

VIROLOGY QUALITY ASSESSMENT PROGRAM

STATISTICAL CENTER

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SUBJECT: Comparison of the new and old lots of standards and controls for quantitative culture

We have completed a comparison of the results for the new lot of standards and controls with the results from the old lot of standards and controls. The analysis was based on the algorithm that is used for scoring results from quantitative cultures. Specifically, results are obtained by determining the p24 antigen concentration in each well of a culture from a standard curve that is fitted to the data from the VQA standards. Wells with p24 concentrations that exceed the estimated concentration for the 30 pg/ml VQA control are considered positive, while those with concentrations below the estimated value for this control are considered negative. Therefore, the new and old lots of standards and controls were compared by calculating the ratio of estimated p24 concentration for the new 30 pg/ml control to the estimated concentration for the old control in each laboratory. The standards and controls are produced as a single lot, so the estimates for the new controls were obtained from the new standards and those for the old controls were obtained from the old standards.

Data from 34 laboratories were included in the analysis. Four p24 antigen assays were used. Descriptive statistics for the p24 ratios described above from each kit and for all laboratories combined are provided in the table below. The overall median ratio was 0.9881. Thus, if the estimated p24 concentration from the old kit was 30 pg/ml, the estimate from the new kit would be 29.64 pg/ml. Median ratios for three of the kits are very close to 1.0. The Organon Teknika assay was only used in two laboratories, so it is difficult to draw any firm conclusions about this kit.

Overall, the results indicate that the two lots of standards and controls produce very similar results. Given the range of p24 values that are typically seen in quantitative cultures, a finding that even one well among the 12 in a culture was considered positive with one set of standards and controls but negative with the other should be extremely rare. Thus, the two sets should produce equivalent estimates of IUPM.

TABLE 1. DESCRIPTIVE STATISTICS FOR THE RATIO OF PREDICTED P24 CONCENTRATION FOR THE NEW LOT OF 30 PG/ML CONTROLS TO PREDICTED P24 CONCENTRATION FROM THE OLD LOT OF CONTROLS. PREDICTED VALUES FOR THE NEW LOT WERE OBTAINED FROM THE NEW LOT OF STANDARDS, WHILE THOSE FOR THE OLD LOT WERE OBTAINED FROM THE OLD LOT OF STANDARDS.

KIT	LABS	MINIMUM	25%	MEDIAN	75%	MAXIMUM
ABBOTT	9	0.75	0.95	0.9827	1.06	1.20
COULTER	13	0.83	0.90	0.9841	1.11	1.67
DUPONT	10	0.91	0.97	1.0015	1.03	1.21
ORGANON TEKNIKA	2	1.20				1.22
ALL KITS	34	0.75	0.93	0.9881	1.07	1.67