NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

January 24, 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: **February 8, 2012**

Samples:
Enclosed are five sealed (5) vials labeled **TM236 to TM240**, 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 February 8, 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-outs are scheduled as follows:

Mail-out date:	Due date:
May 8, 2012	**May 23, 2012**
September 11, 2012	**September 26, 2012**

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state department of
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Nirav R. Shah, M.D., M.P.H.
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March 21, 2012

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

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from January 24, 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 change in report format):

Your laboratory's results, scores and grades together with your grades from the previous two PT events and your overall performance status are displayed on a separate report that was posted on the Department's Health Commerce Site; you should have received an email alerting you to this effect,. This critique with summary tables and graphs is sent electronically by email to all laboratory contacts on record, and is posted on our website at: http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm, and will also be accessible through a 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.

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)

[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.

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: 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, with a few exceptions, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, unless 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 method 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 your information, summary tables are included for each analyte showing the targets and upper and lower limits for each sample and peer group. 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 its 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 also calculated those 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 122 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 56% of the labs gave results within +/- 15% of the all method medians. Of the other three groups, two (Roche and Siemens Immulite) were below -15% from the median, while TOSOH ST-AIA (used by six labs representing about 5% of the participants) gave the highest results that were on average 33% above the all method medians.

CA19-9 (Table 2, Figure 2): Results were reported by 71 labs using nine methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in six peer groups. Forty-nine percent of all reporting labs used Siemens ADVIA-Centaur XP, 18% used either Beckman Unicel or Access/2, 18% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 8% used the Tosoh ST-AIA method. Only the Roche and Beckman methods were within +/- 15% of the all method median. Measurements by Tosoh ST-AIA were lower than the medians by an average of 25%, 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 six 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 111 labs, with slightly more than half (55%) 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). Note that the ADVIA Centaur XP and CP instruments were combined, since only three labs reported using the CP instrument and the means of the CP results were well within the acceptable ranges for the XP instrument for this and the previous proficiency tests. For **CA15-3**, combining results from different instruments made by the same manufacturer and/or brand resulted in six peer groups, three of which comprised less than ten labs each. Two peer groups (Beckman and Ortho Vitros) gave results that were outside the +/- 15% range from the all method median. Siemens ADVIA-Centaur methods (used by 19% of the labs) exhibited a positive bias equivalent to the Siemens Immulite 2000 & 2500 group (used by 10% of labs) each at +14% on average compared to the median. In contrast, both the Vitros ECi/ECiQ results at -16% and especially, the Beckman Unicel/Access results at -44% from the all method medians exhibited a strong negative bias. Of the methods used for measuring **CA27.29**, the ADVIA Centaur XP combined with CP and the Tosoh method showed an 8% difference from each other. The overall median values measured by the CA27.29 methods were lower than those for CA15-3 by 11-22%. In conclusion, there are three distinct groups for CA15-3, namely Abbott, Siemens ADVIA and Immulite at +12% from the all method medians, Roche and Ortho Clinical Diagnostics Vitros at -12.5%, and Beckman at -44%. In contrast, the three methods used for CA27.29 agree relatively well with each other.

CEA (Table 5, Figure 5): Results were reported by 177 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 7 to 50 labs. The one ADVIA Centaur CP result reported was grouped with the Centaur XP results because it fit well with that group, showing no significant difference for this analyte, similar to the previous PT event. Overall, the results reported by the majority of the labs (73%) were fairly consistent, being within +/-10% of the medians. The two Beckman instruments were analyzed together for this event since no significant differences were seen between results from both instruments and both measured CEA on average 2% lower than the all method median. Similarly, no difference was seen between the Roche Elecsys/Cobas e411 group and the E170/Cobas e601 group so they were combined, and together they averaged 16% below the medians. In contrast, the Ortho Clinical Diagnostics Vitros ECi/Q & 5600 methods gave results that averaged 15% higher than the medians, and notably, the TOSOH ST-AIA measurements averaged 49% higher than the medians. 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, free PSA and 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 108 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, but together accounted for twenty-one percent of the total number of labs. Although all but the Ortho Clinical Diagnostics Vitros peer group showed results above the assigned target, there was mostly very little variation (<5% from the all method median) between the results from those methods. The exceptions were the aforementioned Ortho Vitros at -22% and to a lesser extent Roche at +14% from the all method median.

PSA (Table 7, Figures 7A&B): Results were reported by 266 labs using 22 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were 10 peer groups, two 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 free to ACT-complexed PSA of 13%. As shown in Figure 7B and observed in previous PT events, results could be grouped into a low and a high group that were statistically significantly different (P=0.0027). The high group comprised Beckman Unicel and Access with the Hybritech calibration; Siemens Immulite instruments using either the original PSA pack or the Third Generation pack; and Siemens Dimension RxL Max, Xpand Plus, and EXL. Overall the results for those methods ranged from 19-28% higher than the assigned targets (mean 1.24±0.04). The

low group comprised Abbott AxSym; Beckman Unicel/Access with the WHO calibration; Roche Elecsys/Cobas; Siemens ADVIA Centaur XP/CP and Dimension Vista; Ortho Vitros ECi, ECiQ, and 5600; and Tosoh AIA) with the results ranging from 7% to 14% above the assigned targets (mean 1.10±0.02). As expected, a clear difference between the Beckman groups was observed; those calibrated with original Hybritech standard on average measured 24% higher than the targets, whereas those calibrated with the international WHO standard measured the lowest of any method averaging 7% above the assigned targets. Even though this represents only a 17% difference, overall it 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 each method in their respective high or low group is excellent (intermethod %CVs ≤3.0%), 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 90 labs using fourteen different methods. After combining results from different instruments made by the same manufacturer and/or brand there were only six peer groups, three of which comprised less than 10 labs each and together were used by only 12% of the participants. The other methods were used by 31% (Beckman Unicel/Access calibrated with the Hybritech standards), 29% (Roche Elecsys/E170/Cobas) and 23% (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 (59% 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 and Abbott Architect were 35% and 30% above the targets, respectively, and were 15% 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 about 18% above target, while of the three Siemens methods, Immulite 1000/2000 averaged 5% above the assigned target and Dimension Vista was slightly below at -4%. 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 11% with the Siemens Immulite and Dimension methods to a high of 16-18% with the Beckman methods. In general the ratios of free to total PSA were relatively constant across all five samples. In contrast, the 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. However, since the total PSA levels ranged from 1.0 to 9.5 ng/mL the significance of this observation is unclear.

Please note, labs are now required to measure and report **free PSA** for **all proficiency test samples** if they test for free PSA, but we are no longer requesting the percent free PSA to be reported since the intention of the proficiency test is to evaluate differences in the analytical measurements from labs and instrument peer groups rather than mathematical calculations. 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. However, the ability to accurately measure free PSA is an essential process for a testing laboratory, while calculating % free PSA is a secondary operation usually done by a computer. In addition, some labs do not normally calculate % free PSA at all, but only report free and total PSA values, leaving the calculation of % free PSA to the physician. The question under free PSA regarding lab policy on calculation of % free PSA was included for informational purposes only with the answers as follows:

Finally, only 11 labs measured **complexed PSA** and all of these used the Siemens ADVIA-Centaur method, with relatively good agreement between the labs as indicated by an average %CV of 6.32% (Table 9).

In conclusion, the observation has again been made that there are substantial differences between the results obtained with various methods or instruments for many of the analytes. Furthermore, not all methods appear equally reproducible as indicated by the substantial spread of intermethod %CVs. 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 continue to try to minimize the differences that can be attributed to the sample composition. Nevertheless, despite the somewhat artificial nature of the PT samples, we suggest that 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 are **submitted**. If results were **saved** but not submitted, they will be graded as an administrative **fail**.

Please be aware that in each subsequent event, fields will usually be pre-populated based on what you entered this time or a previous time, but you must **verify that the selected instruments and reagents are correct,** whether pre-populated from the last event or newly entered information. That information must be accurate to properly evaluate your results and compare them to those of your peer group. There are instances where individual labs have either **inadvertently selected**

a qualifier (< or >) or an incorrect instrument or reagent when scrolling through the electronic reporting page lists and it has resulted in a failing grade. You are at risk of receiving 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 once the submission deadline has passed.

The PSA2 option still applies to allow entry of results from a second PSA assay, but only for labs that use a different or additional method for total PSA in conjunction with their free PSA measurements**. If only one PSA test was done, then results should be entered in the first PSA line and "test not offered" selected for PSA2.** For labs that enter two PSA tests, the primary PSA test gets entered on the first PSA line and the secondary assay (for use in conjunction with their free PSA results) on the PSA2 line.

Finally, only four labs responded that they are currently testing for HE-4, and only two indicated that they were using it in conjunction with the ROMA algorithm.

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 dates for the remaining 2012 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
May 8, 2012	May 23, 2012
September 11, 2012	September 26, 2012

If you have any questions or wish to discuss some of the issues alluded to in this discussion, 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: 1-12 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									
TM 236	14	**31.5**	**24.0**	**39.0**	7.5	10.95		1.16	
TM 237	14	**69.9**	**57.3**	**82.5**	12.6	7.78		1.12	
TM 238	14	**50.3**	**41.2**	**59.4**	9.1	8.95		1.13	
TM 239	14	**35.4**	**29.0**	**41.8**	6.4	9.35		1.11	
TM 240	14	**41.1**	**33.7**	**48.5**	7.4	8.95		1.15	
					mean±SD	9.20	1.14	1.13	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM 236	13	**27.9**	**20.4**	**35.4**	7.5	5.27		1.03	
TM 237	13	**67.0**	**54.9**	**79.1**	12.1	4.40		1.07	
TM 238	13	**47.1**	**38.6**	**55.6**	8.5	5.05		1.06	
TM 239	13	**34.2**	**26.7**	**41.7**	7.5	5.38		1.08	
TM 240	13	**37.8**	**31.0**	**44.6**	6.8	6.19		1.06	
					mean±SD	5.26	0.64	1.06	0.02
Roche Elecsys & Cobas BME/BMR									
TM 236	18	**22.7**	**15.2**	**30.2**	7.5	5.20		0.84	
TM 237	18	**47.8**	**39.2**	**56.4**	8.6	4.67		0.76	
TM 238	17	**35.1**	**28.8**	**41.4**	6.3	3.53		0.79	
TM 239	18	**25.7**	**18.2**	**33.2**	7.5	5.37		0.81	
TM 240	17	**28.1**	**20.6**	**35.6**	7.5	3.77		0.78	
					mean±SD	4.51	0.83	0.80	0.03
Siemens Advia Centaur XP & CP COB/COC									
TM 236	33	**27.1**	**19.6**	**34.6**	7.5	4.61		1.00	
TM 237	34	**58.5**	**48.0**	**69.0**	10.5	4.67		0.94	
TM 238	34	**42.9**	**35.2**	**50.6**	7.7	5.17		0.96	
TM 239	32	**31.6**	**24.1**	**39.1**	7.5	3.83		0.99	
TM 240	34	**34.5**	**27.0**	**42.0**	7.5	5.07		0.96	
					mean±SD	4.67	0.53	0.97	0.03
Siemens Immulite 2000 & 2500 DPD/DPF									
TM 236	29	**23.0**	**15.5**	**30.5**	7.5	6.43		0.85	
TM 237	29	**52.3**	**42.9**	**61.7**	9.4	5.72		0.84	
TM 238	29	**37.9**	**31.1**	**44.7**	6.8	6.54		0.85	
TM 239	29	**26.6**	**19.1**	**34.1**	7.5	6.84		0.84	
TM 240	29	**29.9**	**22.4**	**37.4**	7.5	6.52		0.84	
					mean±SD	6.41	0.42	0.84	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM 236	7	**27.1**	**19.6**	**34.6**	7.5	7.60		1.00	
TM 237	7	**62.5**	**51.3**	**73.8**	11.3	5.92		1.00	
TM 238	7	**44.5**	**36.5**	**52.5**	8.0	7.48		1.00	
TM 239	7	**31.8**	**24.3**	**39.3**	7.5	4.75		1.00	
TM 240	7	**35.8**	**29.4**	**42.2**	6.4	4.80		1.00	
					mean±SD	6.11	1.39	1.00	0.00
Tosoh AIA TOM									
TM 236	6	**37.4**	**30.7**	**44.1**	6.7	13.69		1.38	
TM 237	5	**81.2**	**66.6**	**95.8**	14.6	2.98		1.30	
TM 238	5	**58.5**	**48.0**	**69.0**	10.5	3.37		1.31	
TM 239	6	**43.4**	**35.6**	**51.2**	7.8	16.71		1.36	
TM 240	5	**45.4**	**37.2**	**53.6**	8.2	3.66		1.27	
					mean±SD	8.08	6.59	1.33	0.05

continued on next page

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

Sample ID	N	All Method Median	Median % CV
TM 236	121	27.1	6.43
TM 237	121	62.5	4.67
TM 238	120	44.5	5.17
TM 239	120	31.8	5.38
TM 240	120	35.8	5.07
		Average	5.35
		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

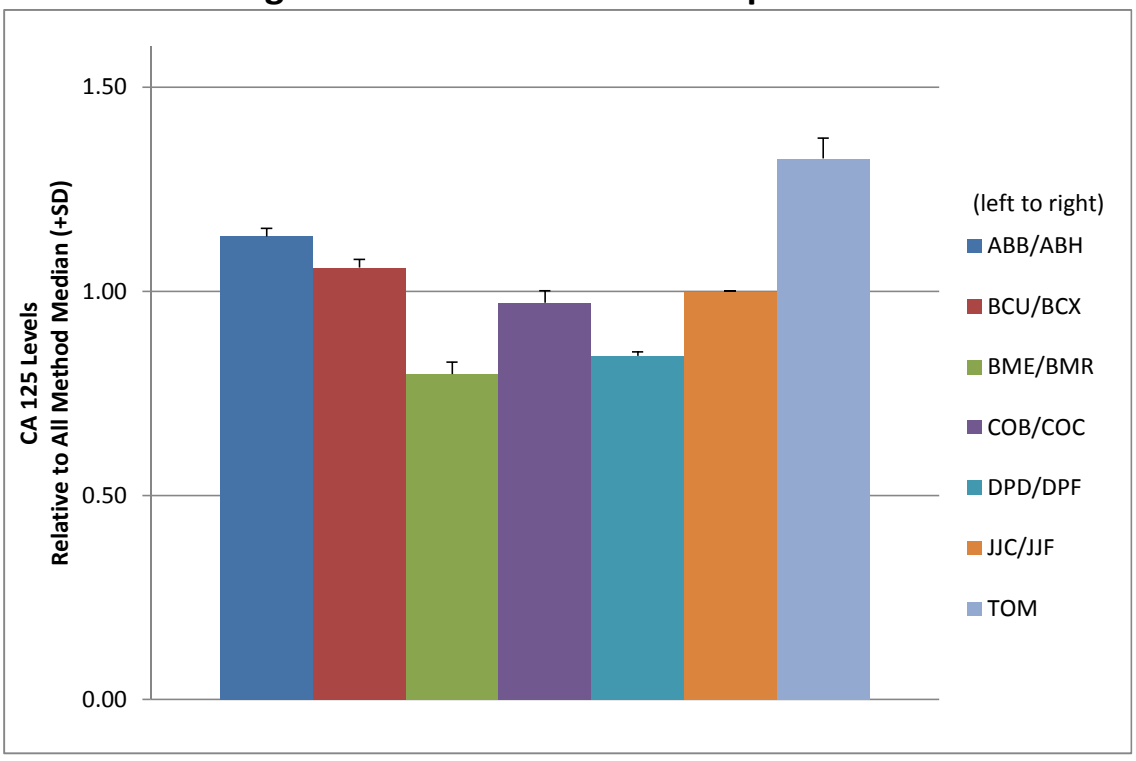

Table 2: 1-12 NYS Tumor Marker PT Summary for CA 19-9

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									
TM 236	2	**223.3**	**183.1**	**263.5**	40.2	6.84		5.92	
TM 237	2	**268.3**	**220.0**	**316.6**	48.3	1.55		6.18	
TM 238	2	**173.7**	**142.4**	**205.0**	31.3	4.48		6.14	
TM 239	2	**340.5**	**279.2**	**401.8**	61.3	3.43		6.31	
TM 240	2	**512.6**	**420.3**	**604.9**	92.3	2.77		6.21	
					mean±SD	3.81	2.00	6.15	0.14
Beckman Unicel & Access/2 BCU/BCX									
TM 236	13	**37.7**	**30.9**	**44.5**	6.8	5.15		1.00	
TM 237	13	**43.4**	**35.6**	**51.2**	7.8	6.41		1.00	
TM 238	13	**28.3**	**23.2**	**33.4**	5.1	5.94		1.00	
TM 239	13	**54.0**	**44.3**	**63.7**	9.7	4.50		1.00	
TM 240	13	**82.5**	**67.7**	**97.4**	14.9	6.56		1.00	
					mean±SD	5.71	0.87	1.00	0.00
Roche Elecsys & Cobas BME/BMR									
TM 236	13	**34.6**	**28.4**	**40.8**	6.2	3.27		0.92	
TM 237	13	**37.8**	**31.0**	**44.6**	6.8	4.97		0.87	
TM 238	13	**26.4**	**21.6**	**31.2**	4.8	2.50		0.93	
TM 239	13	**45.6**	**37.4**	**53.8**	8.2	2.43		0.84	
TM 240	13	**67.5**	**55.4**	**79.7**	12.2	2.70		0.82	
					mean±SD	3.17	1.06	0.88	0.05
Siemens Advia Centaur XP COB									
TM 236	35	**74.4**	**61.0**	**87.8**	13.4	7.43		1.97	
TM 237	35	**82.1**	**67.3**	**96.9**	14.8	7.80		1.89	
TM 238	35	**55.6**	**45.6**	**65.6**	10.0	6.42		1.96	
TM 239	35	**109.7**	**90.0**	**129.4**	19.7	7.44		2.03	
TM 240	35	**171.7**	**140.8**	**202.6**	30.9	5.56		2.08	
					mean±SD	6.93	0.92	1.99	0.07
Tosoh AIA TOM									
TM 236	6	**34.2**	**28.0**	**40.4**	6.2	7.54		0.91	
TM 237	6	**28.5**	**23.4**	**33.6**	5.1	2.63		0.66	
TM 238	6	**25.7**	**21.1**	**30.3**	4.6	5.91		0.91	
TM 239	6	**37.3**	**30.6**	**44.0**	6.7	2.82		0.69	
TM 240	6	**50.3**	**41.2**	**59.4**	9.1	3.08		0.61	
					mean±SD	4.40	2.21	0.75	0.14

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Table 2 (cont.): 1-12 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM 236	69	37.7	6.8
TM 237	69	43.4	5.0
TM 238	69	28.3	5.9
TM 239	69	54.0	3.4
TM 240	69	82.5	3.1
		Average	4.85
		Allowable CV %	6.0
		Allowable Error (+/-)%	18.0

Figure 2: CA 19-9 Method Comparison

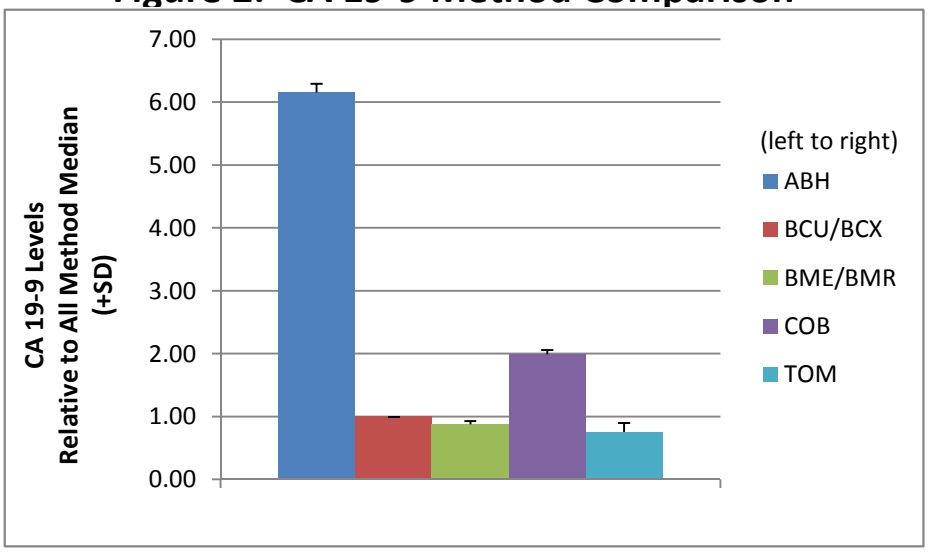

Table 3: 1-12 NYS Tumor Marker PT Summary for CA 15-3

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									
TM 236	7	**102.8**	**81.2**	**124.4**	21.6	11.11		1.10	
TM 237	7	**34.0**	**26.9**	**41.1**	7.1	11.59		1.09	
TM 238	7	**68.7**	**54.3**	**83.1**	14.4	10.36		1.08	
TM 239	7	**54.9**	**43.4**	**66.4**	11.5	9.64		1.08	
TM 240	7	**47.0**	**37.1**	**56.9**	9.9	9.06		1.08	
					mean±SD	10.35	1.03	1.09	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM 236	6	**52.9**	**41.8**	**64.0**	11.1	3.86		0.57	
TM 237	6	**17.1**	**13.5**	**20.7**	3.6	0.94		0.55	
TM 238	6	**35.9**	**28.4**	**43.4**	7.5	1.50		0.57	
TM 239	6	**27.7**	**21.9**	**33.5**	5.8	3.10		0.55	
TM 240	6	**24.6**	**19.4**	**29.8**	5.2	2.68		0.56	
					mean±SD	2.42	1.19	0.56	0.01
Roche Elecsys & Cobas BME/BMR									
TM 236	12	**84.3**	**66.6**	**102.0**	17.7	5.35		0.90	
TM 237	12	**28.5**	**22.5**	**34.5**	6.0	3.61		0.91	
TM 238	12	**58.3**	**46.1**	**70.5**	12.2	4.92		0.92	
TM 239	12	**46.4**	**36.7**	**56.1**	9.7	3.32		0.92	
TM 240	12	**40.2**	**31.8**	**48.6**	8.4	4.85		0.92	
					mean±SD	4.41	0.89	0.91	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM 236	21	**103.7**	**81.9**	**125.5**	21.8	10.06		1.11	
TM 237	21	**35.4**	**28.0**	**42.8**	7.4	10.51		1.13	
TM 238	21	**73.0**	**57.7**	**88.3**	15.3	11.21		1.15	
TM 239	21	**58.2**	**46.0**	**70.4**	12.2	11.68		1.15	
TM 240	21	**50.0**	**39.5**	**60.5**	10.5	11.14		1.15	
					mean±SD	10.92	0.64	1.14	0.02
Siemens Immulite 2000 & 2500 DPD/DPF									
TM 236	11	**109.5**	**86.5**	**132.5**	23.0	10.29		1.17	
TM 237	11	**35.9**	**28.4**	**43.4**	7.5	7.80		1.15	
TM 238	11	**74.1**	**58.5**	**89.7**	15.6	6.80		1.17	
TM 239	11	**55.4**	**43.8**	**67.0**	11.6	10.87		1.09	
TM 240	11	**49.2**	**38.9**	**59.5**	10.3	6.85		1.13	
					mean±SD	8.52	1.93	1.14	0.03
Ortho Clinical Diag Vitros Eci/ECiQ JJC									
TM 236	4	**79.5**	**62.8**	**96.2**	16.7	3.94		0.85	
TM 237	4	**25.4**	**20.1**	**30.7**	5.3	3.74		0.81	
TM 238	3	**55.0**	**43.5**	**66.6**	11.6	0.11		0.87	
TM 239	4	**42.5**	**33.6**	**51.4**	8.9	3.98		0.84	
TM 240	4	**36.7**	**29.0**	**44.4**	7.7	7.11		0.84	
					mean±SD	3.77	2.48	0.84	0.02

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Table 3 (cont.): 1-12 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM 236	61	93.6	7.7
TM 237	61	31.3	5.8
TM 238	60	63.5	5.9
TM 239	61	50.7	6.8
TM 240	61	43.6	7.0
		Average	6.62
		Allowable CV %	7.0
		Allowable Error (+/-)%	21.0

Figure 3: CA 15-3 Method Comparison

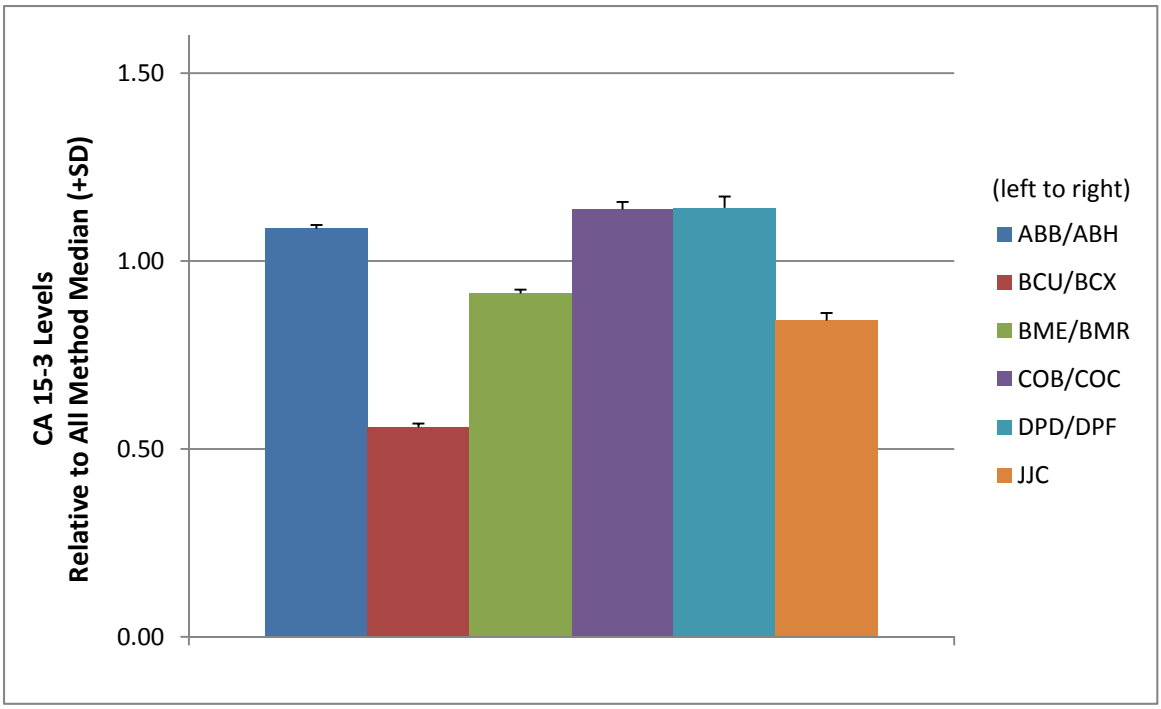

Table 4: 1-12 NYS Tumor Marker PT Summary for CA 27.29

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									
TM 236	44	**84.7**	**66.9**	**102.5**	17.8	5.38		1.03	
TM 237	44	**21.7**	**14.4**	**29.1**	7.4	13.87		0.88	
TM 238	44	**56.2**	**44.4**	**68.0**	11.8	7.38		0.99	
TM 239	44	**42.2**	**33.3**	**51.1**	8.9	8.01		0.97	
TM 240	44	**34.5**	**27.2**	**41.9**	7.4	8.84		0.95	
					mean±SD	8.70	3.16	0.96	0.06
Tosoh AIA TOM									
TM 236	6	**80.0**	**63.2**	**96.8**	16.8	4.64		0.97	
TM 237	6	**27.6**	**20.3**	**35.0**	7.4	8.84		1.12	
TM 238	6	**57.4**	**45.3**	**69.5**	12.1	5.17		1.01	
TM 239	6	**44.4**	**35.1**	**53.7**	9.3	5.07		1.03	
TM 240	6	**38.4**	**30.3**	**46.5**	8.1	5.81		1.05	
					mean±SD	5.91	1.69	1.04	0.06

Sample ID	N	All Method Median	Median % CV
TM 236	**50**	**82.4**	**5.0**
TM 237	**50**	**24.7**	**11.4**
TM 238	**50**	**56.8**	**6.3**
TM 239	**50**	**43.3**	**6.5**
TM 240	**50**	**36.5**	**7.3**
		Average	**6.29**

Allowable CV %	**7.0**
Allowable Error (+/-)% for ≥ 35 U/ml	**21.0**
Allowable Error (+/-) for < 35 U/ml	**7.35**

Figure 4: CA 27.29 Method Comparison

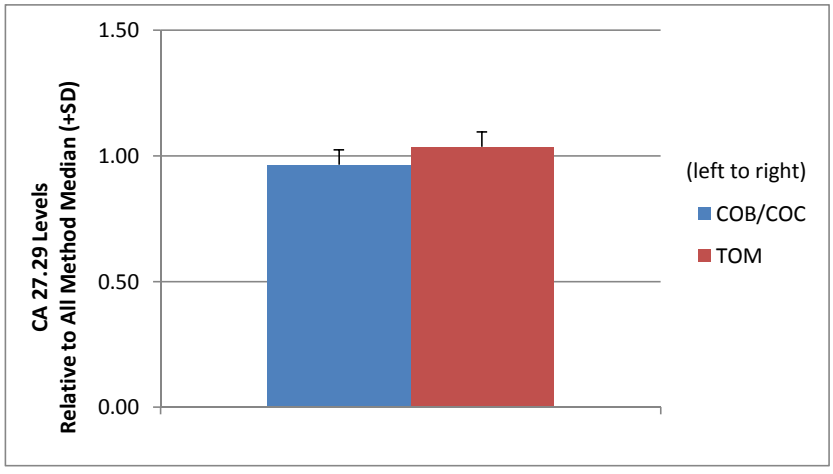

Table 5: 1-12 NYS Tumor Marker PT Summary for CEA

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									
TM 236	19	**15.2**	**12.5**	**17.9**	2.7	4.28		1.04	
TM 237	19	**11.0**	**9.0**	**13.0**	2.0	5.55		1.01	
TM 238	19	**7.3**	**6.0**	**8.6**	1.3	4.93		1.04	
TM 239	19	**6.6**	**5.4**	**7.8**	1.2	4.70		1.06	
TM 240	19	**5.9**	**4.8**	**7.0**	1.1	5.08		1.04	
					mean±SD	4.91	0.47	1.04	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM 236	27	**13.9**	**11.4**	**16.4**	2.5	6.47		0.95	
TM 237	27	**10.3**	**8.4**	**12.2**	1.9	6.80		0.95	
TM 238	27	**6.9**	**5.7**	**8.1**	1.2	7.10		0.98	
TM 239	27	**6.2**	**5.1**	**7.3**	1.1	7.42		0.99	
TM 240	27	**5.7**	**4.7**	**6.7**	1.0	7.72		1.01	
					mean±SD	7.10	0.49	0.98	0.03
RocheElecsys & Cobas BME/BMR									
TM 236	26	**11.4**	**9.3**	**13.5**	2.1	4.82		0.78	
TM 237	26	**8.8**	**7.2**	**10.4**	1.6	4.55		0.81	
TM 238	26	**5.8**	**4.8**	**6.8**	1.0	5.34		0.82	
TM 239	26	**5.4**	**4.4**	**6.4**	1.0	5.56		0.86	
TM 240	26	**5.2**	**4.3**	**6.1**	0.9	5.58		0.92	
					mean±SD	5.17	0.46	0.84	0.05
Siemens Advia Centaur XP & CP COB/COC									
TM 236	50	**14.1**	**11.6**	**16.6**	2.5	5.18		0.97	
TM 237	50	**10.7**	**8.8**	**12.6**	1.9	4.86		0.99	
TM 238	50	**6.9**	**5.7**	**8.1**	1.2	5.65		0.98	
TM 239	50	**6.0**	**4.9**	**7.1**	1.1	5.33		0.96	
TM 240	50	**5.2**	**4.3**	**6.1**	0.9	5.19		0.92	
					mean±SD	5.24	0.29	0.96	0.03
Siemens Immulite 2000 & 2500 DPD/DPF									
TM 236	17	**16.6**	**13.6**	**19.6**	3.0	5.30		1.14	
TM 237	17	**11.7**	**9.6**	**13.8**	2.1	7.01		1.08	
TM 238	17	**7.2**	**5.9**	**8.5**	1.3	7.22		1.02	
TM 239	16	**6.3**	**5.2**	**7.4**	1.1	9.37		1.01	
TM 240	17	**5.3**	**4.3**	**6.3**	1.0	8.87		0.94	
					mean±SD	7.55	1.62	1.04	0.08
Siemens Dimension Vista DUV									
TM 236	17	**14.1**	**11.6**	**16.6**	2.5	3.62		0.97	
TM 237	16	**10.7**	**8.8**	**12.6**	1.9	2.52		0.99	
TM 238	17	**6.9**	**5.7**	**8.1**	1.2	3.77		0.98	
TM 239	17	**6.2**	**5.1**	**7.3**	1.1	3.06		0.99	
TM 240	17	**5.6**	**4.6**	**6.6**	1.0	4.82		0.99	
					mean±SD	3.56	0.86	0.98	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM 236	14	**15.1**	**12.4**	**17.8**	2.7	3.31		1.03	
TM 237	14	**11.7**	**9.6**	**13.8**	2.1	4.10		1.08	
TM 238	14	**8.0**	**6.6**	**9.4**	1.4	5.00		1.13	
TM 239	14	**7.6**	**6.2**	**9.0**	1.4	4.47		1.22	
TM 240	14	**7.2**	**5.9**	**8.5**	1.3	4.31		1.27	
					mean±SD	4.24	0.62	1.15	0.10

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Table 5 (cont): 1-12 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									
TM 236	7	**21.8**	**17.9**	**25.7**	3.9	4.82		1.49	
TM 237	7	**16.3**	**13.4**	**19.2**	2.9	6.44		1.50	
TM 238	7	**10.8**	**8.9**	**12.7**	1.9	5.93		1.53	
TM 239	7	**9.4**	**7.7**	**11.1**	1.7	5.43		1.50	
TM 240	7	**8.0**	**6.6**	**9.4**	1.4	6.25		1.42	
					mean±SD	5.77	0.66	1.49	0.04

Sample ID	N	All Method Median	Median % CV
TM 236	**177**	**14.6**	**4.8**
TM 237	**176**	**10.9**	**5.2**
TM 238	**177**	**7.1**	**5.5**
TM 239	**176**	**6.3**	**5.4**
TM 240	**177**	**5.7**	**5.4**
		Average	**5.26**
		Allowable CV %	**6.0**
		Allowable Error (+/-)%	**18.0**

Figure 5: CEA Method Comparison

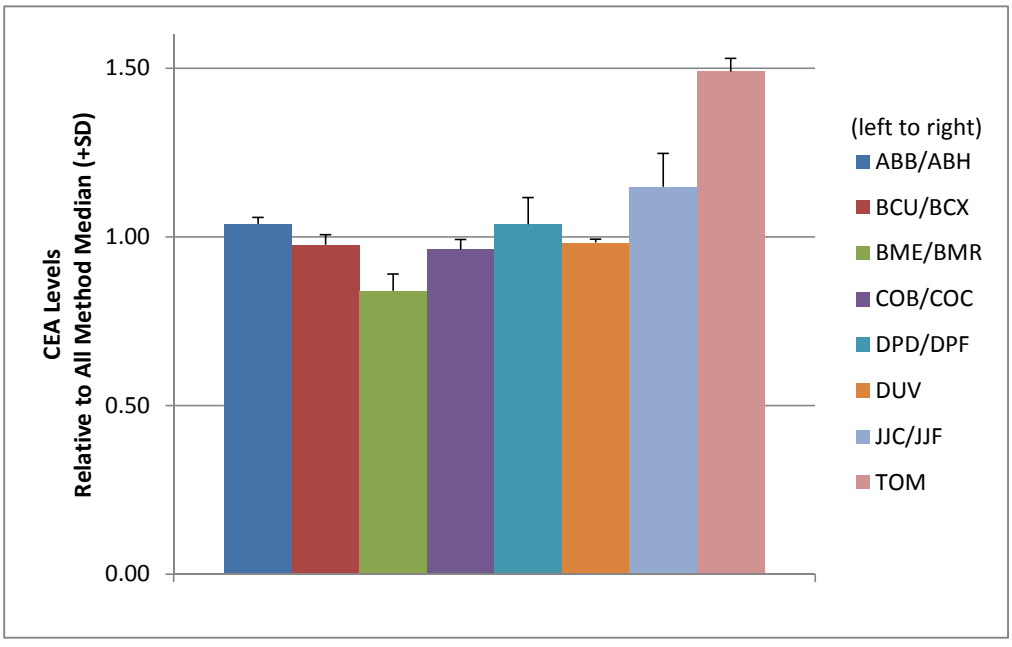

Table 6: 1-12 NYS Tumor Marker PT Summary for AFP

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											
TM 236	8	**22.6**	**18.5**	**26.7**	4.1	3.63		1.04		1.19	
TM 237	8	**12.2**	**10.0**	**14.4**	2.2	4.59		1.06		1.23	
TM 238	8	**15.4**	**12.6**	**18.2**	2.8	4.81		1.08		1.26	
TM 239	8	**28.0**	**23.0**	**33.0**	5.0	13.64		1.00		1.13	
TM 240	7	**18.6**	**15.3**	**21.9**	3.3	7.10		1.03		1.20	
					mean±SD	6.75	4.06	1.04	0.03	1.20	0.05
Beckman Unicel & Access/2 BCU/BCX											
TM 236	18	**20.7**	**17.0**	**24.4**	3.7	6.43		0.95		1.09	
TM 237	18	**11.3**	**9.3**	**13.3**	2.0	8.05		0.98		1.14	
TM 238	18	**13.8**	**11.3**	**16.3**	2.5	7.68		0.97		1.13	
TM 239	18	**26.9**	**22.1**	**31.7**	4.8	6.17		0.96		1.08	
TM 240	18	**17.6**	**14.4**	**20.8**	3.2	6.59		0.97		1.13	
					mean±SD	6.98	0.83	0.97	0.01	1.11	0.03
Roche Elecsys & Cobas BME/BMR											
TM 236	17	**24.3**	**19.9**	**28.7**	4.4	5.31		1.12		1.28	
TM 237	17	**13.2**	**10.8**	**15.6**	2.4	5.83		1.14		1.33	
TM 238	17	**16.3**	**13.4**	**19.2**	2.9	5.71		1.14		1.34	
TM 239	17	**32.6**	**26.7**	**38.5**	5.9	5.80		1.16		1.31	
TM 240	17	**20.5**	**16.8**	**24.2**	3.7	6.05		1.13		1.32	
					mean±SD	5.74	0.27	1.14	0.01	1.31	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM 236	29	**21.6**	**17.7**	**25.5**	3.9	7.36		1.00		1.13	
TM 237	29	**12.0**	**9.8**	**14.2**	2.2	8.58		1.04		1.21	
TM 238	29	**14.7**	**12.1**	**17.3**	2.6	7.82		1.03		1.21	
TM 239	29	**28.2**	**23.1**	**33.3**	5.1	5.96		1.00		1.13	
TM 240	29	**18.2**	**14.9**	**21.5**	3.3	5.99		1.01		1.17	
					mean±SD	7.14	1.15	1.01	0.02	1.17	0.04
Siemens Immulite 1000 & 2000 DPB/DPD											
TM 236	21	**21.8**	**17.9**	**25.7**	3.9	8.26		1.00		1.14	
TM 237	21	**11.3**	**9.3**	**13.3**	2.0	8.58		0.98		1.14	
TM 238	21	**13.9**	**11.4**	**16.4**	2.5	7.99		0.97		1.14	
TM 239	21	**28.5**	**23.4**	**33.6**	5.1	8.70		1.01		1.15	
TM 240	21	**18.0**	**14.8**	**21.2**	3.2	8.22		0.99		1.16	
					mean±SD	8.35	0.29	0.99	0.02	1.15	0.01
Siemens Dimension Vista DUV											
TM 236	5	**20.4**	**16.7**	**24.1**	3.7	1.42		0.94		1.07	
TM 237	5	**11.1**	**9.1**	**13.1**	2.0	1.98		0.96		1.12	
TM 238	5	**13.8**	**11.3**	**16.3**	2.5	0.94		0.97		1.13	
TM 239	5	**27.4**	**22.5**	**32.3**	4.9	2.04		0.98		1.10	
TM 240	5	**17.4**	**14.3**	**20.5**	3.1	2.07		0.96		1.12	
					mean±SD	1.69	0.50	0.96	0.01	1.11	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM 236	6	**16.4**	**13.4**	**19.4**	3.0	5.91		0.76		0.86	
TM 237	6	**9.0**	**7.4**	**10.6**	1.6	6.11		0.78		0.91	
TM 238	6	**11.2**	**9.2**	**13.2**	2.0	5.89		0.78		0.92	
TM 239	6	**22.1**	**18.1**	**26.1**	4.0	4.07		0.79		0.89	
TM 240	6	**14.0**	**11.5**	**16.5**	2.5	3.43		0.77		0.90	
					mean±SD	5.08	1.24	0.78	0.01	0.90	0.02

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Table 6 (cont.): 1-12 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	
Tosoh AIA TOM											
TM 236	4	**21.8**	**17.9**	**25.7**	3.9	2.20		1.00		1.14	
TM 237	4	**11.8**	**9.7**	**13.9**	2.1	3.56		1.02		1.19	
TM 238	4	**14.8**	**12.1**	**17.5**	2.7	3.11		1.03		1.21	
TM 239	4	**28.7**	**23.5**	**33.9**	5.2	3.34		1.02		1.15	
TM 240	4	**18.5**	**15.2**	**21.8**	3.3	3.46		1.02		1.19	
					mean±SD	3.13	0.55	1.02	0.01	1.18	0.03

Sample ID	N	All Method Median	Median % CV	All Method Median/ IS Target
TM 236	**108**	**21.7**	**5.61**	**1.14**
TM 237	**108**	**11.6**	**5.97**	**1.17**
TM 238	**108**	**14.3**	**5.80**	**1.17**
TM 239	**108**	**28.1**	**5.88**	**1.13**
TM 240	**107**	**18.1**	**6.02**	**1.16**

			Average	**5.86**	**mean±SD**	**1.15**	**0.02**
	IS based Target	**SD**	**Allowable CV %**	**6.0**			
TM 236	**19.1**	**0.68**	**Allowable Error (+/-)%**	**18.0**			
TM 237	**9.9**	**0.56**					
TM 238	**12.2**	**0.90**					
TM 239	**24.9**	**1.45**					
TM 240	**15.6**	**1.02**					

Figure 6: AFP Method Comparison

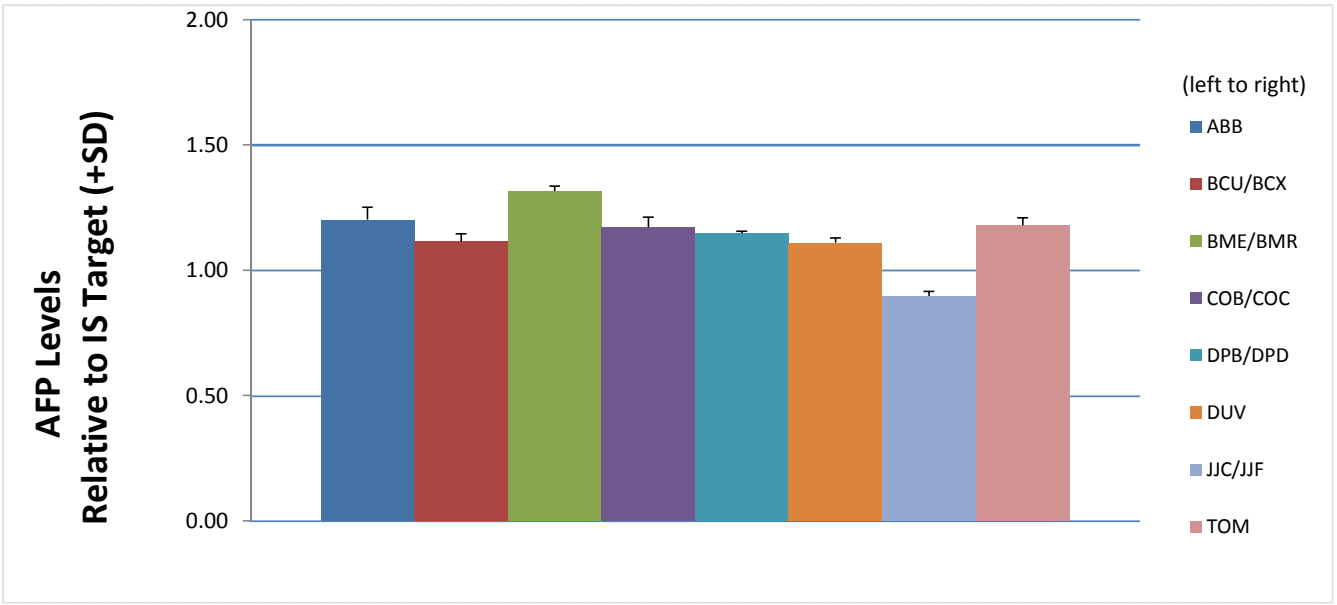

Table 7: 1-12 NYS Tumor Marker PT Summary for PSA

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												
TM 236	20	**1.1**	**0.9**	**1.3**	0.20		8.18		1.00		1.10	
TM 237	20	**2.7**	**2.2**	**3.2**	0.50		6.67		1.04		1.17	
TM 238	20	**4.2**	**3.4**	**5.0**	0.80		6.19		1.02		1.17	
TM 239	20	**8.1**	**6.6**	**9.6**	1.50		6.05		1.05		1.16	
TM 240	20	**10.7**	**8.8**	**12.6**	1.90		6.54		1.04		1.13	
						mean±SD	6.73	0.85	1.03	0.02	1.14	0.03
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)												
TM 236	53	**1.1**	**0.9**	**1.3**	0.20		6.36		1.00		1.10	
TM 237	53	**2.9**	**2.4**	**3.4**	0.50		5.17		1.12		1.26	
TM 238	52	**4.6**	**3.8**	**5.4**	0.80		3.91		1.12		1.28	
TM 239	53	**9.0**	**7.4**	**10.6**	1.60		4.56		1.17		1.29	
TM 240	53	**12.0**	**9.8**	**14.2**	2.20		4.83		1.17		1.26	
						mean±SD	4.97	0.91	1.11	0.07	1.24	0.08
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)												
TM 236	3	**1.0**	**0.8**	**1.2**	0.20		0.00		0.91		1.00	
TM 237	4	**2.6**	**2.1**	**3.1**	0.50		10.00		1.00		1.13	
TM 238	4	**3.9**	**3.2**	**4.6**	0.70		9.74		0.95		1.08	
TM 239	4	**7.6**	**6.2**	**9.0**	1.40		9.61		0.99		1.09	
TM 240	4	**9.9**	**8.1**	**11.7**	1.80		13.74		0.96		1.04	
						mean±SD	8.62	5.11	0.96	0.04	1.07	0.05
RocheElecsys & Cobas BME/BMR												
TM 236	43	**1.0**	**0.8**	**1.2**	0.20		6.00		0.91		1.00	
TM 237	43	**2.6**	**2.1**	**3.1**	0.50		3.08		1.00		1.13	
TM 238	43	**4.1**	**3.4**	**4.8**	0.70		3.17		1.00		1.14	
TM 239	43	**7.7**	**6.3**	**9.1**	1.40		2.99		1.00		1.10	
TM 240	43	**10.3**	**8.4**	**12.2**	1.90		3.20		1.00		1.08	
						mean±SD	3.69	1.30	0.98	0.04	1.09	0.06
Siemens Advia Centaur XP & CP COB/COC												
TM 236	60	**1.1**	**0.9**	**1.3**	0.20		5.45		1.00		1.10	
TM 237	61	**2.6**	**2.1**	**3.1**	0.50		5.00		1.00		1.13	
TM 238	59	**4.1**	**3.4**	**4.8**	0.70		4.15		1.00		1.14	
TM 239	61	**7.6**	**6.2**	**9.0**	1.40		5.00		0.99		1.09	
TM 240	60	**10.3**	**8.4**	**12.2**	1.90		4.08		1.00		1.08	
						mean±SD	4.74	0.60	1.00	0.01	1.11	0.03
Siemens Immulite 1000, 2000 & 2500 - Original Pack DPB/DPD/DPF (DP5)												
TM 236	24	**1.2**	**1.0**	**1.4**	0.20		9.17		1.09		1.20	
TM 237	24	**2.9**	**2.4**	**3.4**	0.50		8.97		1.12		1.26	
TM 238	24	**4.6**	**3.8**	**5.4**	0.80		7.17		1.12		1.28	
TM 239	23	**8.8**	**7.2**	**10.4**	1.60		7.05		1.14		1.26	
TM 240	24	**11.7**	**9.6**	**13.8**	2.10		7.86		1.14		1.23	
						mean±SD	8.04	0.99	1.12	0.02	1.25	0.03
Siemens Immulite 1000, 2000 & 2500 - 3rd Generation Pack DPB/DPD/DPF (DP6)												
TM 236	6	**1.1**	**0.9**	**1.3**	0.20		7.27		1.00		1.10	
TM 237	6	**2.8**	**2.3**	**3.3**	0.50		5.00		1.08		1.22	
TM 238	6	**4.3**	**3.5**	**5.1**	0.80		7.67		1.05		1.19	
TM 239	6	**8.4**	**6.9**	**9.9**	1.50		7.26		1.09		1.20	
TM 240	6	**11.8**	**9.7**	**13.9**	2.10		8.39		1.15		1.24	
						mean±SD	7.12	1.27	1.07	0.05	1.19	0.05

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Table 7 (cont.): 1-12 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 and Vista) DUD/DUX/DUV												
TM 236	22	**1.2**	**1.0**	**1.4**	0.20		7.50		1.09		1.20	
TM 237	22	**3.0**	**2.5**	**3.5**	0.50		6.33		1.15		1.30	
TM 238	22	**4.7**	**3.9**	**5.5**	0.80		6.38		1.15		1.31	
TM 239	22	**9.1**	**7.5**	**10.7**	1.60		5.93		1.18		1.30	
TM 240	22	**12.3**	**10.1**	**14.5**	2.20		6.18		1.19		1.29	
						mean±SD	6.47	0.60	1.15	0.04	1.28	0.05
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF												
TM 236	23	**1.1**	**0.9**	**1.3**	0.20		6.36		1.00		1.10	
TM 237	23	**2.6**	**2.1**	**3.1**	0.50		5.00		1.00		1.13	
TM 238	23	**4.0**	**3.3**	**4.7**	0.70		5.00		0.98		1.11	
TM 239	23	**7.4**	**6.1**	**8.7**	1.30		5.68		0.96		1.06	
TM 240	23	**9.8**	**8.0**	**11.6**	1.80		5.41		0.95		1.03	
						mean±SD	5.49	0.57	0.98	0.02	1.09	0.04
Tosoh AIA TOM												
TM 236	10	**1.1**	**0.9**	**1.3**	0.20		10.00		1.00		1.10	
TM 237	10	**2.6**	**2.1**	**3.1**	0.50		6.15		1.00		1.13	
TM 238	10	**4.0**	**3.3**	**4.7**	0.70		6.75		0.98		1.11	
TM 239	10	**7.6**	**6.2**	**9.0**	1.40		6.45		0.99		1.09	
TM 240	10	**10.1**	**8.3**	**11.9**	1.80		5.54		0.98		1.06	
						mean±SD	6.98	1.75	0.99	0.01	1.10	0.03

Sample ID	N	All Method Median			Median % CV	All Method median/ IS Target	
TM 236	**264**	**1.1**			**6.8**	**1.10**	
TM 237	**266**	**2.6**			**5.7**	**1.13**	
TM 238	**263**	**4.1**			**6.3**	**1.14**	
TM 239	**265**	**7.7**			**6.0**	**1.10**	
TM 240	**265**	**10.3**			**5.9**	**1.08**	
						1.11	**0.02**
		IS based Target	**SD**				
TM 236		**1.0**	**0.05**	**Average**	**6.12**		
TM 237		**2.3**	**0.15**	**Allowable CV %**	**6.0**		
TM 238		**3.6**	**0.20**	**Allowable Error (+/-)%**	**18.0**		
TM 239		**7.0**	**0.35**				
TM 240		**9.5**	**0.37**				

Figure 7A: PSA Method Comparison

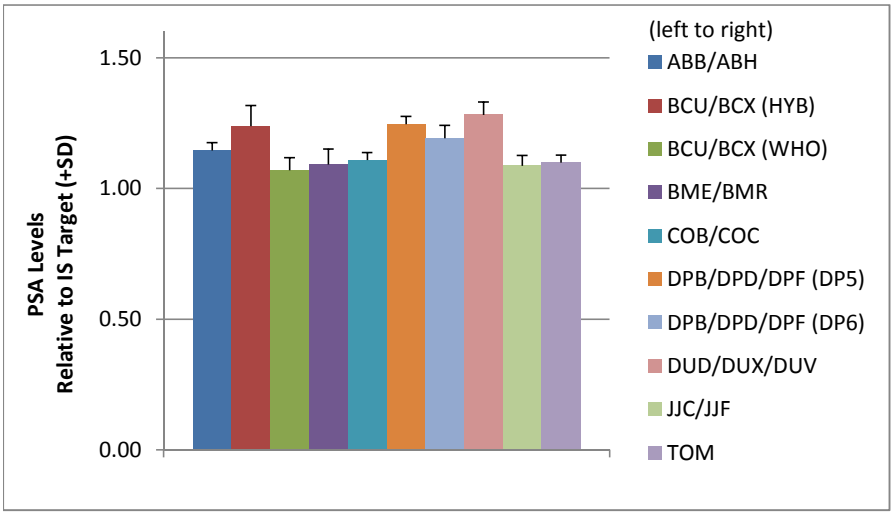

Figure 7B

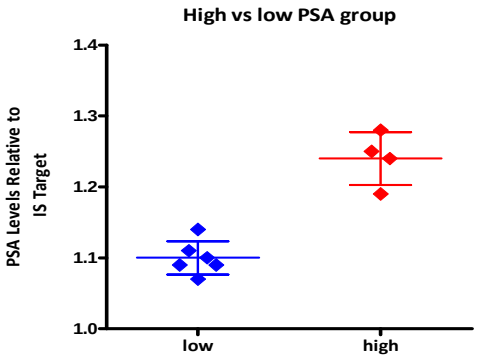

Table 8: 1-12 NYS Tumor Marker PT Summary for Free PSA

Method Method Code Sample ID	N	Target	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											
TM 236	5	**0.16**	**0.13**	**0.19**	0.03	6.25		1.14		1.32	
TM 237	5	**0.40**	**0.32**	**0.48**	0.08	7.50		1.08		1.29	
TM 238	5	**0.61**	**0.48**	**0.74**	0.13	8.20		1.07		1.25	
TM 239	5	**1.21**	**0.96**	**1.46**	0.25	11.57		1.12		1.34	
TM 240	5	**1.59**	**1.26**	**1.92**	0.33	10.69		1.11		1.32	
					mean±SD	8.84	2.22	1.11	0.03	1.30	0.04
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM 236	28	**0.20**	**0.16**	**0.24**	0.04	5.00		1.43		1.65	
TM 237	28	**0.50**	**0.40**	**0.61**	0.11	4.00		1.35		1.61	
TM 238	28	**0.76**	**0.60**	**0.92**	0.16	3.95		1.33		1.56	
TM 239	28	**1.42**	**1.12**	**1.72**	0.30	4.23		1.31		1.58	
TM 240	28	**1.86**	**1.47**	**2.25**	0.39	4.30		1.30		1.55	
					mean±SD	4.29	0.42	1.35	0.05	1.59	0.04
RocheElecsys & Cobas BME/BMR											
TM 236	23	**0.14**	**0.11**	**0.17**	0.03	7.14		1.00		1.15	
TM 237	26	**0.37**	**0.29**	**0.45**	0.08	5.41		1.00		1.19	
TM 238	26	**0.57**	**0.45**	**0.69**	0.12	3.51		1.00		1.17	
TM 239	26	**1.08**	**0.85**	**1.31**	0.23	4.63		1.00		1.20	
TM 240	26	**1.43**	**1.13**	**1.73**	0.30	3.50		1.00		1.19	
					mean±SD	4.84	1.52	1.00	0.00	1.18	0.02
Siemens Immulite 1000 & 2000 DPB/DPD											
TM 236	21	**0.12**	**0.09**	**0.15**	0.03	8.33		0.86		0.99	
TM 237	21	**0.32**	**0.25**	**0.39**	0.07	6.25		0.86		1.03	
TM 238	21	**0.51**	**0.40**	**0.62**	0.11	5.88		0.89		1.05	
TM 239	21	**0.98**	**0.77**	**1.19**	0.21	5.10		0.91		1.09	
TM 240	21	**1.32**	**1.04**	**1.60**	0.28	7.58		0.92		1.10	
					mean±SD	6.63	1.31	0.89	0.03	1.05	0.04
Siemens Dimension (RxL Max, Xpand Plus) DUD											
TM 236	3	**0.19**	**0.15**	**0.23**	0.04	10.53		1.36		1.57	
TM 237	3	**0.41**	**0.32**	**0.50**	0.09	7.32		1.11		1.32	
TM 238	3	**0.62**	**0.49**	**0.75**	0.13	6.45		1.09		1.27	
TM 239	3	**1.19**	**0.94**	**1.44**	0.25	7.56		1.10		1.32	
TM 240	3	**1.54**	**1.22**	**1.86**	0.32	7.79		1.08		1.28	
					mean±SD	7.93	1.54	1.15	0.12	1.35	0.12
Siemens Dimension Vista (LOCI) DUV											
TM 236	3	**0.13**	**0.10**	**0.16**	0.03	9.09		0.79		0.91	
TM 237	3	**0.33**	**0.26**	**0.40**	0.07	3.33		0.81		0.97	
TM 238	3	**0.51**	**0.40**	**0.62**	0.11	2.13		0.82		0.96	
TM 239	3	**0.95**	**0.75**	**1.15**	0.20	3.41		0.81		0.98	
TM 240	3	**1.27**	**1.00**	**1.54**	0.27	2.56		0.82		0.97	
					mean±SD	4.11	2.84	0.81	0.01	0.96	0.03

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Table 8 (cont.) : 1-12 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	Median % CV	All Method median/ IS Target	
TM 236	84	0.14	7.14	1.15	
TM 237	87	0.37	6.25	1.19	
TM 238	87	0.57	5.88	1.17	
TM 239	87	1.08	5.10	1.20	
TM 240	87	1.43	7.58	1.19	
				1.18	0.02

	IS based Targ	SD		
			Average	6.39
TM 236	0.12	0.01		
TM 237	0.31	0.01		
TM 238	0.49	0.01	Allowable CV %	7.0
TM 239	0.90	0.03	Allowable Error (+/-)%	21.0
TM 240	1.20	0.04		

Figure 8: Free PSA Method Comparison

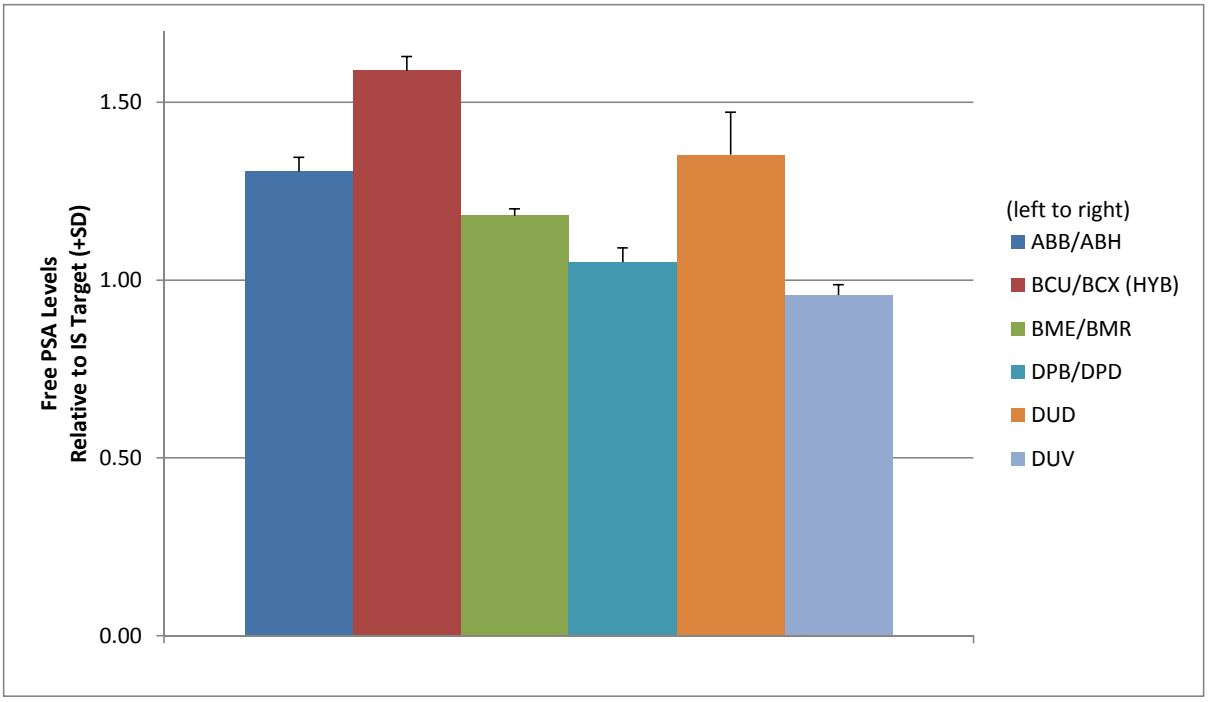

Table 9: 1-12 NYS Tumor Marker PT Summary for Complexed PSA

Method Method Code Sample ID	N	Target	Lower Limit	Upper Limit	Dmax	%CV of Raw Data	
Siemens Advia Centaur XP & CP COB/COC							
TM 236	11	**0.88**	**0.70**	**1.10**	0.20	9.09	
TM 237	11	**2.21**	**1.70**	**2.70**	0.50	5.88	
TM 238	11	**3.48**	**2.70**	**4.20**	0.75	6.90	
TM 239	11	**6.59**	**5.20**	**8.00**	1.40	4.40	
TM 240	11	**8.84**	**7.00**	**10.70**	1.85	5.32	
					mean±SD	6.32	1.80

Sample ID	N	All Method Median	Median % CV
TM 236	**11**	**0.88**	**9.09**
TM 237	**11**	**2.21**	**5.88**
TM 238	**11**	**3.48**	**6.90**
TM 239	**11**	**6.59**	**4.40**
TM 240	**11**	**8.84**	**5.32**
		Average	**6.32**
		Allowable CV %	**7.0**
		Allowable Error (+/-)%	**21.0**

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

INSTRUCTIONS CAN BE FOUND AT:

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

Oncology Soluble Tumor Markers						
		TM236	**TM237**	**TM238**	**TM239**	**TM240**
AFP (ng/ml)	>/<					
	Result					
CA 125 (U/ml)	>/<					
	Result					
CA 15-3 (U/ml)	>/<					
	Result					
CA 19-9 (U/ml)	>/<					
	Result					
CA 27.29 (U/ml)	>/<					
	Result					
CEA (ng/ml)	>/<					
	Result					
PSA (Total) (ng/ml)	>/<					
	Result					
PSA (Total) **for a 2nd method used in conjunction with free PSA (ng/mL)**	>/<					
	Result					
Free PSA (ng/ml) **If test offered, measure and report for all samples**	>/<					
	Result					
Complexed PSA (ng/ml)	>/<					
	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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