NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

May 7, 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: **May 22, 2013**

Samples:
Enclosed are five sealed (5) vials labeled **TM256 to TM260**, 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 May 22, 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 Test is scheduled for:

Mail-out date:	Due date:
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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Electronic Proficiency Test Reporting System Bulletin
May 2013

Laboratories participating in the May 2013 proficiency testing events in the categories listed below are required to submit results through the Electronic Proficiency Test Reporting System (EPTRS) system.

Clinical Chemistry
Endocrinology
Fetal Defect Markers
Mycology (Comprehensive, Identification, and Identification – Yeast Only)
Oncology Soluble Tumor Markers
Parasitology (Antigen Detection, Blood Smears, Comprehensive)
Therapeutic Substance Monitoring
Toxicology Blood Lead
Trace Elements (Serum, Urine and Whole Blood)
Virology (Comprehensive, HSV, Influenza, Rotavirus, RSV and Molecular Influenza)

The Health Commerce System (HCS) Portal URL is https://commerce.health.state.ny.us
After logging into the Portal, 'My Applications' is listed on the left side of the page. If you have access to EPTRS, the acronym 'EPTRS' will be listed under the heading 'My Applications'. Click on 'EPTRS' to access the homepage. If you do not see the acronym 'EPTRS', please send an email to clepeptrs@health.state.ny.us

Important Phone Numbers:

1. Technical Assistance with EPTRS - Monday through Friday between **8am and 4pm** by calling 518-486-5410.
2. Commerce Accounts Management Unit - for account information and passwords - Monday through Friday between 8am and 5 pm by calling 866-529-1890.

HCS Accounts – every user accessing EPTRS must have their own account for the HCS. It is a violation of the security and use agreement to share an account User ID and password with someone else. Sharing your account information with someone else will result in the suspension of your account. Please email clepeptrs@health.state.ny.us for assistance with requesting accounts for additional users.

EPTRS Webpage:

- Event Menu Page - Please review the laboratory's persistent data (instruments, reagents, methods, contact, email, etc). It is the responsibility of each laboratory to verify the data and make any required changes.
- Summary Page
    - Results submission - When you are ready to submit, navigate to the bottom of the Summary Page and click on the Submit/Attest button. **Saving or validating without submitting results will result in a failure for non-participation.** If you do not see the "Submit/Attest" button on the EPTRS Summary Page or if you have questions concerning result entry, please contact the Clinical Laboratory Evaluation Program at clepeptrs@health.state.ny.us.
    - Attestation statement - must be printed and signed by the laboratory director or responsible assistant director, the delegated submitter and the analyst prior to submission of the proficiency test results. The signed document must be kept on file in the laboratory for review by the laboratory surveyor during the next onsite survey.

If you experience any difficulty accessing EPTRS, please contact clepeptrs@health.state.ny.us

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						
		TM256	**TM257**	**TM258**	**TM259**	**TM260**
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!!!!**********

REFRIGERATE SAMPLES UPON ARRIVAL

DO NOT FREEZE

FOR LABS TESTING **FREE PSA,** TEST IT FOR **ALL** SAMPLES.

SEE INSTRUCTIONS FOR MORE INFORMATION.

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

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June 13, 2013

New York State Tumor Marker Proficiency Test 5-2013 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from May 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 human 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.

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

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

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 115 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. There seemed to be a clear separation into two clusters of methods, comprising four peer groups each. The "low" cluster with nearly identical results among the four peer groups, was on average 12% below the all method median; in contrast, results in the "high" cluster were somewhat more diverse, but on average were 20% above the all method median.

CA19-9 (Table 2, Figure 2): Results were reported by 69 labs using instruments from seven different manufacturers, but due to several with N=1, four peer groups remained for grading. Though only used by one lab, the Abbott Architect method result is shown in Table 2 and Figure 2 to highlight its large difference from the other methods. Forty-nine percent of all reporting labs used Siemens ADVIA-Centaur XP, 19% 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 remain large differences in how each method measured CA19-9, ranging from 71% (Tosoh) to 673% (Abbott) of the all method median. The results from Siemens ADVIA-Centaur XP were on average 2.14 times higher than the all method median, whereas results from Beckman and Roche were within +/-10% of the all method median. 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 102 labs, with slightly more than half (54%) 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). Abbott, Roche, Siemens ADVIA and Ortho Clinical were all within +/-10% of the all method median and altogether comprise 75% of the labs measuring CA15-3. In contrast, the Siemens Immulite 2000 system (used by 16% of labs) averaged +15% compared to the medians, while the Beckman Unicel/Access results exhibited a notable negative bias, averaging -36% from the all method medians, which is similar to previous NYS PT events. In contrast, **CA27.29** measurements showed only a 6% difference between the ADVIA Centaur XP/CP and the Tosoh methods. However, median CA27.29 measurements were approximately 12% higher than median CA15-3 measurements in all but the lowest sample TM256.

CEA (Table 5, Figure 5): Results were reported by 168 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 51 labs. Results from the Abbott, Beckman, Siemens Centaur and Siemens Immulite 2000 methods, which accounted for 61% of the labs, were within +/-5% of the medians. In contrast, Roche methods averaged 29%, Siemens Dimension Vista 15%, and Ortho Clinical Diagnostics Vitros ECi/ECiQ & 5600 20% below the median, respectively, whereas TOSOH ST-AIA exhibited a high positive bias averaging 57% above 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 104 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 eighteen percent of the total number of labs. Six of the eight methods gave results within +/-10% of all method median, but were between 5% and 22% higher than the assigned targets. Of the remaining two methods, Roche measured 18% higher than the all method median, and 35% higher than targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants) was the only method with results below the assigned target (10%) and was 21% below the all method median. Thus, it appears that most methods somewhat overestimated AFP levels in our samples, a result that is similar to what has been observed in previous NYS PT events for these methods.

PSA (Table 7, Figure 7): Results were reported by 246 labs using instruments from eleven peer groups. Three of the peer groups comprised fewer than ten members each, and together made up only 5% of the labs. Samples were prepared with varying concentrations of total and free PSA, however two samples (TM256 & 259) were paired to be targeted with 30% free PSA but 10-fold different levels of total PSA in order to assess if the level of total PSA affected the proportion of free PSA. There was no recognizable difference in the proportions of free PSA between the two total PSA concentrations for the paired samples. In contrast to previous PT events, no clear separation into statistically significantly different high and low clusters of methods was seen. Indeed, results from nine of the eleven peer groups were within +/-10% of the all method median, and between +8% and +30% from the assigned targets. Of the remaining two methods, the Siemens Dimension RxL Max/Xpand Plus/EXL was 13% above the all method median and 35% above the assigned targets. In contrast, results from Ortho Clinical Vitros ECi/ECiQ & 5600 were 30% lower than the all method median and 16% lower than the targets. Finally, with regard to the online survey question about Beckman's PHI (Prostate Health Index), three labs responded that they are planning to test pro2PSA within a year in order to generate the PHI.

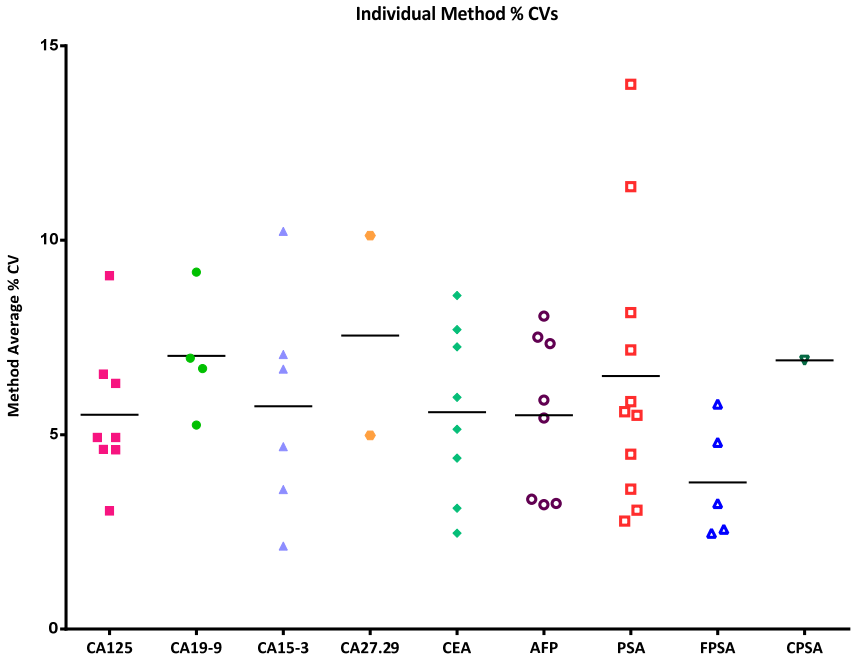
Free PSA (Table 8, Figure 8): Results were reported by 84 labs using instruments from seven manufacturers (Beckman provides two different calibrations) corresponding to five peer groups plus three others with N<3. Two of the five peer groups comprised less than 10 labs each and along with the N<3 methods, made up 17% of the participants. The remaining three methods were used by 30% of labs each for Beckman Unicel/Access calibrated with the Hybritech standards and Roche Elecsys/E170/Cobas, and 23% for Siemens Immulite 1000/ 2000. As seen in previous PTs, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (31% higher than the all method medians and the targets, which incidentally are the same), while there were not enough results from Beckman Unicel/Access calibrated with the WHO standards to allow a comparison to the other methods. Of the other methods, three were within +/-10% of the assigned targets, and one was 13% below the assigned targets. In conclusion, there are still substantial differences in how free PSA is measured, and not every method that is high for total PSA is also high for free PSA.

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. The lowest concentration of total PSA (TM256) gave an unexpectedly high interlaboratory %CV of 10.61%, while the higher concentration samples showed relatively good agreement with an average %CV of 6% (Table 9).

In conclusion, substantial differences remain between the results obtained with various methods or instruments for some analytes. Furthermore, not all methods appear equally reproducible as indicated by the spread of the average within-method %CVs, though many are <10%.



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

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

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

Please be aware that even though the Instrument and Reagent fields will usually be pre-populated in EPTRS based on what was previously entered, it is still necessary to confirm that ALL instruments and reagents have been correctly entered prior to final submission. That information

is critical to evaluate your results within the correct peer group. There have been instances where individual labs either **selected a qualifier (< or >) inadvertently or chose an incorrect instrument or reagent** while scrolling through the electronic reporting page lists. This can result in a **technical failure** for results evaluated outside of the correct peer group or an **administrative failure** for incorrect methodology. No changes can be made for incorrect or missing information after the submission deadline.

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 date for the remaining 2013 Tumor Marker Proficiency Test event is:

Mail-out date:
September 10, 2013

Due date:
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: 5-13 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 Architect ABH									
TM256	11	14.1	**8.7**	**19.5**	5.4	10.43		1.22	
TM257	11	32.6	**26.7**	**38.5**	5.9	9.29		1.23	
TM258	11	43.5	**35.7**	**51.3**	7.8	8.39		1.24	
TM259	11	48.4	**39.7**	**57.1**	8.7	8.10		1.22	
TM260	11	60.2	**49.4**	**71.0**	10.8	9.25		1.21	
					mean ±SD	9.09	0.91	1.22	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM256	13	13.0	**7.6**	**18.4**	5.4	5.54		1.12	
TM257	13	31.8	**26.1**	**37.5**	5.7	4.15		1.20	
TM258	13	40.9	**33.5**	**48.3**	7.4	5.13		1.16	
TM259	13	48.4	**39.7**	**57.1**	8.7	4.09		1.22	
TM260	13	58.3	**47.8**	**68.8**	10.5	4.19		1.17	
					mean ±SD	4.62	0.67	1.18	0.04
Roche Elecsys & Cobas BME/BMR									
TM256	17	10.7	**5.3**	**16.1**	5.4	4.49		0.92	
TM257	17	23.7	**18.3**	**29.1**	5.4	2.49		0.90	
TM258	17	30.9	**25.3**	**36.5**	5.6	2.62		0.88	
TM259	16	34.8	**28.5**	**41.1**	6.3	2.61		0.88	
TM260	17	42.7	**35.0**	**50.4**	7.7	3.00		0.86	
					mean ±SD	3.04	0.83	0.89	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM256	33	12.5	**7.1**	**17.9**	5.4	5.68		1.08	
TM257	34	29.1	**23.7**	**34.5**	5.4	4.05		1.10	
TM258	34	38.7	**31.7**	**45.7**	7.0	4.42		1.10	
TM259	34	43.5	**35.7**	**51.3**	7.8	4.39		1.10	
TM260	34	54.2	**44.4**	**64.0**	9.8	4.50		1.09	
					mean ±SD	4.61	0.62	1.09	0.01
Siemens Immulite 2000 DPD									
TM256	24	9.3	**3.9**	**14.7**	5.4	6.99		0.80	
TM257	24	22.9	**17.5**	**28.3**	5.4	6.64		0.87	
TM258	24	31.6	**25.9**	**37.3**	5.7	5.63		0.90	
TM259	24	35.3	**28.9**	**41.7**	6.4	6.97		0.89	
TM260	24	43.9	**36.0**	**51.8**	7.9	5.38		0.88	
					mean ±SD	6.32	0.76	0.87	0.04
Siemens Diag Dimension Vista (LOCI) DUV									
TM256	3	10.6	**5.2**	**16.0**	5.4	4.15		0.91	
TM257	3	22.9	**17.5**	**28.3**	5.4	8.03		0.87	
TM258	3	31.3	**25.7**	**36.9**	5.6	2.56		0.89	
TM259	3	35.8	**29.4**	**42.2**	6.4	4.13		0.90	
TM260	3	44.1	**36.2**	**52.0**	7.9	5.78		0.88	
						4.93	2.08	0.89	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM256	4	5.8	**0.4**	**11.2**	5.4	4.31		0.50	
TM257	8	21.2	**15.8**	**26.6**	5.4	8.40		0.80	
TM258	8	30.7	**25.2**	**36.2**	5.5	6.68		0.87	
TM259	8	35.8	**29.4**	**42.2**	6.4	7.74		0.90	
TM260	8	45.5	**37.3**	**53.7**	8.2	5.69		0.91	
					mean ±SD	6.56	1.63	0.87	0.05

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Table 1 (cont.): 5-13 NYS Tumor Marker PT Summary for CA 125

Tosoh AIA TOM									
TM256	5	14.6	**9.2**	**20.0**	5.4	6.37		1.26	
TM257	5	35.2	**28.9**	**41.5**	6.3	4.66		1.33	
TM258	5	47.6	**39.0**	**56.2**	8.6	4.60		1.35	
TM259	5	54.5	**44.7**	**64.3**	9.8	2.83		1.37	
TM260	5	68.2	**55.9**	**80.5**	12.3	6.17		1.37	
					mean ±SD	4.93	1.43	1.34	0.05

Sample ID		All Method Median	Median % CV
TM256	110	**11.6**	**5.61**
TM257	115	**26.4**	**5.65**
TM258	115	**35.2**	**4.87**
TM259	114	**39.7**	**4.26**
TM260	115	**49.9**	**5.53**
		Average	**5.18**
		Allowable CV %	**6.0**
		Allowable Error if >/= 30 U/ml (+/-) %	**18.0**
		Allowable Error if < 30 U/ml (+/- U/ml)	**5.4**

Figure 1: CA 125 Method Comparison

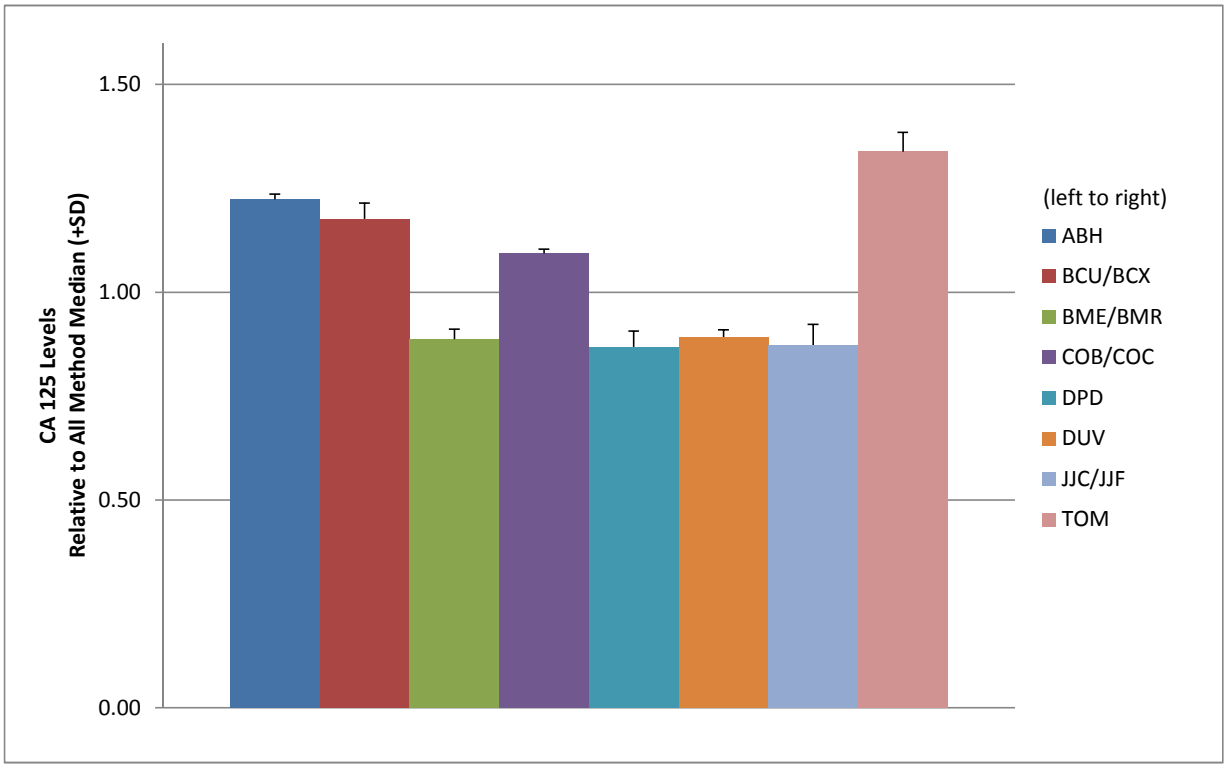

Table 2: 5-13 NYS Tumor Marker PT Summary for CA 19-9

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									
TM256	1	71.5						6.14	
TM257	1	162.5						6.06	
TM258	1	239.2						8.93	
TM259	1	255.1						6.25	
TM260	1	315.1						6.28	
					mean ±SD*			6.73	1.23
Beckman Unicel & Access/2 BCU/BCX									
TM256	13	11.8	**8.2**	**15.4**	3.6	11.02		1.01	
TM257	13	28.6	**23.5**	**33.7**	5.1	7.10		1.07	
TM258	13	38.7	**31.7**	**45.7**	7.0	5.27		1.08	
TM259	13	45.0	**36.9**	**53.1**	8.1	6.38		1.10	
TM260	13	55.2	**45.3**	**65.1**	9.9	5.09		1.10	
					mean ±SD*	6.97	2.41	1.07	0.04
Roche Elecsys & Cobas BME/BMR									
TM256	13	11.5	**7.9**	**15.1**	3.6	5.91		0.99	
TM257	13	25.0	**20.5**	**29.5**	4.5	4.84		0.93	
TM258	13	32.9	**27.0**	**38.8**	5.9	5.65		0.92	
TM259	13	36.6	**30.0**	**43.2**	6.6	4.54		0.90	
TM260	13	45.2	**37.1**	**53.3**	8.1	5.29		0.90	
					mean ±SD*	5.25	0.57	0.93	0.04
Siemens Advia Centaur XP COB									
TM256	34	24.8	**20.3**	**29.3**	4.5	7.58		2.13	
TM257	34	55.3	**45.3**	**65.3**	10.0	6.09		2.06	
TM258	34	75.0	**61.5**	**88.5**	13.5	7.03		2.09	
TM259	34	87.5	**71.8**	**103.3**	15.8	6.87		2.14	
TM260	34	114.0	**93.5**	**134.5**	20.5	5.93		2.27	
					mean ±SD*	6.70	0.68	2.14	0.08
Tosoh AIA TOM									
TM256	5	9.8	**6.2**	**13.4**	3.6	15.10		0.84	
TM257	5	18.9	**15.3**	**22.5**	3.6	8.73		0.71	
TM258	5	24.5	**20.1**	**28.9**	4.4	7.06		0.68	
TM259	5	27.4	**22.5**	**32.3**	4.9	7.34		0.67	
TM260	5	32.9	**27.0**	**38.8**	5.9	7.66		0.66	
					mean ±SD*	9.18	3.37	0.71	0.07

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Table 2 (cont.): 5-13 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median	Median % CV
TM256	69	11.7	9.30
TM257	69	26.8	6.60
TM258	69	35.8	6.34
TM259	69	40.8	6.62
TM260	69	50.2	5.61
		Average*	6.89
		Allowable CV %	6.00
		Allowable Error if >/= 20 U/ml (+/-) %	18.0
		Allowable Error if < 20 U/ml (+/- U/ml)	3.6

Figure 2: CA 19-9 Method Comparison

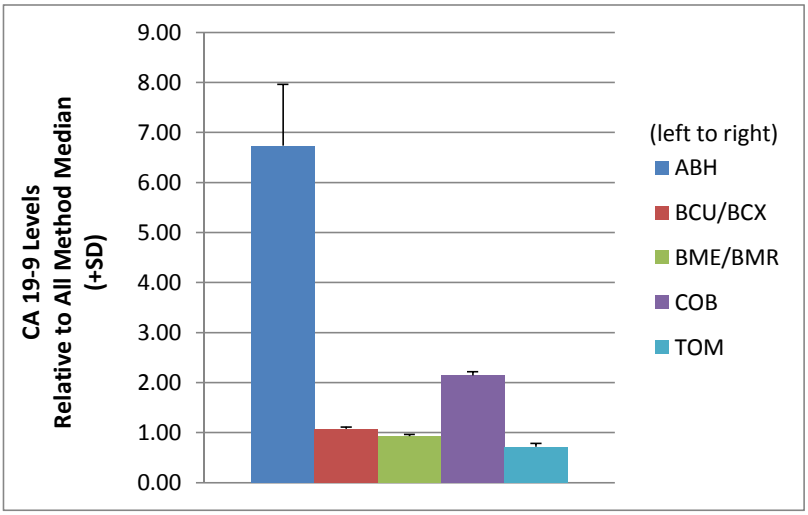

Table 3: 5-13 NYS Tumor Marker PT Summary for CA 15-3

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									
TM256	5	15.8	**13.0**	**18.6**	2.8	3.61		1.12	
TM257	5	39.6	**32.5**	**46.7**	7.1	5.78		1.11	
TM258	5	54.1	**44.4**	**63.8**	9.7	7.36		1.08	
TM259	5	64.2	**52.6**	**75.8**	11.6	6.60		1.08	
TM260	5	79.0	**64.8**	**93.2**	14.2	7.03		1.06	
					mean ±SD	6.69	0.68	1.08	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM256	5	9.8	**8.0**	**11.6**	1.8	6.02		0.69	
TM257	5	23.3	**19.1**	**27.5**	4.2	4.25		0.65	
TM258	5	32.5	**26.7**	**38.4**	5.9	5.38		0.65	
TM259	5	37.6	**30.8**	**44.4**	6.8	4.10		0.63	
TM260	5	46.4	**38.0**	**54.8**	8.4	5.04		0.62	
					mean ±SD	4.69	0.62	0.64	0.01
Roche Elecsys & Cobas BME/BMR									
TM256	14	14.2	**11.6**	**16.8**	2.6	4.01		1.00	
TM257	14	35.2	**28.9**	**41.5**	6.3	4.06		0.99	
TM258	14	48.9	**40.1**	**57.7**	8.8	3.99		0.98	
TM259	13	57.0	**46.7**	**67.3**	10.3	1.96		0.96	
TM260	14	70.6	**57.9**	**83.3**	12.7	4.33		0.95	
					mean ±SD	3.59	1.09	0.97	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM256	20	14.1	**11.6**	**16.6**	2.5	11.35		1.00	
TM257	20	36.0	**29.5**	**42.5**	6.5	9.64		1.01	
TM258	20	49.9	**40.9**	**58.9**	9.0	10.60		1.00	
TM259	20	59.5	**48.8**	**70.2**	10.7	10.81		1.00	
TM260	20	75.2	**61.7**	**88.7**	13.5	9.85		1.01	
					mean ±SD	10.23	0.57	1.01	0.01
Siemens Immulite 2000 DPD									
TM256	9	16.0	**13.1**	**18.9**	2.9	7.50		1.13	
TM257	9	39.9	**32.7**	**47.1**	7.2	7.14		1.12	
TM258	9	56.4	**46.2**	**66.6**	10.2	5.23		1.13	
TM259	9	69.3	**56.8**	**81.8**	12.5	8.69		1.17	
TM260	9	87.0	**71.3**	**102.7**	15.7	7.16		1.17	
					mean ±SD	7.06	1.42	1.15	0.03
Ortho Clinical Diag Vitros Eci/ECiQ JJC									
TM256	2	14.1	**11.6**	**16.6**	2.5	0.50		1.00	
TM257	2	35.0	**28.7**	**41.3**	6.3	0.60		0.98	
TM258	2	50.0	**41.0**	**59.0**	9.0	3.68		1.00	
TM259	2	59.1	**48.5**	**69.7**	10.6	2.15		1.00	
TM260	2	73.6	**60.4**	**86.8**	13.2	1.25		0.99	
					mean ±SD	2.14	1.54	0.99	0.01

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Table 3 (cont.): 5-13 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM256	55	14.2	5.02
TM257	55	35.6	5.02
TM258	55	50.0	5.31
TM259	54	59.3	5.35
TM260	55	74.4	6.03
		Average	5.43
		Allowable CV %	6.00
		Allowable Error (+/-)%	18.0

Figure 3: CA 15-3 Method Comparison

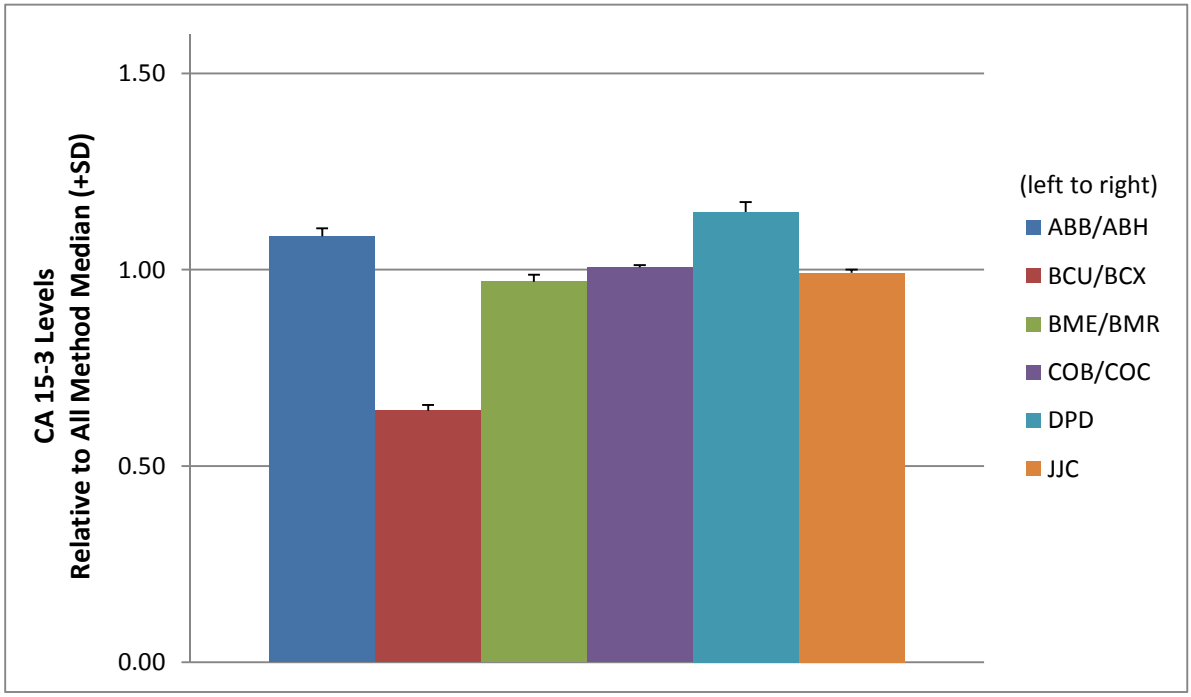

Table 4: 5-13 NYS Tumor Marker PT Summary for CA 27.29

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									
TM256	41	11.6	**4.3**	**19.0**	7.4	24.48		0.83	
TM257	41	40.4	**31.9**	**48.9**	8.5	9.18		1.03	
TM258	40	60.6	**47.9**	**73.3**	12.7	5.45		1.07	
TM259	41	72.8	**57.5**	**88.1**	15.3	5.76		1.10	
TM260	40	92.4	**73.0**	**111.8**	19.4	5.73		1.10	
					mean ±SD	10.12	8.18	1.03	0.11
Tosoh AIA TOM									
TM256	6	16.2	**8.9**	**23.6**	7.4	5.80		1.17	
TM257	6	38.2	**30.2**	**46.2**	8.0	6.94		0.97	
TM258	6	52.4	**41.4**	**63.4**	11.0	2.71		0.93	
TM259	6	59.5	**47.0**	**72.0**	12.5	5.23		0.90	
TM260	6	74.9	**59.2**	**90.6**	15.7	4.21		0.90	
					mean ±SD	4.98	1.61	0.97	0.11

Sample ID		All Method Median	Median % CV
TM256	47	**13.9**	**15.14**
TM257	47	**39.3**	**8.06**
TM258	46	**56.5**	**4.08**
TM259	47	**66.2**	**5.49**
TM260	46	**83.7**	**4.97**

Average	**7.55**
Allowable CV %	**7.0**
Allowable Error if >/= 35 U/ml (+/-) %	**21.0**
Allowable Error if < 35 U/ml (+/- U/ml)	**7.35**

Figure 4: CA 27.29 Method

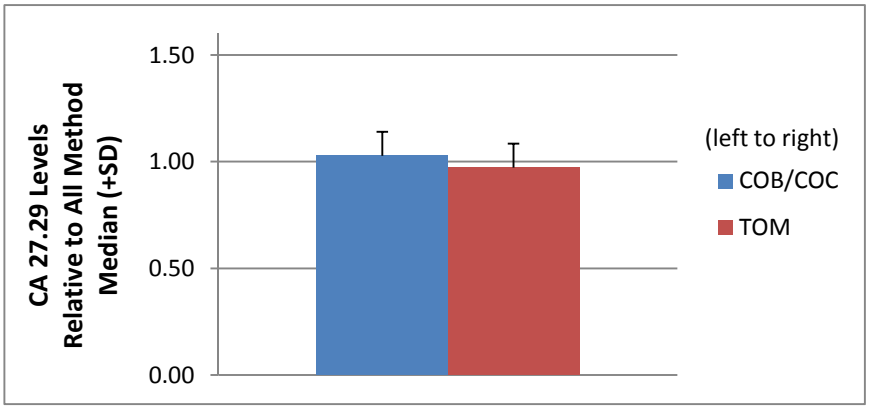

Table 5: 5-13 NYS Tumor Marker PT Summary for CEA

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									
TM256	14	4.6	**3.7**	**5.5**	0.9	7.17		1.06	
TM257	15	12.7	**10.4**	**15.0**	2.3	5.83		1.02	
TM258	15	19.6	**16.1**	**23.1**	3.5	4.59		1.03	
TM259	15	17.6	**14.4**	**20.8**	3.2	4.26		1.02	
TM260	15	23.9	**19.6**	**28.2**	4.3	3.85		1.03	
					mean ±SD	5.14	1.36	1.03	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM256	23	4.3	**3.4**	**5.2**	0.9	7.21		0.99	
TM257	23	12.1	**9.9**	**14.3**	2.2	5.87		0.98	
TM258	23	18.6	**15.3**	**21.9**	3.3	7.31		0.97	
TM259	23	16.8	**13.8**	**19.8**	3.0	7.98		0.98	
TM260	23	22.6	**18.5**	**26.7**	4.1	7.92		0.98	
					mean ±SD	7.26	0.85	0.98	0.01
Roche Elecsys & Cobas BME/BMR									
TM256	21	3.3	**2.4**	**4.2**	0.9	5.76		0.76	
TM257	21	8.8	**7.2**	**10.4**	1.6	4.55		0.71	
TM258	21	13.4	**11.0**	**15.8**	2.4	4.10		0.70	
TM259	21	11.8	**9.7**	**13.9**	2.1	3.90		0.69	
TM260	21	15.8	**13.0**	**18.6**	2.8	3.67		0.68	
					mean ±SD	4.40	0.83	0.71	0.03
Siemens Advia Centaur XP & CP COB/COC									
TM256	51	4.6	**3.7**	**5.5**	0.9	5.65		1.06	
TM257	51	12.9	**10.6**	**15.2**	2.3	6.05		1.04	
TM258	51	19.8	**16.2**	**23.4**	3.6	5.86		1.04	
TM259	51	17.7	**14.5**	**20.9**	3.2	5.93		1.03	
TM260	51	23.7	**19.4**	**28.0**	4.3	6.29		1.02	
					mean ±SD	5.96	0.23	1.04	0.01
Siemens Immulite 2000 DPD									
TM256	14	4.4	**3.5**	**5.3**	0.9	9.77		1.01	
TM257	14	12.8	**10.5**	**15.1**	2.3	6.88		1.03	
TM258	14	20.5	**16.8**	**24.2**	3.7	6.68		1.07	
TM259	14	18.2	**14.9**	**21.5**	3.3	7.31		1.06	
TM260	14	25.0	**20.5**	**29.5**	4.5	7.88		1.08	
					mean ±SD	7.70	1.24	1.05	0.03
Siemens Dimension Vista DUV									
TM256	23	3.8	**2.9**	**4.7**	0.9	2.37		0.87	
TM257	23	10.6	**8.7**	**12.5**	1.9	2.64		0.85	
TM258	23	16.4	**13.4**	**19.4**	3.0	2.07		0.86	
TM259	23	14.1	**11.6**	**16.6**	2.5	2.41		0.82	
TM260	23	19.3	**15.8**	**22.8**	3.5	2.85		0.83	
					mean ±SD	2.47	0.29	0.85	0.02
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM256	15	1.2	**0.3**	**2.1**	0.9	19.17		0.28#	
TM257	15	8.8	**7.2**	**10.4**	1.6	8.64		0.71	
TM258	15	15.9	**13.0**	**18.8**	2.9	5.53		0.83	
TM259	15	13.9	**11.4**	**16.4**	2.5	5.11		0.81	
TM260	15	20.1	**16.5**	**23.7**	3.6	4.48		0.87	
					mean ±SD	8.58	6.13	0.80	0.07

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Table 5 (cont.): 5-13 NYS Tumor Marker PT Summary for CEA

Tosoh AIA TOM									
TM256	5	7.3	**6.0**	**8.6**	1.3	0.68		1.68	
TM257	6	19.6	**16.1**	**23.1**	3.5	2.19		1.58	
TM258	6	29.5	**24.2**	**34.8**	5.3	5.59		1.54	
TM259	6	26.3	**21.6**	**31.0**	4.7	3.92		1.53	
TM260	6	34.7	**28.5**	**40.9**	6.2	3.17		1.50	
					mean ±SD	3.11	1.84	1.57	0.07

Sample ID	N	All Method Median	Median % CV	
TM256	166	**4.4**	**6.47**	# excluded
TM257	168	**12.4**	**5.85**	
TM258	168	**19.1**	**5.56**	
TM259	168	**17.2**	**4.68**	
TM260	168	**23.2**	**4.16**	
		Average	**5.35**	
		Allowable CV %	**6.0**	
		Allowable Error if >/= 5 ng/ml (+/-) %	**18.0**	
		Allowable Error if < 5 ng/ml (+/- ng/ml)	**0.9**	

Figure 5: CEA Method Comparison

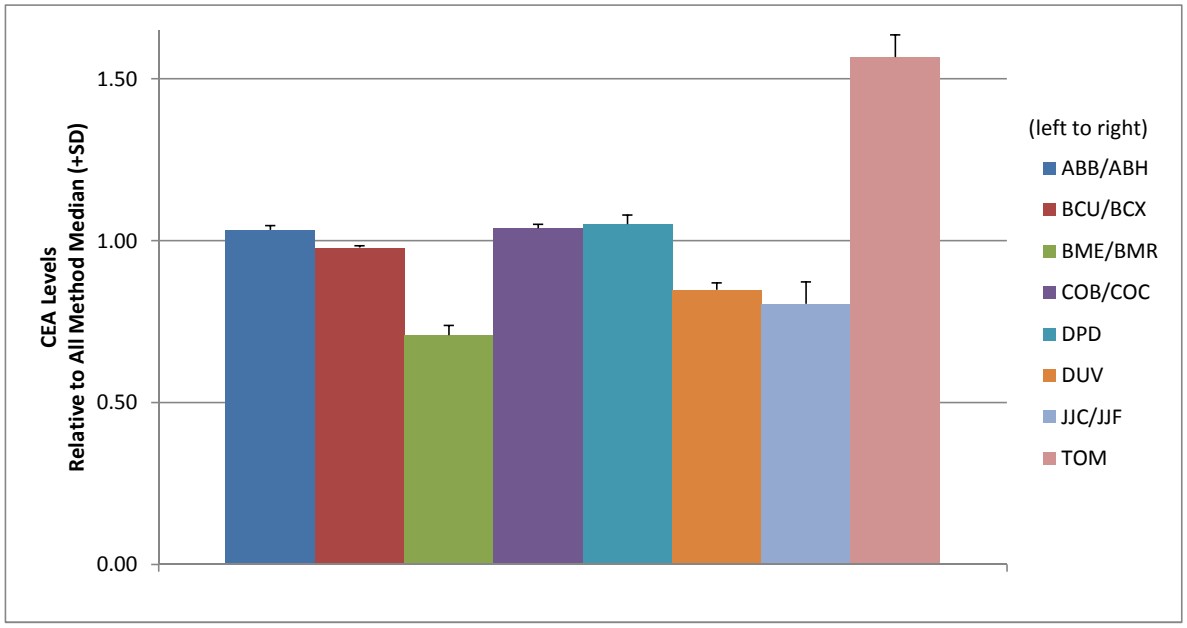

Table 6: 5-13 NYS Tumor Marker PT Summary for AFP

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											
TM256	4	9.0	**7.4**	**10.6**	1.6	6.67		1.05		1.25	
TM257	4	15.8	**13.0**	**18.6**	2.8	6.52		1.00		1.15	
TM258	4	23.8	**19.5**	**28.1**	4.3	3.70		1.00		1.15	
TM259	4	31.2	**25.6**	**36.8**	5.6	6.86		0.99		1.10	
TM260	4	37.8	**31.0**	**44.6**	6.8	3.39		0.99		1.08	
					mean ±SD	5.43	1.73	1.01	0.03	1.15	0.07
Beckman Unicel & Access/2 BCU/BCX											
TM256	18	8.2	**6.7**	**9.7**	1.5	8.41		0.96		1.14	
TM257	18	15.6	**12.8**	**18.4**	2.8	5.45		0.99		1.14	
TM258	18	23.1	**18.9**	**27.3**	4.2	8.40		0.97		1.11	
TM259	18	30.1	**24.7**	**35.5**	5.4	8.41		0.95		1.06	
TM260	18	36.7	**30.1**	**43.3**	6.6	6.02		0.96		1.05	
					mean ±SD	7.34	1.48	0.97	0.01	1.10	0.04
Roche Elecsys & Cobas BME/BMR											
TM256	19	9.8	**8.0**	**11.6**	1.8	7.86		1.15		1.36	
TM257	19	18.7	**15.3**	**22.1**	3.4	8.77		1.19		1.37	
TM258	19	28.3	**23.2**	**33.4**	5.1	7.95		1.19		1.36	
TM259	19	37.5	**30.8**	**44.3**	6.8	7.60		1.19		1.32	
TM260	19	46.1	**37.8**	**54.4**	8.3	8.05		1.20		1.32	
					mean ±SD	8.05	0.44	1.18	0.02	1.35	0.02
Siemens Advia Centaur XP & CP COB/COC											
TM256	27	9.8	**8.0**	**11.6**	1.8	6.43		1.15		1.36	
TM257	29	16.7	**13.7**	**19.7**	3.0	6.71		1.06		1.22	
TM258	28	25.2	**20.7**	**29.7**	4.5	6.51		1.06		1.21	
TM259	29	32.7	**26.8**	**38.6**	5.9	5.99		1.04		1.15	
TM260	28	40.2	**33.0**	**47.4**	7.2	3.81		1.05		1.15	
					mean ±SD	5.89	1.19	1.07	0.04	1.22	0.09
Siemens Immulite 1000 & 2000 DPB/DPD											
TM256	19	8.3	**6.8**	**9.8**	1.5	8.07		0.97		1.16	
TM257	19	15.7	**12.9**	**18.5**	2.8	9.49		1.00		1.15	
TM258	19	23.9	**19.6**	**28.2**	4.3	7.45		1.00		1.15	
TM259	19	31.9	**26.2**	**37.6**	5.7	7.49		1.01		1.13	
TM260	18	39.4	**32.3**	**46.5**	7.1	5.05		1.03		1.13	
					mean ±SD	7.51	1.60	1.00	0.02	1.14	0.01
Siemens Dimension Vista DUV											
TM256	6	7.8	**6.4**	**9.2**	1.4	3.59		0.91		1.09	
TM257	6	14.7	**12.1**	**17.3**	2.6	3.06		0.93		1.07	
TM258	6	22.1	**18.1**	**26.1**	4.0	3.67		0.93		1.07	
TM259	6	29.2	**23.9**	**34.5**	5.3	3.56		0.93		1.03	
TM260	6	35.7	**29.3**	**42.1**	6.4	2.27		0.93		1.02	
					mean ±SD	3.23	0.59	0.93	0.01	1.05	0.03
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM256	6	7.1	**5.8**	**8.4**	1.3	3.24		0.83		0.99	
TM257	6	12.6	**10.3**	**14.9**	2.3	3.65		0.80		0.92	
TM258	6	18.4	**15.1**	**21.7**	3.3	3.59		0.77		0.89	
TM259	6	24.0	**19.7**	**28.3**	4.3	2.67		0.76		0.85	
TM260	6	29.6	**24.3**	**34.9**	5.3	2.87		0.77		0.85	
					mean ±SD	3.20	0.43	0.79	0.03	0.90	0.06
Tosoh AIA TOM											
TM256	3	8.8	**7.2**	**10.4**	1.6	2.61		1.03		1.22	
TM257	3	16.4	**13.4**	**19.4**	3.0	2.44		1.04		1.20	
TM258	3	24.5	**20.1**	**28.9**	4.4	3.76		1.03		1.18	
TM259	3	31.9	**26.2**	**37.6**	5.7	4.45		1.01		1.13	
TM260	3	38.8	**31.8**	**45.8**	7.0	3.45		1.01		1.11	
					mean ±SD	3.34	0.83	1.02	0.01	1.17	0.05

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Table 6 (cont.): 5-13 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD	Median % CV	All Method Median/ IS Target
TM256	102	8.6	7.2	0.63	6.55	1.19
TM257	104	15.8	13.7	1.26	5.98	1.15
TM258	103	23.9	20.7	0.59	5.13	1.15
TM259	104	31.6	28.3	1.45	6.43	1.11
TM260	102	38.3	35.0	0.65	3.63	1.09
				Average	5.54	mean ±SD 1.14 0.04
				Allowable CV %	6.0	
				Allowable Error (+/-)%	18.0	

Figure 6: AFP Method Comparison

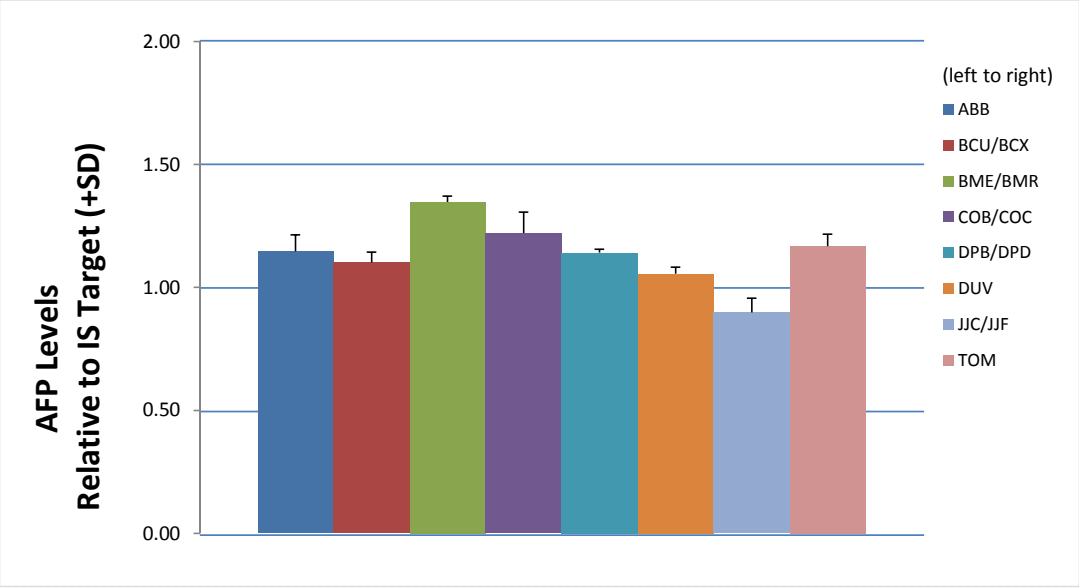

Table 7: 5-13 NYS Tumor Marker PT Summary for PSA

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 Architect ABH											
TM256	17	1.0	**0.8**	**1.2**	0.2	6.00		1.00		1.11	
TM257	17	3.8	**3.1**	**4.5**	0.7	3.68		1.00		1.23	
TM258	17	7.0	**5.7**	**8.3**	1.3	4.00		1.00		1.23	
TM259	17	9.3	**7.6**	**11.0**	1.7	5.27		1.00		1.22	
TM260	17	19.6	**16.1**	**23.1**	3.5	3.57		1.00		1.21	
					mean ±SD	4.50	1.07	1.00	0.00	1.20	0.05
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM256	46	1.0	**0.8**	**1.2**	0.2	7.00		1.00		1.11	
TM257	46	4.1	**3.4**	**4.8**	0.7	4.39		1.08		1.32	
TM258	46	7.5	**6.2**	**8.9**	1.4	6.13		1.07		1.32	
TM259	46	10.1	**8.3**	**11.9**	1.8	5.84		1.09		1.33	
TM260	46	21.4	**17.5**	**25.3**	3.9	5.89		1.09		1.32	
					mean ±SD	5.85	0.94	1.07	0.04	1.28	0.09
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)											
TM256	4	0.9	**0.7**	**1.1**	0.2	8.89		0.90		1.00	
TM257	4	3.5	**2.9**	**4.1**	0.6	10.57		0.92		1.13	
TM258	4	6.3	**5.2**	**7.4**	1.1	10.63		0.90		1.11	
TM259	4	8.4	**6.9**	**9.9**	1.5	13.33		0.90		1.11	
TM260	4	17.6	**14.4**	**20.8**	3.2	13.47		0.90		1.09	
					mean ±SD	11.38	1.97	0.90	0.01	1.09	0.05
Roche Elecsys & Cobas BME/BMR											
TM256	28	1.0	**0.8**	**1.2**	0.2	0.00		1.00		1.11	
TM257	37	3.7	**3.0**	**4.4**	0.7	4.05		0.97		1.19	
TM258	37	6.6	**5.4**	**7.8**	1.2	3.94		0.94		1.16	
TM259	36	9.0	**7.4**	**10.6**	1.6	3.44		0.97		1.18	
TM260	37	18.7	**15.3**	**22.1**	3.4	3.85		0.95		1.15	
					mean ±SD	3.06	1.72	0.97	0.02	1.16	0.03
Siemens Advia Centaur XP & CP COB/COC											
TM256	59	1.0	**0.8**	**1.2**	0.2	6.00		1.00		1.11	
TM257	59	3.6	**3.0**	**4.2**	0.6	5.28		0.95		1.16	
TM258	59	6.5	**5.3**	**7.7**	1.2	5.38		0.93		1.14	
TM259	58	8.9	**7.3**	**10.5**	1.6	5.17		0.96		1.17	
TM260	59	18.7	**15.3**	**22.1**	3.4	6.10		0.95		1.15	
					mean ±SD	5.59	0.43	0.96	0.03	1.15	0.02
Siemens Immulite 1000 &2000 - Original Pack DPB/DPD (DP5)											
TM256	19	1.0	**0.8**	**1.2**	0.2	8.00		1.00		1.11	
TM257	18	4.2	**3.4**	**5.0**	0.8	5.71		1.11		1.35	
TM258	20	7.7	**6.3**	**9.1**	1.4	9.87		1.10		1.35	
TM259	20	10.4	**8.5**	**12.3**	1.9	8.65		1.12		1.37	
TM260	20	21.6	**17.7**	**25.5**	3.9	8.47		1.10		1.33	
					mean ±SD	8.14	1.52	1.09	0.05	1.30	0.11
Siemens Immulite 1000 & 2000 - 3rd Generation Pack DPB/DPD (DP6)											
TM256	2	1.0	**0.8**	**1.2**	0.2	0.00		1.00		1.11	
TM257	2	3.8	**3.1**	**4.5**	0.7	15.00		1.00		1.23	
TM258	2	7.0	**5.7**	**8.3**	1.3	15.14		1.00		1.23	
TM259	2	9.9	**8.1**	**11.7**	1.8	20.71		1.06		1.30	
TM260	2	20.6	**16.9**	**24.3**	3.7	19.22		1.05		1.27	
					mean ±SD	14.01	8.22	1.02	0.03	1.23	0.07
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM256	13	1.1	**0.9**	**1.3**	0.2	8.18		1.10		1.22	
TM257	13	4.4	**3.6**	**5.2**	0.8	7.95		1.16		1.42	
TM258	13	7.8	**6.4**	**9.2**	1.4	7.18		1.11		1.37	
TM259	13	10.3	**8.4**	**12.2**	1.9	5.53		1.11		1.36	
TM260	13	22.5	**18.5**	**26.6**	4.1	7.07		1.15		1.39	
					mean±SD	7.18	1.04	1.13	0.03	1.35	0.08
Siemens Dimension Vista DUV											
TM256	18	1.0	**0.8**	**1.2**	0.2	5.00		1.00		1.11	
TM257	18	3.8	**3.1**	**4.5**	0.7	3.42		1.00		1.23	
TM258	18	7.0	**5.7**	**8.3**	1.3	2.71		1.00		1.23	
TM259	18	9.3	**7.6**	**11.0**	1.7	3.44		1.00		1.22	
TM260	18	20.1	**16.5**	**23.7**	3.6	3.43		1.03		1.24	
					mean ±SD	3.60	0.84	1.01	0.01	1.21	0.05

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Table 7 (cont.): 5-13 NYS Tumor Marker PT Summary for PSA

Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM256	24	0.6	**0.5**	**0.7**	0.1	11.67		0.60		0.67	
TM257	24	2.8	**2.3**	**3.3**	0.5	4.64		0.74		0.90	
TM258	23	4.9	**4.0**	**5.8**	0.9	4.08		0.70		0.86	
TM259	24	6.8	**5.6**	**8.0**	1.2	3.82		0.73		0.89	
TM260	23	14.0	**11.5**	**16.5**	2.5	3.29		0.71		0.86	
					mean ±SD	5.50	3.48	0.70	0.06	0.84	0.10
Tosoh AIA TOM											
TM256	6	0.9	**0.7**	**1.1**	0.2	0.00		0.90		1.00	
TM257	7	3.5	**2.9**	**4.1**	0.6	3.71		0.92		1.13	
TM258	7	6.2	**5.1**	**7.3**	1.1	3.06		0.89		1.09	
TM259	7	8.3	**6.8**	**9.8**	1.5	3.49		0.89		1.09	
TM260	7	17.3	**14.2**	**20.4**	3.1	3.64		0.88		1.07	
					mean ±SD	2.78	1.58	0.90	0.02	1.08	0.05

Sample ID	N	All Method Median	IS based Target	SD		Median % CV
TM256	236	**1.0**	**0.9**	**0.06**		**6.00**
TM257	245	**3.8**	**3.1**	**0.09**		**4.64**
TM258	246	**7.0**	**5.7**	**0.14**		**5.38**
TM259	245	**9.3**	**7.6**	**0.17**		**5.27**
TM260	246	**19.6**	**16.2**	**0.34**		**5.89**
					Average	**5.44**
					Allowable CV %	**6.00**
					Allowable Error (+/-)%	**18.0**

Figure 7: PSA Method Comparison

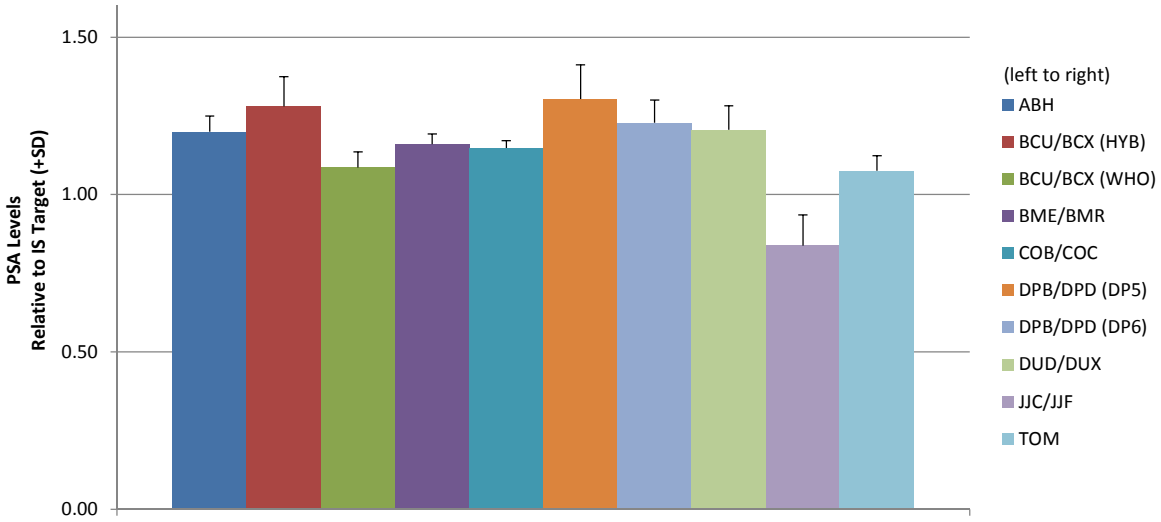

Table 8: 5-13 NYS Tumor Marker PT Summary for Free PSA

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											
TM256	5	0.27	**0.20**	**0.35**	0.08	0.00		1.13		1.16	
TM257	5	0.85	**0.72**	**0.98**	0.13	4.71		1.12		1.10	
TM258	5	0.87	**0.74**	**1.00**	0.13	2.30		1.09		1.08	
TM259	5	2.42	**2.06**	**2.78**	0.36	1.65		1.10		1.08	
TM260	5	1.90	**1.62**	**2.19**	0.29	3.68		1.07		1.06	
					mean ±SD	2.47	1.82	1.10	0.02	1.10	0.04
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM256	25	0.32	**0.25**	**0.40**	0.08	6.25		1.33		1.37	
TM257	25	1.01	**0.86**	**1.16**	0.15	3.96		1.33		1.31	
TM258	25	1.05	**0.89**	**1.21**	0.16	4.76		1.31		1.31	
TM259	25	2.84	**2.41**	**3.27**	0.43	4.23		1.29		1.27	
TM260	25	2.28	**1.94**	**2.62**	0.34	4.82		1.29		1.28	
					mean ±SD	4.80	0.89	1.31	0.02	1.31	0.04
Roche Elecsys & Cobas BME/BMR											
TM256	23	0.24	**0.17**	**0.32**	0.08	4.17		1.00		1.03	
TM257	25	0.76	**0.65**	**0.87**	0.11	3.95		1.00		0.98	
TM258	25	0.80	**0.68**	**0.92**	0.12	2.50		1.00		1.00	
TM259	25	2.21	**1.88**	**2.54**	0.33	2.71		1.00		0.99	
TM260	25	1.77	**1.50**	**2.04**	0.27	2.82		1.00		0.99	
					mean ±SD	3.23	0.77	1.00	0.00	1.00	0.02
Siemens Immulite 1000 & 2000 DPB/DPD											
TM256	18	0.22	**0.15**	**0.30**	0.08	4.55		0.92		0.94	
TM257	19	0.70	**0.60**	**0.81**	0.11	8.57		0.92		0.91	
TM258	18	0.75	**0.64**	**0.86**	0.11	5.33		0.94		0.93	
TM259	19	2.10	**1.79**	**2.42**	0.32	5.71		0.95		0.94	
TM260	19	1.67	**1.42**	**1.92**	0.25	4.79		0.94		0.93	
					mean ±SD	5.79	1.62	0.93	0.01	0.93	0.01
Siemens Dimension Vista DUV											
TM256	7	0.20	**0.13**	**0.28**	0.08	5.00		0.83		0.86	
TM257	7	0.67	**0.57**	**0.77**	0.10	2.99		0.88		0.87	
TM258	6	0.70	**0.60**	**0.81**	0.11	1.43		0.88		0.87	
TM259	7	1.98	**1.68**	**2.28**	0.30	1.52		0.90		0.88	
TM260	7	1.57	**1.33**	**1.81**	0.24	1.91		0.89		0.88	
					mean ±SD	2.57	1.49	0.87	0.02	0.87	0.01

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Table 8 (cont.): 5-13 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV
TM256	81	0.24	0.23	0.03	4.55
TM257	84	0.76	0.77	0.05	3.96
TM258	82	0.80	0.80	0.04	2.50
TM259	84	2.21	2.24	0.09	2.71
TM260	84	1.77	1.79	0.08	3.68
				Average	3.48
				Allowable CV %	5.0
				Allowable Error if >/= 0.5 ng/ml (+/-)%	15.0
				Allowable Error if < 0.5 ng/ml (+/- ng/ml)	0.075

Figure 8: Free PSA Method Comparison

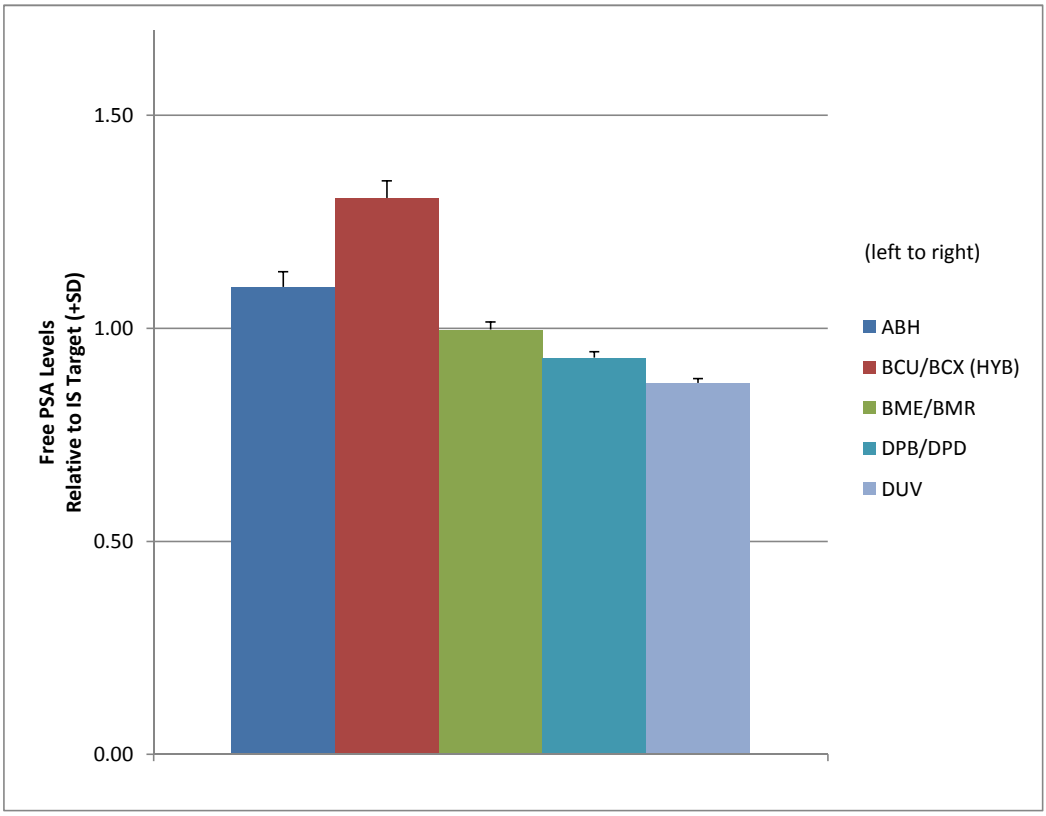

Table 9: 5-13 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM256	12	0.7	**0.5**	**0.8**	0.2	10.61		1.00	
TM257	12	2.7	**2.2**	**3.2**	0.5	5.49		1.00	
TM258	12	5.6	**4.6**	**6.6**	1.0	6.24		1.00	
TM259	12	6.4	**5.2**	**7.5**	1.2	5.34		1.00	
TM260	12	16.3	**13.3**	**19.2**	3.0	6.89		1.00	
					mean ±SD	6.91	2.16	1.00	0.00

Sample ID	N	All Method Median	Median % CV
TM256	12	**0.7**	**10.61**
TM257	12	**2.7**	**5.49**
TM258	12	**5.6**	**6.24**
TM259	12	**6.4**	**5.34**
TM260	12	**16.3**	**6.89**

***Note: Excludes TM256**

Average* **5.99**

Allowable CV % **6.0**

Allowable Error (+/-)% **18.0**