

## 1. Summary

# cobas pulse, glucose

Manufacturer	Roche Diagnostics GmbH
Supplier in Denmark	Roche Diagnostics A/S
Supplier in Norway	Roche Diagnostics Norge AS
Supplier in Sweden	Roche Diagnostics Scandinavia AB
Launched in Scandinavia	September 2022



### Aim

To assess the analytical performance and user-friendliness of glucose measurements with **cobas pulse** by intended users, which are health care personnel in the hospital as well as in primary health care. The evaluation was performed by both experienced laboratory personnel in a hospital laboratory and by health care personnel in two primary health care centres.

Performance specifications		Conclusion and results
<b>Repeatability</b>	CV $\leq$ 4,0 %	Fulfilled by laboratory personnel (CV 1,8 – 2,3 %) Fulfilled by health care personnel (CV 3,1 – 4,0 %)
<b>Accuracy</b> $\geq$ 95 % of the results within the specified limits compared to the average result of the comparison method	$\pm$ 0,83 mmol/L at glucose concentration $<$ 5,55 mmol/L $\pm$ 15,0 % at glucose concentration $\geq$ 5,55 mmol/L	Fulfilled by laboratory personnel (100 %)
<b>User-friendliness</b>	A total rating of "Satisfactory"	Fulfilled

### Additional information

<b>Participants</b>	217 persons with diabetes. 100 from a hospital laboratory and 117 from two primary health care centres.
<b>Evaluated method</b>	<b>cobas pulse</b> (FAD-GDH method) on fresh capillary whole blood using two lots of test strips. Intended for professional use.
<b>Comparison method</b>	Roche cobas 8000 c 702 (glucose hexokinase method) on capillary plasma samples.
<b>Bias</b>	A positive bias of 0,16 mmol/L between <b>cobas pulse</b> and the comparison method.
<b>Technical errors</b>	1,2 %

Further information about the evaluation and the organisation of SKUP can be found on [www.skup.org](http://www.skup.org).