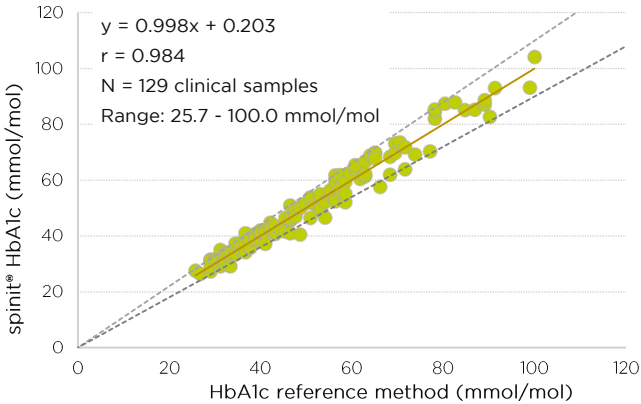


Key features

- One small drop of blood – 5µL
- Results in minutes
- Laboratory quality results
- Self-calibration

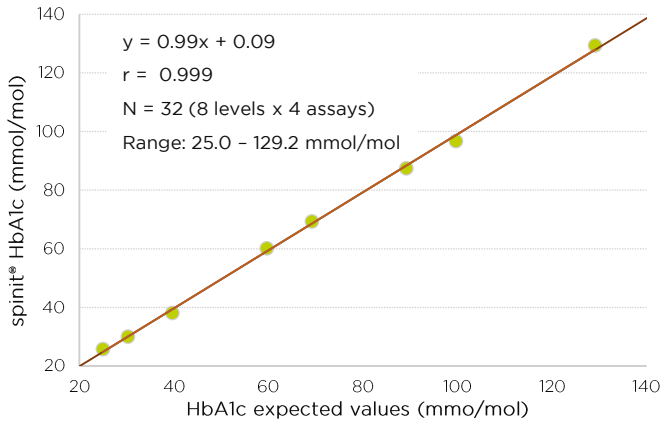
- Analytical range:
 - 4.5-13.1% (NGSP units)
 - 25.7-120.0 mmol/mol (IFCC units)
- IFCC and NGSP certified

Method comparison



Studies performed according to CLSI EP9-A3 guidelines [Approved Guideline – third edition, Vol33 No.11 (2013) CLSI/NCCLS]

Linearity



Linearity studies performed using four different spinit® instruments, five HbA1c cartridge lots. Samples tested ranged from 25.7 – 129.2 mmol/mol. N=32

Imprecision

Total imprecision and bias calculated for the full analytical range and in low, medium and high HbA1c concentration ranges in % DCCT (NGSP units)

HbA1c (% DCCT, NGSP)	4.5 - 13.1	4.5 - 6.1	6.1 - 9.0	9.0 - 13.1
TOTAL IMPRECISION (%)	2.4	2.6	2.1	2.8
BIAS (%)	0.2	0.6	-0.3	0.8
N	129	52	63	14

Total imprecision and bias calculated for the full analytical range and in low, medium and high HbA1c concentration ranges in mmol/mol (IFCC units)

HbA1c (mmol/mol, IFCC)	25.7 - 120.0	25.7 - 43.0	43.0 - 75.0	75.0 - 120.0
TOTAL IMPRECISION (%)	3.8	4.4	3.3	3.4
BIAS (%)	0.2	1.1	-0.5	1.0
N	129	52	63	14

Interference

The following Hb variants have been analysed and found not to affect the spinit® HbA1c test result up to the following concentrations:

Haemoglobin variant	Maximum concentration of Hb variant % tested	% Bias HbA1c
C	35	2.2
D	42	2.2
E	25	4.1
S	40	2.8
A2	4.5	-4.7

The HbF variant was found to interfere with the spinit® HbA1c test cartridge results.

Common HbA1c interferents were analysed and no significant interference was observed up to the following concentrations:

	Maximum concentration of interfering substance mg/dL	% Bias HbA1c
Triglycerides	627	-1.2
Bilirubin	13.3	-0.1
Glucose	556	1.2
Cholesterol	324	-2.7

Contacts