Summary | Afinion 2 Analyzer for measurement of HbA1c

Manufacture: Abbott Diagnostics Technologies AS
Supplier: Abbott Rapid Diagnostics A/S in Denmark, Abbott Rapid Diagnostics AS in Norway and Abbott Rapid Diagnostics AB in Sweden

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was fulfilled**
- **The quality goal for accuracy was fulfilled**
- **The quality goal for user-friendliness was fulfilled**

Background
The Afinion 2 Test System is an in vitro diagnostic device for quantitative measurement of Haemoglobin A1c (HbA1c), C-reactive protein (CRP), albumin/creatinine ratio (ACR) and Lipid Panel. The product is intended for professional use. The sample material is fresh capillary whole blood and venous whole blood with an anticoagulant. The system is produced by Abbott Diagnostics Technologies AS and was launched into the Scandinavian market in 2017. A predecessor of the system, the Afinion AS100 Analyzer, is still on the market. The SKUP evaluation was carried out May to June 2021 at the request of Abbott Rapid Diagnostics GmbH in Germany.

The aim of the evaluation
The aim of the evaluation was to assess the analytical quality and user-friendliness of the Afinion 2 Analyzer for measurement of HbA1c, both when used under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users in primary health care centres (PHCCs).

Materials and methods
Under optimal conditions fresh capillary whole blood samples from 100 patients were measured on the Afinion 2 Analyzer. Under real-life conditions, in two PHCCs, fresh capillary whole blood samples from a total of 97 patients were measured on the Afinion 2 Analyzer. Venous whole blood samples from the same patients were analysed on a comparison method (Tosoh Automated Glycohemoglobin Analyzer HLC-723 G11, Tosoh Bioscience, Inc.). The trueness of the comparison method was verified with fresh frozen venous samples with certified values. The analytical results and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability (CV) ≤3,0 %. For accuracy ≥95 % of the results should be within ±3,0 mmol/mol from the results of the comparison method in HbA1c concentration <35,3 mmol/mol and within ±8,5 % at HbA1c concentration ≥35,3 mmol/mol. The user-friendliness was assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory, and with the quality goal of a total rating of “satisfactory”.

Results
The CV achieved under optimal conditions varied between 1,2 and 1,8 % depending on the concentration level. The CV achieved by intended users varied between 1,2 and 1,7 %. Under optimal conditions, the bias between the Afinion 2 Analyzer and the comparison method was 0,70 and 2,00 mmol/mol at level 2 and level 3, respectively. There were no bias shown at the PHCCs. Under optimal conditions, 95 % of the results were within the allowable deviation limits and when handled by intended users, 97 % of the results were within the limits for accuracy. The user-friendliness was rated as satisfactory.

Comments from Abbott Rapid Diagnostics GmbH
A letter with comments from Abbott Rapid Diagnostics GmbH is attached to the report.