

Blood Glucose Systems											
ID CODE	Precision, CV (%)		Bias (mg/dL)			Accuracy	Lots bias (mg/dL)			Hct Interference	User-friendliness
	under standardised and optimal conditions	user-evaluation among diabetes patients	<126 mg/dL	126-180 mg/dL	>180 mg/dL		Lot 1	Lot 2	Lot 3		
SKUP/2017/112	1.5-2.6	1.8-3.9	-1,8	-5,45	-14,41	The quality goal in ISO 15197:2003 was fulfilled	agreement	agreement	agreement	not affected by values from 31-50%	The user frindliness was rated as satisfactory
SKUP/2014/105	2,4-4,3	4,3-6,0	-3,57	-10,18	-14,29	The quality goal in ISO 15197:2003 and ISO 15197:2013 was fulfilled	agreement	agreement	agreement	not affected by values from 34-51%	Easy to operate. The user-friendliness was rated as "satisfactory"
SKUP/2013/100	1,9-3,2	3,5-4,5	agreement	agreement	agreement	The quality goal in ISO 15197:2003 and ISO 15197:2013 was fulfilled	agreement	agreement	agreement	slightly affected by values from 32-52%	Easy to operate. The user-friendliness was rated as "satisfactory"
SKUP/2013/99*	3,0-4,2	-	agreement	agreement	agreement	The quality goal in ISO 15197:2003 was fulfilled	-6,79	agreement	+4,46	-	-
SKUP/2013/98*	2,8-4,5	-	-2,68	-5,89	-12,14	The quality goal in ISO 15197:2003 was fulfilled	agreement	agreement	agreement	-	-
SKUP/2013/87	3,5-5,1	5,7-6,0	Lab: -4,82 Diabetes: agreement	Lab: -12,68 Diabetes: -7,67	Lab: -23,48 Diabetes: -13,21	The Hospital Laboratory fulfilled most likely the quality goal for the precision, the diabetes didn't fulfilled the quality goal for precision proposed in ISO 15197:2003. bOth Hospital Laboratory and the diabetes fulfilled the quality goal for accuracy proposed in ISO 15197:2003	agreement	agreement	agreement	slightly affected by values from 35-49%	The user-friendliness was rated as satisfactory
SKUP/2013/85	Lab: 3% Wards: 5,0-7,2%	-	Lab: +5 Wards: +5,71	Lab: +2,5 Wards: +6,07	Lab: + 3,57 Wards: +9,64	Hospital Laboratory fulfilled the quality goal proposed in Iso 151971. Hospital Wards didn't fulfilled the precision quality goal proposed in ISO 151971, and only one ward fulfilled the accuracy quality goal proposed in ISO 151971	agreement	agreement	agreement	not affected by values from 20-47%	Easy to operate but several operators find that the devices requires too many procedure steps
SKUP/2012/95	2,8-4,1	2,5-5,2	-1,96	-3,93	-6,61	Quality goal proposed in ISO 151971 ¹ was obtained.	agreement	agreement	agreement	slightly affected by values from 31-48%	Approximately 2/3 of the participants did not find the meter easy to operate
SKUP/2012/94	1,8-3,3	1,5-4,2	+4,82	+4,28	agreement	Quality goal proposed in ISO 151971 ¹ was obtained.	+4,64	+5,00	+3,39	not affected by values from 34-49%	Easy to operate but someone had problems with the meter during the evaluation period

SKUP/2011/93*	2.9-4.1	-	agreement	agreement	-9,11	Quality goal proposed in ISO 15197 ¹ were obtained	-5	agreement	-7,32	-	Easy to operate
SKUP/2011/86	3	4,5	4,9	4,3	agreement	Quality goal proposed in ISO 15197 ¹ , the "adjusted ISO-goal" ² and quality goal suggested by NOKLUS (<10%) were obtained.	agreement	agreement	agreement	not affected by values from 30-49%	Easy to operate but several commented that the size of the booklet was too large
SKUP/2010/89*	<3	-	agreement	-3,6	-17,1	Quality goal proposed in ISO 15197 ¹ and quality goal suggested by NOKLUS (<10%) were obtained	-6,3	agreement	-11,7	-	-
SKUP/2010/81*	2	-	-10,8	-16,2	-25,2	Quality goal proposed in ISO 15197 ¹ was obtained. Quality goal suggested by NOKLUS (<10%) was not obtained	-20,52	-17,46	-20,88	-	-
SKUP/2009/75	4	-	agreement	agreement	-9	Total Error: 10%; Quality goal proposed in ISO 15197 ¹ and quality goal suggested by NOKLUS (<10%) were obtained	agreement	-5,4	agreement	not affected by values from 27-49%	Easy to operate
SKUP/2009/74	<3	4	+5,4	+3,6	agreement	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	+7,2	+7,2	agreement	slightly affected by values from 27-49%	Easy to operate but someone had problems related to opening the tip cover.
SKUP/2009/71	4,5	6	+8,1	agreement	-7,2	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	agreement	agreement	agreement	not affected by values from 30-49%	Easy to operate
SKUP/2008/66	3	3-6	+1,8	agreement	-10,8	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	-7,2	agreement	agreement	slightly affected by values from 30-47%	Easy to operate but someone had problems related to test strips
SKUP/2007/64	2-3	4	agreement	-5,4	-14,4	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	-7,2	-6,3	+4,5	not affected by values from 31-48%	Easy to operate
SKUP/2007/59	3	3-5	agreement	agreement	-5,4	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	agreement	agreement	agreement	seem to be affected by values from 33-50%	Easy to operate
SKUP/2005/51*	2,7-5	2,7-5	-	-	-	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	-	-	-	-	-
SKUP/2006/50	5	6	agreement	agreement	-10,8	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	agreement	-10,8	-7,2	seem to be affected by values from 32-51%	Easy to operate
SKUP/2006/49*	6	5	+3,6	+7,2	+5,4	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	+9	agreement	+5,4	not affected by values from 35-49%	Easy to operate
SKUP/2006/48	3	2-6	+1,8	+3,6	+5,4	Quality goal proposed in ISO 15197 ¹ and "adjusted ISO-goal" ² were obtained	+5,4	agreement	+3,6	not affected by values from 35-50%	Easy to operate

goal: <5%

¹ ISO 15197, minimum acceptable accuracy: 95% of the individual glucose results shall fall within $\pm 0,83$ mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within $\pm 20\%$ at glucose concentrations $\geq 4,2$ mmol/L.

² "Adjusted ISO-goal", quality demands adjusted to the diabetes patients self-measurements: 95% of the individual glucose results shall fall within $\pm 1,0$ mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within $\pm 25\%$ a

* Supplementary Evaluation