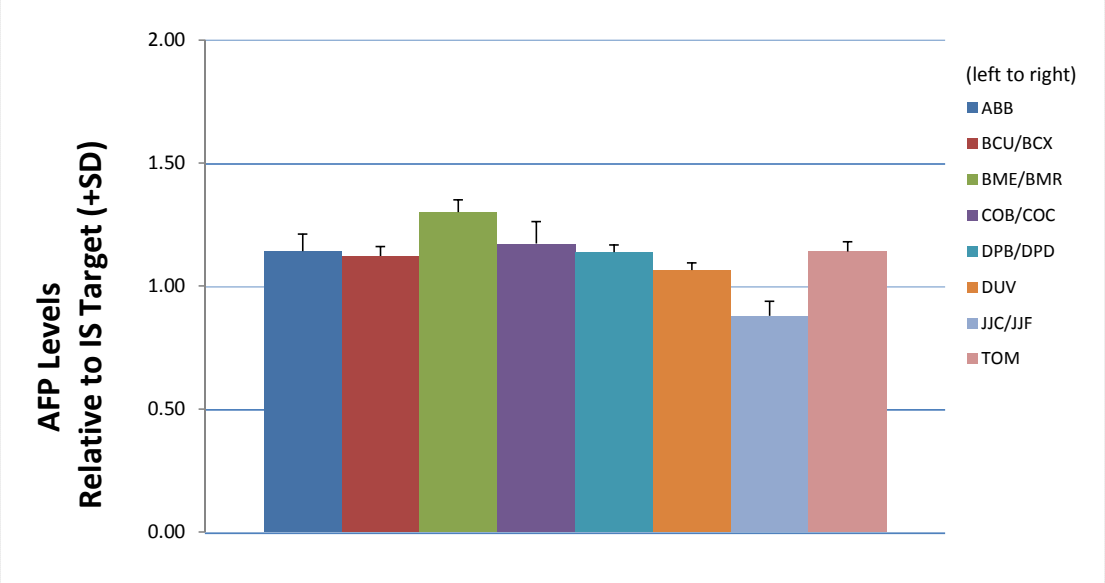

Table 7: 5-12 NYS Tumor Marker PT Summary for PSA

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 AxSYM & Architect ABB/ABH											
TM241	18	16.5	**13.5**	**19.5**	3.0	4.48		1.03		1.17	
TM242	19	7.3	**6.0**	**8.6**	1.3	8.36		1.00		1.14	
TM243	19	4.2	**3.4**	**5.0**	0.8	8.10		1.00		1.17	
TM244	19	2.7	**2.2**	**3.2**	0.5	7.41		1.00		1.17	
TM245	15	0.5	**0.4**	**0.6**	0.1	0.00		1.00		1.00	
					mean ±SD*	7.09	1.78	1.01	0.01	1.13	0.07
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM241	51	18.0	**14.8**	**21.2**	3.2	4.44		1.13		1.28	
TM242	51	8.2	**6.7**	**9.7**	1.5	4.76		1.12		1.28	
TM243	51	4.6	**3.8**	**5.4**	0.8	3.91		1.10		1.28	
TM244	50	3.0	**2.5**	**3.5**	0.5	4.33		1.11		1.30	
TM245	51	0.6	**0.5**	**0.7**	0.1	8.33		1.20		1.20	
					mean ±SD*	4.36	0.35	1.13	0.04	1.27	0.04
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)											
TM241	3	14.2	**11.6**	**16.8**	2.6	7.11		0.89		1.01	
TM242	3	6.4	**5.2**	**7.6**	1.2	5.00		0.88		1.00	
TM243	3	3.8	**3.1**	**4.5**	0.7	3.95		0.90		1.06	
TM244	3	2.4	**2.0**	**2.8**	0.4	4.17		0.89		1.04	
TM245	3	0.5	**0.4**	**0.6**	0.1	0.00		1.00		1.00	
					mean ±SD*	5.06	1.44	0.91	0.05	1.02	0.03
Roche Elecsys & Cobas BME/BMR											
TM241	41	15.4	**12.6**	**18.2**	2.8	3.57		0.96		1.09	
TM242	41	7.1	**5.8**	**8.4**	1.3	3.66		0.97		1.11	
TM243	42	4.1	**3.4**	**4.8**	0.7	4.39		0.98		1.14	
TM244	38	2.6	**2.1**	**3.1**	0.5	3.08		0.96		1.13	
TM245	35	0.5	**0.4**	**0.6**	0.1	0.00		1.00		1.00	
					mean ±SD*	3.68	0.54	0.97	0.02	1.09	0.06
Siemens Advia Centaur XP & CP COB/COC											
TM241	63	15.5	**12.7**	**18.3**	2.8	5.81		0.97		1.10	
TM242	62	7.1	**5.8**	**8.4**	1.3	5.35		0.97		1.11	
TM243	61	4.0	**3.3**	**4.7**	0.7	5.25		0.95		1.11	
TM244	63	2.6	**2.1**	**3.1**	0.5	6.54		0.96		1.13	
TM245	62	0.5	**0.4**	**0.6**	0.1	10.00		1.00		1.00	
					mean ±SD*	5.74	0.59	0.97	0.02	1.09	0.05
Siemens Immulite 1000, 2000 & 2500 - Original Pack DPB/DPD/DPF (DP5)											
TM241	23	18.2	**14.9**	**21.5**	3.3	10.00		1.14		1.29	
TM242	23	8.5	**7.0**	**10.0**	1.5	10.59		1.16		1.33	
TM243	23	4.8	**3.9**	**5.7**	0.9	10.21		1.14		1.33	
TM244	23	3.2	**2.6**	**3.8**	0.6	8.44		1.19		1.39	
TM245	17	0.6	**0.5**	**0.7**	0.1	3.33		1.20		1.20	
					mean ±SD*	9.81	0.95	1.17	0.03	1.31	0.07
Siemens Immulite 1000 & 2000 - 3rd Generation Pack DPB/DPD (DP6)											
TM241	5	16.2	**13.3**	**19.1**	2.9	13.83		1.01		1.15	
TM242	5	7.8	**6.4**	**9.2**	1.4	15.90		1.07		1.22	
TM243	5	4.2	**3.4**	**5.0**	0.8	17.38		1.00		1.17	
TM244	5	2.8	**2.3**	**3.3**	0.5	22.50		1.04		1.22	
TM245	5	0.6	**0.5**	**0.7**	0.1	13.33		1.20		1.20	
					mean ±SD*	17.40	3.70	1.06	0.08	1.19	0.03
Siemens Dimension Vista DUV											
TM241	6	16.0	**13.1**	**18.9**	2.9	1.19		1.00		1.13	
TM242	6	7.4	**6.1**	**8.7**	1.3	1.35		1.01		1.16	
TM243	6	4.2	**3.4**	**5.0**	0.8	1.90		1.00		1.17	
TM244	5	2.7	**2.2**	**3.2**	0.5	0.00		1.00		1.17	
TM245	6	0.5	**0.4**	**0.6**	0.1	0.00		1.00		1.00	
					mean ±SD*	1.11	0.80	1.00	0.01	1.13	0.07

* TM 245 excluded from mean % CV calculation

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Table 7 (cont.): 5-12 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	
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM241	13	18.0	**14.8**	**21.2**	3.2	2.56		1.13		1.28	
TM242	14	8.3	**6.8**	**9.8**	1.5	3.61		1.14		1.30	
TM243	14	4.6	**3.8**	**5.4**	0.8	5.00		1.10		1.28	
TM244	14	3.0	**2.5**	**3.5**	0.5	6.67		1.11		1.30	
TM245	11	0.6	**0.5**	**0.7**	0.1	0.00		1.20		1.20	
					mean ±SD*	4.46	1.78	1.13	0.04	1.27	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM241	25	14.1	**11.6**	**16.6**	2.5	4.26		0.88		1.00	
TM242	25	6.6	**5.4**	**7.8**	1.2	4.85		0.90		1.03	
TM243	25	3.9	**3.2**	**4.6**	0.7	3.33		0.93		1.08	
TM244	25	2.6	**2.1**	**3.1**	0.5	5.00		0.96		1.13	
TM245	25	0.5	**0.4**	**0.6**	0.1	10.00		1.00		1.00	
					mean ±SD*	4.36	0.76	0.94	0.05	1.05	0.06
Tosoh AIA TOM											
TM241	8	15.5	**12.7**	**18.3**	2.8	3.68		0.97		1.10	
TM242	8	7.2	**5.9**	**8.5**	1.3	3.19		0.99		1.13	
TM243	8	4.2	**3.4**	**5.0**	0.8	4.05		1.00		1.17	
TM244	8	2.7	**2.2**	**3.2**	0.5	3.33		1.00		1.17	
TM245	6	0.5	**0.4**	**0.6**	0.1	2.00		1.00		1.00	
					mean ±SD*	3.56	0.38	0.99	0.01	1.11	0.07

* TM 245 excluded from mean % CV calculation

Sample ID	N	All Method Median	IS based Target	SD		Median % CV		Average Bias	SD
TM241	**80**	**16.0**	**14.1**	**0.20**		**4.44**	Low group	1.09	0.04
TM242	**64**	**7.3**	**6.4**	**0.17**		**4.85**	High group	1.26	0.05
TM243	**64**	**4.2**	**3.6**	**0.11**		**4.39**			
TM244	**64**	**2.7**	**2.3**	**0.06**		**5.00**			
TM245	**59**	**0.5**	**0.5**	**0.04**		**2.00**			
					Average	**4.67**			
					Allowable CV %	**6.0**			
					Allowable Error (+/-)%	**18.0**			

	Low Group			High Group		
Sample ID	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
TM241	**15.3**	**0.88**	**5.76**	**17.6**	**0.94**	**5.33**
TM242	**7.0**	**0.37**	**5.30**	**8.2**	**0.29**	**3.59**
TM243	**4.1**	**0.16**	**3.99**	**4.6**	**0.25**	**5.53**
TM244	**2.6**	**0.11**	**4.09**	**3.0**	**0.16**	**5.44**
TM245	**0.5**	**0.00**	**0.00**	**0.6**	**0.00**	**0.00**
		Mean	**4.78**		**Mean**	**4.97**

Figure 7A: PSA Method Comparison

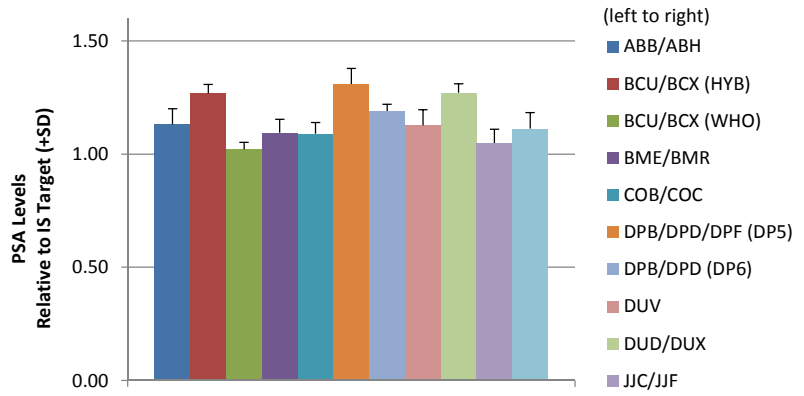

Figure 7B

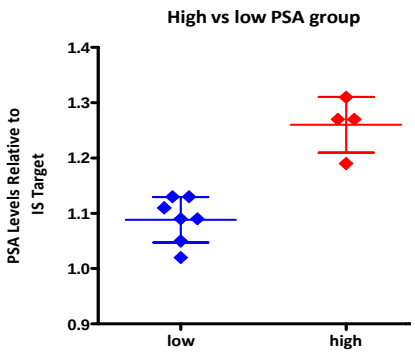

Table 8: 5-12 NYS Tumor Marker PT Summary for Free PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott AxSYM & Architect ABB/ABH											
TM241	5	4.36	**3.58**	**5.14**	0.78	9.40		1.14		1.37	
TM242	5	1.99	**1.63**	**2.35**	0.36	6.53		1.12		1.31	
TM243	5	1.12	**0.92**	**1.32**	0.20	7.14		1.13		1.32	
TM244	5	0.72	**0.59**	**0.85**	0.13	8.33		1.12		1.31	
TM245	5	0.13	**0.00**	**0.28**	0.14	15.38		1.04		1.25	
					mean ±SD*	7.85	1.28	1.11	0.04	1.31	0.04
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM241	27	4.93	**4.04**	**5.82**	0.89	5.68		1.29		1.55	
TM242	27	2.33	**1.91**	**2.75**	0.42	6.01		1.31		1.54	
TM243	27	1.34	**1.10**	**1.58**	0.24	5.22		1.35		1.58	
TM244	26	0.88	**0.72**	**1.04**	0.16	6.82		1.36		1.61	
TM245	27	0.18	**0.03**	**0.33**	0.15	11.11		1.44		1.73	
					mean ±SD*	5.93	0.67	1.35	0.06	1.60	0.08
Roche Elecsys & Cobas BME/BMR											
TM241	26	3.73	**3.06**	**4.40**	0.67	4.29		0.98		1.17	
TM242	26	1.75	**1.44**	**2.07**	0.32	4.00		0.98		1.16	
TM243	26	0.99	**0.81**	**1.17**	0.18	4.04		0.99		1.17	
TM244	26	0.64	**0.52**	**0.76**	0.12	4.69		0.99		1.17	
TM245	26	0.12	**0.00**	**0.27**	0.14	8.33		0.96		1.15	
					mean ±SD*	4.25	0.32	0.98	0.01	1.16	0.01
Siemens Immulite 1000 & 2000 DPB/DPD											
TM241	21	3.64	**2.98**	**4.30**	0.66	6.59		0.95		1.15	
TM242	21	1.70	**1.39**	**2.01**	0.31	5.88		0.96		1.12	
TM243	21	0.94	**0.77**	**1.11**	0.17	7.45		0.94		1.11	
TM244	21	0.60	**0.49**	**0.71**	0.11	5.00		0.93		1.10	
TM245	21	0.11	**0.00**	**0.26**	0.13	9.09		0.88		1.06	
					mean ±SD*	6.23	1.04	0.93	0.03	1.11	0.03
Siemens Dimension (RxL Max, Xpand Plus) DUD											
TM241	3	3.92	**3.21**	**4.63**	0.71	2.30		1.02		1.23	
TM242	3	1.81	**1.48**	**2.14**	0.33	2.76		1.02		1.20	
TM243	3	1.00	**0.82**	**1.18**	0.18	6.00		1.01		1.18	
TM244	3	0.65	**0.53**	**0.77**	0.12	3.08		1.01		1.19	
TM245	3	0.13	**0.00**	**0.28**	0.14	15.38		1.04		1.25	
					mean ±SD*	3.53	1.68	1.02	0.01	1.21	0.03
Siemens Dimension Vista DUV											
TM241	4	3.38	**2.77**	**3.99**	0.61	3.25		0.88		1.06	
TM242	4	1.57	**1.29**	**1.85**	0.28	3.18		0.88		1.04	
TM243	4	0.87	**0.71**	**1.03**	0.16	4.60		0.87		1.03	
TM244	4	0.57	**0.47**	**0.67**	0.10	1.75		0.88		1.04	
TM245	3	0.11	**0.00**	**0.26**	0.13	0.00		0.88		1.06	
					mean ±SD*	3.20	1.16	0.88	0.00	1.04	0.02

* TM 245 excluded from mean % CV calculation

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Table 8 (cont.): 5-12 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV
TM241	86	3.83	3.18	0.19	4.98
TM242	86	1.78	1.51	0.08	4.94
TM243	86	1.00	0.85	0.04	5.61
TM244	85	0.65	0.55	0.03	4.84
TM245	85	0.13	0.10	0.00	10.10
				Average	5.10
				Allowable CV %	6.0
				Allowable Error if >/= 0.5 ng/ml (+/-)%	18.0
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	0.15

Figure 8: Free PSA Method Comparison

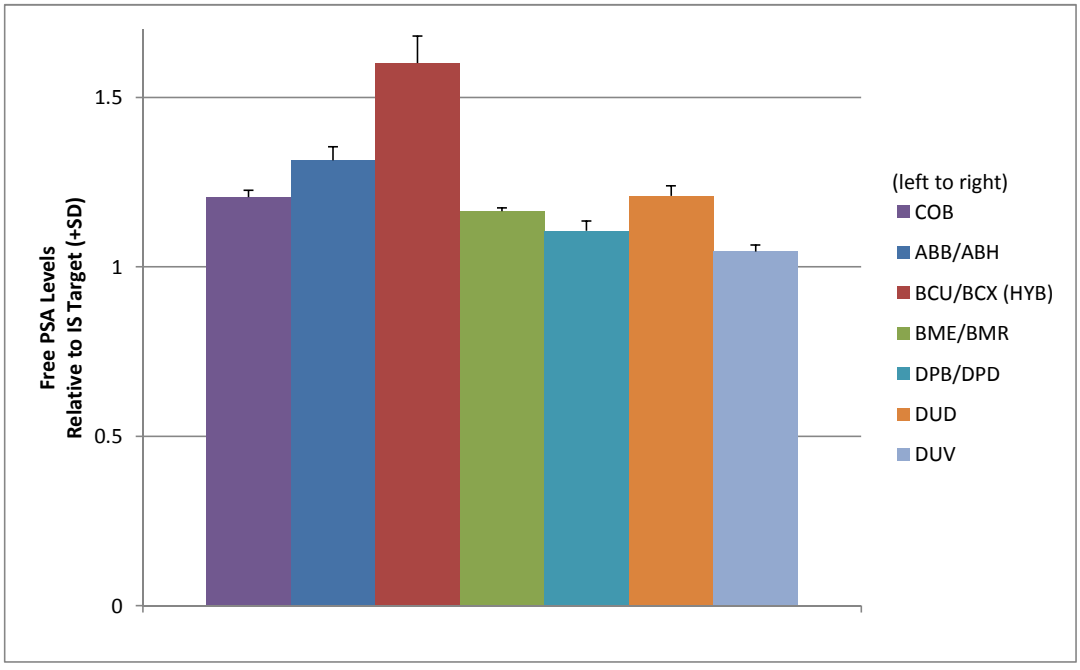

Table 9: 5-12 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM241	11	11.3	**9.6**	**13.0**	1.7	3.28		1.00	
TM242	10	5.2	**4.4**	**6.0**	0.8	2.51		1.00	
TM243	11	3.0	**2.6**	**3.5**	0.5	5.07		1.00	
TM244	11	1.9	**1.6**	**2.2**	0.3	5.29		1.00	
TM245	11	0.4	**0.3**	**0.5**	0.1	0.00		1.00	
					mean ±SD	4.04	1.36	1.00	0.00

* TM 245 excluded from mean % CV calculation

Sample ID	N	All Method Median	Median % CV
TM241	**11**	**11.3**	**3.28**
TM242	**10**	**5.2**	**2.51**
TM243	**11**	**3.0**	**5.07**
TM244	**11**	**1.9**	**5.29**
TM245	**11**	**0.4**	**0.00**
		Average	**4.04**
		Allowable CV %	**5.0**
		Allowable Error (+/-)%	**15.0**

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

http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2012/index.htm

Oncology Soluble Tumor Markers						
		TM241	**TM242**	**TM243**	**TM244**	**TM245**
AFP (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 125 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 15-3 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 19-9 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CA 27.29 (U/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
CEA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
PSA (Total) **for a 2nd method used in conjunction with free PSA (ng/mL)** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Free PSA (ng/ml) **If test offered, measure and report for all samples** **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					
Complexed PSA (ng/ml) **Reagent Lot_____** **Calibrator Lot_____**	>/<					
	Result					

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

FOR LABS THAT TEST **FREE PSA,** RESULTS MUST NOW BE SUBMITTED FOR **ALL** SAMPLES WHILE **PERCENT** FREE PSA WILL NO LONGER BE REPORTED. SEE INSTRUCTIONS FOR MORE INFORMATION.

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

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