

Abbott ARCHITECT[®] Tumor Marker Assays: Lot-to-Lot Consistency for Patient Monitoring

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Abstract

Aims

Consistent tumor marker reagent lot-to-lot performance over time is imperative for patient management. Monitoring patients' tumor marker levels post-therapy aids in determination of the presence of residual tumor, tumor recurrence, progressive malignant disease, or therapeutic response. Consistent reagent lot-to-lot performance has been demonstrated using chemiluminescent microparticle immunoassay technology for AFP, CA 19-9*, CEA, Free PSA, and Total PSA on the ARCHITECT instrument system.

Methods

Controls and serum panels at appropriate clinical levels were tested as part of quality control procedures for each ARCHITECT tumor marker assay. Data was collected from reagent lots manufactured over four to five years.

*Not available in the U.S.

Results

Each of the control levels for each assay exhibited percent coefficients of variation (CV) of <4.5%. The serum panels at each level for each assay exhibited the following CVs: AFP, <6.5%; CA 19-9, <10.0%; CEA, <4.1%; Free PSA, <7.1%; and Total PSA, <4.8%.

Conclusions

Consistent results between manufactured lots were demonstrated for all 5 ARCHITECT tumor marker assays. Consistent performance over time allows laboratorians to have greater confidence in the results they provide to physicians resulting in better clinical decisions and management of patients. Physicians can be confident that changes in the concentrations of tumor markers in patients' serum is indicative of changes in the patients' disease status and not a result of variability in assay manufacturing.

Introduction

Measuring patients' levels of AFP, CA 19-9, CEA, Free PSA, and Total PSA are clinically useful in the monitoring of cancers. Monitoring patients' tumor marker levels post-therapy aids in determination of the presence of residual tumor, tumor recurrence, progressive malignant disease, or therapeutic response. Decreases or increases in the concentration of these analytes are indicative of changes in the patients' disease state. Total PSA can also be used in the early detection of prostate cancer. And the use of % Free PSA aids in discriminating between prostate cancer and benign disease, thus helping to eliminate unnecessary biopsies. Therefore, it is imperative for manufacturers to provide reliable tumor marker assays which produce consistent laboratory results over time.

Objectives

The consistency of ARCHITECT tumor markers was previously reported¹ at the 2001 ISOBM meeting which covered manufactured reagent lots over one to two years. This study is an extension of this previous report and reviewed the consistency of tumor marker serum panel values and control values produced in an artificial matrix as reported by the ARCHITECT assays covering manufactured reagent lots over four to five years.

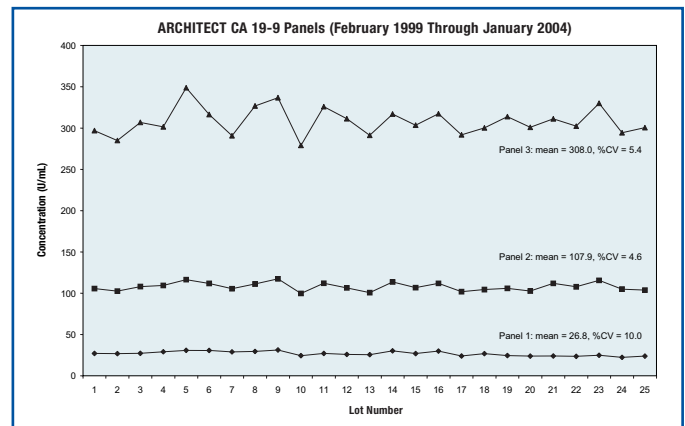
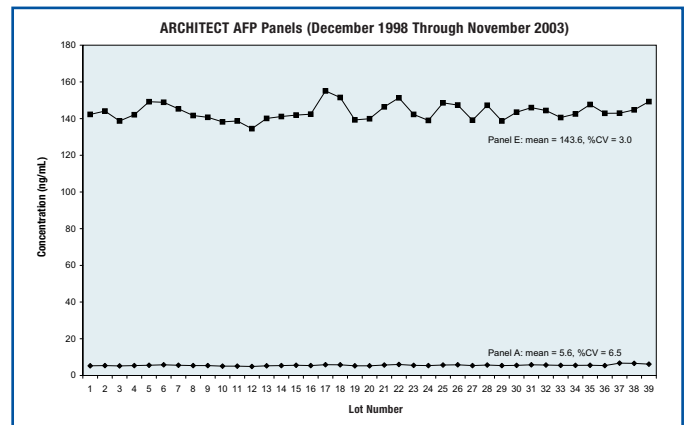
¹ The Abbott ARCHITECT i2000 System and Consistency of Tumor Marker Assay Reagents, ISOBM, 2001.

Methods

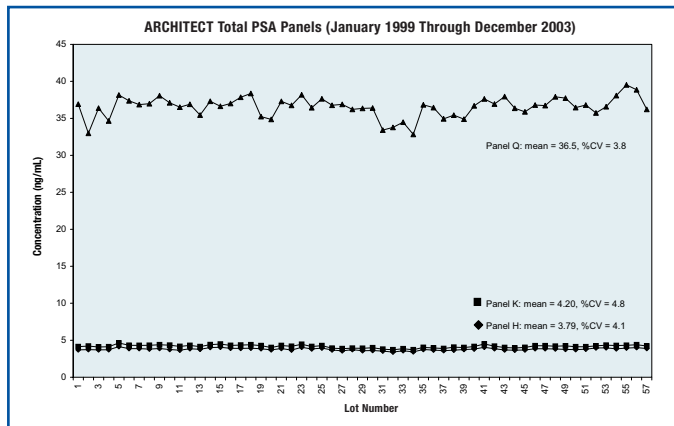
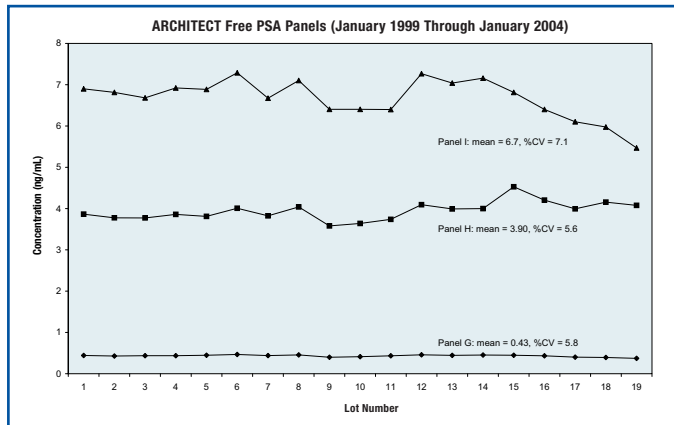
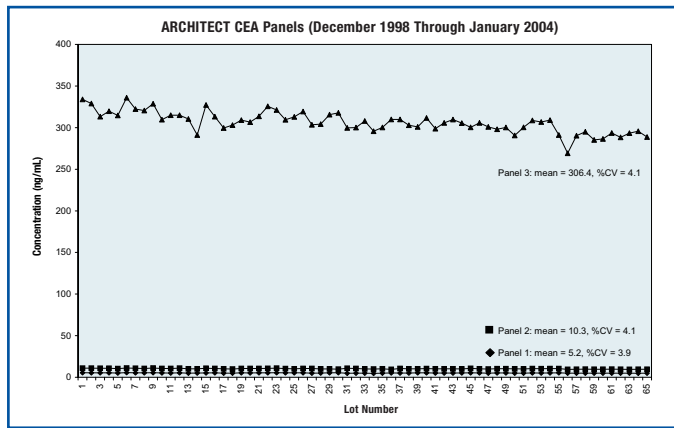
Internal quality control procedures at Abbott Laboratories require the testing of both serum panels and controls at various concentration levels throughout the assay range. The testing of serum panels imitates values expected with patient samples tested in clinical laboratories. The testing of controls validates reported patient results. Serum panels were prepared from patient samples or spiked analyte in a human serum matrix. Controls were prepared with spiked analyte in a buffer with protein stabilizers. These panels and controls were tested with each manufactured reagent lot of AFP, CA 19-9, CEA, Free PSA, and Total PSA over four to five years. Mean values and % coefficient of variation were determined for each level of serum panels and controls.

Results

Lot-to-Lot Consistency – Controls							
		Low		Med		High	
Assay	# of Lots	Mean	CV	Mean	CV	Mean	CV
AFP	40	24.9 ng/mL	3.2%	86.3 ng/mL	3.7%	191.6 ng/mL	2.3%
CA 19-9	25	39.7 U/mL	3.0%	125.4 U/mL	2.5%	251.2 U/mL	2.8%
CEA	65	5.1 ng/mL	3.2%	20.3 ng/mL	2.4%	97.1 ng/mL	2.2%
Free PSA	19	0.40 ng/mL	2.1%	1.01 ng/mL	1.8%	7.2 ng/mL	2.6%
Total PSA	57	0.48 ng/mL	4.5%	3.94 ng/mL	2.7%	24.1 ng/mL	2.4%



Results cont.



Conclusion

Consistent results between manufactured lots were demonstrated for ARCHITECT AFP, CA 19-9, CEA, Free PSA, and Total PSA assays. Consistent performance over time allows laboratorians to have greater confidence in the results they provide to physicians resulting in better clinical decisions and management of patients. Physicians can be confident that changes in the concentrations of tumor markers in patients' serum is indicative of changes in the patients' disease status and not a result of variability in assay manufacturing.

