EQUALIS

Participant terms and conditions

Who can participate?

The Equalis external quality assessment scheme is primarily intended for bodies performing clinical diagnostics in healthcare in Sweden, such as hospital laboratories, clinics and wards, as well as primary care laboratories, doctors in private practice and occupational healthcare. Only bodies that have the necessary authorisation to handle the test material in question and to carry out the surveys involved may participate in the Equalis quality assessment scheme.

Manufacturers of medical devices for *in vitro* diagnostics and sales organisations for such products may participate in the schemes provided the information from Equalis is used to follow up the quality of the products in question, and not for marketing purposes. For some schemes, Equalis offers the opportunity for manufacturers of medical devices for *in vitro* diagnostics, without actively participating in the schemes, to access reports that do not disclose individual participants' results. An administration fee is charged.

Schemes offered to foreign participants are listed at www.equalis.se. For foreign participants, the same terms and conditions apply as for Swedish participants (shipping costs may be charged).

Registration

Registration can be carried out at any time of the year, on a registration form at www.equalis.se. Extensions or other amendments to existing registrations is made in the same way as for new registrations. Unless stated otherwise on registration, participation in a scheme continues automatically until it is terminated on a registration form at www.equalis.se . To all regularly recurring schemes participation is thus equivalent to a subscription.

Participation fee

Equalis finances the activity through participation fees. The fee for each scheme is stated on the price list. Foreign participants may be charged for shipping. Invoices are submitted in advance every six months, except for schemes where registration is for one year at a time, which are invoiced at the end of every six months. Payments invoiced in advance are non-refundable.

Confidentiality

Individual results are the property of Equalis and are confidential. Data on individual results will be communicated only to the participant concerned's receiver of reports and to any group receiver of reports. There may be exceptions in certain cases by agreement with the participant concerned.

Each participant is assigned a unique code (lab code) that is stated on all reply forms. The link between the code and the individual participant is known only by the respective participant and the Equalis office.

However, participation in the Equalis external quality assessment scheme is public.

Responsibility and copyright

Reports from the Equalis external quality assessment scheme contain copyrighted material. The reports and other material from Equalis shall not be used for marketing of services and products. For all other uses, prior permission from Equalis is required. Equalis is not liable for any indirect consequences, for example lost trading revenue, as a result of conclusions based on Equalis reports or other assessments.

Assessment of results

The reports from Equalis show how the participant's own results relate to the results of other participants. The participant is solely responsible for assessing their own results in Equalis reports and for taking appropriate action if necessary. The quality goals sometimes specified in the reports complement the participant's own assessment criteria, and do not replace the participant's responsibility for assessing the results. Participants who report deviating results are not normally contacted by Equalis.

Test material

Equalis distributes test material to the participants for the survey in accordance with the schedule in the appropriate planning calendar. Calendars can be downloaded from www.equalis.se or ordered from the Equalis office. Test material is either commercially available or manufactured by subcontractors on behalf of Equalis. Equalis suppliers are not generally made public.

As a rule, test material of human origin used in the Equalis external quality assessment scheme has been tested and found negative with regard to HBsAg (hepatitis B virus surface antigen), anti-HCV (antibodies to hepatitis C virus) HIV Ag and anti-HIV (antibodies to hu-

man immunodeficiency virus). There are exceptions, which are noted on the accompanying instructions for use. All test material from Equalis must be considered potentially infectious, and handled in accordance with the same safety procedures as for patient samples.

Equalis usually retains a limited number of units of despatched test material that can be requested after despatch, for example if the test material is lost or to make additional measurements (not applicable to materials with a very short shelf life).

Participants who need multiple sets of test material to carry out the surveys in the external quality assessment scheme can obtain them by contacting Equalis. The cost of additional test material depends on the scheme.

Amendment of recorded results

Normally, results may only be amended subsequently if they have been recorded incorrectly by Equalis. Unless otherwise stated in the appropriate instructions for use, any errors must be notified to Equalis within two weeks of the report being sent out.

Method details

If necessary, Equalis can help in the investigation of deviating results in an entire method group or instrument group by indicating differences in the methods from method comparisons in the Equalis reports to the manufacturer of the IVD products concerned. For the method comparisons in the Equalis reports to be reliable, Equalis must have at the result compilation stage correct details of the methods used by participants. Participants are responsible for the correct method details being notified to Equalis, and for the details being updated when methods change. Participants may change their method details via Equalis Online. Where results are reported by post or fax, method details can be changed in the reply form that accompanies each test material. The details are saved in the Equalis information system. They are quoted on the reply form sent to participants each time an analysis is carried out, and shown on Equalis Online.

Additional instruments

For participants with several instruments or measuring procedures (max. 5) using the same test material, the scheme's basic fee applies provided results are recorded and reports downloaded online via Equalis Online. For participants who report by fax or post there is an additional charge of 25% of the basic fee for each additional instrument or measuring procedure.

Contact information

The names of the receivers of material, reports and group reports, as well as address details and organisational affiliations, are recorded in the Equalis information system.

Receiver of material

The receiver of material is a person, section or special body, nominated by the participant, to whom the test material is sent.

Receiver of reports

The receiver of reports is a person, section or special body, nominated by the participant, who is authorised to download the participant's reports via Equalis Online. When reports are available to download, Equalis notifies the receiver of reports by e-mail. Where paper reports are sent by post, they are addressed to the receiver of reports. Multiple receivers of reports can be registered at the same address for each external quality assessment scheme.

Group receiver of reports

Group receivers of reports are coordinators who are responsible for coordinating several participants. The participant must give permission in writing for Equalis to distribute reports to receivers outside the participant's own organisation. A special form must be used, which is available from Equalis on request. Group receivers of reports can only download reports via Equalis Online.

Archiving

Reports are available via Equalis Online for a limited period. If required subsequently, they can be ordered via the Equalis office. The reports are saved electronically for at least four years. Paper reply forms sent to Equalis by post or fax for the recording of results are kept until the next despatch within the same external quality assessment scheme or a until a time stated in the appropriate instructions for use.