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Evaluation of Ektachem DT-60

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Ektachem DT-60 is a bench-top instrument for analysis of short series of serum samples. It consists of a central unit which performs analysis of the majority of available methods and handles the data processing. A separate unit is available for analysis of electrolytes (potassium, sodium, carbon dioxide and cloride) and a third is projected for rate analysis. The Ektachem system has been operative for many years and a variety of instruments have been marketed. The DT-60, is essance a single-channel instrument which can use a variety of slides for the determination of serum components. Special slides are required for the instrument and minute amounts of serum is required. The theoretical through-put of samples is about 65 per hour for the spectrometer and results are presented after up to about 5 minutes of reaction. The electrometer allows analysis of about 15 samples per hour. These can be carried out at the same time as the spectrometer is used. Samples can be entered in random order since the slides are marked with barcodes which are read by the instrument.

In this study four (potassium, cholesterol, triglycerides and urate) of the presently available rather limited number of components have been tested. The choice has been made to show the performance of the instrument for some components which might be of interest for the primary health care. Unfortunately, no enzymes, nor creatinine or urea were available when this study was initiated. These and other components will be released in the near future.

A tentative test protocol established by the 'Group on reagent sets' (Swed Doc Clin Chem) was used to standardize the evaluation.

Evaluation design

Accuracy. The protocol is designed to evaluate the accuracy of a new technique by comparing concentrations of patient specimens as determined by an accepted routine method under controlled conditions with those found with the instrument (Fig 1,2). Also, accuracy is determined by analyzing commercially available reference materials of several levels of concentrations (Table 1).

Precision. The precision was estimated in two ways. Firstly, coefficients of variation (CV) were calculated from repeated determinations of the same reference material. Three levels of frozen material (bovine serum Nycomed) were used. Secondly, an estimate of the CV was made from duplicate determinations of patient samples (Dahlberg's formula) at different levels (Table 2).

Variance analysis. Day-to-day variations were followed in conventional Shewhart-plots using the control material supplied by the manufacturer (DT-control).
Also, 'within batch', 'between batch' variations as well as 'total variation' were calculated. Data accumulated from five analyses during 15 successive days were used for these estimates (Table 3).

Influence of lipids and hemolysis

Lipids. Intralipid^{R} (Kabi-Vitrum) was diluted with 0.15 mol/L NaCl and added to patient serum to final concentrations of 10, 5, 2.5, 1.2 and 0.6 g/L and the concentration of the component again determined.

Hemolysis. Washed erytrocytes were hemolysed by freezing and thawing. The hemoglobin concentration was determined after centrifugation. Aliquots of this preparation was added to serum to make final concentrations of 28, 14, 7, 3.5, 1.8, 1.0 and 0.7 g/L.

Drift. Quality control material was analyzed in the beginning of the evaluation and at the end (three weeks later) in batches of 25 samples. For comparison Student's test for independent means was used.

Linearity. The linearity of analysis was checked by chosing a specimen of a high concentration and one of a low concentration and mixing them to achieve five different concentrations.

Stability of slides. Slides for cholesterol were exposed to air in light and darkness outside the envelope. Slides were exposed to the atmosphere in office and laboratory environments. After various times, ranging from 5 to 25 minutes determination of one and the same patient specimens was performed.

Operation. The instructions from the manufacturer were closely followed.

Calibration should, according to the manufacturer, be performed every 3 months or when a new lot number of slides is obtained. In our case only one recalibration was needed according to these instructions (new lot of triglyceride slides).

RESULTS AND DISCUSSION

The precision of the methods tested was generally good and agreeable. Consistant results were obtained both with reference materials and patient samples. Also, the accuracy was acceptable but for triglycerides and urate.

In determinations of the concentrations of triglycerides in the reference material too high values were obtained, particularly at higher levels. The same phenomenon but not so marked was also observed in the comparison of patient specimens, all which were within the reference range. Determination of triglycerides also constitutes a problem in the determination of lipemic sera. The normal routine involves dilution of such samples but if this is neccesary at too low levels much of the advantages of the Ektachem methodology would be lost. In the presentation of results with patient sera, all those appering lipemic have been eliminated. If this was not done a very large scatter of the results was obtained.

The accuracy of urate determinations was low and the results in patient sera were generally lower with the Ektachem than with the PRISMA method. This was also clearly demonstrated in relation to the target values of the control material. The difference is most marked in the lower region.

Comparison between determination of potassium with flamespectrometry and Ektachem indicates highly diverging results wereas a comparison with ISE (NOVA I) gives satisfactory results. (Samples from sets of different patients were used in the two comparisons.)

Analysis of variances of the four components studied reveals a remarkable stability of the instrument (Table 3). The instrument was not turned off between series and thus the model of evaluation is not quite compatible with other evaluations. However, the recommended mode of operation was followed and the results should be regarded as describing a normal performance of the instrument.

The manufacturer prescribes that the instrument should be calibrated with long intervals. Although statistically significant the relative change over this time period appears marginal.

As expected, a considerable influence was recorded of Intralipid^{R} on the analysis of triglycerides whereas the other components were markedly unaffected by this interference. Hemolysis, of course, influenced the concentration of potassium but also affected the determination of cholesterol and urate at high hemoglobin concentrations.

The linearity of the methods was excellent as judged from dilution of sera with high concentrations with such with a low concentration. It should be pointed out that no check of the linearity covering the entire specified range.

It was observed that the cholesterol slide changes in background color on exposure to air and light. The performance of such slides does not seem to be particularly affected after an exposure time of up to 25 minutes which is more than allowed in the manual.

CONCLUSION

The Ektachem DT-60 has been tested according to a test protocol aiming at describing accuracy, precision, drift, interferance, linearity and stability. Only potassium, cholesterol, triglycerides and urate were tested and of these determinations of triglycerides and urate indicated problems as concerns accuracy. Cholesterol and potassium analysis showed a high degree of deterioration with time implying that the calibration procedure should be reviewed. Potassium should be compared with ISE methods. Excellent agreement was found between the Ektachem and the reference methods for potassium and cholesterol. Linearity was excellent in the range tested and the instrument showed a remarkable stability as described by the precision within and between batches.

A full report, including unabbreviated tables and comprehensive plots can be obtained from the author.

Table 1

Accuracy and precision

Means and standard deviations of concentrations of reference materials.

	x	SD	CV%	N	Target value
Potassium					
low	2.77	0.033	1.2	25	2.5 mmol/L
medium	4.15	0.035	0.8	25	4.0
high	5.47	0.073	1.3	25	5.1
Cholesterol					
low	4.03	0.130	3.2	23	4.0 mmol/L
medium	5.63	0.155	2.8	23	5.6
high	8.42	0.159	1.9	24	8.6
Triglycerides					
low	1.12	0.033	2.9	24	1.0 mmol/L
medium	2.49	0.171	6.9	19	1.7
high	4.08	0.127	3.1	21	2.6
Urate					
low	180	3.14	1.7	22	220 umol/L
medium	373	6.46	1.7	17	412
high	529	12.43	2.4	25	540

Table 2

Precision estimated from duplicate determinations. Patient samples.

	x	SD	CV	N (duplicates)
Potassium (mmol/L)				
0 - 5.2	4.58	0.095	2.1	83
5.2 - 10	5.43	0.077	1.4	7
Cholesterol (mmol/L)				
0 - 8	5.77	0.108	1.8	82
8 - 10	8.64	0.127	1.5	8
Triglycerides (mmol/L)				
0 - 2.2	1.48	0.036	2.4	65
2.2 - 10	2.37	0.039	1.6	4
Urate (umol/L)				
0 - 300	248	2.74	1.1	30
300 - 500	374	3.68	1.0	57
500 - 1000	576	6.45	1.1	4

Table 3

Imprecision within and between batches (SD).

	Potassium mmol/L	Cholesterol mmol/L	Triglycerides mmol/L	Urate umol/L
Within-day	0.034	0.142	0.024	3.55
Pure between-day	0.037	0.075	0.034	5.50
Total	0.051	0.160	0.041	6.55
Mean	4.16	5.56	2.35	375
CV%	1.2	2.9	1.8	1.7
Number of obs.	75	74	75	74