

MEDICINSK DIAGNOSTIK KAROLINSKA
GENERAL TERMS AND CONDITIONS
FOR CLINICAL LABORATORY MEDICINE

4/24

1. ABILITY

- 1.1. Karolinska University Hospital, by Medicinsk Diagnostik Karolinska with Corporate Registration No 232100-0016, provides laboratory services in the form of diagnostic services.
- 1.2. These general terms and conditions apply to the contractual relations entered into between Medicinsk Diagnostik Karolinska and the client of laboratory services within the diagnostic services area (hereinafter referred to as "the Purchaser").
- 1.3. In the event that a separate agreement on laboratory services has been concluded between Medicinsk Diagnostik Karolinska and the Purchaser, these general terms and conditions form an integral part of that agreement. In the event of any ambiguity or conflict between these General Terms and Conditions and the separate agreement, the terms of the separate agreement shall prevail.
- 1.4. These general terms and conditions may be amended from time to time by Medicinsk Diagnostik Karolinska.

2. SCOPE OF SERVICES

- 2.1. Sample-bound diagnostic services include the following laboratory specialties:
 - a) transfusion medicine;
 - b) clinical pharmacology;
 - c) clinical immunology;
 - d) clinical chemistry;
 - e) clinical pathology and cytology;
 - f) clinical genetics; and
 - g) clinical microbiology.
- 2.2. Test-based diagnostic services include the following services and products:
 - a) sample-based diagnostics;
 - b) sampling;
 - c) information services;
 - d) education;
 - e) electronic orders and responses;
 - f) blood components and substrates;
 - g) support for patient-oriented analyses;
 - h) collaboration on process development; and
 - i) medical consultation, counselling, and on-call activities.

- 2.3. The range of services and products offered by Medicinsk Diagnostik Karolinska (the "Services") can be found here: karolinska.se/examination-instructions.
- 2.4. As a rule, Medicinsk Diagnostik Karolinska will not establish a point-of-care laboratory on behalf of the Purchaser.
- 2.5. Medicinsk Diagnostik Karolinska may use subcontractors (so-called referral laboratories defined according to ISO 15189:2012) in whole or in part for the performance of the Services.

3. POINT-OF-CARE TESTING

- 3.1. Medicinsk Diagnostik Karolinska offers, in accordance with Region Stockholm's governing regulations, quality assurance support for point-of-care testing ("POCT") performed by the Purchaser in-house outside the laboratory but within the laboratory's catchment area. Medicinsk Diagnostik Karolinska's range of POCT services, the applicable terms and conditions for POCT support from Medicinsk Diagnostik Karolinska, including prices, the governing regulations for the Stockholm Region and more detailed information, can be found at: karolinska.se/pna.

4. QUALITY MANAGEMENT SYSTEM

- 4.1. Medicinsk Diagnostik Karolinska works according to internationally established quality standards that enable the structure, monitoring and development of an accredited clinical laboratory. Medicinsk Diagnostik Karolinska is accredited by SWEDAC (accreditation number 1886) according to ISO 15189 "Medical laboratories - Particular requirements for quality and competence". The Doping Laboratory, Clinical Pharmacology is also accredited according to ISO/IEC17025 "General requirements for the competence of testing and calibration laboratories". The accreditation covers all clinics, hospitals, and outpatient laboratories where Medicinsk Diagnostik Karolinska operates. Up-to-date information on accreditation services can be found at: karolinska.se/ackrediterings-tjanster.

5. PERFORMANCE OF THE SERVICES

- 5.1. Medicinsk Diagnostik Karolinska is responsible for ensuring that the Services, within the scope of Medicinsk Diagnostik Karolinska's resources, are performed in accordance with the provisions of these General Terms and Conditions and the Swedish laws and regulations in force from at the times in question, as well as the applicable regulations and general guidelines of the National Board of Health and Welfare. This includes the requirement that Medicinsk Diagnostik Karolinska has the necessary authorisations for the performance of the Services.
- 5.2. Medicinsk Diagnostik Karolinska follows applicable national guidelines and regional and local care and action programmes available in the VISS decision support system, see the Healthcare Provider Guide (*Vårdgivarguiden*).
- 5.3. Medicinsk Diagnostik Karolinska will provide the Purchaser with instructions for the taking of samples. These must be followed by the Purchaser in order for Medicinsk Diagnostik Karolinska to comply with the terms of these General Terms and Conditions and perform the Services. The instructions for the taking of samples include ordering and response procedures. The sampling instructions are available at: karolinska.se/provtagningsanvisningar.

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The business hours for [Karolinska's](https://karolinska.se) medical diagnostic testing units are listed at karolinska.se/lab.

- 5.4. Medicinsk Diagnostik Karolinska provides sampling materials that the Purchaser can order from the Medicinsk Diagnostik Karolinska online store, which can be found here: karolinska.se/lab/webbutik. Ordering sampling material from the online shop only applies to those samples sent to Medicinsk Diagnostik Karolinska by the Purchaser.
- 5.5. Ordering of the Services is mainly done via the medical record systems TakeCare, CGMJ4 or Medicinsk Diagnostik Karolinska's web service, LabPortalen. Medicinsk Diagnostik Karolinska's analysis responses are made available via the system that the Purchaser uses to place the order. Paper orders and paper responses are mainly used as back-up procedures or when an electronic service is not available.
- 5.6. Medicinsk Diagnostik Karolinska's analysis responses are available in LabPortalen for three months. During this period, the Purchaser undertakes to take note of and keep a record of the responses received. Medicinsk Diagnostik Karolinska is not responsible for the transfer of analysis responses to record-keeping systems. After three months, analysis responses can only be retrieved in accordance with specific procedures.

6. KOMBIKAKOD

- 6.1. In order to order the Services, the Purchaser is required to have an identification/order code, known as a Kombikakod.
- 6.2. For ordering Services performed under an agreement with Region Stockholm, or under the Medical Care Compensation Act (1993:1651), a kombikakod is obtained and used from the Health Care Administration of Region Stockholm ("HSF") in accordance with the terms of the Purchaser's agreement with Region Stockholm or the Medical Care Compensation Act, respectively. For other cases, a Kombikakod can be obtained for use from Medicinsk Diagnostik Karolinska. The application form for becoming a purchaser of Medicinsk Diagnostik Karolinska and thereby obtaining a Kombikakod from Medicinsk Diagnostik Karolinska is available at: karolinska.se/labkund.
- 6.3. The Kombikakod must be entered when ordering and deciding who is to be the recipient of Medicinsk Diagnostik Karolinska's invoice and analysis response.
- 6.4. The Kombikakod obtained by the Purchaser from HSF may only be used for ordering Services carried out within the assignment with HSF to which the Kombikakod relates and in accordance with the specific terms and conditions applicable to the assignment.
- 6.5. The Kombikakod received by the Purchaser from Medicinsk Diagnostik Karolinska may only be used to order the Services from Medicinsk Diagnostik Karolinska.
- 6.6. When using his/her Kombikakod to order the Services, the Purchaser is obliged to comply with Region Stockholm's instructions for the use of Kombikakods for referrals to medical services, in effect for the time in question.

These instructions can be found at:

<https://vardgivarguiden.se>.

- 6.7. The Purchaser is responsible for ensuring that orders for the Services are placed using the correct Kombikakod, i.e. the one that is related to the assignment within which the Service is performed. If the Purchaser uses the Kombikakod incorrectly and/or misuses the Kombikakod, Medicinsk Diagnostik Karolinska or HSF may deactivate the Kombikakod, and claims for payment will be directed to the Purchaser either by Medicinsk Diagnostik Karolinska or by HSF.

7. MEDICINSK DIAGNOSTIK KAROLINSKA'S RESPONSIBILITY

- 7.1. Medicinsk Diagnostik Karolinska is responsible for the following:
- a) Providing the Purchaser with instructions regarding sampling and instructions for completing the remittances in accordance with paragraph 5.3 above;
 - b) The sample from the moment it arrives at the premises of Medicinsk Diagnostik Karolinska;
 - c) The performance of the analysis according to the query;
 - d) Providing the Purchaser with analysis responses in accordance with paragraph 5.5 above; and
 - e) Ensuring that only those medical devices that have been manufactured and approved in accordance with the relevant regulations in force at the time in question are used in the performance of the Services.

8. TRANSPORTS

- 8.1. Medicinsk Diagnostik Karolinska will pay for sample transports within the Stockholm Region's geographical area between the Purchaser and Medicinsk Diagnostik Karolinska according to a separate agreement. In the event such a separate agreement is entered into, the Purchaser shall be required to inform Medicinsk Diagnostik Karolinska if the needs of the Purchaser change or no longer apply. If this is not done, Medicinsk Diagnostik Karolinska will invoice the Purchaser for transport performed. Transports over and above those to which these separate agreements apply and emergency transports are to be paid for by the Purchaser.

9. THE PURCHASER'S RESPONSIBILITY

- 9.1. The purchaser is responsible for the following:
- a) Using correct sampling material including sampling tubes and take samples according to the instructions regarding sampling of Medicinsk Diagnostik Karolinska (see paragraph 5.3 above);
 - b) Ensuring that each sample is transported with proper packaging material approved for transport;
 - c) Being a registered health care provider with the Inspectorate for Health and Social Care (IVO) in the event that the Purchaser is to receive human sample results; and
 - d) In the event the Purchaser engages in POCT, to comply with the applicable terms and conditions relating to POCT (see paragraph 3.1 above).

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10. PRICES AND PAYMENT

- 10.1. For the provision of the Services, the Purchaser shall pay in accordance with the prices in force at the time in question. These can be found at karolinska.se/lab/prislista.
- 10.2. The list prices are adjusted from time to time and are quoted in SEK, excluding VAT and other additional taxes imposed after these general terms and conditions. Under current legislation, healthcare is exempt from VAT. In the event of a change in legislation regarding VAT or other taxes, this may affect prices.
- 10.3. The Purchaser shall pay as invoiced to the account designated by Medicinsk Diagnostik Karolinska no later than thirty (30) days after the date of the invoice.
- 10.4. If payment is not made on time, Medicinsk Diagnostik Karolinska shall be entitled to interest on arrears in accordance with the law and, where applicable, to withhold delivery or part thereof.
- 10.5. Objections to an invoice must be made in writing within three months of receipt in order to be considered. Settlement of the incorrectly invoiced amount must take place within 30 days of the parties agreeing that the correction should be made. Medicinsk Diagnostik Karolinska has the right to request correction of the incorrectly invoiced amount even after this three-month period.

11. SECRECY

- 11.1. Medicinsk Diagnostik Karolinska's activities are subject to the Public Access to Information and Secrecy Act (2009:400).

12. TRADEMARKS AND OTHER DISTINCTIVE MARKS

- 12.1. The Purchaser may not, without the written consent of Karolinska Diagnostik Karolinska, use the trademarks, graphic profiles, names, or other characteristics of Karolinska University Hospital that may be associated with Karolinska University Hospital.

13. INTEGRITY AND PROCESSING OF PERSONAL DATA

- 13.1. Medicinsk Diagnostik Karolinska needs to process personal data regarding the employees of the Purchaser in order to be able to carry out its responsibilities as supplier of laboratory services to the Purchaser. Karolinska University Hospital is the data controller with regard to the processing of personal data. The information processed can be names, personal identity numbers, corporate registration numbers, contact details, invoice documentation, and order history. Read more about how Karolinska University Hospital processes personal data, and how you can contact the Hospital's data protection officer at karolinska.se/om-oss.

- 13.2. By approving these General Terms and Conditions by means of placing an order with Medicinsk Diagnostik Karolinska, the Purchaser confirms that the Purchaser has informed its appropriate employees of Medicinsk Diagnostik Karolinska's processing of their personal data.

14. LIABILITY FOR DAMAGES

- 14.1. Medicinsk Diagnostik Karolinska's liability for damages only covers compensation for direct damages, and not compensation for damage to third parties, or damage or loss to the Purchaser's purchasers. Nor does any other consequential, indirect or individual loss, such as loss of property, loss of profits, anticipated savings, loss of revenue, loss of production, loss of intellectual property or other general pecuniary loss, fall within the scope of Medicinsk Diagnostik Karolinska's liability under these General Terms and Conditions.
- 14.2. Medicinsk Diagnostik Karolinska is not liable under any circumstances for errors due to circumstances that fall under the Purchaser's responsibility according to paragraph 9 or otherwise due to the Purchaser, such as for example that the Purchaser has made incorrect assumptions or provided incorrect information, has not followed Medicinsk Diagnostik Karolinska's instructions regarding sampling or has changed the results provided by Medicinsk Diagnostik Karolinska without the approval of Medicinsk Diagnostik Karolinska.
- 14.3. In order for the Purchaser to be entitled to terminate an assignment prematurely due to delay by cancelling the agreement, reducing the price, or claiming damages, Medicinsk Diagnostik Karolinska and the Purchaser must have reached a separate written agreement allowing this to be done.

15. FORCE MAJEURE

- 15.1. If Medicinsk Diagnostik Karolinska is prevented from fulfilling its obligations under these General Terms and Conditions as a result of circumstances beyond its control, such as war, strike, lockout, fire, flood, shortage of transport or energy, government action, new or amended legislation or any other circumstance beyond Medicinsk Diagnostik Karolinska's control, this shall constitute grounds for a release from a condition, postponement of the date of performance and exemption from damages and other possible penalties. Medicinsk Diagnostik Karolinska shall resume performance of the obligations prevented or delayed, as soon as practicable.

16. DISPUTES

- 16.1. Swedish law shall apply to these General Terms and Conditions.
- 16.2. Disputes arising from these General Terms and Conditions shall preferably be settled by the parties jointly and in the event this is not done, disputes shall be referred to court of general jurisdiction with the Stockholm District Court as first venue.