

Afinion™ HbA1c SKUP evaluation

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SKUP (Scandinavian evaluation of laboratory equipment for primary health care) performed a full SKUP evaluation of Afinion™ HbA1c in April - June 2007 according to the standard protocol.

The evaluation was performed in Sweden at UMAS Malmö University Hospital and at Södervärn and Granen primary care centres.

What was evaluated?

A full SKUP evaluation comprises the following:

- Analytical quality evaluated in a hospital laboratory and in two primary care centres.
 1. imprecision within day (100 samples in hospital, 40 samples in primary care)
 2. imprecision between day (40 samples in hospital)
 3. method comparison to Mono-S (100 samples in hospital, 100 samples in primary care)
- User-friendliness evaluated at all sites

SKUP quality goals

Imprecision (CVa)	< 4.0%
Bias	< ±4.0%
Total error	< ±10.0%

Summary and conclusions

- The overall opinion was that Afinion™ Test System was user-friendly and easy to handle.
- The packaging materials, time factors, quality control possibilities and operations as such were all rated the top score "Satisfactory".
- The frequency of error codes was 8%. Afinion™ AS100 software has since this evaluation been optimised and the frequency of false alarms significantly reduced (<4%).
- Afinion™ AS100 Analyzer never failed to show an appropriate information code, i.e. no incorrect test results were reported.
- Agreement
 - 3 lots of Afinion™ HbA1c were used. No calibration difference was observed.
 - 6 Afinion™ AS100 Analyzer were used. The mean results showed very good agreement between the Analyzers.
- The precision of Afinion™ was good and clearly fulfilled the quality goal.
 - Venous patient samples, hospital: CV = 2.2%
 - Capillary patient samples, primary care: CV = 1.4% and CV = 2.1%
 - Between-days imprecision: CV = 1.6%, not statistically significant different from within-day.
 - Between-days imprecision for the controls: CV = 1.5% and CV = 1.3%
- Method comparison to Mono-S
 - Afinion™ fulfilled the quality goal for low and high level venous samples in the hospital. At medium level Afinion™ showed a negative bias to the hospital (-4.9%).
 - Afinion™ fulfilled the quality goal for all capillary samples in primary care.
- Total error
 - 92% of the venous samples and 93% of the capillary samples were within SKUP quality goal for total error. SKUP criteria was 95% of samples within total error limits.

Results

Imprecision

Calculation of imprecision was based on duplicate measurements of patient samples (venous or capillary).

Imprecision of duplicate measurements, capillary samples, two sites.

Level	N	% HbA1c	CV (%)	Goal
Low	18	6.1	1.1	< 4.0%
High	14	7.6	1.6	
All	32	6.7	1.4	
Low	14	6.0	1.8	
High	19	7.3	2.2	
All	33	6.7	2.1	

Between-days imprecision, venous samples, hospital.

Level	N	% HbA1c	CV (%)	Goal
Low	8	5.2	1.1	< 4.0%
Medium	26	7.1	1.7	
High	5	11.6	1.3	
All	39	7.3	1.6	

User-friendliness

Immediately after the evaluation each operator completed a questionnaire on the user-friendliness of the Afinion™ Test System.

Rating

The operators evaluated Afinion™ according to the following criteria:

- Unsatisfactory
- Less satisfactory
- Satisfactory

Category	N	Overall rating
Manual/insert	11	Satisfactory
Time factors	2	Satisfactory
Quality control	5	Satisfactory
Operation facilities	16	Satisfactory

N=No. of questions

Comments

- The control material was difficult to mix
- The Test Cartridge has good room temp stability
- Too high frequency of error codes
- The Afinion™ Analyzer is easy to handle and silent

Method comparison

Venous samples were analysed on Afinion™ and Mono-S at UMAS. Bias, systematic deviation from the comparison method, was calculated at 3 HbA1c levels.

Level	n	% HbA1c	Bias (%)	Goal
Low	18	5.0	+1.4	< ±4.0%
Medium	61	7.5	-4.9	
High	13	11.5	-3.9	

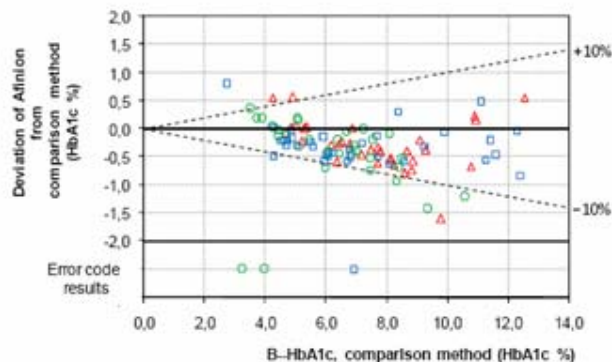
Capillary patient samples were analysed on Afinion™ in primary care and venous samples were analysed on Mono-S. Bias was calculated for all samples.

Site	n	% HbA1c	Bias (%)	Goal
Site 1	32	7.0	-3.3	< ±4.0%
Site 2	33	7.0	-3.6	

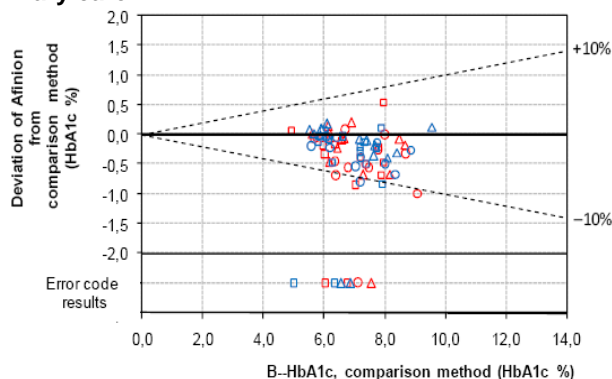
Total error

Total error was calculated for all samples in hospital and all samples in primary care.

Hospital:



Primary care:



Please see www.skup.nu for the complete SKUP report.