Swedish National Quality Goals for Measurement of Glucose
Guidance for the Laboratory

1. Introduction

This guidance is intended for the staff at laboratories that measure plasma glucose (P-Glucose), but it also covers guidance for measurement using Point of Care (PoC) systems for glucose. In 2007 the first Swedish national quality goals for measurement of P-Glucose in the clinic were published; these were subsequently revised in 2015.

The two major changes in the 2015 revision were the removal of the quality level Iron and the addition of a recommendation to use citrate blood collection tubes when sampling venous blood. In the current revision no quality goals have been changed, only other minor revisions.

The measurement of glucose is a common analysis in general healthcare and elderly care. This guidance covers verification of quality goals for sample collection, sample treatment and glucose measurement when diagnosing diabetes mellitus in fasting samples. Other than the condition that the patient must be fasting, this document can also apply to other glucose measurements requiring high accuracy.

2. The quality goals

This guidance presents the Swedish national quality goals for P-Glucose methods used in various clinical settings. The intention is to raise the analytical quality and to increase understanding of the fact that all measurements have a degree of uncertainty which is affected by how the measurement has been performed. The quality goals for diagnosis of diabetes are defined by the clinical need. The quality goals include pre-analytical errors. The quality goals are divided into different levels designated diamond, gold, silver and bronze, where the diamond level has the highest quality (lowest uncertainty) and the bronze level has the lowest quality (highest uncertainty).

Diamond Should be attained by reference methods:

A reference method for P-Glucose should fulfil the following requirements:

- The method should be performed by a laboratory accredited as a calibration laboratory (or which has applied for accreditation), and which demonstrates an appropriate low uncertainty of measurement and which participates in ring tests for reference laboratories. Only methods listed by JCTLM are approved [1]. For glucose these methods are ID/GC/MS or spectrophotometric hexokinase.

Gold Should be attained by plasma glucose methods used as comparison methods when evaluating other methods:

- With a comparison method, at least 95% of the individual results should be within **±7%** of the results using a reference method at glucose concentrations ≥4.2 mmol/L and within ±0.29 mmol/L at glucose concentrations <4.2 mmol/L.

Silver Should be attained by plasma glucose methods used for the diagnosis of diabetes:

- These methods can be used both by hospital laboratories and primary healthcare services. At least 95% of the individual results should be within **±10%** of the results using a comparison

method at glucose concentrations ≥4.2 mmol/L and within ±0.42 mmol/L at glucose concentrations <4.2 mmol/L.

- This level of quality should be attained when the instrument is used by professional users for diagnosis of diabetes for patients in the borderline area and in other situations that require high clinical certainty, such as women with gestational diabetes and patients using continuous glucose monitoring (CGM), where the glucose meter is used as a calibrator unit. In addition, children with diabetes could benefit from glucose meters with accuracy at the silver level.

Bronze Should be attained by glucose meters used for follow-up/monitoring of known diabetes. According to international standard ISO 15197:2013 [2], the manufacturer should show that the following goals can be achieved when the instrument/meter is used not only by professional users but also by the patients themselves:

- At least 95% of the individual results should be within **±15%** of the results using a comparison method at glucose concentrations ≥5.55 mmol/L and within ±0.83 mmol/L at glucose concentrations <5.55 mmol/L. Note that there are some exceptions, see level Silver.

The quality goals have, after an initiative of the Swedish Association of Diabetology, been defined by Equalis in cooperation with the organisations presented below. The revised quality goals were accepted at a meeting in May 2015.

The Swedish Association of Diabetology	Organises physicians and others active in diabetology in Sweden.
Swedish Society for Clinical Chemistry	Organises physicians, chemists, laboratory engineers and biomedical scientists active in clinical chemistry laboratories in Sweden.
Swedish Association of Nurses in Diabetes Care	Organises nurses active in diabetes care in Sweden.
The Swedish Diabetes Association	Organises patients with diabetes and their families in Sweden.
Equalis	Equalis is a provider of external quality assessment for clinical laboratory investigations based in Sweden. The purpose of Equalis is to improve analytical quality and patient safety. Equalis standpoints are often based on knowledge provided by various advisory groups. In this case: Equalis advisory group for general clinical chemistry and Equalis advisory group for Point of Care analyses.

3. Nomenclature

The glucose concentration should always be expressed as the concentration in plasma, even if the measurement has been performed on full blood.

Glucose that has been measured on samples collected from fasting patients for diagnosis of diabetes is designated P(vB; fPt)-Glucose [NPU02195] for a venous sample and P(cB; fPt)-Glucose [NPU02193] for a capillary sample. The designation P(fPt)-Glucose [NPU22069] can be used if it is not known whether the sample is venous or capillary. If it is not known whether the sample has been taken from a fasting patient, the designations P(vB)-Glucose [NPU21531] or P(cB)-Glucose [NPU22089] should be used [3].

4. Optimal measurement routine; quality level Gold

The optimal routine for measuring fasting venous plasma glucose that satisfies the high requirements for accuracy is presented below. This routine is mainly used in scientific projects and as a comparison method when verifying other methods.

4.1. Pre-analysis

- At least 10 hours [4] of fasting, no smoking, and 15 minutes' rest before sampling. Fasting means absolutely no intake of solid food or fluids except pure water.
- Venous samples are collected in citrate blood collection tubes containing sodium fluoride and EDTA as dry additives (chapter 5). The additives immediately stop the glucose consumption in the sample. The sample is centrifuged and the plasma is separated.
- The pre-analytical procedure must be documented, i.e. in a checklist with check boxes and signatures.
- The result can only be reported as a fasting sample in accordance with the nomenclature in chapter 3 if the laboratory can document that the pre-analytical procedure has been followed.

4.2. Analysis

- P-Glucose is measured using a quality-assured method.
- The laboratory must demonstrate that the intra-laboratory imprecision is 3.0% CV or lower, see comment 1. The simplest way to demonstrate this is by using internal quality control.
- The laboratory has to demonstrate that the systematic error (bias) of the method is ±2.0% or lower when compared to a comparison method. This can be shown by external quality control assurance if those values are set by a reference method, see comment 2.

The analytical quality goals above are based on the literature on biological variation for P-Glucose, where the imprecision is 2.3% or lower and the bias is ±1.8% or lower [5].

4.3. The uncertainty of the result

If the pre-analytical conditions and the analytical quality goals are fulfilled, it can be assumed that 95% of the individual results are within ±0.29 mmol/L or within ±7% of the results that would have been achieved if an optimal pre-analytical procedure and a reference method had been used. In this calculation, the pre-analytical error is assumed to be negligible. Thus, even if the goals are met, there is a potential uncertainty. Note that similar uncertainties are present in the results used for calculations of decision limits by the World Health Organization (WHO).

5. Measurement routines for diagnosis of diabetes; quality level Silver

We recommend the use of citrate blood collection tubes when glucose is to be analysed by a hospital laboratory.

Historically, collection tubes with sodium fluoride and potassium oxalate additives have been used in the Swedish healthcare services. However, it takes 60-90 minutes before the additive has full effect on glucose catabolism, resulting in underestimation of the glucose concentration by an average of 6% [6]. In citrated blood collection tubes (which also include sodium fluoride and EDTA) the glycolysis is stopped immediately [7]. These tubes have been used for many years in Finland, and many of the Swedish counties have switched to these tubes in recent years. Evaluations from the Swedish

healthcare services show that the switch to citrated blood collection tubes has had a clear effect on the measured glucose concentrations [8, 9].

Citrated blood collection tubes with either dry or wet additives are available. We recommend that tubes with dry additives are used to avoid the problems with diluting the samples [10]. The citrated blood collection tubes have been the subject of international debate and discussions as to whether the recommendations for collection tubes should be changed, including re-evaluation of the current medical decision limits for diabetes, which are generally based on studies using suboptimal pre-analytical procedures [11].

The development of blood collection tubes that stop glycolysis immediately has further reinforced the advantages of venous sampling for measurement of plasma glucose. This is particularly important when high analytical quality is needed, for example when used in the diagnosis of diabetes.

5.1. Standard measurement routines for plasma glucose (vP-Glucose) in hospital laboratories

- Venous samples should be collected in citrated blood collection tubes.
- Collection tubes with sodium fluoride and potassium oxalate additives, and tubes with gel for serum or heparin plasma are still used in some counties in Sweden, see comment 3.
- Some laboratories measure venous serum glucose in their routine work, in scientific projects and in clinical trials. However, there is a risk that glucose concentrations could differ from samples measured using citrated blood collection tubes.

5.2. Standard measurement routines for PoC glucose measurements (cP-Glucose)

Capillary samples are collected directly into a cuvette or on a test strip, and then measured immediately. Thus, no glucose consumption occurs before measurement. When measuring PoC capillary plasma glucose in Sweden, the optimal measurement routine is generally deviated from as follows:

- The measurement is performed on full blood and not on plasma. The instrument recalculates the measured blood glucose value to a plasma glucose value using a fixed factor. The factor is correct when the instrument use mean values in the calculations, but introduces an error for individual results.
- The measurement is performed on capillary samples instead of venous samples. The results of capillary samples often deviate from results of venous samples, both systematically and randomly, when measuring samples from non-fasting patients. It is assumed that there are no systematic differences in glucose concentrations between capillary samples and venous samples when fasting, see comment 4.

5.3. The uncertainty of the results

The total error of the measurement routine can be calculated for both venous and capillary samples using the equation below:

$$\text{Total error} = \pm 1.64 \times \sqrt{\text{imprecision}^2 + \text{matrix effect}^2 + \text{preanalytical random error}^2} + |\text{bias}|$$

The total error should be ±10% or less to fulfil the quality goal. Note that the matrix effect and the pre-analytical error are difficult to quantify.

6. Verification of measurement routines for diagnosis of diabetes

6.1. Verification of measurement routines for vP-Glucose; quality level Silver

- The laboratory must document that the total error for the individual results is ±10% or less.
- The most reliable way to verify a measurement routine is to compare the results to those achieved with an optimal measurement routine.
- The simplest way for a laboratory to demonstrate that the analytical quality goal is met is to document and evaluate the following factors; imprecision (comment 1), bias (comment 2), and the pre-analytical routine (see above).

  The laboratory can calculate its imprecision using statistics from the internal quality control results.

  The laboratory can calculate its bias using statistics from the external quality control results if those results have been set using a reference method.

6.2. Verification of measurement routines for cP-Glucose

The measurement routine for PoC analysis of capillary glucose samples, cP-Glucose, should be verified with the actual instrument used:

- The person responsible for the method must document the total error of the individual results. Preferably, the total error should not exceed ±10%.
- The simplest method for the responsible person to show that the analytical quality goal is met, is by documenting and evaluating the imprecision and bias.

  The responsible person can document the imprecision by regular duplicate measurements on patients, e.g. one patient per month. Each duplicate measurement should be performed from two different blood drops from the same patient. The imprecision can be calculated from the results from the last six months, or at least ten duplicate measurements, see comment 1. Alternatively, control solutions or control blood can be used for regular monitoring of the imprecision. In this case, the responsible person must first document the imprecision of the control material.

  The responsible person must document the bias by participating in external quality assurance or by regularly performing comparisons with a quality-assured hospital method that meets quality level Gold.
- The pre-analytical error is assumed to be negligible.
- The individual result's trueness is affected by matrix effects in addition to imprecision and bias. The matrix effects can be caused e.g. by the water content in full blood, which varies more than in plasma, a variation that is affected by varying the fraction of erythrocyte volume in the blood (haematocrit). There are no separate measurements for matrix effects.

If the total error of the verified measurement system exceeds the quality goal, consideration should be given to switching to venous sampling and measurement of plasma glucose. The responsible physician where the measurement system is used has the formal responsibility for such a switch. The person responsible for the method should also contact the supplier of the measurement system for technical support.

7. Quality level Silver; applications

The analytical quality achieved at the Silver level is the preferred quality for diagnosis of diabetes. This quality level is also important when monitoring some groups of patients, for example those using continuous glucose monitoring (CGM) and women with gestational diabetes. Furthermore, children with diabetes could also benefit from using glucose meters with the accuracy achieved at the Silver level. The quality level should be attained when the instrument is used by professional users.

The diagnosis is made by comparing the results with the decision limits set by WHO [12]. If the laboratory marks pathological results with an asterisk, the asterisk should be shown for results at or

above 6.1 mmol/L. Results in the interval 6.1−6.9 mmol/L are called non-diabetic fasting hyperglycaemia and should not be interpreted as diabetes, but as an increased risk of diabetes. The diagnosis diabetes should be made when the patient has two results at 7.0 mmol/L or above. Venous sampling is recommended rather than capillary sampling when the results are to be used for diagnostics, see comment 4. However, the Swedish Association of Diabetology does acknowledge that capillary sampling on a PoC instrument does have advantages such as simplicity and an immediate result. PoC capillary sampling is common particularly in maternity centres and primary healthcare centres, but is also used in paediatric diabetes clinics and other places performing oral glucose tolerance testing (OGTT).

OGTT and measurement of HbA1c can also be used to diagnose diabetes. The use of HbA1c in diagnostics in Sweden can be reviewed in a publication by Lilja *et al.* [13].

7.1. CGM

There are two types of continuous glucose monitoring meters available; real time CGM (rtCGM) and intermittent scanning CGM (isCGM). Users of CGM still need a glucose meter on certain occasions, such as at hypoglycaemia, when the glucose level fluctuates fast (the glucose level in the interstitial fluid does not reflect the level in blood at rapid changes), and if the values from the CGM does not match how the person with diabetes feels.

isCGM is calibrated from the factory and no further calibration by the user is needed. Some rtCGM systems are calibrated from the factory, but the rest of them should be calibrated by the user according to the manufacturer's instructions. Calibration should be performed using results from capillary glucose values measured on a glucose meter. If calibration is not performed, or if a glucose meter with low accuracy is used, the results from the rtCGM system will not be trustworthy. Note that the measurements from both the glucose meter and the rtCGM system have a certain degree of uncertainty; the less the uncertainty per system, the less the total error. Thus, choosing a glucose meter with as high an accuracy as possible (quality level Silver) will be advantageous.

A rtCGM connected to an insulin pump is quite common in insulin-treated diabetes. Certain glucose meters can be connected to the pump, enabling automatic transfer of results from the glucose meter to the pump. If possible, choose one of these meters.

7.2. Gestational diabetes

The previous Swedish national consensus has lacked the clinical limit for gestational diabetes. The Swedish National Board of Health and Welfare recommends the following limits: fP-Glucose ≥5.1 mmol/L, P-Glucose (1 hour, 75 g OGTT) ≥10.0 mmol/L and P-Glucose (2 hours, 75 g OGTT) ≥8.5 mmol/L [14]. The limits follow the recommendations of WHO [15] and the HAPO Study (The Hyperglycemia and Adverse Pregnancy Outcome Study) [16, 17]. It is, however, not completely clear whether the WHO recommendations for sample treatment were strictly followed in the studies that formed the basis for the limits recommendation. The Swedish National Board of Health and Welfare has not set any limits regarding glucose concentrations in capillary samples. The Swedish Association of Diabetology is currently discussing the issue of diagnostics in gestational diabetes as well as the use of venous or capillary sampling for diagnosis of diabetes.

8. Measurements when monitoring diabetes; quality level Bronze

Glucose measurements used for monitoring patients with known diabetes usually lack routines for verifying whether the quality goals have been met by the individual glucose meters. Several of the glucose meters have been evaluated by SKUP (Scandinavian evaluation of laboratory equipment for point of care testing). SKUP evaluations show whether the evaluated meters, at the time of the evaluation, fulfil the quality goals. The evaluation reports are published on www.skup.org.

The groups of patients who require a higher analytical quality than that at the Bronze level are presented in chapter 7.

8.1. Annual check of the measurement quality of glucose meters

We recommend that patients with diabetes compare the results of their glucose meters with the results of the instrument in their diabetes centre at least once a year. At the check-up, the patient should perform the measurement on their meter themselves to enable detection of any handling errors. The instrument at the diabetes centre should be quality-controlled and any handling errors by the patient, such as use of outdated test strips, should be checked.

We recommend that when results exceed ±20% from the results achieved on the instrument in the diabetes centre, the glucose meter should be replaced because the analytical quality is not satisfactory. Recommended approach for the annual check is as follows:

- Compare the results achieved by the patient on his/her glucose meter to the results achieved by the diabetes nurse on the instrument in the diabetes centre. The difference between the results should not exceed ±20%.
- If the deviation is greater, the patient should take another sample and perform a second measurement.
- If the second result also deviates more than ±20%, the patient should be given a new glucose meter.

The limit ±20% includes the glucose meter error (max ±15%, quality level Bronze) and the measurement error of the instrument in the diabetes centre.

9. References

1. JCTLM www.bipm.org/jctlm/

2. ISO 15197:2013 www.iso.org/iso/catalogue_detail?csnumber=54976

3. NPU database www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/

4. Guidance of healthcare in the Swedish counties www.vardhandboken.se

5. Westgard data base www.westgard.com/biodatabase1.htm

6. Chan AYW, Swaminathan R & Cockram CS. Effectiveness of sodium fluoride as a preservative of glucose in blood. Clin Chem. 1989; 35(2): 315-317.

7. Uchida K, Matuse R, Toyoda E, Okuda S & Tomita S. A new method of inhibiting glycolysis in blood samples. Clin Chem Acta. 1988; 172: 101-108.

8. Ridefelt P, Åkerfeldt T & Helmersson-Karlqvist J. Increased plasma glucose levels after change of recommendation from NaF to citrate blood collection tubes. Clin Biochem. 2014; 47: 625-628.

9. Norman M & Jones I. The shift from fluoride/oxalate to acid citrate/fluoride blood collection tubes for glucose testing – the impact upon patient results. Clin Biochem. 2014; 47: 683-685.

10. Dimeski G, Yow KS & Brown NN. What is the most suitable blood collection tube for glucose estimation? Ann Clin Biochem. 2015; 52: 270-275.

11. Gambino R & Bruns DE. Stabilization of glucose in blood samples: out with the old, in with the new. Clin Chem Lab Med. 2013; 51: 1883-1885.

12. WHO classification of diabetes mellitus www.staff.ncl.ac.uk/philip.home/who_dmc.htm#Diagnosis

13. Lilja M, Jansson S, Alvarsson M, Aldrimer M, Nordin G & Attvall S. HbA1c blir kompletterande metod för diagnostik av diabetes – samordnat införande i Sverige januari 2014. Läkartidningen. 2013; 110: 1-4.

14. The Swedish National Board of Health and Welfare www.socialstyrelsen.se/publikationer2015/2015-6-52

15. WHO. Diagnostic Criteria and Classification of Hyperglycaemia First Detected in Pregnancy. Geneva: World Health Organisation, 2013 Contract No.: WHO/NMH/MND/13. www.who.int/diabetes/publications/Hyperglycaemia_In_Pregnancy/en/

16. Croustan DR, Lowe LP, Metzger BE & Dyer AR. The hyperglycemia and adverse pregnancy outcome (HAPO) study: Paving the way for new diagnostic criteria for GDM. Am J Obstet Gynecol. 2010; 202(6): 654.e1-654.e6.

17. Metzger BE for the International Association of Diabetes and Pregnancy Study Groups Consensus Panel. Recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diab Care. 2010; 33(3): 676-682.

18. Le Roux CW, Wilkinson SD, Pavitt DV, Muller BR & Alaghband-Zadeh J. A new antiglycolytic agent. Ann Clin Biochem. 2004; 41(Pt 1): 43-46.

19. Boyanton Jr BL & Blick KE. Stability studies of twenty-four analytes in human plasma and serum. Clin Chem. 2002; 48(12): 2242-2247.

20. WHO. Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia. Report of a WHO/IDF consultation, Editors: WHO; IDF. 2006. ISBN: 978 92 4 159493 6.

21. Carstensen B, Lindström J, Sundvall J, Borch-Johnsen K & Tuomilehto J; DPS Study Group. Measurement of blood glucose: comparison between different types of specimens. Ann Clin Biochem. 2008; 45(2): 140-148.

22. DSAM Klinisk vejledning for almen praksis. Type 2-diabetes - et metabolisk syndrom. 2012 2nd Ed. ISBN: 978-87-92462-69-5.

23. Stahl M, Brandslund I, Jørgensen LG, Hyltoft Petersen P, Borch-Johnsen K & de Fine Olivarius N. Can capillary whole blood glucose and venous plasma glucose measurements be used interchangeably in diagnosis of diabetes mellitus? Scand J Clin Lab Invest. 2002; 62(2): 159-166.

24. Kruijshoop M, Feskens EJ, Blaak EE & de Bruin TW. Validation of capillary glucose measurements to detect glucose intolerance or type 2 diabetes mellitus in the general population. Clin Chim Acta. 2004; 341: 33-40.

25. Haeckel R, Raber R & Wosniok W. Prevalence-dependent decision limits for the early detection of type 2 diabetes mellitus in venous blood, venous plasma and capillary blood during glucose challenge. Clin Chem Lab Med. 2006; 44(12): 1462-1471.

Address any questions to Equalis:
Phone. +46 18 490 31 00 E-mail: info@equalis.se

Attachment

This attachment has, in the most part, been written by people involved in clinical chemistry, and is primarily addressed to laboratories.

Comment 1

All imprecision results must be followed by a description of the calculations and the pre-analytical and analytical circumstances. If the imprecision for vP-Glucose and cP-Glucose is calculated as we have suggested, the numbers will not be completely comparable.

For vP-Glucose “the intra-laboratory imprecision” is the imprecision normally seen when looking at the internal quality control statistics. This imprecision is affected by performing measurements on different days, by different people, using different lot numbers of reagents and calibrators and perhaps using different instruments. An internal quality control sample should be measured at least once every day the instrument is used. The calculation should be done at least every month and should include the last six months.

For cP-Glucose the imprecision is calculated as the mean of duplicate samples. This imprecision is affected by sampling errors and by measuring different glucose levels. However, it is not affected by performing measurements on different days, by different people, using several lot numbers of cuvettes or test strips, or using different instruments.

Comment 2

The International Committee of Weights and Measures (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) are cooperating in the Joint Committee for Traceability in Laboratory Medicine (JCTLM). The reference laboratories that have reference methods for glucose in serum or plasma are listed in a JCTLM data base [1]; the methods are ID/GC/MS (isotope dilution/gas chromatography/mass spectrometry) and spectrophotometric hexokinase. A common comparison method, Yellow Springs Instrument (YSI), is often used by global suppliers during product development. This method is not recommended as a reference method by JCTLM.

The systematic error (bias) with a certain measurement routine can be evaluated by using certified reference materials or results from external quality assurance programs as long as these values are set by a reference method that has a low degree of uncertainty.

The bias shown by a laboratory should comprise a certain time span; we recommend follow-up at least every month and that the bias should include data from at least a six-month period.

In the Equalis quality assessment program for general clinical chemistry, the quality goal for P-Glucose is ±10%. In the participant reports, the biases from the total mean values for the last ten rounds are shown, which corresponds to the rounds from one year.

In the Equalis quality assessment program for PoC analysis (Hb:Glucose:CRP), the quality goal for P-Glucose is ±15%. Also here the biases for the last ten rounds (one year) are presented in a non-conformity graph.

Comment 3

We recommend citrated blood collection tubes. Be aware that if collection tubes with only sodium fluoride additive are used, this additive does not reduce the glucose consumption during the first hour after sampling [18]. There is no difference between the glucose concentrations in serum and glucose concentrations in plasma with sodium fluoride, if the cells are separated within one hour. A more accurate glucose concentration is obtained by measuring in serum separated from the cells within 30 minutes after sampling than by measuring glucose in plasma - with or without the addition of sodium fluoride - that has been separated from the cells within 120 minutes after sampling.

Glucose is more stable in non-centrifuged serum tubes with gel than in non-centrifuged lithium heparin tubes with gel [19]. In serum that has been separated from the cells, the glucose is quite stable and,

when stored at room temperature, no differences are seen in the glucose concentrations over a two-day period [19].

Comment 4

Venous sampling and measurement of plasma glucose should be the standard method for measuring glucose in blood [20]. Capillary sampling and PoC analysis can be an option when quick results are required, but capillary sampling does have several drawbacks.

The measurement uncertainty is usually greater with PoC instruments than with the instruments in clinical chemistry laboratories [21]. In Denmark, the Association of General Practitioners recommends venous sampling and suggests that with capillary sampling, if the results are to be used in the diagnosis of diabetes, two separate samples should be taken and the mean value calculated [22].

Capillary sampling gives a higher uncertainty than venous sampling; this depends on factors such as the mixing of tissue fluid and difficulties performing a correct sampling procedure. Nevertheless, the Swedish healthcare services continue to use capillary sampling in many situations for diagnostic purposes, e.g. in glucose tolerance testing. A switch to venous sampling should be prioritised. According to Stahl [23] there is a poor correlation between fasting blood and plasma glucose; the same results are not achieved when measuring samples from the same individual. Equalis is calling for evidence on how to ensure a correct diabetes diagnosis when using capillary sampling and PoC equipment. If the diagnosis is made using capillary samples and glucose tolerance testing, only some of the individuals will be correctly diagnosed compared to those diagnosed using venous plasma samples [24]. According to Haeckel [25] you can use capillary samples, but the limits set by WHO, particularly for capillary samples, are too high. According to both Kruijshoop and Haeckel [24, 25] the limit at two hours' glucose tolerance testing should be higher for capillary blood than for venous plasma.