EFFICACY OF A HOME MADE QUALITY CONTROL SERUM

Pages with reference to book, From 317 To 320

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Abstract

With increasing automation in Clinical Laboratories, the requirements for quality control material have greatly increased in order to monitor performance. The constant use of commercial control material is not economically feasible for many countries because of non-availability or the high cost of these materials. Here we describe a simple technique to prepare Home Made Quality Control serum using blood from polycythaemic patients. This preparation is stable for about six months without any alterations in the concentration of any of the chemical constituents. Extensive use of Home Made Quality Control sera in our laboratories have saved about 69% of the amount spent on the commercial material without any compromise in quality of the laboratory performance (JPMA 39 : 317, 1989).

INTRODUCTION

The use of quality control serum to monitor day to day laboratory performance is an essential part of any health care laboratocy. However, laboratories in many third world countries are disadvantaged because of the non-availability or the high cost of commercially available quality control material. For the preparation of quality control samples, several methods, including a varietyofstartingmaterials, have been proposedin the literature[1-3]. Herewedescribe a methodfor the preparation of a quality control serum which is economically feasible and technically simple.

MATERIAL AND METHOD

Selection of Subjects:
Blood was obtained from polycythaemic patients byvenesection as part of the management for the disease. Informed consent was obtained from each donor before blood collection.

Collection of Blood:
Blood was collected from each subject without any anticoagulant in a plain blood collection bag and placed in a water bath at 37°C for about 2 hours for optimum coagulation. Serum was then separated after ceptrifugation for about 15 to 20 minutes at 3000 RPM at 4°C. A small aliquot of 2ml was separated from each patient's serum for screeningpurposes and the rest was frozen at -20°C after adding 0.1 percent sodium azide as preservative.

Preventive Screening:
The serum was screened for hepatitis and HIV antibodies according to our routine procedure for the handling of donor's blood by the ELISA technique, using kits from Abbott.

Preparation of Aliquots:
All serum samples negative for Hepatitis and HJV antibodies Were thawed and pooled together, and then mixed very gently on a magnetic stirrer, keeping the contents cool, preferably in an ice-water bath. Aliquots of 0.5 ml samples were prepared using an autodiluter and stored frozen at -70°C until used further. Using some of the aliquots, the pooled serum was tested repeatedly for the concentration of all biochemical constituents using a Beckman Astra Autoanalyzer atleast thirty times on different days.

Assignment of Analytes conc. ranges:
The concentration ranges as calculated by using the formula: mean ± 2SD for each analyte was determined according to the procedure described previously for the commercial control[4].

Stability and precision checks:
After the preparation of the control, precision and stability were studied for a 6 month period. The analytes were considered stable, if the values did not differ significantly (P >0.05) from zero by the student's 't' test[5,6].

RESULTS

Out of 23 analytes tested on autoanalyzer, we have selected a few representative parameters to show the accuracy and precision of our results, presented in Table I,

TABLE I. Estimation of accuracy and precision using commercial quality control serum*

(Mean ± S.D.)

Chemical constituents	Level 1		Level 2		Level 3	
	C.M.	I.M.	C.M.	I.M.	C.M.	I.M.
GLU (mg/dl)	45 ± 2.50	44 ± 1.10	118 ± 5.00	116 ±1.60	250 ± 7.5	248 ± 1.80
Na (mmol/1)	129 ± 2.00	129 ± 2.00	141 ± 2.00	141 ± 0.80	155 ± 2.0	155 ± 0.80
K (mmol/1)	2.5 ± 0.10	2.6 ± 0.08	4.0 ± 0.15	4.2 ± 0.09	5.4 ± 0.2	5.6 ± 0.07
ALT (IU/L)	28 ± 3.50	28 ± 0.90	48 ± 4.0	48 ± 1.20	90 ± 6.0	88 ± 1.50
AST (IU/L)	30 ± 4.00	28 ± 0.90	54 ± 5.0	54 ± 1.30	94 ± 6.0	94 ±1.90

*Beckman decision levels
C.M. = Mean given by the manufacturer
I.M. = Mean obtained in the laboratory

where we have used commercial quality control samples of three different concentrations, low, medium and high. mean values given by the manufacturers (C.M) and the internal mean values (I.M) derived in our laboratory and similarly the values of commercial and internal standard deviation (S.D.) are given.

TABLE II. Precision and stability of home made quality control serum.

(Mean ± S. D.)

Months	BUN (mg/dl)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)	Co_2 (mmol/L)	GLU (mg/dl)
March	14 ± 1^a	139 ± 1^c	6.3 ± 0.1^e	98 ± 2^g	12.5 ± 0.7^i	52 ± 2^k
April	14 ± 1	140 ± 1	6.3 ± 0.1	100 ± 1	12.0 ± 0.9	52 ± 2
May	15 ± 1	140 ± 2	6.4 ± 0.2	99 ± 1	13.0 ± 1.2	52 ± 2
June	16 ± 1	139 ± 2	6.4 ± 0.1	100 ± 2	13.0 ± 1.0	53 ± 1
July	16 ± 1	141 ± 2	6.5 ± 0.1	100 ± 2	14.0 ± 1.2	53 ± 1
August	16 ± 1^b	141 ± 1^d	6.4 ± 0.2^f	100 ± 1^h	15.0 ± 2.0^j	53 ± 2^l

a vs b; c vs d; e vs f; g vs h; i vs j; k vs l; p >0.05 not significant.

TABLE III. Precision and stability of home made quality control serum.

(Mean ± S. D.)

Months	GGT (IU/L)	ALT (SGPT) (IU/L)	AST (SGOT) (IU/L)
March	43 ± 1^{a}	21 ± 1^{c}	27 ± 1^{e}
April	41 ± 2	21 ± 2	28 ± 2
May	42 ± 1	20 ± 2	27 ± 2
June	42 ± 1	20 ± 2	26 ± 1
July	42 ± 1	19 ± 1	27 ± 2
August	42 ± 2^{b}	21 ± 2^{d}	27 ± 2^{f}

a vs b; c vs d; e vs f; $p > 0.05$ not significant.

Table II (routine analytes) and Table III (enzymes) show the precision and the stability of the analytes over a period of six months, in our home made control sera. The P values are greater than 0.05.

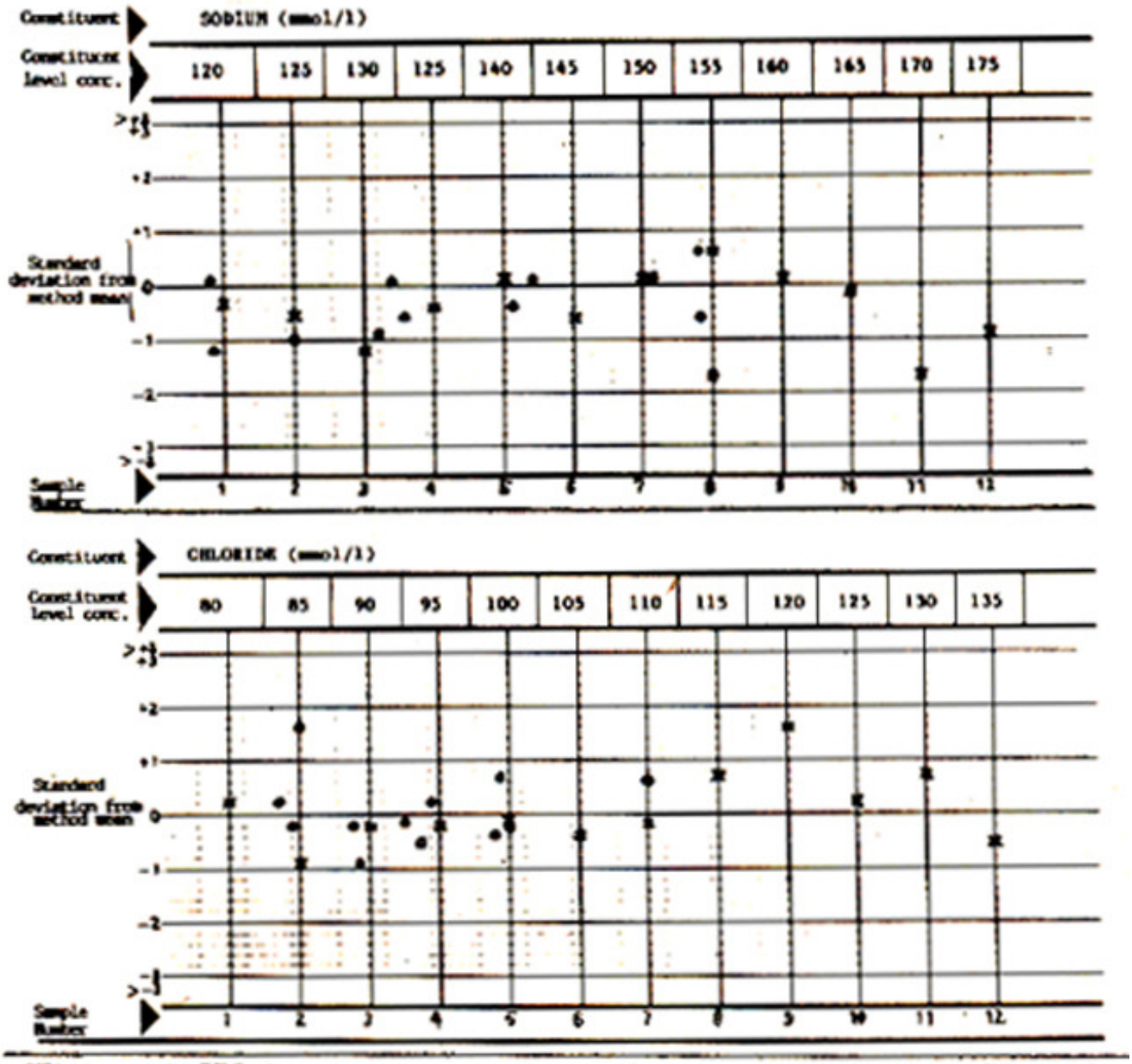

Figure 1. Welcome external quality control results. (For six months cycle).

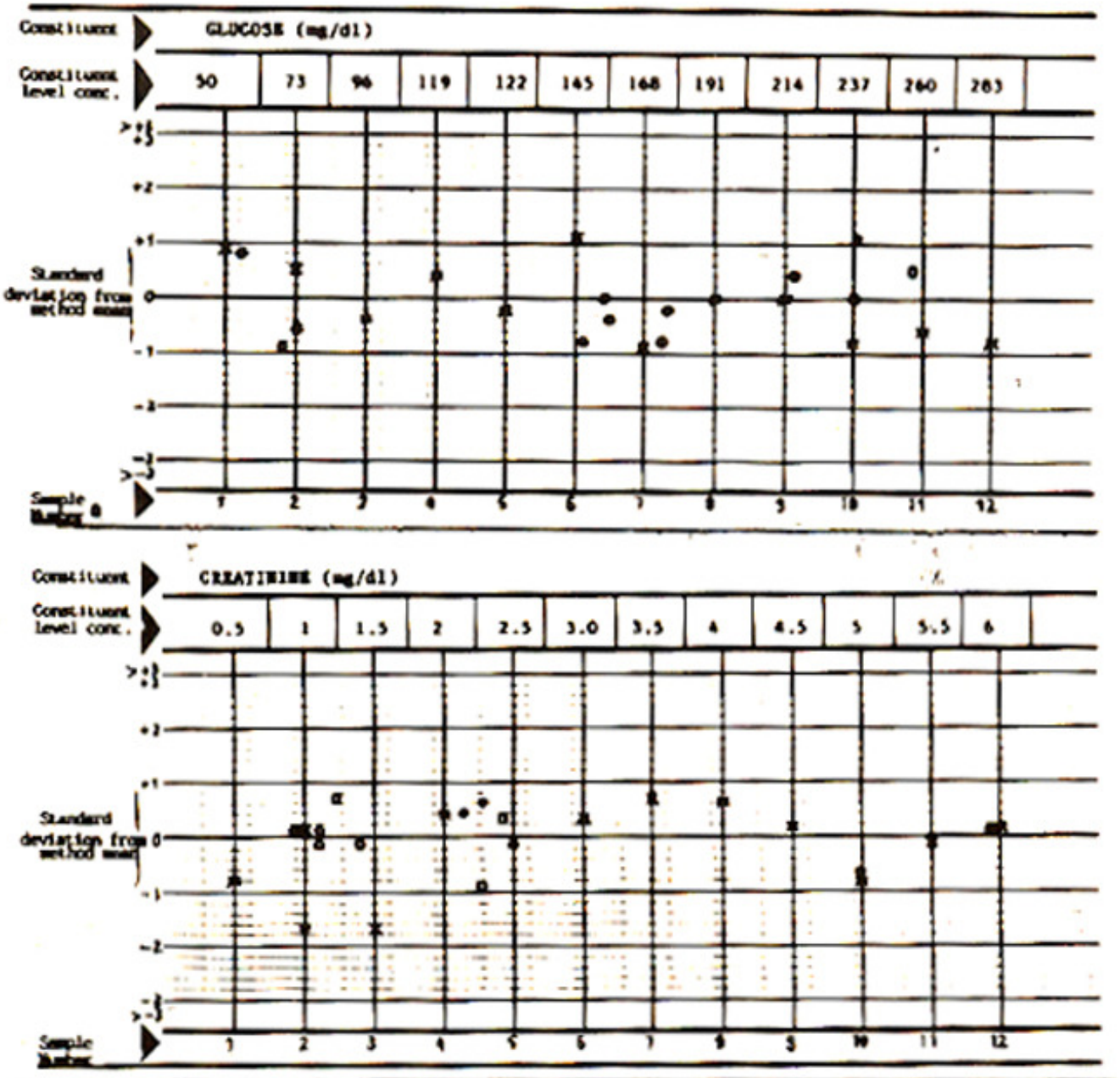

Figure 2. Welcome external quality control results (For six months cycle).

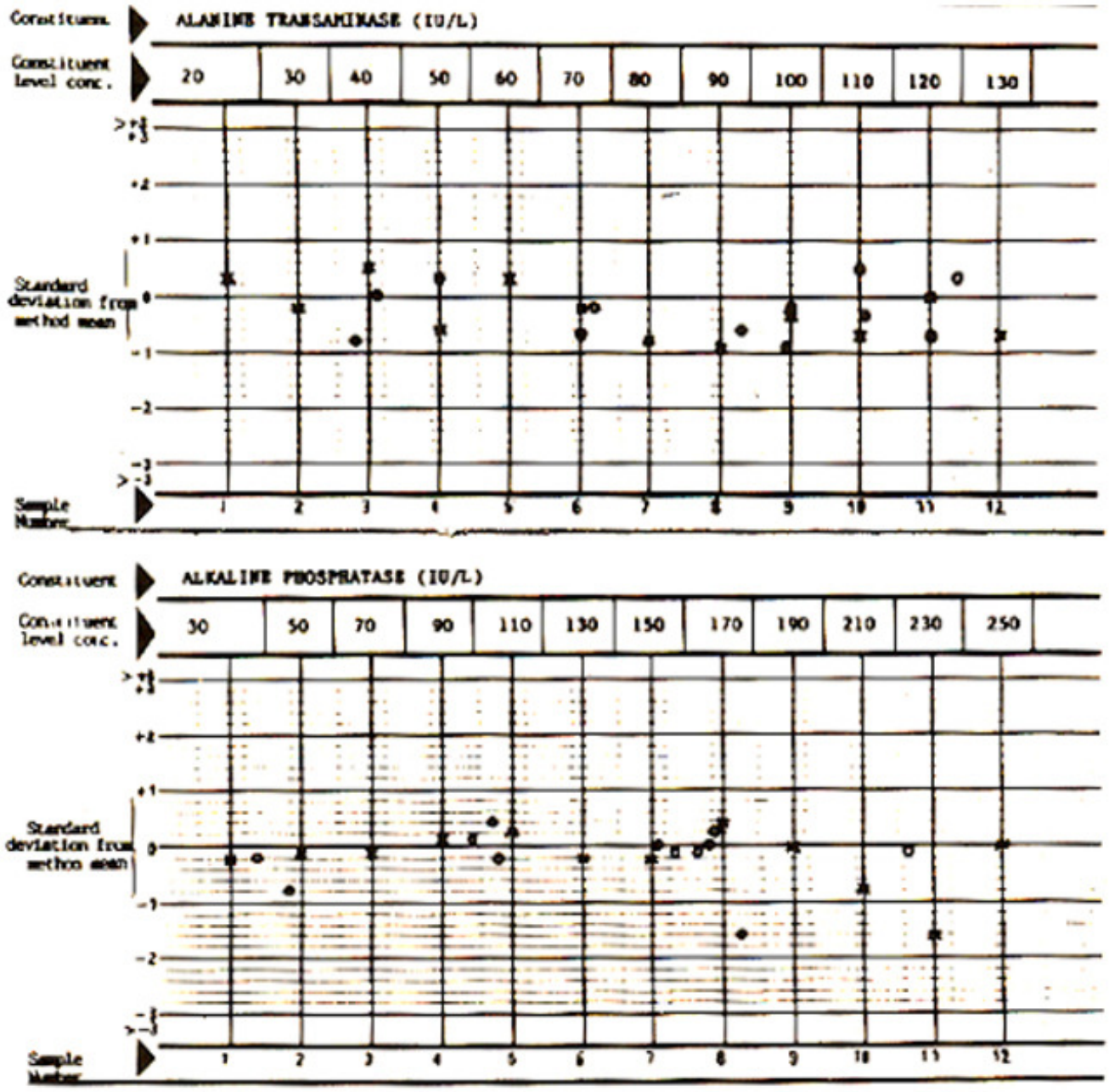

Figure 3. Wellcome external quality control results (For six months cycle).

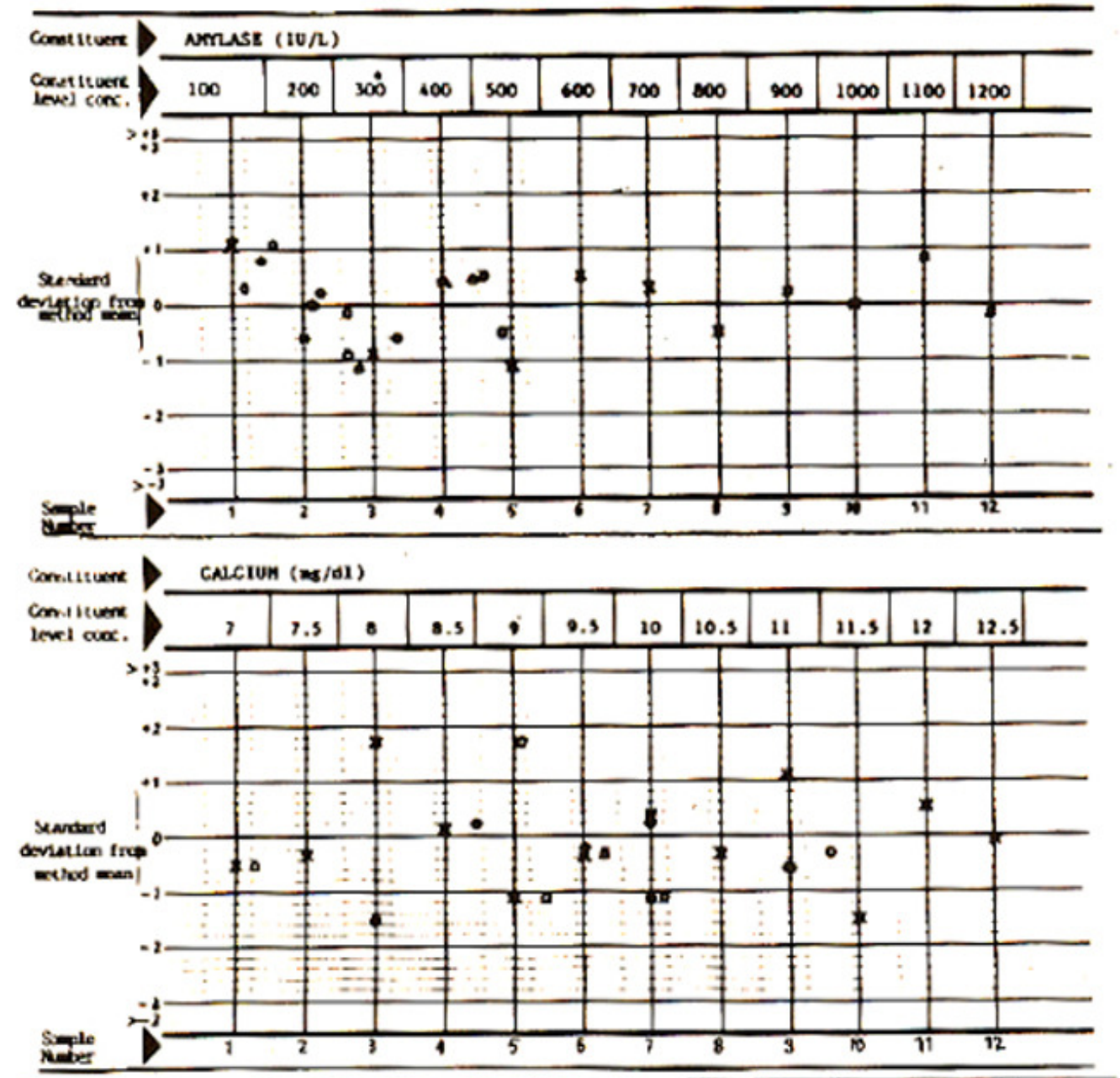

Figure 4. Wellcome external quality control results (For six months cycle).

Figures 1 to 4 show the external quality control results for the period under study. These are the Levy-Jenning's charts where the middle heavy line indicates zero standard deviation from the mean. The figures mentioned at the top are the concentrations of a chemistry and the figures at the bottom indicate the numbers of the external quality control sample sent to the laboratory from abroad. Each 'X' indicates the deviation of that sample concentration from the true value, either on the positive or negative side of the middle line. The '0'S (whose constituent level can be seen directly under a specific concentration) indicates the value of positive or negative standard deviation from the true concentration.

DISCUSSION

With increasing automation in the laboratory, the requirements for quality control material have greatly increased in order to monitor performance. The constant use of commercial control is not economically feasible for many other third world countries because of the non-availability and/or the high cost of these materials. On consideration of the World Health Organization Document LAB/81.4[7] which encourages the local production of quality control material, we tried several alternatives including the use of patients' pooled sera, donor's expired plasma and animal blood. Patients' pooled sera was not favoured for being hazardous. Control sera prepared from expired plasma usually contained minute fibrin clots and thus gave technical problems. The problem of hemolysis arose while animal blood was collected from slaughter houses. A fourth alternative was to use polycythaemic patient's blood, which we found was safe and did not have any of the above mentioned problems. As shown in Table II, the stability for a period of six months for the routine analytes BUN, Na, K, Cl, C02 and Glu was good and results did not vary significantly ($P > 0.05$). The enzymes which are most susceptible to environmental changes, were also monitored (Table III) and the variations observed were quite acceptable under the mentioned storage conditions. Our External Quality Control results as is shown in Figures 1 to 4 with regard to the linearity of the concentration range encountered, has strengthened our confidence in preparing control material. Furthermore, after using home made preparations, about 69% (Rs. 53,460) of the initial expenses (Rs. 77,760) were saved annually by our clinical laboratory. Thus, home made quality control sera can easily be prepared in any small laboratory as it does not require sophisticated technology and it can have its own supplies using this simple technique. Further extension of the project has also been initiated at the Aga Khan University Hospital Laboratories for the mass scale production of home made control in different concentration levels using animal blood and to lyophilize it. This will facilitate the transportation of these materials to various organizations throughout the nation.

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