Fimlab

Self-Monitoring Plan

Fimlab

Content

1 Information about the Service Provider, Service Unit and Operations

1.1 Basic Information About the Service Provider

Fimlab Laboratoriot Oy

Company ID: 2392519-6

Arvo Ylpön katu 4, 33520 Tampere, Finland

Fimlab Laboratoriot Oy is a joint stock company, wholly owned by the public sector's service providers in social welfare and healthcare, which produces laboratory services for its owners. The main shareholders of the company are the wellbeing services counties of Pirkanmaa, Kanta-Häme, Central Finland, Päijät-Häme and Ostrobothnia. The above-mentioned wellbeing services counties have agreed to produce laboratory services jointly, and commissioned Fimlab to deliver all, or most, of the laboratory services for which these wellbeing services counties are responsible. The company's minority shareholders in the wellbeing services counties of Southern Ostrobothnia, Satakunta and Southwest Finland, as well as the NordLab joint county authority, have commissioned Fimlab to deliver the laboratory services needed for service production and to the extent required, for optimum quality, know-how and cost-effectiveness. The company is an affiliated unit of the owners and also produces laboratory services for other actors in the health care sector, though only to the extent permitted as an affiliated unit.

The laboratory services produced by Fimlab include expert services, such as support of the entire chain of care – from ordering tests to sampling, sample transport, analysis and communicating the test results to the client. For its part, Fimlab oversees the basic and specialist training of medical doctors and other healthcare professionals, as well as for the research in the field and other statutory obligations of the wellbeing services counties regarding laboratory services, such as preparing in the event of disturbances and emergencies and guaranteeing the continuity of operations.

Laboratory activities are support services that are crucial for a functioning healthcare system. All organisations and levels of the healthcare system need laboratory service. Laboratory results play an important role in clinical decision-making. Fimlab's main tasks are sampling and analysis of samples. Approximately 3.3 million samples are collected each year, and more than 17 million studies are carried out at Fimlab in the laboratory's various specialties. Fimlab's area of operations has a population base of approximately 1.4 million Finns.

Fimlab's Self-Monitoring Plan is a part of Fimlab's internal management system. In addition to the Self-Monitoring Plan, the management system includes a system for quality control and sustainability factors. The management system takes into account the governing legislation and other regulations.

1.2 1.2. Services, Operational Concept and Operating Principles

Fimlab's service production includes analyses in the specialised fields of clinical chemistry, haematology, microbiology, pathology and related genetic and sampling activities. Furthermore, Fimlab provides a Fertility Treatment Laboratory. Fimlab manages the blood bank services in the area of operations, performs patient tests in the field of clinical physiology, and is a support laboratory for the operational units that perform patient-related analyses in the wellbeing services counties that are the main shareholders. In addition to examining and caring for patients, Fimlab also provides sampling, analysis and project services for scientific research projects. Fimlab's core processes are divided into customer services and diagnostic services.

Fimlab's main facility and central laboratory is located in Tampere. Furthermore, Fimlab has 4 large laboratories with operations 24/7 at the central hospitals in Jyväskylä, Lahti, Hämeenlinna and Vaasa. We also have small analytical laboratories in the area of operations that support the on-call activities of the well-being services counties. Furthermore, Fimlab supports and provides the conditions for patient-based analyses at the facilities of the well-being services counties, where tests are carried out by their employees. There are more than 100 service locations in Pirkanmaa, Varsinais-Suomi, Central Finland and Ostrobothnia. As for sampling, our service production includes both outpatient sampling, ward sampling and on-call sampling in a hospital environment. Biobank samples and samples related to scientific research projects are also collected at the service locations.

Fimlab's mission is to work now and, in the future, to ensure that every individual has the answers to promote their own health in collaboration with healthcare professionals.

Fimlab's vision is to be a responsible forerunner in laboratory services. Fimlab is the laboratory company of the wellbeing services counties and an expert in Finnish laboratory services, with cutting-edge expertise based on state-of-the-art knowledge and best practices. Our development is based on responsible operations, continuous renewal, committed customers and profitable growth. Our ambition is to master the entire service process in a superior way.

Fimlab's values are responsibility, collaboration, continuous development and trust. These are also the basis for Fimlab's Code of Ethics. Our goal is pursuing efficient and cost-effective operations. Our position as the leading laboratory in Finland is based on solid expertise and continuous assessment and development of our operations. We develop service processes together with service providers and their partners in the public healthcare sector to provide a smooth, efficient and effective service package.

Fimlab's strategy includes three strategic promises: our customer promise, our employee promise, and our environmental promise.

Our Customer Promise

Fimlab

We provide answers to treat disease and promote health. We are a top laboratory at an international level.

Our Employee Promise

We are a responsible and evolving community of experts who value each other. We develop occupational well-being and leadership. With us, one can delve into one's work, make a difference and flourish.

Our Environmental Promise

We develop our activities to maintain the carrying capacity of nature and mitigate climate change. A thriving nature forms the foundation for human health.

2 Customer and Patient Safety

2.1 Requirements relating to the Quality of Service

Fimlab's implementation of quality management, quality requirements and quality control are based on the standard SFS-EN ISO 15189 for quality and competence requirements of medical laboratories. Fimlab proves its competence in producing medical laboratory services by complying with the accreditation procedure in the Tampere Central Laboratory. The accreditation body is FINAS accreditation services. Self-monitoring, including corresponding requirements, is observed in the other laboratories.

The company has appointed a Quality Manager, who is in charge at company level for the operative self-monitoring of quality. Every 4 months, the regions and fields of specialisation collect quality indicators for laboratory operations together with reports for self-monitoring.

The company has a Quality Management Team that meets regularly at least 3 times a year. The Quality Management Team establishes performance indicators for self-monitoring and quality management and monitors the implementation throughout the area of operations. The Medical Director elects members to the working group from the different fields of specialisation and geographical areas. The Quality Manager coordinates the work of the Quality Management Team.

In the fields of specialisation, customer service, information management and other service areas, the medical and production-related, or other specifically designated employees, oversee procedures and documentation related to quality control. Their task consists of arranging internal audits and reviews in their areas of responsibility, have the key responsibility for arranging external quality assessment, setting quality objectives and monitoring that they are fulfilled.

Fimlab

2.2 Responsibility for the Quality of Service

The Medical Director oversees Fimlab's healthcare services. The Medical Director is thus in charge of Fimlab's diagnostic activities and the contact person in relation to regulatory authorities. The Medical Director is also in charge of laboratory operations quality, while the Service Director oversees customer service quality.

In the fields of specialisation, customer service, information management and other service areas, the medical and production-related or other specifically designated employees oversee the procedures and documentation related to quality control.

The Quality Manager coordinates and administers the procedures required by the accreditation for self-monitoring and competence verification, as well as documentation, and ensures that the procedures related to quality control are carried out in a consistent manner and at all service locations. Furthermore, the Quality Manager is the contact person for the personnel in charge of quality control and the accreditation body (FINAS), and in charge, at company level, of reporting self-monitoring and quality control to FINAS.

Every individual employee at Fimlab is responsible for quality at all times, and for complying with quality control practices in their own work.

2.3 Status and Rights of the Patient

The status and rights of the patient are regulated by the Patient Act. Our laboratory services are organised to allow each patient the opportunity to receive the prescribed examinations in a timely manner. Access and accessibility to the services are ensured in an equal manner.

A patient has the right to a confidential treatment of information relating to their health and care. A patient decides for themselves to whom their data can be disclosed. A patient has the right to be informed in a clear and understandable way about their examination results. As a rule, Fimlab produces information to the parties with overall responsibility for the care, and to healthcare units that have ordered tests, and, to a limited extent, directly to the patients.

Healthcare professionals should treat patients equally and with respect. Patients have the right to be heard and treated in a non-discriminatory way.

A patient has the right to provide feedback and, if necessary, to lodge complaints about the organisation of care and the quality of care. Lodging a complaint is straightforward and patients can request help when lodging a complaint.

Fimlab actively collects feedback from individual customers. The feedback is used to support the development of customer processes. The wellbeing services counties are in charge of naming patient representatives. Contact information for patient representatives in wellbeing services counties within Fimlab's area of operations is available on Fimlab's public website.

Fimlab

2.4 Processing of Complaints

The Medical Director oversees processing complaints that have been lodged by both the authorities and the patients. A reply to a complaint is submitted within the set time limit, and a copy of both the complaint and the reply is saved in an electronic folder with limited access rights. A summary of the lodged complaints is prepared and discussed annually in the management team. If necessary, the operations are adjusted based on the complaints.

2.5 Employees

Fimlab has approximately 1,200 employees. Of these, approximately 88 per cent are permanent workers, and 12 per cent have a fixed term contract. The goal of the company’s operations always informs the allocation and requirements of human resources. The number of employees is determined by the amount and nature of the work carried out.

External workers are used if the in-house personnel are not available, and recruitment has not led to the desired result. Some tasks have been outsourced and are produced based on various purchase agreements entered into with different service providers, such as instrument care and sanitation.

In the case of healthcare professionals, the right to work and basic knowledge are checked in Valvira’s register JulkiTerhikki before signing an employment contract. During the recruitment process, the degree and education certificates and previous work certificates are requested, which ensure a relevant education and experience for the task in question. The potential employee's references are also verified. This data is stored in the HRM system, and the certificates are stored in an electronic archive.

The right to work for students who have temporary work duties in the healthcare system is verified against a study register extract and completed studies according to the study certificate. The task of the supervisor is to formulate an introduction plan for students as well as for other employees, and to evaluate and supervise the work in accordance with the supervision and monitoring responsibilities.

For laboratory and sampling work, no investigation is required for people working with the elderly and people with disabilities, in accordance with the Act on the Control of Criminal Background of people working with children (604/2002) and paragraph 28 of the Supervision Act.

Each employee is expected to maintain confidentiality with reference to patient data and our business operations. When signing an employment contract, a separate non-disclosure agreement is also signed.

A written job description is prepared for all employees. Human Resources administers a register of job descriptions. The job descriptions are registered in each person's employment information

in the HRM system. The accuracy of the job description is reviewed by the supervisor at least annually or when the content changes.

The strategic development of competence is a future-oriented leadership, where the competence of the employees is the organisation's key competitive factor, as well as an enabler of business operations. The decisions taken in the business operations depend on the competence of our employees, and how this competence is organised. Competence development is planned training and coaching, as well as other measures aimed at renewing, securing and developing the competence of the future. This ensures that the competence of all personnel, both employees and supervisors, is maintained and developed, and meets the requirements of the work and its tasks, and the predictable needs for change.

Well-being at work and its management are central parts of Fimlab's strategy and operations. In line with our employee promise, we develop well-being at work as part of our leadership.

2.6 Follow-Up as to whether the Number of Employees in Customer and Patient Work is Sufficient

Ensuring adequate staffing guarantees the quality and efficiency of work and promotes the well-being and endurance of employees. The follow-up is done using various indicators, such as customer feedback, performance amount and the degree of service utilisation. The follow-up is done with the aim of continuous development of the business. Service Managers and Customer Service Coordinators monitor whether the number of employees is sufficient for service production on a weekly and daily basis. Furthermore, the customer service and diagnostic management teams quarterly review whether the number of employees is sufficient for customer management. This overall approach contributes to a more sustainable and customer-oriented operating environment.

2.7 Multi-Professional Collaboration and Coordination of Services

Multi-professional collaboration and coordination of services are done in cooperation with customers. Fimlab has several different customer groups.

An ordering client has a contractual relationship with Fimlab’s operations. The main ordering clients are the well-being services counties that are the owners of Fimlab. In addition to these, Fimlab has clients among public and private organisations in the social welfare and health care sectors as well as the state (including the Finnish Defence Forces and prisons).

A healthcare unit produces healthcare services in an ordering client’s organisation, or in a contractual relationship with an ordering client.

A professional client operates in a healthcare unit and provides services under the supervision of an ordering client. These decide on the need for laboratory examinations, on orders and the

interpretation of responses to individual customers. A professional client can also be a direct customer of Fimlab if they work as a private entrepreneur or work as a healthcare professional in a private company. The group of professional clients also includes researchers.

A consumer customer is a person that uses our services with a referral from a healthcare professional or with his or her own referral as a paying customer. Our service is free of charge for a consumer customer if they have a referral from an organisation that is our ordering client. A consumer customer can also visit Fimlab with a referral from a private doctor or with a referral of their own, in which case they pay for their own services.

Strategic and operational steering group meetings are arranged with an ordering client on a regular basis, in order to have a common approach to the situation and the development needs of the laboratory operations. Ordering clients, care units and professional clients are provided with access to the Fimlab Extranet service, which contains real-time information on the use of laboratory services and on cost development.

Fimlab produces customer service and guidance through several channels for ordering clients, professional clients and consumer customers. The services are delivered in Finnish, Swedish and English. Services are delivered in electronic channels, on websites and by telephone. Through the service you can book an appointment for the laboratory's sampling, cancel an appointment and receive training and guidance for laboratory tests and processes. Professional clients are provided with training and guidance on laboratory services and related processes and, if necessary, they are directed to the right expert for consultation.

2.8 Premises and Equipment

Fimlab has more than 100 service locations, and Fimlab's local services oversee maintenance and safety together with the directors in charge of operations at the locations. The Medical Director of Fimlab, together with the regional directors and directors of the fields of specialisation, is in charge of ensuring that the premises are fit for their purpose. Fimlab has developed a local concept for the premises, which is based on Fimlab's standardised operating models, values, business goals and safety.

Fimlab rents premises owned by wellbeing services counties, municipalities and private property owners.

Fimlab strives for a network of service locations to meet the need of sampling services for the population of the region. When selecting new service locations, it is vital that the service location can be reached by public transport, that parking spaces are available, that it is accessible, that it is located along the routes of the users of the service (e.g. shopping centres) and that safety is good. When new locations are selected, responsibility aspects are considered, and these must be verified by the property owner.

The premises are equipped with sampling equipment that is approved for medical use and with high-quality office furniture. The sampling staff will be given an introduction on safety aspects

related to the sampling room, equipment and their use. Service Managers are in charge of providing new employees with an introduction.

The premises manager, together with the Medical Director, the responsible regional directors and the directors of fields of specialisation, are in charge of the equipment and the safety of the central laboratories. Central laboratories are located in Tampere, Hämeenlinna, Vaasa, Jyväskylä and Lahti. The central laboratories are located in the central hospitals of the wellbeing services county, and the Fimlab premises manager is in charge of safety on the premises, in cooperation with the parties in charge of the safety and effectiveness of the central hospitals in the wellbeing services county. In Pirkanmaa, Fimlab is an independent tenant in its own central laboratory. The environment of the laboratory is Tampere University Hospital.

Fimlab purchases the equipment needed for operations and maintenance. Purchases of instruments are made in accordance with Fimlab's purchasing practices. When purchasing equipment, we ensure that the equipment is safe and fit for its purposes.

When sampling and analysing, Fimlab uses equipment that complies with officially approved instructions and work instructions. The effectiveness, safety and need for verification of new equipment are evaluated and, if necessary, a verification is carried out before using the equipment. New equipment must be approved by a person in charge of the function, such as a process manager, a chief physician or other equivalent. Employees are introduced to the use of the equipment needed for their work.

2.9 Medical Devices, Computer Systems and the Use of Technology

The Medical Director is in charge of ensuring that the company complies with the obligations laid down in the Medical Devices Act (719/2021). The purchase of medical devices is carried out in accordance with Fimlab's purchasing practice, by ensuring that the products are CE marked medical devices, intended for individual use, manufactured in accordance with the regulations for self-manufacture or that they have been granted a regulatory permit for placing them on the market or commissioning.

The basis is that Fimlab's laboratory data system serves Fimlab's core processes, i.e. sampling and analysis. Fimlab receives an electronic test request via a message service, submitted by customers in a patient information system. A request for a test submitted internally within Fimlab is processed in Fimlab's own laboratory data system. The analysis uses various intermediate programs and applications that support the analysis. The laboratory results are communicated to the patient data system of the care unit that ordered the examinations. As a general rule, laboratory results are transferred to the Kanta archive from patient data systems.

The data systems at Fimlab comply with the Act on the Processing of Customer Data in Social Welfare and Healthcare, and correspond to the purpose of Fimlab's operations, and are located in Valvira's data system register. The requirements for the data systems that comply with the Act on the Processing of Customer Data in the Social Welfare and Healthcare sector, and which are

used within the company, are verified in accordance with the data security plan. The Data Security Manager and the Data Protection Officers are in charge of the data security plan.

2.10 Pharmacotherapy Plan

Fimlab has an up-to-date pharmacotherapy plan. The laboratory patients are research subjects who do not receive actual pharmacotherapy. In certain studies, drugs are used as research substances. The Medical Director is responsible for the pharmacotherapy plan and overseeing its implementation. The Quality Manager is responsible for drafting the pharmacotherapy plan.

2.11 Processing of Client, Customer and Patient Data and Data Protection

Fimlab's CEO has the overall responsibility for record keeping and for resource allocation to data protection and data security. The Medical Director is the Director in charge of Health Services and, in cooperation with the CEO, in charge of the record keeping of the patient register. The Medical Director has the main responsibility for data protection on a practical level at Fimlab. Contact details for Fimlab's Data Protection Officer (03 311 75259, tietosuoja@fimlab.fi) can be found on Fimlab's website. The Data Protection Officer is designated to this position as intended in the EU General Data Protection Regulation, and in the special legislation for social welfare and health care and is appointed by and for the organisation.

Fimlab has its own information management plan, which states the information that is stored, retention period and storage responsibility, method of archiving and any additional information. The directors of the fields of specialisation, regional directors and personnel in charge of other functions are in charge of determining and complying with the information management plan. The Data Protection Officer coordinates the administration of the information management plan.

2.12 Consideration of Regularly Collected Feedback or Other Responses

Fimlab collects customer feedback and measures the customer experience of all customers. Customers can provide customer feedback on the public website, in person, by email, by phone and while the customer experience is being measured.

Our employees record the information on a customer feedback form in the company's intranet, received by e-mail, in person or by phone. Feedback received on the public website or registered on the intranet is automatically directed to the electronic customer feedback system.

Customer feedback is categorised based on the content and severity. The amount of feedback, content and severity is monitored and processed quarterly in the customer service teams and

diagnostics teams. Collecting customer feedback across multiple channels makes it easier for us to listen to our customers. The collected feedback is used to develop the company's operations.

We measure the customer experience using THL's recommended unified way of measuring customer experience. The Net Promoter Score (NPS) is the recommendation index used. The measuring covers all Fimlab's service locations, and the questions are asked after sampling, in the form of a text message sent to the consumer customer. When measuring the customer experience, our consumer customers are also asked to provide written feedback about our services.

Ordering clients are requested to send an NPS assessment by email from those who have participated in client collaboration meetings. The customer experience of professional clients is measured, and feedback is collected continuously and efficiently at least twice yearly through an electronic survey.

3 Risk Management of Self-Monitoring

3.1 Responsibility for Risk Management in the Service Unit, Identification and Assessment of Risks

Risk management is a systematic activity, whose purpose is ensuring that the entire company comprehensively and appropriately identifies, assesses, manages and monitors risks. Risk management is an essential part of the company's planning process, decision-making process, daily management and operations, as well as monitoring and reporting procedures. Risks are assessed and managed in a business-oriented and comprehensive manner.

Fimlab's overall risk management system is based on the COSO ERM framework and the ISO 31000 standard. Risks are classified as strategic, operational and financial risks. Furthermore, the company assesses risks in relation to sustainability factors.

Strategic risks are identified and assessed as part of the annual planning process. The probability and impact of strategic risks, and the risks related to sustainability factors, are assessed over the medium term (3 – 5 years) and over the long term (more than 5 years). Operational and financial risks are assessed in the short term (1 – 2 years).

The responsibility for risk management has been divided in such a way that the board of directors is in charge of the company's risk management and approves the principles for risk management. The CEO and senior management are in charge of the implementation of risk management, and for using the information about risks as a basis for decision-making and information-based leadership. They are also in charge of ensuring that the risk reporting is adequate and appropriate.

The members of the management team identify, assess and monitor the operational risks related to their own area of responsibility, and make use of the organisation’s observations and expertise. The key observed risks are included in the company-level risk management. The CEO and senior management identify, assess and follow-up strategic risks.

The CFO is in charge of the overall development of the company’s risk management process and for the insurance solutions. The risks related to the company’s operations, and which can possibly result in a health hazard, are part of the company’s overall risk management. Separate assessments are made on a yearly basis of data security risks and occupational safety risks.

3.2 Methods for Risk Management and Managing Misconduct and Deficiencies in the Operations

The company manages risks by establishing management measures, personnel in charge and time limits for risks. The management measures may be related to avoiding, mitigating, displacing a risk or preparing for a risk. The risk outcomes are monitored, and information about the outcomes is used for identification and evaluation of risks, and development of management methods.

Fimlab is a FINAS accredited testing laboratory, whose accreditation complies with the requirements of the standard SFS-EN ISO/IEC 15189:2022. Risk management is included in the requirements of the above-mentioned standard, thus ensuring that the company’s risk management procedures are regularly audited by the FINAS accreditation service.

The regulatory authorities’ requests for investigation, governance and decisions are addressed to the Medical Director, who introduces the necessary measures in Fimlab’s operations and coordinates response to the authorities’ requests for investigation.

3.3 Monitoring and Reporting of Risks and Ensuring Competence

The responsible personnel assess and follow-up on the risk environment, and changes in it, as part of the annual planning and strategy planning and regularly document the detected risks and their management in the risk management system. Identified risks and their management are reported to the management at least twice yearly and to the Board of Directors at least once yearly.

Introduction and continuous competence assurance are key elements to ensure competence in risk management. Furthermore, follow-up is done through regular quality evaluations, both internally and externally.

In terms of hygiene instructions and infection control, the respective wellbeing services county's instructions and Fimlab's own instructions are followed. The compliance with hygiene instructions

and the success of infection control is evaluated and followed up, among other things, by assessing the competence of the sampling staff, which is done regularly at Fimlab.

3.4 Purchase Services and Subcontracting

Referring to purchase services and subcontracting, the essential risk management factors are considered in the requirements imposed on subcontracting laboratories in competitive tendering and in contractual practices. Purchasing and subcontracting partners are expected to commit to Fimlab's risk management requirements. Auditing will be carried out in a subcontracting laboratory, if necessary, to ensure quality requirements are fulfilled.

3.5 Emergency and Continuity Management

The continuity of Fimlab's operations and readiness for disturbances in normal and exceptional circumstances, are ensured as part of the company's risk management. The Medical Director, together with the CEO, is in charge of the laboratory operations' readiness and for the continuity management in the event of disturbances and emergencies. Other members of senior management are in charge of determining contingency and continuity plans and for applying them within their areas of responsibility.

Members of the management team identify and evaluate the operational risks within their area of responsibility, which may affect the company's readiness and jeopardise the continuity of critical operations.

4 Application, Publication, Follow-Up of Implementation and Updating of the Self-Monitoring Plan

4.1 Execution

Every year an overview is conducted of Fimlab's Self-Monitoring Plan and, if necessary, updates are implemented.

The Self-Monitoring Plan is a part of Fimlab's internal management system and treated as such by the management team and all operational units. Management and supervisors are in charge of ensuring that all employees are familiar with the content of the management system and can act in accordance with the system. Quality auditing ensures that all business units can comply with the management system.

4.2 Publication, Follow-Up of Implementation and Updating

Fimlab's management system, which includes the Self-Monitoring Plan, is provided to Fimlab's employees on the company's intranet.

The Self-Monitoring Plan published on the Fimlab.fi website contains excerpts from the management system.

Self-monitoring is followed up every four months. Information about significant changes or developments related to self-monitoring is published internally on the intranet and externally on the company's website.