

Nova StatStrip™ Glucose and β -Ketone Hospital Meter System

SKUP/2013/85

Background

The Nova StatStrip™ Glucose and β -Ketone Hospital Meter System (StatStrip) is intended for measuring glucose in fresh capillary, venous, or arterial blood including neonate blood, by health care professionals. The glucose results are calibrated to agree with a method measuring the concentration in plasma. StatStrip is manufactured by Nova Biomedical Corporation, USA. The agent for the system in the Nordic countries is A. Menarini Diagnostics Nordic Countries in Sweden, who also requested this evaluation. The StatStrip system consists of the StatStrip meter and the StatStrip test strips. The sample volume, 1,2 μ L, is aspirated to the test strip by capillary draw.

The aim of this study was to evaluate

- the analytical quality of glucose measurements
- the user-friendliness

The evaluation was performed both under optimal conditions when operated by an experienced biomedical laboratory scientist and under “real life” conditions when operated by the intended users, nurses and midwives

Materials and methods

StatStrip is evaluated under different conditions and with tighter accuracy goals compared to SKUP evaluations of meters for glucose self-monitoring.

In a hospital laboratory, an experienced biomedical laboratory scientist carried out StatStrip measurements on arterial samples. In one hospital ward, the measurements were carried out by nurses on capillary samples from adult persons with diabetes and in another ward midwives measured on venous samples from healthy newborn children. Three lots of test strips were used.

The comparison method was the routine method for P—Glucose in the Karolinska University Laboratory, Huddinge. The method is accredited. It is the Roche hexokinase method, Glucoquant Glukos/HK, applied on a Modular Analytics P instrument from Roche Diagnostics.

The analytical quality goals set by SKUP for this evaluation were that repeatability should not exceed 4% CV and that at least 95% of the results should fall within $\pm 0,83$ mmol/L at glucose concentrations $< 5,6$ mmol/L and within $\pm 15\%$ at glucose concentrations $\geq 5,6$ mmol/L, from the comparison method results.

Results

In the hospital laboratory. With arterial samples the obtained repeatability was 3% CV.

Patient sample results showed a bias of approximately +0,2 mmol/L. Ninety-nine percent of the results were inside the accuracy goal limits. The StatStrip results were not influenced by haematocrit, pO₂, pH and sodium concentrations in the samples within the examined intervals (for haematocrit 20 to 47%). The results in the hospital laboratory fulfilled the quality goals.

At the hospital wards. With venous and capillary samples the obtained repeatability was from 5 to 7% CV. The quality goal for imprecision was not fulfilled. Patient sample results showed a bias of about +0,3 mmol/L. The accuracy goal was fulfilled in the hospital ward using venous samples, with 95% of the results inside the limits, but not in the ward using capillary samples, where 93% of the results were inside the limits. See an overview of the analytical quality results on page 32.

User-friendliness. The evaluators' general opinion was that StatStrip was user-friendly and easy to handle. For most of the items StatStrip got the best assessment “Satisfactory”.

The evaluators remarked that the operation of StatStrip requires several procedure steps; scanning the test strip lot number, operator ID and patient ID.

Conclusion

In the hands of an experienced biomedical laboratory scientist, with arterial samples from adult intensive care patients, the analytical quality of StatStrip was good and fulfilled the quality goals. When nurses and midwives measured venous and capillary patient samples, the quality goal for imprecision was not fulfilled. The quality goal for accuracy was fulfilled in one ward measuring venous neonatal samples but not in another ward measuring capillary adult samples. The accuracy of the StatStrip results was not influenced by haematocrit, pO₂, pH and sodium. StatStrip was easy to handle.