STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

**********PLEASE NOTE**********

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

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

TO: Laboratory Director

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

DATE: **January 25, 2011**

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

DUE DATE: February 9, 2011

PLEASE READ-INFORMATION IS IMPORTANT

Samples:
There are five sealed (5) vials labeled **TM221 to TM225**, each containing diagnostic specimens for proficiency testing. 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 pancreatic 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 analyze for all of those markers tested in your laboratory the same way as you would with a patient sample. If your lab is also measuring free and/or complexed PSA in addition to total PSA, you are also required to measure those forms of PSA in **ALL** of the samples provided. All materials used to prepare the enclosed samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, it is recommended that universal precautions be used for handling samples. Samples are in a human-derived serum base, sterile filtered and dispensed. Please keep **refrigerated** until use, but **do not freeze**. Before analyzing make sure samples are completely mixed.

Reporting of results: Results must be submitted electronically before 11:59 PM of February 9, 2011.
Please submit a little earlier if possible to allow time to resolve any problem you might have with result submission. Please also read the enclosed bulletin with important updates regarding the electronic proficiency testing reporting system.

All laboratories must submit their proficiency testing results over the internet through the 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 directed to clepeptrs@health.state.ny.us.

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

Please turn over

Results must be reported for all five samples for all analytes you routinely measure, otherwise a zero grade will be given to the missing data. Please enter your results in the spaces provided on the electronic PT form. If a result exceeds your analytical range, indicate this with a "less than (<)" or "greater than (>)" sign if similar results from patient samples are reported in the same manner. If such samples are routinely retested after dilution, you may do so provided that the result is identified accordingly. Select the instrument and reagent/kit used for each analyte using the drop-down menus provided. **Please check that the information is current**, since the EPTRS form is pre-populated from previous entries. It is very important to correctly complete all applicable fields as **missing or incorrect entries may result in an inability to move to the next screen, or possibly in test failure. If your lab has temporarily or permanently stopped testing for an analyte** 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 listed on the report form. When a test is deleted, you should select 'test deleted' and also submit a 'delete analyte' form as required by the CLEP office (http://www.wadsworth.org/labcert/clep/Administrative/chngaddanalyte.pdf). **Absence of results for any analyte without appropriate notification will result in a failing grade for the missing results.**

Note: The event menu page includes a space to enter your lab's upper limit of normal reference range, i.e. cut-off value, for the individual analytes measured. There is also a space to interpret whether an individual sample result is abnormal or normal with respect to this cut-off. If you use tables, such as age-specific reference ranges or risk probabilities, to evaluate whether a sample is normal, please indicate this in the comment section and include additional specific information if possible.

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker.

PSA

IMPORTANT NOTE: Labs are **no longer required to calculate % free PSA**. However, labs **are required to measure and report results for free PSA for all samples** if they measure this analyte as part of their regular test menu. There is also a question at the bottom of the free PSA requesting additional information regarding when you would normally calculate % free PSA. Please choose the appropriate drop-down menu selection according to your laboratory's policy. We are no longer asking for the specific PSA range used to determine measuring free PSA or calculating the % free PSA at this time.

Note: For those cases where a lab measures total PSA by a second method in order to use these PSA results in conjunction with free PSA results, there is a place on the form to enter the data from these secondary measurements of PSA.

The laboratory director or the assistant director who must hold a CQ in Oncology-Sera and Soluble Tumor Markers and all laboratory personnel analyzing these specimens **must sign the printed electronic summary** page in the space for attestations. These signatures attest that the proficiency testing samples were analyzed in the same manner as patient samples, and **this signed summary page should be kept on file** for review by surveyors.

Please check your electronic report carefully since missing or incorrect information, especially for instrument and reagent codes, can result in a PT failure. For any correspondence regarding the PT, please address mail to:

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

If you do not receive the samples in satisfactory condition call Ms. McHale at 486-5775 or Ms. Ling at 474-0036. The next two Oncology Tumor Marker Proficiency Test mail-outs for **2011** are scheduled as follows:

Mail-out date:	Due date:
May 10, 2011	**May 25, 2011**
September 13, 2011	**September 27, 2011**

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509
www.health.ny.gov

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

Sue Kelly
Executive Deputy Commissioner

March 1, 2011

New York State Tumor Marker Proficiency Test 1/2011 Evaluation [1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from January 25, 2011 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 in various amounts to a protein-based matrix, sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. Analyte levels were pre-assayed and stability tested in our laboratory. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

Result evaluation:

Your laboratory's results, scores and grades are printed on a separate page, together with the grades from the previous two PT events and your performance status. As with previous evaluations, only the laboratory's individual result and score report was mailed, whereas the overall evaluation with the summary tables and graphs is sent electronically and will also be posted on our website at:

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

Please **review 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. Please note that we combined results from different instruments made by the same manufacturer or brand that use the same reagent kits into peer groups, unless a t-test showed a significant difference between them ($p<0.05$ for at least three of the five samples). In order for you to more easily compare your results to those of your peer group, we have calculated a D/Dmax value and displayed it directly under your individual results. D/Dmax is a measure of how much your result (x) deviates from your peer group mean, D/Dmax=(x-mean)/3SD, with D being the difference of your result from the mean, and Dmax being the maximal allowable deviation, i.e., three standard deviations. Thus, D/Dmax needs to be between –1 and +1 for a result to be considered correct. **Note: If your D/Dmax is not within +/- 0.66 (equivalent to 2SD), especially for more than one or two samples, you should carefully check your result(s) since this indicates that they are significantly different from the mean(s) of your peer group.** While this could be an isolated incident, it could also potentially indicate that your assay may not be performing as well as it should. Furthermore, if the **average D/Dmax is greater than +/- 0.5,** then your results

[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.

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

For your information, summary tables are included for each peer group showing the means and high/low cut-off values (mean +/-3SD) for each analyte. We also present graphical comparisons of the results among the different peer groups. In order to compare results between different peer groups more easily across all five samples, graphs for CA125, CA15-3, CA19-9, CA27.29 and CEA were prepared from normalized values that were calculated by dividing the mean values for each peer group by the median of the means for all peer groups (all kit median) for each sample. The all kit median is used instead of the all lab mean to reduce the bias towards methods that are used by a greater proportion of labs. For AFP, PSA and free PSA, the graphs show the ratio of the peer group means to the assigned target values (see below), instead of the all kit median. When comparing the results, please keep in mind that for some peer groups the number of results (i.e., N as the number of labs measuring a particular analyte with a specific method) 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. Note that all means were calculated from results that fell within +/- 3SD of the corresponding mean after exclusion of outliers. The tabular summary and the graphs include the results from peer groups consisting of at least two labs. The bars represent the "average bias" across all five samples. The error bars represent the standard deviation. In the legend, the numbers in parentheses after each label represent the number of labs that used that particular method.

Discussion:

CA125 (Figure 1) Results were reported by 113 labs using 13 methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in eight peer groups. A t-test also showed a significant difference between the results of the Abbott AxSYM and Architect so they were not grouped together this time although they have been previously. Of the eight peer groups, four included ten or more labs each. Fifty percent of the labs are in one of four groups that gave results within +/- 10% of the medians. Two of the other four groups reported somewhat lower results, but were within 20% of the median (Roche Elecsys/Cobas /E170 and Siemens Immulite 1000/2000/2500 groups were both -16%). Thus, results from 96% of the total labs agreed reasonably well on how CA125 was measured in these samples with less than +/-20% deviation from the medians. In contrast, TOSOH ST-AIA (used by six labs representing 5% of the participants) gave results that were on average 27% higher than the medians and the Abbott Architect (used by 6% of the labs) gave results 22% higher.

CA19-9 (Figure 2) Results were reported by 62 labs using eight methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in five peer groups, one of which comprised only one lab. Over half of the labs (52%) used Siemens ADVIA-Centaur, 21% used Beckman Unicel or Access/2, 13% used Roche Elecsys/Cobas e411 or E170/Cobas e601, and 11% used the Tosoh ST-AIA method. Only two of the methods, Beckman and Roche, gave CA19-9 results that were close to each other and represent the medians. In contrast, measurements of CA19-9 by Tosoh ST-AIA were lower than the medians by 35%, and, on the opposite side, those by Siemens ADVIA-Centaur were on average 230% higher than those from four of the other five methods. As a consequence, the all lab means (calculations exclude Abbott Architect) are substantially higher than the medians, reflecting the higher measurements from the comparatively large ADVIA Centaur group. In addition, the Abbott Architect method (used by only 1 lab) gave measurements for CA19-9 that were at least six times higher than the all kit medians, and about nine times higher than the results obtained with the Tosoh ST-AIA. These high measurements by the Abbott Architect are consistent with previous CA19-9 NYS PT results by this method, as well as those obtained in previous corresponding CAP surveys, showing it to be at least four-fold higher than the all kit medians. Thus, as Figure 2 shows, there seems to be little agreement between the various methods used to measure CA19-9.

The MUC1 breast cancer antigen was measured by 103 labs, with slightly more than half (55%) using one of ten **CA15-3** methods (Figure 3) and the remainder using one of two different methods for the **CA27.29** assay (Figure 4). For CA15-3, combining results from different instruments made by the same manufacturer and/or brand resulted in six CA15-3 peer groups, three of which comprised less than 10 labs each. The Siemens ADVIA-Centaur method (used by 36% of the labs) did not have as marked a positive bias as in previous PT events, but still gave results 16% higher than the medians, which was the same bias shown by the Abbott methods, but slightly less than shown by the Immulite 2000/2500 instruments (+22%). In contrast, the Beckman Access and Unicel results were 33% lower, the Vitros ECi/ECiQ results were 15% lower and the Roche Elecsys/Cobas/E170 results were 8% lower than the medians. Consequently, as Figure 3 shows, the results from the different methods used to measure CA15-3 spanned a rather wide range. The two methods used for measuring CA27.29 showed a 6% difference between them; and the median values from the CA27.29 results were on average 13% lower than those from the CA15-3 assays.

CEA (Figure 5) Results were reported by 168 labs using 14 different methods. After combining results from different instruments made by the same manufacturer and/or brand (provided a t-test indicated no significant differences between them) there remained eleven peer groups. Seven of the groups contained the majority (73%) of labs and the results among these groups were fairly consistent, being on average within +/-7% of the medians. In contrast, the Ortho Clinical Diagnostics Vitros ECi/Q & 5600 and the TOSOH ST-AIA methods gave results that averaged 25% and 44% higher, respectively. The results from the Roche E170/Cobas e601 and Roche Elecsys/Cobas e411 groups were separated this time due to significant differences between the two method results, and they ran 20% and 17% lower than the medians, respectively.

For **AFP, free PSA and PSA,** target values were assigned using traceable International Standards. Although for grading purposes results for AFP, PSA and free PSA are evaluated based on their respective peer group means, the performance of the methods are compared relative to the target values graphically.

AFP (Figure 6) Results were reported by 100 labs using twelve different methods, three of which were used by less than 10 labs each, and together accounted for 10% of the total number of labs. After combining results from different instruments made by the same manufacturer and/or brand there were eight peer groups. Results were evaluated according to traditional peer group statistics and received a passing score if they fell within the mean +/-3SD. In addition to the peer group statistics, the average ratio of the group mean/target value is given for each sample to compare measurement and/or calibration biases between the different methods. Two methods (Immulite and Vitros ECi/ECiQ) gave results that were noticeably lower than the rest (see figure 6), with the Vitros method averaging 16% lower than the target across the five samples and the Immulite method averaging 8% lower. The remaining groups (with the exception of Tosoh ST-AIA) were on average 8% higher than the target as a group, but did not differ greatly among each other. As seen in previous NYS PT events, the Tosoh ST-AIA is essentially right at the target. Although the differences are not huge, they are consistent across samples and are statistically significant.

PSA (Figure 7) Results were reported by 258 labs using 21 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were 12 peer groups, four of which comprised less than 10 labs each. The five samples were all prepared with the same ratio of free to ACT-complexed PSA, but different concentrations of total PSA. Results were evaluated according to traditional peer group statistics and received a passing score if they fell within the mean +/-3SD. In addition to the peer group statistics, the average ratio of the group mean/target value is given for each sample to compare measurement and/or calibration biases between the different methods. For all methods across all five samples there was an average bias of 19% compared to the target values. In contrast to observations on previous proficiency tests, however, there was no clear separation of methods into distinct high and low groups. The highest method (Siemens Immulite 1000/2000/2500 -- original PSA pack) was at +41% above the target, while the two lowest methods (Beckman Unicel/Access with WHO calibration and Tosoh ST-AIA) were on average just 3% above the target value. The Siemens Dimension EXL and RxL Max/Xpand Plus groups, although distinct and separate

methods, both ran on average 34% higher than the target, whereas the Immulite 1000/2000 /2500 3rd generation PSA methods, as well as the Beckman instruments (Unicel and Access with Hybritech standard calibration) were all 24% higher than the target. The rest of the groups measured somewhere in between 7-18% above the target values. As seen previously for the Beckman Unicel or Access/2 assays, which are available with either the original Hybritech calibration or the new WHO calibration, the difference between the results based on the two calibration standards was 22%, in agreement with the information Beckman has supplied indicating a 22% difference between them (Access Hybritech PSA Hybritech and WHO Calibration Information #A59476A, 2008).

Free PSA (Figure 8) Results were reported by 85 labs using 11 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were six peer groups, three of which comprised less than 10 labs each. Most results (39%) were reported with the Beckman Access/2 or Unicel methods (two labs used the WHO standard calibration and the rest used the Hybritech calibration). Results were evaluated according to traditional peer group statistics and received a passing score if they fell within the mean +/-3SD. In addition to the peer group statistics, the average ratio of the group mean/target value is given to compare measurement and/or calibration biases between the different groups. As seen in the previous PT, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained with the rest of the methods (+64%), while the Dimension did not run as high as last time but was still 35% above the target. The results from Beckman Access and Unicel calibrated with the WHO standards were 28% above the target, which was 37% lower than those from the original Hybritech-calibrated Beckman methods and more comparable to the results of other methods. The Roche instruments and the Abbott instruments all ran about 17% above target. The lowest running method was Siemens Immulite 1000/2000, whose results were only 2% above the target.

Labs are now required to measure and report free PSA for **all proficiency test samples** if they test for free PSA, but we are no longer requesting the percent free PSA be reported since the intention of the proficiency test is to evaluate differences in the actual measurements from labs and instrument peer groups more so than mathematical calculations. We understand that this may in some cases be a deviation from a lab's policy in dealing with free PSA and could mean that PT samples are not treated exactly like patient samples. However, the ability to accurately measure free PSA is an essential process for a testing laboratory, while calculating % free PSA is a secondary operation usually done by a computer. In addition, some labs do not normally calculate % free PSA at all, but only report free and total PSA values, leaving the calculation of % free PSA to the physician. The question under free PSA regarding lab policy on calculation of % free PSA was included for informational purposes only with the answers shown below.

Does your lab calculate % Free PSA?

Answer	**N**	**% of labs**
Yes, always	26	31%
Yes, but only within a specific PSA range	26	31%
No	15	18%
Yes, but only when requested	5	6%
Yes, but only when requested and only within a specific PSA range	8	10%
Other	3	4%
Total	83	100%

Finally, only 8 labs measured **complexed PSA**, and all of these used the Siemens ADVIA-Centaur method, with good agreement between the labs as indicated by an average %CV of 4.5%.

In conclusion, the observation has again been made that there are significant differences between the results obtained with various methods or instruments, especially for CA125, CA15-3, CA19-9 and CEA. While some of these differences could be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We continue to try to minimize the differences that can be attributed to the sample composition. Nevertheless, despite the somewhat artificial nature of the PT samples, we suggest that differences between the results obtained by various methods might also be reflected in patient serum samples. Therefore, we encourage labs and physicians to use caution when comparing the results from the same patient measured with different methods on different instruments, since clearly not all methods are equal. For this reason, we require that the method used must be clearly indicated on the patient report (Oncology Standard OC 1b). We also encourage you to educate your physician clients about this potential problem. Furthermore, the comparison of method means to target values set by traceable International Standards for PSA and free PSA clearly shows that not all methods are calibrated equally, as discussed in the respective analyte discussions above.

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

Important Reminder regarding the data submission process: Be sure your results are **submitted**. If results are saved but **not submitted**, they will be graded as an administrative **fail**.

Note: Please be aware that in each subsequent event, fields will be pre-populated based on what you entered this time or a previous time. **Therefore, make sure that the selected instruments and reagents are correct, whether this is pre-populated from the last event or newly entered information.** This is in your interest since that information must be accurate to properly evaluate your results and compare them to those of your peer group. There are still instances where individual labs have either **inadvertently selected a qualifier (< or >) or an incorrect instrument or reagent** when scrolling through the electronic reporting page lists and it has resulted in a failing grade. **You are at risk** of receiving a technical failure for results evaluated outside of the correct peer group or an administrative failure for incorrect methodology. **No changes can be made for incorrect or missing information once the submission deadline has passed**.

Additionally, the information regarding the PSA2 line in the event menu still applies. The PSA2 option was added to allow entry of results from a second PSA assay only for those labs that use a different or additional method for total PSA in conjunction with their free PSA measurements. If only one PSA test was done, then those results should be entered in the first PSA line. Most labs should have selected "test not offered" for PSA2 since only a few actually do perform a second assay. For labs that entered two PSA tests, the primary PSA test should have been entered on the first PSA line and the secondary assay for use in conjunction with their free PSA results on the PSA2 line.

Finally, on both the event menu and the results page, the absence of data in the required fields for **upper limit of normal reference range** (which is the cut-off level below which a patient result is normal) as well as **sample interpretation** (which should be based on the reference range) has continued to cause problems and should be looked at during the subsequent event to ensure accurate reporting. Furthermore, some labs still appear to be confusing the limits of the normal reference range with the assay's lower or upper limits of detection.

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.

For your information, the scheduled dates of the remaining 2011 Tumor Marker Proficiency Test events are:

Mail-out date:	**Due date:**
May 10, 2011	May 25, 2011
September 13, 2011	**September 27, 2011** (Please note this is a Tuesday.)

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

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

Method comparisons based on average biases

Figure 1

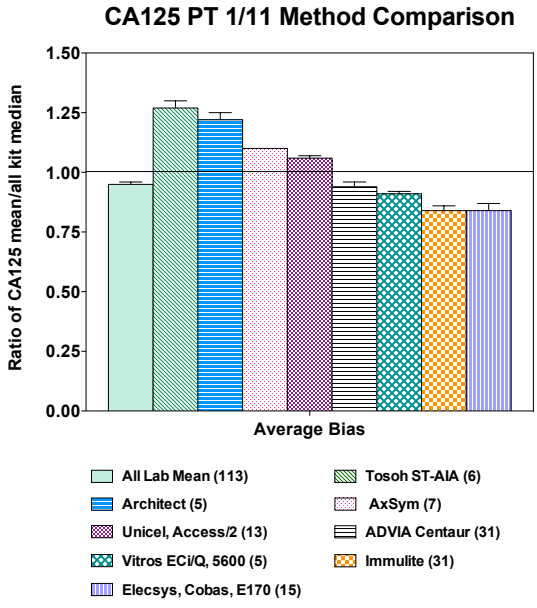


Figure 2

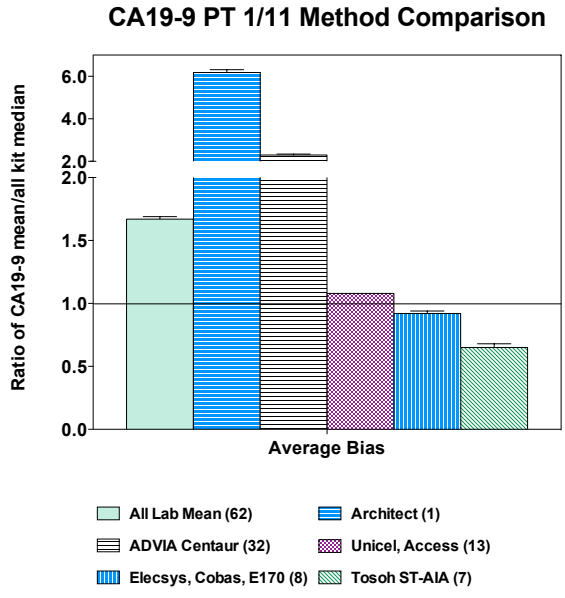


Figure 3

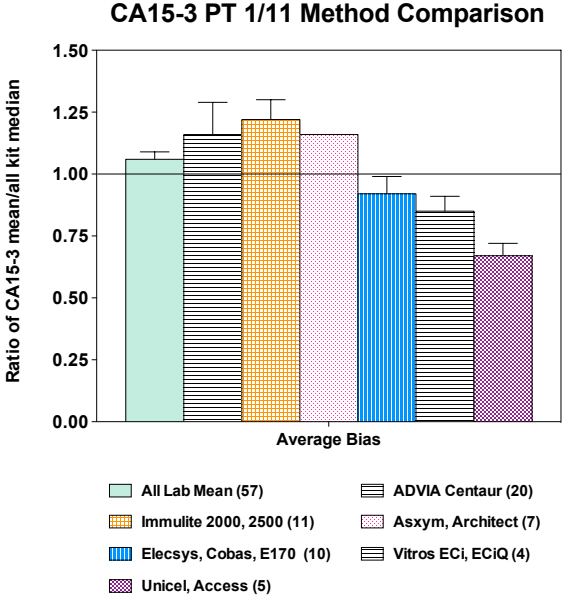
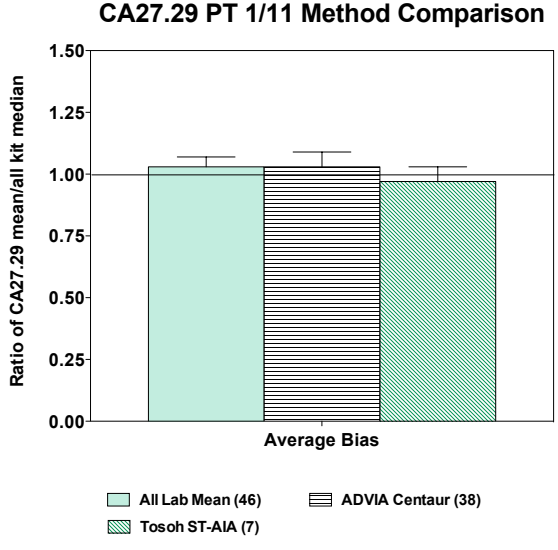


Figure 4



Method comparisons based on average biases

Figure 5

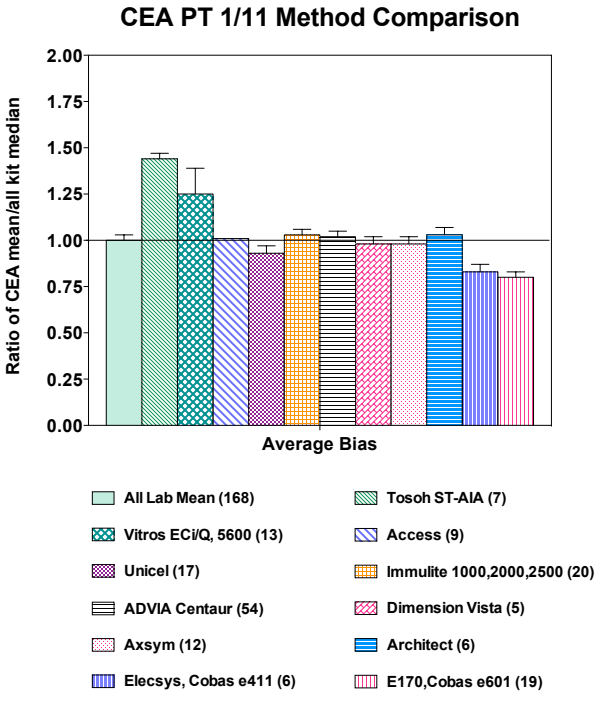


Figure 6

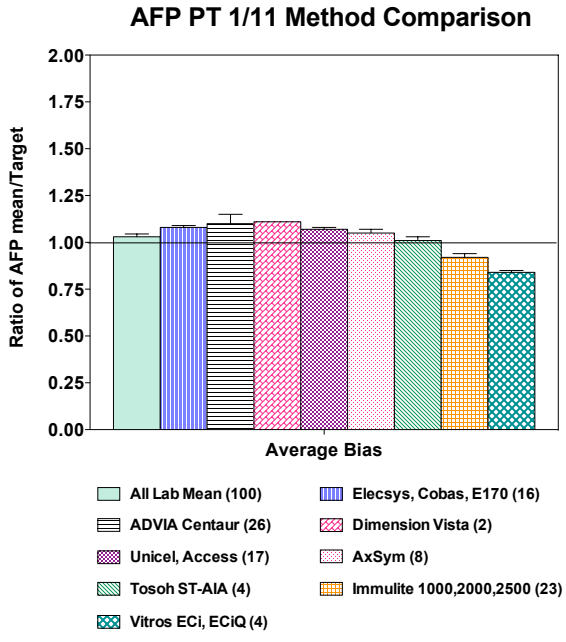


Figure 7

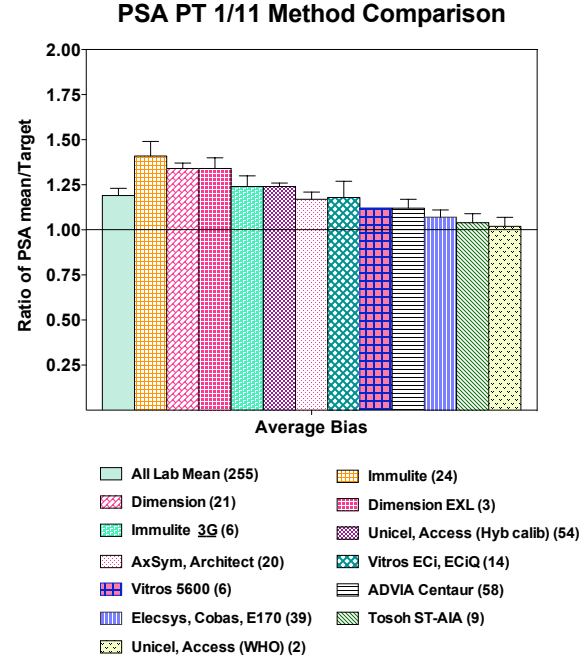
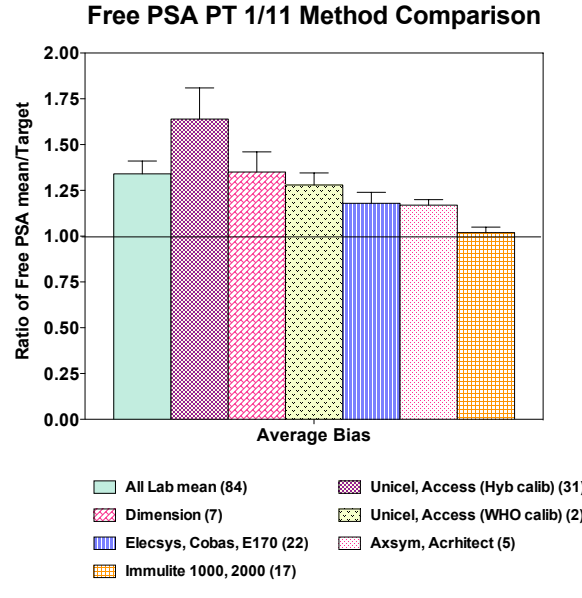


Figure 8



CA125

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method			All lab			
mean	19.3	48.5	32.4	26.7	31.4	
SD	3.0	7.1	4.8	4.2	4.8	
%CV	15.4%	14.6%	14.7%	15.9%	15.4%	
mean+3SD	28.3	69.8	46.7	39.4	45.9	
mean-3SD	10.4	27.2	18.1	14.0	16.9	
N	113	113	113	113	113	
all median	18.7	47.8	31.1	25.6	30.8	
mean/all kit median	0.96	0.95	0.95	0.96	0.93	0.95
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	19.1	47.8	32.4	25.3	31.6	
SD	1.4	2.3	1.8	2.0	1.4	
%CV	7.1%	4.9%	5.5%	7.7%	4.5%	
mean+3SD	23.2	54.9	37.7	31.2	35.9	
mean-3SD	15.0	40.8	27.1	19.5	27.4	
N	31	31	31	31	30	
kit median	19.1	48.3	32.6	26.0	31.5	
mean/all kit median	0.95	0.93	0.95	0.91	0.94	0.94
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	ABB	AB1	Abbott Axsym			
mean	21.9	55.1	35.6	33.1	36.3	
SD	3.1	5.2	4.8	4.8	3.1	
%CV	14.2%	9.5%	13.5%	14.6%	8.5%	
mean+3SD	31.2	70.7	50.1	47.6	45.5	
mean-3SD	12.5	39.4	21.2	18.6	27.0	
N	7	7	7	7	7	
kit median	21.5	56.3	37.6	30.2	35.7	
mean/all kit median	1.09	1.07	1.05	1.19	1.08	1.10
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	DP B/D/F	DP5	Siemens Immulite 1000/2000/2500			
mean	17.0	44.1	28.7	23.9	27.1	
SD	1.2	3.0	1.5	1.3	1.9	
%CV	6.9%	6.8%	5.2%	5.3%	6.9%	
mean+3SD	20.6	53.1	33.2	27.7	32.6	
mean-3SD	13.5	35.0	24.2	20.1	21.5	
N	31	31	31	31	31	
kit median	17.0	44.0	29.0	23.5	26.7	
mean/all kit median	0.85	0.86	0.84	0.86	0.81	0.84
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	ABH	AB1	Abbott Architect			
mean	25.2	61.4	41.3	34.1	40.3	
SD	1.7	3.5	2.5	1.9	2.7	
%CV	6.7%	5.8%	6.1%	5.7%	6.7%	
mean+3SD	30.3	72.0	48.8	39.9	48.4	
mean-3SD	20.2	50.8	33.8	28.3	32.2	
N	5	5	5	5	5	
kit median	25.8	62.3	41.9	35.0	39.7	
mean/all kit median	1.26	1.20	1.21	1.23	1.20	1.22
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	JJ C/F	JJ1	Ortho Clinical Vitros ECi/Q/5600			
mean	18.1	46.6	31.0	25.4	30.1	
SD	0.5	1.9	1.4	1.4	1.7	
%CV	2.8%	4.1%	4.5%	5.5%	5.8%	
mean+3SD	19.6	52.4	35.2	29.6	35.3	
mean-3SD	16.6	40.9	26.9	21.2	24.9	
N	5	5	5	5	5	
kit median	18.2	46.4	31.1	25.6	30.1	
mean/all kit median	0.90	0.91	0.91	0.92	0.90	0.91
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	20.9	54.7	36.0	30.1	35.5	
SD	1.3	3.6	2.8	2.1	2.9	
%CV	6.3%	6.6%	7.7%	6.9%	8.2%	
mean+3SD	24.9	65.6	44.3	36.3	44.3	
mean-3SD	17.0	43.9	27.7	23.9	26.7	
N	13	13	13	13	13	
kit median	21.0	55.3	36.2	30.0	35.5	
mean/all kit median	1.05	1.07	1.06	1.08	1.06	1.06
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	TOM	TO1	TOSOH ST-A1A			
mean	26.2	64.3	43.7	35.1	41.2	
SD	1.6	3.2	0.7	1.2	2.1	
%CV	6.1%	4.9%	1.5%	3.5%	5.1%	
mean+3SD	31.0	73.8	45.7	38.8	47.5	
mean-3SD	21.4	54.8	41.6	31.5	34.8	
N	6	6	6	6	6	
kit median	25.8	65.0	43.8	35.0	40.4	
mean/all kit median	1.31	1.25	1.28	1.27	1.23	1.27
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA125					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	17.6	40.7	28.4	23.8	27.7	
SD	1.6	2.5	2.1	1.9	1.8	
%CV	8.9%	6.1%	7.3%	7.8%	6.6%	
mean+3SD	22.3	48.2	34.6	29.4	33.2	
mean-3SD	12.9	33.3	22.1	18.2	22.3	
N	15	15	15	15	15	
kit median	18.0	41.3	29.0	24.3	28.4	
mean/all kit median	0.88	0.79	0.83	0.86	0.83	0.84
all kit median	20.0	51.3	34.0	27.7	33.6	

Sample	TM221	TM222	TM223	TM224	TM225	Average
CA125 kit average:						
mean	20.8	51.8	34.6	28.8	33.7	
SD	3.5	8.4	5.6	4.8	5.4	
all kit median	20.0	51.3	34.0	27.7	33.6	
average %CV	7.4%	6.1%	6.4%	7.1%	6.5%	6.7%
SD %CV	3.3%	1.6%	3.4%	3.3%	1.4%	2.6%

CA19-9

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA19-9					
Method			All lab			
mean	34.9	99.9	59.1	67.1	51.9	
SD	14.5	43.5	25.0	28.6	22.1	
%CV	41.5%	43.6%	42.4%	42.6%	42.5%	
mean+3SD	78.2	230.4	134.1	153.0	118.1	
mean-3SD	-8.5	-30.6	-16.0	-18.7	-14.3	
N	61	61	61	61	61	
all median	43.5	129.0	74.5	86.0	65.2	
mean/all kit median	1.64	1.69	1.67	1.67	1.66	1.67
all kit median	21.3	59.1	35.4	40.3	31.2	

Sample	TM2221	TM2222	TM2223	TM2224	TM2225	
Analyte	CA19-9					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	20.3	53.1	32.7	36.9	29.1	
SD	0.9	2.0	1.3	1.8	1.2	
%CV	4.3%	3.8%	4.0%	4.8%	4.2%	
mean+3SD	22.9	59.1	36.7	42.3	32.7	
mean-3SD	17.6	47.1	28.8	31.6	25.5	
N	8	8	8	8	8	
kit median	20.4	52.7	32.9	36.5	29.0	
mean/all kit median	0.95	0.90	0.92	0.92	0.93	0.92
all kit median	21.3	59.1	35.4	40.3	31.2	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA19-9					
Method	ABH	AB1	Abbott Architect			
result	128.0	365.3	222.3	254.4	190.3	
N	1	1	1	1	1	
result/all kit median	6.01	6.18	6.28	6.32	6.10	6.18

* **Note**: The ABH result was not included in the calculation of the all lab and all kit means (SDs) and medians because the results from this method were very different from the results of all the others.

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA19-9					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	47.9	139.3	81.7	92.4	70.9	
SD	2.9	7.3	5.6	4.7	4.1	
%CV	6.1%	5.2%	6.9%	5.1%	5.8%	
mean+3SD	56.7	161.2	98.5	106.6	83.3	
mean-3SD	39.1	117.5	64.9	78.2	58.5	
N	32	32	32	31	31	
kit median	47.7	138.1	81.0	92.1	70.8	
mean/all kit median	2.25	2.36	2.31	2.29	2.27	2.30
all kit median	21.3	59.1	35.4	40.3	31.2	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA19-9					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	22.3	65.0	38.1	43.6	33.3	
SD	1.6	3.7	2.3	3.1	1.8	
%CV	7.2%	5.8%	6.0%	7.2%	5.4%	
mean+3SD	27.1	76.3	44.9	53.0	38.7	
mean-3SD	17.5	53.8	31.3	34.2	28.0	
N	13	13	13	13	13	
kit median	21.7	64.9	38.0	43.4	33.5	
mean/all kit median	1.05	1.10	1.08	1.08	1.07	1.08
all kit median	21.3	59.1	35.4	40.3	31.2	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA19-9					
Method	TOM	TO1	TOSOH ST-A1A			
mean	14.2	36.1	23.6	25.7	21.0	
SD	0.6	1.3	1.0	1.0	1.0	
%CV	4.4%	3.6%	4.3%	3.8%	4.8%	
mean+3SD	16.0	39.9	26.7	28.6	24.0	
mean-3SD	12.3	32.2	20.6	22.8	18.0	
N	7	7	7	7	7	
kit median	14.3	35.8	23.8	25.8	21.2	
mean/all kit median	0.66	0.61	0.67	0.64	0.67	0.65
all kit median	21.3	59.1	35.4	40.3	31.2	

Sample	TM221	TM222	TM223	TM224	TM225	Average
CA19-9 kit average:						
mean*	26.2	73.4	44.0	49.7	38.6	
SD*	14.9	45.5	25.8	29.4	22.2	
all kit median	21.3	59.1	35.4	40.3	31.2	
average %CV	5.5%	4.6%	5.3%	5.2%	5.0%	5.1%
SD %CV	1.4%	1.1%	1.3%	1.4%	0.7%	1.2%

CA15-3

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method			All lab			
mean	25.2	46.5	77.2	33.7	53.1	
SD	5.4	9.8	15.3	8.2	11.1	
%CV	21.2%	21.0%	19.8%	24.3%	20.9%	
mean+3SD	41.3	75.8	122.9	58.3	86.4	
mean-3SD	9.1	17.2	31.4	9.1	19.7	
N	57	57	57	57	57	
all median	25.7	49.6	80.5	33.0	55.9	
mean/all kit median	1.02	1.08	1.07	1.06	1.07	1.06

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	27.2	54.6	88.1	30.5	62.1	
SD	5.4	5.8	8.1	5.2	6.3	
%CV	19.8%	10.6%	9.2%	17.2%	10.1%	
mean+3SD	43.5	72.0	112.6	46.2	81.0	
mean-3SD	11.0	37.2	63.7	14.7	43.2	
N	20	20	20	19	20	
kit median	28.6	53.5	87.0	31.2	62.8	
mean/all kit median	1.10	1.27	1.22	0.96	1.26	1.16
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	AB B/H	AB1	Abbott AxSym & Architect			
mean	28.2	47.7	80.1	42.0	55.4	
SD	2.2	4.6	6.1	3.7	3.8	
%CV	7.8%	9.7%	7.7%	8.8%	6.9%	
mean+3SD	34.8	61.5	98.5	53.1	66.9	
mean-3SD	21.5	33.8	61.7	30.9	43.9	
N	7	7	7	7	7	
kit median	28.3	49.3	81.9	43.7	55.9	
mean/all kit median	1.14	1.11	1.11	1.33	1.12	1.16
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	DP D/F	DP5	Siemens Immulite 2000/2500			
mean	28.6	51.1	86.6	43.0	58.4	
SD	2.9	2.0	9.0	3.1	3.6	
%CV	10.2%	3.9%	10.4%	7.2%	6.2%	
mean+3SD	37.3	57.2	113.6	52.3	69.2	
mean-3SD	19.9	45.1	59.6	33.7	47.5	
N	11	11	11	11	11	
kit median	28.7	51.1	89.9	43.8	59.0	
mean/all kit median	1.15	1.19	1.20	1.36	1.18	1.22
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	15.8	27.8	47.2	24.0	31.1	
SD	0.4	0.7	2.2	1.1	1.0	
%CV	2.5%	2.7%	4.7%	4.7%	3.3%	
mean+3SD	16.9	30.0	53.8	27.4	34.2	
mean-3SD	14.6	25.6	40.5	20.6	28.0	
N	5	5	5	5	5	
kit median	15.8	27.4	46.1	24.2	31.3	
mean/all kit median	0.64	0.65	0.65	0.76	0.63	0.67
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	JJC	JJ1	Ortho Clinical Vitros ECi/Q			
mean	19.7	35.6	61.8	30.1	41.1	
SD	0.8	0.7	1.9	1.3	1.7	
%CV	3.9%	2.0%	3.1%	4.2%	4.0%	
mean+3SD	22.0	37.7	67.5	33.9	46.1	
mean-3SD	17.4	33.5	56.1	26.4	36.2	
N	4	4	4	4	4	
kit median	19.6	35.5	61.6	30.1	41.0	
mean/all kit median	0.79	0.83	0.86	0.95	0.83	0.85
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA15-3					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	22.3	38.0	64.0	32.9	43.4	
SD	1.2	2.2	3.3	1.7	2.2	
%CV	5.2%	5.8%	5.1%	5.3%	5.0%	
mean+3SD	25.8	44.7	73.8	38.1	49.9	
mean-3SD	18.8	31.4	54.1	27.7	36.8	
N	10	10	10	10	10	
kit median	21.9	36.8	63.0	32.4	42.7	
mean/all kit median	0.90	0.89	0.89	1.04	0.88	0.92
all kit median	24.8	42.9	72.0	31.7	49.4	

Sample	TM221	TM222	TM223	TM224	TM225	Average
CA15-3 kit average:						
mean	23.6	42.5	71.3	33.8	48.6	
SD	5.2	10.3	16.2	7.4	11.9	
all kit median	21.0	36.8	62.9	31.5	42.3	
average %CV	8.2%	5.8%	6.7%	7.9%	5.9%	6.9%
SD %CV	6.3%	3.6%	2.9%	4.9%	2.4%	1.6%

CA27.29

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA27.29					
Method			All lab			
mean	18.3	36.1	67.4	33.4	43.8	
SD	3.1	3.2	8.5	4.6	3.8	
%CV	16.9%	8.9%	12.6%	13.6%	8.6%	
mean+3SD	27.5	45.7	92.9	47.1	55.1	
mean-3SD	9.0	26.4	41.9	19.7	32.5	
N	46	46	46	46	45	
all median	18.2	36.0	69.0	33.0	44.0	
mean/all kit median	0.95	1.01	1.05	1.04	1.03	1.02
all kit median	19.2	35.5	64.2	32.1	42.5	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA27.29					
Method	TOM	TO1	TOSOH ST-A1A			
mean	20.4	34.5	58.1	30.1	40.2	
SD	1.0	1.6	3.6	0.9	1.1	
%CV	4.7%	4.7%	6.1%	3.0%	2.8%	
mean+3SD	23.4	39.4	68.8	32.8	43.6	
mean-3SD	17.5	29.7	47.4	27.4	36.9	
N	7	7	7	7	7	
kit median	20.7	35.4	58.5	30.1	40.2	
mean/all kit median	1.07	0.97	0.90	0.94	0.95	0.97
all kit median	19.2	35.5	64.2	32.1	42.5	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CA27.29					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	17.9	36.5	70.3	34.2	44.7	
SD	3.2	3.1	3.9	4.6	3.5	
%CV	17.8%	8.6%	5.5%	13.5%	7.8%	
mean+3SD	27.5	46.0	81.9	48.0	55.1	
mean-3SD	8.3	27.1	58.8	20.4	34.2	
N	38	38	37	38	37	
kit median	17.4	36.5	69.7	34.0	44.5	
mean/all kit median	0.93	1.03	1.10	1.06	1.05	1.03
all kit median	19.2	35.5	64.2	32.1	42.5	

Sample	TM221	TM222	TM223	TM224	TM225	Average
CA27.29 kit average:						
mean	19.2	35.5	64.2	32.1	42.5	
SD	1.8	1.4	8.6	2.9	3.1	
all kit median	19.2	35.5	64.2	32.1	42.5	
average %CV	11.3%	6.6%	5.8%	8.2%	5.3%	7.4%
SD %CV	9.3%	2.8%	0.4%	7.4%	3.6%	3.6%

CEA

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method			All lab			
mean	4.8	11.9	12.7	5.4	7.9	
SD	0.8	1.4	1.5	0.9	1.1	
%CV	16.2%	11.9%	11.9%	16.6%	14.1%	
mean+3SD	7.1	16.2	17.3	8.1	11.2	
mean-3SD	2.5	7.7	8.2	2.7	4.5	
N	164	160	157	168	162	
kit median	4.7	12.1	12.9	5.3	7.9	
mean/all kit median	1.03	0.98	0.96	1.03	1.00	1.00
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	ABB	AB1	Abbott Axsym			
mean	4.6	11.8	12.3	5.5	7.7	
SD	0.3	1.2	1.2	0.4	0.7	
%CV	7.6%	10.0%	9.9%	7.5%	8.9%	
mean+3SD	5.7	15.3	15.9	6.7	9.7	
mean-3SD	3.6	8.3	8.6	4.2	5.6	
N	12	12	12	12	12	
kit median	4.7	11.5	12.4	5.5	7.8	
mean/all kit median	1.00	0.97	0.93	1.05	0.97	0.98
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	ABH	AB1	Abbott Architect			
mean	4.9	12.1	13.2	5.6	7.9	
SD	0.2	0.7	0.8	0.3	0.3	
%CV	3.9%	6.1%	6.3%	5.9%	3.5%	
mean+3SD	5.5	14.3	15.7	6.6	8.7	
mean-3SD	4.3	9.9	10.7	4.6	7.0	
N	6	6	6	6	6	
kit median	5.0	12.1	13.1	5.6	8.0	
mean/all kit median	1.06	0.99	1.00	1.07	1.00	1.03
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	BCU	BC1	Beckman Unicel CEA2			
mean	4.4	11.0	11.8	5.2	7.2	
SD	0.3	0.4	0.5	0.2	0.3	
%CV	6.8%	3.5%	4.7%	4.7%	3.5%	
mean+3SD	5.2	12.1	13.4	5.9	8.0	
mean-3SD	3.5	9.8	10.1	4.5	6.5	
N	17	17	17	17	17	
kit median	4.4	11.0	12.0	5.2	7.3	
mean/all kit median	0.94	0.90	0.89	0.99	0.92	0.93
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	BCX	BC1	Beckman Access/2 CEA2			
mean	4.8	12.2	13.3	5.4	7.9	
SD	0.3	1.3	0.7	0.5	0.4	
%CV	6.2%	11.0%	5.3%	9.8%	5.7%	
mean+3SD	5.7	16.2	15.4	7.0	9.3	
mean-3SD	3.9	8.1	11.2	3.8	6.6	
N	8	8	8	9	8	
kit median	4.8	12.6	13.4	5.5	7.9	
mean/all kit median	1.03	1.00	1.01	1.03	1.00	1.01
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	JJ C/F	JJ1	Ortho Clinical Vitros ECi/Q & 5600			
mean	6.5	13.8	14.5	7.3	9.8	
SD	0.8	0.6	0.8	0.7	0.8	
%CV	11.9%	4.5%	5.2%	9.6%	8.3%	
mean+3SD	8.8	15.6	16.8	9.3	12.3	
mean-3SD	4.2	11.9	12.3	5.2	7.4	
N	13	13	13	13	13	
kit median	6.4	14.0	14.6	7.7	10.2	
mean/all kit median	1.40	1.13	1.10	1.39	1.25	1.25
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	BME	BM1	Roche Elecsys & Cobas e411			
mean	4.0	9.9	10.2	4.6	6.5	
SD	0.1	0.5	0.6	0.2	0.5	
%CV	3.4%	4.7%	6.1%	4.4%	8.5%	
mean+3SD	4.4	11.3	12.1	5.2	8.1	
mean-3SD	3.6	8.5	8.3	4.0	4.8	
N	6	6	6	6	6	
kit median	4.0	9.8	10.1	4.7	6.6	
mean/all kit median	0.86	0.81	0.78	0.88	0.82	0.83
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	BMR	BM1	Roche E170 & Cobas e601			
mean	3.8	9.6	10.1	4.5	6.3	
SD	0.4	0.9	1.0	0.4	0.7	
%CV	11.0%	9.9%	9.8%	9.9%	10.3%	
mean+3SD	5.0	12.4	13.0	5.8	8.3	
mean-3SD	2.5	6.7	7.1	3.2	4.4	
N	19	19	19	19	19	
kit median	3.9	9.6	10.3	4.5	6.4	
mean/all kit median	0.82	0.79	0.76	0.85	0.80	0.80
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	4.9	12.2	13.2	5.2	8.1	
SD	0.3	0.6	0.7	0.4	0.5	
%CV	6.4%	5.2%	5.7%	7.5%	6.1%	
mean+3SD	5.9	14.1	15.5	6.4	9.6	
mean-3SD	4.0	10.3	11.0	4.0	6.7	
N	53	54	53	53	53	
kit median	5.0	12.3	13.3	5.2	8.1	
mean/all kit median	1.06	1.00	1.00	0.99	1.03	1.02
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	DP B/D/F	DP5	Siemens Immulite 1000/2000/2500			
mean	4.6	12.9	14.0	5.2	8.1	
SD	0.4	1.2	1.0	0.6	0.8	
%CV	8.9%	8.9%	7.4%	10.9%	9.7%	
mean+3SD	5.8	16.4	17.1	6.9	10.5	
mean-3SD	3.4	9.5	10.9	3.5	5.8	
N	20	20	19	20	20	
kit median	4.5	12.5	13.9	5.0	8.0	
mean/all kit median	0.99	1.06	1.06	1.00	1.03	1.03
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	DUV	DA2	Siemens Dimension VISTA			
mean	4.5	12.7	12.6	5.1	7.5	
SD	0.2	1.2	0.6	0.3	0.4	
%CV	4.4%	9.8%	4.4%	5.4%	4.9%	
mean+3SD	5.1	16.4	14.2	6.0	8.6	
mean-3SD	3.9	9.0	10.9	4.3	6.4	
N	5	5	5	5	5	
kit median	4.4	12.6	12.7	5.0	7.3	
mean/all kit median	0.97	1.04	0.95	0.98	0.95	0.98
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	CEA					
Method	TOM	TO1	TOSOH ST-A1A			
mean	6.8	17.1	18.9	7.5	11.5	
SD	0.3	0.7	0.9	0.3	0.5	
%CV	3.9%	4.3%	4.9%	4.4%	4.5%	
mean+3SD	7.6	19.3	21.6	8.5	13.0	
mean-3SD	6.0	14.9	16.1	6.6	9.9	
N	7	7	7	7	7	
kit median	6.8	17.2	18.9	7.4	11.6	
mean/all kit median	1.48	1.41	1.43	1.44	1.46	1.44
all kit median	4.6	12.2	13.2	5.2	7.9	

Sample	TM221	TM222	TM223	TM224	TM225	Average
CEA kit average:						
mean	4.9	12.3	13.1	5.6	8.0	
SD	0.9	2.0	2.4	1.0	1.5	
all kit median	4.6	12.2	13.2	5.2	7.9	
average %CV	6.8%	7.1%	6.3%	7.3%	6.7%	6.8%
SD %CV	2.9%	2.8%	1.9%	2.4%	2.5%	0.4%

AFP

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method			**All lab**			
mean	9.7	17.9	13.9	23.3	26.8	
SD	1.1	1.6	1.7	2.5	2.7	
%CV	11.6%	9.0%	12.2%	10.7%	10.2%	
mean+3SD	13.1	22.8	19.0	30.8	35.0	
mean-3SD	6.3	13.1	8.8	15.8	18.6	
N	100	100	100	100	100	
all median	9.8	18.1	13.9	23.5	27.3	
mean/all kit median	0.98	0.98	0.98	0.98	0.97	0.98
mean/target	1.05	1.02	1.03	1.05	1.02	1.03
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	DP B/ D/F	DP5	**Siemens Immulite 1000/2000/2500**			
mean	8.4	16.2	12.1	20.5	24.6	
SD	0.4	1.0	0.6	1.1	1.4	
%CV	5.0%	6.3%	5.0%	5.6%	5.5%	
mean+3SD	9.6	19.3	13.9	23.9	28.7	
mean-3SD	7.1	13.2	10.3	17.1	20.6	
N	23	23	23	23	23	
kit median	8.5	16.1	12.1	20.6	24.7	
mean/all kit median	0.84	0.88	0.85	0.86	0.89	0.87
mean/target	0.90	0.93	0.90	0.92	0.93	0.92
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	ABB	AB1	**Abbott AxSym**			
mean	10.0	18.3	13.9	23.9	27.4	
SD	0.5	1.0	0.9	1.7	2.3	
%CV	5.3%	5.2%	6.1%	7.3%	8.3%	
mean+3SD	11.5	21.2	16.5	29.1	34.2	
mean-3SD	8.4	15.4	11.4	18.7	20.5	
N	8	8	8	8	8	
kit median	9.9	18.3	13.7	23.9	26.3	
mean/all kit median	1.00	1.00	0.98	1.01	0.99	0.99
mean/target	1.07	1.04	1.03	1.08	1.04	1.05
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	DUV	DA2	**Siemens Dimension VISTA**			
mean	10.1	19.4	14.9	25.0	30.1	
SD						
%CV						
mean+3SD						
mean-3SD						
N	2	2	2	2	2	
kit median						
mean/all kit median	1.01	1.05	1.04	1.05	1.09	1.05
mean/target	1.09	1.11	1.10	1.12	1.14	1.11
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	BC U/X	BC1	**Beckman Unicel & Access/2**			
mean	10.0	18.4	14.6	23.6	28.0	
SD	0.6	1.1	0.7	1.6	2.1	
%CV	6.2%	5.8%	4.9%	6.8%	7.5%	
mean+3SD	11.9	21.6	16.8	28.4	34.3	
mean-3SD	8.2	15.3	12.5	18.8	21.7	
N	17	17	17	17	17	
kit median	9.9	18.3	14.6	23.6	28.0	
mean/all kit median	1.00	1.00	1.03	0.99	1.02	1.01
mean/target	1.08	1.05	1.08	1.06	1.06	1.07
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	JJC	JJ1	**Ortho Clinical Vitros ECi/Q**			
mean	8.0	14.6	11.2	18.9	22.3	
SD	0.2	0.3	0.2	0.2	0.5	
%CV	2.1%	2.1%	2.2%	0.8%	2.4%	
mean+3SD	8.5	15.5	11.9	19.3	23.9	
mean-3SD	7.5	13.6	10.5	18.4	20.7	
N	4	4	4	4	4	
kit median	8.0	14.6	11.2	18.9	22.4	
mean/all kit median	0.80	0.79	0.79	0.79	0.81	0.80
mean/target	0.86	0.83	0.83	0.85	0.84	0.84
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	BM E/R	BM1	**Roche Elecsys, Cobas, E170**			
mean	10.1	19.0	14.5	24.2	28.5	
SD	0.7	1.3	1.1	1.5	1.9	
%CV	6.5%	6.6%	7.5%	6.1%	6.7%	
mean+3SD	12.1	22.8	17.8	28.7	34.2	
mean-3SD	8.2	15.3	11.2	19.8	22.8	
N	16	16	16	16	16	
kit median	10.1	19.1	14.4	24.2	28.6	
mean/all kit median	1.01	1.04	1.02	1.02	1.03	1.02
mean/target	1.09	1.09	1.08	1.09	1.08	1.08
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	TOM	TO1	**TOSOH ST-A1A**			
mean	9.6	17.8	13.7	22.5	26.0	
SD	0.4	0.6	0.2	0.2	0.8	
%CV	3.8%	3.2%	1.5%	1.0%	3.3%	
mean+3SD	10.7	19.5	14.3	23.2	28.5	
mean-3SD	8.5	16.0	13.1	21.9	23.5	
N	4	4	4	4	4	
kit median	9.7	17.8	13.8	22.5	26.2	
mean/all kit median	0.96	0.97	0.96	0.95	0.94	0.96
mean/target	1.03	1.01	1.01	1.01	0.98	1.01
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**AFP**					
Method	COB	BA1	**Siemens ADVIA-Centaur**			
mean	10.7	18.8	14.7	25.5	27.9	
SD	1.0	1.0	1.1	1.9	1.6	
%CV	8.9%	5.6%	7.2%	7.3%	5.7%	
mean+3SD	13.6	21.9	17.8	31.1	32.7	
mean-3SD	7.9	15.6	11.5	19.9	23.1	
N	26	26	25	26	25	
kit median	10.5	18.6	14.5	25.4	28.2	
mean/all kit median	1.07	1.02	1.03	1.07	1.01	1.04
mean/target	1.15	1.07	1.09	1.15	1.06	1.10
target	9.3	17.5	13.5	22.2	26.4	

Sample	TM221	TM222	TM223	TM224	TM225	Average
AFP kit average:						
mean	9.5	17.6	13.5	22.7	26.4	
SD	0.9	1.6	1.3	2.3	2.5	
all kit median	10.0	18.4	14.2	23.8	27.6	
average %CV	5.3%	4.8%	4.9%	4.7%	5.3%	5.0%
SD %CV	2.3%	1.8%	2.6%	3.0%	2.2%	0.5%

AFP	TM221	TM222	TM223	TM224	TM225
IS target	9.3	17.5	13.5	22.2	26.4
high (25%)	11.6	21.9	16.9	27.8	33.0
low (25%)	7.0	13.1	10.1	16.7	19.8
high (30%)	12.1	22.8	17.6	28.9	34.3
low (30%)	6.5	12.3	9.5	15.5	18.5

* target value from a traceable AFP standard

PSA

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method			All lab			
mean	1.96	3.9	2.4	7.5	14.4	
SD	0.21	0.4	0.2	1.1	1.6	
%CV	10.6%	10.8%	10.2%	14.3%	11.3%	
mean+3SD	2.6	5.1	3.1	10.7	19.3	
mean-3SD	1.3	2.6	1.7	4.3	9.5	
N	253	255	253	254	255	
all median	1.9	3.8	2.4	7.3	14.1	
mean/all kit median	1.00	1.02	1.00	1.03	1.04	1.02
mean/target	1.23	1.17	1.20	1.21	1.12	1.19
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	DP B/D/F	DP5	Siemens Immulite 1000, 2000, 2500			
mean	2.40	4.5	2.8	9.2	16.6	
SD	0.19	0.4	0.3	0.8	0.9	
%CV	7.8%	8.3%	10.1%	8.2%	5.6%	
mean+3SD	3.0	5.6	3.7	11.5	19.4	
mean-3SD	1.8	3.4	2.0	6.9	13.8	
N	24	24	24	24	24	
kit median	2.4	4.5	2.9	9.2	16.6	
mean/all kit median	1.22	1.20	1.17	1.26	1.20	1.21
mean/target	1.50	1.37	1.41	1.48	1.30	1.41
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	AB B/H	AB1	Abbott Axsym & Architect			
mean	1.90	3.8	2.3	7.7	14.3	
SD	0.11	0.2	0.1	0.4	0.8	
%CV	5.7%	6.1%	4.5%	5.3%	5.9%	
mean+3SD	2.2	4.5	2.7	8.9	16.8	
mean-3SD	1.6	3.1	2.0	6.4	11.8	
N	20	20	20	20	20	
kit median	1.9	3.8	2.3	7.7	14.2	
mean/all kit median	0.96	1.01	0.97	1.05	1.03	1.01
mean/target	1.19	1.15	1.17	1.23	1.12	1.17
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	DP B/D/F	DP6	Siemens Immulite 1000, 2000, 2500 3rd generation			
mean	2.02	4.0	2.6	8.2	14.8	
SD	0.13	0.4	0.3	1.1	1.8	
%CV	6.6%	10.7%	10.2%	13.1%	12.4%	
mean+3SD	2.4	5.3	3.3	11.4	20.3	
mean-3SD	1.6	2.7	1.8	5.0	9.3	
N	6	6	6	6	6	
kit median	2.0	4.2	2.6	8.2	14.5	
mean/all kit median	1.02	1.05	1.06	1.12	1.07	1.06
mean/target	1.26	1.21	1.28	1.32	1.15	1.24
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	BC U/X	BC2	Beckman Unicel/Access Hybritech calibration			
mean	2.01	4.1	2.5	7.2	15.5	
SD	0.11	0.2	0.1	1.7	0.7	
%CV	5.3%	4.5%	4.3%	23.6%	4.8%	
mean+3SD	2.3	4.6	2.8	12.3	17.7	
mean-3SD	1.7	3.5	2.2	2.1	13.3	
N	52	52	52	54	53	
kit median	2.0	4.1	2.5	7.5	15.5	
mean/all kit median	1.02	1.08	1.04	0.99	1.12	1.06
mean/target	1.26	1.24	1.25	1.16	1.21	1.24
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	DUD	DA1	Siemens Dimension (RxL Max, Xpand Plus)			
mean	2.19	4.4	2.7	8.4	16.6	
SD	0.11	0.2	0.2	0.4	0.8	
%CV	5.1%	4.2%	6.4%	5.0%	5.0%	
mean+3SD	2.5	4.9	3.2	9.7	19.1	
mean-3SD	1.9	3.8	2.1	7.2	14.1	
N	21	21	21	21	21	
kit median	2.2	4.3	2.7	8.3	16.6	
mean/all kit median	1.11	1.16	1.11	1.16	1.20	1.15
mean/target	1.37	1.33	1.33	1.36	1.30	1.34
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	BC U/X	BC3	Beckman Unicel/Access WHO calibration			
mean	1.70	3.3	2.1	6.6	12.2	
SD	0.00	0.1	0.1	0.5	0.1	
%CV	0.0%	3.0%	2.8%	7.1%	0.8%	
mean+3SD	1.7	3.6	2.2	8.1	12.5	
mean-3SD	1.7	3.0	1.9	5.2	11.9	
N	3	3	3	3	3	
kit median	1.7	3.3	2.1	6.8	12.2	
mean/all kit median	0.86	0.87	0.86	0.91	0.88	0.88
mean/target	1.06	1.00	1.03	1.07	0.95	1.02
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	DUX	DA3	Siemens Dimension EXL (HM)			
mean	2.27	4.3	2.7	8.4	16.2	
SD	0.15	0.2	0.2	0.2	0.9	
%CV	6.7%	4.8%	5.7%	1.8%	5.3%	
mean+3SD	2.7	5.0	3.1	8.8	18.8	
mean-3SD	1.8	3.7	2.2	7.9	13.6	
N	3	3	3	3	3	
kit median	2.3	4.4	2.7	8.4	16.3	
mean/all kit median	1.15	1.15	1.11	1.15	1.17	1.14
mean/target	1.42	1.31	1.33	1.35	1.27	1.34
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	1.76	3.4	2.2	6.9	12.8	
SD	0.08	0.2	0.1	0.3	0.6	
%CV	4.6%	5.1%	4.3%	4.5%	4.7%	
mean+3SD	2.0	4.0	2.4	7.8	14.6	
mean-3SD	1.5	2.9	1.9	5.9	11.0	
N	39	39	39	39	39	
kit median	1.8	3.5	2.2	6.9	13.0	
mean/all kit median	0.89	0.91	0.90	0.94	0.93	0.91
mean/target	1.10	1.04	1.08	1.11	1.00	1.07
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	JJC	JJ1	Ortho Clinical Vitros ECi/Q			
mean	2.07	3.8	2.5	7.3	13.4	
SD	0.09	0.2	0.1	0.3	0.5	
%CV	4.3%	4.0%	5.0%	4.7%	4.0%	
mean+3SD	2.3	4.2	2.8	8.3	15.0	
mean-3SD	1.8	3.3	2.1	6.3	11.8	
N	12	12	12	12	12	
kit median	2.1	3.7	2.5	7.2	13.5	
mean/all kit median	1.05	0.99	1.03	1.00	0.97	1.01
mean/target	1.29	1.14	1.23	1.18	1.05	1.18
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	1.86	3.6	2.3	7.3	13.4	
SD	0.10	0.2	0.1	0.4	0.7	
%CV	5.5%	4.5%	4.9%	6.0%	5.2%	
mean+3SD	2.2	4.1	2.6	8.6	15.4	
mean-3SD	1.5	3.1	1.9	6.0	11.3	
N	58	58	57	57	57	
kit median	1.8	3.6	2.3	7.2	13.3	
mean/all kit median	0.94	0.95	0.95	1.00	0.96	0.96
mean/target	1.16	1.09	1.14	1.17	1.04	1.12
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	TOM	TO1	TOSOH ST-A1A			
mean	1.74	3.4	2.1	6.8	12.4	
SD	0.11	0.1	0.1	0.4	0.5	
%CV	6.2%	4.0%	5.5%	5.3%	4.3%	
mean+3SD	2.1	3.8	2.4	7.8	14.0	
mean-3SD	1.4	3.0	1.8	5.7	10.8	
N	10	10	10	10	10	
kit median	1.7	3.4	2.1	6.8	12.5	
mean/all kit median	0.88	0.90	0.87	0.93	0.89	0.90
mean/target	1.09	1.03	1.05	1.09	0.97	1.04
target	1.6	3.3	2	6.2	12.8	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	PSA					
Method	JJF	JJ1	Ortho Clinical Vitros 5600			
mean	1.93	3.6	2.3	7.1	13.0	
SD	0.08	0.2	0.1	0.4	0.8	
%CV	4.2%	4.4%	3.9%	5.9%	6.1%	
mean+3SD	2.2	4.1	2.6	8.3	15.3	
mean-3SD	1.7	3.1	2.0	5.8	10.6	
N	6	6	6	6	6	
kit median	2.0	3.6	2.3	7.0	12.8	
mean/all kit median	0.98	0.96	0.96	0.97	0.93	0.96
mean/target	1.21	1.10	1.15	1.14	1.01	1.12
target	1.6	3.3	2	6.2	12.8	

see next page for summaries and targets

Sample	TM221	TM222	TM223	TM224	TM225	Average
PSA kit average:						
mean	2.0	3.9	2.4	7.6	14.3	
SD	0.2	0.4	0.2	0.8	1.6	
all kit median	2.0	3.8	2.4	7.3	14.3	
average %CV	5.2%	5.3%	5.6%	7.5%	5.3%	5.8%
SD %CV	1.9%	2.1%	2.3%	5.7%	2.6%	1.6%

PSA	TM221	TM222	TM223	TM224	TM225
IS target	**1.60**	**3.3**	**2.0**	**6.2**	**12.8**
high (25%)	2.01	4.1	2.5	7.7	16.0
low (25%)	1.21	2.5	1.5	4.6	9.6
high (30%)	2.09	4.3	2.6	8.1	16.6
low (30%)	1.13	2.3	1.4	4.3	8.9

* target value from a traceable PSA standard
**30% allowable for PSA targets < 4.0 ng/ml

Free PSA

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method			**All lab**			
mean	0.26	0.50	0.31	0.98	1.82	
SD	0.06	0.10	0.07	0.19	0.31	
%CV	21.1%	20.3%	21.2%	19.1%	17.0%	
mean+3SD	0.43	0.80	0.51	1.54	2.75	
mean-3SD	0.10	0.20	0.11	0.42	0.89	
N	84	84	84	84	84	
all median	0.24	0.47	0.30	0.90	1.75	
mean/all kit median	1.10	1.08	1.08	1.08	1.06	1.08
mean/target	1.38	1.35	1.42	1.29	1.24	1.34
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	BM E/R	BM1	**Roche Elecsys, Cobas, E170**			
mean	0.23	0.44	0.28	0.87	1.63	
SD	0.02	0.03	0.01	0.04	0.07	
%CV	9.2%	6.0%	5.3%	4.5%	4.4%	
mean+3SD	0.29	0.52	0.32	0.99	1.84	
mean-3SD	0.17	0.36	0.23	0.75	1.41	
N	22	22	22	22	22	
kit median	0.23	0.44	0.28	0.88	1.63	
mean/all kit median	0.97	0.96	0.96	0.96	0.95	0.96
mean/target	1.22	1.19	1.27	1.14	1.11	1.18
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	AB B/ H	AB1	**Abbott Axsym & Architect**			
mean	0.22	0.43	0.27	0.87	1.70	
SD	0.01	0.01	0.00	0.02	0.08	
%CV	3.8%	2.8%	1.7%	2.5%	4.6%	
mean+3SD	0.25	0.47	0.28	0.94	1.93	
mean-3SD	0.20	0.39	0.25	0.81	1.47	
N	5	5	5	5	5	
kit median	0.22	0.43	0.27	0.86	1.74	
mean/all kit median	0.93	0.93	0.93	0.97	0.99	0.95
mean/target	1.17	1.16	1.22	1.15	1.16	1.17
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	DP B/D	DP5	**Siemens Immulite 1000 & 2000**			
mean	0.20	0.38	0.23	0.76	1.44	
SD	0.01	0.03	0.02	0.04	0.05	
%CV	5.2%	9.0%	9.5%	4.8%	3.8%	
mean+3SD	0.23	0.48	0.30	0.87	1.60	
mean-3SD	0.17	0.28	0.16	0.65	1.28	
N	17	17	17	17	17	
kit median	0.20	0.38	0.23	0.75	1.44	
mean/all kit median	0.85	0.82	0.80	0.84	0.84	0.83
mean/target	1.06	1.02	1.05	1.00	0.98	1.02
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	BC U/X	BC2	**Beckman Unicel/Access Hybritech calibration**			
mean	0.32	0.62	0.39	1.20	2.18	
SD	0.03	0.04	0.02	0.07	0.11	
%CV	9.3%	5.7%	5.2%	6.0%	5.2%	
mean+3SD	0.41	0.72	0.45	1.42	2.51	
mean-3SD	0.23	0.51	0.33	0.99	1.84	
N	31	31	30	31	31	
kit median	0.32	0.60	0.40	1.20	2.17	
mean/all kit median	1.36	1.34	1.35	1.33	1.26	1.33
mean/target	1.71	1.67	1.78	1.58	1.48	1.64
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	DUD	DA1	**Siemens Dimension**			
mean	0.27	0.51	0.32	0.93	1.87	
SD	0.02	0.03	0.02	0.05	0.09	
%CV	7.5%	5.7%	6.5%	4.9%	4.7%	
mean+3SD	0.34	0.60	0.38	1.07	2.14	
mean-3SD	0.21	0.42	0.26	0.80	1.60	
N	7	7	7	7	7	
kit median	0.27	0.50	0.31	0.93	1.85	
mean/all kit median	1.15	1.11	1.10	1.03	1.09	1.09
mean/target	1.44	1.37	1.44	1.23	1.27	1.35
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	
Analyte	**free PSA**					
Method	BC U/X	BC3	**Beckman Unicel/Access WHO calibration**			
mean	0.25	0.48	0.30	0.95	1.75	
SD						
%CV						
mean+3SD						
mean-3SD						
N	2	2	2	2	2	
kit median						
mean/all kit median	1.03	1.04	1.04	1.05	1.01	1.03
mean/target	1.29	1.30	1.36	1.25	1.19	1.28
target	0.19	0.37	0.22	0.76	1.47	

Sample	TM221	TM222	TM223	TM224	TM225	Average
free PSA kit average:						
mean	0.19	0.36	0.22	0.70	1.32	
SD	0.04	0.08	0.05	0.15	0.25	
all kit median	0.24	0.46	0.29	0.90	1.72	
average %CV	6.4%	5.9%	5.8%	4.2%	4.4%	5.3%
SD %CV	2.4%	2.5%	3.2%	1.1%	0.4%	1.1%

free PSA	TM221	TM222	TM223	TM224	TM225
IS target	**0.19**	**0.37**	**0.22**	**0.76**	**1.47**
high (25%)	0.24	0.463	0.28	0.95	1.84
low (25%)	0.14	0.28	0.17	0.57	1.10
high (30%)	0.25	0.48	0.29	0.99	1.91
low (30%)	0.13	0.26	0.15	0.53	1.03

* target value from a traceable free PSA standard.

Complexed PSA

Sample	TM221	TM222	TM223	TM224	TM225	Average
Analyte	**complexed PSA**					
Method			**All lab**			
mean	1.6	3.2	2.0	6.4	11.7	
SD	0.1	0.1	0.1	0.2	0.6	
%CV	5.6%	3.4%	4.7%	3.7%	4.9%	4.5%
mean+3SD	1.9	3.5	2.2	7.1	13.4	
mean-3SD	1.4	2.8	1.7	5.7	9.9	
N	8	8	8	8	8	
all median	1.6	3.1	2.0	6.4	11.5	

**********PLEASE NOTE**********

INSTRUCTIONS CAN NOW BE FOUND AT
http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm

Oncology Soluble Tumor Markers
Worksheet Only - Do Not Mail

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker						
		TM221	TM222	TM223	TM224	TM225
AFP (ng/ml)	>/<					
	Result					
	Interpretation					
CA 125 (U/ml)	>/<					
	Result					
	Interpretation					
CA 15-3 (U/ml)	>/<					
	Result					
	Interpretation					
CA 19-9 (U/ml)	>/<					
	Result					
	Interpretation					
CA 27.29 (U/ml)	>/<					
	Result					
	Interpretation					
CEA (ng/ml)	>/<					
	Result					
	Interpretation					
PSA (Total) (ng/ml)	>/<					
	Result					
	Interpretation					

Oncology Soluble Tumor Markers
Worksheet Only - Do Not Mail

For the interpretations, the patient is a 60 year-old non-smoking Caucasian male or female as appropriate for the marker						
		TM221	TM222	TM223	TM224	TM225
Complexed PSA (ng/ml)	>/<					
	Result					
	Interpretation					
PSA (Total) for a 2nd method used in conjunction with free PSA (ng/mL)	>/<					
	Result					
	Interpretation					
Free PSA (ng/ml) If test offered, measure and report for all samples	>/<					
	Result					

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

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

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

****