Evaluation and selection of POCT

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Why do not all use POCT?

- The benefits of POCT is questioned
- Regulations by local authorities
- Cost limitations

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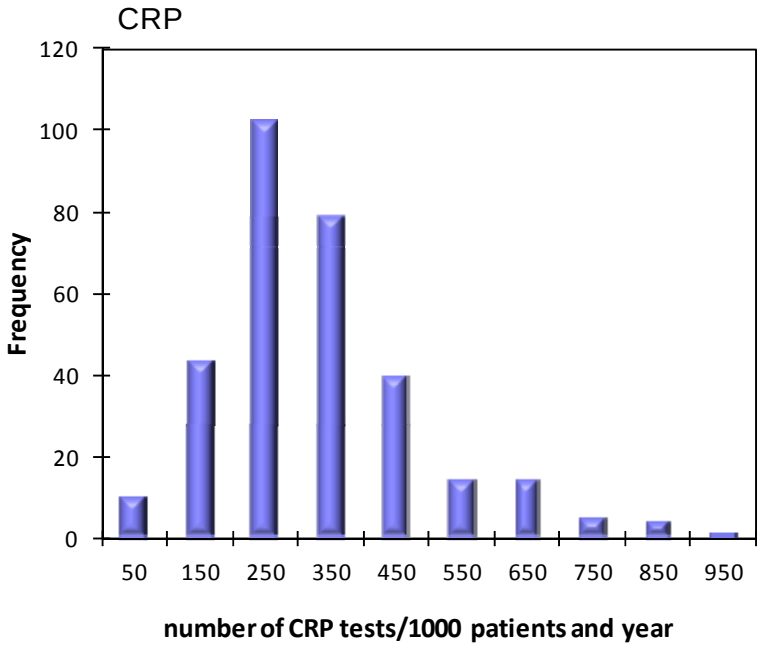
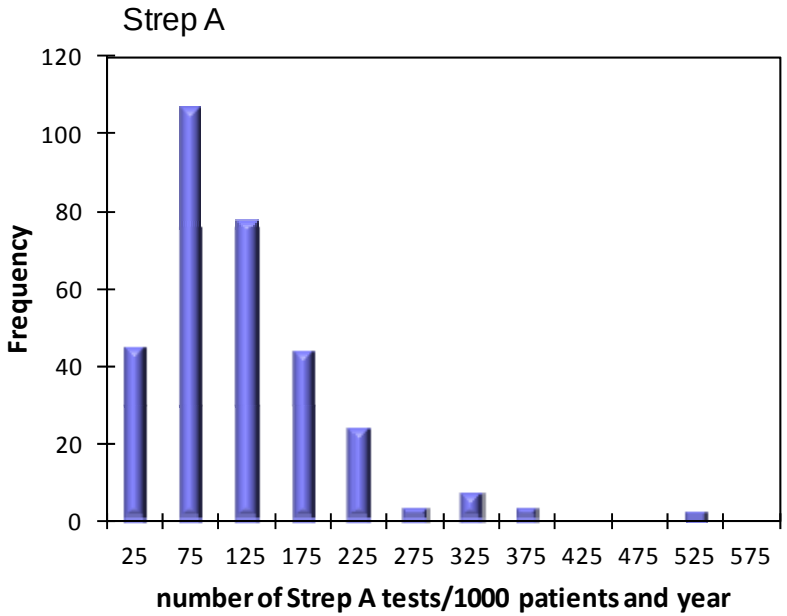
Variation of POCT use in 300 Primary Health Care centers in Sweden





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Possible explanations for the variation

	Frequency of Strep A tests	Frequency of CRP tests
Private vs publicly owned PHC	-ns-	-ns-
Short vs long distance to hospital	-ns-	-ns-
Participation in EQA vs non participation	-ns-	-ns-
Accreditated vs non-accreditated laboratory	-ns-	-ns-
Biotechnologist vs non-biotechnologists as performer of POCT	-ns-	-ns-
Small PHC versus large PHC	-ns-	-ns-
Regional differences n.o.s	yes	yes

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Other explanations for the variation?

- Different ”case-mix” among the patients
  - we did not ask about that
- Individual decisions by local doctors or organisations
  - We did not ask for ”local enthusiasts”

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What might reason be for ”local enthusiasm” to use POCT?

1. Simplify logistics
2. Improve decision making
3. Reduce prescription of antibiotics
4. Improve patient confidence
5. Back up procedure in case of emergencies
6. Convincing distributers of POCT devices

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What should be considered

- Is the analytical quality good enough?
- Are internal and external quality assessment available?

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What also should be considered

- Do we have a freezer, if necessary for reagents?
- Do we have the necessary work space?
- How easy is the device to use? Education?
- What is the connectivity and communication possibilities with other systems?
- Do the distributor has the necessary service and maintenance organisation?
- What will the total cost be (including consumables, IQA, EQA, education)?

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POCT results are like any other laboratory results

- Measurement results must be stored in the records
- Information about the method used shall also be stored
  - when data are collected year 2025 for a study, it is not unusable to find that it is a “POCT result”. The method information will be needed!
  - Distinguish between “what is measured” (e.g CRP in plasma) and “how it is measured” (e.g. “Afinion CRP”) in the database!

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How to search the best device for POCT?

- (Test all available devices your self)
- Get information from manufacturers and distributors
- Take part of evaluations and scientific reports

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Understanding evaluation reports

What is the evaluated device

- Coaguchek or Coaguchek XS?
- DCA 2000 or DCA Vantage?
- Which version or model of the device has been evaluated?

Many synonyms for the same device:

1. Microsemi
2. ABX Microsemi
3. Microsemi CRP
4. Horiba Microsemi

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Understanding the evaluation reports

What do the device measure?

- ”the intended measurand”
  - do the glucometer measure the concentration of glucose in blood or plasma?
  - do the device measure “prothrombin complex (INR)” or “something similar”?

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Understanding evaluation reports

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Understanding the evaluation

What is the reference and comparison method used for an evaluation?

- Plasma or whole blood glucose with a hexokinase method,
  ID-MS, or YSI glucose electrode?
- How is the quality of comparison method checked?

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Independent and non-biased evaluations

Scandinavian evaluation of laboratory equipment for primary health care

SKandinavisk Utprövning av laboratorieutrustning för Primärvården

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- Activity started 1997
- Collaboration between national EQA organisations in Norway, Sweden and Denmark
- Provide independent evaluations of high quality for POCT on the Scandinavian market
- Staff from the national organisations
  - Noklus (Norway) 4 persons incl secretariate
  - Equalis (Sweden) 2 persons
  - DAK-E (Denmark) 1 person
- Cost of staff mainly covered by each organisation
- The cost of evaluations is covered by the requester of an evaluation

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The expected information from a SKUP evaluation

- Is the measurement quality good enough?
- Is the device robust?
- Is the device easy to use?
- What is the time and work load for each test?

- (Not covered by the SKUP evaluation:

  What is the cost per test?)

The SKUP evaluation process

1. A request from a distributer/manufacturer
2. Adoption of the SKUP standard protocol, and agreement with the requester on the protocol and quality goals
3. Evaluation, data collection
4. Statistics, production of a report
5. Internal and external (the requesters) review of the report
6. Publication of the report, if the products appears on the Scandinavian market

No publication bias!

The evaluation

- At a hospital laboratory, with trained staff (standardized conditions)
- At two PHC, with the end users
- During the evaluation all data are confidential
- The requester (distributer or manufacturer) are not involved during the evaluation process

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The statistics and the report

- All data are treated according to the agreed protocol, including e.g. exclusion of outliers
- The results are compared with in advanced agreed quality goals.
- The results discussed and conclusions made

- Two examples

Eurolyser smart 700/340

C-reactive protein (CRP)
A system for measurement of CRP
manufactured by Eurolyser Diagnostica GmbH, Austria

Report from the evaluation SKUP/2013/92

organised by SKUP at the request of

HaemoMedtec ApS, Denmark

Ilerod, Phone +45 4829 4176

1. Summary

Background

The measurement of C-reactive protein (CRP) with the Eurolyser smart 700/340 instrument has previously been evaluated by SKUP (SKUP/2011/70*). That evaluation was performed in a hospital laboratory and included capillary samples and control materials. Since that evaluation, the lid on the cuvettes has been reconstructed to include a sample collector device. The supplier for Eurolyser in Denmark, HaemoMedtec, has requested this evaluation.

The aim of the evaluation was to

- examine the analytical quality of Eurolyser smart CRP when measuring venous whole blood samples in a hospital laboratory
- examine the analytical quality of Eurolyser smart CRP when measuring capillary blood samples at two primary health care centres
- evaluate the Eurolyser control material
- evaluate the user-friendliness of Eurolyser smart CRP at two primary health care centres

Materials and methods

Three Eurolyser smart instruments and three lots of Eurolyser test cuvettes were used. 100 venous whole blood EDTA patient samples in a hospital laboratory were included as well as capillary samples from 86 patients in two primary health care centres. In addition two levels of control materials were analysed.

HaemoMedtec ApS, Denmark

SKUP Scandinavian evaluation of laboratory equipment for primary health care

Results

Capillary samples at two primary health care centres: A coefficient of variation (CV) <10,0% was obtained for capillary blood CRP concentrations ≥3,2 mg/L in both primary health care centres, n=62. For CRP concentrations <3,2 mg/L the CV was higher than 10%. (For the mean concentrations 4,4 – 9,0 – 34,1 and 38,6 mg/L the CV% was 15,4-8,3-8,6 and 8,3% and bias was –17%, –11,2%, –4,8% and –8,6%). 96,4% of the sample results fulfilled the quality goal of a deviation less than ±1 mg/L or <26% from the comparison method.

Venous EDTA samples in a hospital laboratory: The CV and the upper confidence interval for CV were <10,0% in the range CRP 1,8 to 281 mg/L. The bias was negative for concentrations <16,7 mg/L and positive for higher concentrations. 98% of the results had a deviation less than ±1,0 mg/L or <26% from the comparison method.

User-friendliness: The quick manual, the time factors and the operation were rated as satisfactory by the four evaluators. All evaluators had difficulties with the *control material*, which had a CV <10,0% in the hospital laboratory evaluation and ≥20% in the two primary health care centres.

Technical errors: There were in total three technical errors.

organised by SKUP at the request of

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Table 14 Rating of the information in the manual / insert

Information in the manual / insert	Ratings	Red	Yellow	Green
General impression	G, G	Unsatisfactory	Intermediate	Satisfactory
Table of contents	G, G	Unsatisfactory	Intermediate	Satisfactory
Preparations / Pre-analytic procedure	G, G	Unsatisfactory	Intermediate	Satisfactory
Specimen collection	G, G	Unsatisfactory	Intermediate	Satisfactory
Measurement / Reading	G, G	Unsatisfactory	Intermediate	Satisfactory
Measurement principle	G, G	Unsatisfactory	Intermediate	Satisfactory
Sources of error	G, G	Unsatisfactory	Intermediate	Satisfactory
Fault-tracing / Troubleshooting	G, G	Unsatisfactory	Intermediate	Satisfactory
Keyword index	R*, G**	Unsatisfactory	Intermediate	Satisfactory
Readability / Clarity of presentation	G, G	Unsatisfactory	Intermediate	Satisfactory
Available insert in Danish, Norwegian, Swedish	G, G	Unsatisfactory	Intermediate	Satisfactory
Others comments about information in the manual / insert (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating for the information in the manual				Satisfactory

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Table 16. Rating of quality control possibilities

Quality control	Ratings*	Red	Yellow	Green
Internal quality control	Y* , -	Un-satisfactory	Intermediate	Satisfactory
External quality control	- , -	Un-satisfactory	Intermediate	Satisfactory
Stability of quality control material, unopened	G , -	<3 months	3 to5 months	>5 months
Stability of quality control material, opened	G, -	≤1 day	2 to 6 days	>6 days or disposable
Storage conditions for quality control materials, unopened	Y, -	−20°C	+2 to +8°C	+15 to +30°C
Storage conditions for quality control materials, opened	Y, -	−20°C	+2 to +8°C	+15 to +30°C
Usefulness of the quality control	R**, -	Unsatisfactory	Intermediate	Satisfactory
Other comments about quality control (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of quality control			Intermediate	

*The internal quality control material is impossible to see, when it is sucked up. Label on the control material was not attached to the bottle. **Primary health care centre 2 was unhappy with the control material results during the evaluation and contacted SKUP. They had 'no further' comments after the evaluation.

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Conclusion

The Eurolyser smart CRP fulfilled the quality goals for imprecision with venous EDTA whole blood samples in the hospital laboratory and with capillary CRP results above 3,2 mg/L in the primary health care centres. CRP concentrations <3,2 mg/L do not fulfil the quality goal. The quality goal for accuracy was fulfilled with venous EDTA samples in the hospital evaluation and with capillary samples at both primary health care centres.

User-friendliness: Both primary health care centres found the instrument easy to use. The control materials were not useful in the primary health care centres as the CV was ≥20%.

The fraction of technical errors: was less than 1,0%

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It is essential to know that the QC has been performed with the integrated capillary on the CRP test cuvette. This capillary has been designed to aspirate whole blood; the operator clearly can see when the capillary is filled with the red blood – hence exactly 5µl sample are aspirated every time a test is performed.

However, when using the transparent control liquid it may be difficult to judge if the capillary has aspirated the total amount of the required 5µl QC material – which can lead to high variations when performing control measurements.

Eurolyser has changed the IFU for the control measurement. It is now requested that the control material is aspirated with a 5 µl pipette. This eliminates the risk of variations in the quantity of the QC material used in the QC measurement.

Internal evaluations and the feedback from our customers have demonstrated that this improvement leads to QC measurements resulting in CV values below 3%.

Sincerely

Gerhard Bonecker
CEO, Eurolyser Diagnostica GmbH

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Accu-Chek Aviva

Meter and test strips
designed for glucose self-measurement
and measurements by health care professionals
Manufactured by Roche Diagnostics GmbH

Report from the evaluation SKUP/2013/98*

organised by SKUP at the request of Roche Diagnostics Scandinavia AB

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Definition of the device and of what is measured

4.1 Definition of the measurand

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Union of Pure and Applied Chemistry (IUPAC) work in a joint Committee on Nomenclature, Properties and Units (C-NPU). The descriptions of clinical laboratory tests are listed in the "NPU database" [6]. In the database the full name is given for the measurand together with which unit the result should be reported in. In this report the term "glucose" will be used for the measurand. Glucose concentrations will be given in mmol/L.

4.2 The evaluated measurement system, Accu-Chek Aviva

Accu-Chek Aviva is a blood glucose monitoring system based on electrochemical technology. The system consists of the Accu-Chek Aviva meter (figure 1) and dry reagent test strips. The system is designed for blood glucose testing performed by persons with diabetes or by health care professionals. Fresh, whole blood (capillary, venous, arterial or neonatal blood) is required to perform a blood glucose test. Accu-Chek Aviva reports plasma glucose values. The system is calibrated with a black snap-in code chip already placed in the device. The black code chip works for all Accu-Chek Aviva test strips and shall be left in place even when the user receives code chips with other colours and numbers in new packages of test strips. The test strips are packed in a plastic bottle with flip-top closure and desiccant. The system requires a blood volume of 0,6 µL. The blood is automatically

Figure 1. Accu-Chek Aviva meter

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The comparison method

4.3.1 The selected comparison method in this evaluation

The selected comparison method in this evaluation is the routine method for quantitative determination of glucose in human serum and plasma in the laboratory at Haraldsplass Diaconal Hospital (HDH) in Bergen. The method is a photometric glucose hexokinase method. The method is implemented on Cobas 6000 System from Roche Diagnostics. The laboratory can document good analytical quality of the method through participation in an external analytical quality assessment program.

4.3.2 Verification of the analytical quality of the comparison method

Precision

The repeatability of the comparison method was estimated from duplicate measurements of capillary patient samples.

Trueness

To document the trueness of the comparison method, the standard reference material (SRM 965b) from National Institute of Standards & Technology, NIST, was used [7]. The SRM 965b consists of ampoules with human serum with certified concentrations of glucose at four levels, with given uncertainties.

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Repeatability

Table 7. Repeatability, Accu-Chek Aviva. Results achieved with capillary blood samples

Glucose interval, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV(90% CI) %
<7	23	0	5,5	2,8 (2,2 — 3,8)
7 – 10	30	0	8,6	4,2 (3,5 — 5,3)
>10	37	1*	14,0	4,5 (3,8 — 5,7)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers.

* One statistical outlier (ID 33) according to Burnett's model

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Accuracy

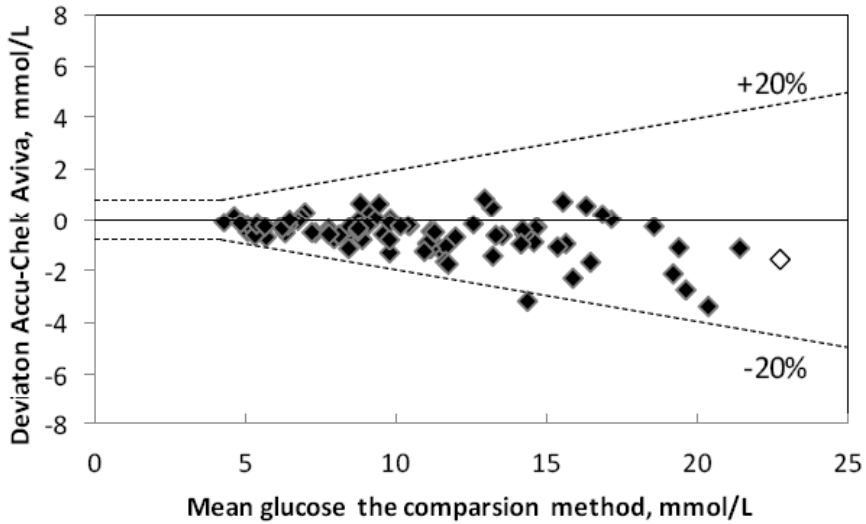

Figure 2. Accuracy. Accu-Chek Aviva with three test strip lots under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Aviva and the mean value of the duplicate results on the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2003 (within ±0,83 mmol/L for glucose concentrations <4,2 mmol/L and within ±20% for glucose concentrations ≥4,2 mmol/L). ID 33, a statistical outlier in the calculation of repeatability on Accu-Chek Aviva, is shown with an open symbol. Number of results (n) = 90.

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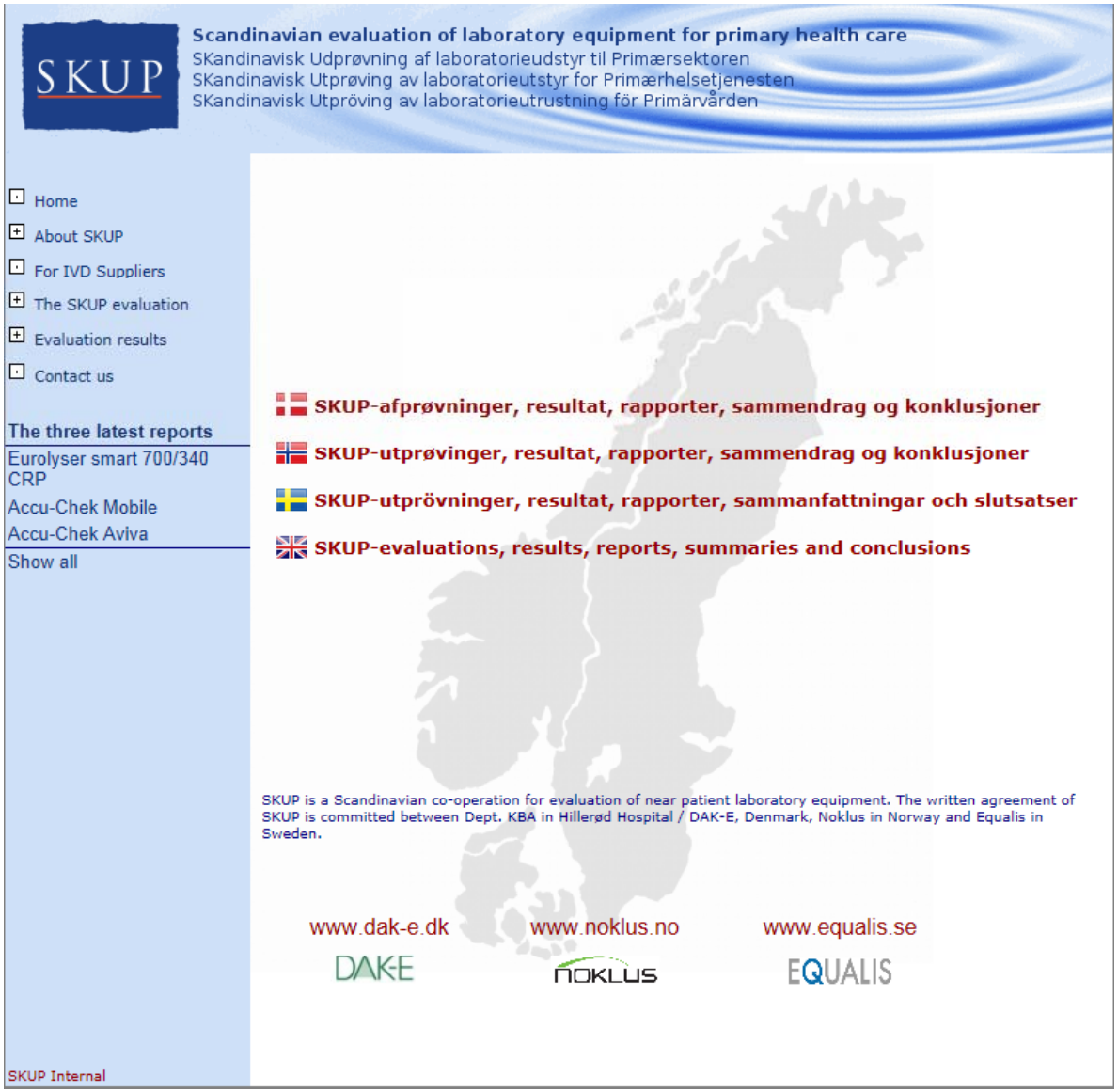

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Thank you!

Questions?