Afinion HbA1c

Summary of an evaluation under the direction of SKUP
Report SKUP/2008/65

The Afinion™ system (Afinion) is intended for measurements performed by personnel in primary health care. Afinion is so far launched with tests for C-reactive protein (CRP), Albumin/Creatinine Ratio (ACR) and Haemoglobin A1c (HbA1c). CRP and ACR have not been evaluated by SKUP. The test menu will be upgraded when new tests are launched. The HbA1c test measures on whole blood from a capillary finger prick or a venous sample. Afinion is manufactured by Axis-Shield PoC AS, Norway. The Medinor companies are the agents for the system in the Scandinavian countries. Medinor AB in Sweden ordered this evaluation.

The Afinion system for HbA1c consists of the Afinion AS 100 Analyzer and the Afinion HbA1c Test Cartridges. The sampling device, which is a part of the Test Cartridge, is used to bring the correct sample volume to the Test Cartridge. Afinion uses boronate affinity chromatography to separate HbA1c in the sample. After the addition of the sample to the cartridge and placement of the cartridge in the Analyzer, the procedure is automatic. The result is displayed on the screen at the end of the test. The measuring range is 4,0 to 15,0 HbA1c% (NGSP standardised). The sample volume is about 1,5 µL blood. Measurement duration is 3 minutes and 15 seconds.

This evaluation is a complete SKUP evaluation. An experienced biomedical scientist (medical laboratory technologist) in a hospital laboratory carried out measurements on venous samples and two staff nurses in two primary care centres carried out measurements on capillary samples.

The comparison method was an accredited High Performance Liquid Chromatography (HPLC) method using an ion exchange column called Mono S supplied by General Diagnostics. The Mono S measurements were made in the Department of Clinical Chemistry at the University Hospital MAS in Malmö (UMAS), Sweden. Their method is the Swedish Designated Comparison Method (DCM) and their results are regularly compared with the IFCC Reference Methods.

Results

The HbA1c values in this report are NGSP standardised.

Imprecision

According to the quality goals set by SKUP, the imprecision of Afinion should not exceed 4,0% in CV. The imprecision calculated for venous patient samples measured in the hospital laboratory was 2,2% in CV. The imprecision calculated for capillary patient samples measured at the primary care centres was 2,1% in CV. The imprecision expressed as standard deviations was 0,1 to 0,3 HbA1c% for all the checked concentration intervals – the highest figure for the high level group. The between-days imprecision calculated on patient sample results was 1,6% in CV and not statistically significant different from the within-day imprecision. The between-days imprecision from measurements on control blood materials was about the same as from patient samples. The overall assessment is that the precision of Afinion was good and fulfilled the quality goal.

Bias

According to the quality goals set by SKUP, the bias of Afinion should not exceed ±4,0%. For all capillary sample results together (measured at the primary care centres), the Afinion bias was estimated to approximately –3,5% and therefore fulfilled the quality goals.

In the hospital evaluation Afinion showed both positive and negative bias depending on the HbA1c level. The bias could therefore only be assessed at different levels and a calculated mean bias for all levels has no meaning. When the results were divided into three separate levels the estimated bias for the low level was non-significant positive and for the high level non-significant negative. The bias for the medium level was estimated to –4,9% and was significantly below

−4,0%. This level with HbA1c concentrations between 5,7 and 9,7 HbA1c% is clinically interesting and includes two thirds of all results in the hospital evaluation. When Afinion is used in primary health care it is expected that about 90% of the results will be in this concentration interval. This justifies the assessment that Afinion did not fulfil the SKUP quality goal for bias.

Total error

According to the quality goals set by SKUP, 95% of the B—HbA1c results of Afinion should not deviate more than ±10% from the corresponding Comparison Method results. The Afinion results with venous samples measured in the hospital laboratory did not fulfil the quality goal for total error as only 88 out of 96 results, 92%, were inside the limits. The Afinion results with capillary samples measured at the primary care centres did not either fulfil the quality goal as only as 67 out of 72 results, 93%, were inside the limits. However, many of the measurements outside the 10% limits were very close to the limits.

Analytical quality summarised

Afinion fulfilled the quality goal for precision. For the medium level group in the hospital laboratory evaluation the bias was estimated to −4,9%. As this level group, with HbA1c concentration from 5,7 to 9,7 HbA1c%, is clinically interesting and is expected to include about 90% of all results in practical use, it justifies the overall assessment that Afinion did not fulfil the quality goals for bias. Afinion did not neither fulfil the quality goals for total error.

User-friendliness summarised

The evaluators had the general opinion that Afinion was user-friendly. They liked the system and thought it was easy to handle. The most important negative opinion concerns the high frequency of error codes. The other negative opinion concerns the internal quality control materials which were very viscous and difficult to mix and handle.

The error code frequency was 8%. The probable explanation was that the detection systems causing the error codes were too sensitive. Regardless of cause, the frequency of error codes was assessed as too high.

Conclusion

Afinion was easy to handle. The precision of Afinion was good and fulfilled the quality goal. However, the bias for the medium level was −4,9 % and too many results were outside the total error limits. Afinion did therefore not fulfil all analytical quality goals. The error code frequency was also too high.

Comments from the manufacturer

For comments from Axis-Shield, please see attachment 5.

The complete report is found at www.skup.nu