PICCOLO®

PERFORMANCE EVALUATION

NATO S.H.A.P.E. LABORATORY

ABAXIS
September 2000

Introduction:

On September 26 to 28, 2000, a comparison study between the Kodak Ektachem Clinical Chemistry System and the Abaxis Piccolo® Point-of-Care Clinical Chemistry system was performed at the Belgium S.H.A.P.E. Laboratory.

The first part of the study consisted of the determination of the precision of the Piccolo system, by using two different analyzers and a commercial control material (Monitrol levels 1 and 2). The protocol was as follows:

Monitrol level 1 and 2 were measured by two Piccolo analyzers twice a day (10 AM and 4 PM) on September 27 and 28, for a total of 8 measurements per analyte. The standard deviation and coefficient of variation (CV) measured is representative of the within day, between days and between instrument variability, giving a good estimation of the total system performance. Mean values were compared to the acceptance range specified for the control level. Since Abaxis is a young company, we do not yet have acceptance values developed for Piccolo with the manufacturers of control material. However, multiple evaluations showed that Piccolo correlates very well with Hitachi analyzers, therefore Hitachi acceptance ranges are used for Piccolo results.

Six replicas of Monitrol control levels 1 and 2 were run back-to-back in the Ektachem analyzer to establish a statistically significant mean value for each analyte. This value was compared to the acceptance range of the Monitrol control for the Ektachem analyzer. Since the replicas were run back-to-back, a calculation of standard deviation and coefficient of variation is not relevant, because day-to-day calibration and intra-day drift could not be evaluated.

A comparison of mean values with respect to the maximum and minimum acceptable values allows us to compare different systems that may utilize different methods of measuring the concentration of an analyte.

The second part of the study consisted of the simultaneous analysis of 40 serum samples by both Piccolo and Ektachem analyzers. The samples were divided in groups of 10 and, since the time required for the analysis of a panel by Piccolo is longer than the time required by the Ektachem, the analysis by the Ektachem was started after Piccolo completed the analysis of 5 samples. This minimizes errors introduced by exposing the samples to room temperature for different periods of time. Linear Regression Analysis was used to calculate the slope, intercept and correlation coefficient for the data sets of each analyte.

Results:

Glucose:

Piccolo glucose shows a coefficient of variation better than 1% for both Monitrol Level 1 and 2. The maximum and minimum acceptance values for Monitrol Controls are slightly smaller for Ektachem as compared to Piccolo. The mean values of Ektachem are slightly higher with respect to its acceptance ranges, while Piccolo is slightly lower. This difference appears also in the accuracy study where Ektachem is almost 4% higher (slope). A bias of 5.4 mg/dL is negligible. The correlation of the instruments is extraordinary at 100%.

Urea Nitrogen (BUN):

Piccolo BUN shows a coefficient of variation of 4.1% for Monitrol Level 1 and 1.1% for Monitrol Level 2. This method shows a constant standard deviation of 0.46 mg/dL; therefore the C.V. increases with decreasing concentration. A standard deviation smaller than 0.5 mg/dL is excellent. The Monitrol maximum and minimum acceptance limits for Ektachem are significantly lower than Piccolo and the mean values of Ektachem are on the high side of its range. Piccolo mean values are, however, slightly lower with respect to its acceptance range. This difference is also shown in the accuracy data, where Ektachem is 2.2% higher (slope). A small bias of 2.8 mg/dL is observed (intercept). The correlation between instruments is almost perfect at 99.8%.

Creatinine:

Piccolo creatinine shows a coefficient of variation of 25.3% for Monitrol Level 1 and 2.9% for Level 2. The standard deviation of 0.16 mg/dL for very low concentrations is considered normal for the coupled enzyme reaction method used by Piccolo. The standard deviation drops to 0.1 mg/dL, resulting in a significantly improved coefficient of variation for concentrations larger than 1 mg/dL. The Monitrol Level 1 maximum and minimum acceptance range for Ektachem are significantly smaller than the ranges for Piccolo, reflecting the differences in methodology between the two analyzers, where Ektachem is significantly more precise at very low concentrations. Minimum and Maximum acceptance ranges for Monitrol Level 2 are slightly higher for Ektachem as well as the mean values. This difference is also reflected in the accuracy data where Ektachem values are 5.2% higher than the ones for Piccolo (slope). There is no bias between the instruments. Also, the correlation is almost perfect at 99.9%.

Creatine Kinase (CK):

Piccolo CK shows a coefficient of variation of 2.8% for Monitrol Level 1 and 1.7% for Level 2. The maximum and minimum acceptance range for Monitrol controls are significantly lower for Ektachem as compared to Piccolo. Ektachem mean values are very close to the upper range of acceptance, while Piccolo is slightly in the lower side of the range. Since the Ektachem is linear for concentration below 1600 U/L, for values larger than 2000 U/L the concentration was obtained by diluting the sample. The values obtained by dilution are highlighted in yellow in the data set. The first plot of CK data (<1700 U/L) show a significant curvature at both the upper and lower range of concentrations. The second plot covers the entire range, showing the diluted values. Since dilutions introduce a significant imprecision in the measurements, a scattering of the data points can be observed. In spite of these differences, the correlation coefficient between the analyzers is excellent at 98%.

Sodium (Na+):

Piccolo shows a coefficient of variation of 1.1% and 0.6% for Monitrol control Levels 1 and 2. The acceptance range for Monitrol controls are higher for Ektachem as compared to Piccolo. The mean values of Ektachem and Piccolo are almost perfectly in the center of their respective acceptance ranges. This difference is reflected in 12% higher values of Ektachem (slope). There is a negligible bias (intercept) between the two instruments. The correlation is, again, almost perfect at 99.7%.

Potassium (K+):

Piccolo potassium shows a coefficient of variation of 2.1% and 1.8% for Monitrol control Levels 1 and 2. Acceptance ranges and mean values for Ektachem and Piccolo are similar. The same situation is reflected in the accuracy data, showing a perfect slope of 1. Piccolo has, however, a bias of 0.7 mmol/L. This bias can be corrected by calibration. The correlation between the two instruments is outstanding at 98.8%.

Total CO2 (tCO2):

Piccolo total CO2 shows a coefficient of variation of 10.5% and 12.7% for Monitrol control Levels 1 and 2. Acceptance ranges for Ektachem are lower than the ones for Piccolo for Monitrol Level 1 and higher for Level 2. Both instruments' mean values read in the high side of the respective ranges. This suggests a difference in slope between the instruments. The accuracy data show that Ektachem readings are 26% smaller than the Piccolo ones, confirming the precision information. The accuracy data shows how noisy the method is in both instruments by the scattering of the data points. The very broad acceptance range for Monitrol controls also shows this. This is inherent to the methodology of measuring tCO2.

Conclusions:

The precision study shows that the Piccolo analyzer performs well within the acceptance ranges of the Monitrol controls and correlates extremely well with the Ektachem analyzer utilized at S.H.A.P.E. Laboratory. The lowest correlation coefficient was for creatine kinase at 98%. This was due to several data points, in the range of 1600 to 3000 U/L, that shows out-of-dynamic range saturation for Ektachem. At the time this saturation was not noticed, but subsequent measurements were performed by diluting the sample, reaching values as high as 5000 U/L. These extremely high concentrations are unlikely to be found under normal circumstances.

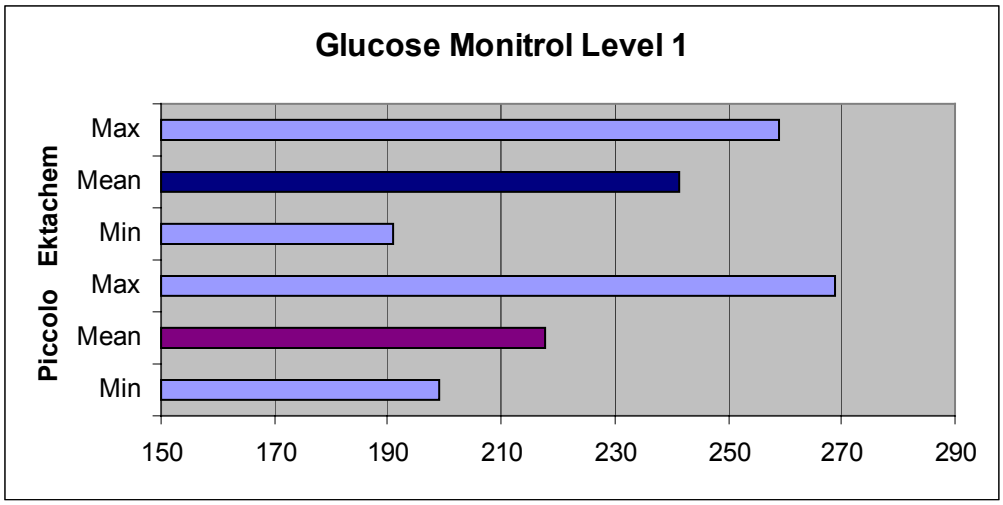
Precision Study

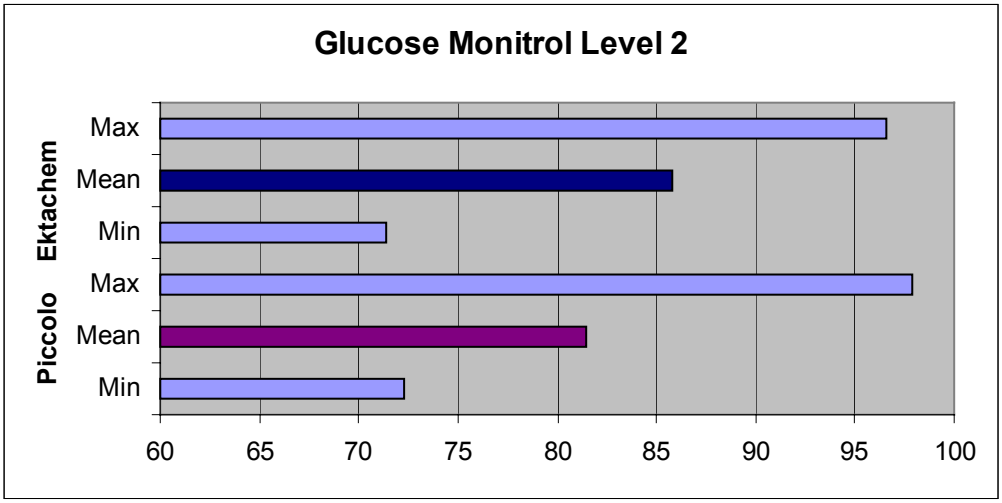
Light blue bars: Monitrol maximum and minimum acceptance values

Dark blue bars: Ektachem mean values

Purple: Piccolo mean values

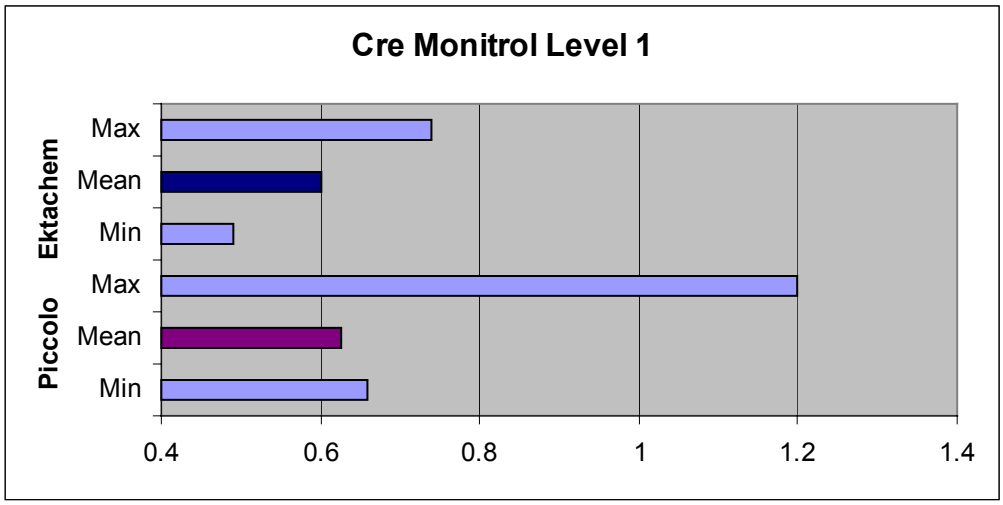
NATO Study
Precision

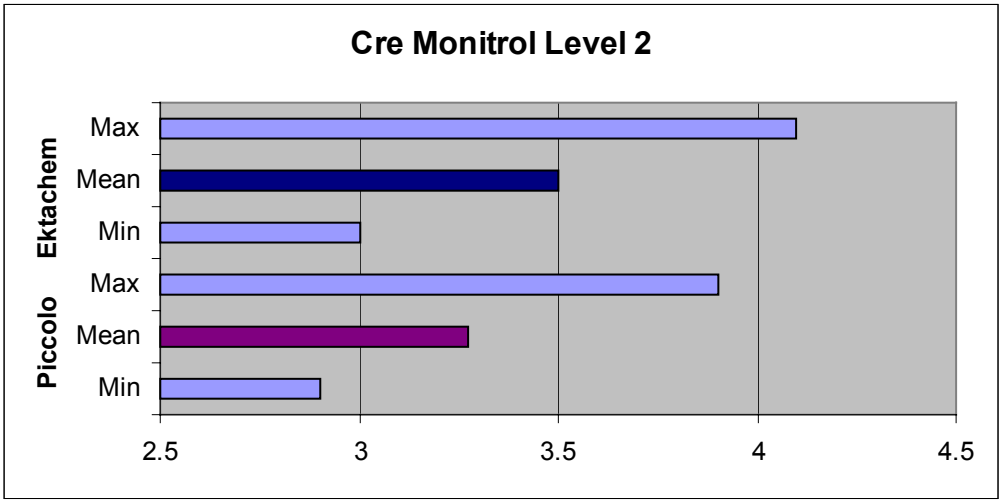




September 2000

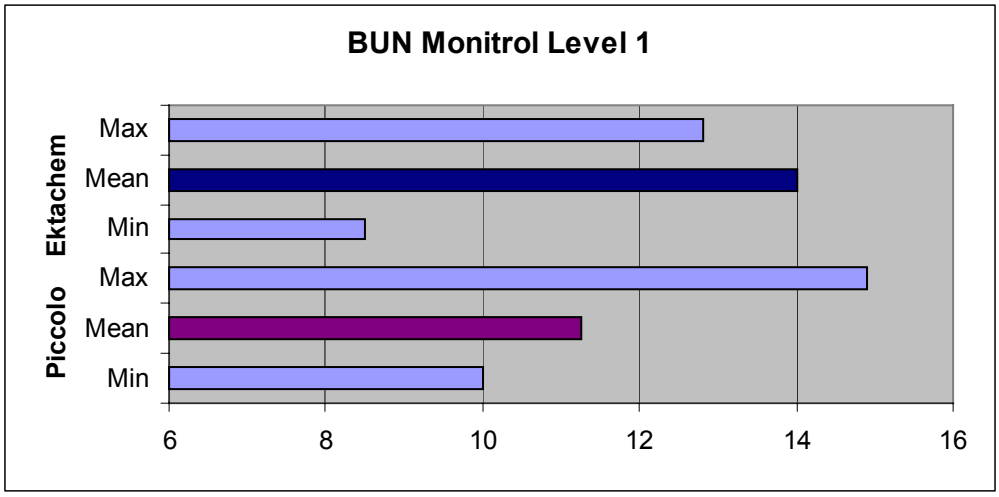
NATO Study
Precision

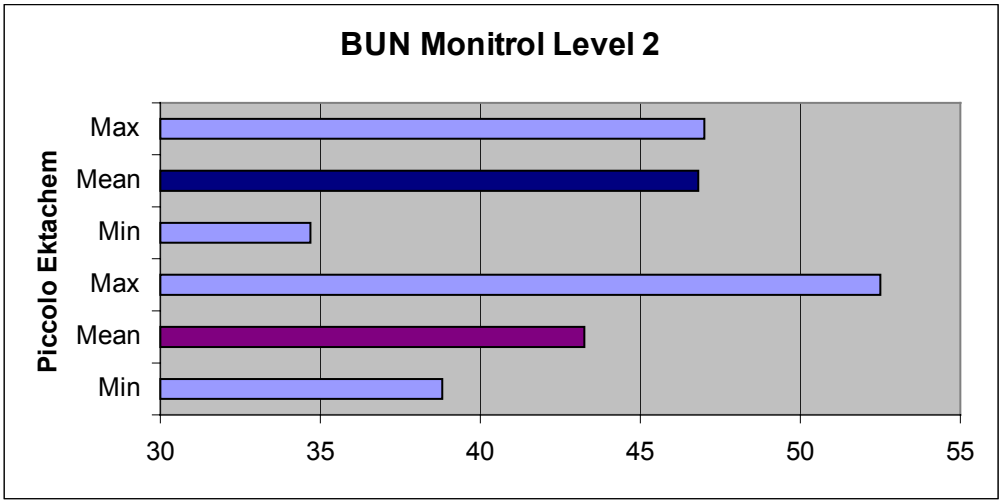




September 2000

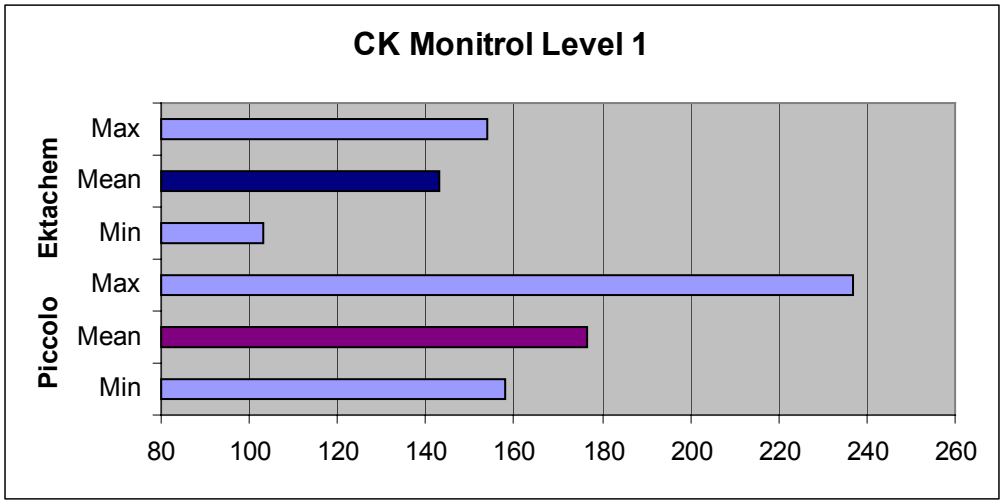
NATO Study
Precision

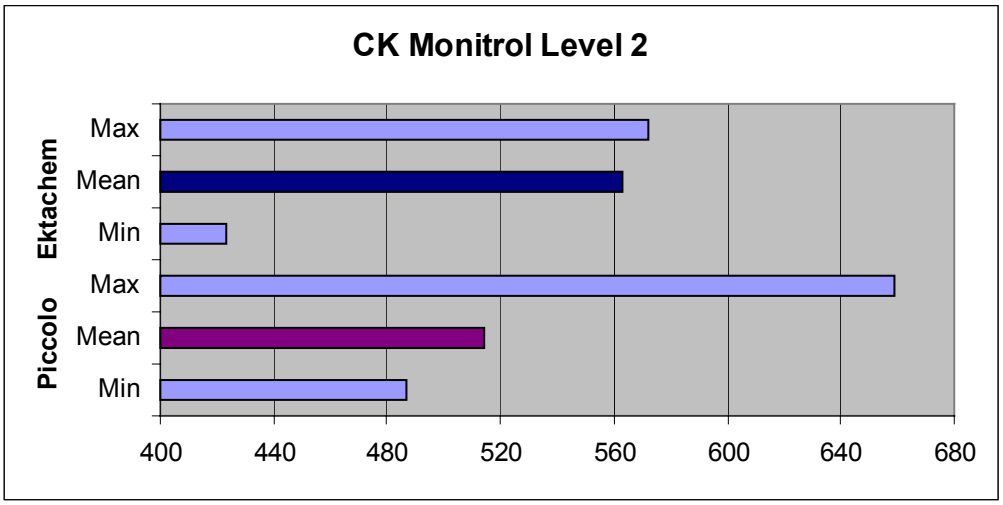




September 2000

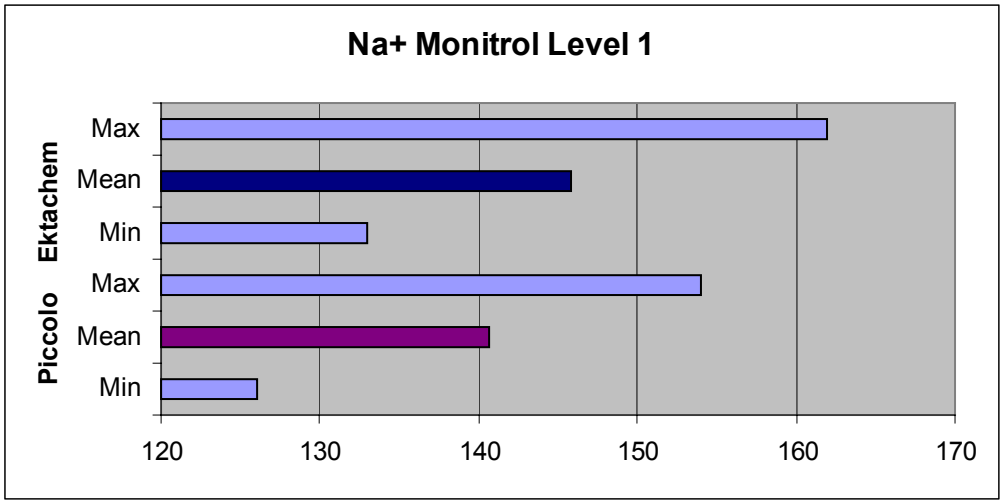
NATO Study
Precision

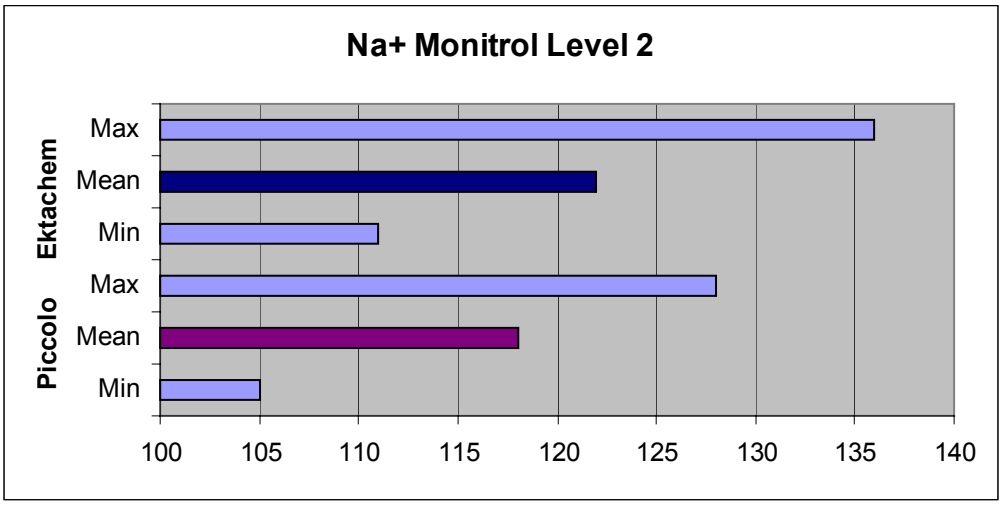




September 2000

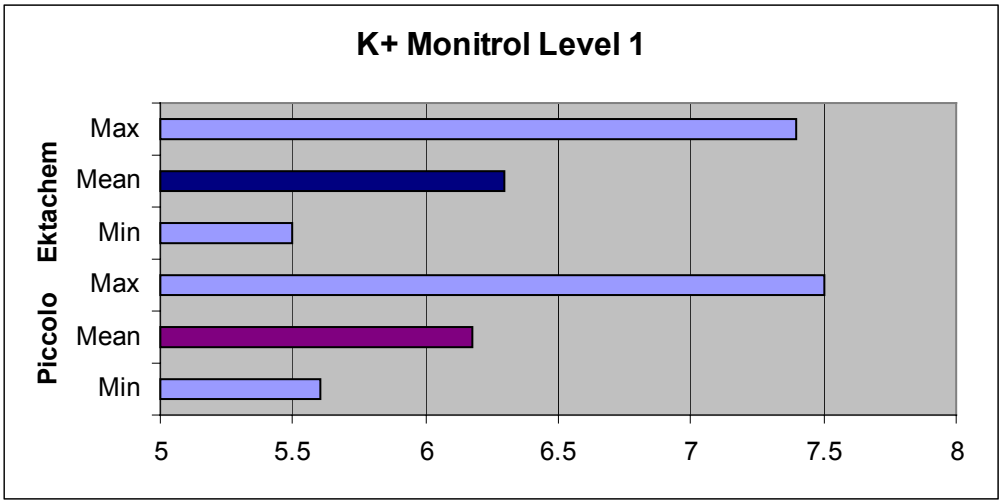
NATO Study
Precision

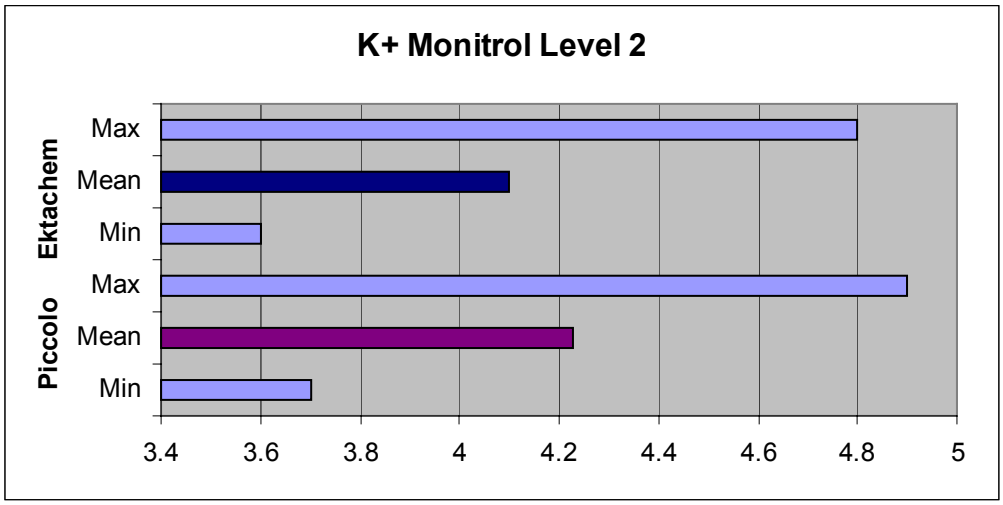




September 2000

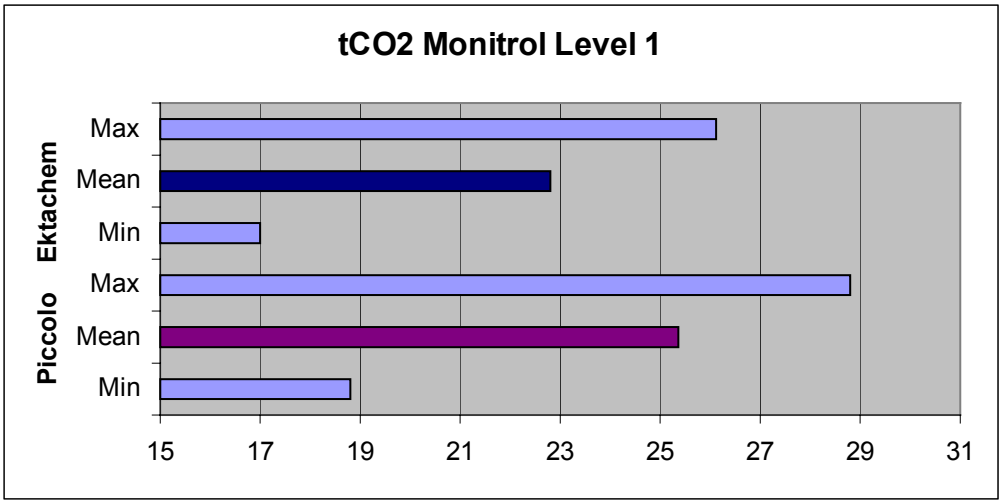
NATO Study
Precision

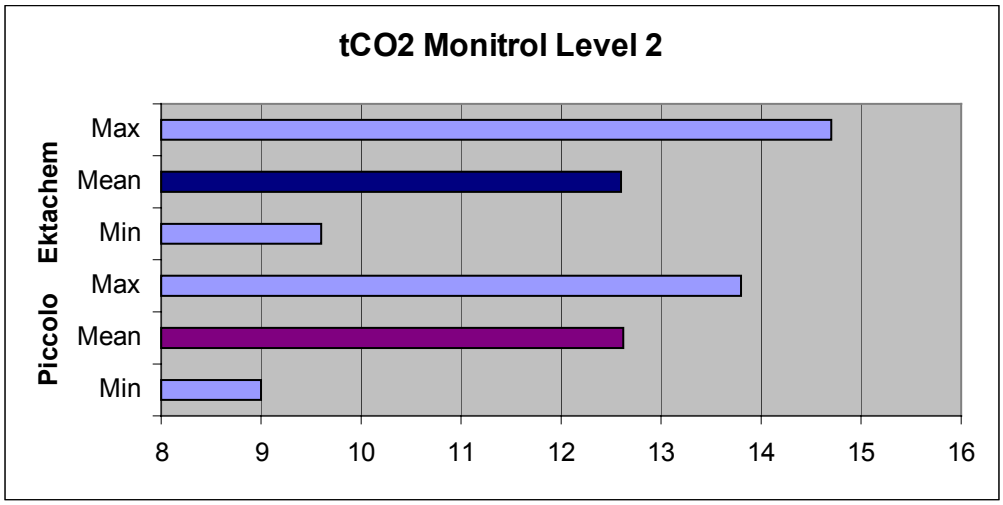




September 2000

NATO Study
Precision

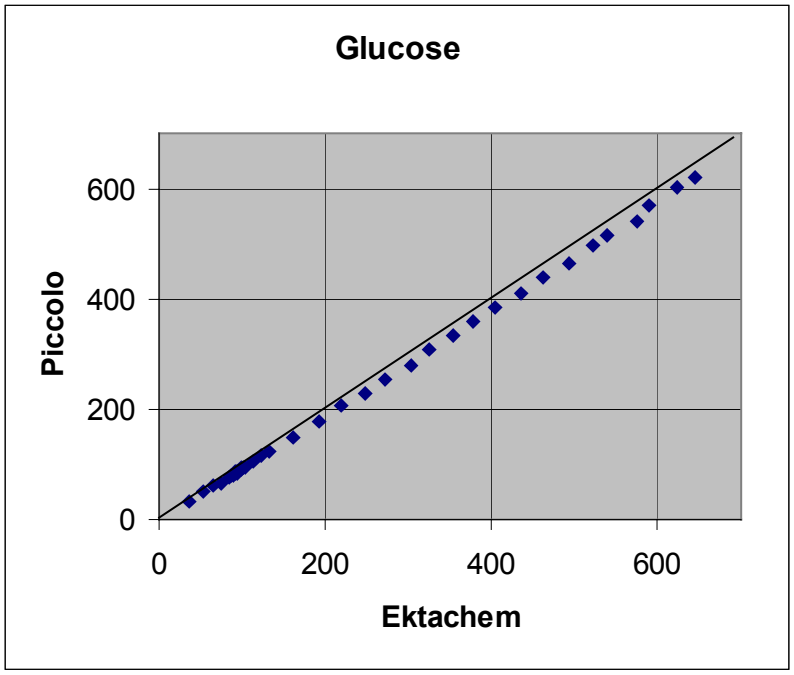




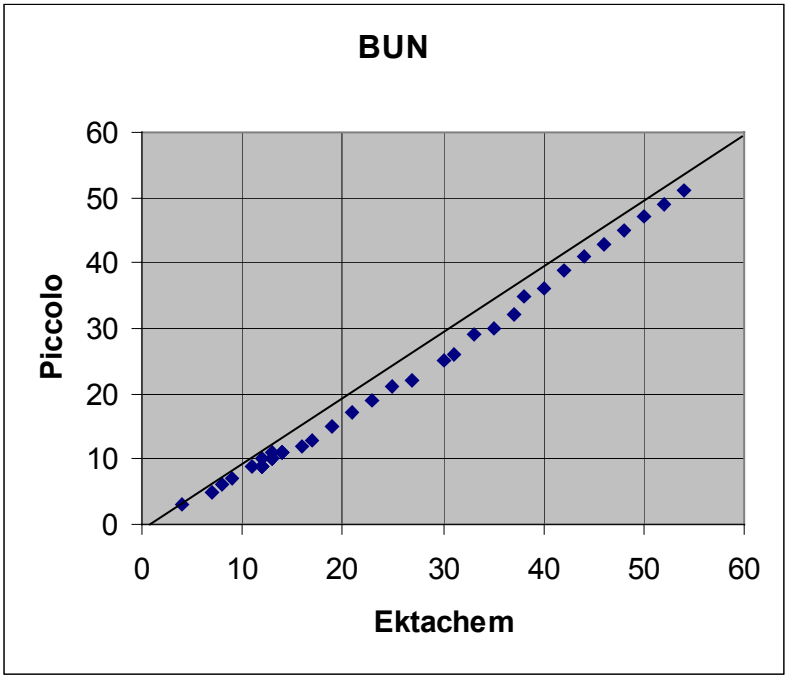
September 2000

Accuracy Study

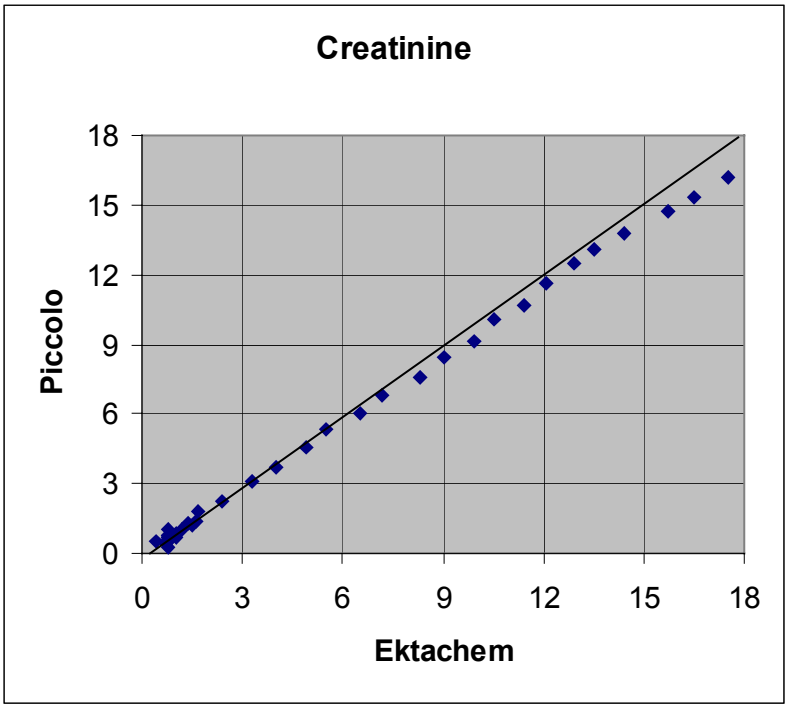
NATO Evaluation



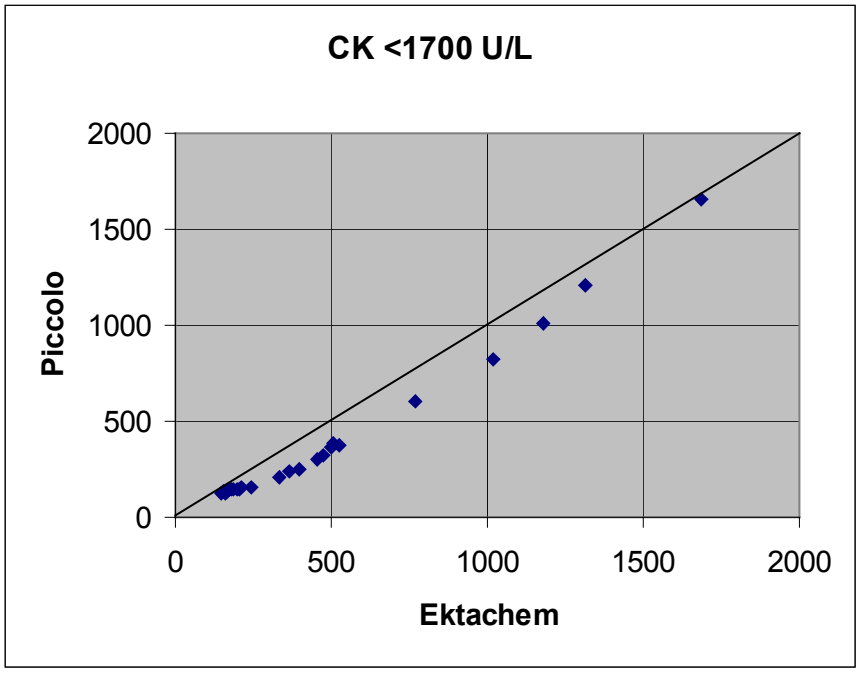
NATO Evaluation



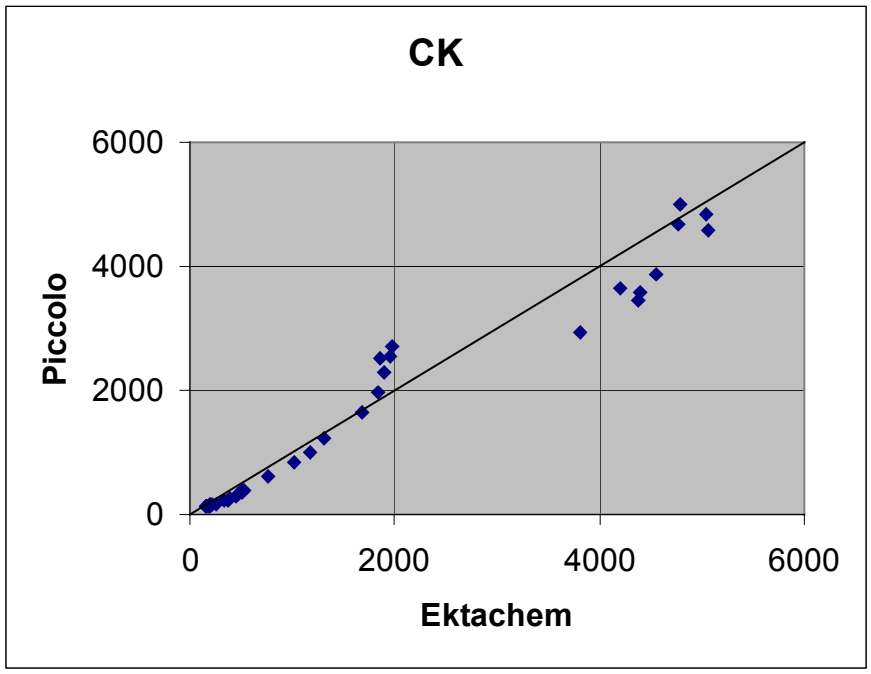
NATO Evaluation



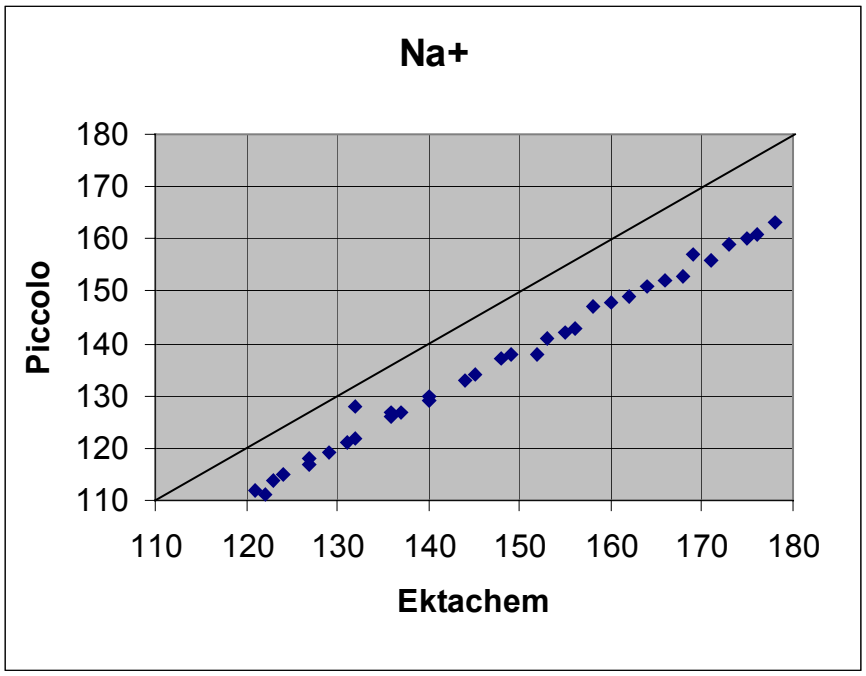
NATO Evaluation



NATO Evaluation



NATO Evaluation



NATO Evaluation