NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

January 29, 2013

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 13, 2013**

Samples:
Enclosed are five sealed (5) vials labeled **TM251 to TM255**, 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.

If a test is Temporarily Suspended, choose the appropriate selection from the **Test Status** list on the **Event Menu** page. When temporary suspension of testing is selected, the reason for this suspension must be indicated in the appropriate box at the bottom of the event menu page.

If a test is permanently deleted, select 'test not offered' and also submit the 'delete analyte' form found at: (http://www.wadsworth.org/labcert/TestApproval/forms/DOH3519f.pdf). **Absence of results for any analyte without appropriate notification will result in a failing grade for the missing results.**

The **Event Menu** page also includes a space to enter your lab's upper limit of normal reference range, i.e. cut-off value, for each individual analyte measured. It should indicate the **highest result** measurement that would be **considered NORMAL** as reported back to a physician. Please enter this value with the same precision as you report your results for that analyte.

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

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

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

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

Results must be submitted electronically before 11:59 PM on February 13, 2013. It is advisable to submit earlier to allow time to resolve any problem that could occur with result submission. Results not submitted by the due date are categorized as missing with an administrative **failure** and receive a failing grade, even if results were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must **contact the PT section by email as soon as possible before the due date** to see if this can be arranged.

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

For any correspondence regarding the Oncology PT contact:

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

The remaining 2013 Oncology Tumor Marker Proficiency Tests are scheduled for:

Mail-out date:	Due date:
May 7, 2013	**May 22, 2013**
September 10, 2013	**September 25, 2013**

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

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

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

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March 7, 2013

New York State Tumor Marker Proficiency Test 1-2013 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from January 2013 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 serum-based matrix, sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. Analyte levels were pre-assayed and stability tested in our laboratory. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

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

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

(copy and paste the link into your browser's address bar if the hyperlink does not connect)

Laboratory contacts should have already received an email alert indicating the availability of the individual result report. This critique with summary tables and graphs is sent by a separate email to the same laboratory contacts and will also be posted on our section's website:

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

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

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

[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®6 software (Harvey J Motulsky and Ronald E Brown, "Detecting outliers when fitting data with nonlinear regression – a new method based on robust nonlinear regression and the false discovery rate," BMC Bioinformatics 7:123 (2006). Available at: http://www.biomedcentral.com/1471-2105/7/123). This method identifies outliers through robust statistical analysis with a nonlinear curve fit of the data, thus removing points that can skew calculations of the mean. For our purposes, the target is the mean determined from the best fit values derived from that analysis while the standard deviation (SD) was calculated by multiplying the standard error of the mean for each individual peer group with the square root of the number of labs in that peer group. 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 >2). We also present graphical comparisons of the results among the different peer groups. In order to compare results between peer groups more easily, average normalized values were calculated for each sample by dividing the individual peer group mean by the median of the means from all peer groups (all method median). The all method medians are used instead of the all lab means to reduce the bias towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, we calculated these values relative to the assigned target values (see below) as well as the all method median. Keep in mind when comparing methods that in some of the peer groups the number of results (N) was small. However, the fact that the relative performance for almost all methods has been very constant over the last several years indicates that the results shown reflect the true behavior of each method compared to its peers, at least under the conditions of the NYS PT.

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 114 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of them included ten or more labs each, together comprising 86% of the labs. Four peer groups, comprising 47% of the labs, gave results within +/-15% of the all method medians. Of the other groups, Siemens Immulite was -16% from the median and Roche was -18%, while on the other side, Abbott AxSYM and Architect (grouped together) were 16% above the median on average. TOSOH ST-AIA (used by five labs representing about 4% of the participants) was the highest method averaging 43% above the all method medians.

CA19-9 (Table 2, Figure 2): Results were reported by 70 labs using instruments from six different manufacturers corresponding to six peer groups. Fifty-one percent of all reporting labs used Siemens ADVIA-Centaur XP or CP, 17% used either Beckman's 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. As seen with previous PT events, there were large differences in how each method measured CA19-9, ranging from 50% to 402% of the all method median. Measurements by Tosoh ST-AIA were lower than the medians by an average of 60%, whereas on the opposite side, the results from the Siemens ADVIA-Centaur XP were on average 29% higher than the all method median. Notably, the Abbott Architect method (used by only 2 labs) gave measurements for CA19-9 averaging over four times higher than the all method medians, which is similar to what has been seen with previous CA19-9 NYS PT results by this method as well as the latest CAP results (TM-A 2013). 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 103 labs, with slightly more than half (53%) using an instrument from one of six manufacturers to measure **CA15-3** (Table 3, Figure 3) and the remainder using an instrument from one of two manufacturers to measure **CA27.29** (Table 4, Figure 4). Sample TM251 was a blank for this analyte and therefore was not included in the calculations and was deemed non-gradable on the evaluations; thus, all labs received pass credit (P/C) for this sample. Abbott, Roche, Siemens ADVIA and Ortho Clinical were within +/-10% of the all method median and altogether comprise 78% of the labs measuring CA15-3. Of the other two, the Siemens Immulite 2000 system (used by 16% of labs) averaged +16% compared to the medians, while the Beckman Unicel/Access results exhibited a notable negative bias, averaging -34% from the all method medians. In contrast, **CA27.29** measurements showed only a 10% difference between the ADVIA Centaur XP/CP and the Tosoh methods.

CEA (Table 5, Figure 5): Results were reported by 169 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 51 labs. Overall, the results reported by the majority of the labs (70%) were fairly consistent, being within +/-10% of the medians. There were three exceptions however: the Roche methods averaged 30% below the medians, the Siemens Dimension Vista method measured 13% lower than the medians on average, and the TOSOH ST-AIA method exhibited a high positive bias averaging 53% higher than the medians. This is consistent with what has been seen on previous NYS PT events.

For **AFP, PSA and free PSA,** target values were assigned using traceable International Standards. However, for 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, the tables show the bias against both the all method medians and the assigned target values, but the graphical figures show the performance relative only to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 102 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to twenty percent of the total number of labs. Six of the eight methods gave results between 0% and +15% of the assigned targets; the exceptions were the Roche group, which was 29% higher, and the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants), which was the lowest with results 12% below the assigned target and 21% below the all method median. These results are similar to what has been observed in previous NYS PT events for these methods.

PSA (Table 7, Figure 7): Results were reported by 255 labs using instruments from thirteen different manufacturers comprising eleven peer groups plus two methods with N=1 (Qualigen FastPack IP and bioMerieux VIDAS.) Three of the peer groups comprised fewer than ten members each, but together made up 7% of the labs. Two pairs (TM251/252 and TM253/254) of samples were prepared with identical concentrations of total PSA but different proportions (10% and 30%) of free PSA. There were no differences in the measured amounts of total PSA between the high and low % free PSA samples. In contrast, the differences between methods were substantial, and there appeared a separation into statistically significantly different (P=0.011) high and low groups. The highest results came from the Beckman Unicel/Access with the Hybritech calibration and the Siemens Dimension RxL Max/Xpand Plus/EXL groups, which were 27% and 34% above the assigned targets, respectively. Results from the Abbott, Siemens Dimension Vista, and Siemens Immulite 1000/2000-Original Pack groups were 17%, 16% and 18% above the assigned targets, respectively. The rest of the methods averaged between -10% and +11% from the assigned targets.

For the Beckman instruments, those calibrated using the original Hybritech standard measured on average 27% higher than the targets, while those calibrated with the international WHO standard averaged 6% higher than the assigned target levels. Similarly, measurements made with the Siemens Immulite 1000/2000-Original Pack were 20% higher than those made with the 3rd generation pack. This 20-21% observed difference 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). Finally, the two single use methods, Qualigen FastPack IP and bioMerieux VIDAS were 67% and 55%, respectively, higher than the assigned targets. In conclusion, the differences seen across methods are significant and mostly consistent with what is seen in patient samples.

Free PSA (Table 8, Figure 8): Results were reported by 83 labs using instruments from seven manufacturers (Beckman provides two different calibrations) corresponding to five peer groups plus three with N<3. Two of the peer groups comprised less than 10 labs each and along with the N<3 methods, made up 17% of the participants. The remaining three methods were used by 30% (Beckman Unicel/Access calibrated with the Hybritech standards), 29% (Roche Elecsys/E170/Cobas) and 24% (Siemens Immulite 1000 and 2000) of labs, respectively. As seen in previous PTs, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained with the rest of the methods (35% higher than the all method medians and 27% above the targets), while there were not enough results from Beckman Unicel/Access calibrated with the WHO standards to allow a comparison to the

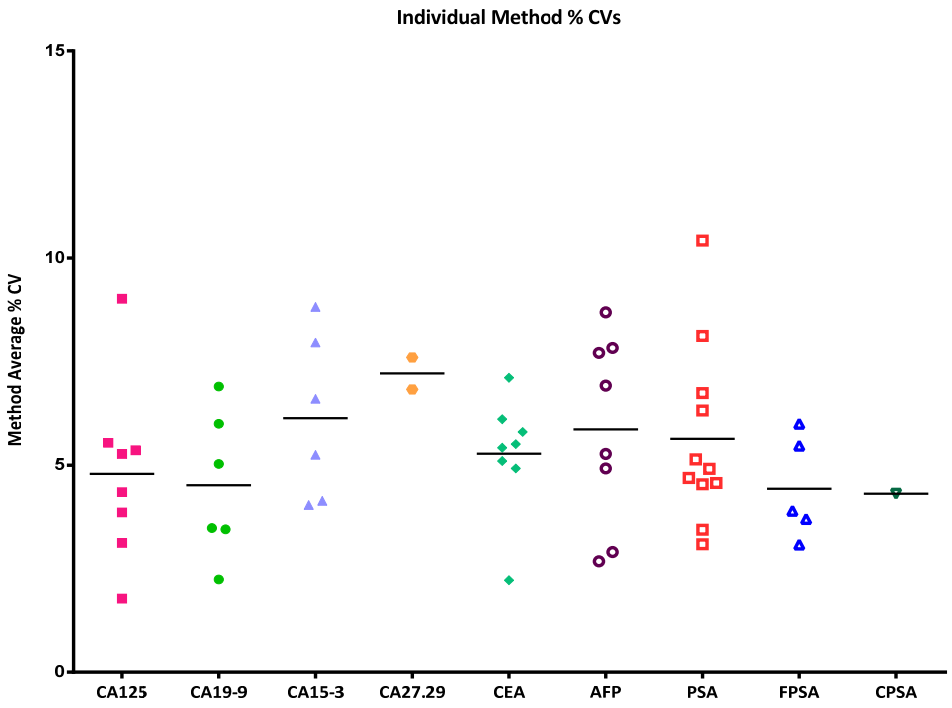
other methods. The Abbott Architect results were 6% above the targets while the Roche instruments, Siemens Immulite 1000/2000 and Siemens Dimension Vista instruments averaged 6%, 14% and 16% below the assigned targets, respectively. In conclusion, there are still substantial differences in how free PSA is measured, and the various methods do not fall into clearly defined high and low groups. Furthermore, not every method that is high for total PSA is also high for free PSA.

Samples TM251, TM253 and TM255 were prepared with equal % free PSA and showed that the measured proportions remained steady across methods, averaging 11%, even as the total PSA levels increased from 2 to 4 to 8 ng/ml for those samples, respectively. Samples TM252 and TM254 were prepared with equal but higher % free PSA, which also remained steady, averaging 30% across methods, even as total PSA levels doubled from 2 to 4 ng/ml in TM254. Beckman Access/Unicel calibrated with the Hybritech standards showed a somewhat inverse relationship between the % free PSA and the total PSA levels, meaning that as the total PSA levels went up, measuring on average 2.5, 5.2 and 10.5 ng/ml with that calibration, the % free PSA values decreased somewhat from 14.4% to 13.1% to 12.7%, respectively. For all other methods, although the % free value varied between methods, they individually did not show a trend in their measured proportion of free PSA across varying total PSA concentrations.

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, 12 labs measured **complexed PSA** and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little difference between them. Overall, excellent agreement between the labs was seen as evidenced by an average %CV of 4.31% (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%.



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

While some of the 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.

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

The PSA for a 2nd method analyte option allows labs to enter results from a second PSA assay if a different method for total PSA is used in conjunction with their free PSA measurements**.** If only one PSA test was done, then results should **only** be entered in the first PSA (Total) entry line.

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

The scheduled dates for the remaining 2013 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
May 7, 2013	May 22, 2013
September 10, 2013	September 25, 2013

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

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

Table 1: 1-13 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									
TM251	10	29.2	**23.2**	**35.2**	6.0	4.59		1.15	
TM252	10	33.9	**27.9**	**39.9**	6.0	5.78		1.15	
TM253	10	38.2	**31.3**	**45.1**	6.9	6.88		1.17	
TM254	10	41.9	**34.4**	**49.4**	7.5	5.01		1.15	
TM255	10	47.5	**39.0**	**56.1**	8.6	4.11		1.16	
					mean ±SD	5.27	1.09	1.16	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM251	12	28.1	**22.1**	**34.1**	6.0	2.88		1.11	
TM252	12	31.3	**25.3**	**37.3**	6.0	3.74		1.06	
TM253	11	35.5	**29.1**	**41.9**	6.4	4.08		1.09	
TM254	12	39.4	**32.3**	**46.5**	7.1	3.73		1.08	
TM255	12	44.2	**36.2**	**52.2**	8.0	4.89		1.08	
					mean ±SD	3.86	0.72	1.08	0.02
Roche Elecsys & Cobas BME/BMR									
TM251	15	20.2	**14.2**	**26.2**	6.0	1.44		0.80	
TM252	18	23.9	**17.9**	**29.9**	6.0	3.26		0.81	
TM253	18	26.8	**20.8**	**32.8**	6.0	3.62		0.82	
TM254	18	30.2	**24.2**	**36.2**	6.0	3.68		0.83	
TM255	18	34.0	**28.0**	**40.0**	6.0	3.59		0.83	
					mean ±SD	3.12	0.95	0.82	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM251	34	26.7	**20.7**	**32.7**	6.0	5.51		1.05	
TM252	34	30.7	**24.7**	**36.7**	6.0	5.50		1.04	
TM253	34	34.1	**28.1**	**40.1**	6.0	5.54		1.04	
TM254	34	37.7	**30.9**	**44.5**	6.8	4.80		1.03	
TM255	34	42.0	**34.4**	**49.6**	7.6	5.43		1.03	
					mean ±SD	5.36	0.31	1.04	0.01
Siemens Immulite 2000 DPD									
TM251	24	21.3	**15.3**	**27.3**	6.0	4.98		0.84	
TM252	24	24.4	**18.4**	**30.4**	6.0	6.97		0.83	
TM253	24	27.4	**21.4**	**33.4**	6.0	5.00		0.84	
TM254	24	31.3	**25.3**	**37.3**	6.0	5.18		0.86	
TM255	24	35.0	**28.7**	**41.3**	6.3	5.60		0.86	
					mean ±SD	5.54	0.83	0.84	0.01
Siemens Diag Dimension Vista (LOCI) DUV									
TM251	3	21.0	**15.0**	**27.0**	6.0	1.19		0.83	
TM252	3	25.9	**19.9**	**31.9**	6.0	1.78		0.88	
TM253	3	30.4	**24.4**	**36.4**	6.0	3.75		0.93	
TM254	3	35.2	**28.9**	**41.5**	6.3	1.31		0.97	
TM255	3	39.7	**32.6**	**46.8**	7.1	0.88		0.97	
					mean ±SD	1.78	1.15	0.92	0.06
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM251	8	24.0	**18.0**	**30.0**	6.0	3.75		0.95	
TM252	8	28.1	**22.1**	**34.1**	6.0	5.48		0.96	
TM253	8	31.2	**25.2**	**37.2**	6.0	3.94		0.96	
TM254	8	34.8	**28.8**	**40.8**	6.0	4.54		0.95	
TM255	8	39.4	**32.3**	**46.5**	7.1	4.04		0.96	
					mean ±SD	4.35	0.70	0.96	0.01

continued on next page

Table 1 (cont.): 1-13 NYS Tumor Marker PT Summary for CA 125

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Tosoh AIA TOM									
TM251	5	33.9	**27.9**	**39.9**	6.0	15.19		1.34	
TM252	4	44.1	**36.2**	**52.0**	7.9	1.41		1.50	
TM253	5	45.6	**37.4**	**53.8**	8.2	13.66		1.40	
TM254	4	54.2	**44.4**	**64.0**	9.8	1.03		1.49	
TM255	5	58.0	**47.6**	**68.4**	10.4	13.79		1.42	
					mean ±SD	9.02	7.14	1.43	0.07

Sample ID	N	All Method Median	Median % CV
TM251	**111**	**25.4**	**4.17**
TM252	**113**	**29.4**	**4.61**
TM253	**113**	**32.7**	**4.54**
TM254	**113**	**36.5**	**4.14**
TM255	**114**	**40.9**	**4.50**
		Average	**4.39**
		Allowable CV %	**6.0**
		Allowable Error if >/= 35 U/ml (+/-) %	**18.0**
		Allowable Error if < 35 U/ml (+/- U/ml)	**6.0**

Figure 1: CA 125 Method Comparison

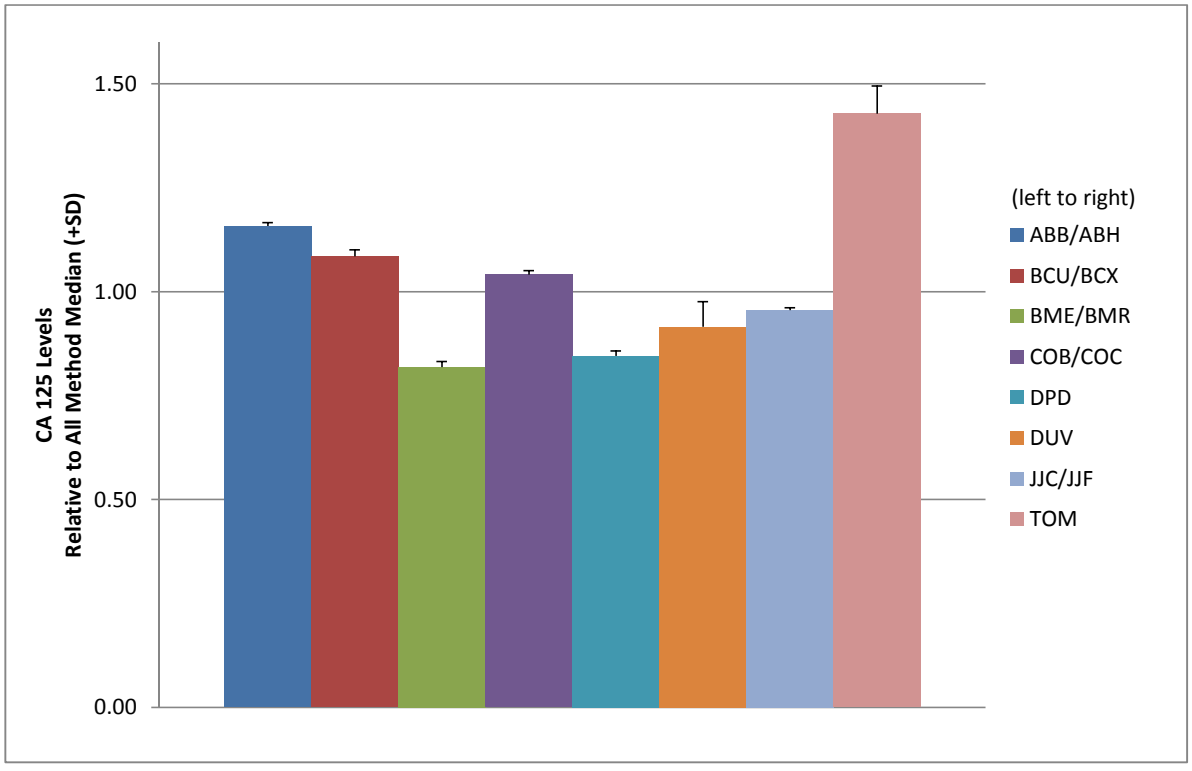


Table 2: 1-13 NYS Tumor Marker PT Summary for CA 19-9

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									
TM251	2	403.6	**331**	**476.2**	72.6	3.77		6.52	
TM252	2	166.3	**136.4**	**196.2**	29.9	4.55		2.69	
TM253	2	211.7	**173.6**	**249.8**	38.1	1.00		3.42	
TM254	2	131.8	**108.1**	**155.5**	23.7	1.02		2.13	
TM255	2	330.3	**270.8**	**389.8**	59.5	0.86		5.34	
					mean ±SD	2.24	1.78	4.02	1.85
Beckman Unicel & Access/2 BCU/BCX									
TM251	12	61.9	**50.8**	**73.0**	11.1	4.96		1.00	
TM252	12	27.7	**22.7**	**32.7**	5.0	8.12		0.45	
TM253	12	35.0	**28.7**	**41.3**	6.3	5.86		0.57	
TM254	12	22.5	**18.5**	**26.6**	4.1	6.18		0.36	
TM255	12	53.8	**44.1**	**63.5**	9.7	4.87		0.87	
					mean ±SD	6.00	1.32	0.65	0.27
Roche Elecsys & Cobas BME/BMR									
TM251	13	46.5	**38.1**	**54.9**	8.4	5.08		0.75	
TM252	13	21.6	**17.7**	**25.5**	3.9	4.58		0.35	
TM253	13	27.5	**22.6**	**32.5**	5.0	4.69		0.44	
TM254	13	18.6	**15.3**	**21.9**	3.3	5.38		0.30	
TM255	13	40.9	**33.5**	**48.3**	7.4	5.40		0.66	
					mean ±SD	5.03	0.38	0.50	0.20
Siemens Advia Centaur XP/CP COB/COC									
TM251	36	129.6	**106.3**	**152.9**	23.3	6.35		2.09	
TM252	36	51.5	**42.2**	**60.8**	9.3	7.13		0.83	
TM253	36	66.8	**54.8**	**78.8**	12.0	7.51		1.08	
TM254	36	43.1	**35.3**	**50.9**	7.8	6.45		0.70	
TM255	36	108.9	**89.3**	**128.5**	19.6	7.04		1.76	
					mean ±SD	6.90	0.49	1.29	0.61
Ortho Clinical Diag Vitros Eci/ECiQ JJC/JJF									
TM251	2	109.5	**89.8**	**129.2**	19.7	4.52		1.77	
TM252	2	46.0	**37.7**	**54.3**	8.3	3.70		0.74	
TM253	2	60.2	**49.4**	**71.0**	10.8	3.41		0.97	
TM254	2	38.3	**31.4**	**45.2**	6.9	1.67		0.62	
TM255	2	93.2	**76.4**	**110.0**	16.8	4.10		1.51	
					mean ±SD	3.48	1.09	1.12	0.50
Tosoh AIA TOM									
TM251	5	34.6	**28.4**	**40.8**	6.2	3.21		0.56	
TM252	5	17.5	**14.4**	**20.7**	3.2	4.46		0.28	
TM253	5	22.1	**18.1**	**26.1**	4.0	3.08		0.36	
TM254	5	16.5	**13.5**	**19.5**	3.0	4.00		0.27	
TM255	5	33.2	**27.2**	**39.2**	6.0	2.50		0.54	
					mean ±SD	3.45	0.78	0.40	0.14

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Table 2 (cont.): 1-13 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM251	70	61.9	4.96
TM252	70	27.7	4.58
TM253	70	35.0	4.69
TM254	70	22.5	5.38
TM255	70	53.8	4.87
		Average	4.90
		Allowable CV %	6.0
		Allowable Error (+/-)%	18.0

Figure 2: CA 19-9 Method Comparison

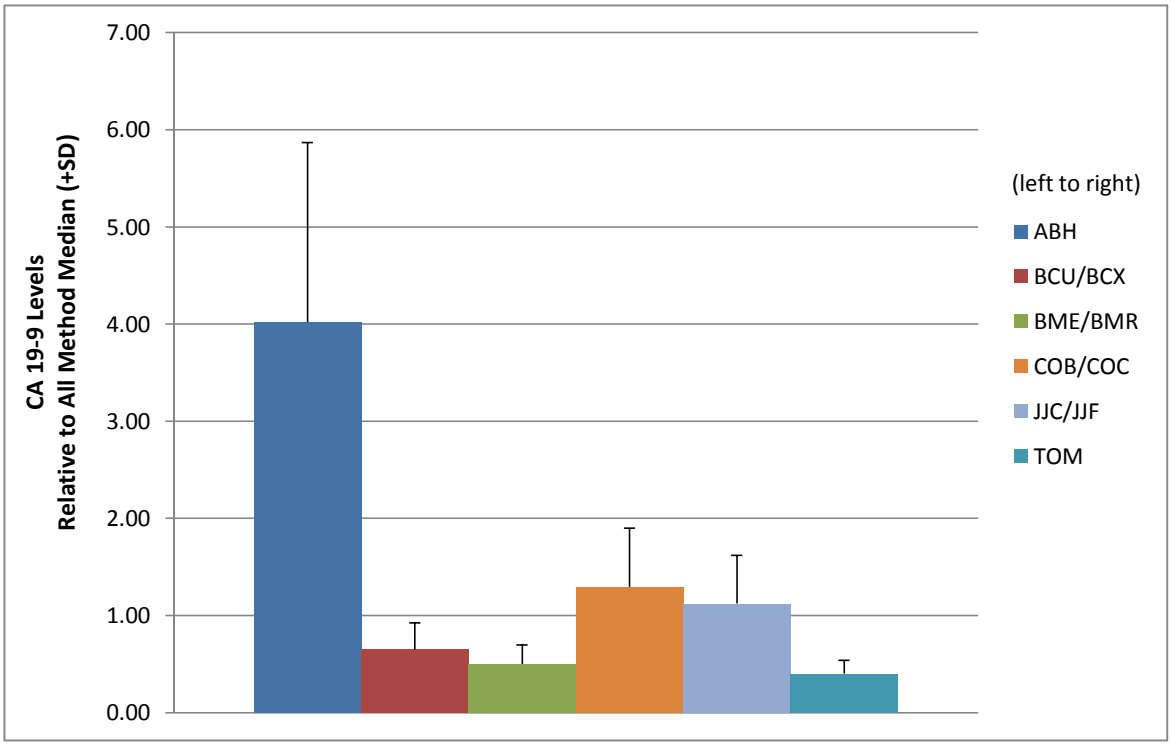

Table 3: 1-13 NYS Tumor Marker PT Summary for CA 15-3

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									
TM251		NG							
TM252	6	28.0	**23.0**	**33.0**	5.0	9.54		1.09	
TM253	6	49.1	**40.3**	**57.9**	8.8	10.77		1.09	
TM254	6	70.9	**58.1**	**83.7**	12.8	8.46		1.07	
TM255	6	90.2	**74.0**	**106.4**	16.2	6.52		1.05	
					mean ±SD*	8.82	1.80	1.07	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM251		NG							
TM252	4	17.2	**14.1**	**20.3**	3.1	3.72		0.67	
TM253	4	29.9	**24.5**	**35.3**	5.4	6.05		0.66	
TM254	4	43.0	**35.3**	**50.7**	7.7	5.84		0.65	
TM255	4	57.6	**47.2**	**68.0**	10.4	5.38		0.67	
					mean ±SD*	5.25	1.06	0.66	0.01
Roche Elecsys & Cobas BME/BMR									
TM251		NG							
TM252	12	25.8	**21.2**	**30.4**	4.6	3.68		1.00	
TM253	12	45.0	**36.9**	**53.1**	8.1	3.11		0.99	
TM254	12	64.1	**52.6**	**75.6**	11.5	4.77		0.96	
TM255	12	83.2	**68.2**	**98.2**	15.0	4.59		0.97	
					mean ±SD*	4.04	0.78	0.98	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM251		NG							
TM252	20	25.8	**21.2**	**30.4**	4.6	6.63		1.00	
TM253	20	45.5	**37.3**	**53.7**	8.2	6.88		1.01	
TM254	20	66.5	**54.5**	**78.5**	12.0	6.78		1.00	
TM255	20	88.1	**72.2**	**104.0**	15.9	6.11		1.03	
					mean ±SD*	6.60	0.34	1.01	0.01
Siemens Immulite 2000 DPD									
TM251		NG							
TM252	9	30.1	**24.7**	**35.5**	5.4	7.31		1.17	
TM253	9	52.3	**42.9**	**61.7**	9.4	9.98		1.16	
TM254	9	77.2	**63.3**	**91.1**	13.9	5.44		1.16	
TM255	9	100.0	**82.0**	**118.0**	18.0	9.10		1.17	
					mean ±SD*	7.96	2.01	1.16	0.01
Ortho Clinical Diag Vitros Eci/ECiQ JJC									
TM251		NG							
TM252	4	25.2	**20.7**	**29.7**	4.5	3.37		0.98	
TM253	4	44.8	**36.7**	**52.9**	8.1	4.73		0.99	
TM254	4	66.5	**54.5**	**78.5**	12.0	4.30		1.00	
TM255	5	80.1	**65.7**	**94.5**	14.4	24.88		0.94	
					mean ±SD*	4.14	0.69	0.98	0.03

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Table 3 (cont.): 1-13 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM251	NA	NA	NA
TM252	55	25.80	5.17
TM253	55	45.25	6.47
TM254	55	66.50	5.64
TM255	56	85.65	6.31
		Average*	5.90
		Allowable CV %	6.0
		Allowable Error (+/-)%	18.0

*TM251 excluded from calculation

Figure 3: CA 15-3 Method Comparison

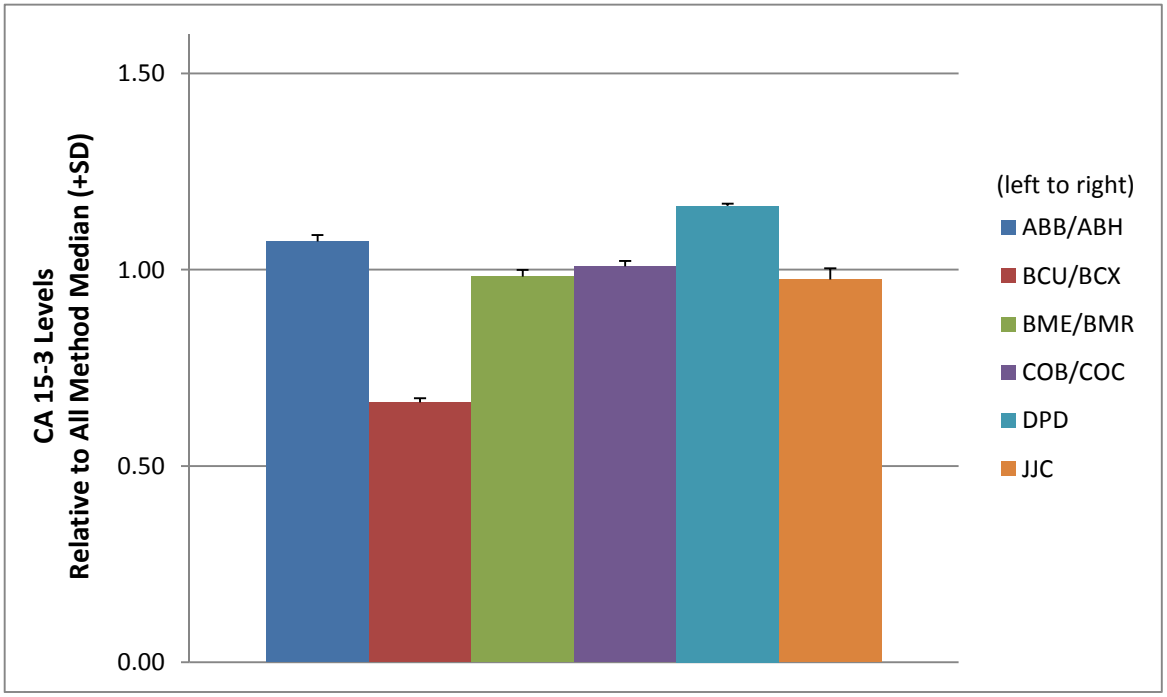

Table 4: 1-13 NYS Tumor Marker PT Summary for CA 27.29

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									
TM251		NG							
TM252	41	25.6	**18.1**	**33.1**	7.5	10.39		0.98	
TM253	41	54.0	**42.7**	**65.3**	11.3	6.22		1.05	
TM254	41	81.5	**64.4**	**98.6**	17.1	5.67		1.06	
TM255	41	108.1	**85.4**	**130.8**	22.7	5.03		1.10	
					mean ±SD*	6.83	2.42	1.05	0.05
Tosoh AIA TOM									
TM251		NG							
TM252	6	26.4	**18.9**	**33.9**	7.5	6.44		1.02	
TM253	6	48.4	**38.2**	**58.6**	10.2	6.80		0.95	
TM254	6	72.9	**57.6**	**88.2**	15.3	7.57		0.94	
TM255	6	89.0	**70.3**	**107.7**	18.7	9.57		0.90	
					mean ±SD*	7.60	1.40	0.95	0.05

Sample ID	N	All Method Median	Median % CV
TM251	**NA**	**NA**	**NA**
TM252	**47**	**26.0**	**8.42**
TM253	**47**	**51.2**	**6.51**
TM254	**47**	**77.2**	**6.62**
TM255	**47**	**98.6**	**7.30**

Average*	**7.21**
Allowable CV %	**7.0**
Allowable Error if >/= 35 U/ml (+/-) %	**21.0**
Allowable Error if < 35 U/ml (+/- U/ml)	**7.5**

***TM251 excluded from calculation**

Figure 4: CA 27.29 Method Comparison

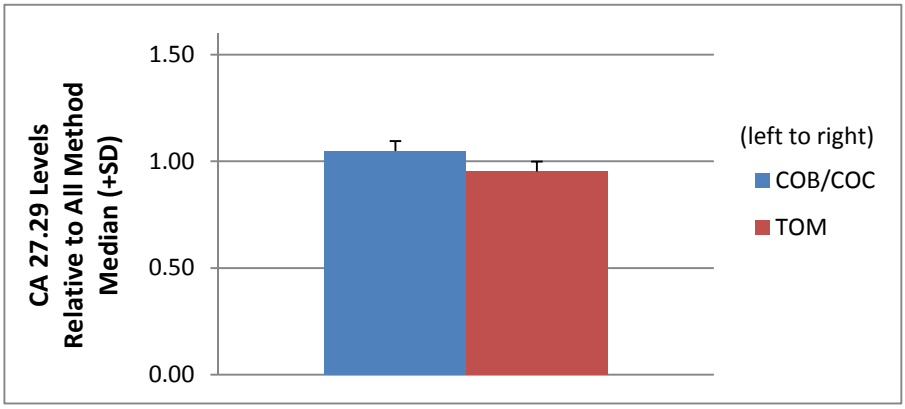

Table 5: 1-13 NYS Tumor Marker PT Summary for CEA

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									
TM251	15	9.1	**7.5**	**10.7**	1.6	4.84		1.03	
TM252	15	14.3	**11.7**	**16.9**	2.6	4.34		1.00	
TM253	15	19.7	**16.2**	**23.2**	3.5	5.58		1.00	
TM254	15	24.6	**20.2**	**29**	4.4	5.28		1.00	
TM255	15	31.5	**25.8**	**37.2**	5.7	4.57		1.00	
					mean ±SD	4.92	0.51	1.01	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM251	23	8.3	**6.8**	**9.8**	1.5	5.30		0.94	
TM252	23	13.1	**10.7**	**15.5**	2.4	6.72		0.92	
TM253	23	19.0	**15.6**	**22.4**	3.4	4.63		0.96	
TM254	23	23.6	**19.4**	**27.8**	4.2	6.27		0.96	
TM255	23	30.0	**24.6**	**35.4**	5.4	6.07		0.95	
					mean ±SD	5.80	0.83	0.95	0.02
Roche Elecsys & Cobas BME/BMR									
TM251	22	7.3	**6**	**8.6**	1.3	5.75		0.82	
TM252	22	9.9	**8.1**	**11.7**	1.8	5.56		0.69	
TM253	21	13.4	**11**	**15.8**	2.4	5.52		0.68	
TM254	22	16.1	**13.2**	**19**	2.9	4.72		0.66	
TM255	22	20.4	**16.7**	**24.1**	3.7	5.54		0.65	
					mean ±SD	5.42	0.40	0.70	0.07
Siemens Advia Centaur XP & CP COB/COC									
TM251	51	8.7	**7.1**	**10.3**	1.6	6.09		0.98	
TM252	51	14.3	**11.7**	**16.9**	2.6	6.01		1.00	
TM253	51	19.7	**16.2**	**23.2**	3.5	5.63		1.00	
TM254	51	25.1	**20.6**	**29.6**	4.5	6.37		1.02	
TM255	51	32.1	**26.3**	**37.9**	5.8	6.42		1.02	
					mean ±SD	6.11	0.32	1.01	0.02
Siemens Immulite 2000 DPD									
TM251	14	9.0	**7.4**	**10.6**	1.6	6.67		1.02	
TM252	14	14.7	**12.1**	**17.3**	2.6	6.87		1.03	
TM253	14	20.6	**16.9**	**24.3**	3.7	7.72		1.05	
TM254	14	26.0	**21.3**	**30.7**	4.7	5.77		1.06	
TM255	14	32.9	**27**	**38.8**	5.9	8.51		1.05	
					mean ±SD	7.11	1.05	1.04	0.02
Siemens Dimension Vista DUV									
TM251	23	8.3	**6.8**	**9.8**	1.5	4.94		0.94	
TM252	23	12.3	**10.1**	**14.5**	2.2	5.28		0.86	
TM253	23	16.9	**13.9**	**19.9**	3.0	4.91		0.86	
TM254	23	20.8	**17.1**	**24.5**	3.7	5.58		0.85	
TM255	23	26.5	**21.7**	**31.3**	4.8	4.79		0.84	
					mean ±SD	5.10	0.32	0.87	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM251	15	10.4	**8.5**	**12.3**	1.9	5.96		1.18	
TM252	15	14.5	**11.9**	**17.1**	2.6	6.28		1.01	
TM253	15	20.0	**16.4**	**23.6**	3.6	5.55		1.02	
TM254	15	24.5	**20.1**	**28.9**	4.4	5.02		1.00	
TM255	15	31.4	**25.7**	**37.1**	5.7	4.75		1.00	
					mean ±SD	5.51	0.64	1.04	0.08

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Table 5 (cont.): 1-13 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									
TM251	6	13.2	**10.8**	**15.6**	2.4	1.89		1.49	
TM252	6	22.1	**18.1**	**26.1**	4.0	2.53		1.55	
TM253	6	30.5	**25**	**36**	5.5	1.77		1.55	
TM254	6	38.1	**31.2**	**45**	6.9	2.62		1.55	
TM255	6	47.5	**39**	**56.1**	8.6	2.29		1.51	
					mean ±SD	2.22	0.38	1.53	0.03

Sample ID	N	All Method Median		Median % CV
TM251	**169**	**8.9**		**5.53**
TM252	**169**	**14.3**		**5.78**
TM253	**168**	**19.7**		**5.54**
TM254	**169**	**24.6**		**5.43**
TM255	**169**	**31.5**		**5.17**
			Average	**5.49**
			Allowable CV %	**6.0**
			Allowable Error (+/-)%	**18.0**

Figure 5: CEA Method Comparison

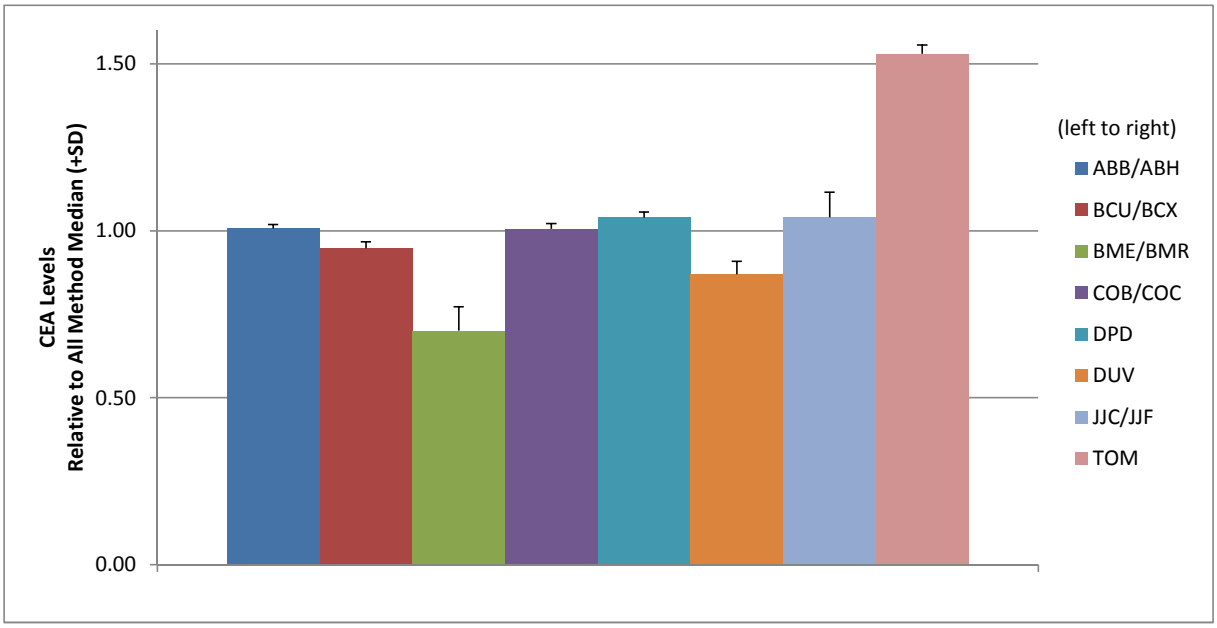

Table 6: 1-13 NYS Tumor Marker PT Summary for AFP

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											
TM251	5	12.2	**10.0**	**14.4**	2.2	11.07		1.04		1.16	
TM252	5	23.8	**19.5**	**28.1**	4.3	7.06		1.06		1.14	
TM253	5	14.6	**12.0**	**17.2**	2.6	8.49		1.01		1.13	
TM254	5	37.3	**30.6**	**44.0**	6.7	6.57		1.03		1.15	
TM255	5	32.0	**26.2**	**37.8**	5.8	5.38		1.03		1.16	
					mean ±SD	7.71	2.18	1.03	0.02	1.15	0.01
Beckman Unicel & Access/2 BCU/BCX											
TM251	17	11.6	**9.5**	**13.7**	2.1	8.10		0.99		1.10	
TM252	17	22.3	**18.3**	**26.3**	4.0	9.51		0.99		1.07	
TM253	17	14.0	**11.5**	**16.5**	2.5	8.57		0.97		1.08	
TM254	17	34.8	**28.5**	**41.1**	6.3	7.04		0.96		1.07	
TM255	16	30.6	**25.1**	**36.1**	5.5	5.95		0.99		1.11	
					mean ±SD	7.83	1.38	0.98	0.01	1.09	0.02
Roche Elecsys & Cobas BME/BMR											
TM251	19	13.7	**11.2**	**16.2**	2.5	7.45		1.17		1.30	
TM252	19	26.2	**21.5**	**30.9**	4.7	9.24		1.17		1.25	
TM253	19	16.6	**13.6**	**19.6**	3.0	8.80		1.15		1.28	
TM254	19	42.6	**34.9**	**50.3**	7.7	9.65		1.18		1.31	
TM255	19	36.0	**29.5**	**42.5**	6.5	8.31		1.16		1.30	
					mean ±SD	8.69	0.86	1.16	0.01	1.29	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM251	29	12.6	**10.3**	**14.9**	2.3	7.54		1.07		1.20	
TM252	29	23.2	**19.0**	**27.4**	4.2	7.89		1.03		1.11	
TM253	29	15.0	**12.3**	**17.7**	2.7	8.00		1.04		1.16	
TM254	28	36.4	**29.8**	**43.0**	6.6	4.56		1.00		1.12	
TM255	29	30.3	**24.8**	**35.8**	5.5	6.60		0.98		1.10	
					mean ±SD	6.92	1.43	1.02	0.04	1.14	0.04
Siemens Immulite 1000 & 2000 DPB/DPD											
TM251	17	11.6	**9.5**	**13.7**	2.1	3.62		0.99		1.10	
TM252	17	22.2	**18.2**	**26.2**	4.0	5.45		0.99		1.06	
TM253	15	14.3	**11.7**	**16.9**	2.6	4.06		0.99		1.10	
TM254	17	37.2	**30.5**	**43.9**	6.7	6.45		1.03		1.15	
TM255	17	31.5	**25.8**	**37.2**	5.7	6.76		1.01		1.14	
					mean ±SD	5.27	1.40	1.00	0.02	1.11	0.03
Siemens Dimension Vista DUV											
TM251	6	11.0	**9.0**	**13.0**	2.0	2.64		0.94		1.05	
TM252	6	21.0	**17.2**	**24.8**	3.8	3.14		0.94		1.01	
TM253	6	13.4	**11.0**	**15.8**	2.4	2.61		0.93		1.03	
TM254	6	33.8	**27.7**	**39.9**	6.1	3.14		0.93		1.04	
TM255	6	29.0	**23.8**	**34.2**	5.2	2.97		0.93		1.05	
					mean ±SD	2.90	0.26	0.93	0.00	1.04	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM251	6	9.6	**7.9**	**11.3**	1.7	3.75		0.82		0.91	
TM252	5	17.7	**14.5**	**20.9**	3.2	1.24		0.79		0.85	
TM253	6	11.5	**9.4**	**13.6**	2.1	3.22		0.80		0.89	
TM254	6	28.6	**23.5**	**33.7**	5.1	2.87		0.79		0.88	
TM255	6	24.1	**19.8**	**28.4**	4.3	2.32		0.78		0.87	
					mean ±SD	2.68	0.96	0.79	0.02	0.88	0.02
Tosoh AIA TOM											
TM251	3	11.9	**9.8**	**14.0**	2.1	5.63		1.01		1.13	
TM252	3	22.6	**18.5**	**26.7**	4.1	4.87		1.01		1.08	
TM253	3	14.6	**12.0**	**17.2**	2.6	5.55		1.01		1.13	
TM254	3	36.1	**29.6**	**42.6**	6.5	4.10		1.00		1.11	
TM255	3	31.6	**25.9**	**37.3**	5.7	4.46		1.02		1.14	
					mean ±SD	4.92	0.67	1.01	0.01	1.12	0.02

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Table 6 (cont.): 1-13 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD	Median % CV	All Method Median/ IS Target
TM251	102	11.75	10.5	0.63	6.54	1.12
TM252	101	22.45	20.9	1.26	6.25	1.07
TM253	100	14.45	13.0	0.59	6.77	1.11
TM254	101	36.25	32.5	1.45	5.51	1.12
TM255	101	31.05	27.6	0.65	5.66	1.12
				Average	6.15	mean ±SD 1.11 0.02
				Allowable CV %	6.0	
				Allowable Error (+/-)%	18.0	

Figure 6: AFP Method Comparison

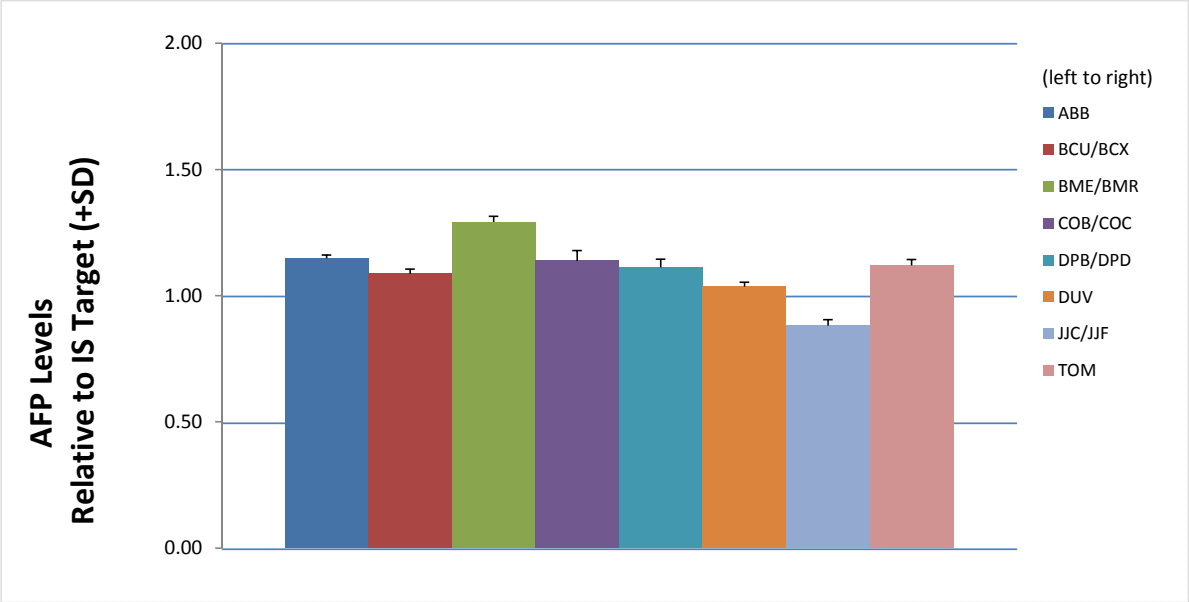

Table 7: 1-13 NYS Tumor Marker PT Summary for PSA

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											
TM251	18	2.4	**2.0**	**2.8**	0.4	5.83		1.04		1.20	
TM252	18	2.4	**2.0**	**2.8**	0.4	5.42		1.04		1.14	
TM253	19	4.7	**3.9**	**5.5**	0.8	6.60		1.04		1.18	
TM254	19	4.7	**3.9**	**5.5**	0.8	7.45		1.02		1.12	
TM255	18	9.8	**8.0**	**11.6**	1.8	4.29		1.05		1.20	
					mean ±SD	6.32	0.89	1.04	0.01	1.17	0.03
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM251	45	2.5	**2.1**	**3.0**	0.5	4.80		1.09		1.25	
TM252	47	2.6	**2.1**	**3.1**	0.5	5.00		1.13		1.24	
TM253	47	5.2	**4.3**	**6.1**	0.9	4.42		1.16		1.30	
TM254	47	5.3	**4.3**	**6.3**	1.0	4.53		1.15		1.26	
TM255	47	10.5	**8.6**	**12.4**	1.9	5.52		1.13		1.28	
					mean ±SD	4.69	0.26	1.13	0.03	1.27	0.02
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)											
TM251	4	2.2	**1.8**	**2.6**	0.4	7.73		0.96		1.10	
TM252	4	2.2	**1.8**	**2.6**	0.4	5.91		0.96		1.05	
TM253	4	4.3	**3.5**	**5.1**	0.8	9.07		0.96		1.08	
TM254	4	4.3	**3.5**	**5.1**	0.8	9.77		0.93		1.02	
TM255	4	8.8	**7.2**	**10.4**	1.6	17.73		0.95		1.07	
					mean ±SD	8.12	1.70	0.95	0.01	1.06	0.03
Roche Elecsys & Cobas BME/BMR											
TM251	38	2.3	**1.9**	**2.7**	0.4	3.48		1.00		1.15	
TM252	38	2.3	**1.9**	**2.7**	0.4	3.91		1.00		1.10	
TM253	38	4.5	**3.7**	**5.3**	0.8	3.11		1.00		1.13	
TM254	37	4.6	**3.8**	**5.4**	0.8	3.26		1.00		1.10	
TM255	38	9.0	**7.4**	**10.6**	1.6	2.89		0.97		1.10	
					mean ±SD	3.44	0.35	0.99	0.01	1.11	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM251	59	2.3	**1.9**	**2.7**	0.4	4.78		1.00		1.15	
TM252	60	2.3	**1.9**	**2.7**	0.4	4.35		1.00		1.10	
TM253	60	4.5	**3.7**	**5.3**	0.8	5.11		1.00		1.13	
TM254	60	4.6	**3.8**	**5.4**	0.8	3.91		1.00		1.10	
TM255	59	9.0	**7.4**	**10.6**	1.6	4.11		0.97		1.10	
					mean ±SD	4.54	0.52	0.99	0.01	1.11	0.02
Siemens Immulite 1000 &2000 - Original Pack DPB/DPD (DP5)											
TM251	20	2.4	**2.0**	**2.8**	0.4	11.25		1.04		1.20	
TM252	20	2.5	**2.1**	**3.0**	0.5	10.00		1.09		1.19	
TM253	20	4.8	**3.9**	**5.7**	0.9	10.63		1.07		1.20	
TM254	20	4.9	**4.0**	**5.8**	0.9	9.80		1.07		1.17	
TM255	19	9.3	**7.6**	**11.0**	1.7	8.92		1.00		1.13	
					mean ±SD	10.42	0.66	1.05	0.03	1.18	0.03
Siemens Immulite 1000 & 2000 - 3rd Generation Pack DPB/DPD (DP6)											
TM251	5	2.0	**1.6**	**2.4**	0.4	5.50		0.87		1.00	
TM252	5	2.1	**1.7**	**2.5**	0.4	4.29		0.91		1.00	
TM253	5	3.9	**3.2**	**4.6**	0.7	7.18		0.87		0.98	
TM254	5	4.1	**3.4**	**4.8**	0.7	10.00		0.89		0.98	
TM255	5	7.8	**6.4**	**9.2**	1.4	7.56		0.84		0.95	
					mean ±SD	6.74	2.48	0.88	0.03	0.98	0.02
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM251	12	2.8	**2.3**	**3.3**	0.5	6.43		1.22		1.40	
TM252	12	2.7	**2.2**	**3.2**	0.5	4.44		1.17		1.29	
TM253	12	5.4	**4.4**	**6.4**	1.0	5.37		1.20		1.35	
TM254	12	5.4	**4.4**	**6.4**	1.0	4.63		1.17		1.29	
TM255	12	11.2	**9.2**	**13.2**	2.0	4.82		1.20		1.37	
					mean±SD	5.14	0.80	1.19	0.02	1.34	0.05
Siemens Dimension Vista DUV											
TM251	17	2.4	**2.0**	**2.8**	0.4	3.33		1.04		1.20	
TM252	17	2.4	**2.0**	**2.8**	0.4	3.33		1.04		1.14	
TM253	17	4.8	**3.9**	**5.7**	0.9	3.33		1.07		1.20	
TM254	17	4.7	**3.9**	**5.5**	0.8	2.34		1.02		1.12	
TM255	16	9.5	**7.8**	**11.2**	1.7	2.53		1.02		1.16	
					mean ±SD	3.09	0.50	1.04	0.02	1.16	0.04

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Table 7 (cont.): 1-13 NYS Tumor Marker PT Summary for PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM251	24	1.9	**1.6**	**2.2**	0.3	5.26		0.83		0.95	
TM252	24	2.0	**1.6**	**2.4**	0.4	4.50		0.87		0.95	
TM253	24	3.6	**3.0**	**4.2**	0.6	4.44		0.80		0.90	
TM254	24	3.7	**3.0**	**4.4**	0.7	4.05		0.80		0.88	
TM255	24	6.9	**5.7**	**8.1**	1.2	5.36		0.74		0.84	
					mean ±SD	4.57	0.51	0.81	0.05	0.90	0.05
Tosoh AIA TOM											
TM251	6	2.2	**1.8**	**2.6**	0.4	3.64		0.96		1.10	
TM252	8	2.2	**1.8**	**2.6**	0.4	5.00		0.96		1.05	
TM253	8	4.2	**3.4**	**5.0**	0.8	6.67		0.93		1.05	
TM254	6	4.4	**3.6**	**5.2**	0.8	4.32		0.96		1.05	
TM255	8	9.4	**7.7**	**11.1**	1.7	12.02		1.01		1.15	
					mean ±SD	4.91	1.30	0.96	0.03	1.08	0.04

Sample ID	N	All Method Median	IS based Target	SD		Median % CV		Average Bias	SD
TM251	**248**	**2.3**	**2.0**	**0.06**		**5.26**	**Low group**	1.08	0.01
TM252	**253**	**2.3**	**2.1**	**0.09**		**4.50**	**High group**	1.30	0.02
TM253	**254**	**4.5**	**4.0**	**0.14**		**5.37**			
TM254	**251**	**4.6**	**4.2**	**0.17**		**4.53**			
TM255	**250**	**9.3**	**8.2**	**0.34**		**5.36**			
					Average	**5.00**			
					Allowable CV %	**6.00**			
					Allowable Error (+/-)%	**18.0**			

	Low Group			High Group		
Sample ID	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
TM251	**2.0**	**0.18**	**8.97**	**2.7**	**0.21**	**8.00**
TM252	**2.0**	**0.16**	**7.75**	**2.7**	**0.07**	**2.67**
TM253	**3.9**	**0.41**	**10.49**	**5.3**	**0.14**	**2.67**
TM254	**4.0**	**0.37**	**9.20**	**5.4**	**0.07**	**1.32**
TM255	**8.0**	**0.92**	**11.58**	**10.9**	**0.49**	**4.56**
		Mean	**9.60**		**Mean**	**3.85**

Figure 7: PSA Method Comparison

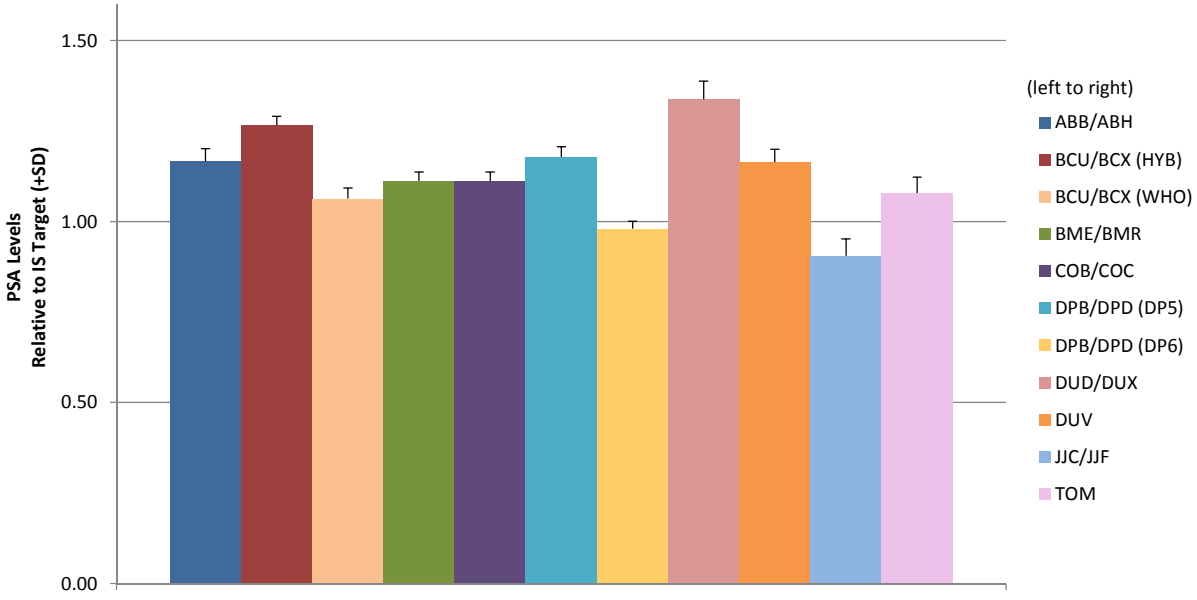

Table 8: 1-13 NYS Tumor Marker PT Summary for Free PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
Abbott Architect ABH											
TM251	3	0.30	**0.15**	**0.45**	0.15	0.00		1.15		1.08	
TM252	4	0.69	**0.59**	**0.79**	0.10	2.90		1.08		1.03	
TM253	4	0.57	**0.48**	**0.66**	0.09	5.26		1.14		1.07	
TM254	4	1.40	**1.19**	**1.61**	0.21	2.86		1.11		1.05	
TM255	4	1.14	**0.97**	**1.31**	0.17	4.39		1.14		1.06	
					mean ±SD	3.08	2.00	1.12	0.03	1.06	0.02
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM251	25	0.36	**0.21**	**0.51**	0.15	8.33		1.38		1.30	
TM252	25	0.85	**0.72**	**0.98**	0.13	5.88		1.33		1.27	
TM253	25	0.68	**0.58**	**0.78**	0.10	5.88		1.36		1.28	
TM254	25	1.67	**1.42**	**1.92**	0.25	5.39		1.33		1.25	
TM255	25	1.33	**1.13**	**1.53**	0.20	4.51		1.33		1.24	
					mean ±SD	6.00	1.42	1.35	0.03	1.27	0.03
Roche Elecsys & Cobas BME/BMR											
TM251	23	0.26	**0.11**	**0.41**	0.15	3.85		1.00		0.94	
TM252	23	0.64	**0.54**	**0.74**	0.10	4.69		1.00		0.95	
TM253	23	0.50	**0.43**	**0.58**	0.08	4.00		1.00		0.94	
TM254	24	1.26	**1.07**	**1.45**	0.19	3.97		1.00		0.94	
TM255	23	1.00	**0.85**	**1.15**	0.15	3.00		1.00		0.93	
					mean ±SD	3.90	0.60	1.00	0.00	0.94	0.01
Siemens Immulite 1000 & 2000 DPB/DPD											
TM251	19	0.23	**0.08**	**0.38**	0.15	4.35		0.88		0.83	
TM252	19	0.57	**0.48**	**0.66**	0.09	5.26		0.89		0.85	
TM253	20	0.45	**0.30**	**0.60**	0.15	6.67		0.90		0.85	
TM254	19	1.17	**0.99**	**1.35**	0.18	6.84		0.93		0.88	
TM255	19	0.94	**0.80**	**1.08**	0.14	4.26		0.94		0.87	
					mean ±SD	5.47	1.23	0.91	0.02	0.86	0.02
Siemens Dimension Vista DUV											
TM251	6	0.23	**0.08**	**0.38**	0.15	4.35		0.88		0.83	
TM252	7	0.57	**0.48**	**0.66**	0.09	3.51		0.89		0.85	
TM253	7	0.45	**0.30**	**0.60**	0.15	4.44		0.90		0.85	
TM254	7	1.11	**0.94**	**1.28**	0.17	1.80		0.88		0.83	
TM255	7	0.91	**0.77**	**1.05**	0.14	4.40		0.91		0.85	
					mean ±SD	3.70	1.13	0.89	0.01	0.84	0.01

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV
TM251	**76**	**0.26**	**0.28**	**0.03**	**4.35**
TM252	**78**	**0.64**	**0.67**	**0.05**	**4.69**
TM253	**79**	**0.50**	**0.53**	**0.04**	**5.26**
TM254	**79**	**1.26**	**1.34**	**0.09**	**3.97**
TM255	**78**	**1.00**	**1.07**	**0.08**	**4.39**
				Average	**4.53**
				Allowable CV %	**5.0**
				Allowable Error if >/= 0.5 ng/ml (+/-)%	**15.0**
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	**0.15**

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Table 8 (cont.): 1-13 NYS Tumor Marker PT Summary for Free PSA

Figure 8: Free PSA Method Comparison

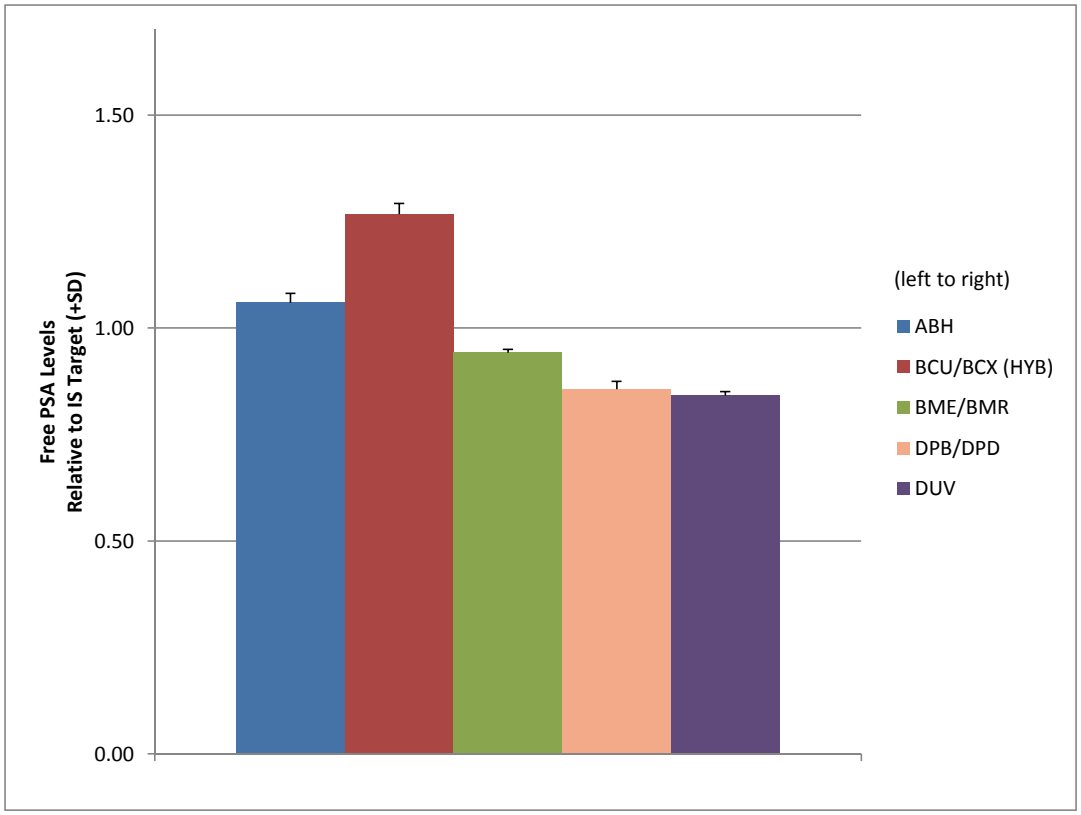

Table 9: 1-13 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM251	12	2.0	**1.7**	**2.3**	0.3	4.59		1.00	
TM252	12	1.6	**1.4**	**1.9**	0.3	4.91		1.00	
TM253	12	4.0	**3.4**	**4.6**	0.6	3.77		1.00	
TM254	12	3.2	**2.7**	**3.7**	0.5	4.09		1.00	
TM255	12	7.9	**6.7**	**9.1**	1.2	4.19		1.00	
					mean ±SD	4.31	0.45	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM251	**12**	**2.0**		**4.59**
TM252	**12**	**1.6**		**4.91**
TM253	**12**	**4.0**		**3.77**
TM254	**12**	**3.2**		**4.09**
TM255	**12**	**7.9**		**4.19**
			Average	**4.31**
			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/2013/index.htm

Oncology Soluble Tumor Markers						
		TM251	**TM252**	**TM253**	**TM254**	**TM255**
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 BE SUBMITTED FOR **ALL** SAMPLES. SEE INSTRUCTIONS FOR MORE INFORMATION.

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

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