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Evaluation of Reflotron—A System Near the Patient Working on Whole Blood

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One of the drawbacks with the earlier analytical systems near the patient is that serum samples are used. This means that the 'analytical station' - the laboratory has to be equipped with a centrifuge and often that a certain time has been lost for the coagulation to take place and the centrifugation to be performed. In order to make a real near-the-patient analysis whole blood should be used. It was therefore with great interest that we accepted to take part in the evaluation of such a system.

In the Reflotron system (Boehringer Mannheim, W-Germany) the reagent carrier (the 'test strip') contains a separation area as well as a reagent area. This means that separation of blood cells from plasma as well as analysis of the component takes place almost simultaneously and that various components can be analysed in whole blood within a few minutes' time. We have had Reflotron systems in our laboratory for two periods:

1. As a part of the external evaluation conducted by Boehringer Mannheim (1). Then we used an apparatus from the zero series, which later has been modified. We only investigated two methods: γ-Glutamyltransferase (GT) and urea and followed the test protocol suggested by the company. The work was performed by one technician.
2. Later we have investigated one instrument from the production series. Due to shortage of reagent carriers, we were not - as intended - able to investigate the system according to the evaluation protocol of the working group (See this issue!). Five technicians investigated five methods: cholesterol, glucose, GT, hemoglobin and triglycerides.

Sample handling: According to the manufacturer 32 ul of blood, serum or plasma should be pipetted on the separator

part of the reagent carrier. Various volumes of blood (20-45 ul) have been pipetted and as shown in Fig 1 the volume factor is especially critical for glucose.

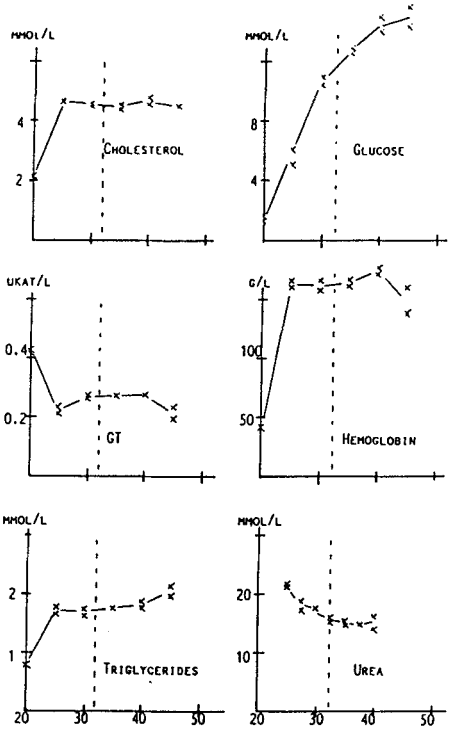

Fig. 1. Various volumes of one blood sample have been applied to the reagent carriers. The line of short dashes marks the recommended volume.

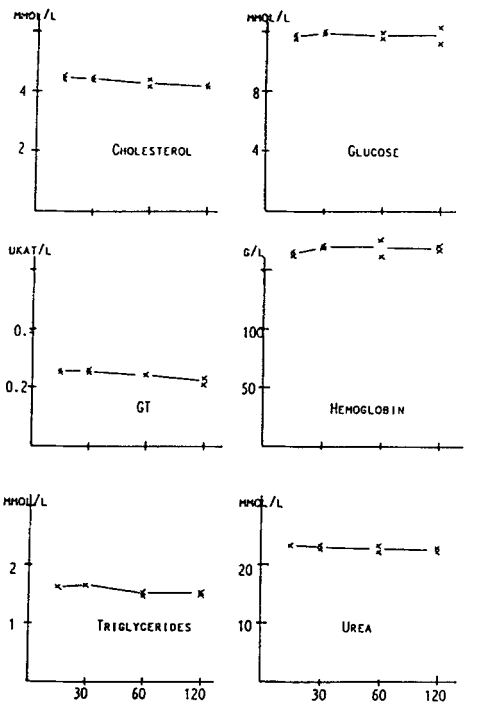

Fig. 2. Effect of varying time (s) between application of the sample and introducing the reagent carrier into the Reflotron.

The time. The reagent carrier should be introduced into the Reflotron within 15 s after the pipetting of blood. This time factor has been varied from 15 s to 120 s. As can be seen from Fig. 2 this factor is not critical.

Sample factors. Theoretically viscosity factors is of importance. With increasing viscosity the separation process is slowed down. We investigated the possibility in two ways:

1. The effect of varying hematocrit values. One blood sample was distributed into 20 different test tubes. After centrifu-

gation different plasma volumes were pipetted off after which the erythrocytes were suspended. For urea we could see no changes in concentration up to a hematocrit of about 55%.
2. The second way was to investigate blood samples from two cases of polycytemia and two caes of Waldenströms macroglobulinemia. In neither of these samples viscosity depending changes could be found for urea and GT.
Hemolysis. Extracts from human frozen erythrocytes were added to obtain hemoglobin concentrations in plasma of 0.3 - 11 g/l. No changes of the level of GT and urea were seen.
Function of the separator. We performed double analysis in the way that we first analysed whole blood and after centrifugation repeated the analysis on the EDTA-plasma. As can be seen in Fig. 3 the separator part of the regent carrier has worked properly in analysis for GT.

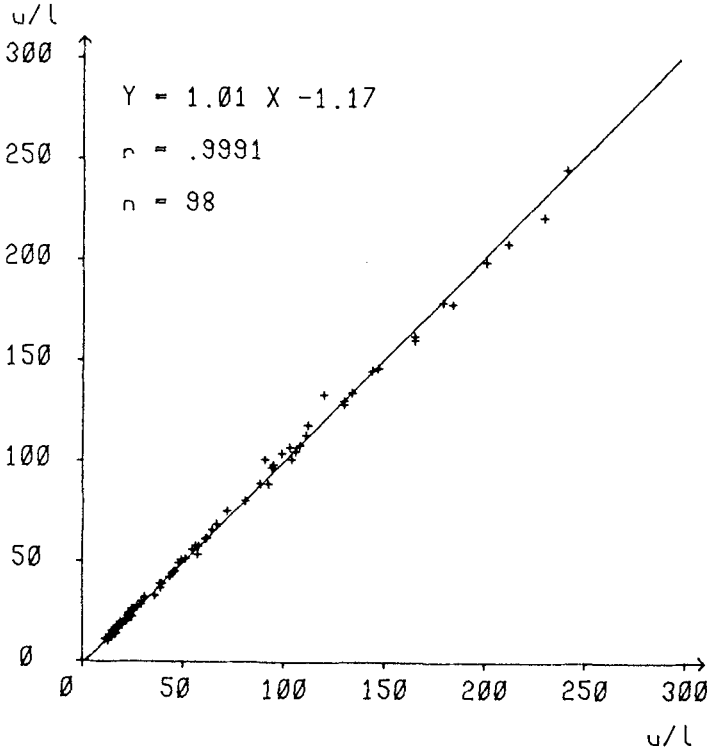

Fig. 3. Function of the separator. Blood samples (y-axis) from 98 patients were analysed for GT. After centrifugation the analyses were repeated on plasma (x-axis).

Precision of the system. For urea and GT each 400 analyses were performed using four different samples run during 10 days. The total imprecision was calculated for urea to be 2.0 - 4.6 CV% in the Reflotron system and 1.4 - 3.6 CV% in the reference method. For GT the corresponding figures were 2.6 - 4.5 CV% in the Reflotron system and 1.0 - 3.3 CV% in the reference method. The total imprecision is thus almost of the same size in the Reflotron system as in the reference methods used.

Comparison. We compared the six Reflotron methods with methods at our laboratory: Cholestrol and triglycerides, both enzymatically on Greiner G-300, Glucose with a glucose oxidase method and Hemoglobin with a cyanmethemoglobin method both on LKB 7400, GT with a Glutamyl-3-Carboxylate-4-Nitroanilide method and Urea with a urease-glutamatedehydrogenase method both on a Multistat. We regularly got a reasonable agreement. In the urea method, however, 5 out of 100 samples showed values exceeding 30% of that found for the reference method. These drop-out values were found only using whole blood. We have therefore referred them to the separation part of the reagent carrier.

Conclusion: Reflotron is a system working on whole blood samples which is advantageous in the near-the-patient situation. Of the six methods tested all but one showed a good correlation with comparing methods. One method, urea, showed an unacceptable high amount of drop-out values which was referred to the separator part of the reagent carrier. The precision when analysing control sera is almost as good as that of the comparing methods. The volume to be pipetted on the reagent carrier is not very critical except in the glucose method. The time taken to introduce the carrier into the instrument is not critical. The system is completely locked; there is no way for the user to standardize it. In practice each analysis takes about 5 minutes giving the system a practical through put of 10-15 analyses per hour.

References:

1. Price, C.P. and Koller, P.U.: The evaluation of the new Reflotron-system. Results of a multicentre study. To be published.