STATE OF NEW YORK
DEPARTMENT OF HEALTH

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Commissioner

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Executive Deputy Commissioner

October 27, 2010

New York State Tumor Marker Proficiency Test 9/2010 Evaluation [1]

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from September 14, 2010 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 four 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 exhibited a substantial high or low bias when compared to the rest of your method peer group. This suggests that

[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.

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 of at least two labs. The sixth group of bars on the graph labeled "average bias" is shown to make it easier to compare the methods across all five samples. The straight lines above each bar in this group 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 114 labs using 13 methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in seven peer groups, five of which include ten or more labs each. Fifty-four percent of the labs are in one of four groups that gave results at or within +/- 10% of the medians. Two of the other three groups reported somewhat lower results, but were still within 15% of the median (Roche Elecsys, Cobas and E170 at -14% and Siemens Immulite 1000, 2000, 2500 at -13%). Thus, results from 96% of the total labs agreed reasonably well on how CA125 was measured in these samples with less than +/-15% deviation from the medians. In contrast, TOSOH ST-A1A (used by five labs representing only 4% of the participants) gave results that were on average 23% higher than the medians.

CA19-9 (Figure 2) Results were reported by 58 labs using eight methods. Combining results from different instruments made by the same manufacturer and/or brand resulted in six peer groups, two of which comprised only one lab each, however. Over half of the labs (55%) used Siemens ADVIA-Centaur, 12 labs (21%) used Beckman Unicel or Access/2, 7 labs (12%) used Roche Elecsys/Cobas e411 or E170/Cobas e601, and 6 labs (10%) used the Tosoh ST-A1A 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-A1A were lower than the medians by about 37%, and, on the opposite side, those by Siemens ADVIA-Centaur were almost two and a half times higher than those from four of the other five methods. As a consequence, the all lab means (excluding Abbott Architect) are substantially higher than the medians, reflecting the higher measurements from the comparatively large ADVIA Centaur group. Finally, as the graph shows, the Abbott Architect method (used by only 1 lab) gave measurements for CA19-9 that were over 6 times higher than the all kit medians, and about ten times higher than the results obtained with the Tosoh ST-A1A. These high measurements by the Abbott Architect are consistent with previous CA19-9 results by this method, as well as those obtained in the corresponding CAP surveys, which were also 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 102 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 we have combined results from different instruments made by the same manufacturer and/or brand except for Abbott AxSym and Architect, for which a t-test showed a significant ($p<0.05$) difference between them for four of the five samples. This resulted in seven CA15-3 peer groups, three of which comprised less than 10 labs each. Overall, the differences between the methods used for CA15-3 were substantial. In particular, the Siemens ADVIA-Centaur method used by 36% of the labs gave results 53% higher than the medians, whereas the Beckman Access and Unicel methods used by 9% of the labs gave results that were 33% lower than the medians. Results from the other five peer groups varied from -10% to +25% from the median. Consequently, as Figure 3 shows, the results from the different methods used to measure CA15-3 spanned a two-fold range. In contrast, there was only a small difference (<10%) between the two methods used for CA27.29; however, the median values from the CA27.29 measurements were on average 7% lower than those from the CA15-3 assays.

CEA (Figure 5) Results were reported by 161 labs using 14 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were nine peer groups. Six out of the nine groups contain the majority (78%) of labs and the results among these groups were relatively consistent and on average within +/-7% of the medians. In contrast, the Ortho Clinical Diagnostics Vitros ECi/Q & 5600 and the TOSOH ST-A1A methods gave results that were on average 30% and 43% higher, respectively. On the opposite side, the results from the Roche E170/Cobas e601 and Elecsys/Cobas e411 group were on average 19% lower than the medians. Similar to the previous proficiency test event, measurements from the Ortho Clinical Diagnostics instruments used by 11 labs were the least consistent with %CVs as high as 34.9% for the lowest level sample (TM 217). In contrast, the results reported with the other instruments/methods show relatively good intra-method correlation with %CVs generally less than 10% (refer to summary tables).

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 were evaluated based on their respective peer group means, the performance of the methods were compared relative to the target values graphically.

AFP (Figure 6) Results were reported by 100 labs using twelve different methods, four of which were used by less than 10 labs each, together accounting for 17% of the total number of labs. After combining results from different instruments made by the same manufacturer and/or brand there were nine 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 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/Q) gave results that were significantly lower than the rest, and also 11% lower than the target. In contrast, all but one of the remaining groups were on average 13% higher than the target, but did not differ much among each other. The exception is Tosoh ST-A1A, which is in between the two groups and essentially right on target. While these differences are not huge, they are consistent across samples and are statistically significant.

PSA (Figure 7) Results were reported by 254 labs using 20 different methods. After combining results from different instruments made by the same manufacturer and/or brand there were 11 peer groups, four of which comprised less than 10 labs each, together accounting for only 8% of the total number of labs. All five samples were prepared as mixtures of 10% free and 90% ACT-complexed 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 ratio of the group mean/target value is given for each sample to compare measurement and/or calibration biases between the different methods. The lowest PSA sample, TM216, showed the greatest variability among methods with an average bias of 20% compared to that of the target values. The average bias for all methods across all five samples was 15.5%, which is slightly lower than the 18.1% observed in the previous PT. As observed previously, there

seemed to be a separation of results into a high and low group with an average bias of +29.8% (+/-6.0%) and +7.1% (+/-5.5%), respectively. These two groups are statistically significantly different from each other ($p<0.0001$). The highest method (Siemens Immulite 1000, 2000 and 2500) was at +35%, while the two lowest methods (Beckman Unicel/Access with WHO calibration and Tosoh ST-A1A) were just 2% above the target value. The high groups together comprised 110 labs (43%), whereas the low groups together comprised 144 labs (57%). 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 about 21%, which agrees fairly well 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 81 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 (38%) were reported with the Beckman Access/2 or Unicel methods (two of those used the WHO standard calibration and the rest used the Hybritech calibration). All 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 ratio of the group mean/target value is given for each sample 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 and the Siemens Dimension were distinctly higher than those obtained with the rest of the methods (+58% and +46%, respectively). However, measurements in sample TM216 with its very low free PSA levels are probably not representative of the overall method performance. The other methods showed average biases of 13-21% above the target value, with the exception of Siemens Immulite 1000/2000, whose results were approximately 2% below the target. The average bias from the WHO-calibrated Beckman method was 37% lower than that from the original Hybritech-calibrated Beckman method and was comparable to the results from the other methods.

We would like to reiterate that since the last PT labs are now required to measure and **report free PSA for all samples** if they test for free PSA, but are not required to calculate % 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 exactly treated 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 calculate % free PSA at all, but only report free and total PSA values and leave the calculation to the physician. These changes were made in order to improve our ability to evaluate a lab's performance for measuring free PSA as an essential part of laboratory testing. The question under free PSA regarding calculation of % free PSA was included for informational purposes only and the answers are shown in the table below.

Does your lab calculate % Free PSA?

Answer	**N**	**% of labs**
Yes, always	28	35%
Yes, but only within a specific PSA range	24	30%
No	13	16%
Yes, but only when requested	8	10%
Yes, but only when requested and only within a specific PSA range	6	8%
Other	1	<1%
Total	80	100%

Finally, only 10 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, it is a continued observation that there can be quite significant differences between the results obtained with various methods, 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 likely due to inherent differences in the assays themselves. We will 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, caution needs to be used when comparing the results from the same patient obtained with different methods, 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 paragraphs about those analytes.

Finally, we would like to raise the usual cautionary notes when interpreting these results which are 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 an accurate comparison of results when the % CVs are large; and 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 important and in your interest since we need this information to properly evaluate your results and compare them to those of your peers. There are still many instances where individuals have either **inadvertently selected a qualifier (< or >) or an incorrect instrument/reagent pair when scrolling** through the instrument or reagent lists and this has resulted in failed samples or tests. **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 line was added to allow entry of results from a second PSA assay **only** for those labs that use a different method for total PSA to be used in conjunction with free PSA measurements. If only one PSA test was done, then these results should have been entered in the first PSA line. Most labs should have selected "test not performed" 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 tentative schedule for the 2011 Tumor Marker Proficiency Test mail-out follows:

Mail-out date:	**Due date:**
January 25, 2011	February 9, 2011
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 us at the address below.

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Figure 1

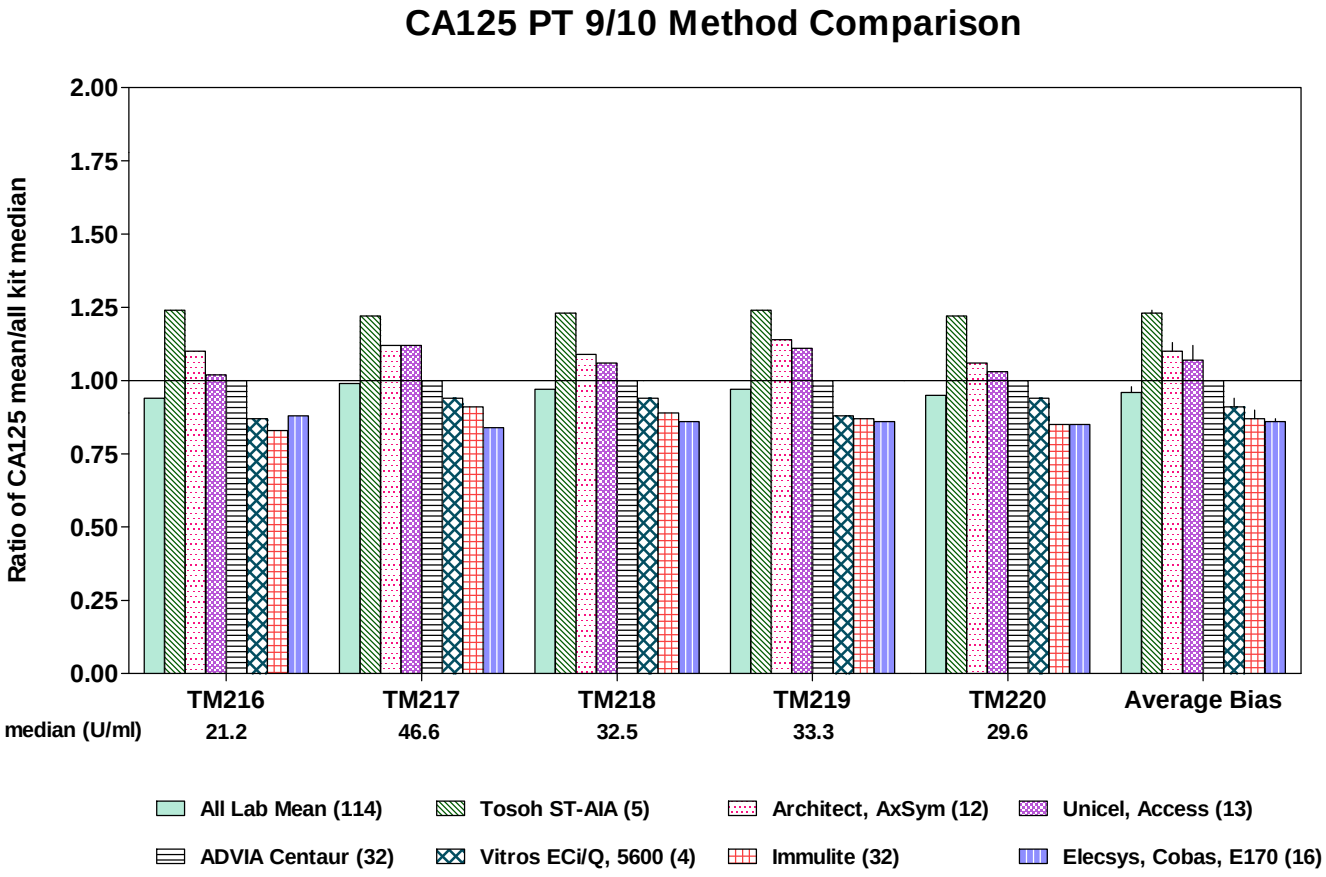


Figure 2

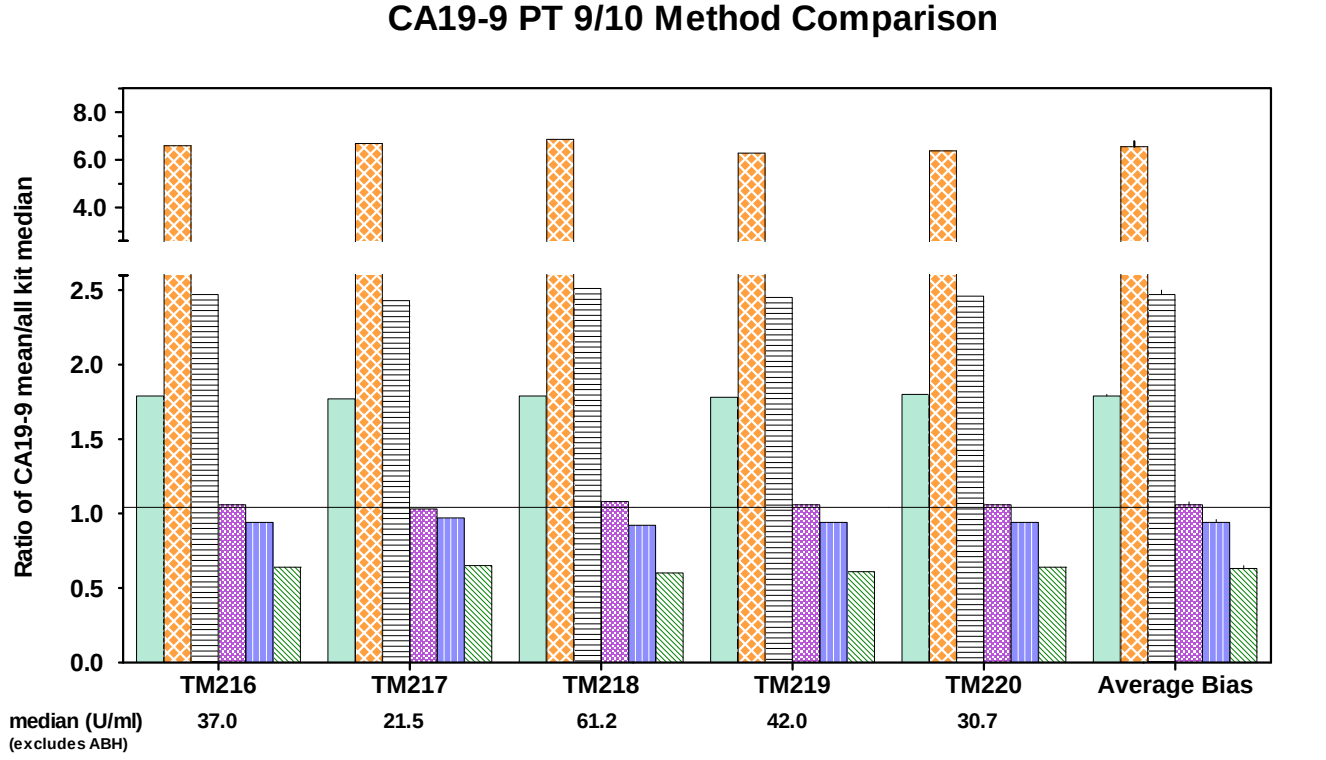


Figure 3

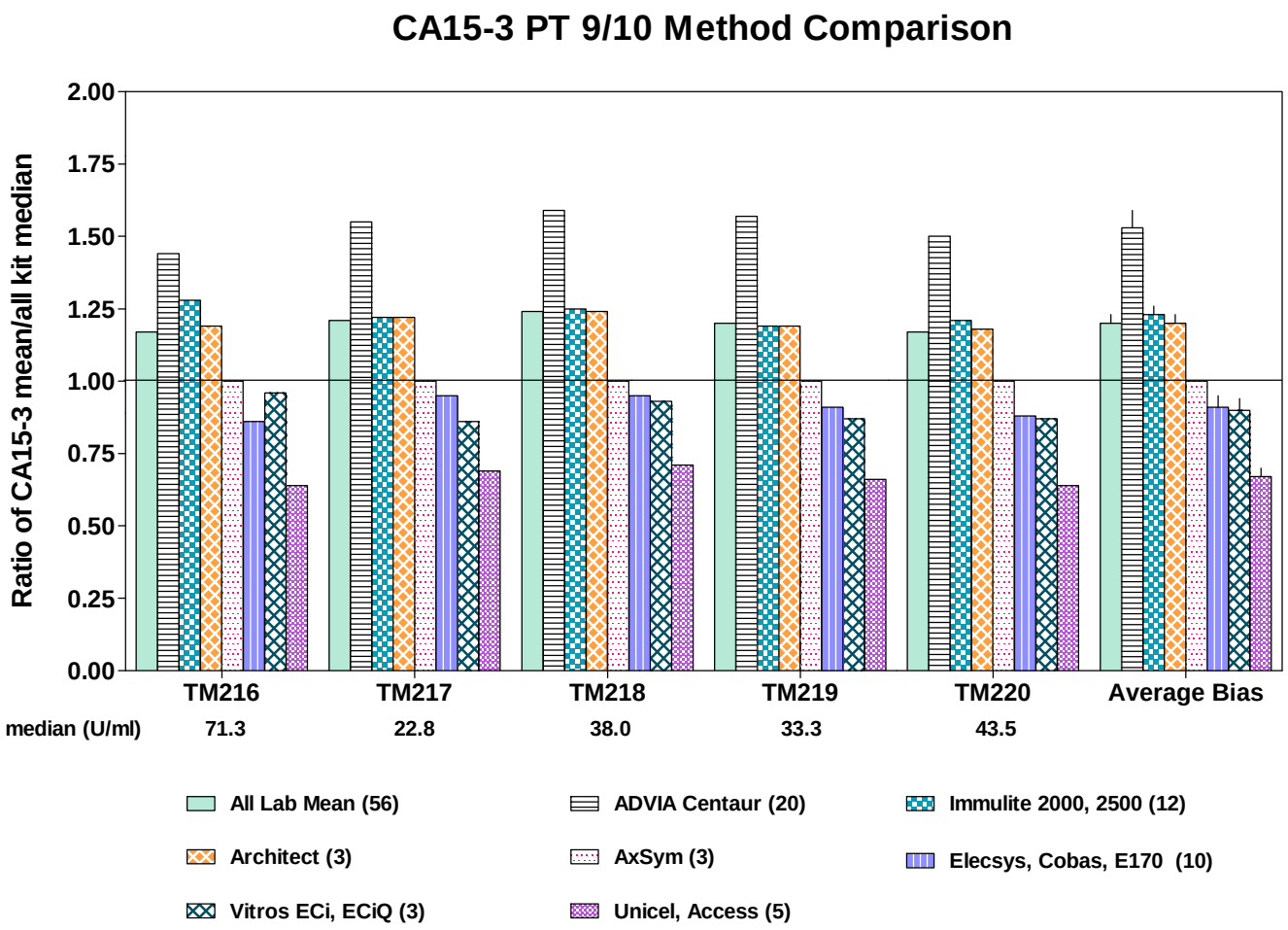


Figure 4

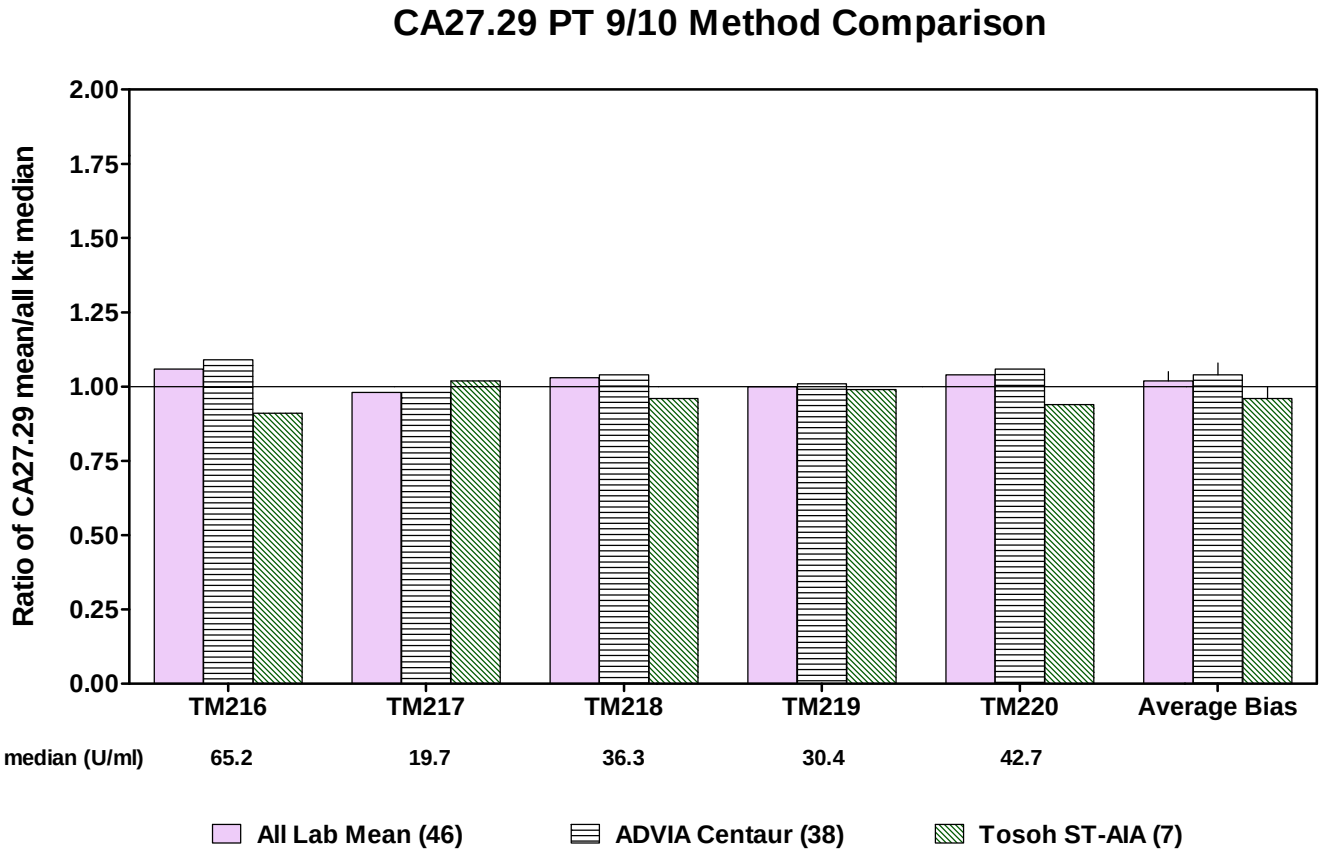


Figure 5

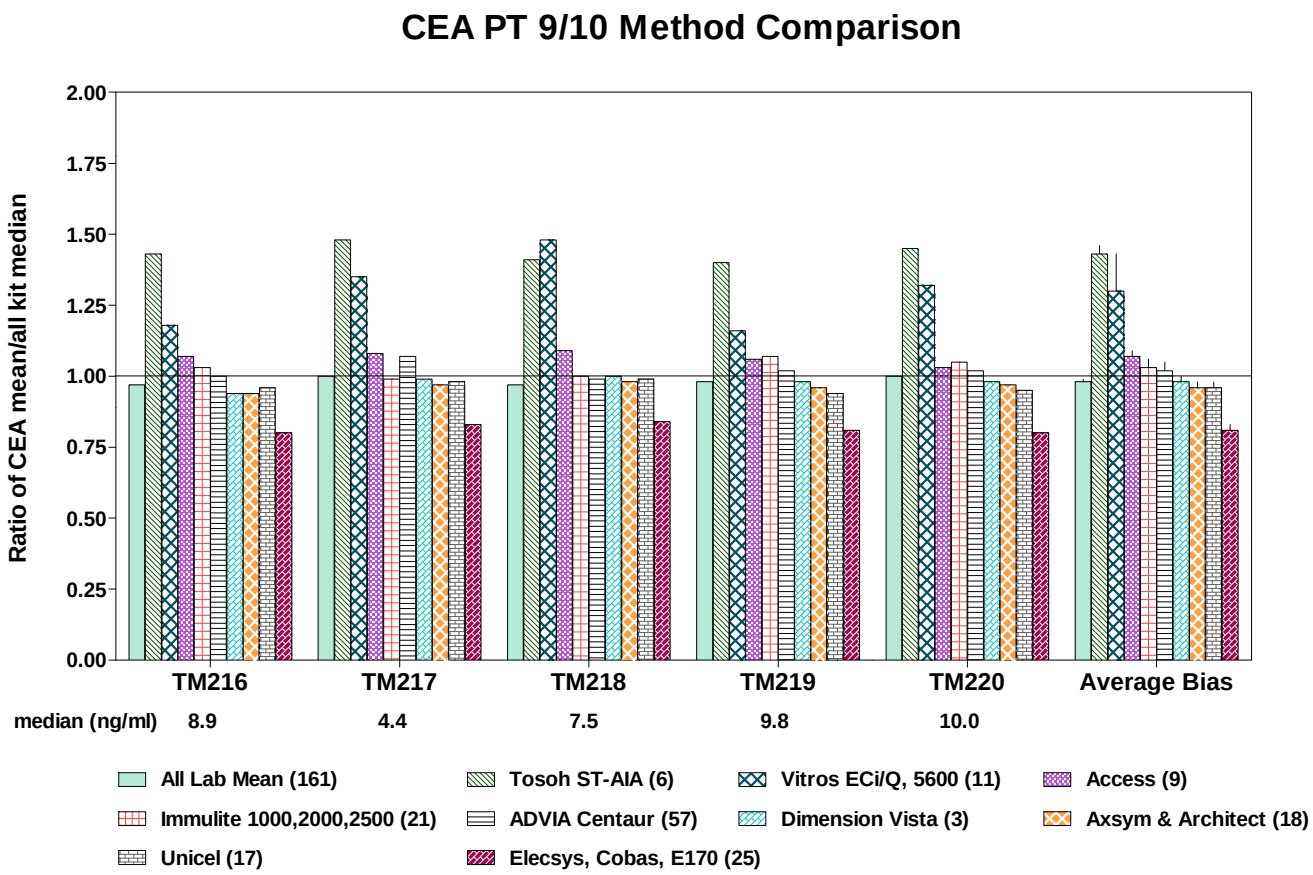


Figure 6

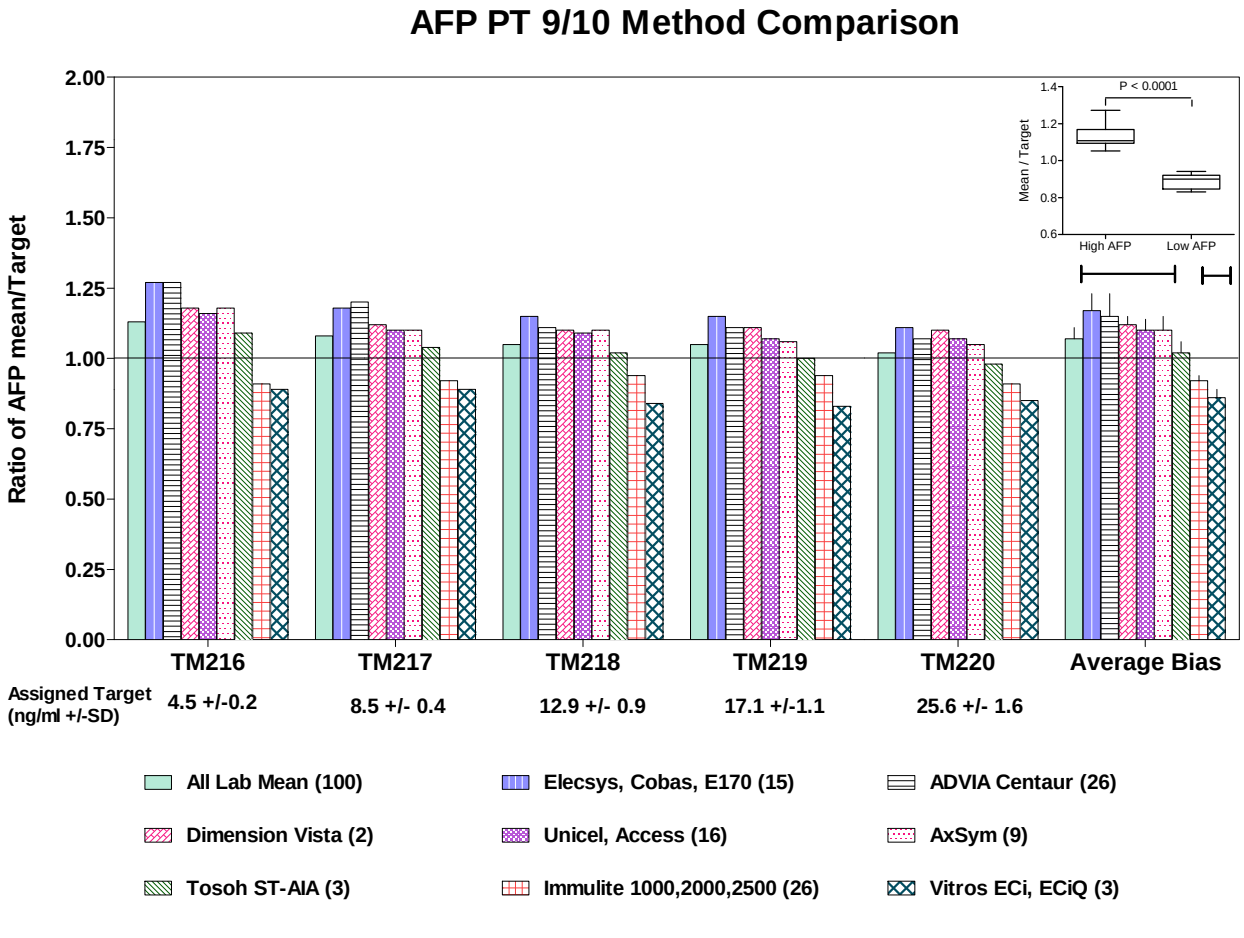


Figure 7

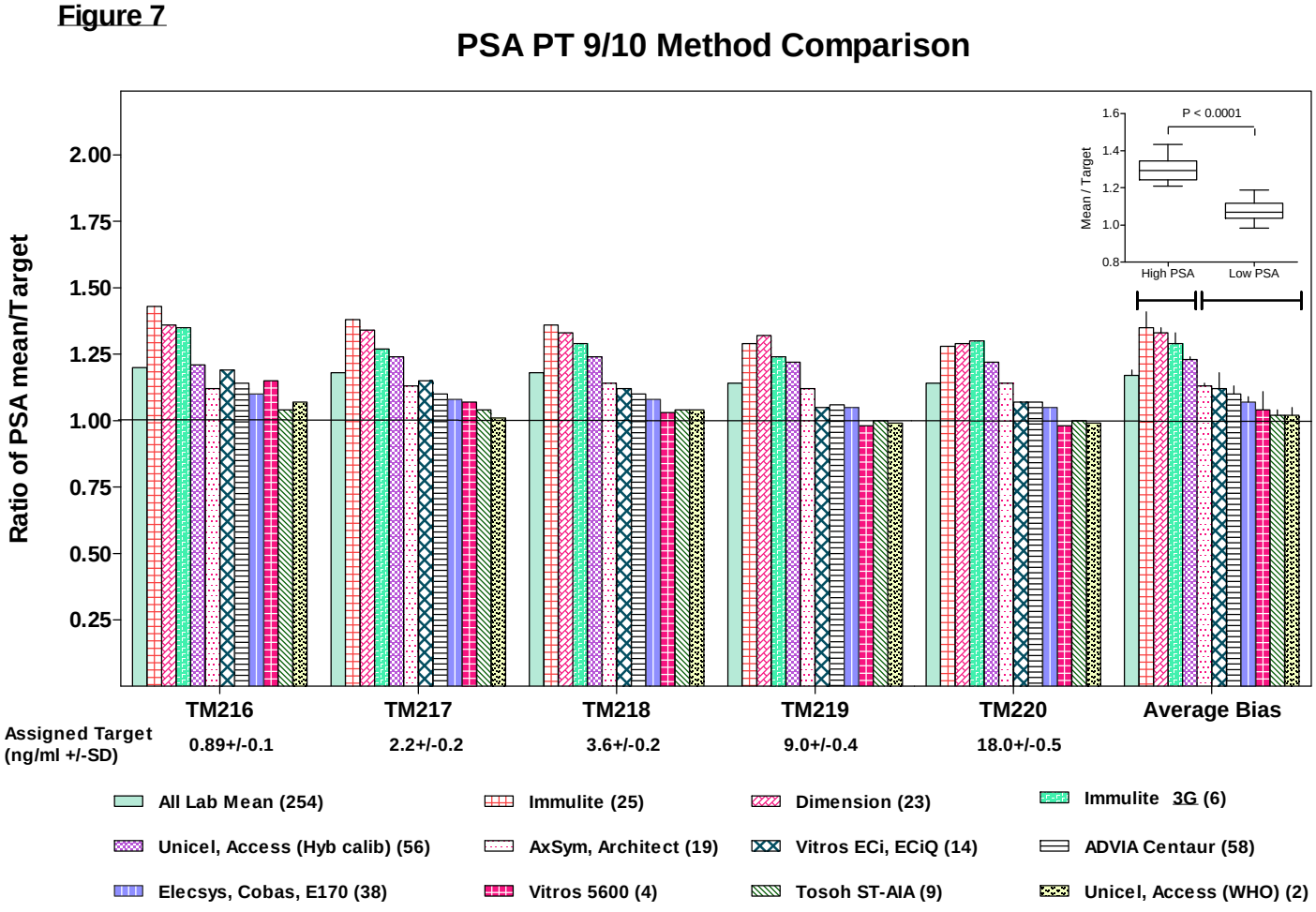
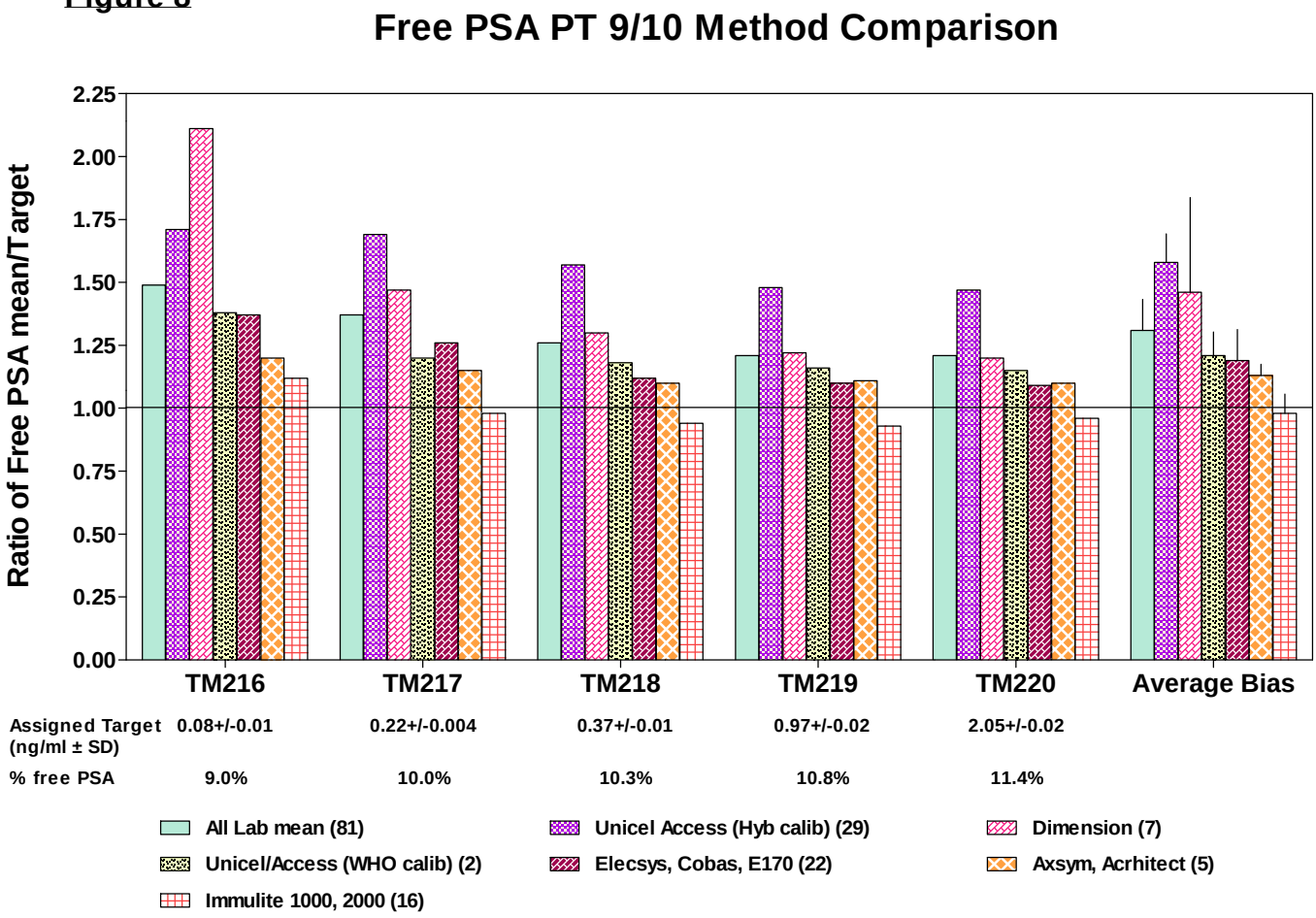


Figure 8



CA125

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method			All lab			
mean	20.1	46.0	31.5	32.4	28.1	
SD	2.5	5.7	3.9	4.4	3.5	
%CV	12.7%	12.3%	12.3%	13.5%	12.5%	12.7%
mean+3SD	27.7	63.1	43.2	45.5	38.6	
mean-3SD	12.4	29.0	19.9	19.2	17.6	
N	112	114	114	113	113	
mean/all kit median	0.94	0.99	0.97	0.97	0.95	0.96

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	21.2	46.6	32.5	33.3	29.6	
SD	0.8	2.3	1.6	1.4	1.4	
%CV	3.6%	4.9%	5.0%	4.2%	4.7%	4.5%
mean+3SD	23.6	53.5	37.4	37.4	33.8	
mean-3SD	18.9	39.8	27.7	29.1	25.4	
N	32	32	32	32	32	
kit median	21.3	46.2	32.6	33.2	29.5	
mean/all kit median	1.00	1.00	1.00	1.00	1.00	1.00

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	TOM	TO1	TOSOH ST-A1A			
mean	26.4	57.0	39.9	41.4	36.0	
SD	2.7	4.7	2.6	4.2	3.3	
%CV	10.2%	8.3%	6.5%	10.2%	9.2%	8.9%
mean+3SD	34.5	71.3	47.7	54.1	45.9	
mean-3SD	18.3	42.8	32.2	28.8	26.1	
N	5	5	5	5	5	
kit median	24.9	59.2	39.8	40.0	36.9	
mean/all kit median	1.24	1.22	1.23	1.24	1.22	1.23

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	JJ C/F	JJ1	Ortho Clinical Vitros ECi/Q/5600			
mean	18.6	43.7	30.7	29.4	27.7	
SD	2.3	4.1	1.2	3.7	1.4	
%CV	12.5%	9.3%	3.9%	12.5%	5.1%	8.7%
mean+3SD	25.5	55.9	34.3	40.4	31.9	
mean-3SD	11.6	31.5	27.0	18.3	23.4	
N	4	4	4	4	4	
kit median	19.5	45.2	30.9	30.3	27.0	
mean/all kit median	0.87	0.94	0.94	0.88	0.94	0.91

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	AB B/H	AB1	Abbott Axsym & Architect			
mean	23.3	52.3	35.3	37.9	31.5	
SD	3.0	5.1	3.8	4.2	4.1	
%CV	12.7%	9.7%	10.8%	11.1%	13.0%	11.5%
mean+3SD	32.2	67.5	46.8	50.4	43.8	
mean-3SD	14.4	37.1	23.9	25.3	19.2	
N	11	12	12	12	12	
kit median	24.3	54.8	36.0	39.5	32.4	
mean/all kit median	1.10	1.12	1.09	1.14	1.06	1.10

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	DP B/D/F	DP5	Siemens Immulite 1000/2000/2500			
mean	17.6	42.7	28.8	29.1	25.0	
SD	1.5	2.5	2.4	2.5	1.8	
%CV	8.4%	5.8%	8.3%	8.7%	7.2%	7.7%
mean+3SD	22.0	50.1	36.0	36.6	30.5	
mean-3SD	13.1	35.2	21.6	21.5	19.6	
N	32	32	32	32	32	
kit median	17.8	42.7	28.2	29.4	25.0	
mean/all kit median	0.83	0.91	0.89	0.87	0.85	0.87

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	21.6	52.2	34.5	36.9	30.5	
SD	1.0	1.9	1.9	2.1	1.8	
%CV	4.9%	3.7%	5.6%	5.6%	6.0%	5.2%
mean+3SD	24.7	58.0	40.3	43.0	36.0	
mean-3SD	18.4	46.3	28.7	30.7	25.0	
N	13	13	13	13	13	
kit median	21.8	51.7	34.5	37.6	30.7	
mean/all kit median	1.02	1.12	1.06	1.11	1.03	1.07

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA125					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	18.6	39.1	27.8	28.6	25.1	
SD	1.3	2.3	0.9	0.9	1.5	
%CV	6.8%	6.0%	3.3%	3.2%	5.8%	5.0%
mean+3SD	22.4	46.0	30.6	31.4	29.5	
mean-3SD	14.8	32.1	25.1	25.8	20.7	
N	16	16	15	15	16	
kit median	18.9	39.9	27.9	28.9	25.7	
mean/all kit median	0.88	0.84	0.86	0.86	0.85	0.86

Sample	TM216	TM217	TM218	TM219	TM220	Average
CA125 kit average:						
mean	21.0	47.6	32.8	33.8	29.3	
SD	3.1	6.4	4.2	5.1	3.9	
all kit median	21.2	46.6	32.5	33.3	29.6	
average %CV	8.4%	6.8%	6.2%	7.9%	7.3%	7.3%
SD %CV	3.6%	2.3%	2.6%	3.6%	2.9%	3.0%

CA19-9

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method			All lab			
mean	66.4	38.0	109.5	75.0	55.4	
SD	29.1	16.5	49.9	32.8	23.8	
%CV	43.8%	43.3%	45.5%	43.8%	43.0%	43.9%
mean+3SD	153.6	87.5	259.1	173.5	126.7	
mean-3SD	-20.9	-11.4	-40.1	-23.6	-16.0	
N	58	58	58	58	58	
all median	81.6	48.0	139.7	93.9	68.6	
mean/all kit median	1.79	1.77	1.79	1.78	1.80	1.79

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	39.2	22.2	65.8	44.6	32.5	
SD	2.1	1.4	3.5	3.3	1.6	
%CV	5.4%	6.5%	5.3%	7.4%	4.9%	5.9%
mean+3SD	45.5	26.5	76.3	54.5	37.3	
mean-3SD	32.9	17.9	55.3	34.8	27.7	
N	12	12	12	12	11	
kit median	39.5	22.2	66.0	44.9	32.6	
mean/all kit median	1.06	1.03	1.08	1.06	1.06	1.06

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method	ABH	AB1	Abbott Architect			
result	244.2	143.5	418.6	263.9	195.7	
N	1	1	1	1	1	
result/all kit median	6.59	6.68	6.85	6.28	6.37	6.55

* **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	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	34.9	20.8	56.5	39.4	28.9	
SD	1.0	0.7	1.7	1.0	1.1	
%CV	3.0%	3.2%	3.0%	2.5%	3.9%	3.1%
mean+3SD	38.0	22.7	61.5	42.4	32.2	
mean-3SD	31.8	18.8	51.5	36.5	25.5	
N	7	7	7	7	7	
kit median	35.0	20.6	55.6	39.2	29.3	
mean/all kit median	0.94	0.97	0.92	0.94	0.94	0.94

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	91.4	52.3	153.7	103.1	75.5	
SD	6.8	3.4	10.8	6.9	5.6	
%CV	7.4%	6.6%	7.0%	6.7%	7.4%	7.0%
mean+3SD	111.7	62.6	186.1	123.7	92.2	
mean-3SD	71.2	42.0	121.3	82.5	58.7	
N	32	32	31	32	32	
kit median	91.5	52.0	154.9	102.6	75.3	
mean/all kit median	2.47	2.43	2.51	2.45	2.46	2.47

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA19-9					
Method	TOM	TO1	TOSOH ST-A1A			
mean	23.8	13.9	36.9	25.7	19.7	
SD	1.2	0.6	2.2	1.7	1.4	
%CV	4.9%	4.3%	5.9%	6.6%	7.1%	5.8%
mean+3SD	27.3	15.7	43.4	30.8	23.9	
mean-3SD	20.3	12.2	30.3	20.6	15.5	
N	6	6	6	6	6	
kit median	23.9	14.0	37.4	26.3	20.1	
mean/all kit median	0.64	0.65	0.60	0.61	0.64	0.63

Sample	TM216	TM217	TM218	TM219	TM220	Average
CA19-9 kit average:						
mean*	47.3	27.3	78.2	53.2	39.1	
SD*	30.1	17.1	51.8	34.2	24.8	
all kit median	37.0	21.5	61.2	42.0	30.7	
average %CV	5.2%	5.1%	5.3%	5.8%	5.8%	5.4%
SD %CV	1.8%	1.7%	1.7%	2.2%	1.7%	1.8%

CA15-3

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method			All lab			
mean	86.7	29.2	49.7	44.0	57.7	
SD	21.8	7.6	12.9	12.2	15.3	
%CV	25.1%	26.1%	25.9%	27.8%	26.5%	26.3%
mean+3SD	152.2	52.0	88.3	80.6	103.6	
mean-3SD	21.3	6.4	11.2	7.4	11.8	
N	56	56	56	56	56	
all median	90.7	29.2	49.4	43.3	57.5	
mean/all kit median	1.17	1.21	1.24	1.20	1.17	1.20

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	ABB	AB1	Abbott AxSym			
mean	74.3	24.1	40.2	36.6	49.3	
SD	5.9	2.9	1.9	2.5	1.7	
%CV	8.0%	11.9%	4.7%	6.8%	3.5%	7.0%
mean+3SD	92.1	32.6	45.9	44.1	54.4	
mean-3SD	56.5	15.5	34.5	29.2	44.2	
N	3	3	3	3	3	
kit median	77.0	23.0	40.0	35.4	49.2	
mean/all kit median	1.00	1.00	1.00	1.00	1.00	1.00

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	106.7	37.3	63.8	57.4	73.8	
SD	11.2	3.9	5.7	6.2	7.7	
%CV	10.5%	10.6%	9.0%	10.8%	10.4%	10.3%
mean+3SD	140.3	49.2	81.0	76.0	96.8	
mean-3SD	73.2	25.5	46.6	38.8	50.8	
N	20	20	20	20	20	
kit median	108.0	37.6	64.4	57.8	76.0	
mean/all kit median	1.44	1.55	1.59	1.57	1.50	1.53

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	64.2	22.8	38.0	33.3	43.5	
SD	1.8	0.5	1.3	1.3	1.6	
%CV	2.9%	2.4%	3.5%	3.9%	3.8%	3.3%
mean+3SD	69.7	24.4	41.9	37.2	48.4	
mean-3SD	58.7	21.2	34.1	29.4	38.5	
N	10	10	10	10	10	
kit median	63.7	22.8	37.5	33.1	43.5	
mean/all kit median	0.86	0.95	0.95	0.91	0.88	0.91

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	DP D/F	DP5	Siemens Immulite 2000/2500			
mean	94.9	29.5	50.3	43.8	59.4	
SD	7.8	2.3	3.4	3.0	4.3	
%CV	8.2%	7.9%	6.7%	6.8%	7.2%	7.4%
mean+3SD	118.3	36.4	60.4	52.7	72.3	
mean-3SD	71.4	22.5	40.1	34.8	46.6	
N	12	12	12	12	12	
kit median	92.0	29.5	49.3	43.7	58.8	
mean/all kit median	1.28	1.22	1.25	1.19	1.21	1.23

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	JJC	JJ1	Ortho Clinical Vitros ECi/Q			
mean	71.3	20.8	37.2	32.0	42.7	
SD	12.6	0.4	0.7	0.0	1.2	
%CV	17.7%	1.9%	1.9%	0.0%	2.7%	4.9%
mean+3SD	109.2	22.0	39.4	32.0	46.1	
mean-3SD	33.4	19.6	35.0	32.0	39.2	
N	3	3	3	3	3	
kit median	64.0	21.0	37.0	32.0	42.0	
mean/all kit median	0.96	0.86	0.93	0.87	0.87	0.90

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	ABH	AB1	Abbott Architect			
mean	88.8	29.3	49.9	43.6	57.9	
SD	3.4	0.4	0.5	1.6	1.0	
%CV	3.8%	1.2%	1.0%	3.6%	1.8%	2.3%
mean+3SD	98.8	30.4	51.4	48.3	60.9	
mean-3SD	78.7	28.3	48.4	38.8	54.9	
N	3	3	3	3	3	
kit median	90.5	29.3	50.0	43.2	57.7	
mean/all kit median	1.19	1.22	1.24	1.19	1.18	1.20

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA15-3					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	47.8	16.7	28.6	24.1	31.7	
SD	3.2	0.6	0.6	0.9	1.8	
%CV	6.6%	3.4%	2.0%	3.8%	5.8%	4.3%
mean+3SD	57.3	18.4	30.3	26.8	37.2	
mean-3SD	38.3	15.0	26.9	21.4	26.2	
N	5	5	5	5	5	
kit median	49.7	16.9	28.8	24.0	32.3	
mean/all kit median	0.64	0.69	0.71	0.66	0.64	0.67

Sample	TM216	TM217	TM218	TM219	TM220	Average
CA15-3 kit average:						
mean	78.3	25.8	44.0	38.7	51.2	
SD	19.9	6.8	11.5	10.7	13.8	
all kit median	71.3	22.8	38.0	33.3	43.5	
average %CV	8.2%	5.6%	4.1%	5.1%	5.0%	5.6%
SD %CV	4.9%	4.4%	2.9%	3.4%	3.0%	0.9%

CA27.29

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA27.29					
Method			All lab			
mean	69.2	19.3	37.3	30.5	44.4	
SD	5.9	2.3	3.7	3.2	5.0	
%CV	8.5%	11.8%	9.8%	10.6%	11.4%	10.4%
mean+3SD	86.9	26.2	48.4	40.1	59.5	
mean-3SD	51.5	12.5	26.3	20.8	29.2	
N	46	45	45	44	46	
all median	70.7	19.3	37.2	30.5	44.0	
mean/all kit median	1.06	0.98	1.03	1.00	1.04	1.02

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA27.29					
Method	TOM	TO1	TOSOH ST-A1A			
mean	59.3	20.2	34.7	30.0	40.1	
SD	3.3	0.9	2.6	2.5	2.8	
%CV	5.5%	4.6%	7.4%	8.2%	7.1%	6.5%
mean+3SD	69.0	22.9	42.3	37.4	48.6	
mean-3SD	49.5	17.4	27.0	22.6	31.6	
N	7	7	7	7	7	
kit median	59.6	20.2	34.6	30.2	39.1	
mean/all kit median	0.91	1.02	0.96	0.99	0.94	0.96

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CA27.29					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	71.0	19.2	37.9	30.8	45.2	
SD	4.3	2.5	3.7	4.3	5.0	
%CV	6.1%	12.8%	9.7%	13.9%	11.1%	10.7%
mean+3SD	84.0	26.6	49.0	43.6	60.3	
mean-3SD	58.1	11.9	26.8	18.0	30.2	
N	38	37	37	38	38	
kit median	71.0	19.0	37.9	30.6	44.4	
mean/all kit median	1.09	0.98	1.04	1.01	1.06	1.04

Sample	TM216	TM217	TM218	TM219	TM220	Average
CA27.29 kit average:						
mean	65.2	19.7	36.3	30.4	42.7	
SD	8.3	0.7	2.3	0.5	3.6	
all kit median	65.2	19.7	36.3	30.4	42.7	
average %CV	5.8%	8.7%	8.6%	11.0%	9.1%	8.6%
SD %CV	0.4%	5.8%	1.7%	4.0%	2.8%	2.1%

CEA

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method			All lab			
mean	8.6	4.4	7.3	9.5	9.7	
SD	1.0	0.6	0.6	1.1	1.3	
%CV	11.8%	12.4%	8.8%	11.5%	13.7%	11.6%
mean+3SD	11.7	6.1	9.2	12.7	13.7	
mean-3SD	5.6	2.8	5.4	6.2	5.7	
N	160	157	149	159	161	
all median	8.8	4.5	7.4	9.5	9.7	
mean/all kit median	0.97	1.00	0.97	0.98	1.00	0.98

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	JJ C/F	JJ1	Ortho Clinical Vitros ECi/Q & 5600			
mean	10.5	6.0	11.1	11.2	12.9	
SD	1.7	2.1	0.8	1.9	0.9	
%CV	15.8%	34.9%	7.1%	16.7%	6.9%	16.3%
mean+3SD	15.4	12.3	13.4	16.8	15.6	
mean-3SD	5.5	-0.3	8.7	5.6	10.2	
N	11	11	11	11	11	
kit median	10.8	6.0	10.9	11.6	13.1	
mean/all kit median	1.18	1.35	1.48	1.16	1.32	1.30

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	TOM	TO1	TOSOH ST-A1A			
mean	12.6	6.6	10.5	13.6	14.2	
SD	0.7	0.4	0.6	0.9	0.9	
%CV	5.7%	5.6%	5.7%	6.5%	6.6%	6.0%
mean+3SD	14.8	7.7	12.3	16.2	17.0	
mean-3SD	10.5	5.5	8.7	10.9	11.4	
N	6	6	6	6	6	
kit median	12.7	6.7	10.6	13.7	14.3	
mean/all kit median	1.43	1.48	1.41	1.40	1.45	1.43

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	BCX	BC1	Beckman Access/2 CEA2			
mean	9.5	4.8	8.2	10.2	10.1	
SD	0.6	0.3	0.4	0.5	0.3	
%CV	6.1%	6.5%	4.9%	5.4%	3.1%	5.2%
mean+3SD	11.2	5.8	9.4	11.9	11.0	
mean-3SD	7.8	3.9	7.0	8.6	9.1	
N	9	9	9	9	9	
kit median	9.3	4.8	8.1	10.1	10.0	
mean/all kit median	1.07	1.08	1.09	1.06	1.03	1.07

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	DP B/D/F	DP5	Siemens Immulite 1000/2000/2500			
mean	9.2	4.4	7.5	10.3	10.3	
SD	0.7	0.4	0.6	0.9	0.7	
%CV	7.2%	9.1%	8.0%	8.8%	7.3%	8.1%
mean+3SD	11.2	5.6	9.3	13.0	12.5	
mean-3SD	7.2	3.2	5.7	7.6	8.0	
N	21	21	21	21	21	
kit median	9.2	4.4	7.6	9.9	10.2	
mean/all kit median	1.03	0.99	1.00	1.07	1.05	1.03

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	AB B/H	AB1	Abbott Axsym & Architect			
mean	8.3	4.4	7.3	9.2	9.4	
SD	0.8	0.6	0.8	0.9	1.1	
%CV	9.3%	12.9%	10.4%	9.8%	11.9%	10.8%
mean+3SD	10.7	6.0	9.6	12.0	12.8	
mean-3SD	6.0	2.7	5.1	6.5	6.1	
N	18	18	18	18	18	
kit median	8.4	4.6	7.6	9.3	9.5	
mean/all kit median	0.94	0.97	0.98	0.96	0.97	0.96

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	8.9	4.8	7.4	9.8	10.0	
SD	0.5	0.3	0.4	0.5	0.7	
%CV	5.7%	6.7%	5.8%	5.4%	7.1%	6.1%
mean+3SD	10.4	5.7	8.7	11.4	12.1	
mean-3SD	7.4	3.8	6.1	8.2	7.8	
N	57	57	57	57	57	
kit median	8.9	4.7	7.4	9.8	9.9	
mean/all kit median	1.00	1.07	0.99	1.02	1.02	1.02

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	BCU	BC1	Beckman Unicel CEA2			
mean	8.5	4.4	7.4	9.1	9.3	
SD	0.4	0.2	0.3	0.4	0.5	
%CV	5.1%	5.4%	3.8%	4.5%	5.0%	4.8%
mean+3SD	9.8	5.1	8.3	10.3	10.7	
mean-3SD	7.2	3.7	6.6	7.9	7.9	
N	17	17	17	17	17	
kit median	8.4	4.4	7.4	9.1	9.2	
mean/all kit median	0.96	0.98	0.99	0.94	0.95	0.96

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	DUV	DA2	Siemens Dimension VISTA			
mean	8.3	4.4	7.5	9.5	9.5	
SD	0.3	0.1	0.2	0.3	0.1	
%CV	3.6%	2.3%	2.3%	2.7%	1.2%	2.4%
mean+3SD	9.2	4.7	8.0	10.2	9.9	
mean-3SD	7.4	4.1	7.0	8.7	9.2	
N	3	3	3	3	3	
all median	8.3	4.4	7.6	9.5	9.6	
mean/all kit median	0.94	0.99	1.00	0.98	0.98	0.98

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	CEA					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	7.1	3.7	6.3	7.8	7.8	
SD	0.4	0.3	0.4	0.5	0.4	
%CV	6.4%	7.1%	6.0%	6.0%	5.2%	6.1%
mean+3SD	8.4	4.5	7.4	9.2	9.0	
mean-3SD	5.7	2.9	5.2	6.4	6.5	
N	25	25	25	25	25	
kit median	7.2	3.7	6.4	7.8	7.9	
mean/all kit median	0.80	0.83	0.84	0.81	0.80	0.81

Sample	TM216	TM217	TM218	TM219	TM220	Average
CEA kit average:						
mean	9.2	4.8	8.1	10.1	10.4	
SD	3.3	1.8	3.0	3.5	3.8	
all kit median	8.9	4.4	7.5	9.8	10.0	
average %CV	7.2%	10.1%	6.0%	7.3%	6.0%	7.3%
SD %CV	3.6%	9.8%	2.4%	4.1%	3.0%	3.0%

AFP

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method			All lab			
mean	5.1	9.2	13.6	17.9	26.1	
SD	0.8	1.2	1.4	1.9	2.6	
%CV	15.7%	13.0%	10.6%	10.7%	9.8%	12.0%
mean+3SD	7.5	12.8	17.9	23.6	33.8	
mean-3SD	2.7	5.6	9.3	12.2	18.4	
N	99	99	99	100	99	
all median	5.3	9.2	13.9	18.0	26.7	
mean/target	1.13	1.08	1.05	1.05	1.02	1.07

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	TOM	TO1	TOSOH ST-A1A			
mean	4.9	8.8	13.1	17.0	25.0	
SD	0.5	1.0	1.2	1.6	2.5	
%CV	10.8%	11.0%	9.3%	9.3%	10.1%	10.1%
mean+3SD	6.5	11.7	16.7	21.8	32.5	
mean-3SD	3.3	5.9	9.5	12.3	17.5	
N	3	3	3	3	3	
kit median	5.1	9.2	13.8	17.9	26.3	
mean/target	1.09	1.04	1.02	1.00	0.98	1.02

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	5.7	10.2	14.3	19.0	27.5	
SD	0.5	0.5	0.7	1.0	1.5	
%CV	8.4%	5.4%	5.1%	5.1%	5.4%	5.9%
mean+3SD	7.1	11.8	16.5	21.9	31.9	
mean-3SD	4.3	8.5	12.1	16.1	23.0	
N	25	25	26	26	26	
kit median	5.7	10.1	14.4	19.2	27.3	
mean/target	1.27	1.20	1.11	1.11	1.07	1.15

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	5.7	10.1	14.8	19.7	28.3	
SD	0.5	0.9	1.3	1.4	2.2	
%CV	9.1%	9.0%	8.7%	7.3%	7.7%	8.4%
mean+3SD	7.3	12.8	18.6	23.9	34.8	
mean-3SD	4.2	7.3	10.9	15.4	21.8	
N	15	15	15	15	15	
kit median	5.9	10.3	15.0	19.8	28.4	
mean/target	1.27	1.18	1.15	1.15	1.11	1.17

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	DUV	DA2	Siemens Dimension VISTA			
mean	5.3	9.6	14.3	19.0	28.1	
N	2	2	2	2	2	
mean/target	1.18	1.12	1.10	1.11	1.10	1.12

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	DP B/ D/F	DP5	Siemens Immulite 1000/2000/2500			
mean	4.1	7.8	12.2	16.1	23.4	
SD	0.4	0.6	0.4	0.8	1.5	
%CV	9.0%	8.1%	2.9%	5.2%	6.5%	6.3%
mean+3SD	5.2	9.7	13.2	18.5	27.9	
mean-3SD	3.0	5.9	11.1	13.6	18.8	
N	26	26	23	25	26	
kit median	4.2	7.8	12.2	16.2	23.5	
mean/target	0.91	0.92	0.94	0.94	0.91	0.92

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	BC U/X	BC1	Beckman Unicel & Access/2			
mean	5.2	9.3	14.1	18.3	27.3	
SD	0.3	0.7	0.7	0.7	1.5	
%CV	4.9%	7.2%	5.2%	4.1%	5.3%	5.3%
mean+3SD	6.0	11.3	16.3	20.6	31.7	
mean-3SD	4.5	7.3	11.9	16.1	23.0	
N	16	16	16	16	16	
kit median	5.3	9.3	14.2	18.2	27.6	
mean/target	1.16	1.10	1.09	1.07	1.07	1.10

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	JJC	JJ1	Ortho Clinical Vitros ECi/Q			
mean	4.0	7.5	10.8	14.2	21.7	
SD	0.0	0.2	0.4	0.4	0.9	
%CV	0.0%	3.1%	3.8%	2.5%	4.1%	2.7%
mean+3SD	4.0	8.2	12.1	15.3	24.4	
mean-3SD	4.0	6.8	9.6	13.1	19.0	
N	3	3	3	3	3	
kit median	4.0	7.4	10.7	14.1	21.7	
mean/target	0.89	0.89	0.84	0.83	0.85	0.86

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	AFP					
Method	ABB	AB1	Abbott AxSym			
mean	5.3	9.3	14.2	18.1	27.0	
SD	0.6	0.8	1.4	2.3	3.3	
%CV	11.2%	8.4%	10.0%	12.5%	12.1%	10.9%
mean+3SD	7.1	11.7	18.5	24.8	36.7	
mean-3SD	3.5	7.0	9.9	11.3	17.2	
N	9	9	9	9	9	
kit median	5.4	9.2	13.7	17.5	26.2	
mean/target	1.18	1.10	1.10	1.06	1.05	1.10

Sample	TM216	TM217	TM218	TM219	TM220	Average
AFP kit average:						
mean	4.9	8.9	13.3	17.4	25.7	
SD	0.7	1.0	1.3	1.8	2.4	
all kit median	5.3	9.3	14.1	18.2	27.1	
average %CV	7.6%	7.5%	6.4%	6.6%	7.3%	7.1%
SD %CV	3.9%	2.6%	2.8%	3.4%	2.9%	0.5%

Sample	TM216	TM217	TM218	TM219	TM220
AFP					
*IS target	4.5	8.5	12.9	17.1	25.6
SD (+/-)	0.20	0.39	0.92	1.06	1.57
% CV	4.4%	4.6%	7.1%	6.2%	6.1%
high (30%)	5.9	11.1	16.8	22.2	33.3
low (30%)	3.2	6.0	9.0	12.0	17.9

* target value from a traceable AFP standard

PSA

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method			All lab			
mean	1.07	2.6	4.2	10.3	20.5	
SD	0.12	0.3	0.4	1.1	2.1	
%CV	11.1%	10.5%	10.6%	10.9%	10.3%	10.7%
mean+3SD	1.4	3.4	5.5	13.7	26.9	
mean-3SD	0.7	1.8	2.9	6.9	14.2	
N	254	254	254	254	253	
all median	1.0	2.6	4.1	10.1	20.3	
mean/target	1.20	1.18	1.18	1.14	1.14	1.17

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	DP B/D/F	DP5	Siemens Immulite 1000, 2000, 2500			
mean	1.28	3.1	4.8	11.7	22.9	
SD	0.11	0.28	0.36	0.67	1.40	
%CV	8.5%	9.1%	7.5%	5.8%	6.1%	7.4%
mean+3SD	1.6	3.9	5.9	13.7	27.1	
mean-3SD	0.9	2.2	3.7	9.7	18.7	
N	25	25	25	25	24	
kit median	1.3	3.0	4.8	11.7	23.0	
mean/target	1.43	1.38	1.36	1.29	1.28	1.35

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	DUD	DA1	Siemens Dimension			
mean	1.21	3.0	4.7	11.9	23.2	
SD	0.06	0.1	0.2	0.4	0.8	
%CV	4.9%	3.6%	4.8%	3.4%	3.6%	4.1%
mean+3SD	1.4	3.3	5.4	13.1	25.7	
mean-3SD	1.0	2.6	4.0	10.7	20.7	
N	23	23	23	23	23	
kit median	1.2	3.0	4.7	11.9	23.3	
mean/target	1.36	1.34	1.33	1.32	1.29	1.33

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	DP B/D/F	DP6	Siemens Immulite 1000, 2000, 2500 3rd generation			
mean	1.20	2.8	4.6	11.2	23.3	
SD	0.09	0.43	0.53	1.44	1.71	
%CV	7.5%	15.3%	11.7%	12.9%	7.3%	10.9%
mean+3SD	1.5	4.1	6.2	15.5	28.4	
mean-3SD	0.9	1.5	3.0	6.9	18.2	
N	6	6	6	6	5	
kit median	1.2	2.7	4.7	10.4	24.0	
mean/target	1.35	1.27	1.29	1.24	1.30	1.29

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	BC U/X	BC2	Beckman Unicel/Access Hybritech calibration			
mean	1.08	2.7	4.4	11.0	22.0	
SD	0.06	0.15	0.21	0.54	1.13	
%CV	5.6%	5.3%	4.8%	5.0%	5.1%	5.2%
mean+3SD	1.3	3.2	5.1	12.6	25.4	
mean-3SD	0.9	2.3	3.8	9.4	18.6	
N	56	55	54	54	55	
kit median	1.1	2.7	4.4	11.0	21.9	
mean/target	1.21	1.24	1.24	1.22	1.22	1.23

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	TOM	TO1	TOSOH ST-A1A			
mean	0.92	2.3	3.7	9.0	17.9	
SD	0.04	0.1	0.2	0.5	1.1	
%CV	4.8%	4.0%	4.4%	5.4%	6.1%	4.9%
mean+3SD	1.1	2.6	4.2	10.5	21.2	
mean-3SD	0.8	2.0	3.2	7.6	14.6	
N	9	9	9	9	9	
kit median	0.9	2.3	3.7	8.9	18.4	
mean/target	1.04	1.04	1.04	1.00	1.00	1.02

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	BC U/X	BC3	Beckman Unicel/Access WHO calibration			
mean	0.95	2.3	3.7	9.0	17.9	
N	2	2	2	2	2	
mean/target	1.07	1.01	1.04	0.99	0.99	1.02

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	AB B/H	AB1	Abbott Axsym & Architect			
mean	0.99	2.5	4.0	10.1	20.4	
SD	0.07	0.14	0.23	0.66	1.03	
%CV	7.1%	5.5%	5.6%	6.5%	5.0%	5.9%
mean+3SD	1.2	2.9	4.7	12.0	23.5	
mean-3SD	0.8	2.1	3.4	8.1	17.4	
N	19	19	19	19	19	
kit median	1.0	2.5	4.1	10.1	20.8	
mean/target	1.12	1.13	1.14	1.12	1.14	1.13

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	JJC	JJ1	Ortho Clinical Vitros ECi/Q			
mean	1.06	2.6	4.0	9.5	19.2	
SD	0.13	0.1	0.2	0.3	1.5	
%CV	12.7%	5.2%	4.0%	3.3%	7.8%	6.6%
mean+3SD	1.5	3.0	4.5	10.4	23.7	
mean-3SD	0.7	2.2	3.5	8.5	14.7	
N	14	14	14	13	14	
kit median	1.1	2.5	4.0	9.5	18.7	
mean/target	1.19	1.15	1.12	1.05	1.07	1.12

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	COB	BA1	Siemens ADVIA-Centaur			
mean	1.02	2.5	3.9	9.6	19.2	
SD	0.06	0.1	0.2	0.6	1.2	
%CV	6.1%	4.9%	5.1%	6.2%	6.4%	5.7%
mean+3SD	1.2	2.8	4.5	11.4	22.9	
mean-3SD	0.8	2.1	3.3	7.8	15.5	
N	58	58	57	58	58	
kit median	1.0	2.5	3.9	9.7	19.3	
mean/target	1.14	1.10	1.10	1.06	1.07	1.10

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	0.98	2.4	3.8	9.4	18.8	
SD	0.06	0.11	0.18	0.43	0.80	
%CV	5.7%	4.7%	4.6%	4.6%	4.3%	4.8%
mean+3SD	1.2	2.7	4.4	10.7	21.2	
mean-3SD	0.8	2.1	3.3	8.1	16.4	
N	38	38	38	38	38	
kit median	1.0	2.4	3.8	9.4	18.9	
mean/target	1.10	1.08	1.08	1.05	1.05	1.07

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	PSA					
Method	JJF	JJ1	Ortho Clinical Vitros 5600			
mean	1.03	2.4	3.7	8.9	17.7	
SD	0.10	0.1	0.1	0.1	0.4	
%CV	9.3%	2.1%	1.6%	0.6%	2.1%	3.1%
mean+3SD	1.3	2.5	3.8	9.0	18.8	
mean-3SD	0.7	2.2	3.5	8.7	16.5	
N	4	4	4	4	4	
kit median	1.1	2.4	3.7	8.9	17.8	
mean/target	1.15	1.07	1.03	0.98	0.98	1.04

Sample	TM216	TM217	TM218	TM219	TM220	Average
PSA kit average:						
mean	0.9	2.2	3.5	8.6	17.3	
SD	0.3	0.7	1.1	2.8	5.6	
all kit median	1.0	2.5	4.0	9.8	19.8	
average %CV	7.2%	6.0%	5.4%	5.4%	5.4%	5.9%
SD %CV	2.4%	3.7%	2.6%	3.2%	1.7%	0.8%

Sample	TM216	TM217	TM218	TM219	TM220
PSA					
* IS target	0.89	2.2	3.6	9.0	18.0
SD (+/-)	0.06	0.15	0.22	0.44	0.48
% CV	6.5%	6.8%	6.3%	4.9%	2.7%
high (25%)				11.3	22.4
low (25%)				6.8	13.5
high (30%)**	1.2	2.9	4.6		
low (30%)**	0.6	1.6	2.5		

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

Free PSA

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method			All lab			
mean	0.12	0.30	0.47	1.17	2.47	
SD	0.03	0.07	0.10	0.23	0.45	
%CV	23.9%	21.8%	21.2%	19.5%	18.3%	20.9%
mean+3SD	0.20	0.50	0.76	1.85	3.83	
mean-3SD	0.03	0.10	0.17	0.48	1.11	
N	78	80	81	81	81	
all median	0.11	0.30	0.43	1.12	2.32	
mean/target	1.49	1.37	1.26	1.21	1.21	1.31

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method	DUD	DA1	Siemens Dimension			
mean	0.17	0.32	0.48	1.19	2.45	
SD	0.06	0.04	0.04	0.10	0.17	
%CV	32.7%	11.7%	9.0%	8.0%	7.1%	13.7%
mean+3SD	0.33	0.44	0.61	1.47	2.98	
mean-3SD	0.00	0.21	0.35	0.90	1.93	
N	7	7	7	7	7	
kit median	0.15	0.31	0.49	1.21	2.46	
mean/target	2.11	1.47	1.30	1.22	1.20	1.46

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method	BC U/X	BC2	Beckman Unicel/Access Hybritech calibration			
mean	0.14	0.37	0.58	1.44	3.00	
SD	0.03	0.03	0.04	0.07	0.14	
%CV	18.6%	7.7%	7.4%	4.5%	4.8%	8.6%
mean+3SD	0.21	0.46	0.71	1.63	3.44	
mean-3SD	0.06	0.29	0.45	1.24	2.57	
N	29	29	29	28	29	
kit median	0.14	0.37	0.59	1.44	3.00	
mean/target	1.71	1.69	1.57	1.48	1.47	1.58

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method	DP B/D	DP5	Immulite 1000 & 2000			
mean	0.09	0.22	0.35	0.90	1.96	
SD	0.01	0.02	0.04	0.09	0.09	
%CV	8.2%	9.9%	10.9%	9.5%	4.7%	8.6%
mean+3SD	0.11	0.28	0.46	1.16	2.24	
mean-3SD	0.07	0.15	0.24	0.64	1.68	
N	14	16	16	16	15	
kit median	0.09	0.22	0.35	0.90	1.93	
mean/target	1.12	0.98	0.94	0.93	0.96	0.98

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					Bias
Method	BC U/X	BC3	Beckman Unicel/Access WHO calibration			
mean	0.11	0.27	0.44	1.13	2.36	
N	2	2	2	2	2	
mean/target	1.38	1.20	1.18	1.16	1.15	1.21

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method	AB B/ H	AB1	: Axsym & Architect			
mean	0.10	0.25	0.41	1.07	2.26	
SD	0.01	0.03	0.04	0.08	0.23	
%CV	11.9%	11.7%	9.8%	7.8%	10.2%	10.3%
mean+3SD	0.13	0.34	0.53	1.32	2.95	
mean-3SD	0.06	0.17	0.29	0.82	1.57	
N	5	5	5	5	5	
kit median	0.10	0.25	0.40	1.11	2.23	
mean/target	1.20	1.15	1.10	1.11	1.10	1.13

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	free PSA					
Method	BM E/R	BM1	Roche Elecsys, Cobas, E170			
mean	0.11	0.28	0.42	1.07	2.24	
SD	0.01	0.02	0.03	0.06	0.11	
%CV	7.3%	8.0%	6.6%	6.1%	5.0%	6.6%
mean+3SD	0.13	0.34	0.50	1.26	2.57	
mean-3SD	0.09	0.21	0.33	0.88	1.90	
N	21	21	22	22	22	
kit median	0.11	0.27	0.41	1.08	2.23	
mean/target	1.37	1.26	1.12	1.10	1.09	1.19

Sample	TM216	TM217	TM218	TM219	TM220	Average
free PSA kit average:						
mean	0.09	0.21	0.33	0.85	1.78	
SD	0.03	0.06	0.08	0.18	0.35	
all kit median	0.11	0.27	0.43	1.10	2.31	
average %CV	15.8%	9.8%	8.7%	7.2%	6.4%	9.6%
SD %CV	10.5%	1.9%	1.7%	1.9%	2.3%	3.8%

Sample	TM216	TM217	TM218	TM219	TM220
free PSA					
* IS target	0.08	0.22	0.37	0.97	2.05
SD (+/-)	0.01	0.004	0.01	0.02	0.05
% CV	8.9%	1.7%	2.2%	1.7%	2.4%
high (30%)	0.10	0.29	0.48	1.26	2.67
low (30%)	0.06	0.15	0.26	0.68	1.44

* target value from a traceable free PSA standard.

Complexed PSA

Sample	TM216	TM217	TM218	TM219	TM220	Average
Analyte	Complexed PSA					
Method			All lab			
mean	0.9	2.2	3.6	8.8	17.6	
SD	0.0	0.1	0.2	0.4	0.8	
%CV	5.2%	4.3%	4.4%	4.3%	4.3%	4.5%
mean+3SD	1.0	2.5	4.1	10.0	19.9	
mean-3SD	0.8	1.9	3.1	7.7	15.3	
N	10	10	10	10	10	
all median	0.9	2.2	3.6	8.8	17.8	