January 1988

Efficacy of internal and external quality control in chemical pathology

Rukhsana Lalani
Aga Khan University

Mirza Naqi Zafar
Aga Khan University

Mohammad Khurshid
Aga Khan University, mohammad.khurshid@aku.edu

EFFICACY OF INTERNAL AND EXTERNAL QUALITY CONTROL IN CHEMICAL PATHOLOGY

Pages with reference to book, From 255 To 259

Rukhsana Lalani, Mirza Naqi Zafar, Mohammad Khurshid (Clinical Laboratories, Department of Pathology, The Aga Khan University Hospital, Stadium Road, Karachi-5.)

Abstract

Quality control in chemical pathology is based on internal and external quality assessment. The internal quality control in clinical chemistry section of AKUH laboratory is based on the analysis of commercially available Beckman norma! and abnormal range control sera. These have known concentrations of blood chemistry constituents. After repeated estimations, mean values of all constituents were established for both normal and abnormal sera. Patients samples were analysed only when both controls were within ± 2SD from the mean or one control reads within ± 2SD and the other read between ± 2—3SD (once only) for each constituent. Samples were not analysed if one control was greater than ± 3SD from the mean or both controls were greater than ± 2SD or one control was between ± 2—3 SD on two successive runs. External quality control sera with unknown constituent concentrations were analysed twice monthly and results sent to Weilcome England. Our results were compared with the mean of estimations by 1000 laboratories for each constituent. The acceptable standard deviation from this mean for each constituent was ± 2SD. External quality control evaluated our accuracy in wide ranges of constituent concentrations encountered and helped us identify under or over reporting of differenit parameters, both substrates and enzymes, at high or low levels or vice versa which internal quality control could not address. Hence external quality control formed the basis of our corrective actions in terms of equipment and reagents. We conclude that internal quality control is limited in the sense that its efficacy has to be tested by external quality assessment (JPMA 38: 255, 1988).

INTRODUCTION

Quality control in chemical pathology is concerned with every stage of a procedure right from the collection of the specimen from the patient to the receipt of the report by the clinician. It includes patient's identification and registration, transportation and prqcessing of specimen, and method of reporting result. Monitoring of all these is essential in order to recognize and minimize errors. This requires quality assurance which ultimately deals with the reliability of the analytical results. Many studies of precision and accuracy in clinical laboratories[1-5] emphasize the importance of quality assurance scheme. Quality assurance in chemical pathology basically consists of internal quality control and external quality assessment. Two procedures are complementary; internal quality control primarily monitors day to day reproducibility, that is precision, and detects frank errors (ACCURACY) in any one day's procedures, while external quality assessment primarily aims at detecting constant differences ("BIAS") between the laboratory results and those of others and also establishes under or over reporting of parameters.

This paper reports the daily internal quality control of chemistry parameters performed on Beckman Autoanalyzer, using commercially available quality controlled sera and their assessment by external quality control scheme by Weilcome Foundation, England.

MATERIALS AND METHODS

Internal Quality Control:
A strict system of quality control was observed at all levels such as for the collection of the specimen, its processing, instrumentation, and its maintenance and reporting of the results as recommended by the College of American Pathologists (C.A.P.) for Laboratory Accredition Certificate . Internal quality control was initiated in our laboratories using commercially available Beckman Quality Control sera on our autoanalyzer Astra Ideal. Initial calibration and routine maintenance were carried out periodically as recommended by the manufacturers.

Determination of acceptable standard deviations limits:
This was performed by running a control atleast 30 times on different days and times and calculating the mean and standard deviation (SD) by using standard procedure[6,7]. The acceptable limits were calculated by adding and substracting the value of 2SD to the observed mean for each chemistry parameter. All control results are then plotted on Levy—Jennings chart[8].

Criteria for acceptability of Results:
The following are the rules observed at The Aga Khan University Hospital Laboratory for evaluating the control results:
(a) Both control (Normal and Abnormal levels) are within ± 2SD from the mean;
OR
(b) One control reads within ±2SD; the other between 2-3SD (once only).
Control runs are rejected if:
(a) One control is greater than ±3SD from the mean or,
(b) Both controls are greater than ±2SD from the mean, or
(c) One control is between 2—3SD on two successive runs.

External Quality Control:
It is a retrospective analysis of internal quality control results by an external agency whereby samples provided by the agency are analyzed and the results sent back by each participant, which are evaluated by the agency and calculated, showing the participant's performance in comparison with the other laboratories in the worldwide scheme. We participate in Burroughs Welcome Quality Assessment Scheme in which more than 1500 international laboratories take part and the assessment is made for 31 parameters. The results comprise deviation of our estimations from other laboratories for each chemistry and the bias of our laboratory for over or under reporting a particular parameter. The cycle comprises 12 external quality control samples, twice monthly for a period of six months.

RESULTS

The level of our commercial internal controls are given in

TABLE II. External Q.C. Constituent Ranges & Mean of ISD Values for Six Months Cycles.

Constituents								
	HCO_3	K	CHOL	T.BIL	GGT	AST	AP	AMY
Ranges	9 – 17	2.6–6.0	108–285	2.0–5.0	58–161	47–156	50–230	102–259
Mean ± SD	1.2±0.14	0.09±0.01	10.80±4.65	0.17±0.04	7.68±2.95	4.77±2.50	14.1±8.50	19.39±10.55
Units	mmol/l	mmol/l	mg/dl	mg/dl	IU/L	IU/L	IU/L	IU/L

Table I showing some representative routine chemistry parameters HCO3, K+, Cholesterol, T. Bilirubin GGT, AST, AP and Amylase. Mean values of constituents derived in our laboratory and the acceptable

standard deviation are also given. If any of the results, after calibration, is more than 2SD, the instrument is recalibrated before samples are run. External quality control results are given in Table II.

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It gives the range of constituent concentration encountered in the six month cycle -and mean of acceptable ISD for each parameter for twelve samples.

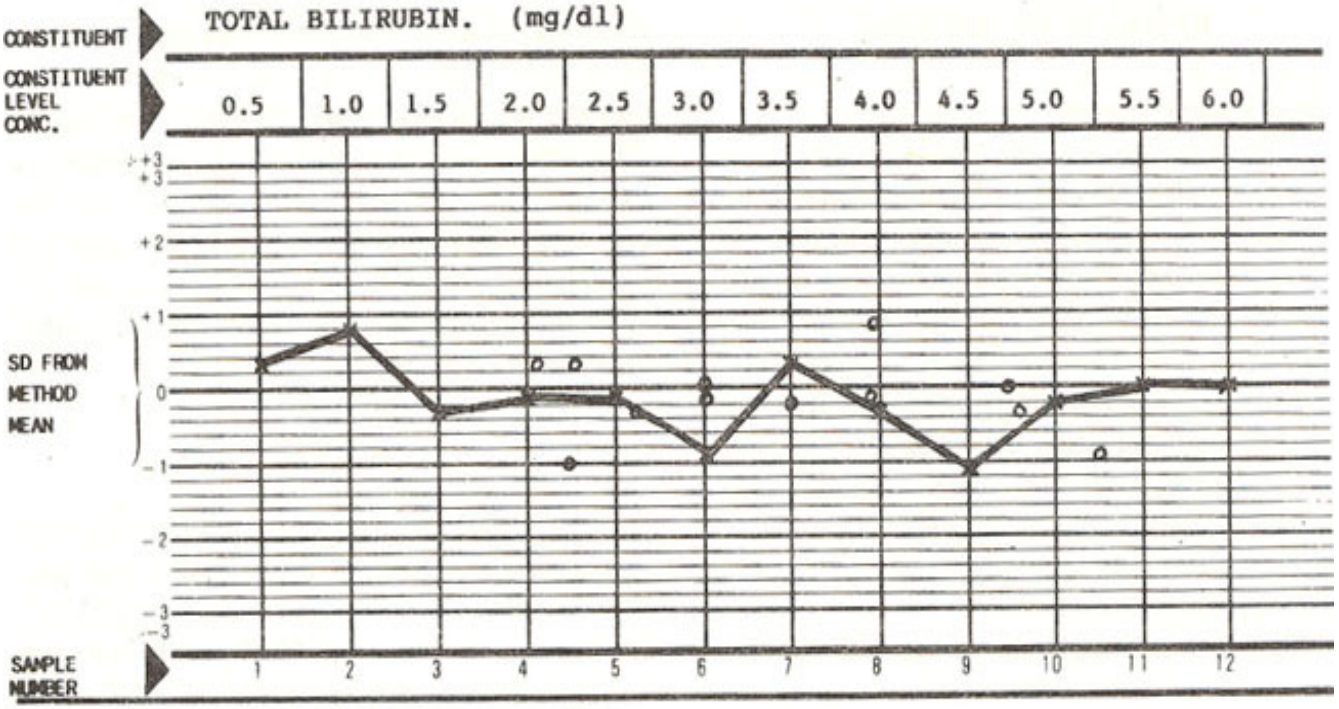

Figure 1. Serum Bilirubin – No bias for over reporting.

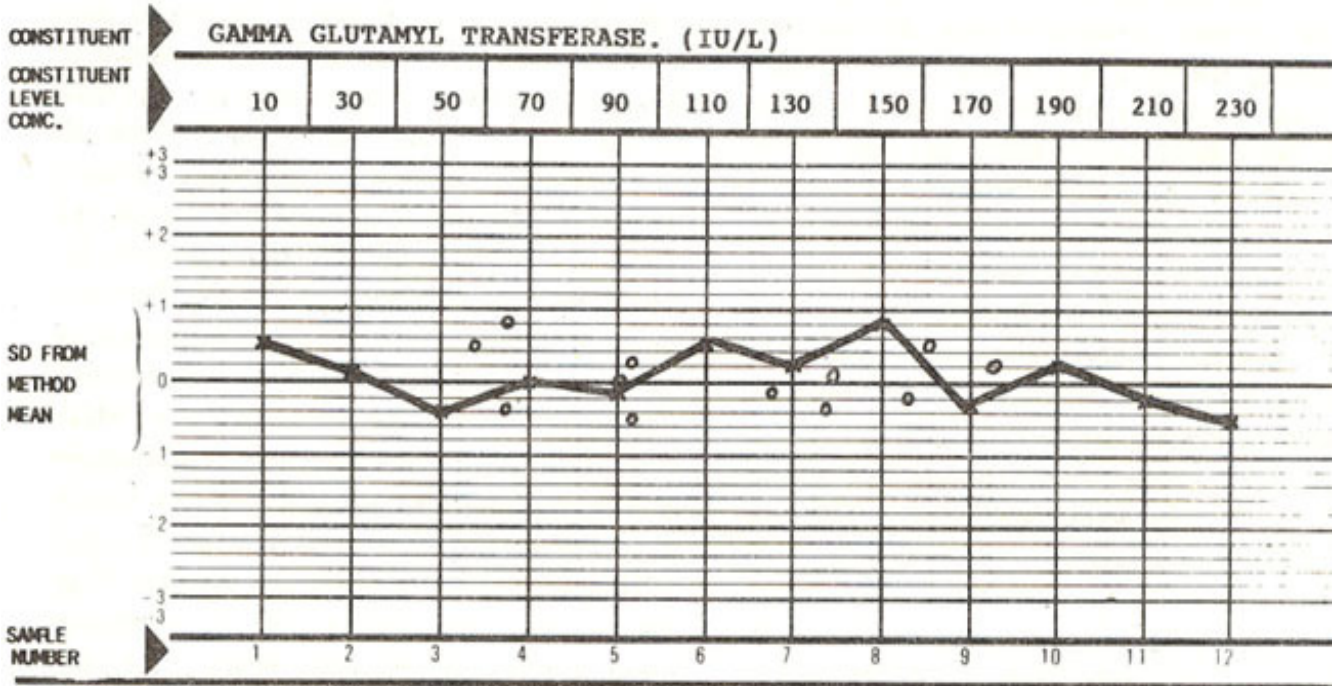

Figure 2. Gamma Glutamyl Transferase – No bias for over reporting.

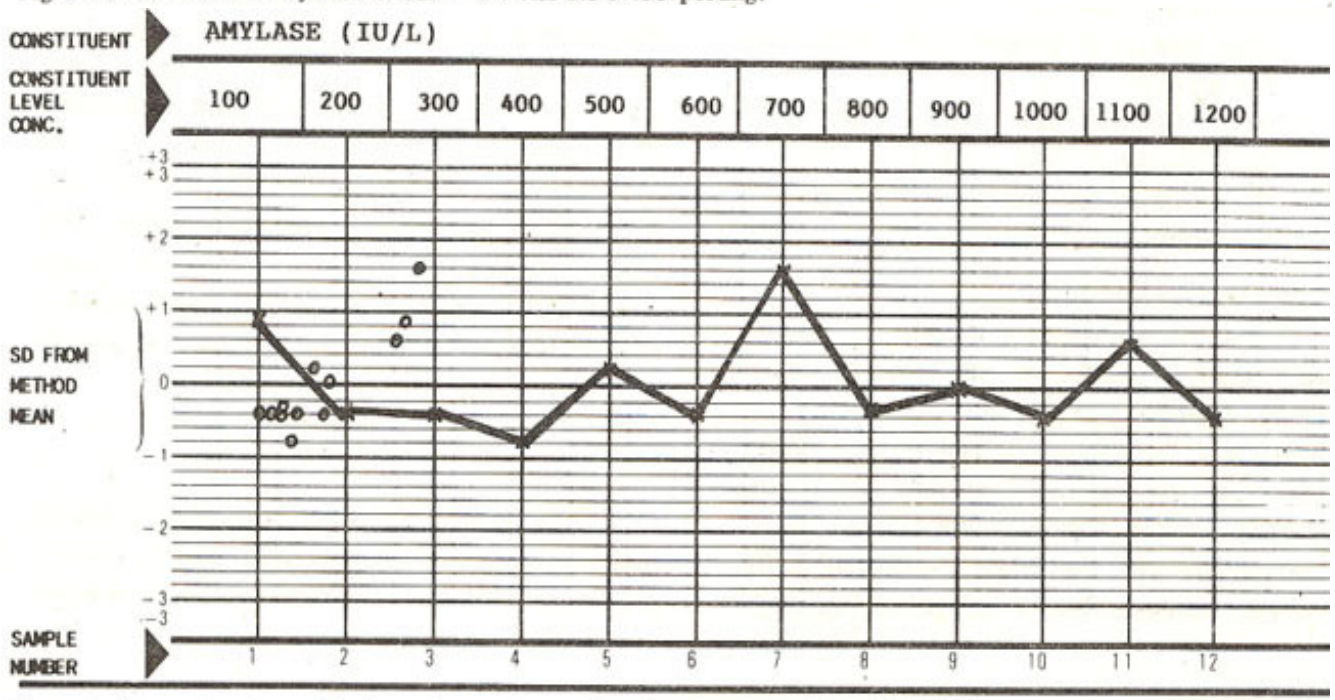

Figure 3. Serum Amylase – Tendency for over reporting above concentration of 250 IU/L.

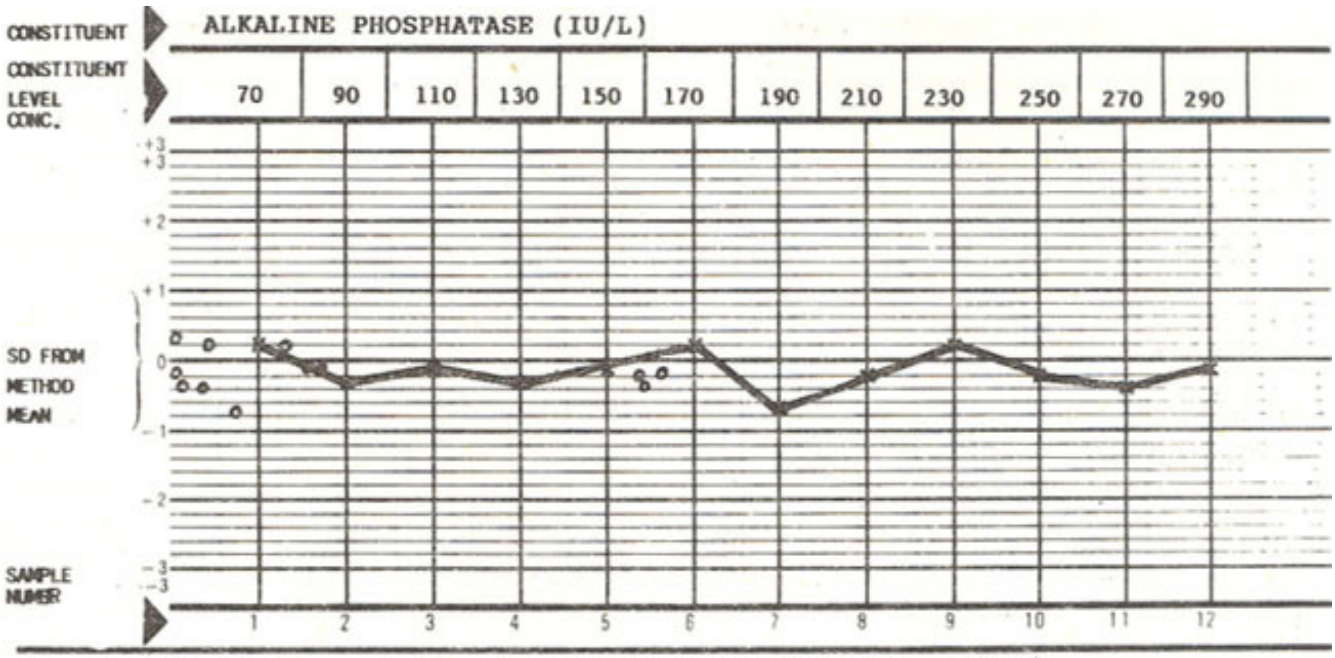

Figure 4. Alkaline Phosphatase – Tendency for low reporting in activity range at 150 – 170 IU/L.

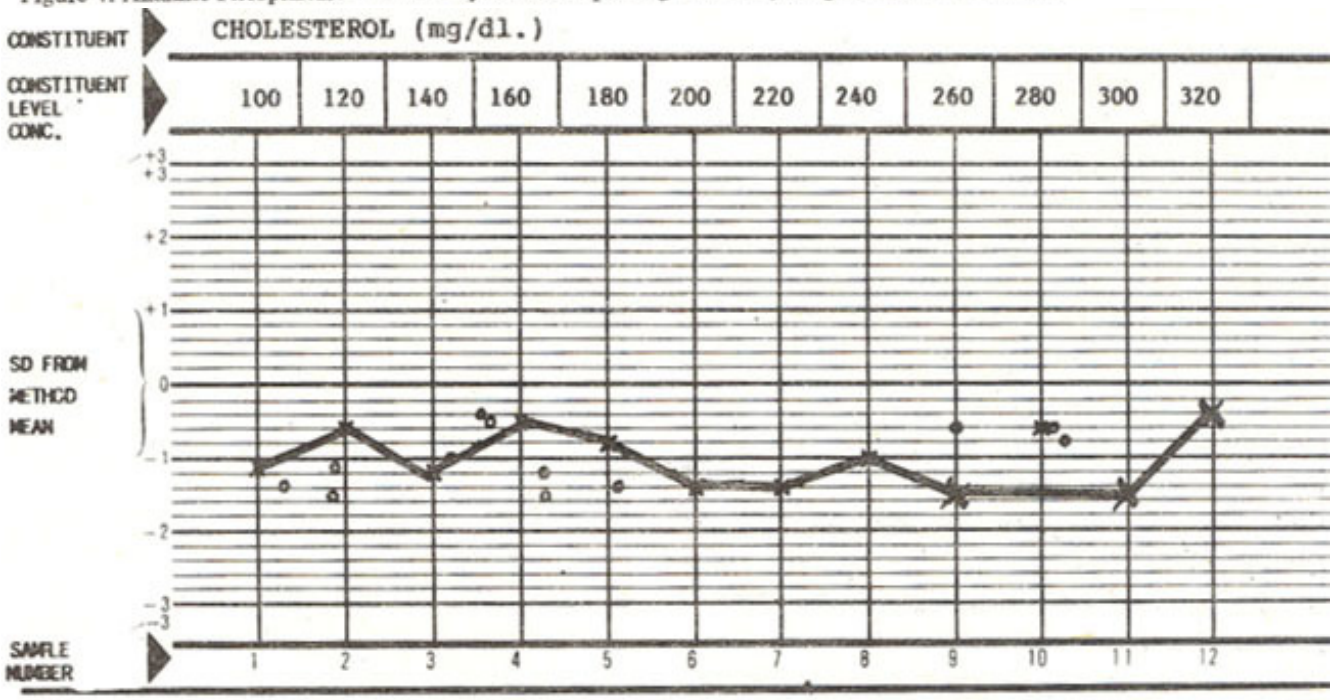

Figure 5. Serum cholesterol – Reported results are on the low side.

In Figures I to 5 (x—x) Plot gives deviation of our results for representative chemistries from the population mean in external quality control and also the Bias plots (0' Points) which thow under or over reporting of their chemistries at different constituent levels (Top of each figure).

Figures 1, 2, 3, 4, show that all 12 results of Bilirubin, GGT, Ainylase and Alkaline Phosphatase were well within 2SD of population mean. Figure I for Bilirubin, Figure 2 for GGT ws that there is no bias for over reporting in these chemistries. Figure 3 for Amylase shows that there is a tendency for over reporting above the concentration of 250 lU/L, though all our results were well within 2SD. Figure 4, Alkaline Phosphatase shows that there is a tendency for low reporting in the activity range of 150-170 IU/L. Here also, results were well within 2SD. figure 5 shows the results of cholesterol though within 2SD from the population mean, however all results were on the low side, (no '0' points on the +ve

side).

TABLE –I. Commercial Controls Ranges, Mean and Mean SD of Constituents.

Controls	HCO_3 (mmol/l)	K (mmol/l)	CHOL (mg/dL)	T.BIL (mg/dL)	GGT (IU/L)	AST (IU/L)	AP (IU/L)	AMY (IU/L)
B.M.L. (I)								
Range	9 – 15	2.4 – 2.8	98 – 128	0.7 – 1.5	14 – 30	21 – 35	37 – 53	119 – 159
Int. Mean	12.0	2.5	112	1.1	21	28	45	131
Int. Mean SD	0.43±0.05	0.09±0.02	2.33±0.47	0.10±0.02	0.95±0.15	1.50±0.50	1.00±0.10	4.87±0.19
B.M.L. (II)								
Range	16 – 22	3.7 – 4.3	108 – 148	1.9 – 3.1	44 – 62	46 – 61	66 – 96	224 – 248
Int. Mean	18.5	4.0	128	2.4	53	58	82	252
Int. Mean SD	0.37±0.09	0.10±0.03	2.90±0.64	0.10±0.05	1.20	2.00±0.70	2.00±0.50	5.80±0.28
B.M.L. (III)								
Range	22 – 32	5.2 – 5.8	140 – 180	3.6 – 5.2	97 – 127	92 – 116	136 – 196	249 – 329
Int. Mean	25.1	5.6	156	4.3	111	103	165	278
Int. Mean SD	0.53±0.03	0.10±0.08	2.67±0.30	0.13±0.08	2.00±0.19	2.10±0.78	3.80±1.28	5.60±0.20

* BML = = Beckman Level
Range = = Range assigned by Manufacturer
Int. Mean = = Mean derived in our Laboratory.
Int. Mean SD = = Mean of ISD derived in our Laboratory.

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