

## Summary of an evaluation under the direction of SKUP Report SKUP/2004/38\*

The GlucoSure Plus measuring system (GlucoSure Plus) is intended for glucose measurements, both self-testing by diabetics and for use by health care personnel. GlucoSure Plus is manufactured by Apex Biotechnology Corporation, Taiwan. The general agent for Scandinavia is HaeMedic AB in Sweden.

The system is based on biosensor technology. To make a measurement, a GlucoSure Plus test strip is inserted into the GlucoSure Plus meter. The sample is drawn directly from a drop of blood on the patient's fingertip into test chamber on the test strip. The sample volume is 3  $\mu$ L. The meter displays the Plasma—Glucose result 10 seconds after a sample has been applied. The measuring range is 1.7 — 30.6 mmol/L.

This evaluation is not a complete SKUP evaluation. Trained biomedical scientists carried out all the measurements on samples from adult diabetes patients. An evaluation how GlucoSure Plus performs in the hands of diabetics has not been performed.

The routine method for P—Glucose in the laboratory for clinical chemistry at the county hospital Norra Älvsborgs Lasarett (NÄL), Trollhättan, Sweden, was the designated comparison method in this evaluation. This is an accredited hexokinase method for glucose in plasma set up on a Roche Hitachi 917 instrument with reagents and calibrators from Roche.

### Results

The imprecision was calculated from duplicate capillary samples from 102 adult diabetics. The coefficient of variation (CV) was low, less than 4 % within the range 4.3 — 29.3 mmol/L. Between-day imprecision was calculated from measurements of the manufacturer's water based control solutions. We found CV values between 4 and 11 %. Probably, these results do not reflect the real between-day imprecision, but rather indicate an unsuitability of the control solutions.

In the interval 4.6 — 12.0 mmol/L, the bias of GlucoSure Plus is negative, but small and of no clinical significance. In the interval above 12.0 mmol/L, the bias is positive (+0.89 mmol/L) but still acceptable.

According to the American Diabetes Association (ADA) the total error for measurements with new instruments for self-testing of diabetics should not exceed  $\pm 10$  %. GlucoSure Plus does not fulfil this goal as only 81 of 103 or 79 % of the results were within the limits. The ADA goal can be seen as an optimal goal. ISO 15197:2003 "In vitro diagnostic test systems -- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus" gives the following minimum requirements: *95 % of the measurements must deviate less than  $\pm 20$  % at level  $\geq 4.2$  mmol/L and less than  $\pm 0.83$  mmol/L at level  $< 4.2$  mmol/L when compared with a reference method.* As 102 out of 103 or 99 % of the results are within these ISO tolerance limits, it is clear that GlucoSure Plus fulfils this quality requirement.

The opinions about the user-friendliness of GlucoSure Plus among the evaluating personnel is summarised by saying that the system is easy and rapid to use.

### Conclusion

GlucoSure Plus can measure plasma glucose with low imprecision. The bias is negligible except for concentrations above 12 mmol/L, where a positive but acceptable bias was noted. The total errors are within the ISO requirements. The system is easy and rapid to operate. These good results with GlucoSure Plus are obtained when operated by biomedical scientists in the primary health care.