

### 1.1 DEKS

DEKS is the Danish institute for external quality assurance for laboratories in the health sector ("danske 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 are expected to lead to increased reliability of these examinations.

#### 1.1.1 Participants

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

#### 1.1.2 DEKS 'professional advisory group (new)

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, a member appointed by the Danish Society for Clinical Microbiology.

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

#### 1.1.3 Experts (new)

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 of the experts. If you want to become an expert, contact DEKS.

### 1.2 SKUP

SKUP - Scandinavian evaluation of laboratory equipment for patient-related analysis (Skandinavisk afprøvning af laboratorieudstyr til patientnære analyser) is a Scandinavian cooperation with the purpose of improving the quality of patient-related analysis and 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 both your buyers and suppliers, and if there is not already a SKUP evaluation, it can be specified in the 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 / validation 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 read reports from evaluations at [www.skup.org](http://www.skup.org). It is also possible to contact Dår Kur (SKUP in Denmark) by email [daar.kur@deks.dk](mailto:daar.kur@deks.dk) for more information.

### 1.3 External quality assurance for the primary care services (new)

It is recommended that patient-centered analyzes (POCT analyzes) be registered with external quality assurance to ensure comparable patient results across equipment and locations. DEKS offers a number of external quality assurance programs for POCT analyzes, which are also suitable for use in the primary care services; general practice and municipal emergency functions. DEKS is happy to collaborate with the local laboratory consultants and others who are responsible for the quality assurance of POCT analyzes on requests for external quality assurance programs in relation to, for example, the number of rounds, samples and analyzes. At [www.deks.dk](http://www.deks.dk) you can find more information about external quality assurance programs for POCT analyzes in the primary care services.

### 1.4 DEKS on the Internet

Stay updated on [www.deks.dk](http://www.deks.dk) which is DEKS' general news page. It also includes package inserts and guides of various kinds. All the quality assurance programs and materials, which DEKS offers can be seen at [www.deksonline.dk](http://www.deksonline.dk). Here you can among other things order EQA-programs and materials, report results, download reports for Danish programs and pick up the participant's certificate for your laboratory. The electronic reports are available at [www.deksonline.dk](http://www.deksonline.dk) for a minimum of 5 years. Every laboratory has a DEKS responsible contact person, who can setup users and assign rights in DEKSONline.

### 1.5 Continued participation applies to all quality assurance programs

Participation in the quality assurance programs continues until they are cancelled with DEKS.

When you enrol in a quality assurance program with DEKS, your participation runs until you actively cancel your order for the program.

DEKS will advise the DEKS responsible contact person at each lab prior to every new period that it is time to make potential updates/changes. The notification will be sent to the e-mail address, the laboratory has provided to DEKS.

If you wish to cancel your participation in a quality assurance program during the year, the terms are the usual, see section 1.8.4 'Continued participation' always follow the supplier's program year/period.

Ordering *materials* and *new* programs is made either as annual orders (see also section 1.6.1) or as ordinary orders during the year.

#### 1.5.1 Changes in the quality assurance programs

If DEKS is informed about changes to a quality assurance program, the changes will be stated at the page "subscriptions/continued participation" on [deksonline.dk](http://deksonline.dk). If there are substantial changes in the number of rounds, more or less components or changes in the sample material, DEKS will write to the program's contact persons.

If a quality assurance program is cancelled, continued participation stops for this program. In these cases DEKS will contact the laboratory.

### 1.6 Enrolments

All orders and enrolments are made by ordering online via [www.deksonline.dk](http://www.deksonline.dk).

#### 1.6.1 Annual orders

DEKS sends an annual main delivery of calibration- and control materials. If the order is placed online to DEKS no later than 30 November, a **discount** is given as invoicing without freight costs inside Denmark. The ordered calibrators and control materials are sent to the laboratories in the weeks 3-6.

#### 1.6.2 Orders during the year

During the year additional deliveries of calibration- and control materials are sent out on Tuesdays. Orders for in stock materials must be with DEKS no later than Monday of the week, that the delivery is required. Orders, which is requested as fast as possible and at

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other times than Tuesday, are called urgent deliveries. For urgent deliveries an "urgent" fee is charged, see section 1.9.

### *1.6.3 Ordering of certified reference materials etc.*

Shipment from abroad is expensive, so to make the shipment cheaper, DEKS attempts to gather orders for certified reference materials and microbiological calibration- and reference materials for delivery twice a year.

When ordering before November 30 for the annual delivery and when ordering before June 6 for the summer delivery the shipment from abroad is free. Please note, this does not apply to quality assurance programs.

### *1.6.4 Are you looking for a quality assurance program*

If you are looking for a quality assurance program, you are welcome to contact DEKS. We will do all we can to find a quality assurance program that covers your requirements.

## **1.7 Guide to ordering online**

*Log on to [www.deksonline.dk](http://www.deksonline.dk)*

To place orders you have to have a personal login for [deksonline.dk](http://deksonline.dk). At every laboratory there is a DEKS responsible contact person, who decides who has access and whether the different contact persons have permission to place orders.

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

Click on 'Årsbestilling' to start the reordering of the materials, you would like to order again. At the annual ordering page you can see a more specified guide by clicking on 'Vejledning til bestilling'.

*Find or order a product (both programs and materials)*

In the menu 'Bestilling' choose 'Søg efter produkt', to open the page, where it is possible to search for e.g. product name, program code or a component. At the page you can find a guide (pdf-file) by clicking on 'Vejledning til bestilling'.

*To close the order*

When the product is placed in the basket, and the required amount and other information in connection with the order have been entered the order can be closed. Go through the order and close the order by clicking 'Godkend og send bestilling'. You will then receive an e-mail with an order confirmation.

## **1.8 Cancellation of participation**

For all quality assurance programs participation must be cancelled, if you do not want to participate anymore. If participation in a program is not cancelled, you will automatically be re-enrolled the following year, as there is 'continued participation' – see section 1.4. In connection with cancellation of participation in a program, where there are still rounds left, the principle of cancellation of participation after start of a program applies, see 1.9.4.

## **1.9 Prices**

There are a few price changes for DEKS' Danish programs compared the 2020 prices. The prices for the foreign programs follow a potential price change from the foreign collaborators. Please note that there can be some programs from foreign collaborators where only a tentative price is known. If the final price deviates a great deal, the difference is either credited or debited by DEKS.

### *1.9.1 Shipment costs in Denmark*

- Shipment: 220 DKK + VAT
- Shipment on dry ice: 310 DKK + VAT
- At urgent deliveries a fee of 300 DKK + VAT is charged.

See also section 1.5.1 regarding annual orders.

### *1.9.2 Courier and shipment from abroad, excl United Kingdom*

- When using courier freight and for shipments from abroad a special shipment fee is charged.
- For some foreign programs extra shipment costs can be added to the list price.

### *1.9.3 Courier and shipment from United Kingdom (New)*

Due to Brexit, there are unfortunately doubts as to whether the price for shipping from the UK will change for 2021 and an additional expense may therefore be added to the list price for programs from the UK. PostNord states that there will be a "Brexit fee", but the details about it and the size of the fee are not yet known. As soon as DEKS becomes aware of this, the affected laboratories will be informed.

### *1.9.4 Courier*

In special situations, courier shipments can be made, this is agreed in the individual cases with DEKS

### *1.9.5 Special tasks*

When calculating the price for DEKS' own services and for solving special tasks (e.g. Nordic Reference Interval Project) DEKS use the following hourly rates (2021 rate): 600 DKK + VAT for non-academics and 1500 DKK + VAT for academics.

### *1.9.6 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.

## **1.10 Payment**

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

DEKS' GLN-number is **5798001530781**.

DEKS' CVR-number is: **DK29190623**.

## **1.11 Receiving packages from DEKS**

We request that packages from DEKS are opened on receipt, even if the contact person stated at 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 on receipt. On the package it is usually stated 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.

## **1.12 Extra samples**

If your laboratory has made 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 for e.g. verification of new instruments, this is also possible while stock lasts.

The price for extra samples varies from one supplier to the other and payment is always made for shipment and administration fees.

## **1.13 Handling of reporting of incorrect results**

If your laboratory has reported a wrong result and discover this after the external quality assurance report has been issued, then it is unfortunately not possible to change the result. It is unfortunately not possible either to change this in the historical data in the later reports. This wrong reporting should be handled in the quality system of your laboratory. If DEKS is responsible for the mistake, it will of course be changed.

## **1.14 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.

### 1.15 Safety

DEKS assume that the recipients of EQA-materials, etc. take the necessary precautions. All calibrators and control materials must safetywise be treated as patient sample which means that the materials must be seen as potentially contagious.

This also implies 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 programs, including the virus screening programs. These samples can contain virulent pathogenic organisms, and therefore the shipment is marked *UN3373*, cf. the ADR-convention.

#### 1.15.1 Product liability

DEKS make reservations for product liability as a result of infection with HIV, Hepatitis B and Hepatitis C. Furthermore, DEKS do not cover loss as a result of DEKS' products fail to turn up or do not arrive on time.

### 1.16 Copyright

All written material issued by DEKS is subject to copyright. This includes texts at DEKS' website. Sections from EQA-reports, "Programmer og Materialer" and "DEKS informer" can however be reprinted with source reference. Permission for the use of data, etc. can be granted. Contact DEKS for further information. There are similar conditions for reports, etc. from foreign EQA-organisations.

#### 1.16.1 Using EQA results (new)

Reported EQA results from various EQA programs are occasionally used in scientific projects and presentations both nationally and internationally, however in anonymised form, which means that results are not attributable to a specific laboratory. This is done with a view to increasing the reliability of results in laboratory medicine and for educational purposes.

### 1.17 Inquires to DEKS

Questions about programs, improvement suggestions or objections to ratings are welcome. We recommend using the online form on the website [www.deks.dk](http://www.deks.dk) or e-mail to [deks@deks.dk](mailto:deks@deks.dk), but you are also very welcome to call us on 3863 4400.

### 1.18 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 who are participating 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 there are laboratories who do not want this, please contact DEKS.*

DEKS' confidentiality policy can be found at [www.deks.dk](http://www.deks.dk).

See also section 1.16.1 *Using EQA results*.

### 1.19 DEKS Users Meeting 2021

In 2021 DEKS Users Meeting is held as part of the world congress IFBLS2021. It is held in Copenhagen on August 24<sup>th</sup> – 28<sup>th</sup> 2021.

This means that the classic users meeting in 2021 is replaced by IFBLS2021. DEKS is co-organizer of IFBLS2021 – world congress, both generally and by planning sessions.

IFBLS2021 join the forces of dbio, LSB and DEKS under one umbrella. Further information about the congress can be found at: [www.ifbls2021.org](http://www.ifbls2021.org) and in the Facebook-group IFBLS2021 – join the lab race.

#### 1.19.1 Registration deadline

See [www.ifbls2021.org](http://www.ifbls2021.org).