NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

September 10, 2013

IMPORTANT INSTRUCTIONS—PLEASE READ

TO: Laboratory Director

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

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

DUE DATE: **September 25, 2013**

Samples:
Enclosed are five sealed (5) vials labeled **TM261 to TM265**, 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 measure it in **ALL** of the samples. If your lab measures total PSA by a **second method** in conjunction with free PSA, you will receive TWO sets of samples which must be accessioned and tested separately and reported without inter-method comparison. You may enter those results in the corresponding fields of PSA for a 2nd method on the EPTRS entry webpage.

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 September 25, 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 us by e-mail at smchale@wadsworth.org or:

Tumor Marker Proficiency Testing c/o Susanne McHale
Wadsworth Center, Room E600
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509

The tentative 2014 Oncology Tumor Marker Proficiency Test schedule is:

Mail-out date:	Due date:
January 28, 2014	**February 12, 2014**
May 6, 2014	**May 21, 2014**
September 9, 2014	**September 24, 2014**

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
September 2013

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

Bacteriology (Comprehensive, Gram Stains, Group A Streptococcus, Gonorrhea & Chlamydia, Throat Culture and Urine Culture)
Clinical Chemistry
Cytokines
Diagnostic Immunology (Diagnostic and Donor)
Endocrinology
Fetal Defect Markers
Mycology (Comprehensive, Direct Detection, Identification, and Identification – Yeast Only)
Oncology Soluble Tumor Markers
Parentage/Identity DNA Testing
Therapeutic Substance Monitoring
Toxicology Blood Lead
Trace Elements (Serum, Urine and Whole Blood)
Transplant Monitoring (Engraftment Monitoring)
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 the 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						
		TM261	**TM262**	**TM263**	**TM264**	**TM265**
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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October 21, 2013

New York State Tumor Marker Proficiency Test 9-2013 Evaluation[1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from September 2013 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

Laboratories were challenged with five (5) different coded specimens prepared by Wadsworth Center personnel. Purified analyte preparations were added to a 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.

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

[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.

(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 or smaller than -0.5,** then your results exhibited a substantial high or low bias compared to the rest of your peer group, suggesting a potentially significant systematic error with your assay. Possible causes could include a calibration drift, reagents that are close to their expiration date, or subtle malfunction of your instrument. We strongly encourage you to take a close look at the run in question as well as others performed around that time and/or with the same reagent lots, and to evaluate if patient results might have been similarly affected.

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

Discussion:

CA125 (Table 1, Figure 1): Results were reported by 115 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 87% of the labs. Although there was a separation of groups into high and low clusters with the same bias as seen in the past, the results within the two groups were somewhat diverse. The "low" cluster ranged from 5% to 21% below the all method median with Siemens Dimension Vista being the lowest, while the "high" cluster ranged from 5% to 32% above the all method median with the Tosoh instrument being the highest.

CA19-9 (Table 2, Figure 2): Results were reported by 64 labs using instruments from seven different manufacturers, but due to two having N=1, five peer groups remained for grading. Thirty-nine percent of all reporting labs used Siemens ADVIA-Centaur XP, 23% used either Beckman's Unicel or Access/2, 20% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 8% 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 69% (Tosoh) to 451% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP were on average 1.78 times higher than the all method median, whereas results from Beckman and Roche were within +/-3% of the all method median. Used by three labs, the Abbott Architect method results averaged 4.5 times higher than the all method median as shown in Table 2 and Figure 2 and displayed a rather large variation between those labs. As previously seen, there continues to be 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 104 labs, with slightly more than half (56%) using an instrument from one of six manufacturers to measure **CA15-3** (Table 3, Figure 3) and the remainder using an instrument from one of two manufacturers to measure **CA27.29** (Table 4, Figure 4). Abbott, Roche, Siemens Advia, Siemens Immulite and Ortho Clinical (with only one lab reporting) were all within +/-10% of the all method median and altogether comprise 87% of the labs measuring CA15-3. In contrast, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -37% from the all method medians, which is similar to previous NYS PT events. **CA27.29** measurements showed a 14% difference between the ADVIA Centaur XP/CP and the Tosoh methods and the median CA27.29 measurements averaged 4% higher than the median CA15-3 measurements.

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 47 labs. Results from the Abbott Architect, Siemens Advia Centaur, Siemens Immulite and Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 methods, which altogether accounted for 54% of the labs, were within +/-3% of the medians. In contrast, Beckman methods were 14% below, Roche methods 31% below, and Siemens Dimension Vista 18% below the median, whereas TOSOH ST-AIA exhibited a high positive bias averaging 48% above the median. 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 scoring purposes the results were evaluated based on their respective peer group mean in the same way as all the other analytes. For the purpose of method comparison, the tables show the method bias against both the all method medians and the assigned target values, but the graphical figures show the performance relative only to the assigned targets.

AFP (Table 6, Figure 6): Results were reported by 101 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to seventeen percent of the total number of labs. Six of the eight methods, used by 75% of the labs, gave results within +/-10% of the all method median, but were between 6% and 20% higher than the assigned targets. Of the remaining two methods, Roche measured 16% higher than the all method median, and 35% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 6% of participants) was the only method with results below the assigned target (7%) and also was 20% 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 253 labs using instruments from ten peer groups. Two of the peer groups comprised fewer than ten members each, but together made up only 4% of the labs. Samples were prepared with varying concentrations of total and free PSA, however three samples (TM261, 263 & 265) were targeted with 25% free PSA but different levels of total PSA to assess if the total PSA level affected the proportion of free PSA. Similar to previous NYS PT events, there was no recognizable difference in the proportions of free PSA between the three total PSA concentrations for those samples. Also, no clear separation into statistically significantly different high and low clusters of methods was seen. Results from seven of the ten peer groups were within +/-10% of the all method median, and between +1% and +15% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 11% above the all method median and 24% above the target, and Siemens Dimension RxL Max/Xpand Plus/EXL was 14% above the all method median and 27% above the assigned targets. In contrast, results from Ortho Clinical Vitros ECi/ECiQ & 5600 were 20% lower than the all method median and 11% lower than the targets.

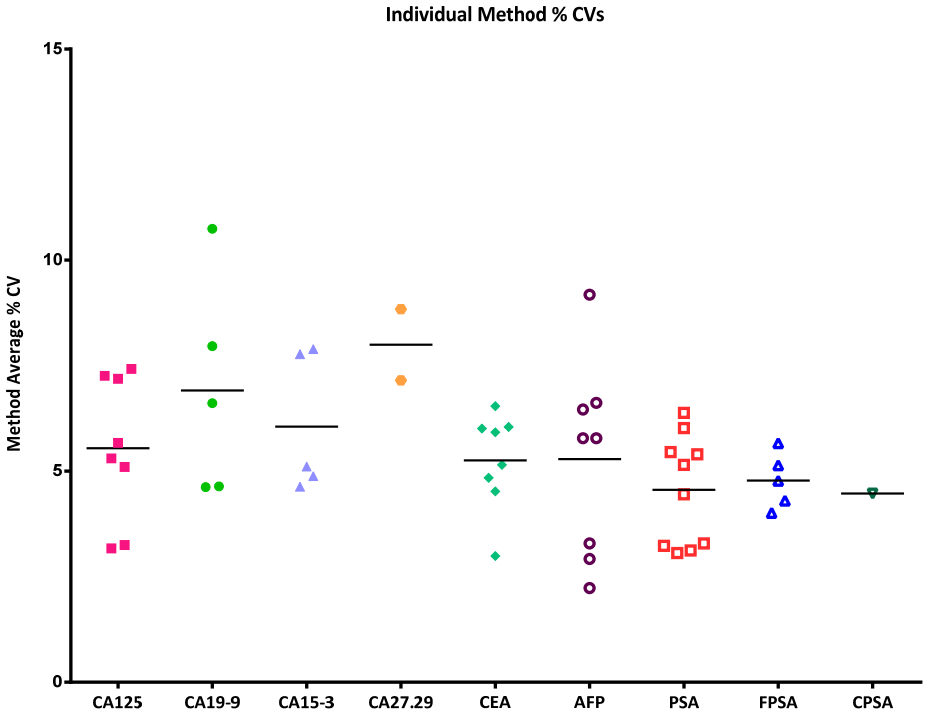
Free PSA (Table 8, Figure 8): Results were reported by 84 labs using instruments from six manufacturers (Beckman provides two different calibrations) corresponding to five peer groups plus two others with N<3. Two of the five peer groups comprised less than 10 labs each and along with the N<3 methods, made up 18% of the participants. The remaining three methods were used by 31% of labs each for Beckman Unicel/Access calibrated with the Hybritech standards and Roche Elecsys/E170/Cobas, and 18% for Siemens Immulite 1000/2000. As seen in previous PT events, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (32% higher than the all method medians and 22% higher than 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. Of the other methods, two (Abbott Architect and Roche Elecsys & Cobas) were within +/-10% of the assigned targets and two (Siemens Immulite and Siemens Dimension Vista) were 14% and 18% below the assigned targets respectively. 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. Overall, the samples showed relatively good agreement with an average %CV of 4.5% (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 dates for the 2014 Tumor Marker Proficiency Test event are:

Mail-out date:	**Due date:**
January 28, 2014	February 12, 2014
May 6, 2014	May 21, 2014
September 9, 2014	September 24, 2014

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: 9-13 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									
TM261	10	72.3	**59.3**	**85.3**	13.0	6.61		1.20	
TM262	10	45.1	**37.0**	**53.2**	8.1	6.67		1.22	
TM263	10	39.6	**32.5**	**46.7**	7.1	8.64		1.24	
TM264	10	68.6	**56.3**	**80.9**	12.3	6.97		1.20	
TM265	10	45.6	**37.4**	**53.8**	8.2	7.41		1.23	
					mean ±SD	7.26	0.83	1.22	0.02
Beckman Unicel & Access/2 BCU/BCX									
TM261	15	68.9	**56.5**	**81.3**	12.4	6.66		1.14	
TM262	15	43.4	**35.6**	**51.2**	7.8	4.82		1.18	
TM263	15	34.8	**28.5**	**41.1**	6.3	5.06		1.09	
TM264	15	66.9	**54.9**	**78.9**	12.0	5.01		1.17	
TM265	15	42.3	**34.7**	**49.9**	7.6	4.96		1.14	
					mean ±SD	5.30	0.77	1.14	0.03
Roche Elecsys & Cobas BME/BMR									
TM261	17	48.7	**39.9**	**57.5**	8.8	4.35		0.81	
TM262	17	30.1	**24.7**	**35.5**	5.4	6.15		0.82	
TM263	17	27.6	**22.2**	**33.0**	5.4	5.87		0.86	
TM264	17	46.7	**38.3**	**55.1**	8.4	6.79		0.81	
TM265	17	31.5	**25.8**	**37.2**	5.7	5.17		0.85	
					mean ±SD	5.67	0.93	0.83	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM261	34	62.8	**51.5**	**74.1**	11.3	4.97		1.04	
TM262	35	38.5	**31.6**	**45.4**	6.9	5.51		1.04	
TM263	34	33.7	**27.6**	**39.8**	6.1	5.61		1.05	
TM264	34	59.8	**49.0**	**70.6**	10.8	4.28		1.04	
TM265	35	39.3	**32.2**	**46.4**	7.1	5.11		1.06	
					mean ±SD	5.10	0.53	1.05	0.01
Siemens Immulite 2000 DPD									
TM261	23	52.7	**43.2**	**62.2**	9.5	6.26		0.87	
TM262	23	32.1	**26.3**	**37.9**	5.8	6.92		0.87	
TM263	22	26.7	**21.3**	**32.1**	5.4	8.16		0.83	
TM264	23	49.6	**40.7**	**58.5**	8.9	7.04		0.86	
TM265	23	31.9	**26.2**	**37.6**	5.7	7.59		0.86	
					mean ±SD	7.19	0.72	0.86	0.02
Siemens Diag Dimension Vista (LOCI) DUV									
TM261	3	45.3	**37.1**	**53.5**	8.2	3.69		0.75	
TM262	3	28.0	**22.6**	**33.4**	5.4	3.86		0.76	
TM263	3	27.4	**22.0**	**32.8**	5.4	2.70		0.86	
TM264	3	43.9	**36.0**	**51.8**	7.9	3.58		0.76	
TM265	3	29.8	**24.4**	**35.2**	5.4	2.42		0.80	
						3.25	0.64	0.79	0.04
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM261	7	58.1	**47.6**	**68.6**	10.5	2.99		0.96	
TM262	7	35.3	**28.9**	**41.7**	6.4	2.75		0.96	
TM263	7	30.3	**24.8**	**35.8**	5.5	2.94		0.95	
TM264	7	55.0	**45.1**	**64.9**	9.9	2.96		0.96	
TM265	7	35.1	**28.8**	**41.4**	6.3	4.19		0.94	
					mean ±SD	3.17	0.58	0.95	0.01

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Table 1 (cont.): 9-13 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									
TM261	5	78.3	**64.2**	**92.4**	14.1	6.04		1.30	
TM262	5	46.2	**37.9**	**54.5**	8.3	7.27		1.25	
TM263	5	43.3	**35.5**	**51.1**	7.8	7.04		1.35	
TM264	5	76.3	**62.6**	**90.0**	13.7	7.13		1.33	
TM265	5	50.1	**41.1**	**59.1**	9.0	9.62		1.35	
					mean ±SD	7.42	1.32	1.32	0.04

Sample ID	N	All Method Median	Median % CV
TM261	114	**60.5**	**5.50**
TM262	115	**36.9**	**5.83**
TM263	113	**32.0**	**5.74**
TM264	114	**57.4**	**5.90**
TM265	115	**37.2**	**5.14**
		Average	**5.62**
		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

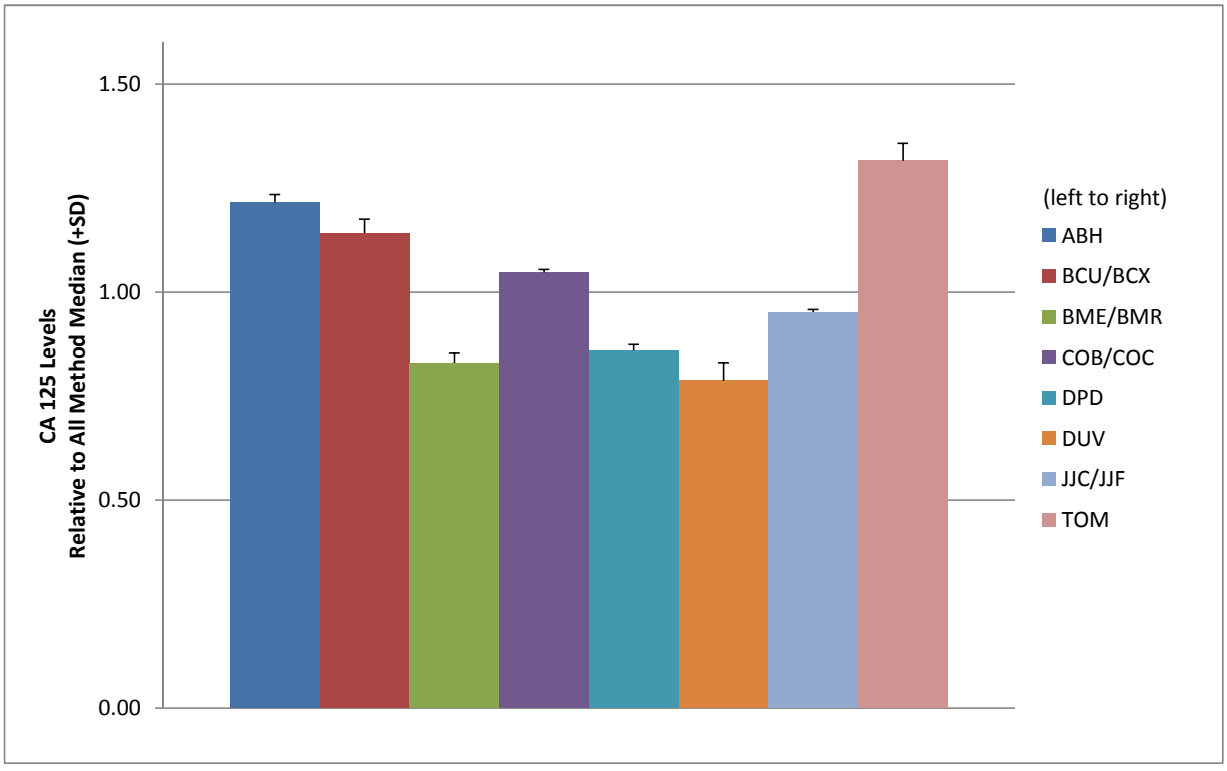

Table 2: 9-13 NYS Tumor Marker PT Summary for CA 19-9

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									
TM261	3	255.7	**209.7**	**301.7**	46.0	10.66		6.81	
TM262	3	227.5	**186.6**	**268.5**	41.0	7.30		6.95	
TM263	3	218.7	**179.3**	**258.1**	39.4	13.12		3.98	
TM264	3	45.1	**37.0**	**53.2**	8.1	14.92		2.52	
TM265	3	104.5	**85.7**	**123.3**	18.8	7.68		2.31	
					mean ±SD*	10.74	3.33	4.51	2.25
Beckman Unicel & Access/2 BCU/BCX									
TM261	15	40.6	**33.3**	**47.9**	7.3	4.38		1.08	
TM262	15	35.3	**28.9**	**41.7**	6.4	4.87		1.08	
TM263	15	57.8	**47.4**	**68.2**	10.4	3.67		1.05	
TM264	15	16.7	**13.1**	**20.3**	3.6	4.85		0.93	
TM265	15	44.8	**36.7**	**52.9**	8.1	5.33		0.99	
					mean ±SD*	4.62	0.63	1.03	0.06
Roche Elecsys & Cobas BME/BMR									
TM261	13	34.5	**28.3**	**40.7**	6.2	3.54		0.92	
TM262	13	30.2	**24.8**	**35.6**	5.4	3.84		0.92	
TM263	13	52.0	**42.6**	**61.4**	9.4	4.46		0.95	
TM264	13	19.1	**15.5**	**22.7**	3.6	6.49		1.07	
TM265	13	45.6	**37.4**	**53.8**	8.2	4.89		1.01	
					mean ±SD*	4.64	1.16	0.97	0.06
Siemens Advia Centaur XP COB									
TM261	24	78.1	**64.0**	**92.2**	14.1	5.21		2.08	
TM262	24	66.4	**54.4**	**78.4**	12.0	5.63		2.03	
TM263	25	94.6	**77.6**	**111.6**	17.0	7.40		1.72	
TM264	24	27.2	**22.3**	**32.1**	4.9	7.72		1.52	
TM265	25	69.2	**56.7**	**81.7**	12.5	7.11		1.53	
					mean ±SD*	6.61	1.12	1.78	0.27
Tosoh AIA TOM									
TM261	5	25.5	**20.9**	**30.1**	4.6	11.49		0.68	
TM262	5	22.3	**18.3**	**26.3**	4.0	7.67		0.68	
TM263	5	32.5	**26.7**	**38.4**	5.9	6.95		0.59	
TM264	5	14.3	**10.7**	**17.9**	3.6	7.90		0.80	
TM265	5	31.4	**25.7**	**37.1**	5.7	5.76		0.69	
					mean ±SD*	7.96	2.14	0.69	0.07

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

Sample ID	N	All Method Median	Median % CV	
TM261	60	37.6	4.80	
TM262	60	32.8	5.25	
TM263	61	54.9	5.71	
TM264	60	17.9	7.11	
TM265	61	45.2	5.55	
		Average*	5.68	*Abbott excluded
		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

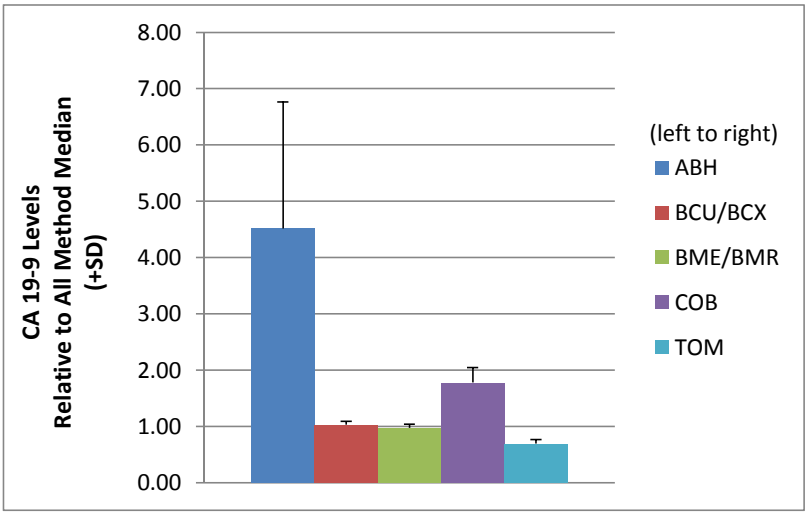

Table 3: 9-13 NYS Tumor Marker PT Summary for CA 15-3

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 Architect ABH									
TM261	6	47.6	**39.0**	**56.2**	8.6	5.95		1.02	
TM262	6	30.4	**24.9**	**35.9**	5.5	5.30		1.02	
TM263	6	79.3	**65.0**	**93.6**	14.3	4.53		1.02	
TM264	6	54.0	**44.3**	**63.7**	9.7	4.85		1.00	
TM265	6	62.5	**51.3**	**73.8**	11.3	3.86		1.01	
					mean ±SD	4.90	0.61	1.01	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM261	7	28.4	**23.3**	**33.5**	5.1	4.68		0.61	
TM262	7	19.1	**15.7**	**22.5**	3.4	3.25		0.64	
TM263	7	48.4	**39.7**	**57.1**	8.7	7.52		0.62	
TM264	7	34.0	**27.9**	**40.1**	6.1	6.00		0.63	
TM265	7	38.3	**31.4**	**45.2**	6.9	3.66		0.62	
					mean ±SD	5.02	1.76	0.62	0.01
Roche Elecsys & Cobas BME/BMR									
TM261	13	42.7	**35.0**	**50.4**	7.7	2.97		0.92	
TM262	14	28.1	**23.0**	**33.2**	5.1	5.05		0.94	
TM263	14	70.3	**57.6**	**83.0**	12.7	4.64		0.90	
TM264	14	48.8	**40.0**	**57.6**	8.8	5.37		0.91	
TM265	14	56.5	**46.3**	**66.7**	10.2	4.48		0.91	
					mean ±SD	4.50	0.92	0.92	0.01
Siemens Advia Centaur XP & CP COB/COC									
TM261	19	47.3	**38.8**	**55.8**	8.5	7.42		1.02	
TM262	19	31.5	**25.8**	**37.2**	5.7	7.65		1.05	
TM263	20	77.2	**63.3**	**91.1**	13.9	8.77		0.99	
TM264	18	55.0	**45.1**	**64.9**	9.9	6.64		1.02	
TM265	20	61.6	**50.5**	**72.7**	11.1	8.49		1.00	
					mean ±SD	7.79	0.86	1.02	0.02
Siemens Immulite DPB/DPD									
TM261	9	50.5	**41.4**	**59.6**	9.1	7.50		1.09	
TM262	9	31.7	**26.0**	**37.4**	5.7	5.93		1.06	
TM263	9	78.8	**64.6**	**93.0**	14.2	13.26		1.01	
TM264	9	56.3	**46.2**	**66.4**	10.1	6.31		1.05	
TM265	9	65.7	**53.9**	**77.5**	11.8	5.57		1.06	
					mean ±SD	7.71	3.18	1.05	0.03

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Table 3 (cont.): 9-13 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median	Median % CV
TM261	54	47.3	5.95
TM262	55	30.4	5.30
TM263	56	77.2	7.52
TM264	54	54.0	6.00
TM265	56	61.6	4.48
		Average	5.85
		Allowable CV %	6.00
		Allowable Error (+/-)%	18.0

Figure 3: CA 15-3 Method Comparison

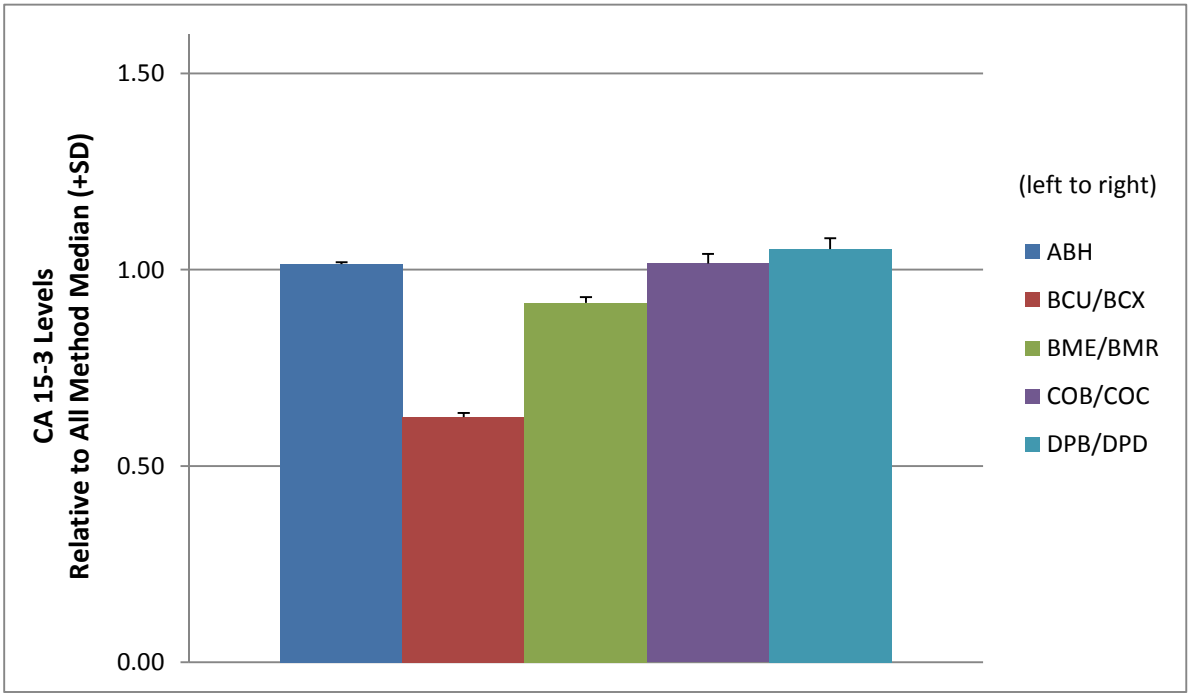

Table 4: 9-13 NYS Tumor Marker PT Summary for CA 27.29

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									
TM261	40	51.5	**40.7**	**62.3**	10.8	7.22		1.08	
TM262	39	30.2	**22.9**	**37.6**	7.4	10.70		1.00	
TM263	39	92.4	**73.0**	**111.8**	19.4	5.53		1.10	
TM264	39	61.0	**48.2**	**73.8**	12.8	6.34		1.08	
TM265	39	71.6	**56.6**	**86.6**	15.0	5.98		1.10	
					mean ±SD	7.15	2.07	1.07	0.04
Tosoh AIA TOM									
TM261	6	43.8	**34.6**	**53.0**	9.2	9.91		0.92	
TM262	6	30.1	**22.8**	**37.5**	7.4	8.44		1.00	
TM263	6	75.1	**59.3**	**90.9**	15.8	9.68		0.90	
TM264	6	51.5	**40.7**	**62.3**	10.8	7.83		0.92	
TM265	6	58.8	**46.5**	**71.1**	12.3	8.35		0.90	
					mean ±SD	8.84	0.91	0.93	0.04

Sample ID	N	All Method Median	Median % CV
TM261	46	**47.7**	**8.57**
TM262	45	**30.2**	**9.57**
TM263	45	**83.8**	**7.61**
TM264	45	**56.3**	**7.08**
TM265	45	**65.2**	**7.16**
		Average	**8.00**
		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

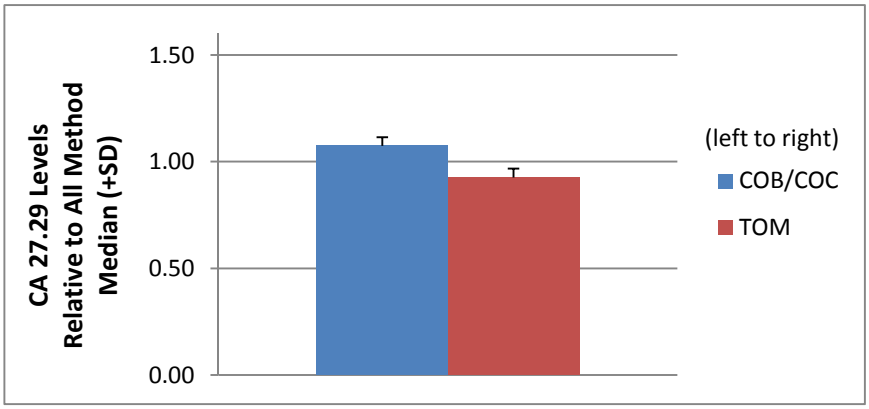

Table 5: 9-13 NYS Tumor Marker PT Summary for CEA

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 Architect ABH									
TM261	15	17.1	**14.0**	**20.2**	3.1	6.90		1.03	
TM262	15	11.2	**9.2**	**13.2**	2.0	5.98		1.04	
TM263	15	39.2	**32.1**	**46.3**	7.1	4.36		1.02	
TM264	15	33.8	**27.7**	**39.9**	6.1	4.79		1.02	
TM265	15	50.9	**41.7**	**60.1**	9.2	3.69		1.04	
						5.15	1.29	1.03	0.01
Beckman Unicel & Access/2 BCU/BCX									
TM261	25	14.4	**11.8**	**17.0**	2.6	4.86		0.87	
TM262	25	9.7	**8.0**	**11.4**	1.7	6.80		0.90	
TM263	24	32.7	**26.8**	**38.6**	5.9	7.19		0.85	
TM264	25	28.0	**23.0**	**33.0**	5.0	6.39		0.84	
TM265	25	40.7	**33.4**	**48.0**	7.3	7.47		0.83	
					mean ±SD	6.54	1.02	0.86	0.03
Roche Elecsys & Cobas BME/BMR									
TM261	22	11.5	**9.4**	**13.6**	2.1	7.30		0.69	
TM262	22	7.8	**6.4**	**9.2**	1.4	5.26		0.73	
TM263	22	25.7	**21.1**	**30.3**	4.6	6.69		0.67	
TM264	22	22.8	**18.7**	**26.9**	4.1	5.18		0.69	
TM265	22	34.1	**28.0**	**40.2**	6.1	5.63		0.70	
					mean ±SD	6.01	0.94	0.69	0.02
Siemens Advia Centaur XP & CP COB/COC									
TM261	47	16.7	**13.7**	**19.7**	3.0	5.09		1.01	
TM262	47	10.9	**8.9**	**12.9**	2.0	5.23		1.01	
TM263	47	39.2	**32.1**	**46.3**	7.1	4.74		1.02	
TM264	47	32.6	**26.7**	**38.5**	5.9	5.06		0.98	
TM265	47	47.3	**38.8**	**55.8**	8.5	4.06		0.96	
					mean ±SD	4.84	0.47	1.00	0.02
Siemens Immulite DPB/DPD									
TM261	14	16.8	**13.8**	**19.8**	3.0	7.02		1.01	
TM262	14	10.6	**8.7**	**12.5**	1.9	5.66		0.99	
TM263	14	40.4	**33.1**	**47.7**	7.3	6.44		1.05	
TM264	14	33.9	**27.8**	**40.0**	6.1	4.84		1.02	
TM265	14	50.8	**41.7**	**59.9**	9.1	6.30		1.04	
					mean ±SD	6.05	0.83	1.02	0.02
Siemens Dimension Vista DUV									
TM261	23	13.4	**11.0**	**15.8**	2.4	4.10		0.81	
TM262	23	8.9	**7.3**	**10.5**	1.6	4.49		0.83	
TM263	23	31.7	**26.0**	**37.4**	5.7	5.02		0.82	
TM264	23	27.0	**22.1**	**31.9**	4.9	4.63		0.81	
TM265	23	40.4	**33.1**	**47.7**	7.3	4.36		0.82	
					mean ±SD	4.52	0.34	0.82	0.01
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF									
TM261	14	16.5	**13.5**	**19.5**	3.0	7.27		0.99#	
TM262	13	10.9	**8.9**	**12.9**	2.0	7.52		1.01	
TM263	14	37.9	**31.1**	**44.7**	6.8	5.04		0.98	
TM264	14	34.2	**28.0**	**40.4**	6.2	5.41		1.03	
TM265	14	51.6	**42.3**	**60.9**	9.3	4.36		1.05	
					mean ±SD	5.92	1.40	1.02	0.03

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Table 5 (cont.): 9-13 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									
TM261	6	25.1	**20.6**	**29.6**	4.5	2.07		1.51	
TM262	6	16.6	**13.6**	**19.6**	3.0	3.19		1.54	
TM263	6	54.6	**44.8**	**64.4**	9.8	3.61		1.42	
TM264	6	48.8	**40.0**	**57.6**	8.8	2.91		1.47	
TM265	6	70.7	**58.0**	**83.4**	12.7	3.15		1.44	
					mean ±SD	2.99	0.57	1.48	0.05

Sample ID	N	All Method Median	Median % CV
TM261	166	**16.6**	**6.00**
TM262	165	**10.8**	**5.46**
TM263	165	**38.6**	**5.03**
TM264	166	**33.2**	**4.95**
TM265	166	**49.1**	**4.36**
		Average	**5.16**
		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

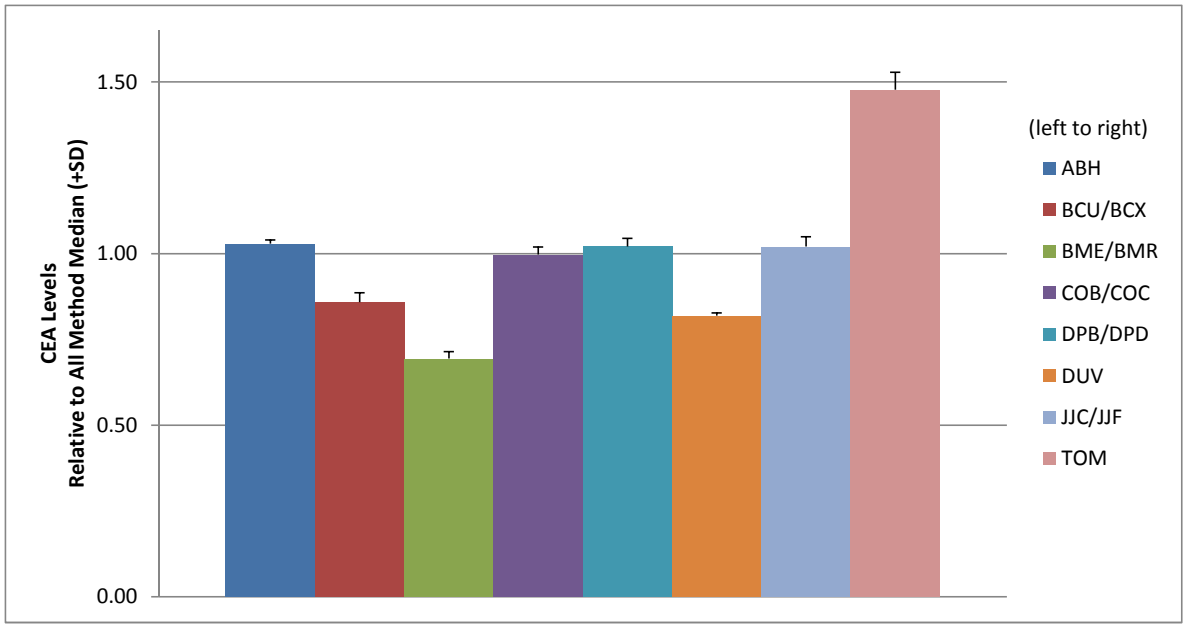

Table 6: 9-13 NYS Tumor Marker PT Summary for AFP

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	
Beckman Unicel & Access/2 BCU/BCX											
TM261	20	13.3	**10.9**	**15.7**	2.4	6.02		0.98		1.14	
TM262	20	6.0	**4.9**	**7.1**	1.1	5.83		0.99		1.26	
TM263	19	21.0	**17.2**	**24.8**	3.8	4.71		0.97		1.08	
TM264	20	32.3	**26.5**	**38.1**	5.8	5.54		1.00		1.09	
TM265	20	11.0	**9.0**	**13.0**	2.0	6.82		1.00		1.20	
					mean ±SD	5.78	0.76	0.99	0.01	1.15	0.08
Roche Elecsys & Cobas BME/BMR											
TM251	18	15.7	**12.9**	**18.5**	2.8	7.32		1.15		1.35	
TM252	18	6.9	**5.7**	**8.1**	1.2	6.67		1.14		1.45	
TM253	18	25.2	**20.7**	**29.7**	4.5	7.06		1.17		1.29	
TM254	18	38.8	**31.8**	**45.8**	7.0	6.37		1.20		1.30	
TM255	18	12.5	**10.3**	**14.8**	2.3	5.68		1.14		1.36	
					mean ±SD	6.62	0.64	1.16	0.02	1.35	0.06
Siemens Advia Centaur XP & CP COB/COC											
TM261	27	14.0	**11.5**	**16.5**	2.5	5.14		1.03		1.21	
TM262	27	6.6	**5.4**	**7.8**	1.2	9.55		1.09		1.38	
TM263	28	22.3	**18.3**	**26.3**	4.0	4.66		1.03		1.14	
TM264	27	32.2	**26.4**	**38.0**	5.8	4.97		0.99		1.08	
TM265	27	11.0	**9.0**	**13.0**	2.0	8.00		1.00		1.20	
					mean ±SD	6.46	2.18	1.03	0.04	1.20	0.11
Siemens Immulite 1000 & 2000 DPB/DPD											
TM261	18	13.3	**10.9**	**15.7**	2.4	7.97		0.98		1.14	
TM262	18	5.7	**4.7**	**6.7**	1.0	10.18		0.94		1.19	
TM263	18	21.2	**17.4**	**25.0**	3.8	10.28		0.98		1.09	
TM264	18	32.6	**26.7**	**38.5**	5.9	10.43		1.00		1.10	
TM265	18	10.4	**8.5**	**12.3**	1.9	7.02		0.95		1.13	
					mean ±SD	9.18	1.57	0.97	0.03	1.13	0.04
Siemens Dimension Vista DUV											
TM261	6	12.4	**10.2**	**14.6**	2.2	3.15		0.91		1.07	
TM262	6	5.5	**4.5**	**6.5**	1.0	4.00		0.91		1.15	
TM263	6	19.6	**16.1**	**23.1**	3.5	2.60		0.91		1.01	
TM264	6	30.2	**24.8**	**35.6**	5.4	2.42		0.93		1.02	
TM265	6	9.8	**8.0**	**11.6**	1.8	2.45		0.89		1.07	
					mean ±SD	2.92	0.67	0.91	0.01	1.06	0.06
Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF											
TM261	6	10.8	**8.9**	**12.7**	1.9	3.61		0.79		0.93	
TM262	6	5.0	**4.1**	**5.9**	0.9	3.80		0.83		1.05	
TM263	6	17.4	**14.3**	**20.5**	3.1	2.36		0.81		0.89	
TM264	6	25.9	**21.2**	**30.6**	4.7	2.93		0.80		0.87	
TM265	6	8.5	**7.0**	**10.0**	1.5	3.76		0.77		0.93	
					mean ±SD	3.29	0.63	0.80	0.02	0.93	0.07
Tosoh AIA TOM											
TM261	3	13.9	**11.4**	**16.4**	2.5	3.17		1.02		1.20	
TM262	3	6.3	**5.2**	**7.4**	1.1	2.38		1.04		1.32	
TM263	3	22.1	**18.1**	**26.1**	4.0	1.99		1.03		1.13	
TM264	3	32.9	**27.0**	**38.8**	5.9	2.28		1.01		1.11	
TM265	3	11.4	**9.3**	**13.5**	2.1	1.32		1.04		1.24	
					mean ±SD	2.23	0.67	1.03	0.01	1.20	0.09

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Table 6 (cont.): 9-13 NYS Tumor Marker PT Summary for AFP

Sample ID	N	All Method Median	IS based Target	SD	Median % CV	All Method Median/ IS Target
TM261	100	13.3	11.6	0.48	5.14	1.17
TM262	100	6.0	4.8	0.35	5.83	1.27
TM263	100	21.2	19.5	0.92	4.66	1.11
TM264	100	32.3	29.7	1.18	4.97	1.09
TM265	100	11.0	9.2	0.52	5.68	1.20
				Average	5.26	mean ±SD 1.17 0.07
				Allowable CV %	6.0	
				Allowable Error (+/-)%	18.0	

Figure 6: AFP Method Comparison

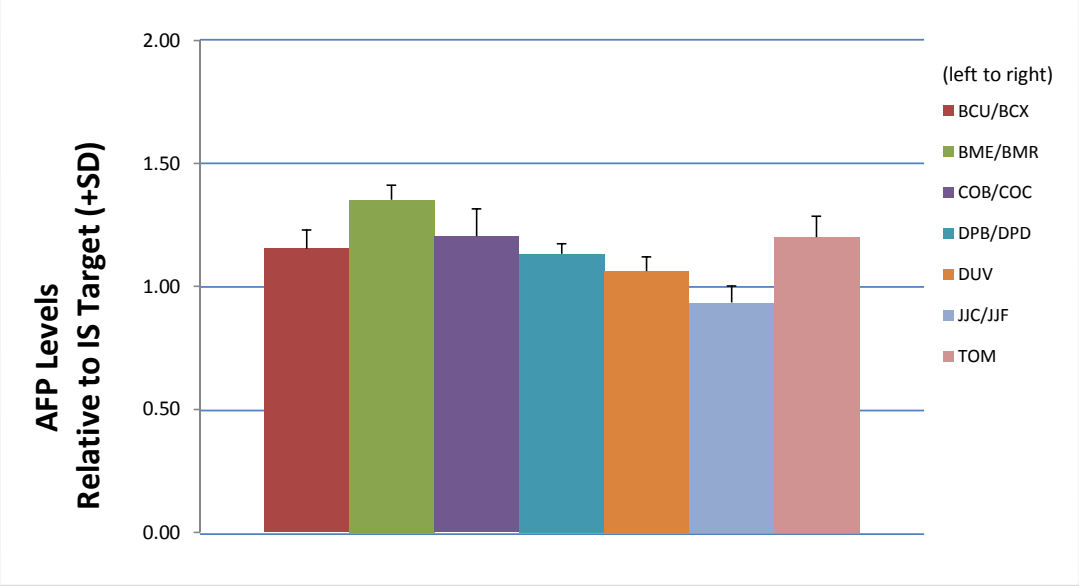

Table 7: 9-13 NYS Tumor Marker PT Summary for PSA

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											
TM261	18	3.3	**2.7**	**3.9**	0.6	4.24		1.03		1.18	
TM262	18	2.5	**2.1**	**3.0**	0.5	4.40		1.00		1.14	
TM263	14	0.8	**0.7**	**0.9**	0.1	0.00		1.00		1.00	
TM264	18	11.2	**9.2**	**13.2**	2.0	4.29		1.06		1.22	
TM265	18	6.8	**5.6**	**8.0**	1.2	2.35		1.05		1.21	
					mean ±SD	3.06	1.91	1.03	0.03	1.15	0.09
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM261	48	3.5	**2.9**	**4.1**	0.6	5.14		1.09		1.25	
TM262	48	2.7	**2.2**	**3.2**	0.5	5.56		1.08		1.23	
TM263	48	0.9	**0.7**	**1.1**	0.2	5.56		1.13		1.13	
TM264	48	12.0	**9.8**	**14.2**	2.2	4.42		1.13		1.30	
TM265	48	7.3	**6.0**	**8.6**	1.3	5.07		1.12		1.30	
					mean ±SD	5.15	0.47	1.11	0.02	1.24	0.07
Beckman Unicel & Access/2 (WHO Calibration) BCU/BCX (WHO)											
TM261	4	3.1	**2.5**	**3.7**	0.6	8.06		0.97		1.11	
TM262	4	2.3	**1.9**	**2.7**	0.4	6.52		0.92		1.05	
TM263	4	0.8	**0.7**	**0.9**	0.1	0.00		1.00		1.00	
TM264	4	10.4	**8.5**	**12.3**	1.9	6.92		0.98		1.13	
TM265	4	6.4	**5.2**	**7.6**	1.2	5.47		0.98		1.14	
					mean ±SD	5.40	3.16	0.97	0.03	1.09	0.06
Roche Elecsys & Cobas BME/BMR											
TM261	40	3.2	**2.6**	**3.8**	0.6	4.69		1.00		1.14	
TM262	40	2.5	**2.1**	**3.0**	0.5	4.00		1.00		1.14	
TM263	40	0.8	**0.7**	**0.9**	0.1	6.25		1.00		1.00	
TM264	40	10.6	**8.7**	**12.5**	1.9	3.30		1.00		1.15	
TM265	40	6.5	**5.3**	**7.7**	1.2	4.00		1.00		1.16	
					mean ±SD	4.45	1.12	1.00	0.00	1.12	0.07
Siemens Advia Centaur XP & CP COB/COC											
TM261	60	3.2	**2.6**	**3.8**	0.6	5.31		1.00		1.14	
TM262	60	2.5	**2.1**	**3.0**	0.5	5.20		1.00		1.14	
TM263	60	0.9	**0.7**	**1.1**	0.2	5.56		1.13		1.13	
TM264	60	10.6	**8.7**	**12.5**	1.9	6.04		1.00		1.15	
TM265	60	6.6	**5.4**	**7.8**	1.2	5.15		1.02		1.18	
					mean ±SD	5.45	0.36	1.03	0.05	1.15	0.02
Siemens Immulite 1000 &2000 - Original Pack DPB/DPD (DP5)											
TM261	17	3.0	**2.5**	**3.5**	0.5	9.00		0.94		1.07	
TM262	18	2.2	**1.8**	**2.6**	0.4	9.09		0.88		1.00	
TM263	13	0.7	**0.6**	**0.8**	0.1	0.00		0.88		0.88	
TM264	17	9.6	**7.9**	**11.3**	1.7	5.52		0.91		1.04	
TM265	17	6.0	**4.9**	**7.1**	1.1	6.50		0.92		1.07	
					mean ±SD	6.02	3.71	0.90	0.03	1.01	0.08
Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX											
TM261	13	3.6	**3.0**	**4.2**	0.6	5.83		1.13		1.29	
TM262	13	2.8	**2.3**	**3.3**	0.5	5.71		1.12		1.27	
TM263	13	0.9	**0.7**	**1.1**	0.2	10.00		1.13		1.13	
TM264	13	12.4	**10.2**	**14.6**	2.2	4.76		1.17		1.35	
TM265	13	7.5	**6.2**	**8.9**	1.4	5.60		1.15		1.34	
					mean±SD	6.38	2.07	1.14	0.02	1.27	0.09
Siemens Dimension Vista DUV											
TM261	19	3.2	**2.6**	**3.8**	0.6	3.75		1.00		1.14	
TM262	19	2.5	**2.1**	**3.0**	0.5	4.80		1.00		1.14	
TM263	15	0.8	**0.7**	**0.9**	0.1	0.00		1.00		1.00	
TM264	19	11.0	**9.0**	**13.0**	2.0	4.09		1.04		1.20	
TM265	19	6.6	**5.4**	**7.8**	1.2	3.48		1.02		1.18	
					mean ±SD	3.23	1.87	1.01	0.02	1.13	0.08

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Table 7 (cont.): 9-13 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											
TM261	23	2.6	**2.1**	**3.1**	0.5	3.85		0.81		0.93	
TM262	23	2.0	**1.6**	**2.4**	0.4	5.00		0.80		0.91	
TM263	19	0.7	**0.6**	**0.8**	0.1	0.00		0.88		0.88	
TM264	23	7.9	**6.5**	**9.3**	1.4	3.92		0.75		0.86	
TM265	22	4.9	**4.0**	**5.8**	0.9	3.67		0.75		0.88	
					mean ±SD	3.29	1.91	0.80	0.05	0.89	0.03
Tosoh AIA TOM											
TM261	7	3.1	**2.5**	**3.7**	0.6	4.19		0.97		1.11	
TM262	7	2.4	**2.0**	**2.8**	0.4	4.58		0.96		1.09	
TM263	6	0.8	**0.7**	**0.9**	0.1	0.00		1.00		1.00	
TM264	7	10.2	**8.4**	**12.0**	1.8	3.92		0.96		1.11	
TM265	7	6.2	**5.1**	**7.3**	1.1	2.90		0.95		1.11	
					mean ±SD	3.12	1.85	0.97	0.02	1.08	0.05

Sample ID	N	All Method Median	IS based Target	SD	Median % CV
TM261	251	**3.2**	**2.8**	**0.16**	**4.69**
TM262	252	**2.5**	**2.2**	**0.10**	**5.00**
TM263	234	**0.8**	**0.8**	**0.05**	**0.00**
TM264	251	**10.6**	**9.2**	**0.54**	**4.29**
TM265	250	**6.6**	**5.6**	**0.41**	**4.00**
				Average*	**4.49**
				Allowable CV %	**6.00**
				Allowable Error (+/-)%	**18.0**

* Excludes TM263 from average

Figure 7: PSA Method Comparison

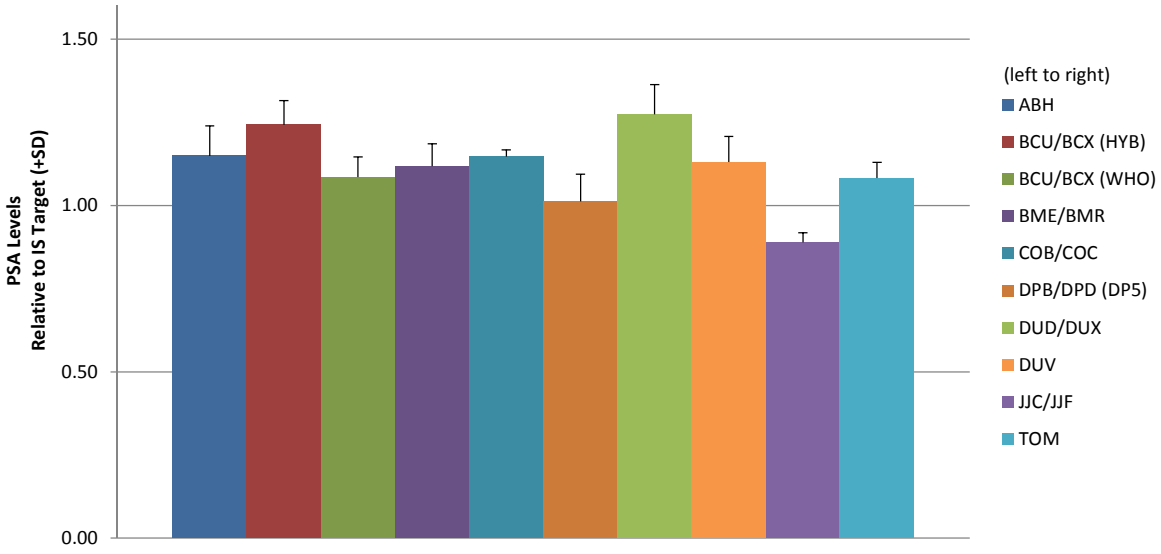

Table 8: 9-13 NYS Tumor Marker PT Summary for Free PSA

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											
TM261	5	0.64	**0.54**	**0.74**	0.10	4.69		1.10		1.00	
TM262	5	0.39	**0.32**	**0.47**	0.08	5.13		1.05		0.98	
TM263	5	0.16	**0.09**	**0.24**	0.08	6.25		1.00		1.03	
TM264	5	1.03	**0.88**	**1.18**	0.15	4.85		1.08		0.95	
TM265	5	1.26	**1.07**	**1.45**	0.19	4.76		1.09		0.96	
						5.14	0.64	1.07	0.04	0.98	0.03
Beckman Unicel & Access/2 (Hybritech Calibration) BCU/BCX (HYB)											
TM261	26	0.78	**0.66**	**0.90**	0.12	5.13		1.34		1.22	
TM262	21	0.50	**0.43**	**0.58**	0.08	2.00		1.35		1.25	
TM263	26	0.20	**0.13**	**0.28**	0.08	5.00		1.25		1.29	
TM264	26	1.24	**1.05**	**1.43**	0.19	4.84		1.31		1.15	
TM265	26	1.54	**1.31**	**1.77**	0.23	4.55		1.33		1.17	
					mean ±SD	4.30	1.31	1.32	0.04	1.22	0.06
Roche Elecsys & Cobas BME/BMR											
TM261	26	0.58	**0.49**	**0.67**	0.09	3.45		1.00		0.91	
TM262	22	0.37	**0.30**	**0.45**	0.08	2.70		1.00		0.93	
TM263	23	0.16	**0.09**	**0.24**	0.08	6.25		1.00		1.03	
TM264	26	0.95	**0.81**	**1.09**	0.14	4.21		1.00		0.88	
TM265	26	1.16	**0.99**	**1.33**	0.17	3.45		1.00		0.88	
					mean ±SD	4.01	1.36	1.00	0.00	0.93	0.06
Siemens Immulite 1000 & 2000 DPB/DPD											
TM261	14	0.55	**0.47**	**0.63**	0.08	5.45		0.95		0.86	
TM262	15	0.34	**0.27**	**0.42**	0.08	5.88		0.92		0.85	
TM263	14	0.14	**0.07**	**0.22**	0.08	7.14		0.88		0.90	
TM264	14	0.90	**0.77**	**1.04**	0.14	4.44		0.95		0.83	
TM265	14	1.12	**0.95**	**1.29**	0.17	5.36		0.97		0.85	
					mean ±SD	5.66	0.98	0.93	0.04	0.86	0.03
Siemens Dimension Vista DUV											
TM261	8	0.52	**0.44**	**0.60**	0.08	3.85		0.90		0.82	
TM262	8	0.33	**0.26**	**0.41**	0.08	6.06		0.89		0.83	
TM263	8	0.13	**0.06**	**0.21**	0.08	7.69		0.81		0.84	
TM264	8	0.87	**0.74**	**1.00**	0.13	3.45		0.92		0.81	
TM265	8	1.07	**0.91**	**1.23**	0.16	2.80		0.92		0.81	
					mean ±SD	4.77	2.04	0.89	0.04	0.82	0.01

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Table 8 (cont.): 9-13 NYS Tumor Marker PT Summary for Free PSA

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV
TM261	72	0.58	0.64	0.03	4.69
TM262	64	0.37	0.40	0.02	5.13
TM263	69	0.16	0.16	0.01	6.25
TM264	72	0.95	1.08	0.03	4.44
TM265	72	1.16	1.32	0.03	4.55
				Average	5.01
				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

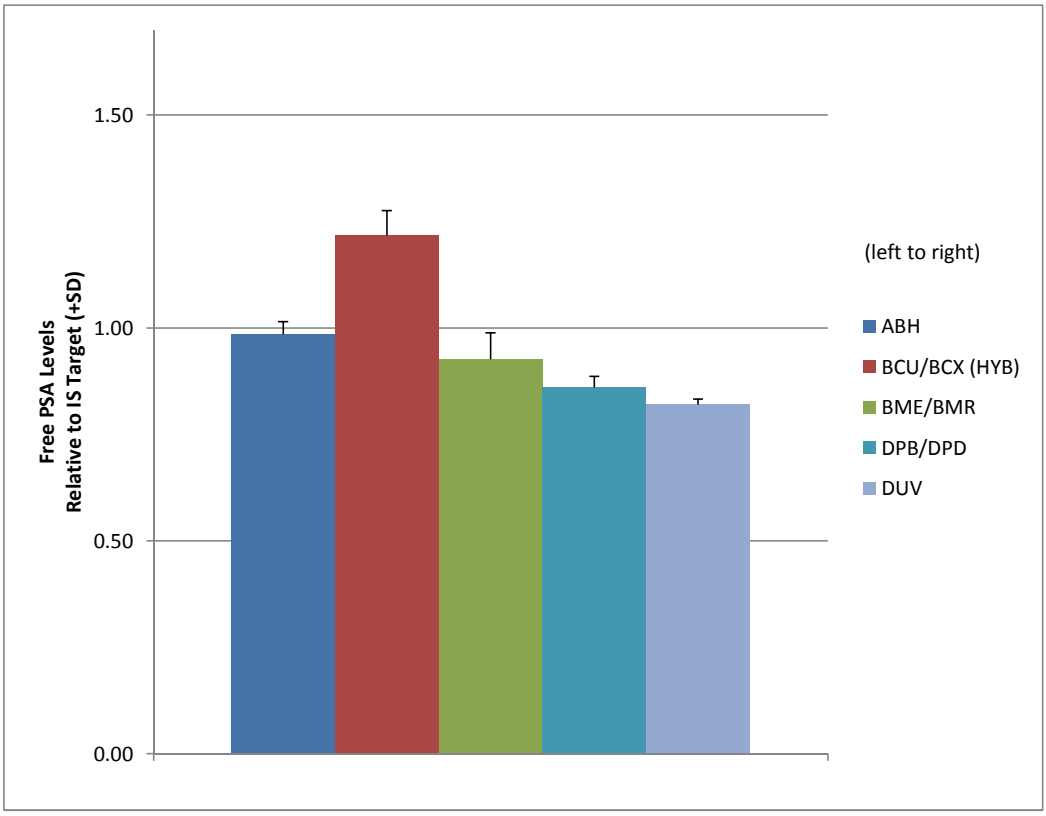

Table 9: 9-13 NYS Tumor Marker PT Summary for Complexed PSA

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									
TM261	12	2.5	**2.1**	**3.0**	0.5	4.35		1.00	
TM262	12	2.0	**1.6**	**2.3**	0.4	4.02		1.00	
TM263	12	0.7	**0.5**	**0.8**	0.2	7.69		1.00	
TM264	12	9.4	**7.7**	**11.0**	1.7	3.10		1.00	
TM265	12	5.0	**4.1**	**5.9**	0.9	3.18		1.00	
					mean ±SD	4.47	1.88	1.00	0.00

Sample ID	N	All Method Median		Median % CV
TM261	12	**2.5**		**4.35**
TM262	12	**2.0**		**4.02**
TM263	12	**0.7**		**7.69**
TM264	12	**9.4**		**3.10**
TM265	12	**5.0**		**3.18**
			Average	**4.47**
			Allowable CV %	**6.0**
			Allowable Error (+/-)%	**18.0**