Service Provision Agreement of Sanquin Diagnostiek B.V.

01 February 2025

Purpose:

This Service Provision Agreement of Sanquin Diagnostiek B.V. ("**Sanquin**") sets out the conditions under which regular diagnostic results and services are provided. The Service Provision Agreement also aims to explain communication, procedures and reporting method. Parties who send Specimen to Sanquin Diagnostiek B.V. agree to this service provision agreement.

Contact details of Sanquin Diagnostiek:

Sanquin Diagnostiek B.V., Plesmanlaan 125, 1066 CX Amsterdam
Chamber of Commerce number: 67177476
Email address for service provision: diagnostiek@sanquin.nl
Email address for financial administration: debiteuren@sanquin.nl

Accreditation and quality standards of Sanquin:

Sanquin is accredited by the "Dutch Accreditation Council" for the activities and/or work areas stated in the scope of the accreditation. Its registration number is M005. Sanquin's laboratories work in accordance with ISO 15189 standards. For the other specifications and standards, see the competency statement in Appendix 2. If the accreditation expires and if this is relevant for the Client's service provision, Sanquin will inform the Client within 10 working days. The Client remains obliged to pay Sanquin for Services already invoiced or Services performed before the expiry of the accreditation.

CLAUSE 1: DEFINITIONS

The following terms are used in these general terms and conditions:

BEA	Management of External Application Users (*Beheer Externe Applicatiegebruikers*): the application for registering and controlling CLAUS users.
CLAUS	Central Laboratory Application and Results System (*Centraal Laboratorium Aanvraag en Uitslag Systeem*).
CLAUS computer	the Hardware, any virtualisation layer and operating system made available by the Client within the organisation for receiving and processing Sanquin test results, unless the Client has also entered into a TRIX agreement. In that case, the CLAUS computer can also be used for the TRIX system.
CLAUS application	the Application running on HCL Domino on the CLAUS computer and intended exclusively for receiving and processing test results from Sanquin.
CLAUS database	a defined combination of stored data related to Sanquin's test results in HCL Domino on the CLAUS computer.
Services	Diagnostic results, operation(s) or consultancy, possibly related to blood product selection, whether or not combined with procurement and/or consultancy or services and supplies not related to the foregoing. In accordance with Appendix 1 and all in the broadest sense of the word.
Service Provision Agreement	these terms and conditions of Sanquin.
Laboratory	The laboratories that provide Services.

LIMS	Laboratory Information Management System (in some laboratories this is also called the LIS (Laboratory Information System).
Specimen	Body fluids/tissues required for the performance of the Assignment.
Assignment	A request for a quotation, a request for a test, a request to perform services or give advice, the sending of Specimen to or receipt thereof by Sanquin.
Client	A party that requests services from Sanquin or gives Sanquin an Assignment.
Parties	The Client and Sanquin.
Written/In Writing	via (secure) email, digital LIMS link (such as HL7 Lab2Lab message), post, fax and/or CLAUS.

CLAUSE 2: SCOPE AND APPLICABILITY

2.1 The Service Provision Agreement applies in full to the Assignment to and/or Services of Sanquin, unless the Parties have expressly agreed otherwise in writing. In that case, these further agreements are supplementary or are replacement agreements to the extent expressly provided for in these different written agreements.
2.2 Sanquin expressly rejects the application of other (general) terms and conditions (of, for example, the Client or an industry association).
2.3 Sanquin may amend the Service Provision Agreement. The (amended) Service Provision Agreement has been or will be posted on Sanquin's website (www.sanquin.org). It will also be posted on the NVKC website. In case of essential amendments, Sanquin will notify the Client of the amendments.
2.4 Sanquin has prepared a competency statement, see Appendix 2.

CLAUSE 3: PERFORMANCE OF SERVICES

3.1 Sanquin performs the Services after it has received all information, forms and Specimen required for this purpose.
3.2 After receipt of the Specimen, deviations from normal or specified conditions, such as the condition in which the Specimen was received, are recorded. If there is any doubt about the suitability of the Specimen, the Client will be informed.
3.3 The Laboratory will carry out the work in accordance with the method described on Sanquin's website.

CLAUSE 4: GENERAL OBLIGATIONS AND WORKING METHOD OF SANQUIN

4.1 Sanquin will perform Services with care and in accordance with professional standards.
4.2 The working method, forms and timelines can be found on the website https://www.sanquin.org/nl/producten-en-diensten/diagnostiek/diagnostische-testen/index. In case of specific assignments or additional conditions, the working method and timelines will be described in the quotation.
4.3 Sanquin will make every effort to share the requested test results with the Client within the specified reporting time. In doing so, however, Sanquin is largely dependent on fully and correctly completed instructions and forms and, if applicable, timely delivery of Specimen as well as the correct information about the Client's contact persons and how they can be contacted quickly.
If Sanquin expects the relevant reporting time to be exceeded, it will contact the Client's contact person as stated on the application form in a timely manner and consult about the procedure to be followed, such as outsourcing the assignment, making use of alternatives or changing the timelines.

4.4 Sanquin will inform the Client immediately, both orally and in writing, if there are any problems/errors relating to the performance of the Services which make the report unreliable or less reliable or if an essential change takes place in the Services.
4.5 Sanquin will share its results in the first place by means of the Central Laboratory Application and Results System ("CLAUS"), if the Client has access to this system, and in writing if the Client does not have access to this system. Or otherwise as further agreed in writing.
4.6 Sanquin will advise on the results upon request or, if applicable, discuss the results. To this end, the Client can contact the contact person as stated on Sanquin's website, the application form, Sanquin's results or, if applicable, Sanquin's quotation. Sanquin will also provide (unsolicited) written consultations on the result provided the person and receiving institution are sufficiently identified. No charge will be made for a single telephone consultation.
4.7 If Sanquin provides (unsolicited) advice, the Client is obliged to read the advice carefully, taking the patient data into account. If and to the extent that an advice or result contains a factual inaccuracy and/or an incompleteness on the part of Sanquin that the Client could reasonably have noticed and/or of which the Client should have been aware, the Client must inform Sanquin within eight (8) days of the provision of the advice.
4.8 At the end of the service provision, the Laboratory may use Specimen remaining after performing the requested diagnostics, in pseudonymised form, for optimising or testing diagnostics, scientific research and teaching. If the patient objects to this, the Client should make this known to the Laboratory at the start of the service. Unless otherwise agreed, the remaining Specimens will be destroyed.

CLAUSE 5: OBLIGATIONS OF THE CLIENT/TRANSPORT
5.1 The Client shall ensure the taking and storage of the Specimen in accordance with the specifications as described on Sanquin's website and/or NVKC's 'Who-does-what database', unless agreed otherwise.
5.2 The Client shall, if applicable, package the Specimen in accordance with applicable regulations, including ADR Packaging Instruction 650.
5.3 For urgent shipments, the Client must contact the Laboratory's person responsible for the relevant testing in advance and in a timely manner.
5.4 Sanquin has a logistics service that collects Specimen from various hospitals and GP laboratories in the Netherlands free of charge. The applicable collection schedule for this is listed at: https://www.sanquin.org/nl/producten-en-diensten/diagnostiek/contact/inhoudsdeskundigen-diagnostiek .

> **If the Client sends Specimen by post, it must be addressed to: Sanquin Diagnostiek B.V., Department UDC, Antwoordnummer 16031, 1000 SE in Amsterdam.**

If the Client uses one of the above transport options to transport the Specimen to Sanquin, the cost shall be born by Sanquin. If Sanquin's logistics service is used, the risk of transport shall also be borne by Sanquin. If the Client sends Specimen by post, the risk of shipment shall be borne by the Client.
In case another mode of shipment is chosen and in case of submissions from abroad, other than as provided for in this clause, the costs and risks of shipment shall be borne by the Client.

5.5 The Client warrants and is responsible for the accuracy of the information and/or (personal) data provided by or on behalf of the Client and for the timely and complete provision thereof to the Laboratory.
Specimen must be accompanied by an application with the following details (in addition to the required identification and other information and documents as stated in the applicable professional standards and applicable regulations), unless otherwise agreed in writing:
a) patient name, including initials;

b) Citizen Service Number (BSN);
c) date of birth;
d) gender;
e) address/contact details;
f) unique identification (e.g. patient number/client number);
g) type of primary sample and, where relevant, anatomical location of origin;
h) medically relevant information;
i) the collection date and the collection time, if any;
j) name of the requesting physician or laboratory specialist;
k) test(s) to be performed;
l) a unique number for the Specimen;
m) for tests performed by the HLA laboratory in preparation for a kidney transplant, also the medical history; and
n) for testing related to pregnancy immunisations, also the term of the pregnancy.

5.6 The Client shall ensure that the Specimen is unambiguously traceable to the patient, the collection and the application form.

CLAUSE 6: COSTS, FEES AND INVOICING

6.1 The Services, unless otherwise stipulated, will be charged at the applicable rates listed on the website: https://www.sanquin.org/nl/producten-en-diensten/diagnostiek/diagnostische-testen/index.
The rates do not include any applicable VAT and/or other levies.
6.2 Sanquin will send an invoice for the Services. The invoice will be sent to the Client's address and contact person mentioned on the application form, confirmation of application or quotation.
6.3 The Client may submit a complaint about the invoice to Sanquin within 8 days from the invoice date.
6.4 The full amount due shall be received by Sanquin no later than 30 days after the invoice date.
If, after these 30 days, payment has not been made, Sanquin will send a reminder to pay within 15 days of the date indicated on the reminder. If the amount due is not received by this time, Sanquin will charge statutory interest on the amount due. Sanquin also reserves the right to charge extrajudicial collection costs.

CLAUSE 7: ENGAGEMENT OF THIRD PARTIES/OUTSOURCING

7.1 Sanquin is entitled to outsource Services in whole or in part, and under identical conditions, to third parties insofar as the laboratories that will perform the tests for Sanquin are also ISO15189 accredited. In case of outsourcing, the term "Laboratory" includes third-party laboratories.

CLAUSE 8: REPORTING AND COMMUNICATION

8.1 The communication about the Services will take place between the contact persons of the Client and Sanquin. As regards Sanquin, general contact details are provided in this Service Provision Agreement at Sanquin's address https://www.sanquin.org/nl/producten-en-diensten/diagnostiek/inhoudelijk-deskundigen-diagnostiek

CLAUSE 9: CONFIDENTIALITY

9.1 Each Party shall maintain confidentiality in respect of all information received from the other Party, including but not limited to, information on business processes, finances, techniques, procedures, assays, personal data and trade secrets of the other Party. This duty of confidentiality will continue even after termination of the Service Provision Agreement.

CLAUSE 10: INTELLECTUAL PROPERTY RIGHTS

10.1 Sanquin shall retain all intellectual property rights in relation to all other goods and information such as processes, improvements, inventions, assays and data, which it realises for or during the performance of the Service, with the exception of patient data.

CLAUSE 11: LIABILITY AND INDEMNIFICATION

11.1 Sanquin shall exercise the care that can reasonably be expected in the performance of the Services.
11.2 Sanquin excludes any liability, on any grounds whatsoever, if complaints about the Services have not been reported within this period.
11.3 Sanquin excludes any liability for indirect and/or consequential damage and/or property damage, including but not limited to lost revenue and reputation damage.
11.4 Without prejudice to the above, Sanquin limits the liability for damage which the Client or third parties have suffered or will suffer as a result of the Services provided by Sanquin to an amount of two hundred and fifty thousand euros (€250,000) (including costs).
11.5 The Client will indemnify Sanquin against all damage and claims brought by third parties if they relate to:

a) the processing and application of results and outcomes;

b) care provided by the Client;

c) the information and/or data provided by the Client; and/or

d) culpable failure on the part of the Client to fulfil its obligations under this agreement, with the exception of payment obligations.

CLAUSE 12: PROCESSING OF PERSONAL DATA

12.1 In respect of the Services, the Parties are each independent controllers within the meaning of the General Data Protection Regulation ("**GDPR**"). Sanquin is the controller for the performance of the diagnostic testing and receives personal data and Specimen from the Client. Sanquin shall analyse the Specimen of the requested disorders and creates data about the patient's health. The Client is the controller for providing personal data to Sanquin and for her own data processing after delivery of the test results by Sanquin.
12.2 The Client shall be responsible to inform the patients whose personal data will be provided to Sanquin about these processing activities and on the exercise of their rights.
12.3 The Client shall only provide personal data to Sanquin that are necessary for the performance of the Services.
12.4 Sanquin shall only use the personal data provided by the Client and the data obtained by analysing the Specimen for the performance of the Services.
12.5 The legal basis for the processing, which are necessary for the performance of this Service Provision Agreement, for both Parties shall be the medical treatment agreement, which exist between the Client and its patients. The Client shall ensure that this legal basis applies to the necessary processing activities of the Parties in regard to the Services.
12.6 If necessary, Sanquin shall communicate independently with the patient in the event of a violation on the data protection or when the patient submit a request based on the rights of data subjects (article 15-22 GDPR). Sanquin is not obliged to inform the Client about this.
12.7 The Client confirms the applicability of the ground for breach as stipulated in article 9(2)(h) GDPR, in which is stated that the processing activity is allowed if it is necessary for medical diagnoses, including where it concerns processing activities carried out by Sanquin.

12.8 In a limited number of cases, the remainder of submitted Specimen is used pseudonymised for validation, calibration of equipment and optimization of the services based on Sanquin's legitimate interest in ensuring a safe, verifiable service. If the patient objects this, he or she can contact Sanquin. The Client is responsible for verifying that the Specimen they provide to Sanquin may be used for the above purposes (in accordance with the 'no-objection procedure').

CLAUSE 13: RETENTION AND DESTRUCTION OF DATA

13.1 Sanquin has implemented the retention periods arising from applicable regulations for its (automated) systems. After the time periods determined on this basis have expired, the personal data will be deleted.

CLAUSE 14: USE OF CLAUS

14.1 If the Client uses CLAUS for the communication of results, this shall be subject to the conditions as stated in **Clause 16**.

CLAUSE 15: APPLICABLE LAW AND DISPUTES

15.1 Sanquin's Services, the Service Provision Agreement and any other agreements are subject to Dutch law. Sanquin will endeavour to discuss and resolve complaints and disputes with the Client to the best of its ability. If this is not possible within 30 days, the dispute will be submitted to the Amsterdam District Court. If the Client is not domiciled in the Netherlands, the dispute will be submitted to the Amsterdam District Court, specifically to the Netherlands Commercial Court division. If so, the proceedings will be conducted in English. Also in the event of urgent provisions, the dispute will be submitted to the preliminary relief judge of the Amsterdam District Court.

15.2 Complaints about the Services may only be reported to Sanquin within eight (8) days after the Services or, in case of test results, within 30 days after their delivery.
If Sanquin determines as a result thereof that it has failed on essential elements in the performance of the Services, it shall reperform the Services or the relevant parts thereof without charging additional costs unless the failures are attributable to incorrect or incomplete instructions or information or to the Specimen from the Client.

CLAUSE 16: CLAUS

16.1 If no use is made of CLAUS Online, the Client shall, in a timely manner and at its own expense, make a computer/server available in its own organisation for the installation and operation of CLAUS, which shall at minimum meet the specifications agreed upon during implementation. The Client shall install and maintain this computer/server in such a way that Sanquin is able to report the test results pursuant to laboratory requests in a timely manner and without additional costs.
16.2 Sanquin shall provide the CLAUS application for the purpose of electronic communication; this shall be installed by Sanquin employees on the Client's CLAUS computer.
16.3 The CLAUS application remains the property of Sanquin and may only be used for electronic communication regarding test results of laboratory applications with Sanquin. The Client may not modify or analyse the CLAUS application or make it available to third parties.
16.4 The CLAUS application runs within a server version of HCL Domino, which shall be made available to the Client by Sanquin.
16.5 The Client retains the right to deviate from this architecture should it move the IT infrastructure to a Cloud environment.

16.6 The data within CLAUS will be exchanged between Sanquin and Client by means of database replication. This exchange will be secured in the most adequate way possible. For details of how this is done, please refer to the website https://www.sanquin.org/nl/producten-en-diensten/diagnostiek/claus/index
16.7 The Client is only entitled to use the granted licence on HCL Domino within the CLAUS application and, if applicable, TRIX.
16.8 The Client shall ensure that only persons who require access by virtue of their position are granted access to the CLAUS application, and shall take adequate measures to this end, including adequate actions in relation to a change in position or retirement/departure of these persons.
16.9 Sanquin shall bear responsibility for a daily backup and the security only of the centrally stored data. The Client shall bear responsibility for regular backups of the CLAUS Environment present at the Client's premises.
16.10 The Client shall make adequate provision to answer questions and solve problems within the organisation. If the problem is not solvable, the Client may call on Sanquin's CLAUS application manager(s), who may then request advice and/or assistance from the party with whom the maintenance contract for CLAUS has been concluded.
16.11 An application, BEA (or Management of External Application Users), has been developed that allows individuals from the Client to be registered to use CLAUS. The Client is responsible for appointing an administrator/controller for BEA. Using the BEA application, this administrator must maintain the user accounts and perform periodic account checks.
16.12 Sanquin shall make the CLAUS application available to the Client without charge to the extent and for the duration that the Client submits laboratory applications to Sanquin.

Appendix 1: Mutual responsibilities

Responsibilities	Client	Sanquin
Sample collection and transport		
Informing the patient and obtaining necessary consent from the patient	X	
Sample collection	X	
Providing necessary information for performance of the testing	X	
Pre-analysis, storage and transport to Sanquin performed by the Client in accordance with set specifications	X	
Transport to Sanquin carried out by Sanquin		x
Informing the Client if transport conditions have not remained within set specifications		X
Registration of sample for testing		X
Storage under correct specifications of Specimen for testing		X
CLAUS		
Providing, securing and managing computer/server with Windows for CLAUS	x	
Providing, securing and managing HCL Domino with CLAUS and BEA		x
Designating an administrator and controller of user accounts of/for the Applicant		x
Analysis		
Preparing, validating and authorising testing regulations		X
Guaranteeing the quality of the testing carried out		X
Authorising the test result		X
Archiving the test result for at least 20 years		X
Archiving residual Specimen under correct specifications after testing until destruction		X
Destruction of residual Specimen after testing has been performed		X
Informing the client if testing cannot be carried out within the specified timeframe		X
Report on test result		
Particularities that are relevant for interpreting the test result are reported along with the result		X
Complaint handling		
Receipt, investigation, follow-up actions and archiving of complaints		X

Appendix 2: Competency statement

Sanquin Diagnostiek declares the following regarding competency in performing, analysing, interpreting and reporting results of diagnostic testing:

- The Dutch Accreditation Council has accredited Sanquin Diagnostiek under registration number M005 with effect from 26 August 2015 for the activities and/or work areas and location(s) listed in the scope of accreditation.
- The accreditation status and scope can be verified on the website of the Dutch Accreditation Council. This website also provides information about the source codes we use.
- Diagnostic testing for patient care falls within the scope of the current accreditation; see the overview of all accredited parties.
- Patient care equipment and testing methods are validated or verified in accordance with the quality requirements. If requested testing is outsourced, this is stated in the test report. All results are reported with reference values where applicable.
- Changes in the performance of diagnostic testing which are relevant for the party applying for testing will be communicated to the applicant. Doubts about the reliability and/or corrections of results are communicated to the relevant applicant(s) without delay.
- Information on requesting and performing laboratory tests for internal and external applicants is provided on the website of Sanquin Diagnostiek, which can be accessed via this link.
- The laboratory participates in quality assurance inspections organised by recognised supervisory EQA organisations. For testing for which no quality assurance inspections are available, the laboratory has established policy to determine that the test method in question gives valid results for the application described.
- Determination of the suitability of the method and the authorisation of results is carried out by or under the supervision of appropriately qualified laboratory specialists.
- Sanquin Diagnostiek pursues optimal protection of incoming patient data. In doing so, it acts in accordance with the General Data Protection Regulation.
- Specimen is stored in pseudonymised form and can be used for validation, equipment calibration and scientific research within the context of the original requested testing. In doing so, Sanquin Diagnostiek B.V. applies the *Federa code of conduct* and the *Coreon code of conduct for health research* (https://www.coreon.org/). If there are any objections to the further use of Specimen, please contact Sanquin Diagnostiek B.V. by email: diagnostiek@sanquin.nl.

Amsterdam, 01 februari 2025
Michiel van Dongen
Managing Director Sanquin Diagnostiek