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Executive Deputy Commissioner

Howard A. Zucker, M.D., J.D. Acting Commissioner of Health

June 23, 2014

#### New York State Tumor Marker Proficiency Test 5-2014 Evaluation<sup>1</sup>

Dear Laboratory Director,

Attached is a summary and evaluation of the New York State Proficiency Test from May 2014 for Tumor Markers AFP, CA125, CA15-3, CA27.29, CA19-9, CEA, PSA, free PSA and complexed PSA.

Laboratories were challenged with five (5) different coded specimens prepared by Wadsworth Center personnel. Purified analyte preparations were added to a human serum-based matrix, sterile filtered, aseptically dispensed into sample vials and stored at 4°C until mail-out. All laboratories received the same samples, regardless of whether they tested for one or all of the analytes.

#### **Result evaluation:**

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

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

Laboratory contacts were sent an email alert indicating the availability of the individual result report. This critique with summary tables and graphs is then sent by a separate email to the same laboratory contacts. It will also be posted on the Wadsworth website at:

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

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

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

For grading purposes, all results were evaluated based on their respective peer group mean. This mean was determined with the robust regression followed by outlier identification (ROUT) statistical method, as implemented in GraphPad's Prism<sup>®</sup>6 software (Harvey J Motulsky and Ronald E Brown, "Detecting outliers when fitting data with nonlinear regression – a new method based on robust nonlinear regression and the false discovery rate," BMC Bioinformatics 7:123 (2006). Available at: <u>http://www.biomedcentral.com/1471-2105/7/123</u>). This method identifies outliers through robust statistical analysis with a nonlinear curve fit of the data, thus removing

<sup>&</sup>lt;sup>1</sup> 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.



points that can skew calculations of the mean. For our purposes, the target is the mean determined from the best fit values derived from that analysis while the standard deviation (SD) was calculated by multiplying the standard error of the mean for each individual peer group with the square root of the number of labs in that peer group. The allowable error and range were determined from the average of the median %CV's for each sample across all methods (see summary tables); allowances for increased scatter at low concentrations were made for some analytes. Please note that, unless indicated otherwise, we combined results from different instruments made by the same manufacturer and/or brand into one peer group, except where the linear regression line between the results from two instruments showed a significant (p<0.01) deviation from identity.

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

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

#### **Discussion:**

<u>CA125</u> (Table 1, Figure 1): Results were reported by 110 labs using instruments from eight different manufacturers corresponding to eight peer groups. Five of the groups included ten or more labs each, together comprising 89% of the labs. Substantial variation between the peer groups was seen, ranging from 54% to 219% of the all method median.

**CA19-9** (Table 2, Figure 2): Results were reported by 69 labs using instruments from seven different manufacturers, but two manufacturers were used by only two labs each, which left five peer groups for grading. Forty-two percent of all reporting labs used Siemens ADVIA-Centaur XP, 22% used either Beckman's Unicel or Access/2, 19% used either of Roche's Elecsys/Cobas e411 or E170/Cobas e601, and 7% used the Tosoh ST-AIA method. The CA19-9 concentrations in four of the samples were near or below the lower limit of detection for several methods, making the results non-gradable. Labs that used those methods received an automatic "Pass credit" for those samples. TM271 which was not at the LOD, shows large differences in how each method measured CA19-9, ranging from 84% (Tosoh) to 552% (Abbott) of the all method median. The results from Siemens Advia-Centaur XP averaged almost 2 times higher than the all method median, whereas results from Beckman and Roche were within +/-7% of the all method median. Used by three labs, the Abbott Architect method results averaged 5.5 times higher than the all method median, as shown in Table 2 and Figure 2. As previously seen, there continues to be discordance between the various methods used to measure CA19-9, at least under the conditions of the NYS PT.

The MUC1 breast cancer antigen was measured by 102 labs, with slightly more than half (55%) using an instrument from one of six manufacturers to measure CA15-3 (Table 3, Figure 3) and the remainder using an instrument from one of two manufacturers to measure CA27.29 (Table 4, Figure 4). Four of the samples were at or below the lower limit of detection for several methods, and were thus non-gradable. Labs that used those methods received an automatic "Pass credit" for those samples. TM271 which was not at the LOD, shows that Abbott, Roche, and Siemens Advia were all within +/-6% of the all method median and altogether comprise 70% of the labs measuring CA15-3. In contrast, the Beckman Unicel/Access results exhibited a notable negative bias, averaging -33% from the all method medians, while Siemens Immulite showed a high bias of 27% above the median. For TM271, CA27.29 measurements showed an 18% difference between the ADVIA Centaur XP/CP and the Tosoh methods. In contrast the difference in CA27.29 concentrations in the other samples was much larger. The median CA27.29 measurements averaged 24% higher than the median CA15-3 measurements for sample TM271; furthermore, whereas levels of CA15-3 were close to the lower limit of detection for samples TM272-275, they were significantly higher for CA27.29. We are still investigating what may have caused this discrepancy.

<u>**CEA</u>** (Table 5, Figure 5): Results were reported by 162 labs using instruments from eight different manufacturers corresponding to eight peer groups comprising from 6 to 45 labs. Results from the Abbott Architect, Beckman Unicel/Access/2, Siemens Advia Centaur, Siemens Dimension Vista and Ortho Clinical Diagnostics' Vitros ECi/ECiQ & 5600 methods, which altogether accounted for 81% of the labs, were within +/-15% of the medians. In contrast, Roche methods were 26% below the median, whereas TOSOH ST-AIA exhibited a high positive bias averaging 45% <u>above</u> the median, which is consistent with what has been seen on previous NYS PT events.</u>

For **AFP**, **PSA and free PSA**, <u>target values</u> were assigned using traceable International Standards. However, for scoring purposes the results were evaluated based on their respective peer group mean in the same way as all the other analytes. For the purpose of method comparison, the tables show the method bias against both the all method medians and the assigned target values, but the graphs show the performance relative only to the assigned targets.

<u>AFP</u> (Table 6, Figure 6): Results were reported by 96 labs using instruments from eight different manufacturers corresponding to eight peer groups. Four of those comprised less than ten labs each, which together corresponds to nineteen percent of the total number of labs. Six of the eight methods, used by 75% of the labs, gave results within  $\pm$ -5% of the all method median, but averaged 13% higher than the assigned targets. Of the remaining two methods, Roche measured 17% higher than the all method median, and 33% higher than the targets, whereas the Ortho Clinical Diagnostics Vitros peer group (used by only 3% of participants) was the only method with results below the assigned target (-11%) and was 21% below the all method median. Thus, it appears that most methods somewhat overestimated AFP levels in our samples, a result that is similar to what has been observed in previous NYS PT events for these methods.

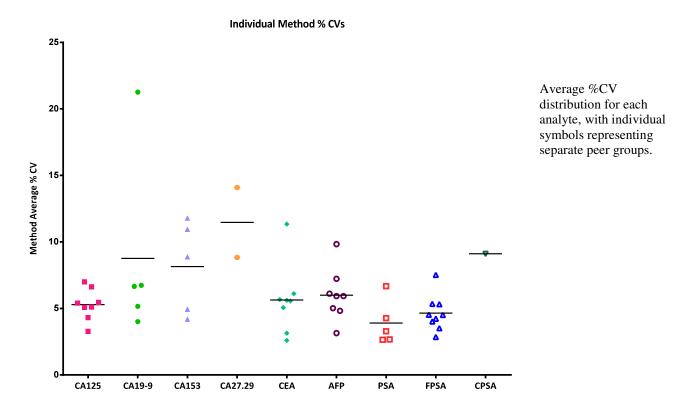
**PSA** (Table 7, Figure 7): Results were reported by 243 labs using instruments from ten manufacturers, although one instrument was used by only one lab (N=1) and was therefore not included in Table 7. Samples were prepared with varying concentrations of total PSA, but the same proportion of free PSA (20%) to assess if the total PSA level affected the proportion of free PSA. While there were substantial differences in total and free PSA measurements between methods, there were only minor differences in the proportion of free PSA between samples (Tables 8 A and B). Results from six of the peer groups were within +/-10% of the all method median, and these were between +3% and +15% from the assigned targets. Of the remaining methods, the Beckman Unicel & Access2 with Hybritech calibration was 14% above the all method median and 26% above the target (no lab used the WHO calibration), and Siemens Dimension RxL Max/Xpand Plus/EXL was 18% above the all method median and 31% above the assigned targets. In contrast, results from Ortho Clinical Vitros ECi/ECiQ & 5600 were 12% lower than the all method median and 2% lower than the targets.

Free PSA (Table 8, Figure 8): Results were reported by 80 labs using instruments from seven manufacturers which corresponded to five peer groups plus two others with N<3. Two more of the five peer groups comprised less than 10 labs each, and along with the N<3 methods made up 22% of the participants. The remaining three methods were used by 33% of labs for Beckman Unicel/Access calibrated with the Hybritech standards, 30% of labs for Roche Elecsys/E170/Cobas, and 15% for Siemens Immulite 2000. As seen in previous PT events, results obtained with the Beckman instruments calibrated with Hybritech calibrators were distinctly higher than those obtained by the rest of the methods (37% higher than the all method medians and 25% higher than the targets), while there were no longer any results reported from Beckman Unicel/Access calibrated with the WHO standards. Of the other methods, two (Abbott Architect and Roche Elecsys & Cobas) were within +/-10% of the assigned targets and two (Siemens Immulite 2000 and Siemens Dimension Vista) were 15% and 20% below the assigned targets respectively. Nevertheless, all but Beckman Unicel/Access methods were within 20% of each other, whereas Beckman remains consistently high. We calculated % free PSA for each peer group using their respective average PSA and free PSA levels. The differences in calculated % free PSA between methods showed a pattern similar to that of the measured free PSA.

Please note, labs are required to measure and report <u>free PSA</u> for all proficiency test samples if free PSA is on their test menu. We understand that this may in some cases be a deviation from a lab's policy in dealing with free PSA and could mean that PT samples are not treated exactly like patient samples.

Finally, 9 labs measured <u>complexed PSA</u> and all of them used either the Siemens ADVIA-Centaur XP or CP instrument, which exhibited little difference between them. Due to the small group size and a couple of outliers, the samples do not show quite as good an agreement within the method as usual, with an average %CV of 9% (Table 9).

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



While some of the differences between methods may be attributed to the artificial nature of the PT samples, others are more likely due to inherent differences in the assays themselves. We make every effort to minimize the differences that can be attributed to the sample composition and suggest that despite the somewhat artificial nature of the PT samples, the differences between the results obtained by various methods might also be reflected in patient serum samples. Therefore, we encourage labs and physicians to use caution when comparing the results from the same patient measured with different methods on different instruments, since clearly not all methods are equal. For this reason, we require that the method used be clearly indicated on the patient report (Oncology Standard OC S1). We also encourage you to educate your physician clients about this potential problem.

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

accurately reflect patient derived samples.

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

Note: As per new guidelines from CMS, measuring and reporting results from a second instrument is no longer allowed.

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 <u>clepeptrs@health.state.ny.us</u>, or directly to Kathi Wagner at (518) 402-4266 or by e-mail at <u>kathleen.wagner@health.ny.gov</u>.

The scheduled date for the remaining 2014 Tumor Marker Proficiency Test event is:

#### Mail-out date:

<u>Due date</u>:

September 9, 2014

September 24, 2014

If you have any questions or wish to discuss topics alluded to in this critique, contact Susanne McHale at <u>susanne.mchale@health.ny.gov</u> (518) 486-5775, or myself at <u>erasmus.schneider@health.ny.gov</u> or (518) 473-4856.

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

# Table 1: 5-14 NYS Tumor Marker PT Summary for CA 125

Abboil Architect         Abb         Automatical and a stress of the stre	Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
TM271       9       27.8       22.4       33.2       5.4       6.55       1.24         TM272       10       89.5       73.4       106.5       16.1       5.51       1.44         TM273       10       119.0       97.6       140.4       21.4       5.85       1.44         TM275       10       89.8       73.6       106.1       12.2       4.21       1.46         TM275       10       89.8       73.6       106.1       15.2       5.19       1.44         TM271       14       23.6       18.2       29.0       5.4       5.47       0.02         TM271       14       60.8       41.7       59.9       9.1       7.70       0.022         TM272       14       60.8       6.03       56.0       80.6       12.2       7.38       0.08         TM271       14       97.6       30.3       44.4       6.8       6.94       0.31         TM271       18       69.7       78.5       12.0       3.22       1.08       1.11         TM271       18       69.7       78.5       12.0       3.22       1.08       1.08         TM272       18       <	· ·		( /			- ()				
TM272     10     89.5     73.4     105.6     16.1     5.51     1.45       TM273     10     68.0     55.8     80.2     12.2     4.21     1.46       TM275     10     68.0     55.8     106.0     112.0     5.46     0.86     1.41       Beckman Unicel & Access/2     E										
TM273       10       119.0       97.6       140.4       21.4       5.85       1.44         TM274       10       68.0       56.8       60.2       12.2       4.21       1.46         TM275       10       69.8       73.6       106.0       16.2       5.19       1.48         TM271       14       23.6       18.2       29.0       5.4       5.47       7.00       0.82         TM272       14       66.8       61.0       13.2       7.38       0.83       0.83         TM274       14       67.8       50.8       60.6       12.3       7.38       0.83         TM274       14       67.8       50.8       60.6       12.3       7.38       0.83         TM274       14       67.8       50.8       6.44       0.81       0.11         Roche Elecsys & Cobes       Elecsys       54.5       78.5       12.0       3.22       10.8       1.14         M272       18       66.5       54.5       78.5       12.0       3.22       10.8       1.08         TM273       18       88.8       72.8       10.4.8       16.0       3.33       1.08       1.08	TM271	9	27.8	22.4	33.2	5.4	6.55		1.24	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	TM272	10	89.5	73.4	105.6	16.1	5.51		1.45	
TM275     10     99.8     73.6     106.0     16.2     5.19     1.48       mean ±SD     5.46     0.86     1.41     0.10       Backman Unicel & Access/2     BCUBCX     1     1.4     23.6     18.2     29.0     5.4     5.47     1.05       TM271     14     68.3     56.0     80.6     12.3     7.38     0.83       TM273     14     68.3     56.0     80.6     12.3     7.38     0.83       TM274     14     37.6     30.8     44.4     6.8     6.94     0.81       TM275     14     49.1     40.3     57.9     8.8     7.49     0.81       TM271     18     19.7     7.85     12.0     3.22     1.08       TM271     18     65.7     54.5     16.0     3.33     1.08       TM273     18     65.7     53.9     77.5     11.8     3.04     1.08       TM275     18     65.7     53.9     77.7     18.8     3.04     1.08       TM275     18     65.7     65.9     10.2     4.36     0.92       TM275     18     65.7     65.9     60.1     10.1     5.09     0.92       TM275     32 <td>TM273</td> <td>10</td> <td>119.0</td> <td>97.6</td> <td>140.4</td> <td>21.4</td> <td>5.85</td> <td></td> <td>1.44</td> <td></td>	TM273	10	119.0	97.6	140.4	21.4	5.85		1.44	
Beckman Uncel & Access/2 BOU/BCX         mean ±SD         5.46         0.86         1.41         0.10           Beckman Uncel & Access/2 BOU/BCX         14         23.6         18.2         29.0         5.4         5.47         1.05           TM271         14         50.8         11.2         29.9         9.1         7.70         0.82           TM273         14         68.3         56.0         80.6         12.3         7.38         0.83           TM274         14         49.1         40.3         57.9         8.8         7.49         0.81           TM271         18         19.7         14.3         25.1         5.4         3.65         0.88         0.11           Roche Elecsys & Cobas BME/BMH         17027         18         66.5         54.5         78.5         12.0         3.22         1.08           TM271         18         50.2         41.2         59.2         9.0         3.15         1.08           TM274         18         50.2         41.2         59.2         9.0         3.15         1.08           TM274         18         50.2         18.8         24.6         5.33         1.08           TM273         33<	TM274	10	68.0	55.8	80.2	12.2	4.21		1.46	
Beckman Unicel & Access/2 BCU/BCX TM271 14 23.6 18.2 29.0 5.4 5.47 1.05 TM272 14 50.8 41.7 59.9 9.1 7.70 0.82 TM273 14 68.3 56.0 80.6 12.3 7.38 0.83 TM274 14 37.6 30.8 44.4 6.8 6.94 0.81 TM275 14 49.1 40.3 57.9 8.8 7.49 0.81 mean ±SD 7.00 0.90 0.86 0.11 Roche Elecsys & Cobas BME/BMR TM271 18 19.7 14.3 25.1 5.4 3.65 0.88 TM272 18 66.5 54.5 78.5 12.0 3.22 1.08 TM275 18 65.7 53.9 77.5 11.8 3.04 1.08 TM272 33 7.64 62.5 69.2 13.8 5.63 0.92 TM271 33 24.2 18.8 29.6 5.4 5.33 1.08 TM272 32 56.7 44.5 66.9 10.2 4.46 0.92 TM271 33 24.2 18.8 29.6 5.4 5.33 1.08 TM272 32 56.0 45.9 66.1 10.1 5.09 0.92 TM274 33 43.0 35.3 50.7 7.7 4.98 0.92 TM274 18 29.3 55.0 45.9 66.1 10.1 5.09 0.92 TM274 33 43.0 35.3 50.7 7.7 4.98 0.92 TM274 18 29.3 23.9 54.7 55.4 5.84 0.48 TM274 18 29.0 65.1 0.43 0.92 TM274 18 29.3 23.9 44.7 55.4 5.84 0.48 TM273 18 38.9 31.9 45.9 7.0 5.91 0.44 TM275 18 28.1 22.7 33.5 5.4 6.26 0.46 TM271 21 19.5 14.1 24.9 5.4 7.59 0.87 TM272 18 29.3 23.9 34.7 5.4 5.84 0.48 TM273 18 38.9 31.9 45.9 7.0 5.91 0.44 TM275 18 28.1 22.7 33.5 5.4 6.26 0.46 TM271 4 21.3 15.9 26.7 5.4 6.62 0.95 TM272 4 154.0 126.3 181.7 2.7.7 4.86 2.50 TM271 4 21.3 15.9 26.7 5.4 6.62 0.95 TM272 4 154.0 126.3 181.7 2.7.7 4.86 2.50 TM271 4 21.3 15.9 26.7 5.4 6.62 0.95 TM272 4 154.0 126.3 181.7 2.7.7 4.86 2.50 TM274 4 20.8 171.2 27.5 5.40 6.28 2.53 TM274 4 115.1 94.4 135.8 20.7 3.78 2.47 TM274 4 19.9 14.5 25.3 5.4 0.50 0.89 TM274 4 9.9 14.5 25.3 5.4 0.50 0.89 TM275 5 7 4.5 7 6.5 7 10.0 4.33 0.99 TM272 5 55.7 4.5 7 6.5 7 10.0 4.33 0.99 TM275 5 7 4.5 7 6.5 7 10.0 4.33 0.99 TM272 5 5.5 7 4.5 7 6.5 7 10.0 4.33 0.99 TM272 5 5.5 7 4.5 7 6.5 7 10.0 4.33 0.99 TM274 5 3.87 71.7 7 5.0 0.83 TM275 5 7 4.5 7 5.0 0.83 T	TM275	10	89.8	73.6	106.0	16.2	5.19		1.48	
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TM271       14       23.6       16.2       29.0       5.4       5.47       105         TM272       14       50.3       41.7       59.9       9.1       7.70       0.82         TM273       14       68.3       56.0       80.6       12.3       7.38       0.83         TM274       14       37.6       30.8       44.4       6.8       6.94       0.81         TM275       14       49.1       40.3       57.9       8.8       7.49       0.81         TM271       18       19.7       14.3       25.1       5.4       3.65       0.88       1.08         TM271       18       66.5       54.5       7.85       12.0       3.22       1.08         TM273       18       68.8       7.28       104.8       16.0       3.33       1.08         TM274       18       50.2       41.2       59.2       9.0       3.15       1.08         TM274       18       50.2       74.5       66.9       10.2       4.46       0.92         TM273       33       76.4       62.6       90.2       13.8       5.63       0.92         TM273       33       43.0		s/2								
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TM273       14       68.3       56.0       80.6       12.3       7.38       0.83         TM274       14       37.6       30.8       44.4       6.8       6.94       0.81         TM275       14       49.1       40.3       57.9       8.88       7.49       0.90       0.86       0.11         Roche Elecsys & Cobas       EME/EMR										
TM274       14       49.1       40.3       57.9       mean ±SD       7.49       0.81         TM275       14       49.1       40.3       57.9       mean ±SD       7.00       0.90       0.86       0.11         Roche Elecays & Cobas       mean ±SD       7.00       0.86       0.11       0.86       0.11         BMC#0MR       18       19.7       14.3       25.1       5.4       3.65       0.88       0.88         TM272       18       66.5       54.5       78.5       12.0       3.22       1.08       0.09         TM273       18       66.7       59.2       9.0       3.15       1.08       0.09         Siemens Advia Centaur XP & CP       mean ±SD       3.28       0.23       1.04       0.09         Siemens Advia Centaur XP & CP       mean ±SD       5.4       5.33       1.08       1.08         TM271       33       24.2       18.8       29.6       5.4       5.33       0.92         TM273       33       76.4       62.6       60.9       10.2       4.46       0.92         TM274       33       45.9       60.7       7.7       4.98       0.92       0.7										
TM275     14     49.1     40.3     57.9     8.8     7.49     0.81       mean ±SD     7.00     0.90     0.86     0.11       Roche Elecsys & Cobas     5000     5000     0.86     0.11       TM271     18     18.7     14.3     25.1     5.4     3.65     0.83       TM271     18     66.5     54.5     76.5     12.0     3.22     1.08       TM273     18     88.8     72.8     104.8     16.0     3.33     1.08       TM274     18     65.7     53.9     77.5     11.8     3.04     1.08       TM275     18     65.7     53.9     77.5     11.8     3.04     1.08       Siemens Advia Centaur XP & CP     COROCO										
mean ±SD         7.00         0.90         0.86         0.11           Roche Elecsys & Cobas         BME/EMR         5.4         3.65         0.88           TM271         18         66.5         54.5         76.5         12.0         3.22         1.08           TM273         18         66.5         54.5         77.5         12.0         3.22         1.08           TM274         18         50.2         41.2         59.2         9.0         3.15         1.08           TM275         18         56.7         53.9         77.5         11.8         3.04         1.08           TM271         33         24.2         56.6         5.4         5.33         1.08           TM272         32         56.7         46.5         66.9         10.2         4.46         0.92           TM273         33         76.4         62.6         90.2         13.8         5.63         0.92           TM273         33         76.4         62.6         90.2         13.8         5.63         0.92           TM273         33         76.4         62.6         90.2         13.8         5.63         0.87           TM274         <										
Roche Eleosys & Cobas           BME/BMR           TM271         18         19.7         14.3         25.1         5.4         3.65         0.88           TM272         18         66.5         54.5         78.5         12.0         3.22         1.0.0           TM273         18         88.8         72.8         104.8         16.0         3.33         1.08           TM274         18         50.2         41.2         59.2         9.0         3.15         1.08           TM275         18         65.7         53.9         77.5         11.8         3.04         1.08           TM271         33         24.2         18.8         29.6         5.4         5.33         1.08           TM271         33         24.2         18.8         29.6         5.4         5.33         1.08           TM272         32         56.7         46.5         66.9         10.2         4.46         0.92           TM273         33         43.0         35.3         5.10         0.43         0.92           TM275         32         56.0         45.9         66.1         10.1         5.9         0.67	TM275	14	49.1	40.3	57.9			0.00		0.11
BME/BMR         Immatrix	Boche Elecsvs & Cobas					mean 100	7.00	0.90	0.00	0.11
TM272       18       66.5       54.5       78.5       12.0       3.22       1.08         TM273       18       88.8       72.8       104.8       16.0       3.33       1.08         TM274       18       65.7       53.9       77.5       11.8       3.04       1.08         TM275       18       65.7       53.9       77.5       11.8       3.04       1.08         Siemens Advia Centaur XP & CP       COB(COC)	BME/BMR									
TM273       18       88.8       72.8       104.8       16.0       3.33       1.08         TM274       18       50.2       41.2       59.2       9.0       3.15       1.08         TM275       18       65.7       53.9       77.5       11.8       3.24       0.03       0.09         Siemens Advia Centaur XP & CP	TM271	18	19.7	14.3	25.1	5.4	3.65		0.88	
TM274       18       50.2       41.2       59.2       9.0       3.15       1.08         TM275       18       65.7       53.9       77.5       11.8       3.04       1.08         Siemens Advia Centaur XP & CP       COB/COC       77.5       11.8       2.28       0.23       1.04       0.09         TM271       33       24.2       18.8       29.6       5.4       5.33       1.08       0.92         TM271       33       76.4       62.6       90.2       13.8       5.63       0.92       0.92         TM275       32       56.0       45.9       66.1       10.1       5.09       0.92       0.92         TM275       32       56.0       45.9       66.1       10.1       5.09       0.92       0.92         TM271       21       19.5       14.1       24.9       5.4       5.84       0.48         TM273       18       38.9       31.9       45.9       7.0       5.91       0.47         TM274       18       28.1       22.7       33.5       5.4       6.62       0.46         TM275       18       28.1       22.7       33.5       5.4       6.26	TM272	18	66.5	54.5	78.5	12.0	3.22		1.08	
TM275       18       65.7       53.9       77.5       11.8       3.04       1.08         mean ±SD       3.28       0.23       1.04       0.09         Siemens Advia Centaur XP & CP       COB/COC       5.4       5.33       1.08         TM271       33       24.2       18.8       29.6       5.4       5.33       1.08         TM272       32       56.7       46.5       66.9       10.2       4.46       0.92         TM273       33       76.4       62.6       90.2       13.8       5.63       0.92         TM274       33       43.0       35.3       50.7       7.7       4.98       0.92         TM275       32       56.0       45.9       66.1       10.1       5.10       0.43       0.95       0.07         Siemens Immulite 2000       DPD	TM273	18	88.8	72.8	104.8	16.0	3.33		1.08	
Mean ±SD         3.28         0.23         1.04         0.09           Siemens Advia Centaur XP & CP         COB/COCC                                       3.28         2.67         46.5         66.9         10.2         4.46         0.92                 0.92              0.92           0.92           0.92           0.92           0.92           0.92           0.92          0.92          0.92          0.92          0.92          0.92          0.92          0.92          0.92          0.92          0.92          0.92         1.92         1.93         1.93	TM274	18	50.2	41.2	59.2	9.0	3.15		1.08	
Siemens Advia Centaur XP & CP         COB/COC         TM271       33       24.2       18.8       29.6       5.4       5.33       1.08         TM272       32       56.7       46.5       66.9       10.2       4.46       0.92         TM273       33       76.4       62.6       90.2       13.8       5.63       0.92         TM274       33       43.0       35.3       50.7       7.7       4.98       0.92         TM275       32       56.0       45.9       66.1       10.1       5.09       0.92         mean ±SD       5.10       0.43       0.95       0.07         Siemens Immulite 2000       pp0	TM275	18	65.7	53.9	77.5	11.8	3.04		1.08	
COB/COC         TM271         33         24.2         18.8         29.6         5.4         5.33         1.08           TM272         32         56.7         46.5         66.9         10.2         4.46         0.92           TM273         33         76.4         62.6         90.2         13.8         5.63         0.92           TM274         33         43.0         35.3         50.7         7.7         4.98         0.92           TM275         32         56.0         45.9         66.1         10.1         5.09         0.92           TM271         21         19.5         14.1         24.9         5.4         7.59         0.87           TM271         21         19.5         14.1         24.9         5.4         7.59         0.87           TM273         18         29.3         23.9         34.7         5.4         5.84         0.48           TM273         18         28.9         31.9         45.9         7.0         5.91         0.47           TM274         18         20.6         15.2         26.0         5.4         6.62         0.87         0.54           TM275         18						mean ±SD	3.28	0.23	1.04	0.09
TM272       32       56.7       46.5       66.9       10.2       4.46       0.92         TM273       33       76.4       62.6       90.2       13.8       5.63       0.92         TM274       33       43.0       35.3       50.7       7.7       4.98       0.92         TM275       32       56.7       66.1       10.1       5.09       0.92         TM270       32       51.0       0.43       0.95       0.07         Siemens Immulite 2000       mean ±SD       5.10       0.43       0.95       0.07         TM271       21       19.5       14.1       24.9       5.4       7.59       0.87         TM273       18       29.3       23.9       34.7       5.4       5.84       0.48         TM273       18       38.9       31.9       45.9       7.0       5.91       0.47         TM274       18       28.1       22.7       5.4       6.62       0.46       mean ±SD       6.63       0.87       0.54       0.18         Siemens Dimension Vista (LOCI)       UV       UV       15.1       94.4       15.63       26.7       5.4       6.62       0.95       124.7		(P & CP								
TM273       33       76.4       62.6       90.2       13.8       5.63       0.92         TM274       33       43.0       35.3       50.7       7.7       4.98       0.92         TM275       32       56.0       45.9       66.1       10.1       5.09       0.92         mean ±SD       5.10       0.43       0.95       0.07         Siemens Immulite 2000         DPD       7       5.4       7.59       0.87         TM272       18       29.3       23.9       34.7       5.4       5.84       0.48         TM273       18       38.9       31.9       45.9       7.0       5.91       0.47         TM274       18       20.6       15.2       26.0       5.4       7.52       0.44         TM275       18       28.1       22.7       33.5       5.4       6.62       0.46         TM274       18       20.6       15.2       26.0       5.4       7.52       0.44         TM275       18       28.1       22.7       33.5       5.4       6.62       0.95         TM271       4       21.3       15.9       26.7       5.4 </td <td>TM271</td> <td>33</td> <td>24.2</td> <td>18.8</td> <td>29.6</td> <td>5.4</td> <td>5.33</td> <td></td> <td>1.08</td> <td></td>	TM271	33	24.2	18.8	29.6	5.4	5.33		1.08	
TM274       33       43.0       35.3       50.7       7.7       4.98       0.92         TM275       32       56.0       45.9       66.1       10.1       5.09       0.92         Siemens Immulite 2000       mean ±SD       5.10       0.43       0.95       0.07         Siemens Immulite 2000       pPp	TM272	32	56.7	46.5	66.9	10.2	4.46		0.92	
TM275       32       56.0       45.9       66.1       10.1       5.09       0.92         mean ±SD       5.10       0.43       0.95       0.07         Siemens Immulite 2000       DPD       5.10       0.43       0.95       0.07         M271       21       19.5       14.1       24.9       5.4       7.59       0.87         TM271       21       19.5       14.1       24.9       5.4       7.59       0.87         TM273       18       29.3       23.9       34.7       5.4       5.84       0.48         TM273       18       29.3       23.9       34.7       5.4       5.91       0.47         TM273       18       29.3       23.9       35.5       5.4       6.62       0.46         TM274       18       20.6       15.2       26.0       5.4       6.62       0.95         Siemens Dimension Vista (LOCI)         mean ±SD       6.62       0.95       114         DUV       1142       24.0       16.1       27.7       4.66       2.50       253         TM273       4       20.8       171.2       246.4       37.6       6.28       2	TM273	33	76.4	62.6	90.2	13.8	5.63		0.92	
Siemens Immulite 2000         DPD         Siemens Immulite 2000         Siemens Immul	TM274	33	43.0	35.3	50.7	7.7	4.98		0.92	
Siemens Immulite 2000           DPD         TM271         21         19.5         14.1         24.9         5.4         7.59         0.87           TM272         18         29.3         23.9         34.7         5.4         5.84         0.48           TM273         18         38.9         31.9         45.9         7.0         5.91         0.47           TM274         18         20.6         15.2         26.0         5.4         7.52         0.44           TM275         18         28.1         22.7         33.5         5.4         6.26         0.46           mean ±SD         6.63         0.87         0.54         0.18           Siemens Dimension Vista (LOCI)           DUV         TM271         4         21.3         15.9         26.7         5.4         6.62         0.95           TM272         4         154.0         126.3         181.7         27.7         4.86         2.50           TM273         4         208.8         171.2         246.4         37.6         6.28         2.53           TM274         4         152.7         125.2         180.2         27.5         5.46<	TM275	32	56.0	45.9	66.1		5.09		0.92	
DPD         TM271         21         19.5         14.1         24.9         5.4         7.59         0.87           TM272         18         29.3         23.9         34.7         5.4         5.84         0.48           TM273         18         38.9         31.9         45.9         7.0         5.91         0.47           TM274         18         20.6         15.2         26.0         5.4         7.52         0.44           TM275         18         28.1         22.7         33.5         5.4         6.26         0.46           mean ±SD         6.63         0.87         0.54         0.18           Siemens Dimension Vista (LOCI)           DUV         mean ±SD         6.62         0.95           TM271         4         21.3         15.9         26.7         5.4         6.62         0.95           TM272         4         154.0         126.3         181.7         27.7         4.86         2.50           TM273         4         208.8         171.2         246.4         37.6         6.28         2.51           TM275         4         152.7         125.2         180.2	01 1 10 0000					mean ±SD	5.10	0.43	0.95	0.07
TM272       18       29.3       23.9       34.7       5.4       5.84       0.48         TM273       18       38.9       31.9       45.9       7.0       5.91       0.47         TM274       18       20.6       15.2       26.0       5.4       7.52       0.44         TM275       18       28.1       22.7       33.5       5.4       6.63       0.87       0.54       0.18         Simens Dimension Vista (LOCI)         DV       mean ±SD       6.63       0.87       0.54       0.18         TM272       4       21.3       15.9       26.7       5.4       6.62       0.95         TM271       4       21.3       15.9       26.7       5.4       6.62       0.95         TM272       4       154.0       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       126.2       180.2       27.5       5.46       2.51 </td <td>Siemens Immulite 2000 DPD</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	Siemens Immulite 2000 DPD									
TM273       18       38.9       31.9       45.9       7.0       5.91       0.47         TM274       18       20.6       15.2       26.0       5.4       7.52       0.44         TM275       18       28.1       22.7       33.5       5.4       6.26       0.46         mean ±SD       6.63       0.87       0.54       0.18         Siemens Dimension Vista (LOCI)         DUV       J       4       21.3       15.9       26.7       5.4       6.62       0.95         TM271       4       21.3       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         JG/JJF       J       14.5       25.3       5.4       0.50       0.89         TM271       4       19.9       14.5       25.3<										
TM274       18       20.6       15.2       26.0       5.4       7.52       0.44         TM275       18       28.1       22.7       33.5       5.4       6.63       0.87       0.54       0.18         Siemens Dimension Vista (LOCI)         DUV       7       5.4       6.62       0.95       0.18         TM271       4       21.3       15.9       26.7       5.4       6.62       0.95         TM272       4       154.0       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       125.2       180.2       27.5       5.46       2.51       10.0         TM275       125.7       125.2       180.2       27.5       5.40       1.14       2.19       0.69         JG/JJJF       125.2       180.2       25.3       5.40       1.14       2.19       0.69         JG/JJJF       7       125.2       180.2       5.40       1.14       2.19       0.69										
TM275       18       28.1       22.7       33.5       5.4       6.26       0.46         Siemens Dimension Vista (LOCI)						7.0				
mean ±SD         6.63         0.87         0.54         0.18           Siemens Dimension Vista (LOCI) DUV         J         J         15.9         26.7         5.4         6.62         0.95           TM271         4         21.3         15.9         26.7         5.4         6.62         0.95           TM272         4         154.0         126.3         181.7         27.7         4.86         2.50           TM273         4         208.8         171.2         246.4         37.6         6.28         2.53           TM274         4         115.1         94.4         135.8         20.7         3.78         2.47           TM275         4         152.7         125.2         180.2         27.5         5.46         2.51           mean ±SD         5.40         1.14         2.19         0.69           Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         Image: Market Mar										
Siemens Dimension Vista (LOCI)           DUV         TM271         4         21.3         15.9         26.7         5.4         6.62         0.95           TM272         4         154.0         126.3         181.7         27.7         4.86         2.50           TM273         4         208.8         171.2         246.4         37.6         6.28         2.53           TM274         4         115.1         94.4         135.8         20.7         3.78         2.47           TM275         4         152.7         125.2         180.2         27.5         5.46         2.51           mean ±SD         5.40         1.14         2.19         0.69           Ortho Clinical Diag Vitros Eci/EciQ & 5600           JJC/JJF           TM271         4         19.9         14.5         25.3         5.4         0.50         0.89           TM272         5         55.7         45.7         65.7         10.0         4.33         0.90           JM272         5         55.7         45.7         65.7         10.0         4.33         0.90           TM273         5         70.7         58.0	TM275	18	28.1	22.7	33.5					
DUV         TM271       4       21.3       15.9       26.7       5.4       6.62       0.95         TM272       4       154.0       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/EciQ & 5600         JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         JDC/JJF       TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7						mean ±SD	6.63	0.87	0.54	0.18
TM271       4       21.3       15.9       26.7       5.4       6.62       0.95         TM272       4       154.0       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7       45.7       7.0       10.23       <										
TM272       4       154.0       126.3       181.7       27.7       4.86       2.50         TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7       45.7       7.0       10.23       0.83         TM275       4       51.2       42.0       60.4       9.2       0.92       <		4	21.3	15.9	26 7	54	6 62		0.95	
TM273       4       208.8       171.2       246.4       37.6       6.28       2.53         TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7       45.7       7.0       10.23       0.83         TM275       4       51.2       42.0       60.4       9.2       0.92       0.84										
TM274       4       115.1       94.4       135.8       20.7       3.78       2.47         TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7       45.7       7.0       10.23       0.83         TM275       4       51.2       42.0       60.4       9.2       0.92       0.84										
TM275       4       152.7       125.2       180.2       27.5       5.46       2.51         mean ±SD       5.40       1.14       2.19       0.69         Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF         TM271       4       19.9       14.5       25.3       5.4       0.50       0.89         TM272       5       55.7       45.7       65.7       10.0       4.33       0.90         TM273       5       70.7       58.0       83.4       12.7       5.57       0.86         TM274       5       38.7       31.7       45.7       7.0       10.23       0.83         TM275       4       51.2       42.0       60.4       9.2       0.92       0.84										
mean ±SD5.401.142.190.69Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJFTM271419.914.525.35.40.500.89TM272555.745.765.710.04.330.90TM273570.758.083.412.75.570.86TM274538.731.745.77.010.230.83TM275451.242.060.49.20.920.84										
Ortho Clinical Diag Vitros Eci/ECiQ & 5600           JJC/JJF           TM271         4         19.9         14.5         25.3         5.4         0.50         0.89           TM272         5         55.7         45.7         65.7         10.0         4.33         0.90           TM273         5         70.7         58.0         83.4         12.7         5.57         0.86           TM274         5         38.7         31.7         45.7         7.0         10.23         0.83           TM275         4         51.2         42.0         60.4         9.2         0.92         0.84		-7	102.1	120.2	100.2			1.14		0.69
TM271419.914.525.35.40.500.89TM272555.745.765.710.04.330.90TM273570.758.083.412.75.570.86TM274538.731.745.77.010.230.83TM275451.242.060.49.20.920.84	Ortho Clinical Diag Vitros JJC/JJF	Eci/ECi	Q & 5600							
TM272555.745.765.710.04.330.90TM273570.758.083.412.75.570.86TM274538.731.745.77.010.230.83TM275451.242.060.49.20.920.84		4	19.9	14.5	25.3	5.4	0.50		0.89	
TM273570.758.083.412.75.570.86TM274538.731.745.77.010.230.83TM275451.242.060.49.20.920.84										
TM274538.731.745.77.010.230.83TM275451.242.060.49.20.920.84										
TM275 4 51.2 42.0 60.4 9.2 0.92 0.84										
								<u>3.9</u> 6		0.03

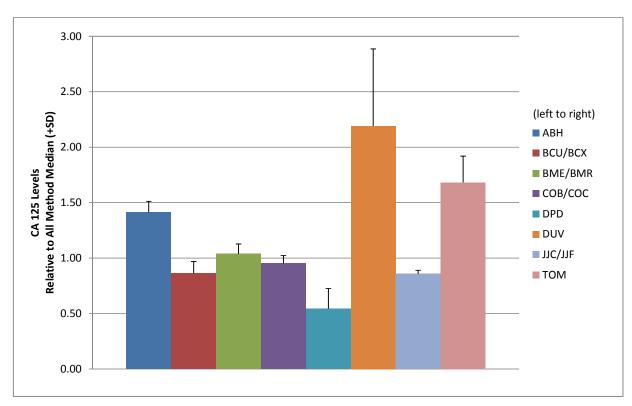
### Table 1 (cont.): 5-14 NYS Tumor Marker PT Summary for CA 125

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to A Aethod Media	II
Tosoh AIA									
ТОМ									
TM271	5	28.3	22.9	33.7	5.4	3.32		1.26	
TM272	5	109.9	90.1	129.7	19.8	5.61		1.78	
TM273	5	150.1	123.1	177.1	27.0	4.20		1.82	
TM274	5	81.8	67.1	96.5	14.7	6.97		1.76	
TM275	5	109.3	89.6	129.0	19.7	5.30		1.80	
					mean ±SD	5.08	1.39	1.68	0.24

		All			
		Method		Median	
Sample ID	Ν	Median		% CV	
TM271	108	22.5		5.40	
TM272	106	61.6		5.19	
TM273	107	82.6		5.74	
TM274	107	46.6		5.96	
TM275	105	60.9		5.24	
			Average	5.51	
			Allowable CV %	6.0	
		Allowable	e Error if >/= 30 U/ml (+/-) %	18.0	

Allowable Error if < 30 U/ml (+/- U/ml) 5.4

## Figure 1: CA 125 Method Comparison

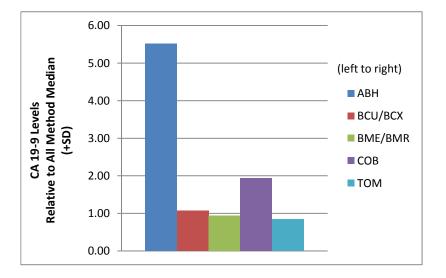


Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	
Abbott Architect									
ABH TM271	0	182.1	149.3	214.9	32.8	0.00		5.52	
TM271 TM272	3 3	NG	149.5	214.9	32.0	6.66		5.52	
TM272 TM273	3	NG							
TM273	3	NG							
TM274 TM275	3	NG							
1101275	5	NG			mean ±SD	6.66	#DIV/0!	5.52	#DIV/0!
Beckman Unicel & A	ccess/2					0.00	1211/01	0.01	1211/01
BCU/BCX									
TM271	15	35.3	28.9	41.7	6.4	5.16		1.07	
TM272	15	NG							
TM273	15	NG							
TM274	15	NG							
TM275	15	NG							
					mean ±SD	5.16	#DIV/0!	1.07	#DIV/0!
Roche Elecsys & Co	bas								
BME/BMR									
TM271	13	30.7	25.2	36.2	5.5	4.01		0.93	
TM272	13	NG							
TM273	13	NG							
TM274	13	NG							
TM275	13	NG							
					mean ±SD	4.01	#DIV/0!	0.93	#DIV/0!
Siemens Advia Cent	taur XP								
COB									
TM271	29	63.9	52.4	75.4	11.5	6.74		1.94	
TM272	29	NG							
TM273	29	NG							
TM274	29	NG							
TM275	29	NG				0.74		1.04	
Tosoh AIA					mean ±SD	6.74	#DIV/0!	1.94	#DIV/0!
TOM									
TM271	5	27.8	22.8	32.8	5.0	2.48		0.84	
TM272	5	1.8	0.0	5.4	2.7	18.33			
TM273	5	1.7	0.0	5.3	2.7	12.94			
TM274	5	1.6	0.0	5.2	2.6	47.50			
TM275	5	1.6	0.0	5.2	2.6	25.00			
					mean ±SD	21.25	16.83	0.84	#DIV/0!

## Table 2 (cont.): 5-14 NYS Tumor Marker PT Summary for CA 19-9

Sample ID	N	All Method Median		Median % CV	
TM271	65	33.0		4.58	
TM272	65	1.8		NA	
TM273	65	1.7		NA	
TM274	65	1.6		NA	
TM275	65	1.6		NA	
			Average*	4.58	*Abbott excluded
			Allowable CV %	6.00	
			Allowable Error if >/= 20 U/ml (+/-) %	18.0	
			Allowable Error if < 20 U/ml (+/- U/ml)	3.6	

## Figure 2: CA 19-9 Method Comparison



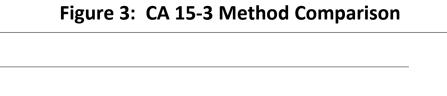
Note: Graph is based on data from TM271 only.

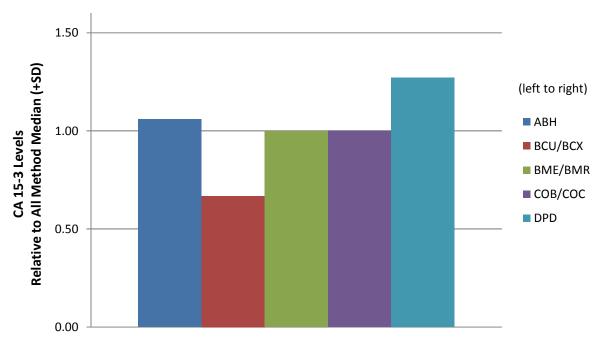
# Table 3: 5-14 NYS Tumor Marker PT Summary for CA 15-3

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data	3	Method Bias Relative to All Method Median	
Abbott Architect									
ABH TM271	6	57.0	38.2	75.8	18.8	5.75		1.06	
TM271 TM272	6 6	1.9	1.3	2.5	0.6	5.75 14.21		1.00	
TM272	6	1.9	1.3	2.5	0.6	13.68			
TM273	6	1.8	1.2	2.5	0.6	10.56			
TM274 TM275	6	1.7	1.1	2.4	0.6	14.71			
	0	1.7	1.1	2.5	mean ±SD		1.87	1.06	#DIV/0!
Beckman Unicel & A	Access/2				moun 100	11.70	1.07	1.00	#D10/0:
BCU/BCX									
TM271	7	35.9	24.1	47.7	11.8	9.03		0.67	
TM272	7	2.4	1.6	3.2	0.8	7.50			
TM273	7	2.3	1.5	3.1	0.8	10.43			
TM274	7	2.3	1.5	3.1	0.8	8.70			
TM275	7	2.4	1.6	3.2	0.8	8.75			
					mean ±SD	8.88	1.05	0.67	#DIV/0!
Roche Elecsys & Co	obas								
BME/BMR									
TM271	14	53.7	36.0	71.4	17.7	4.19		1.00	
TM272	14	NG							
TM273	14	NG							
TM274	14	NG							
TM275	14	NG							
					mean ±SD	4.19	#DIV/0!	1.00	#DIV/0!
Siemens Advia Cen COB/COC	taur XP &	СР							
TM271	18	53.8	36.0	71.6	17.8	4.94		1.00	
TM272	18	NG							
TM273	18	NG							
TM274	18	NG							
TM275	18	NG							
					mean ±SD	4.94	#DIV/0!	1.00	#DIV/0!
Siemens Immulite 2 DPD	000								
TM271	8	68.4	45.8	91.0	22.6	3.52		1.27	
TM272	9	4.3	2.9	5.7	1.4	12.33			
TM273	9	4.3	2.9	5.7	1.4	10.47			
TM274	9	4.3	2.9	5.7	1.4	10.00			
TM275	9	4.2	2.8	5.6	1.4	10.95			
					mean±SD	10.94	1.00	1.27	#DIV/0!

## Table 3 (cont.): 5-14 NYS Tumor Marker PT Summary for CA 15-3

Sample ID	N	All Method Median		Median % CV	
TM271	53	53.8		4.94	
TM272	54	2.4		12.33	
TM273	54	2.3		10.47	
TM274	54	2.3		10.00	
TM275	54	2.4		10.95	
			Average	9.74	
			Allowable CV %	11.0	Note: Higher allowable %CV
			Allowable Error (+/-)%	33.0	due to very low levels in samples TM272-TM275.





Note: Graph is based on data from TM271 only.

## Table 4: 5-14 NYS Tumor Marker PT Summary for CA 27.29

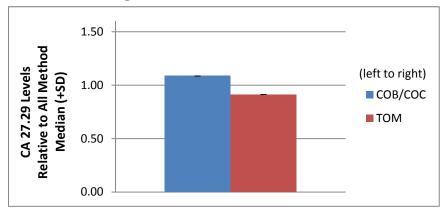
Method Method Code Sample ID	Ν	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Mediar	
Siemens Advia Centaur XP & CP									
COB/COC									
TM271	40	72.5	57.3	87.7	15.2	5.75		1.09	
TM272	40	16.0	8.7	23.4	7.4	15.25			
TM273	40	15.3	8.0	22.7	7.4	15.03			
TM274	40	15.9	8.6	23.3	7.4	16.86			
TM275	40	14.9	7.6	22.3	7.4	17.58			
					mean ±SD	14.09	4.79	1.09	###
Tosoh AIA									
ТОМ									
TM271	6	60.7	48.0	73.4	12.7	6.41		0.91	
TM272	6	60.4	47.7	73.1	12.7	10.60			
TM273	6	58.4	46.1	70.7	12.3	12.50			
TM274	6	59.1	46.7	71.5	12.4	7.97			
TM275	6	59.3	46.8	71.8	12.5	6.73			
					mean ±SD	8.84	2.63	0.91	###

		All	
		Method	Median
Sample ID	N	Median	% CV
M271	46	66.6	6.08
M272	46	NA	12.92
M273	46	NA	13.77
M274	46	NA	12.41
TM275	46	NA	12.16

Average 11.47
---------------

Allowable CV %	7.0
Allowable Error if >/= 35 U/ml (+/-) %	21.0

Allowable Error if < 35 U/ml (+/- U/ml) 7.35



## Figure 4: CA 27.29 Method

Sample 10 N (Mean) Limit Limit Drax (+-) Raw Data Method Median Abbot Achitest ABH TM271 15 7.1 5.8 8.4 1.3 6.06 1.03 TM272 15 12.3 10.1 14.5 2.2 5.85 1.02 TM273 15 15.9 13.0 18.8 2.9 4.78 1.10 TM274 14 22.3 18.3 2.8 4.0 4.82 1.09 TM275 15 5.6 6 5.4 7.8 1.2 Second Unicol & Accessar BCUBOX TM272 25 6.6 5.4 7.8 1.2 TM271 25 6.6 5.4 7.8 1.2 TM272 25 12.8 10.5 15.1 2.3 6.33 0.89 1.07 TM272 25 12.8 10.5 15.1 2.3 6.33 0.89 TM272 25 12.8 10.5 15.1 2.3 6.33 0.89 TM272 25 12.8 10.5 15.1 3.2 5.87 0.87 TM272 25 12.8 10.5 15.1 3.2 5.87 0.87 TM272 25 12.8 10.5 15.1 0.5 6.4 0.80 TM271 23 5.5 4.5 6.5 1.0 5.64 0.88 TM271 23 5.5 4.5 6.5 1.0 5.64 0.88 TM272 2.3 8.5 7.0 10.0 1.5 5.41 0.45 0.88 TM271 2.3 5.5 4.5 6.5 1.0 5.64 0.80 TM272 2.3 8.5 7.0 10.0 1.5 5.41 0.75 TM272 2.3 8.5 7.0 10.0 1.5 5.41 0.75 TM272 2.3 8.5 7.0 10.0 1.5 5.41 0.71 TM273 2.3 10.8 8.9 12.7 1.9 5.56 0.73 TM272 2.3 2.4.3 19.9 2.87 4.44 5.88 0.73 TM275 2.3 2.4.3 19.9 2.87 4.44 5.88 0.73 TM275 2.3 2.4.3 19.9 2.87 4.44 5.88 0.73 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM272 45 12.6 13.2 19.0 2.9 5.47 1.12 TM274 45 6.7 5.5 7.9 1.2 6.57 0.97 TM275 45 3.86 13.5 2.87 4.1 4.37 1.12 TM274 45 0.26 T.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 1.49 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.99 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM271 45 6.7 5.5 7.9 1.2 6.57 0.90 TM271 45 0.26 0.90 1.15 TM271 45 0.26 0.90 1.15 TM271 10 1.29 1.06 1.52 2.3 7.71 1.07 TM272 2.4 9.6 7.9 1.13 1.77 2.50 0.98 TM271 11 2.4 9.6 7.9 1.13 1.77 2.50 0.98 TM271 2.4 9.6 7.9 1.13 1.77 2.50 0.98 TM271 2.4 9.6 7.9 1.13 1.77 2.50 0.98 TM271 1.2 8.4 6.9 9.9 1.5 1.3.33 1.22 TM271 1.2 8.4 6.9 7.9 1.5 1.3.33 1.	Method Method Code		Target	Lower	Upper	<b>-</b> ( ()	%CV of		Method Bias Relative to All	
ABH         Vert         15         7.1         5.8         8.4         1.3         6.06         1.03           TM272         15         12.3         10.1         14.5         2.2         5.85         1.02           TM273         15         15.9         13.0         18.8         2.9         4.73         1.10           TM275         15         36.7         30.1         43.3         6.6         3.99         1.10           Beckman Unicel & Access?         BECUBCX         mem ±SD         5.06         0.88         1.07         0.04           BCUMBCX         15         1.2         5.61         0.96         0.83         1.07         0.04           BCUBCX         17.72         2.5         12.8         10.5         15.1         2.3         6.33         0.89           TM273         2.5         17.9         14.7         2.11         2.2         5.84         0.05           Brobe Elecsys & Cobes         Brobe Elecsys & Cobes         10.05         5.64         0.75         0.75           TM272         2.3         5.5         4.5         6.5         0.15         5.64         0.73           TM272         2.3         8.5 <th>Sample ID</th> <th>Ν</th> <th>(Mean)</th> <th>Limit</th> <th>Limit</th> <th>Dmax (+/-)</th> <th>Raw Data</th> <th></th> <th>Method Median</th> <th></th>	Sample ID	Ν	(Mean)	Limit	Limit	Dmax (+/-)	Raw Data		Method Median	
TM271       15       7.1       5.8       8.4       1.3       6.06       1.03         TM272       15       15.9       13.0       18.8       2.9       4.78       1.10         TM273       15       15.9       13.0       18.8       2.9       4.78       1.10         TM275       15       36.7       30.1       48.3       2.9       4.78       1.10         TM274       14       2.23       16.3       4.0       4.62       1.09       0.04         Beckman Unicel & Access/2       BCUBCX       BCUBCX       BCUBCX       1.8       1.8       6.00       0.83       1.07       0.04         Beckman Unicel & Access/2       25       12.8       11.8       1.8       6.00       0.83       1.07       0.04         TM273       25       12.8       10.5       15.1       2.3       6.33       0.89       1.10       0.45       0.83       0.05         TM273       25       12.8       17.9       1.1       3.2       5.87       0.86       0.05         TM274       23       5.5       4.5       6.5       1.0       5.64       0.73       1.1       1.4       7.8       2.7 <td></td>										
TM272 15 12.3 10.1 14.5 2.2 5.85 1.02 TM273 15 15.9 13.0 18.8 2.9 4.78 1.00 TM275 15 36.7 30.1 43.3 66.3 3.96 1.07 0.04 Bockman Unicel & Access? Bockman Unicel & Access? TM271 25 66 5.4 7.8 1.2 5.61 0.96 TM273 25 12.8 10.5 15.1 2.3 6.33 0.89 TM273 25 12.8 10.5 15.1 2.3 6.33 0.89 TM274 25 17.9 14.7 21.1 2.2 5.87 0.87 TM275 25 28.7 23.5 33.9 5.2 6.76 0.86 TM271 23 5.5 4.5 6.5 1.0 5.64 0.80 TM272 23 8.5 7.0 10.0 1.5 5.41 0.45 0.88 0.05 Roche Elecsys & Cobs BME/BMA TM274 23 15.1 12.4 17.8 2.7 5.56 0.73 TM275 23 24.3 19.9 28.7 4.4 5.86 0.73 TM274 23 15.1 12.4 17.8 2.7 5.56 0.73 TM274 45 6.7 5.7 9 1.2 6.57 0.97 TM274 45 16.1 13.2 19.0 2.9 5.47 1.12 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.3 5.40 1.05 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.9 5.47 1.12 TM274 11 2.49 2.4 45.5 1.4 8.7 1.10 TM275 45 3.8.6 31.7 45.5 6.9 5.49 1.16 TM271 1 7.1 5.8 8.4 1.3 5.35 1.03 TM275 1.0 12.9 10.6 15.2 2.3 7.21 1.07 TM273 2.4 12.4 10.2 13.0 5.0 0.01 TM273 2.4 12.4 10.2 13.6 136 136 3.0 5.00 1.15 TM271 2.4 6.3 5.2 7.4 1.1 3.92 0.91 TM271 1.2 6.4 6.9 9.9 1.5 1.3.3 1.22 TM275 2.4 2.8 2.6 3.4 2.2 3.96 0.86 TM273 2.4 12.4 10.2 14.6 2.2 3.96 0.86 TM273 2.4 12.4 10.2 14.6 5.2 3.3 16.67 0.90 TM273 2.4 12.4 10.2 14.6 5.2 3.3 16.67 0.90 TM274 1.2 1.8 9.7 13.9 2.1 9.24 0.86 TM275 1.2 1.8 9.7 13.9 2.1 9.24 0.98 TM275 1.2 1.8 9.7 13.9 2.1 9.24 0.98 TM275 1.2 1.8 9.7 13		15	7 1	E 0	0 /	1.0	6.06		1.02	
TM273       15       15.9       13.0       18.8       2.9       4.78       1.10         TM274       14       22.3       18.3       26.3       40.0       4.62       1.10         TM275       15       36.7       30.1       43.3       6.6       3.90       1.10         Beckman Unicel & Access?       E       E       1.00       0.04       E       1.00       0.04         Beckman Unicel & Access?       E       E       E       1.10       0.04       E       1.10       0.04         Beckman Unicel & Access?       E       E       E       E       0.06       E       1.10       0.04         Beckman Unicel & Access?       E										
TM274       14       22.3       18.3       26.3       4.0       4.62       1.09         TM275       15       36.7       30.1       43.3       6.6       3.96       1.01         Beckman Unicel & Access/2       E       5.06       0.88       1.07       0.04         Beckman Unicel & Access/2       E       5.06       0.88       1.07       0.04         Beckman Unicel & Access/2       E       7.8       1.2       5.61       0.96       0.83         TM272       25       12.8       10.5       15.1       2.3       6.33       0.089       1.07       0.04         TM274       25       17.9       14.7       21.1       3.2       5.87       0.87       0.05         TM275       25       28.7       23.5       33.9       5.2       6.76       0.88       0.05         TM271       23       5.5       4.5       6.5       1.0       5.64       0.80       0.75         TM272       23       8.5       7.0       10.0       1.5       5.41       0.71       1.10         TM272       23       15.1       12.4       17.8       2.7       5.56       0.73       1.10										
TM275     15     36.7     30.1     43.3     6.6     3.98     1.10       mean ±SD     5.06     0.8     1.07     0.04       Beckman Unicel & Access/2     BCUBCX     1.00     0.82     1.18     1.8     0.00     0.83       TM271     25     6.6     5.4     7.8     1.2     5.61     0.96       TM273     25     12.8     10.5     15.1     2.3     6.33     0.89       TM274     25     17.9     14.7     21.1     3.2     5.87     0.87       TM275     25     28.7     23.5     33.9     5.61     0.45     0.88       PROTE     mean ±SD     6.11     0.45     0.88     0.05       Roche Elecsys & Cobas     mean ±SD     5.61     0.45     0.86       TM274     23     15.5     4.5     6.5     1.0     6.64     0.80       TM274     23     15.8     7.0     10.0     1.5     5.41     0.71       TM273     23     10.8     8.9     12.7     1.9     5.66     0.73       TM274     23     12.4     17.8     2.7     5.56     0.73       TM275     23     24.3     19.9     5.61     0.17 <td></td>										
mean ±SD         5.06         0.88         1.07         0.04           Backman Unicel & Access/2 BCU/BCX         Image: Constraint of the second o										
Beckman Unicel & Access/2           BCUBCX           TM271         25         6.6         5.4         7.8         1.2         5.61         0.96           TM272         25         10.0         8.2         11.8         1.8         6.00         0.83           TM273         25         12.8         10.5         15.1         2.3         6.33         0.89           TM274         25         17.9         14.7         21.1         3.2         5.87         0.87           TM275         25         28.7         23.5         6.5         1.0         6.611         0.45         0.86           BMC/BMR         5         6.5         1.0         1.5         5.41         0.71           TM272         23         8.5         7.0         10.0         1.5         5.41         0.71           TM275         23         15.1         12.4         17.8         2.7         5.6         0.73           TM274         23         15.1         12.4         17.8         2.7         5.6         0.73           TM274         23         15.1         12.4         17.8         2.7         5.61         0.17         0.79 </td <td>1101273</td> <td>15</td> <td>30.7</td> <td>30.1</td> <td>43.3</td> <td></td> <td></td> <td>0 00</td> <td></td> <td>0.04</td>	1101273	15	30.7	30.1	43.3			0 00		0.04
BCUBCX         Image: Section of the section of t	Beckman Unicel & Acces	ss/2				mean ±00	5.00	0.00	1.07	0.04
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		50,2								
TM272     25     10.0     8.2     11.8     1.8     6.00     0.83       TM273     25     12.8     10.5     15.1     2.3     6.33     0.89       TM274     25     28.7     23.5     33.9     5.2     6.76     0.86       TM275     25     28.7     23.5     33.9     5.2     6.76     0.86       Roche Elecsys & Cobas     BME/BMR		25	6.6	5.4	7.8	1.2	5.61		0.96	
TM273         25         12.8         10.5         15.1         2.3         6.33         0.89           TM274         25         17.9         14.7         21.1         3.2         5.67         0.67           TM275         25         28.7         23.5         33.9         5.2         6.76         0.86           BME/EMR										
TM274       25       17.9       14.7       21.1       3.2       5.87       0.87         TM275       25       28.7       23.9       33.9       5.2       6.76       0.86         Roche Eleosys & Cobas       BME?BMR       1       0.45       0.88       0.05         TM271       23       5.5       4.5       6.5       1.0       5.64       0.80         TM272       23       8.5       7.0       10.0       1.5       5.41       0.77         TM273       23       10.8       8.9       12.7       1.9       5.56       0.75         TM274       23       15.1       12.4       17.8       2.7       5.56       0.73         TM273       23       24.3       19.9       28.7       4.4       5.88       0.03         Siemens Advia Centaur XP & CP       Cocolococ       -       -       mean ±SD       5.61       0.17       0.74       0.03         Siemens Inmulite 200       COB       -       1.9       2.3       5.40       1.05       1.12         TM274       45       2.6       18.5       26.7       4.1       4.87       1.10         TM274       45										
TM275     25     28.7     23.5     33.9     5.2     6.76     0.86       mean ±SD     6.11     0.45     0.86     0.05       Roche Elecsys & Cobas     5     4.5     6.5     1.0     5.64     0.80       TM271     23     5.5     7.0     10.0     1.5     5.41     0.71       TM273     23     10.8     8.9     12.7     1.9     5.56     0.73       TM274     23     23     15.1     12.4     17.8     2.7     5.56     0.73       TM275     23     24.3     19.9     28.7     4.4     5.88     0.73       TM275     23     24.3     19.9     28.7     4.4     5.88     0.73       TM275     23     24.3     19.9     28.7     4.4     5.88     0.73       TM275     24.5     12.6     10.3     14.9     2.3     5.40     1.05       TM271     45     12.6     10.3     14.9     2.3     5.40     1.05       TM274     45     22.6     18.5     26.7     4.1     4.87     1.10       TM275     45     38.6     31.7     45.5     6.9     5.49     1.16       TM271     11										
mean ±SD 6.11 0.45 0.88 0.05           Roche Elecsys & Cobas           BMCFBMR         U           TM271         23         5.5         4.5         6.5         1.0         5.64         0.80           TM272         23         8.5         7.0         10.0         1.5         5.41         0.71           TM273         23         10.8         8.9         12.7         1.9         5.56         0.75           TM274         23         15.1         12.4         17.8         2.7         5.56         0.73           TM275         2.3         2.4.3         19.9         2.7         4.4         5.88         0.73           COB/COC										
Broche Elecsys & Cobas           BME/BMR           TM271         23         5.5         4.5         6.5         1.0         5.64         0.80           TM272         23         8.5         7.0         10.0         1.5         5.41         0.71           TM273         23         15.1         12.4         1.8         5.66         0.75           TM274         23         15.1         12.4         7.8         2.7         5.56         0.73           TM275         23         24.3         19.9         28.7         4.4         5.88         0.73           TM270         45         6.67         5.5         7.9         1.2         6.57         0.97           TM271         45         6.7         5.5         7.9         1.2         6.57         0.97           TM272         45         12.6         10.3         14.9         2.3         5.40         1.05           TM271         45         22.6         18.5         25.7         4.1         4.87         1.10           TM275         45         38.6         31.7         45.5         6.9         5.49         1.16           TM271								0.45		0.05
BME/BMR TM271 23 5.5 4.5 7.0 10.0 5.64 0.80 TM272 23 8.5 7.0 10.0 1.5 5.41 0.71 TM273 23 10.8 8.9 12.7 1.9 5.56 0.75 TM274 23 15.1 12.4 17.8 2.7 5.56 0.73 TM275 23 24.3 19.9 28.7 4.4 5.88 0.73 TM275 23 24.3 19.9 28.7 4.4 5.88 0.73 TM271 45 6.7 5.5 7.9 1.2 6.57 0.97 TM272 45 12.6 10.3 14.9 2.3 5.40 1.05 TM273 45 16.1 13.2 19.0 2.9 5.47 1.12 TM274 45 22.6 18.5 26.7 4.1 4.87 1.10 TM274 45 32.6 18.5 26.7 4.1 4.87 1.10 TM274 45 32.6 18.5 26.7 4.1 4.87 1.10 TM272 10 12.9 10.6 15.2 2.3 7.21 1.07 TM272 10 12.9 10.6 15.2 2.3 7.21 1.07 TM272 10 12.9 0.4 29.4 4.5 5.14 1.21 TM274 11 24.9 20.4 29.4 4.5 5.14 1.21 TM275 10 40.9 33.5 48.3 7.4 5.67 .9 1.14 0.20 Siemens Dimension Vista TM271 24 6.3 5.2 7.4 1.1 3.0 5.00 1.15 TM273 11 16.6 13.6 19.6 3.0 5.00 1.15 TM273 11 24.9 20.4 29.4 4.5 5.14 1.21 TM274 11 24.9 20.4 29.4 4.5 5.14 1.21 TM274 11 24.9 20.4 29.4 4.5 5.14 1.21 TM275 10 40.9 33.5 48.3 7.4 5.67 0.89 1.14 0.09 Siemens Dimension Vista TM271 24 6.3 5.2 7.4 1.1 3.02 0.91 TM273 24 12.4 10.2 14.6 2.2 3.95 0.88 TM274 11 24.9 20.4 29.4 4.5 5.14 1.21 TM275 10 40.9 33.5 48.3 7.4 5.67 0.89 1.14 0.09 Siemens Dimension Vista TM271 24 6.3 5.2 7.4 1.1 3.07 0.89 0.04 Siemens Dimension Vista DUV TM271 24 8.4 6.9 9.9 1.5 13.33 1.22 TM275 12 11.8 9.7 13.9 2.1 9.24 0.98 TM271 12 8.4 6.9 9.9 1.5 13.33 1.22 TM273 12 11.8 9.7 13.9 2.1 9.24 0.98 TM274 12 11.8 9.7 13.9 2.1 9.24 0.98 TM273 12 12 11.8 9.7 13.9 2.1 9.24 0.98 TM273 12 12 18.8 15.4 22.2 3.4 12.61 0.91 TM274 12 18.8 15.4 22.2 3.4 12.61 0.91	Roche Elecsys & Cobas									
TM272       23       8.5       7.0       10.0       1.5       5.41       0.71         TM273       23       10.8       8.9       12.7       1.9       5.56       0.75         TM274       23       15.1       12.4       17.8       2.7       5.56       0.73         TM275       23       24.3       19.9       28.7       4.4       5.88       0.73         Siemens Advia Centaur XP & CP       COB/COC           0.74       0.03         Siemens Advia Centaur XP & CP       COB/COC										
TM273       23       10.8       8.9       12.7       1.9       5.56       0.75         TM274       23       15.1       12.4       17.8       2.7       5.56       0.73         TM275       23       24.3       19.9       28.7       4.4       5.88       0.73         Siemens Advia Centaur XP & CP	TM271	23	5.5	4.5	6.5	1.0	5.64		0.80	
TM274       23       15.1       12.4       17.8       2.7       5.56       0.73         TM275       23       24.3       19.9       28.7       4.4       5.88       0.73         Siemens Advia Centaur XP & CP	TM272	23	8.5	7.0	10.0	1.5	5.41		0.71	
TM275         23         24.3         19.9         28.7         4.4         5.88         0.73           Siemens Advia Centaur XP & CP	TM273	23	10.8	8.9	12.7	1.9	5.56		0.75	
mean ±SD         5.61         0.17         0.74         0.03           Siemens Advia Centaur XP & CP COB/COC	TM274	23	15.1	12.4	17.8	2.7	5.56		0.73	
Siemens Advia Centaur XP & CP COB/COC           TM271         45         6.7         5.5         7.9         1.2         6.57         0.97           TM272         45         12.6         10.3         14.9         2.3         5.40         1.05           TM273         45         16.1         13.2         19.0         2.9         5.47         1.12           TM274         45         22.6         18.5         26.7         4.1         4.87         1.10           TM275         45         38.6         31.7         45.5         6.9         5.49         1.16           mean $\pm$ SD         5.56         0.62         1.08         0.07           Siemens Immulite 2000         DPD         D         11         7.1         5.8         8.4         1.3         5.35         1.03           TM271         11         7.1         5.8         8.4         1.3         5.67         1.2         1.3           TM272         10         12.9         10.6         15.2         2.3         7.21         1.07           TM273         11         24.9         13.6         13.6         3.0         5.00         1.15           <	TM275	23	24.3	19.9	28.7	4.4	5.88		0.73	
COB/COC           TM271         45         6.7         5.5         7.9         1.2         6.57         0.97           TM272         45         12.6         10.3         14.9         2.3         5.40         1.05           TM273         45         16.1         13.2         19.0         2.9         5.47         1.12           TM274         45         22.6         18.5         26.7         4.1         4.87         1.10           TM275         45         38.6         31.7         45.5         6.9         5.49         1.16           mean $\pm$ SD         5.56         0.62         1.08         0.07         Sienens Immulite 2000         0.07           DPD         TM271         11         7.1         5.8         8.4         1.3         5.35         1.03           TM273         10         12.9         10.6         15.2         2.3         7.21         1.07           TM274         11         24.9         20.4         29.4         4.5         5.14         1.21           TM275         10         40.9         33.5         48.3         7.4         5.67         0.89         1.14         0.09						mean ±SD	5.61	0.17	0.74	0.03
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		XP & CP								
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	TM271	45	6.7	5.5	7.9	1.2	6.57		0.97	
TM274       45       22.6       18.5       26.7       4.1       4.87       1.10         TM275       45       38.6       31.7       45.5       6.9       5.49       1.16         mean ±SD       5.56       0.62       1.08       0.07         Siemens Immulite 2000         DPD       7       11       7.1       5.8       8.4       1.3       5.35       1.03         TM272       10       12.9       10.6       15.2       2.3       7.21       1.07         TM273       11       16.6       13.6       19.6       3.0       5.00       1.15         TM274       11       24.9       20.4       29.4       4.5       5.14       1.21         TM275       10       40.9       3.5       7.4       5.67       0.89       1.14       0.09         Siemens Dimension Vista         DUV       mean ±SD       5.67       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.02       0.86         TM27	TM272	45	12.6	10.3	14.9	2.3	5.40		1.05	
TM275         45         38.6         31.7         45.5         6.9         5.49         1.16           Mean ±SD         5.56         0.62         1.08         0.07           Siemens Immulite 2000         DPD         5.56         0.62         1.08         0.07           TM271         11         7.1         5.8         8.4         1.3         5.35         1.03           TM272         10         12.9         10.6         15.2         2.3         7.21         1.07           TM273         11         16.6         13.6         19.6         3.0         5.00         1.15           TM274         11         24.9         20.4         29.4         4.5         5.14         1.21           TM275         10         40.9         33.5         48.3         7.4         5.67         0.89         1.14         0.09           Siemens Dimension Vista         UV         UV         11.1         3.02         0.91         1.14         0.09           TM271         24         6.3         5.2         7.4         1.1         3.02         0.86           TM273         24         12.4         10.2         14.6         2.2	TM273	45	16.1	13.2	19.0	2.9	5.47		1.12	
mean ±SD         5.56         0.62         1.08         0.07           Siemens Immulite 2000 DPD	TM274	45	22.6	18.5	26.7	4.1	4.87		1.10	
Siemens Immulite 2000           DPD         TM271         11         7.1         5.8         8.4         1.3         5.35         1.03           TM272         10         12.9         10.6         15.2         2.3         7.21         1.07           TM273         11         16.6         13.6         19.6         3.0         5.00         1.15           TM273         11         24.9         20.4         29.4         4.5         5.14         1.21           TM275         10         40.9         33.5         48.3         7.4         5.67         1.23           mean ±SD         5.67         0.89         1.14         0.09           Siemens Dimension Vista           DUV         TM271         24         6.3         5.2         7.4         1.1         3.02         0.91           TM273         24         12.4         10.2         14.6         2.2         3.95         0.86           TM274         24         17.5         14.4         20.7         3.2         3.02         0.86           TM275         24         28.8         23.6         34.0         5.2         0.86 <t< td=""><td>TM275</td><td>45</td><td>38.6</td><td>31.7</td><td>45.5</td><td>6.9</td><td>5.49</td><td></td><td>1.16</td><td></td></t<>	TM275	45	38.6	31.7	45.5	6.9	5.49		1.16	
DPD           TM271         11         7.1         5.8         8.4         1.3         5.35         1.03           TM272         10         12.9         10.6         15.2         2.3         7.21         1.07           TM273         11         16.6         13.6         19.6         3.0         5.00         1.15           TM274         11         24.9         20.4         29.4         4.5         5.14         1.21           TM275         10         40.9         33.5         48.3         7.4         5.67         0.89         1.14         0.09           Siemens Dimension Vista           DUV         mean ±SD         5.67         0.89         1.14         0.09           Siemens Dimension Vista           DUV         TM271         24         6.3         5.2         7.4         1.1         3.02         0.91           TM273         24         12.4         10.2         14.6         2.2         3.95         0.86           TM274         24         17.5         14.4         20.7         3.2         3.20         0.86           TM275         24         28.8						mean ±SD	5.56	0.62	1.08	0.07
TM271       11       7.1       5.8       8.4       1.3       5.35       1.03         TM272       10       12.9       10.6       15.2       2.3       7.21       1.07         TM273       11       16.6       13.6       19.6       3.0       5.00       1.15         TM274       11       24.9       20.4       29.4       4.5       5.14       1.21         TM275       10       40.9       33.5       48.3       7.4       5.67       0.89       1.14       0.09         Siemens Dimension Vista         DUV       mean ±SD       5.67       0.89       1.14       0.09         TM271       24       6.3       5.2       7.4       1.1       3.02       0.91         TM272       24       9.6       7.9       11.3       1.7       2.50       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.02       0.86         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86										
TM272       10       12.9       10.6       15.2       2.3       7.21       1.07         TM273       11       16.6       13.6       19.6       3.0       5.00       1.15         TM274       11       24.9       20.4       29.4       4.5       5.14       1.21         TM275       10       40.9       33.5       48.3       7.4       5.67       1.23         mean ±SD       5.67       0.89       1.14       0.09         Siemens Dimension Vista         DUV       TM271       24       6.3       5.2       7.4       1.1       3.02       0.91         TM272       24       9.6       7.9       11.3       1.7       2.50       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM273       24       17.5       14.4       20.7       3.2       3.20       0.86         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         TM274       12       8.4       6.9       9.9       1.5       13.33       1.22         TM271		11	7.1	5.8	8.4	1.3	5.35		1.03	
TM273       11       16.6       13.6       19.6       3.0       5.00       1.15         TM274       11       24.9       20.4       29.4       4.5       5.14       1.21         TM275       10       40.9       33.5       48.3       7.4       5.67       0.89       1.14       0.09         Siemens Dimension Vista         DUV       TM271       24       6.3       5.2       7.4       1.1       3.02       0.91         TM272       24       9.6       7.9       11.3       1.7       2.50       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.20       0.85         TM274       24       17.5       14.4       20.7       3.2       3.02       0.86         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         JDC/JJF       TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM271       12       8.4       6.9       9.9	TM272	10								
TM274       11       24.9       20.4       29.4       4.5       5.14       1.21         TM275       10       40.9       33.5       48.3       7.4       5.67       1.23         mean ±SD       5.67       0.89       1.14       0.09         Siemens Dimension Vista         DUV	TM273	11	16.6	13.6			5.00			
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	TM274	11	24.9	20.4			5.14			
mean ±SD         5.67         0.89         1.14         0.09           Siemens Dimension Vista DUV	TM275	10	40.9	33.5	48.3	7.4	5.67		1.23	
DUV TM271 24 6.3 5.2 7.4 1.1 3.02 0.91 TM272 24 9.6 7.9 11.3 1.7 2.50 0.80 TM273 24 12.4 10.2 14.6 2.2 3.95 0.86 TM274 24 17.5 14.4 20.7 3.2 3.20 0.85 TM275 24 28.8 23.6 34.0 5.2 3.02 0.86 Mean ±SD 3.14 0.52 0.86 0.04 Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF TM271 12 8.4 6.9 9.9 1.5 13.33 1.22 TM272 12 11.8 9.7 13.9 2.1 9.24 0.98 TM273 12 12.9 10.6 15.2 2.3 16.67 0.90 TM274 12 18.8 15.4 22.2 3.4 12.61 0.91 TM275 12 30.0 24.6 35.4 5.4 4.83 0.90						mean ±SD		0.89		0.09
TM271       24       6.3       5.2       7.4       1.1       3.02       0.91         TM272       24       9.6       7.9       11.3       1.7       2.50       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.20       0.85         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         mean ±SD       3.14       0.52       0.86         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM272       12       11.8       9.7       13.9       2.1       9.24       0.98         TM273       12       12.9       10.6       15.2       2.3       16.67       0.90         TM273       12       12.8       15.4       22.2       3.4       12.61       0.91         TM275       12       30.0       24.6       35.4       5.4		a								
TM272       24       9.6       7.9       11.3       1.7       2.50       0.80         TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.20       0.85         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         mean ±SD       3.14       0.52       0.86         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM272       12       11.8       9.7       13.9       2.1       9.24       0.98         TM273       12       12.9       10.6       15.2       2.3       16.67       0.90         TM274       12       18.8       15.4       22.2       3.4       12.61       0.91         TM275       12       30.0       24.6       35.4       5.4       4.83       0.90		24	6.3	5.2	7.4	1.1	3.02		0.91	
TM273       24       12.4       10.2       14.6       2.2       3.95       0.86         TM274       24       17.5       14.4       20.7       3.2       3.20       0.85         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         mean ±SD       3.14       0.52       0.86         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM272       12       11.8       9.7       13.9       2.1       9.24       0.98         TM273       12       12.9       10.6       15.2       2.3       16.67       0.90         TM274       12       18.8       15.4       22.2       3.4       12.61       0.91         TM275       12       30.0       24.6       35.4       5.4       4.83       0.90										
TM274       24       17.5       14.4       20.7       3.2       3.20       0.85         TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         mean ±SD       3.14       0.52       0.86         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM272       12       11.8       9.7       13.9       2.1       9.24       0.98         TM273       12       12.9       10.6       15.2       2.3       16.67       0.90         TM274       12       18.8       15.4       22.2       3.4       12.61       0.91         TM275       12       30.0       24.6       35.4       5.4       4.83       0.90										
TM275       24       28.8       23.6       34.0       5.2       3.02       0.86         Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJF       3.14       0.52       0.86       0.04         TM271       12       8.4       6.9       9.9       1.5       13.33       1.22         TM272       12       11.8       9.7       13.9       2.1       9.24       0.98         TM273       12       12.9       10.6       15.2       2.3       16.67       0.90         TM274       12       18.8       15.4       22.2       3.4       12.61       0.91         TM275       12       30.0       24.6       35.4       5.4       4.83       0.90										
mean ±SD3.140.520.860.04Ortho Clinical Diag Vitros Eci/ECiQ & 5600 JJC/JJFTM271128.46.99.91.513.331.22TM2721211.89.713.92.19.240.98TM2731212.910.615.22.316.670.90TM2741218.815.422.23.412.610.91TM2751230.024.635.45.44.830.90										
Ortho Clinical Diag Vitros Eci/ECiQ & 5600           JJC/JJF           TM271         12         8.4         6.9         9.9         1.5         13.33         1.22           TM272         12         11.8         9.7         13.9         2.1         9.24         0.98           TM273         12         12.9         10.6         15.2         2.3         16.67         0.90           TM274         12         18.8         15.4         22.2         3.4         12.61         0.91           TM275         12         30.0         24.6         35.4         5.4         4.83         0.90		27	20.0	20.0	07.0			0.52		0.04
TM271128.46.99.91.513.331.22TM2721211.89.713.92.19.240.98TM2731212.910.615.22.316.670.90TM2741218.815.422.23.412.610.91TM2751230.024.635.45.44.830.90	-	s Eci/ECi	Q & 5600					0.02		0.01
TM2721211.89.713.92.19.240.98TM2731212.910.615.22.316.670.90TM2741218.815.422.23.412.610.91TM2751230.024.635.45.44.830.90		12	8.4	6.9	9.9	1.5	13.33		1.22	
TM2731212.910.615.22.316.670.90TM2741218.815.422.23.412.610.91TM2751230.024.635.45.44.830.90										
TM2741218.815.422.23.412.610.91TM2751230.024.635.45.44.830.90										
TM275 12 30.0 <b>24.6 35.4</b> 5.4 4.83 0.90										
				-	-			4.49		0.14

### Table 5 (cont.): 5-14 NYS Tumor Marker PT Summary for CEA

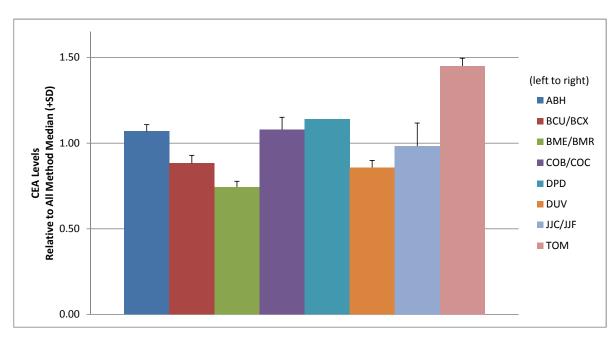
Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data	Method Bias Relative to All Method Median
Tosoh AIA							
ТОМ							
TM271	6	9.9	8.1	11.7	1.8	3.03	1.43
TM272	6	17.0	13.9	20.1	3.1	2.41	1.41
TM273	6	21.9	18.0	25.8	3.9	2.88	1.52
TM274	6	30.2	24.8	35.6	5.4	2.85	1.47
TM275	6	47.0	38.5	55.5	8.5	1.83	1.41
					mean ±SD	2.60 0	.49 <b>1.45</b> 0.05

	All		
	Method	Median	
Sample ID	Median	% CV	
TM271	6.9	5.62	
TM272	12.1	5.63	
TM273	14.4	5.23	
TM274	20.6	5.00	
TM275	33.4	5.16	
		Average 5.33	

Allowable CV % 6.0

Allowable Error if >/= 5 ng/ml (+/-) % 18.0

Allowable Error if < 5 ng/ml (+/- ng/ml) 0.9



### Figure 5: CEA Method Comparison

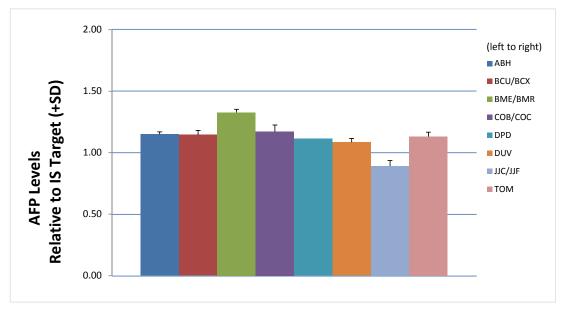
Aboth Architect         Ab	Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target							
ABHINZP1321.417.525.33.92.51.031.16TM272312.910.6015.22.32.71.021.17TM273312.910.6015.22.32.30.991.01TM275319.115.72.43.42.361.010.021.17TM274320.616.924.33.75.490.091.010.021.12Beckmar Unicel & Accessiz'Beckmar Unicel & Accessiz'<			(		,	2	Than Dula				.e .a.get							
TM2723857.010.01.53.530.491.161.17TM273312.810.613.04.74.601.021.171.17TM27432.6.321.63.104.74.601.021.021.131.02TM275319.115.72.5.83.42.560.021.010.021.150.02Beckman Undel & Access?U1.6.92.4.33.75.490.091.161.121.021.011.121.021.011.121.021.011.121.021.011.011.141.041.011.111.021.011.131.021.011.131.021.011.131.021.011.131.021.011.131.021.011.131.021.011.131.021.011.141.041.041.021.011.131.021.011.131.02	ABH																	
TM274328.321.41.0.61.0.4.74.001.0.21.1.7TM274319.115.722.53.42.3.61.010.021.1.2TM275319.115.722.53.42.3.60.921.010.021.1.2TM2711920.616.924.33.75.400.021.011.1.2TM2711920.615.12.36.640.1011.1.11.6TM2731912.810.515.12.36.640.1011.1.10.04TM2741926.021.330.74.74.881.010.011.1.10.04TM2741912.621.330.74.74.881.010.011.1.10.04PME/PMR1712.622.73.45.820.011.161.3.31.341.34 <td>TM271</td> <td>3</td> <td>21.4</td> <td>17.5</td> <td>25.3</td> <td>3.9</td> <td>2.57</td> <td></td> <td>1.03</td> <td></td> <td>1.16</td> <td></td>	TM271	3	21.4	17.5	25.3	3.9	2.57		1.03		1.16							
The274326.321.631.04.74.601.021.12TH2751915.72.503.42.361.010.021.150.02Bockman Unical & Access?553.42.360.921.010.021.150.02Bockman Unical & Access?192.6615.92.165.470.921.011.161.16TH271192.667.210.41.66.701.021.161.16Th274192.662.133.074.74.881.011.111.11Th274192.662.133.074.74.881.011.110.04Th274192.662.133.074.74.891.161.311.331.33Th27419172.452.011.732.63.201.171.331.311.33 </td <td>TM272</td> <td>3</td> <td>8.5</td> <td>7.0</td> <td>10.0</td> <td>1.5</td> <td>3.53</td> <td></td> <td>0.99</td> <td></td> <td>1.16</td> <td></td>	TM272	3	8.5	7.0	10.0	1.5	3.53		0.99		1.16							
TM275     3     19.1     19.7     22.5     3.4     2.86     1.01     0.02     1.13       Backman Unical & Access/2 BOUBCX     50.92     1.01     0.02     1.15     0.02       TM271     19     20.6     16.9     24.3     3.7     5.40     0.99     1.12     1.20       TM272     19     8.8     7.2     10.4     1.6     6.70     1.02     1.20       TM273     19     12.8     10.5     15.1     2.3     6.64     1.01     1.11       TM275     19     19.1     12.3     30.7     4.7     4.88     1.01     1.13       TM275     19     19.1     12.8     3.4     5.92     1.01     0.01     1.14       TM275     17     10.0     8.2     1.18     4.30     1.16     1.36       TM271     17     24.5     20.1     28.9     4.4     4.94     1.16     1.33       TM271     17     20.3     24.8     55.8     7.00     1.17     1.30       TM271     17     22.3     4.3     5.9     1.01     1.31       TM272     17     10.0     8.2     1.7     9.24     1.07     1.33       TM275	TM273										1.17							
near sb0         3.15         0.92         1.01         0.02         1.15         0.02           Beckman Unical Access/2         Beckman Unical Access/2         5.49         0.99         1.12         0.02           TM2/21         19         8.8         7.2         10.4         1.6         6.70         1.01         1.16           TM2/21         19         8.8         7.2         10.4         1.6         6.70         1.01         1.11           TM2/21         19         8.8         7.2         10.4         5.64         1.01         1.11           TM2/21         19         26.0         21.3         30.7         4.7         4.88         1.01         1.11           TM2/21         19         19.1         15.7         22.5         3.4         4.94         1.18         1.33           Machielancy & Cobas         Machielancy & S.Cobas         Machielancy & S.Gobas         3.90         7.66         1.03         1.16           TM2/21         17         22.2         18.2         4.4         4.94         1.16         1.33           TM2/22         17         20.0         1.25         2.135         1.17         0.01         1.33         0.03	TM274	3	26.3	21.6	31.0	4.7	4.60		1.02		1.12							
Backman Unicel & Access/2 EQUBCX TM271 19 28.6 16.9 24.3 3.7 5.49 0.99 1.12 TM272 19 8.8 7.2 104 16 670 102 1.20 TM273 19 12.8 10.5 15.1 2.3 6.64 1.01 1.16 TM274 19 26.0 21.3 30.7 4.7 4.88 1.01 1.11 TM275 19 18.1 15.7 22.5 3.4 5.52 0.01 1.13 TM271 17 24.5 20.1 28.9 4.4 4.94 1.18 1.33 TM272 17 10.0 8.2 11.8 1.8 4.90 1.16 1.36 TM271 17 24.5 20.1 12.1 17.3 2.6 3.20 1.16 1.33 TM272 17 10.0 8.2 11.8 1.8 4.90 1.16 1.36 TM274 17 30.3 24.8 35.8 5.5 7.00 1.177 1.31 TM275 17 22.2 18.2 26.2 4.0 5.05 1.177 1.31 Siemens Advia Centaur XP & CP COB/COC TM271 25 21.4 17.5 25.3 3.9 7.66 1.03 1.16 TM272 25 9.2 7.5 10.9 1.7 9.24 1.07 1.33 0.03 Siemens Advia Centaur XP & CP COB/COC TM271 25 21.4 17.5 25.3 3.9 7.66 1.03 1.16 TM272 25 9.2 7.5 10.9 1.7 9.24 1.07 1.25 TM271 2.5 2.14 10.7 15.5 2.4 0.95 1.03 1.19 TM272 25 9.2 7.5 10.9 1.7 9.24 1.07 1.25 TM271 2.5 2.13 1.0.7 15.5 2.4 0.95 1.03 1.19 TM271 2.5 2.14 17.5 2.53 3.7 5.54 1.00 1.1.12 TM273 2.5 13.1 0.7 15.5 2.4 0.95 1.03 1.19 TM274 2.5 2.6.1 21.4 30.8 4.7 5.79 1.01 1.1.2 TM274 2.5 2.6.1 21.4 30.8 4.7 5.79 1.01 1.1.2 TM274 2.5 2.6.1 21.4 30.8 4.7 5.79 1.01 1.1.2 TM274 2.5 2.6.1 21.4 30.8 4.7 5.79 1.01 1.1.2 TM271 16 20.8 17.1 22.7 3.5 6.51 1.01 0.2 1.17 0.05 Siemens Immulite 2000 DPU TM271 7 1.9.5 6.4 6.9 9.9 1.5 7.14 0.98 1.15 TM272 1.5 8.4 6.9 9.9 0.5 7.1 0.04 1.06 TM271 1.6 2.5.7 21.1 30.3 4.6 7.94 0.99 0.2 1.11 0.03 Siemens Dimension Vista DV TM271 7 1.9.5 16.1 2.1 3.5 5.71 0.04 1.06 TM271 7 1.2.5 1.0.1 0.1 1.00 TM272 7 8.3 6.8 9.8 0.5 1.00 TM271 7 1.2.1 7.3 2.6 5.59 0.9.4 0.98 0.02 1.11 0.03 Siemens Dimension Vista DV TM271 7 1.2.1 9.9 44.3 2.2 5.62 0.97 1.1.0 TM272 7 7 8.3 6.8 9.8 0.5 0.01 1.00 TM274 7 2.2.1 5.3 8.4 1.3 7.89 0.83 0.97 TM274 5 2.0.1 16.5 23.7 3.6 5.07 0.78 0.89 TM274 5 2.0.1 16.5 23.7 3.6 5.07 0.78 0.86	TM275	3	19.1	15.7	22.5	3.4	2.36		1.01		1.13							
BCUBOX TM271 19 20.6 16.9 20.6 17.2 10.7 17.2 19 20.6 17.2 10.4 1.6 5.7 2 10.4 1.6 5.7 1 1.0 1.0 1.1 1.0 1.1 1 1.0 1.1 1.0 1.1 1 1.0 1.1 1 1.0 1.1 1.0 1.1 1 1.0 1.1 1 1.0 1.1 1 1 1						mean ±SD	3.15	0.92	1.01	0.02	1.15	0.02						
TM222       19       8.8       7.2       10.4       1.6       6.70       1.02       1.20         TM273       19       12.6       0.5       15.1       2.3       6.64       1.01       1.16         TM273       19       19.0       10.1       15.7       2.5       3.4       5.92       1.01       1.11         TM275       19       19.1       15.7       2.5       3.4       5.92       1.01       0.01       1.14       0.04         Roche Elecsys & Cobas       Koreenee State       Koreenee State       Koreenee State       1.18       1.48       4.90       1.16       1.33       1.33       1.33       1.33       1.35       1.35       1.35       1.35       1.35       1.36       1.36       1.36       1.33       1.34       1.33       1.34       1.33       1.34<	Beckman Unicel & Access/2 BCU/BCX																	
TM273       19       12.8       10.5       15.1       2.3       6.64       1.01       1.16	TM271	19	20.6	16.9	24.3	3.7	5.49		0.99		1.12							
TM274       19       28.0       21.3       30.7       4.7       4.88       1.01       1.11         TM275       19       19.1       15.7       22.5       3.4       5.92       1.01       0.01       1.13         Rache Elecsys & Cobas       BMEEMAR       BMEEMAR       Seen ± 50       5.92       0.77       1.01       0.01       1.14       0.04         TM271       17       24.5       20.1       28.9       4.4       4.94       1.18       1.8       1.80       1.33	TM272	19	8.8	7.2	10.4	1.6	6.70		1.02		1.20							
TM275       19       19.1       15.7       22.5       3.4       5.92       0.01       1.13       .00         Roche Elecsys & Cobas	TM273	19	12.8	10.5	15.1	2.3	6.64		1.01		1.16							
mean ±SD         5.93         0.77         1.01         0.01         1.14         0.04           Roche Elexys & Cobas         MeZMM          1.14         0.04         1.14         1.03         1.01         1.01         0.01         1.14         0.04           TM271         17         24.5         20.1         28.9         4.4         4.94         1.18         1.33         1.33         1.33         1.34         1.30         1.16         1.33         1.35         1.17         1.33         1.35         1.35         1.17         1.33         1.35         1.35         1.17         1.33         1.33         1.33         1.35         1.17         1.33         1.33         1.35         1.17         1.33         1.33         1.33         1.35         1.17         1.33         1.33         1.33         1.35         1.17         1.33         1.35         5.71         1.31	TM274	19	26.0	21.3	30.7	4.7	4.88		1.01		1.11							
Roche Elessys & Cobas           BME/BMR           TM2/1         17         24.5         20.1         28.9         4.4         4.94         1.18         1.33           TM2/2         17         10.0         8.2         11.8         1.8         4.90         1.16         1.36           TM2/2         17         10.0         8.2         11.8         1.8         4.90         1.16         1.36           TM2/3         16         1.7         1.17         1.30         T         1.18         1.33         1.06           TM2/5         17         22.2         18.2         26.2         4.0         5.05         1.17         0.01         1.33         0.03           Siemens Advia Centaur XP & CP         COB/COC         1.17         2.4         1.07         1.55         2.4         6.95         1.03         1.16           TM2/2         25         9.2         7.5         10.9         1.7         9.24         1.007         1.25           TM2/2         25         12.1         21.7         3.5         6.51         1.01         1.14           TM2/2         15         8.4         6.9         9.9         1.5 </td <td>TM275</td> <td>19</td> <td>19.1</td> <td>15.7</td> <td>22.5</td> <td>3.4</td> <td>5.92</td> <td></td> <td>1.01</td> <td></td> <td>1.13</td> <td></td>	TM275	19	19.1	15.7	22.5	3.4	5.92		1.01		1.13							
DNE_IDM         - </td <td></td> <td></td> <td></td> <td></td> <td></td> <td>mean ±SD</td> <td>5.93</td> <td>0.77</td> <td>1.01</td> <td>0.01</td> <td>1.14</td> <td>0.04</td>						mean ±SD	5.93	0.77	1.01	0.01	1.14	0.04						
TM22       17       10.0       8.2       11.8       1.8       4.90       1.16       1.36         TM273       16       14.7       12.1       17.3       2.6       3.20       1.16       1.33         TM274       17       23.2       18.2       26.2       3.20       1.17       1.33         TM275       17       22.2       18.2       26.2       4.0       5.05       1.17       0.01       1.33         Siemens Advia Centaur XP & CP       COB/COC       1.35       1.7       0.01       1.33       0.03         TM271       25       9.2       7.5       10.9       1.7       9.24       1.07       1.25         TM272       25       9.2       7.5       10.9       1.7       9.24       1.07       1.25         TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.12         TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.12         TM274       16       20.8       17.1       24.5       3.7       5.4       1.00       1.13         TM275       15       8.4       6.9<	Roche Elecsys & Cobas BME/BMR																	
TM273       16       14.7       12.1       17.3       2.6       3.20       1.16       1.33         TM274       17       30.3       24.8       35.8       5.5       7.00       1.17       1.30         TM275       17       2.2       18.2       26.2       4.0       5.02       1.35       1.17       0.01       1.33       0.03         Siemens Advia Centaur XP & CP       COB(COC       502       1.35       1.17       0.01       1.33       0.03         Siemens Advia Centaur XP & CP       COB(COC       1.15       25.3       3.9       7.66       1.03       1.16         TM272       25       9.2       7.5       10.9       1.7       9.24       1.07       1.25         TM273       25       13.1       10.7       15.5       2.4       6.95       1.03       1.14         TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.14         TM275       19       1.5       7.35       6.51       1.01       1.14         TM275       16       12.5       10.3       14.8       2.3       8.64       0.98       1.15         TM271	TM271	17	24.5	20.1	28.9	4.4	4.94		1.18		1.33							
TM274       17       30.3       24.8       35.8       5.5       7.00       1.17       1.30         TM275       17       22.2       18.2       26.8       4.0       5.02       1.17       1.30         Silemens Advia Centaur XP & CP	TM272	17	10.0	8.2	11.8	1.8	4.90		1.16		1.36							
TM275     17     22.2     18.2     26.2     4.0     5.05     1.17     1.31       Imman ±SD     5.02     1.35     1.17     0.01     1.33     0.03       Siemens Advia Centaur XP & CP     COB/COC     1.35     1.17     0.01     1.33     0.03       TM271     25     21.4     17.5     25.3     3.9     7.66     1.03     1.16       TM273     25     13.1     10.7     15.5     2.4     6.95     1.03     1.19       TM274     25     26.1     21.4     30.8     4.7     5.79     1.01     1.12       TM275     25     19.2     15.7     22.7     3.5     6.51     1.01     1.14       TM275     25     19.2     15.7     2.7     3.5     6.51     1.01     1.14       TM275     16     17.1     24.5     3.7     5.24     1.00     1.13       TM271     16     20.8     17.1     24.5     3.7     5.24     1.00     1.13       TM273     16     12.5     10.3     14.8     2.3     8.64     0.98     1.15       TM274     16     25.7     21.1     30.3     4.6     7.94     0.09     1.10 <td>TM273</td> <td>16</td> <td>14.7</td> <td>12.1</td> <td>17.3</td> <td>2.6</td> <td>3.20</td> <td></td> <td>1.16</td> <td></td> <td>1.33</td> <td></td>	TM273	16	14.7	12.1	17.3	2.6	3.20		1.16		1.33							
mean ±SD         5.02         1.35         1.17         0.01         1.33         0.03           Siemens Advia Centaur XP & CP         COB/COC                                      1.13         0.01         1.13         0.03         1.16             1.16           1.17         0.24         1.07         1.55         2.4         6.55         1.03         1.19             1.19           1.12          1.12          1.12          1.12          1.12          1.12          1.12          1.12          1.11         0.05          1.17         0.05          1.17         0.05          1.17         0.05          1.17         0.01         1.13          1.17         1.17         1.13	TM274	17	30.3	24.8	35.8	5.5	7.00		1.17		1.30							
Siemens Advia Centaur XP & CP           COB/COC           TM271         25         21.4         17.5         25.3         3.9         7.66         1.03         1.16           TM272         25         9.2         7.5         10.9         1.7         9.24         1.07         1.25           TM273         25         13.1         10.7         15.5         2.4         6.95         1.03         1.19           TM274         25         26.1         21.4         30.8         4.7         5.79         1.01         1.12           TM275         25         19.2         15.7         22.7         3.5         6.51         1.01         1.14           mean ±SD         7.23         1.31         1.03         0.02         1.17         0.05           Siemens Immulite 2000           DP           TM271         16         25.7         21.1         30.3         4.6         7.94         0.98         1.15           TM273         16         12.5         10.3         14.8         2.3         8.64         0.98         0.02         1.11         0.03 <th colspan="6" td="" th<="" tm275<=""><td>TM275</td><td>17</td><td>22.2</td><td>18.2</td><td>26.2</td><td>4.0</td><td>5.05</td><td></td><td>1.17</td><td></td><td>1.31</td><td></td></th>	<td>TM275</td> <td>17</td> <td>22.2</td> <td>18.2</td> <td>26.2</td> <td>4.0</td> <td>5.05</td> <td></td> <td>1.17</td> <td></td> <td>1.31</td> <td></td>						TM275	17	22.2	18.2	26.2	4.0	5.05		1.17		1.31	
COBICOC         View						mean ±SD	5.02	1.35	1.17	0.01	1.33	0.03						
TM272       25       9.2       7.5       10.9       1.7       9.24       1.07       1.25         TM273       25       13.1       10.7       15.5       2.4       6.95       1.03       1.19         TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.12         TM275       25       19.2       15.7       2.0       3.5       6.51       1.01       1.14         TM274       26       26.8       17.1       24.5       3.7       5.24       1.00       1.13         Siemens Immulite 2000       DPD       1.5       7.14       0.98       1.15       1.5         TM273       16       12.5       10.3       14.8       2.3       8.64       0.98       1.15         TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.00         TM274       16       17.9       14.7       21.5       8.63       3.94       0.96       0.02       1.11       0.03         Siemens Dimension Vista       DuV       106       1.55       9.83       3.94       0.96       1.06       1.06       1.06       1.02	Siemens Advia Centaur XP & COB/COC	& CP																
TM273       25       13.1       10.7       15.5       2.4       6.95       1.03       1.19         TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.12         TM275       25       19.2       15.7       22.7       3.5       6.51       1.01       1.14         mean ±SD       7.23       1.31       1.03       0.02       1.17       0.05         Siemens Immulite 2000       DPD	TM271	25	21.4	17.5	25.3	3.9	7.66		1.03		1.16							
TM274       25       26.1       21.4       30.8       4.7       5.79       1.01       1.12         TM275       25       19.2       15.7       22.7       3.5       6.51       1.01       1.14         TM275       25       19.2       15.7       22.7       3.5       6.51       1.01       1.14         Siemens Immulite 2000       7.23       1.31       1.03       0.02       1.7       0.05         DPD       16       20.8       17.1       24.5       3.7       5.24       1.00       1.13         TM272       15       8.4       6.9       9.9       1.5       7.14       0.98       1.13         TM273       16       12.5       10.3       14.8       2.3       8.64       0.99       1.10         TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.10         TM275       14.7       21.7       3.2       15.5       9.98       0.02       1.11       0.03         Siemens Dimension Vista         9.83       3.54       0.99       1.10       1.12         TM273       7       8.3       6.8	TM272	25	9.2	7.5	10.9	1.7	9.24		1.07		1.25							
TM275       25       19.2       15.7       22.7       3.5       6.51       1.01       1.14         Mean ±SD       7.23       1.31       1.03       0.02       1.17       0.05         Siemens Immulite 2000       DPO	TM273	25	13.1	10.7	15.5	2.4	6.95		1.03		1.19							
mean ±SD         7.23         1.31         1.03         0.02         1.17         0.05           Siemens Immulite 2000         DPD	TM274	25	26.1	21.4	30.8	4.7	5.79		1.01		1.12							
Siemens Immulite 2000           DPD         TM271         16         20.8         17.1         24.5         3.7         5.24         1.00         1.13           TM272         15         8.4         6.9         9.9         1.5         7.14         0.98         1.15           TM273         16         12.5         10.3         14.8         2.3         8.64         0.98         1.13           TM274         16         25.7         21.1         30.3         4.6         7.94         0.99         1.10           TM275         16         17.9         14.7         21.1         3.2         15.59         0.94         1.06           TM275         16         17.9         14.7         21.1         3.2         15.59         0.94         1.06           TM271         7         19.6         16.1         23.1         3.5         5.71         0.94         1.06           TM271         7         8.3         6.8         9.8         1.5         6.27         0.97         1.13           TM273         7         12.1         9.9         2.2         5.62         0.95         1.05           TM275         7 <td>TM275</td> <td>25</td> <td>19.2</td> <td>15.7</td> <td>22.7</td> <td>3.5</td> <td>6.51</td> <td></td> <td>1.01</td> <td></td> <td>1.14</td> <td></td>	TM275	25	19.2	15.7	22.7	3.5	6.51		1.01		1.14							
DPD         TM271       16       20.8       17.1       24.5       3.7       5.24       1.00       1.13         TM272       15       8.4       6.9       9.9       1.5       7.14       0.98       1.15         TM273       16       12.5       10.3       14.8       2.3       8.64       0.98       1.13         TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.10         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         Siemens Dimension Vista       DUV       nean±SD       9.83       3.94       0.98       0.02       1.11       0.03         TM271       7       19.6       16.1       23.1       3.5       5.71       0.94       1.06         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.13         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.10         TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       0.01       1.06 </td <td></td> <td></td> <td></td> <td></td> <td></td> <td>mean ±SD</td> <td>7.23</td> <td>1.31</td> <td>1.03</td> <td>0.02</td> <td>1.17</td> <td>0.05</td>						mean ±SD	7.23	1.31	1.03	0.02	1.17	0.05						
TM272       15       8.4       6.9       9.9       1.5       7.14       0.98       1.15         TM273       16       12.5       10.3       14.8       2.3       8.64       0.98       1.13         TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.10         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         TM275       16       17.9       14.7       21.1       3.5       5.71       0.94       1.06         TM271       7       19.6       16.1       23.1       3.5       5.71       0.94       1.06         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.13         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       0.01       1.08       0.03         TM274	Siemens Immulite 2000 DPD																	
TM273       16       12.5       10.3       14.8       2.3       8.64       0.98       1.13         TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.10         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         mean±SD       9.83       3.94       0.98       0.02       1.11       0.03         Siemens Dimension Vista         DUV       mean±SD       9.83       3.94       0.98       0.02       1.11       0.03         TM271       7       19.6       16.1       23.1       3.5       5.71       0.94       1.06         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.13         TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       1.05         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       0.01       1.08       0.03         Ortho Clinical Diag Vitros Eci/ECiQ & 560U       Juc       1.93       3.3       5.60       0.39       0.95	TM271	16	20.8	17.1	24.5	3.7	5.24		1.00		1.13							
TM274       16       25.7       21.1       30.3       4.6       7.94       0.99       1.10         TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         Mean±SD       9.83       3.94       0.98       0.02       1.11       0.03         Siemens Dimension Vista         DUV       TM271       7       19.6       16.1       23.1       3.5       5.71       0.94       1.06         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.10         TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       1.10         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       1.05         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         M275       7       18.2       14.9       21.5       3.3       5.60       0.95       0.01       1.08       0.03         Ortho Clinical Diag Vitros Eci/ECiQ & 560       5.93       0.39       0.95       0.01       1.08	TM272	15	8.4	6.9	9.9		7.14		0.98		1.15							
TM275       16       17.9       14.7       21.1       3.2       15.59       0.94       1.06         Siemens Dimension Vista	TM273		12.5	10.3	14.8						1.13							
mean±SD         9.83         3.94         0.98         0.02         1.11         0.03           Siemens Dimension Vista DUV         7         19.6         16.1         23.1         3.5         5.71         0.94         1.06           TM271         7         8.3         6.8         9.8         1.5         6.27         0.97         1.13           TM273         7         12.1         9.9         14.3         2.2         5.62         0.95         1.10           TM274         7         24.6         20.2         29.0         4.4         6.42         0.95         1.05           TM275         7         18.2         14.9         21.5         3.3         5.60         0.96         1.08           Mean ±SD         5.93         0.39         0.95         0.01         1.08         0.03           Ortho Clinical Diag Vitros Eci/ECiQ & 5600          mean ±SD         5.93         0.39         0.95         0.01         1.08         0.03           JOC/JJF </td <td>TM274</td> <td>16</td> <td></td> <td>21.1</td> <td>30.3</td> <td></td> <td>7.94</td> <td></td> <td>0.99</td> <td></td> <td>1.10</td> <td></td>	TM274	16		21.1	30.3		7.94		0.99		1.10							
Siemens Dimension Vista           DUV           TM271         7         19.6         16.1         23.1         3.5         5.71         0.94         1.06           TM272         7         8.3         6.8         9.8         1.5         6.27         0.97         1.13           TM273         7         12.1         9.9         14.3         2.2         5.62         0.95         1.10           TM274         7         24.6         20.2         29.0         4.4         6.42         0.95         1.05           TM275         7         18.2         14.9         21.5         3.3         5.60         0.96         1.08           mean ±SD         5.93         0.39         0.95         0.01         1.08         0.03           Ortho Clinical Diag Vitros Eci/ECiQ & 5600           mean ±SD         5.93         0.39         0.95         0.01         1.08         0.03           JDC/JJF         T         5         16.1         13.2         19.0         2.9         6.52         0.78         0.87           TM272         5         7.1         5.8         8.4         1.3         7.89         0.83         0.	TM275	16	17.9	14.7	21.1	3.2												
TM271       7       19.6       16.1       23.1       3.5       5.71       0.94       1.06         TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.13         TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       1.10         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       1.05         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         mean ±SD       5.93       0.39       0.95       0.01       1.08       0.03         Ortho Clinical Diag Vitros Eci/ECiQ & 5600         JJC/JJF         TM271       5       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM273       5       9.8       8.0       11.6       1.8       5.07       0.78	Siemens Dimension Vista					mean±SD	9.83	3.94	0.98	0.02	1.11	0.03						
TM272       7       8.3       6.8       9.8       1.5       6.27       0.97       1.13         TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       1.10         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       1.05         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         Ortho Clinical Diag Vitros Eci/ECiQ & 5600                JJC/JJF       7       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM274       5       20.1       16.5       23.7       3.6       5.07       0.78       0.86         TM275       5       14.7	DUV																	
TM273       7       12.1       9.9       14.3       2.2       5.62       0.95       1.10         TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       1.05         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         mean ±SD       5.93       0.39       0.95       0.01       1.08       0.03         Ortho Clinical Diag Vitros Eci/ECiQ & 5600       JUC/JJF         TM271       5       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM274       5       20.1       16.5       23.7       3.6       5.07       0.78       0.86         TM275       5       14.7       12.1       17.3       2.6       5.37       0.78       0.87	TM271																	
TM274       7       24.6       20.2       29.0       4.4       6.42       0.95       1.05         TM275       7       18.2       14.9       21.5       3.3       5.60       0.96       1.08         Ortho Clinical Diag Vitros Eci/ECiQ & 560U       mean ±SD       5.93       0.39       0.95       0.01       1.08         JJC/JJF       TM271       5       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM274       5       20.1       16.5       23.7       3.6       5.07       0.78       0.86         TM275       5       14.7       12.1       17.3       2.6       5.37       0.78       0.87	TM272																	
TM275       7       18.2       14.9       21.5       3.3 mean ±SD       5.60       0.96       1.08         Ortho Clinical Diag Vitros Eci/ECiQ & 560U JJC/JJF       0.01       1.08       0.03         TM271       5       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM274       5       20.1       16.5       23.7       3.6       5.07       0.78       0.86         TM275       5       14.7       12.1       17.3       2.6       5.37       0.78       0.87	TM273																	
mean ±SD5.930.390.950.011.080.03Ortho Clinical Diag Vitros Eci/ECiQ & 5600JJC/JJFTM271516.113.219.02.96.520.780.87TM27257.15.88.41.37.890.830.97TM27359.88.011.61.85.710.770.89TM274520.116.523.73.65.070.780.86TM275514.712.117.32.65.370.780.87	TM274																	
Ortho Clinical Diag Vitros Eci/ECiQ & 5600           JJC/JJF           TM271         5         16.1         13.2         19.0         2.9         6.52         0.78         0.87           TM272         5         7.1         5.8         8.4         1.3         7.89         0.83         0.97           TM273         5         9.8         8.0         11.6         1.8         5.71         0.77         0.89           TM274         5         20.1         16.5         23.7         3.6         5.07         0.78         0.86           TM275         5         14.7         12.1         17.3         2.6         5.37         0.78         0.87	TM275	7	18.2	14.9	21.5													
JJC/JJF         TM271       5       16.1       13.2       19.0       2.9       6.52       0.78       0.87         TM272       5       7.1       5.8       8.4       1.3       7.89       0.83       0.97         TM273       5       9.8       8.0       11.6       1.8       5.71       0.77       0.89         TM274       5       20.1       16.5       23.7       3.6       5.07       0.78       0.86         TM275       5       14.7       12.1       17.3       2.6       5.37       0.78       0.87						mean ±SD	5.93	0.39	0.95	0.01	1.08	0.03						
TM27257.15.88.41.37.890.830.97TM27359.88.011.61.85.710.770.89TM274520.116.523.73.65.070.780.86TM275514.712.117.32.65.370.780.87	JJC/JJF	I/ECiQ &																
TM27359.88.011.61.85.710.770.89TM274520.116.523.73.65.070.780.86TM275514.712.117.32.65.370.780.87	TM271																	
TM274520.116.523.73.65.070.780.86TM275514.712.117.32.65.370.780.87	TM272																	
TM275 5 14.7 12.1 17.3 2.6 5.37 0.78 0.87	TM273		9.8	8.0	11.6	1.8			0.77		0.89							
	TM274		20.1															
mean ±SD 6.11 1.13 0.79 0.02 0.89 0.04	TM275	5	14.7	12.1	17.3													
						mean ±SD	6.11	1.13	0.79	0.02	0.89	0.04						

### Table 6 (cont.): 5-14 NYS Tumor Marker PT Summary for AFP

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data	I	Method Bias Relative to All Method Median	I	Method Bias Relative to IS Target	i
Tosoh AIA											
ТОМ											
TM271	3	20.7	17.0	24.4	3.7	3.24		1.00		1.12	
TM272	3	8.7	7.1	10.3	1.6	4.14		1.01		1.19	
TM273	3	12.6	10.3	14.9	2.3	5.87		0.99		1.14	
TM274	3	25.5	20.9	30.1	4.6	4.98		0.99		1.09	
TM275	3	18.8	15.4	22.2	3.4	5.85		0.99		1.11	
					mean ±SD	4.82	1.14	1.00	0.01	1.13	0.04

Sample ID	All Method Median	IS based Target	SD		Median % CV		All Method Median/ IS Target	
TM271	20.8	18.4	0.82		5.36		1.13	
TM272	8.6	7.3	0.32		6.48		1.17	
TM273	12.7	11.0	0.53		5.79		1.15	
TM274	25.9	23.4	1.39		5.43		1.11	
TM275	19.0	16.9	1.18		5.73		1.12	
				Average	5.76	mean ±SD	1.14	0.03
			Allow Allowable E	vable CV % Error (+/-)%	6.0 18.0			





Beckman Unicel & Access/2 (Hybritech Galibration) BCU/BCX (HYB)         Int         0.17         4.12         1.09         1.17           TM271         48         0.97         0.80         1.14         0.17         4.12         1.09         1.11         1.26           TM273         48         4.24         3.48         5.00         0.76         4.48         1.14         1.29           TM274         48         15.68         1.00         1.54         4.21         1.16         1.30           TM275         48         16.68         13.68         1.00         4.56         1.18         1.30           Roche Elecsys & Cobas         BME/BMR         1.11         1.26         0.30         1.14         0.04         1.26         0.37         1.10           TM271         41         0.88         0.72         1.04         0.16         5.88         0.99         1.06           TM272         41         3.62         2.97         4.27         0.65         4.97         0.97         1.01           TM274         41         7.15         5.86         0.39         9.97         0.108         0           COBICOC         C         C         COBICOC <t< th=""><th>Method Method Code Sample ID</th><th>N</th><th>Target (Mean)</th><th>Lower Limit</th><th>Upper Limit</th><th>Dmax (+/-)</th><th>%CV of Raw Data</th><th></th><th>Method Bias Relative to All Method Median</th><th></th><th>Method Bias Relative to IS Target</th><th></th></t<>	Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target	
TM271       18       0.89       0.73       1.05       0.16       7.87       1.04       1.07         TM272       18       3.92       2.21       4.63       0.71       8.83       1.05       1.20         TM273       18       3.92       3.21       4.63       0.71       8.83       1.05       1.71         TM275       17       7.46       6.35       8.13       1.39       7.11       1.05       1.17         TM275       17       7.46       6.35       8.13       1.39       7.11       1.05       1.11       1.16       1.77         CM275       17       14.61       1.38       7.72       0.80       1.14       0.20       1.11       1.25       1.11       1.25       1.11       1.26       1.17       1.17       1.12       1.46       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.11       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26       1.26<												
TMC27         18         2.45         2.01         2.89         0.44         6.94         1.04         1.18           TMC27         18         3.92         2.21         4.63         0.71         8.03         1.05         1.05         1.17           TMC75         17         7.74         6.35         9.13         1.39         7.11         1.05         1.17         T         T         1.05         1.17         T         1.05         1.17         T         T         1.16         1.17         T         1.05         1.17         T         1.05         1.17         T         1.07         1.14         1.16         1.16         1.17         1.17         1.17         1.17         1.17         1.17         1.17         1.17         1.17         1.17         1.14         1.16         1.30         1.11         1.25         1.11         1.25         1.11         1.25         1.11         1.25         1.11         1.25         1.11         1.26         1.11         1.25         1.11         1.26         1.11         1.25         1.11         1.25         1.11         1.25         1.11         1.25         1.11         1.26         1.11         1.11         1.26												
TM273     18     3.92     3.21     4.63     0.71     8.93     1.05     1.20       TM275     17     14.61     11.96     17.24     2.63     6.76     1.03     0.02     1.15     0       Brekman Unicel & Accesse 2 (Hybritech Calibration)												
TM274       17       7.74       6.35       9.13       1.39       7.11       1.05       1.17         TM275       17       14.61       11.96       17.24       2.63       6.78       1.03       0.02       1.15       0         Beakman Unicel & Access? (Hybritech Calibration)       E       E       5       0.80       1.14       0.17       4.12       1.09       1.17       1.16         TM271       48       0.97       0.80       1.14       0.17       4.12       1.16       1.30         TM273       48       4.24       3.48       5.00       0.76       4.49       1.11       1.26       1.14       1.29       1.117       1.14       1.14 <td></td> <td></td> <td>2.45</td> <td></td> <td></td> <td></td> <td>6.94</td> <td></td> <td></td> <td></td> <td>1.18</td> <td></td>			2.45				6.94				1.18	
TM275     17     14.61     11.98     7.24     2.83     6.78     1.03     1.03     1.14       Backman Unicel & Accessi2 (Hybritech Calibration)     BCUBCX (HYB)     1.14     0.17     4.12     1.09     1.17     1.17       TM271     48     0.97     0.80     1.14     0.17     4.12     1.09     1.11     1.26       TM273     48     4.24     3.48     5.00     0.76     4.49     1.14     1.29       TM273     48     4.24     3.48     5.00     0.76     4.49     1.14     0.18       TM275     48     15.68     1.868     3.00     4.56     1.18     1.30       TM275     48     15.68     1.868     3.00     4.56     1.14     0.16       TM271     41     0.88     0.72     1.04     0.16     5.26     0.97     1.10       TM274     41     7.15     5.86     8.44     1.29     5.31     0.32     0.97     1.06       TM274     41     7.15     5.86     8.44     1.29     5.31     0.32     0.97     1.06       TM274     41     7.15     5.86     8.44     1.29     5.31     0.32     0.97     1.06       <	TM273	18	3.92	3.21	4.63	0.71	8.93		1.05		1.20	
mean ±SD         7.52         0.89         1.03         0.02         1.15         C           BCUBCK (HVB)         Sectional Colspan="2">Sectional Colspan= Colspan="2">Sectional Colspan="2" <td< td=""><td>TM274</td><td>17</td><td>7.74</td><td>6.35</td><td>9.13</td><td>1.39</td><td>7.11</td><td></td><td>1.05</td><td></td><td>1.17</td><td></td></td<>	TM274	17	7.74	6.35	9.13	1.39	7.11		1.05		1.17	
Beckman Unicel & Access2 (Hybritech Calibration) BCU/BCX (HYB) TM271 48 0.97 0.80 1.14 0.17 4.12 1.09 1.11 TM272 47 2.63 2.19 3.10 0.47 3.80 1.11 1.29 TM273 48 4.24 3.48 5.00 0.76 4.48 1.1.4 1.29 TM274 48 8.56 7.02 10.10 1.54 4.21 1.16 1.30 mean ±SD 4.23 0.30 1.14 0.04 1.26 ( BME/BMR TM271 41 0.88 0.72 1.04 0.16 5.88 0.99 1.06 TM271 41 2.28 1.87 2.69 0.41 5.28 0.97 1.10 TM273 41 3.62 2.97 4.27 0.65 4.97 0.97 1.10 TM274 41 7.15 5.96 8.44 1.29 5.03 0.97 1.08 TM275 41 1.363 11.18 16.08 2.45 5.58 0.96 1.08 TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.08 ( mean ±SD 5.31 0.32 0.97 0.01 1.08 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.08 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.08 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.08 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.03 0.16 4.80 0.99 1.04 ( TM271 53 0.87 0.71 1.49 2.29 3.78 0.90 0.99 ( TM271 53 0.47 0.54 1.49 2.29 3.78 0.90 0.99 ( TM272 1.3 2.46 2.02 2.90 0.44 4.47 1.04 1.19 ( TM273 14 3.89 3.19 4.59 0.70 5.14 1.04 ( TM271 14 0.81 0.66 0.96 0.15 9.88 0.91 0.09 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM271 13 0.01 0.83 1.19 0.18 3.96 1.13 1.22 ( TM272 13 2.76 2.28 3.26 0.50 3.62 1.17 1.33 ( TM274 13 8.90 7.30 10.50 1.60 2.47 1.00 1.13 ( TM274 13 8.90 7.30 10.50 1.60 2.47 1.00 1.13 ( TM274 13 8.90 7.30 10.50 1.60 2.47 1.00 1.13 ( TM274 21 0.39 0.05 1.10 0.17 3.26 1.03 1.11 ( TM273 21 0.39 0.05 1.80 0.47 2.41 1.00 1.13 ( TM274 21 7.39 0.50 6.75 1.09 0.17 3.26 1.03 1.11 ( TM273 21 0.39 0.05 1.97 0.0	TM275	17	14.61	11.98	17.24			0.89		0 02		0.05
TM271       48       0.97       0.80       1.14       0.17       4.12       1.09       1.17         TM272       47       2.63       2.16       3.10       0.47       3.80       1.14       1.26         TM273       48       4.24       3.46       5.00       0.76       4.48       1.14       1.29         TM275       48       16.68       TA22       10.10       1.54       4.21       1.16       1.30         TM275       48       16.68       TA22       10.40       0.16       5.68       0.30       1.14       0.04       1.26       0.07         TM271       41       0.88       0.72       1.04       0.16       5.68       0.97       1.10       1.07         TM272       41       3.62       1.87       2.69       0.41       5.26       0.97       1.10         TM273       41       3.62       2.87       8.64       1.29       5.30       0.97       1.08         TM274       41       7.75       5.48       0.32       0.97       0.101       1.08         TM275       41       13.63       1.16       6.64       6.00       0.98       1.05		cess/2 (Hybritec	h Calibration)			mean 100	1.52	0.00	1.00	0.02	1.15	0.00
TM272       47       2.63       2.16       3.10       0.47       3.80       1.11       1.26         TM273       48       4.24       3.48       5.00       0.76       4.48       1.14       1.29         TM274       48       8.56       7.02       10.10       1.54       4.21       1.16       1.30         TM275       48       16.68       13.68       19.68       3.00       4.56       1.18       0.44       1.26       0.72         Roche Elceys & Cobas       BME/BMR       0.72       1.04       0.16       5.68       0.99       1.06       1.07         TM272       41       0.28       0.72       1.04       0.16       5.68       0.97       1.01         TM273       41       0.82       2.97       4.27       0.56       4.97       0.97       1.00         TM274       41       7.15       5.86       8.44       1.29       5.38       0.97       1.08         TM275       41       13.63       1.16       1.24       2.45       5.58       0.96       1.05         TM274       4.0       0.17       1.03       0.16       4.60       0.98       1.04	· · · ·											
TM273       48       4.24       3.48       5.00       0.76       4.48       1.14       1.29         TM274       48       8.56       7.02       10.10       1.54       4.21       1.16       1.30         TM275       48       16.68       13.68       19.68       3.00       4.56       0.30       1.14       0.04       1.26       0.00         EME/EMR       TM271       41       0.88       0.72       1.04       0.16       5.68       0.99       1.06       1.00         TM271       41       0.82       2.97       4.27       0.65       4.97       0.97       1.10       1.00         TM274       41       7.15       5.66       8.44       1.29       5.03       0.97       1.08       0.66         TM275       41       13.63       11.18       16.08       2.45       5.58       0.96       1.06       0.66       0.66       0.32       0.97       0.01       1.08       0.7       0.22       0.97       0.21       1.04       1.04       1.04       1.04       1.05       1.06       1.06       1.06       1.06       1.06       1.06       1.06       1.06       1.06       1.06 <td< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>												
TM274       48       8.56       7.02       10.10       1.54       4.21       1.16       1.30         TM275       48       16.68       13.69       19.68       3.00       4.56       1.18       1.30         Roche Elecsys & Cobas       mean 15D       4.53       0.30       1.48       0.04       1.26       0.04         Roche Elecsys & Cobas       mean 15D       5.68       0.99       1.06       5.68       0.99       1.06         TM272       41       2.88       1.87       2.69       0.41       5.26       0.97       1.10         TM273       41       3.62       2.97       4.27       0.65       4.97       0.97       1.08         TM275       41       1.83       11.18       16.68       2.45       5.88       0.90       0.01       1.08         Siemens Advia Contaur XP & CP       COEVCOC             1.04       1.49       2.29       3.78       0.90       0.99       1.04         TM271       53       0.87       1.71       1.76       2.56       0.39       5.07       0.92       1.04         TM274       53							3.80		1.11			
TM275     48     16.68     13.68     19.68     3.00     4.23     0.30     1.14     0.04     1.26     0.70       Roche Elecsys & Cobas     Imean tSD     4.23     0.30     1.14     0.04     1.26     0.70       Roche Elecsys & Cobas     Imean tSD     4.23     0.30     1.14     0.04     1.26     0.70       TM271     41     0.28     1.67     2.69     0.41     5.26     0.97     1.10       TM273     41     3.62     2.97     4.27     0.65     4.97     0.97     1.08       TM275     41     13.63     11.18     16.08     2.45     5.58     0.96     0.10     1.08       Simems Advia Centaur XP & CP     CP     mean tSD     5.31     0.32     0.97     0.01     1.08       COB/COC     TM271     5.3     0.87     0.71     1.03     0.16     4.60     0.98     1.05       TM272     55     2.17     1.78     2.56     0.39     5.07     0.92     1.04       TM273     53     0.42     2.80     4.04     0.62     3.22     0.99     1.04       TM275     53     1.27     1.78     2.56     0.39     5.77     0.92     0.03 <td>TM273</td> <td>48</td> <td>4.24</td> <td>3.48</td> <td>5.00</td> <td>0.76</td> <td>4.48</td> <td></td> <td>1.14</td> <td></td> <td>1.29</td> <td></td>	TM273	48	4.24	3.48	5.00	0.76	4.48		1.14		1.29	
mean ±SD         4.23         0.30         1.14         0.04         1.26         0           Roche Elecsys & Cobas         BME/BMR <td>TM274</td> <td>48</td> <td>8.56</td> <td>7.02</td> <td>10.10</td> <td>1.54</td> <td>4.21</td> <td></td> <td>1.16</td> <td></td> <td>1.30</td> <td></td>	TM274	48	8.56	7.02	10.10	1.54	4.21		1.16		1.30	
Proche Elecsys & Cobas           BME/BMR           TM271         41         0.88         0.72         1.04         0.16         5.68         0.99         1.06           TM272         41         2.28         1.47         2.69         0.41         5.26         0.97         1.10           TM273         41         3.62         2.97         4.27         0.65         4.97         0.97         1.08           TM274         41         7.15         5.66         8.44         1.29         5.03         0.97         1.08           TM275         41         13.63         11.18         16.08         2.45         5.58         0.96         1.06           COB/COC         TM271         53         0.87         0.71         1.03         0.16         4.60         0.98         1.05           TM272         53         3.42         2.80         4.04         0.62         3.22         0.92         1.04           TM275         53         12.70         10.41         14.99         2.29         3.78         0.90         0.99           TM275         53         12.70         10.41         14.99         0.70         5.14         1.04<	TM275	48	16.68	13.68	19.68	3.00	4.56		1.18		1.30	
BME/BMR         UN         UN <t< td=""><td></td><td></td><td></td><td></td><td></td><td>mean ±SD</td><td>4.23</td><td>0.30</td><td>1.14</td><td>0.04</td><td>1.26</td><td>0.06</td></t<>						mean ±SD	4.23	0.30	1.14	0.04	1.26	0.06
TM271       41       0.88       0.72       1.04       0.16       5.68       0.99       1.06         TM272       41       2.28       1.87       2.69       0.41       5.26       0.97       1.10         TM273       41       3.62       2.97       4.27       0.65       4.97       0.97       1.06         TM274       41       7.15       5.86       8.44       1.29       5.03       0.97       1.06         TM275       41       13.63       11.18       16.08       2.45       5.31       0.32       0.97       0.01       1.06         Sismens Advia Centaur XP & CP       C	-	as										
TM272       41       2.28       1.87       2.69       0.41       5.26       0.97       1.10         TM273       41       3.62       2.97       4.27       0.65       4.97       0.97       1.10         TM274       41       7.15       5.86       8.44       1.29       5.03       0.97       1.08         TM275       41       13.63       11.18       16.08       2.45       5.58       0.96       1.06         Siemens Advia Centaur XP & CP       COB/COC		41	0.88	0.72	1.04	0.16	5,68		0.99		1.06	
TM273       41       3.62       2.97       4.27       0.65       4.97       0.97       1.10         TM274       41       7.15       5.86       8.44       1.29       5.03       0.97       1.08         TM275       41       13.63       11.18       16.08       2.45       5.58       0.96       1.06         Siemens Advia Centaur XP & CP       COB'COC												
TM274       41       7.15       5.86       8.44       1.29       5.03       0.97       1.08         TM275       41       13.63       11.18       16.08       2.45       5.58       0.96       1.06         Siemens Advia Centaur XP & CP												
TM275       41       13.63       11.18       16.08       2.45       5.58       0.96       1.06       1.08         Siemens Advia Centaur XP & CP            0.97       0.01       1.08       0.97         COB/COC             0.16       4.60       0.98       1.05         TM271       53       0.87       0.71       1.03       0.16       4.60       0.98       1.05         TM272       55       2.17       1.78       2.56       0.39       5.07       0.92       1.04         TM273       53       3.42       2.80       4.04       0.62       3.22       0.92       1.04         TM275       53       12.70       10.41       14.99       2.93       3.78       0.90       0.03       1.02         Siemens Immulite 1000, 2000 - Original Pack        0.92       0.03       1.03       1.10       1.12         TM271       14       0.81       0.66       0.96       0.15       9.88       0.91       0.98       1.19         TM273       14       3.89       3.19       4.59       0.07       5.14 </td <td></td>												
mean ±SD         5.31         0.32         0.97         0.01         1.08         0           Siemens Advia Centaur XP & CP         COB/COC                                      0.97         0.01         1.08                        1.05                   1.04												
Siemens Advia Centaur XP & CP COE/COC TM271 53 0.87 0.71 1.03 0.16 4.60 0.98 1.05 TM272 55 2.17 1.78 2.56 0.39 5.07 0.92 1.04 TM273 53 3.42 2.80 4.04 0.62 3.22 0.92 1.04 TM274 53 6.71 5.50 7.92 1.21 3.43 0.91 1.02 TM275 53 12.70 10.41 14.99 2.29 3.78 0.90 0.99 mean ±SD 4.02 0.79 0.92 0.03 1.03 ( Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5) TM271 14 0.81 0.66 0.96 0.15 9.88 0.91 0.98 TM272 13 2.46 2.02 2.90 0.44 4.47 1.04 1.18 TM273 14 3.89 3.19 4.59 0.70 5.14 1.04 1.19 TM274 11 7.63 6.26 9.00 1.37 1.57 1.03 1.15 TM275 13 14.72 12.07 17.37 2.65 5.64 1.04 1.15 mean ±SD 5.34 2.99 1.01 0.06 1.13 ( Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 1.34 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 1.34 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 1.34 TM273 13 1.703 13.96 2.10 3.07 3.41 1.20 1.33 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 1.34 TM274 13 8.90 7.30 10.50 1.60 2.47 1.20 1.35 TM275 13 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 1.34 TM274 13 8.90 7.30 10.50 1.60 2.47 1.20 1.35 TM275 13 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 0.03 1.31 TM274 13 8.90 7.30 10.50 1.60 2.47 1.20 1.35 TM275 13 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 0.03 1.31 ( TM274 13 8.90 7.30 10.50 1.60 2.47 1.20 1.35 TM275 13 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM273 13 4.39 3.60 5.18 0.79 4.10 1.18 0.03 1.31 ( TM274 13 8.90 7.30 10.50 1.60 2.47 1.20 1.35 TM275 1.3 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM273 1.3 1.703 13.96 2.10 3.07 3.41 1.20 1.33 TM274 1.3 8.90 7.30 10.50 1.60 2.47 1.20 1.33 TM275 1.3 17.03 13.96 2.10 3.07 3.41 1.20 1.33 TM275 1.3 1.703 13.96 4.40 0.67 2.41 1.00 1.114 TM274 2.1 7.39 6.06 8.72 1.33 2.98 1.00 1.14	1111275	41	13.05	11.10	10.00	-		0.33		0.01		0.02
TM272       55       2.17       1.78       2.56       0.39       5.07       0.92       1.04         TM273       53       3.42       2.80       4.04       0.62       3.22       0.92       1.04         TM274       53       6.71       5.00       7.92       1.21       3.43       0.90       0.99         TM275       53       12.70       10.41       14.99       2.29       3.78       0.90       0.99         Siemens Immulite 1000, 2000 - Original Pack       mean ±SD       4.02       0.79       0.92       0.03       1.03       0         TM271       14       0.81       0.66       0.96       0.15       9.88       0.91       0.98         TM272       13       2.46       2.02       2.90       0.44       4.47       1.04       1.18         TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         TM274       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM271 <td></td> <td>ur XP &amp; CP</td> <td></td> <td></td> <td></td> <td></td> <td>0.01</td> <td>0.01</td> <td>0.01</td> <td>0.01</td> <td></td> <td>0.02</td>		ur XP & CP					0.01	0.01	0.01	0.01		0.02
TM273       53       3.42       2.80       4.04       0.62       3.22       0.92       1.04         TM274       53       6.71       5.50       7.92       1.21       3.43       0.91       1.02         TM275       53       12.70       10.41       14.99       2.29       3.78       0.90       0.03       1.03       0         Siemens Immulite 1000, 2000 - Original Pack       mean ±SD       4.02       0.79       0.92       0.03       1.03       0         TM271       14       0.81       0.66       0.96       0.15       9.88       0.91       0.92       0.03       1.03       0         TM272       13       2.46       2.02       2.90       0.44       4.47       1.04       1.19         TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.19         TM274       11       7.63       6.26       9.00       1.37       1.57       1.03       1.15         TM275       13       1.47       12.07       17.37       2.65       5.64       1.04       1.15         TM274       13       2.76       2.26       3.26       0.50	TM271	53	0.87	0.71	1.03	0.16	4.60		0.98		1.05	
TM274       53       6.71       5.50       7.92       1.21       3.43       0.91       1.02         TM275       53       12.70       10.41       14.99       2.29       3.78       0.90       0.99         mean ±SD       0.02       0.79       0.92       0.03       1.03       0         Siemens Immulite 1000, 2000 - Original Pack       Pack       9.88       0.91       0.98       0.91       0.98         TM271       14       0.81       0.66       0.96       0.15       9.88       0.91       0.98       0.91         TM272       13       2.46       2.02       2.90       0.44       4.47       1.04       1.19         TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL       DUD/DUX       1.31       0.26       1.32       1.33       1.27       1.33       1.26       5.64       1.04       1.15       1.34         TM271       13       1.01       0.83       1.19       0.18       3.96	TM272	55	2.17	1.78	2.56	0.39	5.07		0.92		1.04	
TM275       53       12.70       10.41       14.99       2.29       3.78       0.90       0.99         Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)	TM273	53	3.42	2.80	4.04	0.62	3.22		0.92		1.04	
mean ±SD         4.02         0.79         0.92         0.03         1.03         0           Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)	TM274	53	6.71	5.50	7.92	1.21	3.43		0.91		1.02	
Siemens Immulite 1000, 2000 - Original Pack DPB, DPD (DP5)           TM271         14         0.81         0.66         0.96         0.15         9.88         0.91         0.98           TM272         13         2.46         2.02         2.90         0.44         4.47         1.04         1.18           TM273         14         3.89         3.19         4.59         0.70         5.14         1.04         1.19           TM274         11         7.63         6.26         9.00         1.37         1.57         1.03         1.15           TM275         13         14.72         12.07         17.37         2.65         5.64         1.04         1.15           DUD/DUX         TM271         13         1.01         0.83         1.19         0.18         3.96         1.13         1.22           TM272         13         2.76         2.26         3.26         0.50         3.62         1.17         1.33           TM273         13         4.39         3.60         5.18         0.79         4.10         1.18         1.34           TM274         13         8.90         7.30         10.50         1.60         2.47         1.20 </td <td>TM275</td> <td>53</td> <td>12.70</td> <td>10.41</td> <td>14.99</td> <td>2.29</td> <td>3.78</td> <td></td> <td>0.90</td> <td></td> <td>0.99</td> <td></td>	TM275	53	12.70	10.41	14.99	2.29	3.78		0.90		0.99	
DPB, DPD (DP5)         TM271         14         0.81         0.66         0.96         0.15         9.88         0.91         0.98           TM272         13         2.46         2.02         2.90         0.44         4.47         1.04         1.18           TM273         14         3.89         3.19         4.59         0.70         5.14         1.04         1.19           TM274         11         7.63         6.26         9.00         1.37         1.57         1.03         1.15           TM275         13         14.72         12.07         17.37         2.65         5.64         1.04         1.15           Siemens Dimension RxL Max, Xpand Plus, EXL         DUD/DUX         0.06         1.13         1.22           TM272         13         2.76         2.26         3.26         0.50         3.62         1.17         1.33           TM271         13         4.39         3.60         5.18         0.79         4.10         1.18         1.34           TM273         13         17.03         13.96         20.10         3.07         3.41         1.20         1.35           TM275         13         17.03         1.396 <t< td=""><td></td><td></td><td></td><td></td><td></td><td>mean ±SD</td><td>4.02</td><td>0.79</td><td>0.92</td><td>0.03</td><td>1.03</td><td>0.02</td></t<>						mean ±SD	4.02	0.79	0.92	0.03	1.03	0.02
TM272       13       2.46       2.02       2.90       0.44       4.47       1.04       1.18         TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.19         TM274       11       7.63       6.26       9.00       1.37       1.57       1.03       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL       mean ±SD       5.34       2.99       1.01       0.06       1.13       0.07         Siemens Dimension RxL Max, Xpand Plus, EXL       mean ±SD       5.34       2.99       1.01       0.06       1.13       0.06       1.13       0.07       1.01       0.06       1.13       0.07       1.01       0.06       1.13       1.22         TM271       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33       1.34         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       0.34       1.41         TM274       13       8.90       7.30       10.50       1.60 <t< td=""><td></td><td>00, 2000 - Origin</td><td>al Pack</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>		00, 2000 - Origin	al Pack									
TM272       13       2.46       2.02       2.90       0.44       4.47       1.04       1.18         TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.19         TM274       11       7.63       6.26       9.00       1.37       1.57       1.03       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX        1.19       0.18       3.96       1.13       1.22         TM272       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM271       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.33         TM275       13		14	0.81	0.66	0.96	0.15	9.88		0.91		0.98	
TM273       14       3.89       3.19       4.59       0.70       5.14       1.04       1.19         TM274       11       7.63       6.26       9.00       1.37       1.57       1.03       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL       nean ±SD       5.34       2.99       1.01       0.06       1.13       0.00         TM271       13       1.01       0.83       1.19       0.18       3.96       1.13       1.22         TM273       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.33         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         DUV </td <td>TM272</td> <td>13</td> <td>2.46</td> <td>2.02</td> <td>2.90</td> <td>0.44</td> <td>4.47</td> <td></td> <td>1.04</td> <td></td> <td>1.18</td> <td></td>	TM272	13	2.46	2.02	2.90	0.44	4.47		1.04		1.18	
TM274       11       7.63       6.26       9.00       1.37       1.57       1.03       1.15         TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX         TM271       13       1.01       0.83       1.19       0.18       3.96       1.13       1.22         TM272       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       17.03       13.96       20.10       3.07       3.41       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         DUV       TENET       TENET       TENET	TM273	14	3.89	3.19	4.59	0.70	5.14		1.04		1.19	
TM275       13       14.72       12.07       17.37       2.65       5.64       1.04       1.15         Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX       Siman ±SD       5.34       2.99       1.01       0.06       1.13       0.06         TM271       13       1.01       0.83       1.19       0.18       3.96       1.13       1.22         TM272       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         TM275       13       17.03       13.96       20.10       3.07       3.51       0.64       1.18       0.03       1.31       0.00         DUV       1       1.92       1.33       0.42       2.97       1.00	TM274	11	7.63	6.26	9.00	1.37	1.57				1.15	
mean ±SD         5.34         2.99         1.01         0.06         1.13         0           Siemens Dimension RxL Max, Xpand Plus, EXL DUD/DUX         TM271         13         1.01         0.83         1.19         0.18         3.96         1.13         1.22           TM272         13         2.76         2.26         3.26         0.50         3.62         1.17         1.33           TM273         13         4.39         3.60         5.18         0.79         4.10         1.18         1.34           TM274         13         8.90         7.30         10.50         1.60         2.47         1.20         1.35           TM275         13         17.03         13.96         20.10         3.07         3.41         1.20         1.33           TM275         13         17.03         13.96         20.10         3.07         3.41         1.20         1.33           TM275         13         17.03         13.96         20.10         3.07         3.41         1.20         1.33           DUV         TM271         21         0.92         0.75         1.09         0.17         3.26         1.03         1.11           TM272 <td< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>												
DUD/DUX           TM271         13         1.01         0.83         1.19         0.18         3.96         1.13         1.22           TM272         13         2.76         2.26         3.26         0.50         3.62         1.17         1.33           TM273         13         4.39         3.60         5.18         0.79         4.10         1.18         1.34           TM274         13         8.90         7.30         10.50         1.60         2.47         1.20         1.35           TM275         13         17.03         13.96         20.10         3.07         3.41         1.20         1.33           mean±SD         3.51         0.64         1.18         0.03         1.31         0           Siemens Dimension Vista           DUV         TM271         21         0.92         0.75         1.09         0.17         3.26         1.03         1.11           TM272         21         2.36         1.94         2.78         0.42         2.97         1.00         1.13           TM273         21         3.73         3.06         4.40         0.67         2.41         1.00 <t< td=""><td></td><td></td><td></td><td></td><td></td><td>mean ±SD</td><td>5.34</td><td>2.99</td><td>1.01</td><td>0.06</td><td>1.13</td><td>0.09</td></t<>						mean ±SD	5.34	2.99	1.01	0.06	1.13	0.09
TM271       13       1.01       0.83       1.19       0.18       3.96       1.13       1.22         TM272       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         mean±SD 3.51 0.64       1.18       0.03       1.31       0.03         Siemens Dimension Vista         DUV       TM271       21       0.92       0.75       1.09       0.17       3.26       1.03       1.11         TM272       21       2.36       1.94       2.78       0.42       2.97       1.00       1.13         TM273       21       3.73       3.06       4.40       0.67       2.41       1.00       1.14         TM273       21       7.39       6.06       8.72       1.33       2.98       1.00       1.12    <		RxL Max, Xpand	Plus, EXL									
TM272       13       2.76       2.26       3.26       0.50       3.62       1.17       1.33         TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         mean±SD 3.51 0.64       1.18       0.03       1.31       0.03       1.11       1.03       1.11       1.03       1.11       1.03       1.11       1.03       1.11       1.03       1.13       1.13       1.13       1.13       1.13       1.13       1.14		13	1.01	0.83	1 10	0.18	3 96		1 13		1 22	
TM273       13       4.39       3.60       5.18       0.79       4.10       1.18       1.34         TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         mean±SD       3.51       0.64       1.18       0.03       1.31       0         Siemens Dimension Vista         DUV       TM271       21       0.92       0.75       1.09       0.17       3.26       1.03       1.11         TM272       21       2.36       1.94       2.78       0.42       2.97       1.00       1.13         TM273       21       3.73       3.06       4.40       0.67       2.41       1.00       1.14         TM274       21       7.39       6.06       8.72       1.33       2.98       1.00       1.12												
TM274       13       8.90       7.30       10.50       1.60       2.47       1.20       1.35         TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         mean±SD       3.51       0.64       1.18       0.03       1.31       0         Siemens Dimension Vista         DUV       TM271       21       0.92       0.75       1.09       0.17       3.26       1.03       1.11         TM272       21       2.36       1.94       2.78       0.42       2.97       1.00       1.13         TM273       21       3.73       3.06       4.40       0.67       2.41       1.00       1.14         TM274       21       7.39       6.06       8.72       1.33       2.98       1.00       1.12												
TM275       13       17.03       13.96       20.10       3.07       3.41       1.20       1.33         mean±SD       3.51       0.64       1.18       0.03       1.31       0         Siemens Dimension Vista         DUV         TM271       21       0.92       0.75       1.09       0.17       3.26       1.03       1.11         TM272       21       2.36       1.94       2.78       0.42       2.97       1.00       1.13         TM273       21       3.73       3.06       4.40       0.67       2.41       1.00       1.14         TM274       21       7.39       6.06       8.72       1.33       2.98       1.00       1.12												
mean±SD         3.51         0.64         1.18         0.03         1.31         0           Siemens Dimension Vista DUV												
Siemens Dimension Vista           DUV           TM271         21         0.92         0.75         1.09         0.17         3.26         1.03         1.11           TM272         21         2.36         1.94         2.78         0.42         2.97         1.00         1.13           TM273         21         3.73         3.06         4.40         0.67         2.41         1.00         1.14           TM274         21         7.39         6.06         8.72         1.33         2.98         1.00         1.12	1 11/275	13	17.03	13.90	20.10			0.64		0.03		0.05
TM272212.361.942.780.422.971.001.13TM273213.733.064.400.672.411.001.14TM274217.396.068.721.332.981.001.12		/ista				meanitob	0.01	0.04	1.10	5.00	1.01	0.00
TM272212.361.942.780.422.971.001.13TM273213.733.064.400.672.411.001.14TM274217.396.068.721.332.981.001.12	TM271	21	0.92	0.75	1.09	0.17	3.26		1.03		1.11	
TM273         21         3.73         3.06         4.40         0.67         2.41         1.00         1.14           TM274         21         7.39         6.06         8.72         1.33         2.98         1.00         1.12												
TM274 21 7.39 6.06 8.72 1.33 2.98 1.00 1.12												
LIVE 21 14 14 11.09 10.09 2.55 2.62 1.00 1.10	TM275	21	14.14	11.59	16.69	2.55	2.62		1.00		1.10	
		21						0 33		0.02		0.01

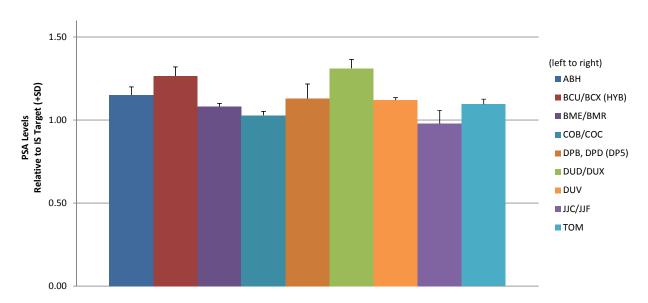
#### Table 7 (cont.): 5-14 NYS Tumor Marker PT Summary for PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median	5	Method Bia Relative to IS Target	-
Ortho Clinical Diag V	itros Eci/ECiQ &	5600									
JJC/JJF											
TM271	22	0.91	0.75	1.07	0.16	5.49		1.02		1.10	
TM272	22	2.11	1.73	2.49	0.38	4.27		0.89		1.01	
TM273	22	3.15	2.58	3.72	0.57	4.13		0.84		0.96	
TM274	22	6.09	4.99	7.19	1.10	4.43		0.82		0.92	
TM275	22	11.50	9.43	13.57	2.07	4.26		0.81		0.90	
					mean ±SD	4.52	0.56	0.88	0.09	0.98	0.08
Tosoh AIA											
TOM											
TM271	8	0.88	0.72	1.04	0.16	5.68		0.99		1.06	
TM272	8	2.35	1.93	2.77	0.42	3.40		1.00		1.13	
TM273	8	3.66	3.00	4.32	0.66	4.64		0.98		1.12	
TM274	8	7.30	5.99	8.61	1.31	4.66		0.99		1.10	
TM275	8	13.67	11.21	16.13	2.46	4.17		0.97		1.07	
					mean ±SD	4.51	0.83	0.98	0.01	1.10	0.03

	All Method	IS based			Median		All Metho Median/	d
Sample ID	Median	Target	SD		% CV		IS Target	t
TM271	0.89	0.83	0.04		5.49		1.07	
TM272	2.36	2.08	0.05		4.27		1.13	
TM273	3.73	3.28	0.12		4.48		1.14	
TM274	7.39	6.61	0.26		4.21		1.12	
TM275	14.14	12.80	0.48		4.26		1.10	
				Average	4.54	mean ±SD	1.11	0.03

Average 4.54
Allowable CV % 6.00

Allowable Error (+/-)% 18.0



#### Figure 7: PSA Method Comparison

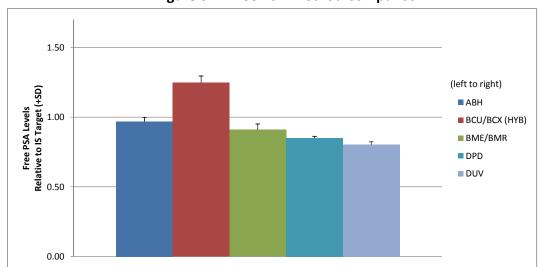
Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data		Method Bias Relative to All Method Median		Method Bias Relative to IS Target		% free PSA (calculated)	
Abbott Architect													
ABH TM271	0	0.10	0.07	0.25	0.09	6.25		1.07		1.00		18.0%	
TM271 TM272	6	0.16	0.07			6.25 2.50		1.07		1.02 0.98			
TM272 TM273	6 6	0.40 0.62	0.31 0.51	0.49 0.73	0.09			1.05 1.03				16.3% 15.8%	
TM273 TM274	6				0.11	3.23				0.95			
	6	1.25	1.03	1.48	0.23	2.40		1.08		0.95		16.1%	
TM275	6	2.41	1.98	2.84	0.43	2.07	4 74	1.10	0.00	0.94	0.00	16.5%	0.00/
Beckman Unicel &	A	/I lubuite els C	olibuotion)		mean ±SD	3.29	1.71	1.07	0.03	0.97	0.03	16.6%	0.8%
BCU/BCX (HYB)	Access/2	(Hybrilech C	alloration)										
TM271	24	0.20	0.11	0.29	0.09	5.00		1.33		1.28		20.6%	
TM271 TM272	24 26	0.20	0.11	0.29	0.09	5.66		1.33		1.20		20.8%	
TM272 TM273	26 26	0.55	0.43	0.83	0.10	3.66		1.39		1.30		19.3%	
TM273 TM274	26 26	1.61	1.32	1.90	0.13	3.66		1.37		1.20		19.3%	
	26 26												
TM275	26	3.03	2.48	3.58	0.55 mean ±SD	3.30 4.27	1.01	1.38 1.37	0.02	1.18 1.25	0.05	18.2% 19.4%	1.0%
Roche Elecsys & C	ohas				mean 13D	4.27	1.01	1.37	0.02	1.25	0.05	15.4 /0	1.0 %
BME/BMR	00003												
TM271	17	0.15	0.06	0.24	0.09	0.00		1.00		0.96		17.0%	
TM272	24	0.38	0.29	0.47	0.09	2.63		1.00		0.93		16.7%	
TM273	24	0.60	0.49	0.71	0.11	5.00		1.00		0.92		16.6%	
TM274	24	1.16	0.95	1.37	0.21	3.45		1.00		0.88		16.2%	
TM275	22	2.19	1.80	2.58	0.39	2.28		1.00		0.85		16.1%	
-					mean ±SD	2.67	1.82	1.00	0.00	0.91	0.04	16.5%	0.4%
Siemens Immulite 2	2000												
DPD													
TM271	12	0.13	0.04	0.22	0.09	7.69		0.87		0.83		16.0%	
TM272	11	0.35	0.26	0.44	0.09	8.57		0.92		0.86		14.2%	
TM273	12	0.56	0.46	0.66	0.10	5.36		0.93		0.86		14.4%	
TM274	12	1.13	0.93	1.33	0.20	5.31		0.97		0.86		14.8%	
TM275	11	2.17	1.78	2.56	0.39	6.45		0.99		0.85		14.7%	
					mean ±SD	6.68	1.44	0.94	0.05	0.85	0.01	14.8%	0.7%
Siemens Dimension	n Vista												
DUV													
TM271	7	0.13	0.04	0.22	0.09	0.00		0.87		0.83		14.1%	
TM272	9	0.33	0.24	0.42	0.09	3.03		0.87		0.81		14.0%	
TM273	9	0.52	0.43	0.61	0.09	3.85		0.87		0.80		13.9%	
TM274	9	1.05	0.86	1.24	0.19	3.81		0.91		0.80		14.2%	
TM275	9	1.99	1.63	2.35	0.36	2.51		0.91		0.77		14.1%	
					mean ±SD	2.64	1.58	0.88	0.02	0.80	0.02	14.1%	0.1%

Sample ID	N	All Method Median	IS based Targ	SD	Median % CV	All Method Median/ IS Target	% free calculate IS Tar	ed from
TM271	66	0.15	0.16	0.003	5.00	0.96	18.8	3%
TM272	76	0.38	0.41	0.01	3.03	0.93	19.6	5%
TM273	77	0.60	0.65	0.02	3.85	0.92	19.9	9%
TM274	77	1.16	1.32	0.04	3.73	0.88	19.9	9%
TM275	74	2.19	2.57	0.18	2.51	0.85	20.1	1%

Allowable CV %

Allowable Error if >/= 0.5 ng/ml (+/-)% 18.0

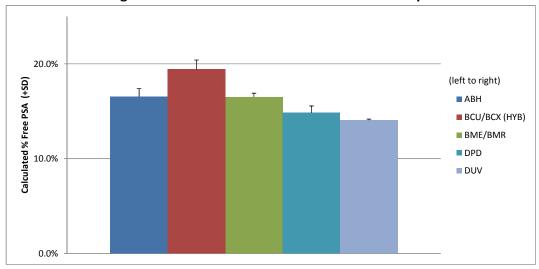
Allowable Error if < 0.5 ng/ml (+/- ng/ml) 0.09



#### Figure 8A: Free PSA Method Comparison

6.0

Figure 8B: Calculated % Free PSA Method Comparison



## Table 9: 5-14 NYS Tumor Marker PT Summary for Complexed PSA

Method Method Code Sample ID	N	Target (Mean)	Lower Limit	Upper Limit	Dmax (+/-)	%CV of Raw Data	Method Bias Relative to All Method Median	
Siemens Advia Cen	taur XP & C	P						
COB/COC								
TM271	9	0.7	0.6	0.8	0.1	8.45	1.00	
TM272	8	1.8	1.5	2.2	0.4	9.24	1.00	
TM273	9	2.8	2.3	3.3	0.5	14.80	1.00	
TM274	9	5.7	4.7	6.8	1.1	6.97	1.00	
TM275	9	10.8	8.9	12.8	2.0	6.09	1.00	
					mean ±SD	9.11 3.4	41 1.00 0	0.00

	All	
	Method	Median
Sample ID	Median	% CV
TM271	0.7	8.45
TM272	1.8	9.24
TM273	2.8	14.80
TM274	5.7	6.97
TM275	10.8	6.09

Average 9.11

Allowable CV % 6.0 Allowable Error (+/-)% 18.0 **NEW YORK** state department of **HEALTH** 

Howard A. Zucker, M.D., J.D. Acting Commissioner of Health

May 6, 2014

Sue Kelly Executive Deputy Commissioner

## \*\*\*REFRIGERATE SAMPLES UPON ARRIVAL\*\*\*

## \*\*\*DO NOT FREEZE\*\*\*

TO: Laboratory Director

FROM: Erasmus Schneider, Ph.D.
 Director, Diagnostic Oncology Section, Clinical Laboratory Evaluation Program
 SUBJECT: ONCOLOGY - SOLUBLE TUMOR MARKERS PROFICIENCY TESTING
 DUE DATE: May 21, 2014

#### \*\*\*IMPORTANT INSTRUCTIONS BELOW-PLEASE READ\*\*\*

#### Samples:

Enclosed are five sealed (5) vials labeled <u>TM271 to TM275</u>, each containing proficiency test specimens in a human-derived serum base, sterile filtered and dispensed. All materials used to prepare the samples were tested and found to be negative for HBV, HCV and HIV. Because no test can guarantee a sample to be non-infectious, universal precautions should be followed when handling samples. Keep refrigerated until use, but <u>do not freeze</u>. Make sure samples are completely mixed before analyzing.

Each vial contains various predetermined amounts of alpha-feto protein (AFP), carcinoembryonic antigen (CEA), cancer antigen 125 (CA125), the breast cancer markers CA15-3 and CA27.29, the GI cancer marker CA19-9 and prostate specific antigen (PSA) in all three currently measured forms, i.e. total PSA, free PSA and complexed PSA (PSA-ACT). Please measure all markers tested in your laboratory.

If your lab measures free and/or complexed PSA measure it in **ALL** of the samples. Please note we can no longer accept results from a second method for any analyte.

All laboratories must submit their proficiency testing results online 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 emailed to <u>clepeptrs@health.state.ny.us</u>.

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

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

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

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

# We are also asking for the lot numbers of the Reagents and Calibrators used when testing the PT samples. Please enter these on the Event Menu page under the Instrument and Reagent Names.

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

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

**Results must be submitted electronically before 11:59 PM on <u>May 21, 2014.</u> It is advisable to submit earlier to allow time to resolve any problem that could occur with result submission. Results not submitted by the due date are categorized as missing with an administrative <b>failure** and receive a failing grade, even if results were entered and saved but not officially **submitted**. Extensions are granted for exceptional reasons only, and you must **contact the PT section by email as soon as possible <u>before</u> the due date to see if this can be arranged.** 

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

For any correspondence regarding the Oncology PT contact us by e-mail at <a href="mailto:smchale@wadsworth.org">smchale@wadsworth.org</a> or:

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

The remaining 2014 Oncology Tumor Marker Proficiency Test schedule is:

Mail-out date:Due date:September 9, 2014September 24, 2014

The above document and the worksheet can be found on the website: <u>http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/index.htm</u> Additional CLEP reference: http://www.wadsworth.org/labcert/clep/PT/ptindex.html

#### ONCOLOGY SOLUBLE TUMOR MARKERS WORKSHEET ONLY---DO NOT MAIL

Oncology Soluble Tumor Markers			
http://www.wadsworth.org/labcert/clep/PT/oncology/serasoluble/2014/index.htm			

http://www.wadsworth.or	g/labcert/clep/PT/oncol	ogy/serasoluble/2014/index.htm
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Ог	Oncology Soluble Tumor Markers									
		TM271	TM272	TM273	TM274	TM275				
<u>AFP (ng/ml)</u> Reagant Lat	>/<									
Reagent Lot     Calibrator Lot	Result									
<u>CA 125 (U/ml)</u>	>/<									
Reagent Lot Calibrator Lot	Result									
<u>CA 15-3 (U/ml)</u>	>/<									
Reagent Lot     Calibrator Lot	Result									
<u>CA 19-9 (U/ml)</u>	>/<		K							
Reagent Lot Calibrator Lot	Result									
<u>CA 27.29 (U/ml)</u>	>/<									
Reagent Lot     Calibrator Lot	Result									
CEA (ng/ml)	>/<									
Reagent Lot Calibrator Lot	Result									
<u>PSA (Total) (ng/ml)</u>	>/<									
Reagent Lot Calibrator Lot	Result									
<u>Free PSA (ng/ml)</u> If test offered, measure and	>/<									
Reagent Lot Calibrator Lot	Result									
Complexed PSA (ng/ml)	>/<									
Reagent Lot Calibrator Lot	Result									

# REFRIGERATE SAMPLES UPON ARRIVAL

## DO NOT FREEZE

# FOR LABS TESTING **FREE PSA**, TEST IT FOR <u>ALL</u> SAMPLES. SEE INSTRUCTIONS FOR MORE INFORMATION.

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

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