# QUALITY ASSESSMENT OF THE REFLOTRON SYSTEM A BLOOD CHEMISTRY REAGENT STRIP ANALYSER

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**Abstract**

We tested the accuracy of the Reflotron System by comparing results given by this system for estimations of glucose, SGOT, SGPT, cholesterol and triglycerides on patients samples which were already analysed on either an autoanalyser HITACHI 705 or manually on CLIN ICON 4010. Reflotron estimations correlated well with both Hitachi and Clinicon estimations and the strips gave reproducible results. We for small laboratories in our expanding rural health conclude that this or similar systems will be ideal services (JPMA 38: 205, 1988).

## INTRODUCTION

The Reflotron System is designed for the quantitative determination of clinical chemistry parameters on whole blood, serum or plasma. This system consists of a Reflotron: a compact portable reflectance photometer for fully automatic evaluation of Reflotron Tests. Within the Reflotron a micro-processor system controls all functions such as temperature regulation, automatic calibration, specific test procedure, evaluation and calculation of results. Reflotron Strips are strip reagent carriers designed for specific determination of important clinical chemistry parameters directly on undiluted whole blood samples. This is possible due to the incorporation of a plasma separating system on the Reflotron Strips. However serum and plasma samples can also be used.

The success of reagent strips for monitoring of clinical chemistry parameters in blood and urine[1-2] and the easy workability and accuracy of reflectance photometers for their evaluation[3-4] have extended the use of this so called " dry chemistry" reagent system to analyse a number of parameters in blood. Since these reagent carriers have a long shelf life[5] and the photometers are small portable equipments, both mains and battery operated, this makes them ideally suited for small volume laboratories, health care centres, physician clinics etc. Their use will be of special value in Pakistani set-up at village and tehsil levels where infrastructure for full-scale laboratories is neither available nor financially possible. This paper presents the quality assessment of one of such systems available in Pakistan, the Reflotron System. The levels of cholesterol, triglycerides, glucose, SGOT and SGPT were evaluated on the Reflotron System on patients samples after they had been assessed on either a autoanalyser (Hitachi 705) or manually on (Clinicon 4010). The accuracy and reproducibility of this system is presented, as compared to standard laboratory methods, the object being the possible use of such systems in our rural health care centres.

## MATERIALS AND METHODS

Routine patients serum samples analysed on autoanalysers Hitachi 705 and Clinicon 4010 were also tested on the Reflotron system for comparative analysis. The number of serum samples analysed both on Hitachi and Reflotron were glucose 37, SGOT 43 and SGPT 47. The number of serum samples

analysed both on Clinicon and Reflotron were Cholesterol 43 and Triglycerides 44. In 16 patients for SGPT and 15 for cholesterol both EDTA anticoagulated whole blood and serum samples were analysed on Re. flotron and results compared. Reproducibility of the Reflotron System was checked by 10 consecutive analyses of SGPT on serum and of glucose on EDTA whole blood on one sample. The methodologies used for analysis on Hitachi 705 were: glucose- GOD-PAP using 4-amino-phenazone as substrate, SGOT- according to IFCC using Alpha Oxoglutarate and aspartate as substrates coupled with malate and lactate dehydrogenase, SGPT-according to IFCC using alpha-oxoglutarate and alanine as substrates coupled with lactate dehydxogenase. The methodologies used for analysis on Clinicon 4010 were, Cholesterol-CHOD-PAP using cholesterol esterase coupled with cholesterol oxidase and peroxidase with 4.aminoantipyrine as colour reagent. Triglycerides were estimated by GPO-PAP using lipases for hydrolysis coupled with glycerol kinase, glycerol -3-phosphate oxidase and peroxidase and 4-aminoantipyrine as colour reagent. Reagent systems for Hitachi in kit form were supplied by (Boehringer) and for Clinicon 4010 by (Human).
Methodologies of the Reflotron strips were glucose GOD-PAP using 3.3,5.5 -tetramethy benzidine (TMB) as indicator, cholesterol: CHOD. PAP using (TMB) as indicator, triglycerides: GPO-PAP plus indicator, SGPT: aipha-ketoglutarate and alanine as substrates coupled with pyru. vate oxidase and peroxidase via an indicator. SGOT: using alphaketoglutarate and alanine sulphinate as substrates coupled with pyruvate oxidase and peroxidase via an indicator. The indicator in many of the methods are not specified (trade secret). These strips were supplied by Boehringer. The quality of tests done on Hitachi and Clinicon were controlled by commercial sera with known levels of constituents in the abnormal (PRECIPATH) and normal (PRECINORM) ranges from Boehringer. The accuracy of the Reflotron was checked by the same control sera. Estimations on the Reflotron System were compared with results obtained from Hitachi 705 for SGOT/ SGPT and glucose and with Clinicon 4010 for cholesterol and triglycerides. Correlation coefficient and regression equations were calculated for each of these comparisons. Similarly correlation coefficient and regression equation was calculated for Reflotron estimation of SGPT and glucose on EDTA whole blood vs serum. Reproducibility of the Reflotron was calculated via mean ±SD.

**RESULTS**

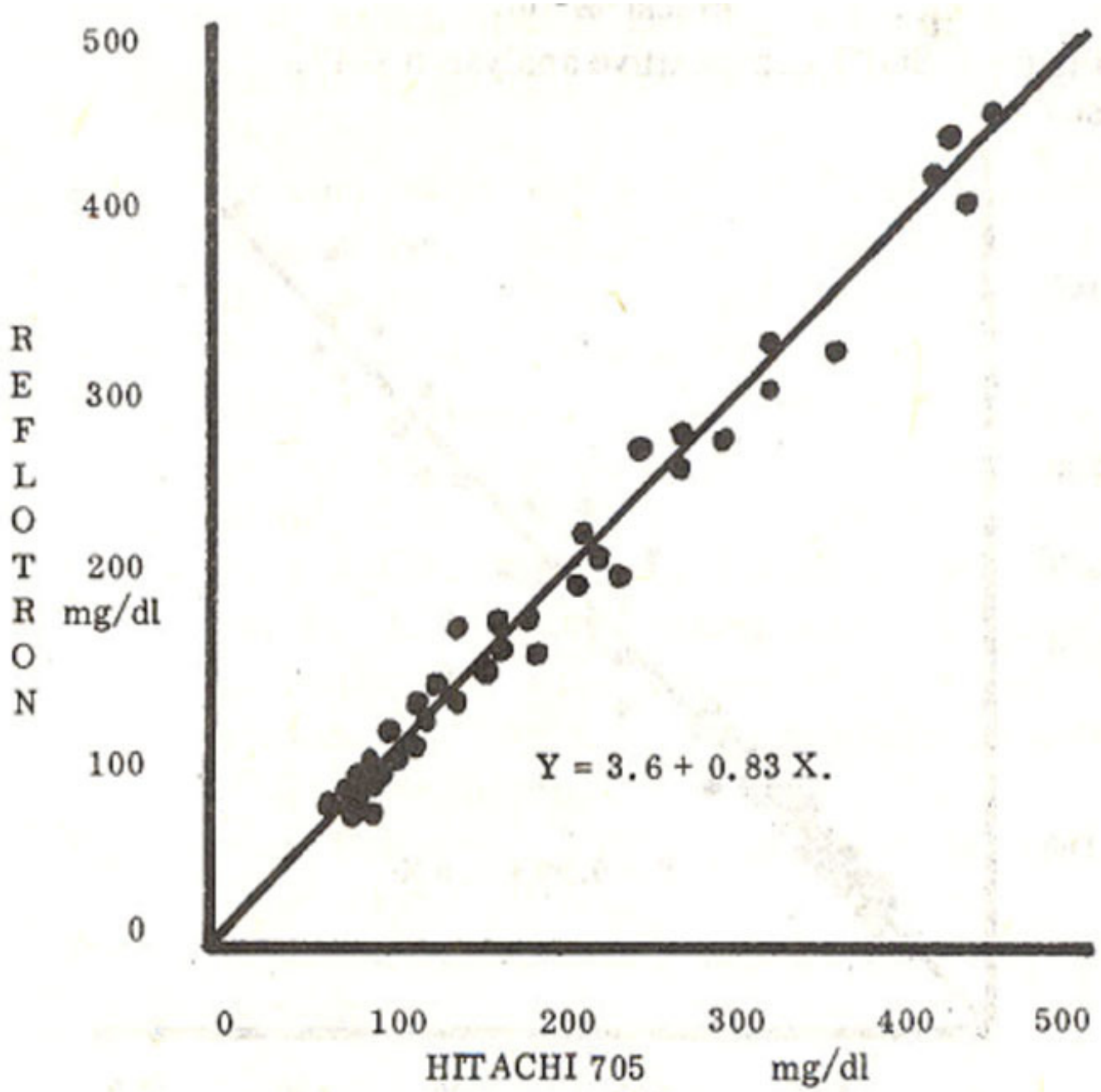


Figure 1. Glucose comparative analysis n=37.

Figure I shows the comparison of results of glucose estimation on Reflotron with Hitachi 705. The correlation coefficient was r=0.94 with regression of y=3.6 + 0.83x. Reflotron estimation show good comparison in the glucose range 100-500 mg/dl.

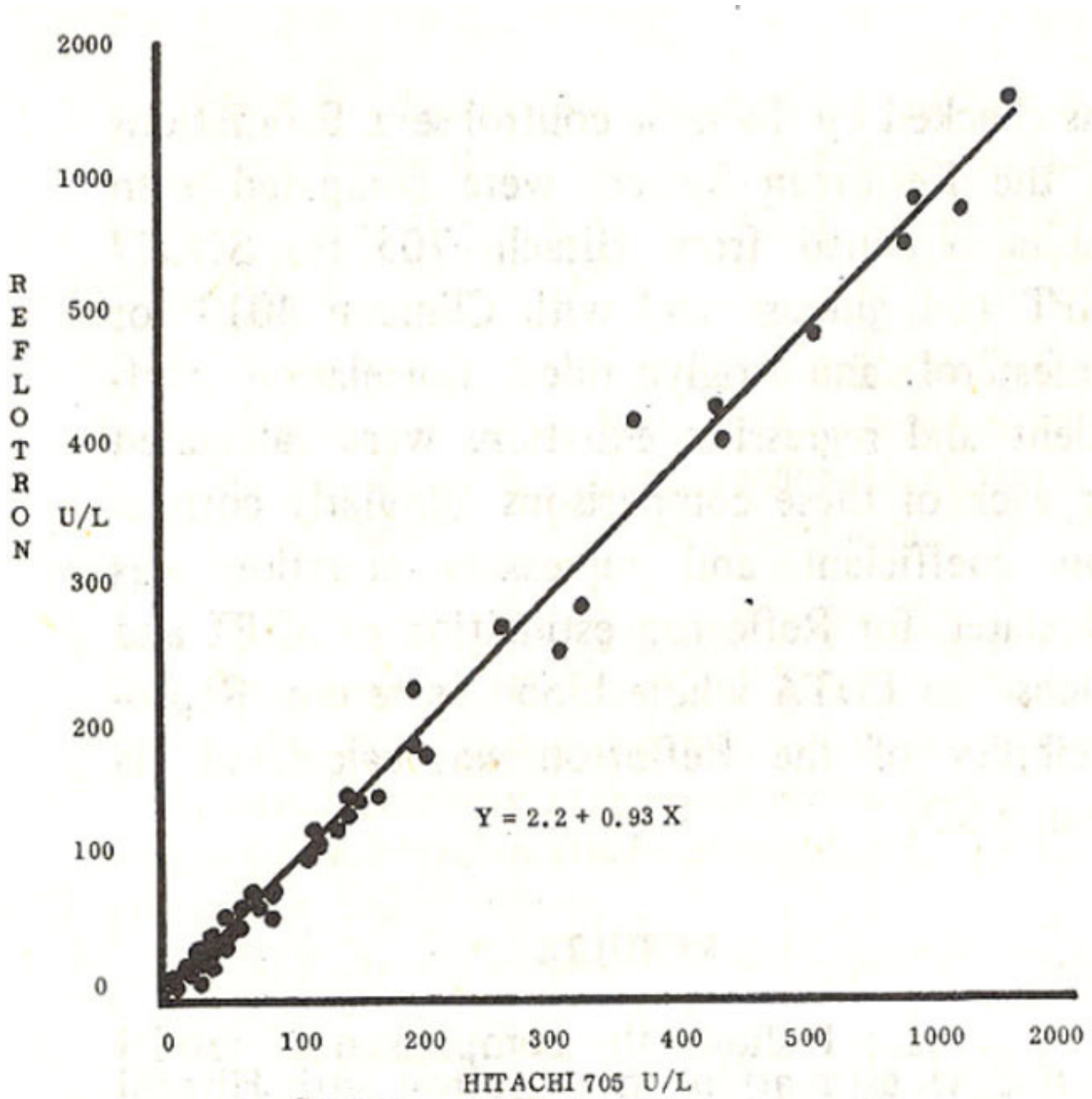


Figure 2. SGOT comparative analysis n = 43.

Figure 2 shows the comparison of SGOT estimation on Reflotron with Hitachi 705. Correlation coefficient of r=0.99 and regression of y=2.2 +0.93x in the range 10—1600 U/L. These results show excellent comparison.

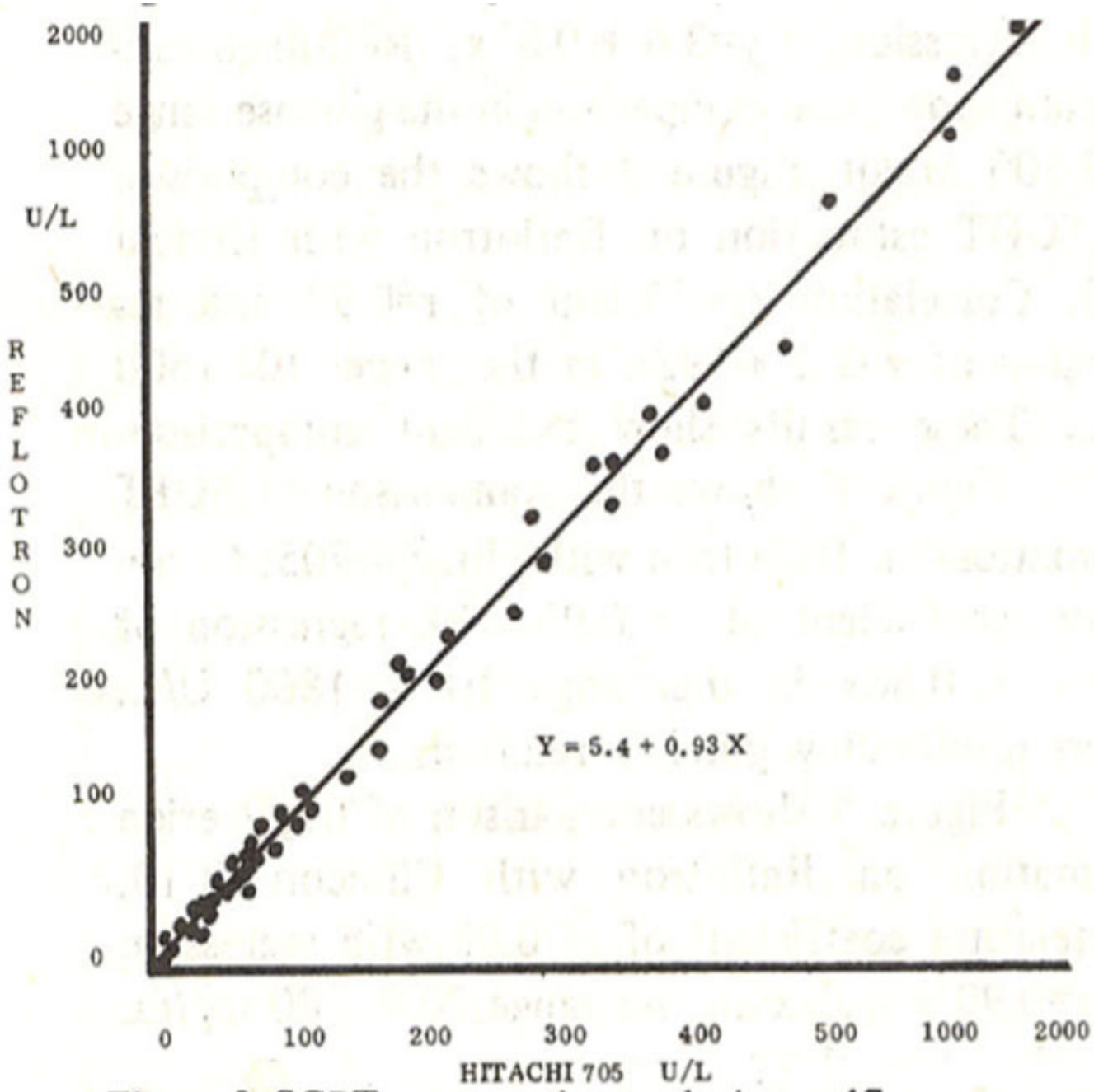


Figure 3. SGPT comparative analysis n = 47.

Figure 3 shows the comparison of SGPT estimation on Reflotron with Hitachi 705. Correlation coefficient of r= 0.99 with regression of y=5.4 + 0.86x in the range 10 - 1800 U/L. These results show good correlation.

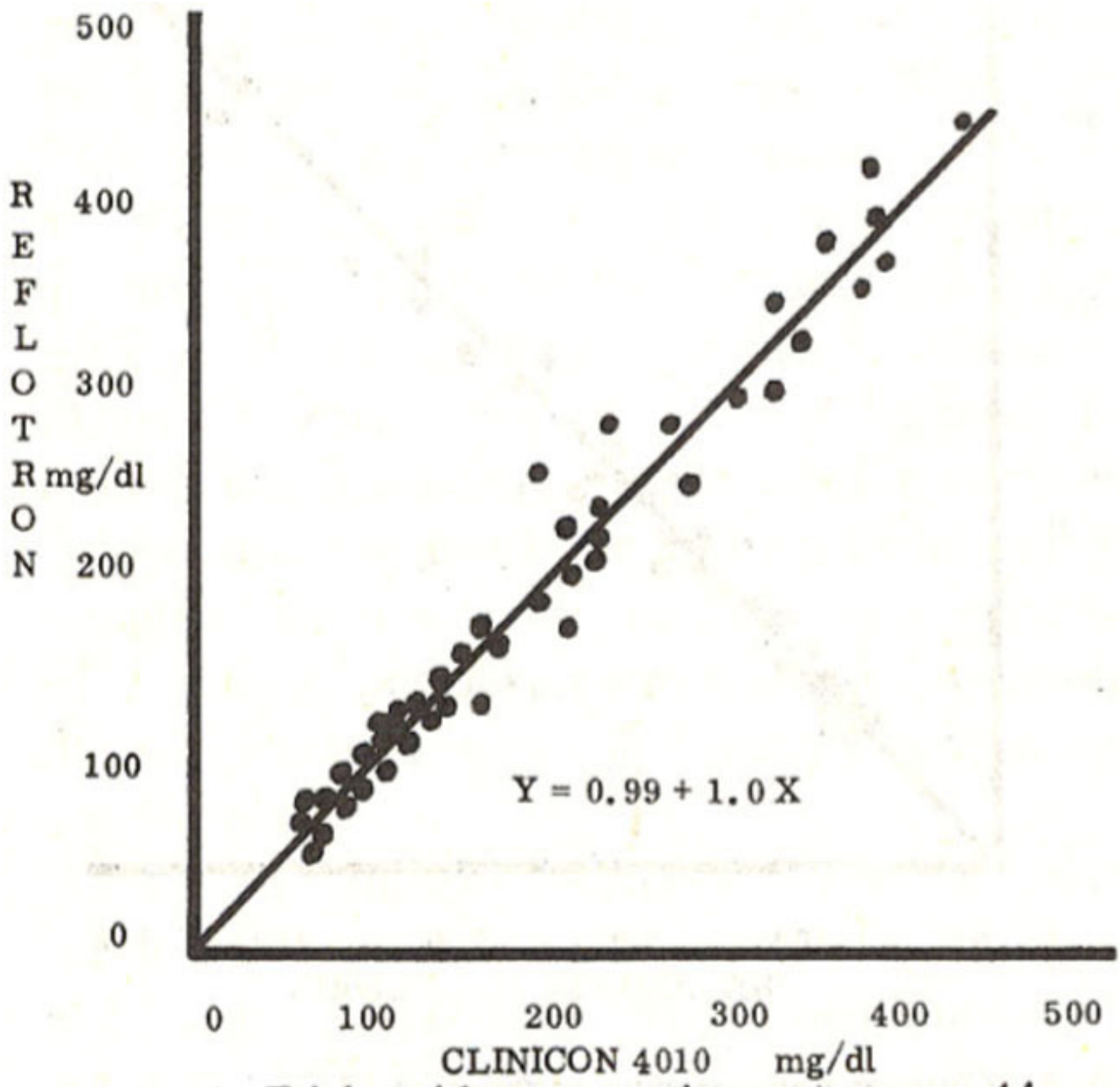


Figure 4. Triglyceride comparative analysis n = 44.

Figure 4 shows comparison of triglyceride estimation on Reflotron with Clinicon 4010. Correlation coefficient of r= 0.98 with regression of yO.99 + 1.0 x in the range 70 - 500 mg/dl. This shows excellent comparison.

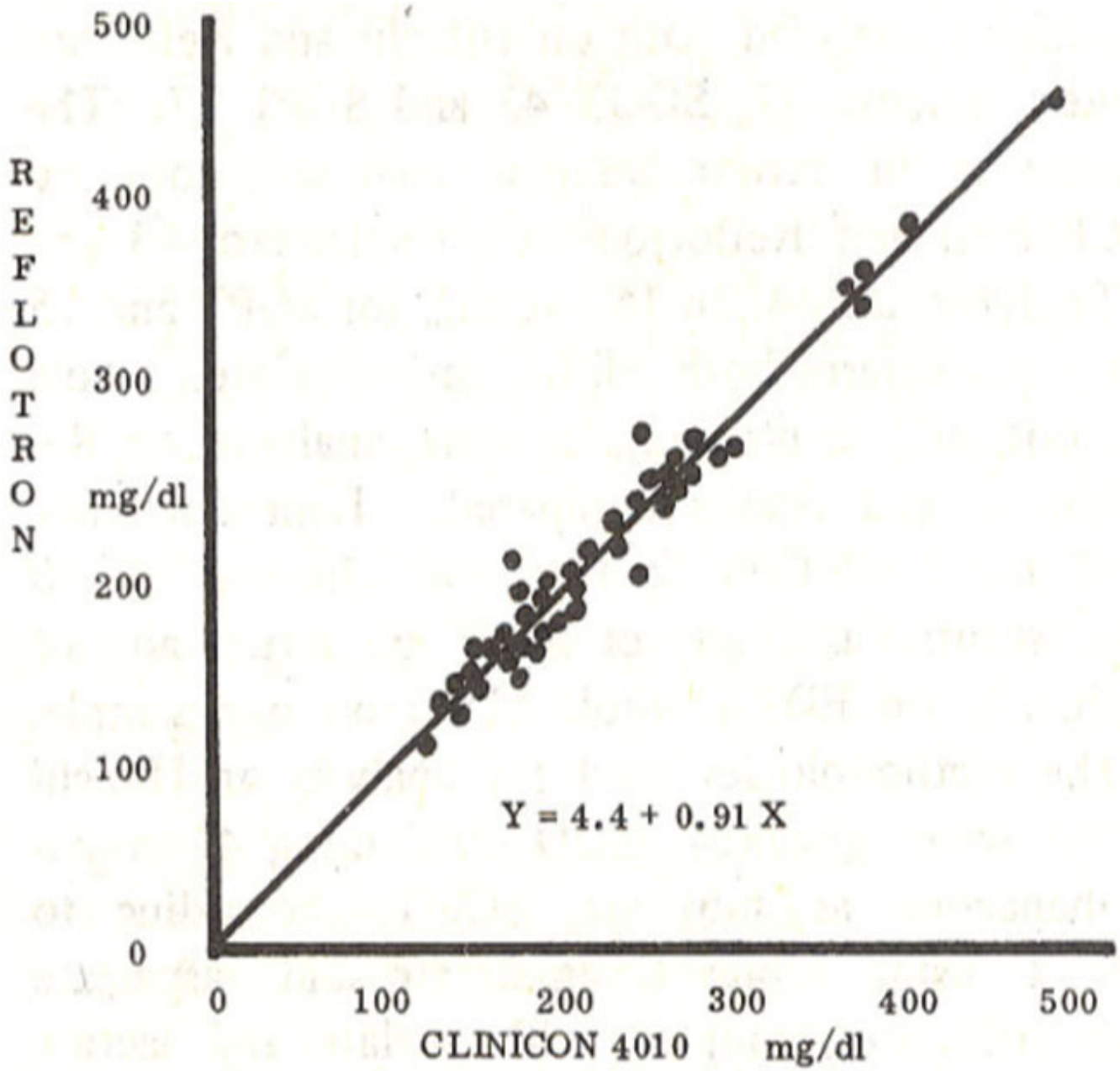


Figure 5. Cholesterol comparative analysis n = 43.

Figure 5 shows comparison of cholesterol estimation on Reflotron with Clinicon 4010. Correlation coefficient of r=0.93 with regression of y=4.4 + 0.91 x in the range 120 - 500 mg/dl. This shows good comparison.

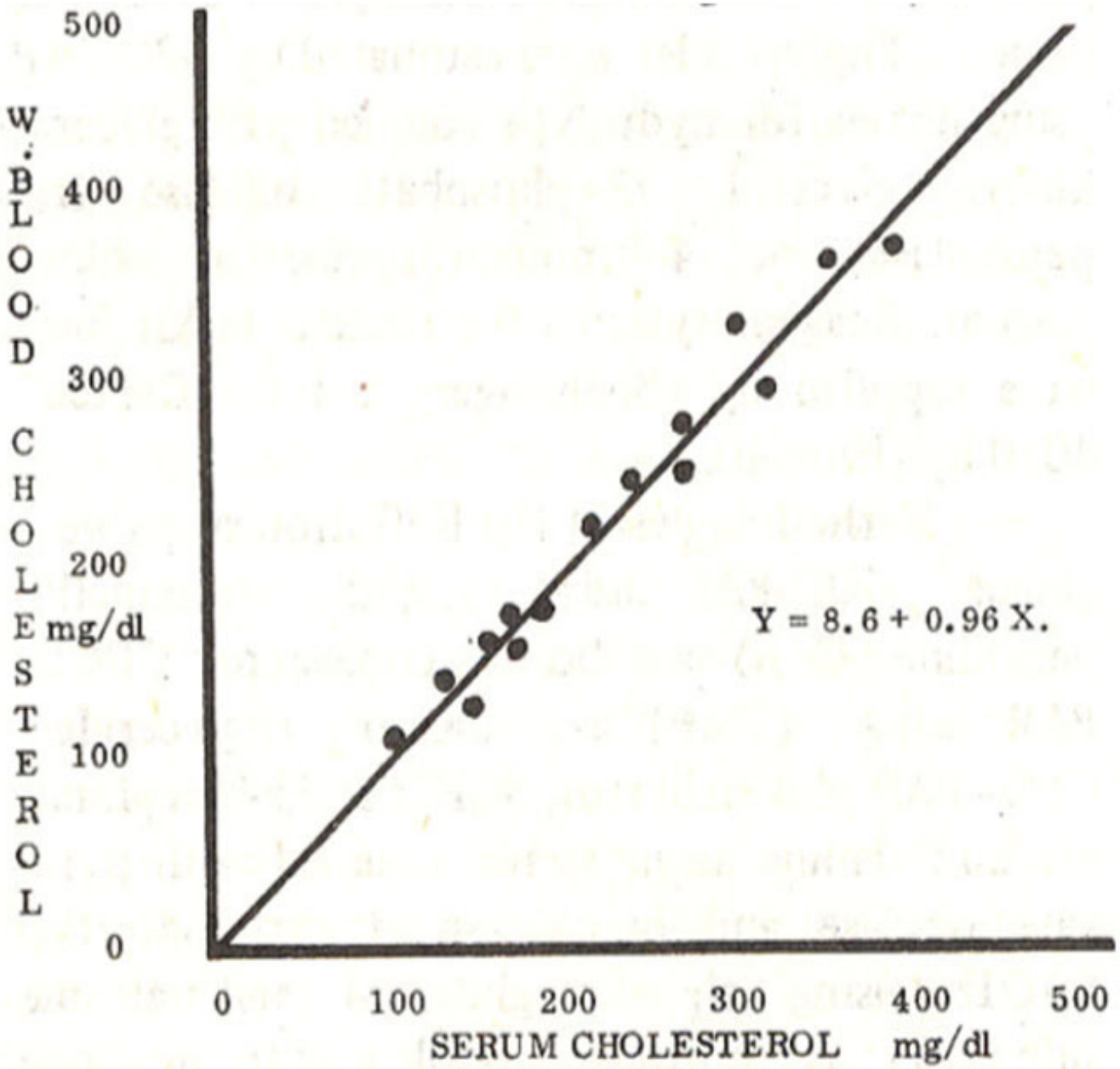


Figure 6. Triglyceride comparative analysis n = 44.

Figure 6 shows comparison of Reflotron cholesterol estimation c whole blood vs that on serum of the same samp1. Correlation coefficient of r = 0.98 with regression of y8 .6 + 0.96 x. Both estimations show good comn

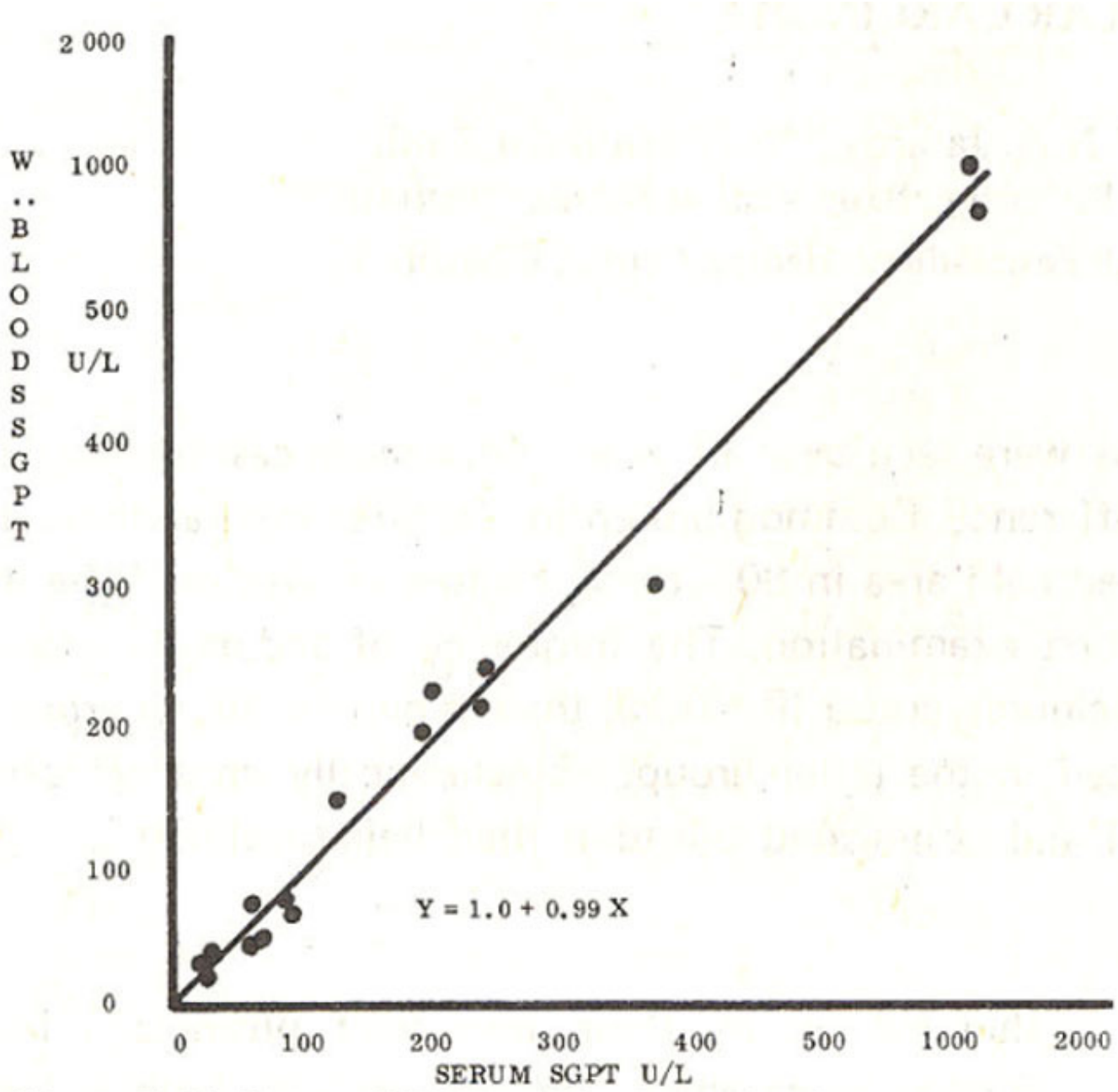


Figure 7. Reflotron SGPT n=16 whole blood vs serum.

Figure 7 shows Reflotron results of SGPT estimation on EDTA whole blood vs that on serum of the same sample. Correlation coefficient of r = 0.99 with regression of y = 1.0 + 0.99 x. Both estimations show excellent comparison.

Reproducibility of the Reflotron system was checked by 10 consecutive estimations of glucose en EDTA whole blood and SGPT on serum of one patient as shown in Table.

TABLE

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | MEAN ± SD | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SGPT in serum | 90 | 89 | 91.4 | 87 | 90 | 89 | 96 | 88 | 90 | 87 | 89.7 ± 2.5 | U/L |
| Glucose in W. Blood | 136 | 130 | 136 | 140 | 142 | 139 | 141 | 138 | 134 | 140 | 137.6 ± 3.6 | mg/dl |

Glucose shows repeatability of 3.6 mg/dl at 137 mg/dl level while SGPT shows repeatability of 2.5 U/L

at 89 U/L levels.

## DISCUSSION

The Reflotron System is based on “dry chemistry” i.e., no liquid reagents are involved in its operation. It is a modern automated analysis system that takes over both manual procedures and the calculations from the operator. In fact only sampling remains, while the machine does the rest, ending in a display of the result. We conducted this trial for checking the accuracy of this system as compared to standard autoanalyser and manual methods. The Reflotron System gives comparable results to these standard lab methods in the few chemistries tested both on whole blood and serum. Our aim of testing this system was to check its application in small rural laboratories. Its advantages are many: it can do one-off analysis and short series directly on whole blood; it can be operated by people who are not trained analysts or laboratory technicians and it gives results in 2-3 minutes.

Our experience with similar system ror glucose estimation has been very encouraging[6] and the present paper highlights the importance of reagent strips and their portable analysers. The Reflotron System[7] is capable of estimating most routine chemistries while other systems have increased the scope of such systems even further by incorporating therapeutic drugs on reagent strips[8]. We conclude that the Reflotron System gives comparable results to standard lab methods and thus this system is ideal for small laboratories wanting to do large numbers and types of tests but with small workloads. This system is presently ideal for our rural health centres.

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