

1.1 DEKS

DEKS is the Danish institute for external quality assurance for laboratories in the health sector ("Dansk Institut for Ekstern Kvalitetssikring for Laboratorier i Sundhedssektoren").

DEKS is a nonprofit institute. DEKS' purpose is to increase patient safety through quality assurance of laboratory medical examinations, which is expected to lead to increased reliability of these examinations.

1.1.1 Participants

Participants in EQA-programs are from the diagnostic specialties clinical biochemistry, clinical immunology, clinical microbiology, clinical physiology and general practice. DEKS is open to assist other laboratory medical specialties as needed. Manufacturers of medical equipment for in vitro diagnostics can also participate, provided that the information from DEKS is used for quality assessment of products and not for marketing purposes.

1.1.2 DEKS' professional advisory group

The advisory group provides advice on health professional issues in relation to DEKS' services.

The advisory group consists of a chairman who is the center director of the Diagnostic Center at Rigshospitalet, a chief physician appointed by the clinic management at the clinical biochemistry department, Rigshospitalet, two members appointed by the Danish Society for Clinical Biochemistry, a member appointed by the Danish Society for Clinical Immunology, and a member appointed by the Danish Society for Clinical Microbiology.

The head of DEKS attends all meetings and provides secretarial services. If other laboratory medical specialties wish to make use of DEKS, it is possible to get a seat in the advisory group.

1.1.3 Experts

For many EQA programs or groups of programs, one or more professionally competent experts have been appointed. The experts guide both DEKS and participants in the programs, e.g. in the form of comments in the reports. DEKS is responsible for the work performed by the experts. If you wish to become an expert, contact DEKS.

1.1.4 Subcontractors

Subcontractors can be used to carry out different parts of EQA-programs. When a subcontractor is used the subcontractor is competent and DEKS is responsible for the work.

Subcontracted work:

- Collection of biological material for the production of EQA-materials.
- Determination of reference (method) value for the EQA-programs using reference (method) value as target value.

1.2 SKUP

SKUP is the Scandinavian evaluation of laboratory equipment for patient-related analysis (**S**kandinavisk **K**valitetssikring af laboratorieudstyr til **p**atientnære analyser). SKUP is a Scandinavian cooperation with the purpose of improving the quality of patient-related analysis as well as ensuring that unfit analysis equipment is not marketed in Scandinavia. SKUP delivers objective and supplier-independent evaluations of laboratory equipment.

1.2.1 SKUP evaluation

If you are going to buy new laboratory equipment for point of care testing, it is recommended that you request a SKUP evaluation from the suppliers. If a SKUP evaluation is not already available, it can be specified in the purchase offer, that a SKUP evaluation should be performed within a given time frame.

With a SKUP evaluation, you can e.g. reduce your workload with verification of POCT equipment and get an independent assessment of analysis quality and usability.

1.2.2 Contact to SKUP

SKUP is handled by DEKS in Denmark, by NOKLUS in Norway and by Equalis in Sweden.

Learn more about SKUP and evaluation reports at www.skup.org. For more information, contact Dår Kur, SKUP coordinator in Denmark, by email daar.kur@deks.dk.

1.3 External quality assurance for primary health care

It is recommended that devices for near patient testing (POCT) are registered with external quality assurance to ensure comparable patient results across equipment type and location. DEKS offers a number of external quality assurance programs for POCT, which are also suitable for use in primary health care; general practice and municipal emergency functions. On requests for EQA-programs, DEKS appreciates collaborations with local laboratory consultants and others responsible for the quality assurance of POCT regarding e.g number of distributions, samples and components. At www.deks.dk you can find more information about external quality assurance programs for POCT in primary health care.

1.4 E-learning

DEKS offers e-learning for POCT. The e-learning is aimed at clinical staff in both primary health care and at hospitals.

The e-learning is component-specific and is currently offered for C-reactive protein (CRP) and glucose.

E-learning for hemoglobin, leucocytes, uric acid and quality assessment of POCT is under development.

You can find more information on DEKS e-learning at www.deks.dk/e-learning/

1.5 DEKS on the Internet

Stay updated on the DEKS general news page.

The news page includes package inserts useful user guides.

You find all quality assurance programs and materials offered by DEKS at www.deksonline.dk. Here you can order EQA-programs and materials, report results, download reports for Danish programs and pick up the participant-certificate for your laboratory. The electronic reports are also available at www.deksonline.dk for a minimum of 5 years.

Each laboratory has a DEKS-responsible contact person, who can setup users and assign user-rights in DEKSONline.

1.6 'Continued participation' applies to all quality assurance programs

Participation in a quality assurance program continues until it is cancelled with DEKS. This is called 'continued participation'.

When you enrol in a quality assurance program via DEKS, your participation runs until you actively cancel your subscription.

DEKS notifies all DEKS-responsible contact persons prior to every new enrolment period that it is time to make potential updates/changes. The notification will be sent to the e-mail address provided to DEKS by the laboratory.

If you wish to cancel your participation in a quality assurance program during the year, please see section 1.10

'Continued participation' always follow the program year/period of the supplier.

You subscribe to quality assurance programs online via deksonline.dk. See section 1.8 for a guide to ordering online.

1.6.1 Changes in quality assurance programs

If DEKS is informed about changes to a quality assurance program, the changes will be stated on www.deksonline.dk at the page "subscriptions/continued participation". If there are substantial changes in the number of rounds, the number of components, or changes in the sample material, DEKS will directly notify the laboratory contact persons.

If a quality assurance program is cancelled, continued participation in the program automatically stops and DEKS will contact the laboratories.

1.7 Ordering materials

All materials are ordered online through www.deksonline.dk. You find a ordering guide in section 1.8.

1.7.1 Materials, annual and summer distribution

DEKS carries out an annual main distribution of calibration and control materials. When an order is placed to DEKS online no later than the 30th of November, a **discount of no shipping costs** within Denmark is obtained. The ordered calibrators and

control materials are distributed to the laboratories in the weeks 1-6.

Shipment from abroad is expensive, so to decrease shipment costs, DEKS attempts to gather orders for certified reference materials and microbiological calibration and reference materials for distribution twice a year.

When ordering before the 30th of November for the annual distribution and before 1st of May for the summer distribution, the shipment from abroad is free. Please note that this does not apply to quality assurance programs.

1.7.2 Ordering materials during the year

Additional deliveries of calibration and control materials are sent out during the year on Tuesdays. Orders for in stock materials must be placed no later than Monday in the same week as delivery is required. Orders requested with delivery 'as fast as possible' or with shipping other weekdays than Tuesday, are called urgent deliveries. For urgent deliveries an "urgent" fee is charged, see section 1.11.1.

1.8 Guide to online ordering

1.8.1 Log on to www.deksonline.dk

To place orders you need a personal login for www.deksonline.dk. Each laboratory has a DEKS-responsible contact person, who assigns user-access and user-rights such as permission to place orders.

1.8.2 Annual ordering of materials based on last year's orders (reordering)

Click the 'Order' and 'Annual order' to start the re-ordering of the materials, you would like to order.

1.8.3 Find or order a product (programs and materials)

To open the page, where it is possible to search for e.g. product name, program code or a component, find the menu 'Order' and choose 'Search for products'.

1.8.4 To finish the order

When your chosen product is placed in the basket, and the required order information is filled in, the order can be processed. Go through the order

and close it by clicking 'Approve and send order'. You will receive an e-mail with an order confirmation.

1.8.5 Are you looking for a quality assurance program?

If you are searching for an appropriate quality assurance program, you are more than welcome to contact DEKS. We will do all we can to match you with a quality assurance program that covers your requirements.

1.9 Cancellation of participation

It applies to all quality assurance programs that participation must be actively cancelled. When program-participation is not cancelled, you will automatically be re-enrolled in the program for the following year, due to 'continued participation' – see section 1.6.

When you cancel the participation in a program with rounds left the principle of cancellation of participation after program-start applies, see 1.10.1

1.10 Program and material prices

In 2024, the DEKS programs are subject to minor price increases. due to price increases on the materials used for the EQA programmes. Program prices on the foreign programs follow a potential price change from the foreign collaborators. Please note that for some foreign programs, only a tentative price is known. If the final price deviates greatly from the list price, the difference is either credited or debited by DEKS.

Shipment from foreign collaborators is often expensive. For some quality assurance programs the shipment costs for 2024 are not known prior to ordering. In such cases the price note will state that shipment is not included in the price.

1.10.1 Ordering and cancellation after program start

In most cases, it is possible to participate in the listed quality assurance programs, after one or more rounds have taken place. For a few programs, the price is reduced correspondingly. When cancelling participation in quality assurance programs after one or more rounds have taken place, crediting is only possible for a few programs.

1.11 Shipment prices

An estimated price is given for shipping costs and courier shipment of quality assurance programs and materials. If the price varies significantly, a price adjustment will be carried out when the actual price is known.

1.11.1 Shipment costs in Denmark

- Shipment: 300 DKK + VAT
- Shipment on dry ice: 1000 DKK + VAT
- For urgent deliveries a fee of 400 DKK + VAT is charged.

See also section 1.7.1 regarding the annual distribution.

1.11.2 Courier and shipment from abroad

- When using courier freight and shipments from abroad a special shipment fee is charged.
- For some foreign programs extra shipment costs can be added to the list price.
- In special situations, courier shipments can be ordered for shipments within Denmark, this is agreed in the individual cases with DEKS

1.11.3 Courier and shipment from the United Kingdom

Due to Brexit and the new EU VAT e-commerce rules, VAT must be paid for all goods imported from countries outside of EU.

No Customs Duty is to be paid on "therapeutic substances from humans" e.g. blood and serum shipped to hospitals, laboratories and institutes. Therefore, samples for external quality assurance (EQA) can be imported without payment of Customs Duty. Unfortunately, EQA-samples distributed as regular shipments are still stopped at customs because the shipping company treats all packages as privat mail - and all privat mail must go through customs processing. This results in prolonged shipping and customs processing fees. To avoid customs processing, DEKS recommends that all samples from the United Kingdom are shipped by courier. Some suppliers ship the samples by courier to DEKS for further distribution and others will ship by courier directly to the Danish laboratories.

1.12 Prices for special tasks

When calculating the price for DEKS' own services and for solving special tasks (e.g. Nordic Reference Interval Project) DEKS uses the following

hourly rates (2024 rate): 650 DKK + VAT for non-academics and 1600 DKK + VAT for academics.

1.13 Payment

Payment deadline is 30 days net cash. Invoicing of the annual order and continued participation is carried out in the beginning of the year. When ordering during the year, the invoice is sent after the enrollment has taken place.

DEKS

GLN number 5798001530781

CVR number DK29190623

EORI number DK190623

VAT number DK29765790

1.14 Receiving packages from DEKS

We request that packages from DEKS are opened upon receipt, even if the contact person stated on the package is not present. Please note that even if it is permissible to send a material at ambient temperature, it often must be placed in the fridge or in the freezer upon receipt. It is usually stated on the package whether the content must be placed in the fridge or in the freezer. It is possible to receive packages from DEKS addressed to a group or a department instead of a specific contact person.

1.15 Extra samples

If your laboratory makes an unexpected finding in an EQA-program, it is to a limited extent possible to require extra samples to clear up the finding. This is only possible for stable materials and while stock lasts.

If your laboratory needs extra samples from previous distributions e.g. for verification of new instruments, this is also possible while stock lasts.

The price for extra samples varies from one supplier to the other and the costs always include shipment and administration fees.

1.16 Handling of reporting of incorrect results

If your laboratory discovers the report of an incorrect result after the external quality assurance report is issued, it is not possible to change the result. It is also not possible to change the result in the historical data in later reports. Wrong reporting should be handled in the quality system of your laboratory. Should DEKS be responsible for the mistake, then of course it will be corrected.

1.17 Returning materials

As a matter of principle DEKS does not take back calibrators and control materials, as it is difficult to document that the materials have not sustained any damage. We aim, however, for a flexible practice in such instances.

1.18 Safety

DEKS assume that recipients of products sold by DEKS, eg. EQA-materials and control materials, take the necessary precautions.

All calibrators and control materials must safely be treated as patient samples which means the materials must be seen as potentially contagious.

This also applies to the materials where blood portions collected from donors have been individually tested and found negative for HIV antibody, HBs antigen, and HCV antibody.

The above mentioned is particularly important for a number of microbiology EQA-programs, including the virus screening programs.

These samples can contain virulent pathogenic organisms, and therefore the shipment is marked UN3373, cf. the ADR-convention.

1.18.1 Product liability

DEKS makes reservations for product liability as a result of infection with HIV, Hepatitis B and Hepatitis C. Furthermore, DEKS does not cover product loss as a result of delayed or failed delivery when delivery is carried out by third party.

1.19 Reports

The reports for DEKS' EQA programs consist of a text report, an overview with a summary of the results from all participants (Summary) and histograms. The reports can be downloaded from deksonline.dk, where they are available for a minimum of 5 years. When there are few participants in a method group the anonymity may be compromised since other participants may know each other.

1.20 Copyright

All written material issued by DEKS is subject to copyright. This includes texts from www.deks.dk. Sections from EQA-reports, "Programmer og Materialer" and "DEKSinformerer" can however be reprinted with source reference. Permission for the use of data, can be granted. Contact DEKS for

further information. There are similar conditions for reports, from foreign EQA-organisations.

1.21 Scientific usage of EQA results from the laboratories

Reported EQA results from various EQA programs are occasionally used in scientific projects and presentations both nationally and internationally. Results are always used in anonymised form, which means results are not attributable to a specific laboratory. Scientific usage of results is carried out with the aim to increase the reliability of results in laboratory medicine and for educational purposes.

1.22 Inquiries to DEKS

Questions concerning programs, suggestions of improvement, or objections to ratings are welcome. We recommend using the online form on the website www.deks.dk or sending an e-mail to deks@deks.dk, but you are also very welcome to call us on +45 3863 4400.

Make sure to state the DEKS number of your laboratory when enquiring.

1.23 Confidentiality

DEKS and DEKS' collaborators treat all data that can be connected to a specific laboratory confidentially and do not pass on information to third parties. It is, however, practical that DEKS can inform individual laboratories about which other laboratories participate in a specific program. In that way DEKS can assist new participants in their choice of program and encourage knowledge sharing among laboratories. This practice has never given cause for concern, which is why DEKS will not collect written consent to use this kind of information in a collegial connection.

If your laboratory object to this practice, please contact DEKS.

DEKS' confidentiality policy can be found at deks.dk/en/about-deks.