Specification of requirements

Functional requirements for Laboratory Information Management System (LIMS) for Department of Medical Genetics, Oslo University Hospital

Comments on this version of the Requirements Specification:
This document is only preliminary and will be finally determined during the dialogue phase.
New requirements can be added, requirements can be changed or deleted, and the categorization of requirements can be changed during the dialogue phase.

Innhold

1 Important Information

1.1.1 Objective

This document will be used for the evaluation/assessment of the Vendor's offered solution for a new LIMS for the Client (Oslo University Hospital Trust, Department for Medical Genetics). Additionally, it shall to the greatest possible extent map the solution's basic functionality and suitability for the Client's need prior to a final customer design. This minimizes the risk of **unintended implementation costs, increased implementation time or that desired and offered functionality must be reduced** in order to meet the Client's mandatory requirements.

1.1.2 Explanation of form for Specification of requirements

Requirements: (A/B/C/D)		
A	Mandatory	Mandatory requirement that must be met. Inability to meet the requirement will entail that the offered solution will be rejected.
B	"Should" requirement	The Vendor's fulfilment of the requirement is either given a suitability assessment at evaluation or a score in the event of an actual tender evaluation.
C	Documentation	May be combined with A/B/D designation of requirement type. Emphasizes thus that the Client expects a more comprehensive answer (>100 words) that is elaborated/documented in appendices. If used alone, C is merely an information item that does not require a response or evaluation.
D	High	Combined with B to indicate that the requirement is very important, but not mandatory. The Vendor's ability to meet the requirement is awarded a score with an associated **high weighting** upon assessment of the offer.

1.1.3 The Client's provisions concerning the Vendor's answer

Answer:

All specified[1] requirements, regardless of requirement type, have to be answered by the Vendor. The answer establishes to which extent the Tenderer meets the requirement's wording and content.

Requirements must be answered with Yes (**Y**), No (**N**) or Elaboration (**E**). Answer category "**E**" covers all options that cannot be answered by an unambiguous Yes/No. For requirements answered with "**E**", that which the Tenderer is unable to cover, a detailed elaboration is expected. This to ensure the Client's understanding of the answer to the requirements have the correct basis for an assessment and/or evaluation.

*The combination No (**N**) and Not applicable (**N/A**) **may also be used where the Tenderer** considers the requirement to be inapplicable based on the offered solution.*

There **must be no** references to or use of manuals, brochures, marketing material, etc. as ***answers*** to requirement items. To ensure a correct basis for comparison when different vendors are to be evaluated/assessed, an answer to a requirement must therefore include necessary copies of the relevant text. This clarification is particularly important for mandatory requirements (A-requirements), as these requirements shall commit the Tenderer and ensure the Client that it is possible to establish the offered solution in the Client's infrastructure.

This ensures that a subsequent design process does not entail unintended implementation costs and a lengthy

[1] By "specified" it is meant requirement items that the Client initially has not marked as inapplicable on his part with the combination: "N" and "N/A"

implementation period, and that requested and offered functionality may be brought into use in accordance with The South-Eastern Norway Regional Health Authority's requirements to information security and privacy.

Nevertheless, the Tenderer is responsible that its design proposal and solution elements are documented in a complete and comprehensive manner to cover all answers and specifications that are included in this specification of requirements. This entails that the Tenderer is also responsible for describing all necessary solution elements in order to achieve a complete and working solution, even though such elements are not explicitly described by the Client in the specification of requirements. The Client therefore assumes that the Tenderer draws attention to any relevant aspects of the solution that are not covered by the Client's specification of requirements.

Elaboration of answers:

Here the Tenderer **may** elaborate responses of types "**Y**" or "**N**" if deemed necessary to ensure comprehension. However, it is not permitted to reword a "**Y**" to "**N**" or vice versa in such elaboration. Unambiguous answers of the type "**Y/N"** without mentionable elaboration are assumed only for simple requirements. With the "**Y/N"** response to simple requirements, the Client assumes that the Tenderer has **accepted/denied** all terms of the requirement 100%, and will assess this accordingly. In the event of "**E**" responses, the Tenderer **must** elaborate what is not met in the Client's requirement. The Tenderer must describe to which extent a non-conformance is permanent, or whether this may be resolved through a design change or an alternative solution proposal. If alternative solution proposals impact the price, we have an elaboration with price consequence that is processed in accordance with the description in the section below for **"Price"**. Here the Tenderer must document the actual price consequence for the Client.

Price:

Answered with a "**Y**" or "**N**". Here the Tenderer states whether there is a separate, dedicated price element in order for the Tenderer is to meet its obligations in accordance with the answer to the requirement. It is then assumed that the associated price element is indicated in the Price Appendix – with reference to the corresponding requirement item. If the answer is "**N**", the Client assumes that the requirement is met upon entry into contract, or within an agreed time during the term of the contract, without triggering additional cost for the Client.

1.1.4 Assessment of the quality of documentation

The Client require all answers of more than 100 words, or that include figures, to be described in the Vendor's appendices with references to improve readability and ensure a comprehensive understanding and correct assessment/evaluation. Such answers must reference the requirement number(s) and be specifically drawn up for the requirement in question.

The Client will assess the overall quality of the submitted documentation and answers in the specification of requirements. This may be assigned an overall score upon evaluation.

2 General information

This competition is conducted by Sykehusinnkjøp HF (Client), on behalf of Oslo University Hospital Trust (Customer).

Sykehusinnkjøp HF is owned by the four regional health authorities; Helse Sør-Øst RHF, Helse Vest RHF, Helse Midt-Norge RHF and Helse Nord RHF, of which the share is 25 % each. For further information, see www.sykehusinnkjøp.no

For clarification, the term *Tenderer* is used as designation of the suppliers participating in this competition, while *Contractor* is used as designation of the supplier(s) awarded a contract.

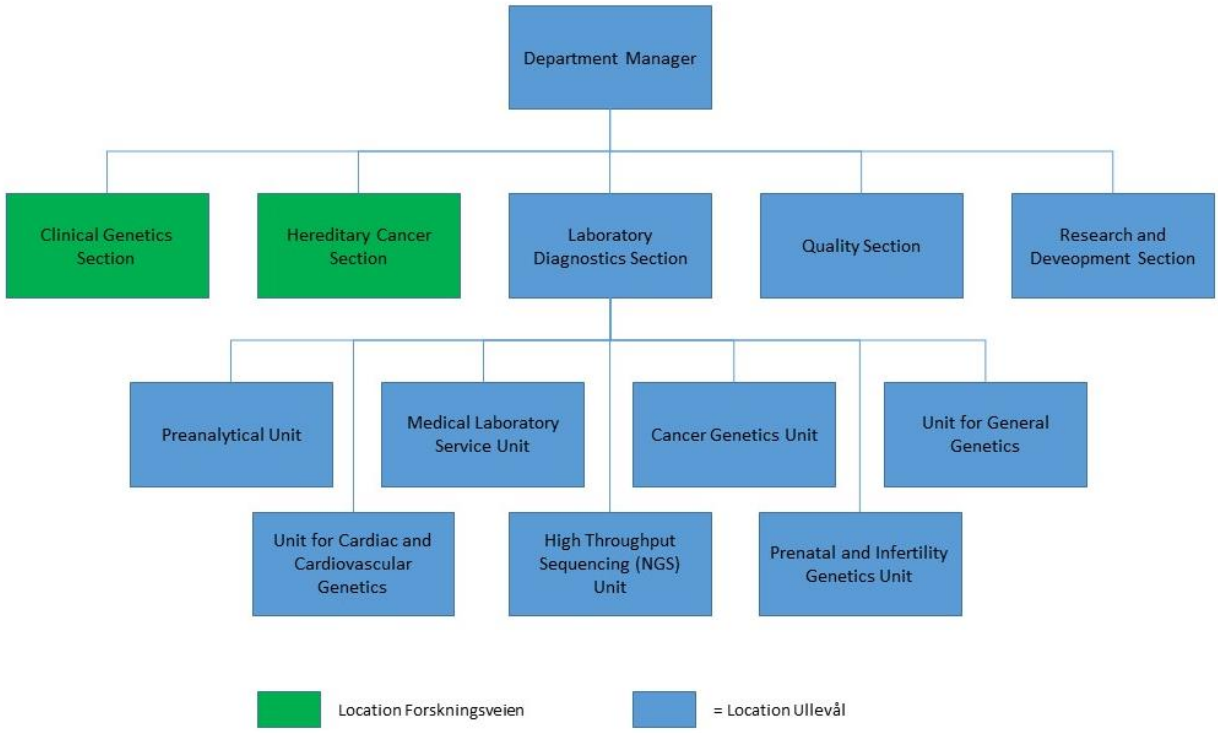
2.1 Oslo University Hospital Trust

Oslo University Hospital is a highly specialized hospital in charge of extensive regional and local hospital assignments and the provision of high quality services for the citizens of Oslo. The hospital has a nationwide responsibility for a number of national and multiregional assignments and has several national centers of competence. Oslo University Hospital is the largest hospital in Scandinavia, and performs more than 1.2 million patient treatments annually. Oslo University Hospital is a public hospital with more than 20 000 employees. For further information, see www.oslo-universitetssykehus.no

2.1.1 Department of Medical Genetics

The Department of Medical Genetics (DMG) at Oslo University Hospital is Norway's largest medical genetics department and provides diagnostics and research within the field of hereditary diseases. Our main areas are genetic diagnostics, genetic counselling and research. The laboratory offer more than 200 different tests, with a large amount of the samples analyzed by Next Generation Sequencing (NGS). The department has approximately 230 employees, spread across 5 sections in two different locations in Oslo. The diagnostic laboratory section is again divided into 7 units. The Oslo University Hospital is currently planning the construction of a new laboratory facility in Oslo with a tentative completion date in 2026.-2027. The laboratory part of Department of Medical Genetics will be part of the relocation to these new facilities, "The Life Science Building".

Figure 1. Organization Department of Medical Genetics



The seven laboratory diagnostic units receive about 25 000 – 30 000 samples a year, doing about 60 000 diagnostic analyses. We offer more than 200 different analyses, performed by either of these methods:

- NGS-based methods, such as whole genome sequencing, whole exome sequencing and targeted NGS-panels

- Non Invasive Prenatal Testing (NIPT), by Veriseq NIPT Solution from Illumina
- Sanger sequencing
- Multiplex Ligation-dependent Probe Amplification (MLPA)
- Array CGH
- Fragment analyses

New methods are quite often established; right now, we are establishing methods for optical mapping (Saphyr Bionano), digital droplet PCR, and preimplantation genetic testing (PGT). Our diagnostic repertoire and instrument park is constantly changing, and there is a need for the new LIMS to support a department in rapid development.

Large amounts of our diagnostic analyses are based on next-generation sequencing (NGS). In 2021 we performed 10 000 NGS-based diagnostic analyses, of them 2700 where whole genome sequencing. In general, our laboratory is modern and well-equipped, focusing on automation of all processes. The diagnostic and research sections share instruments and ICT-infrastructure for NGS. Today, this NGS ICT-infrastructure is connected to secure big data storage facilities at University of Oslo, and not to the network of Oslo University hospital. Clarity LIMS (see table 1) is the only LIMS in this network, while the other LIMS listed in table 1 are implemented in the hospital ICT-network.

There are three section/unit performing genetic counselling in the department; Hereditary Cancer Section, Clinical Genetics Section, and Cardio and cardiovascular Unit. All together, they do app. 12 000 genetic counseling each year, with a wide variety of indications. Their patient examination often involves counselling and genetic diagnostics of entire families.

2.2 Telemark Hospital Trust, Section of Medical Genetics

Section of Medical Genetics at Telemark Hospital Trust is a smaller medical genetic department in South-Eastern Norway Regional Health Authority. This department would like to be included in the offer as an option for purchasing.

The department provides diagnostics, counselling and research within hereditary diseases. The department has approximately 30 employees and is part of the Medical Service Division, which has 300 full-time equivalents. The hospital has more than 3500 employees.

Their activity is also to a large extent based on NGS but have also diagnostics based on cytogenetics and other molecular genetic methods including Sanger sequencing, MLPA, Fragment analyses and array CGH. In 2021 the department completed 10 000 analyses of which 2000 where Next Generation Sequencing (NGS) analyses.

The diagnostic laboratory including all analyses are accredited in compliance with NS-EN ISO 15189 (2011).

2.3 Sykehuspartner Hospital Trust (Sykehuspartner HF)

Sykehuspartner HF currently delivers joint services within ICT, HR and Projects to all the health trusts in the South-Eastern Norway, and with its 1400 employees is one of the Nordic region's largest companies in the field. Sykehuspartner HF is responsible for the delivery of ICT services to all the health trusts in the South-Eastern Norway. For further information, see www.sykehuspartner.no

2.4 South-Eastern Norway Regional Health Authority

The South-Eastern Norway Regional Health Authority (Helse Sør-Øst RHF) is the state health trust group that is responsible for specialist health services in the South-Eastern part of Norway (the county municipalities Viken, Oslo, Innlandet, Telemark, Vestfold and Agder). The enterprise is organized as a parent company (Regional Health Trust), with 11 underlying subsidiaries that are organized as independent health trusts with their own responsibility for results and with employer responsibility for their employees.

South-Eastern Norway is the country's largest health region with responsibility for specialist health services for a population of 2.85 million people. The health region has about 77 000 employees (including temps). Turnover is approx. 77 billion kroner. The head office of the South-Eastern Norway Regional Health Authority is located in Hamar, with another administration office location in Skien. For further information, see www.helse-sorost.no.

2.5 Purpose and scope

2.5.1 Purpose

The purpose of this invitation to tender is to acquire a new, modern Laboratory Information Management System (LIMS) covering the needs for Department of Medical Genetics (DMG). DMG will during the dialogue with the Tenderers identify and define how the needs can best be met.

The LIMS must cover all needs in DMGs diagnostic laboratory; from registration of the referred analyses and all patient/family details, and support the workflow in the laboratory ending with a clinical report to the clinicians. Ideally, it also should support genetic counselling in DMGs clinical sections, or be seamlessly integrated with such systems. The LIMS should be suitable for a modern diagnostics laboratory within medical genetics and be flexible enough to handle the demands arising within a more and more digitized healthcare system. Genetics is a technologic driven field, and the LIMS will need to support this development, hence, be flexible for frequent changes.

Table 1. The ICT-system/LIMS in the department today, their functionality, and the priority of being replaced by the new acquired LIMS. All, despite Clarity LIMS, are patient administrative systems, to some extent integrated with the hospital's electronic health record (EHR) system; DIPS.

Todays' ICT-system	Units in the organization where it is in use	High level functionality	Priority to be replaced
Swisslab (Nexus)	Preanalytic Unit, High Throughput Sequencing Unit, Prenatal and Infertility Genetics Unit, Cancer Genetic Unit, Unit for General Genetics, Medical Laboratory Service Unit	Laboratory system. Receiving electronic referrals/manual registration of patient/family info. Supports workflows throughout the lab, MD-integrations. Integrated with EHR, patient registry and invoicing system. Patient reports. Statistics.	1
FileMakerPro laboratory functions (Claris.com) (in-house developed)	Unit for Cardiac and Cardiovascular Genetics	Laboratory system. Same as Swisslab, but used in another unit. Some additional features.	1
Clarity LIMS (Illumina)	High Throughput Sequencing Unit, Research and Development Section, Cancer Genetic Unit	Laboratory system. Support NGS workflows, integrated with NGS-instrument and other MDs. Reagent tracking. Today in a separate network.	2

FileMakerPro clinical functions (in-house developed), and Cyrillic pedigree drawing	Unit for Cardiac and Cardiovascular Genetics	Clinical. Pedigrees. Family data and genetic information.	3
CGEN (in-house developed Oracle database)	Hereditary Cancer Section	Clinical. Pedigrees. Family data and genetic information.	4
MedInsight (medinsight.no)	Clinical Genetics Section	Clinical. Family data and genetic information.	5

MD=Medical devices

NGS=next generation sequencing

DMG currently use several systems that we hope to combine into a single one. DMG consider that a gradual merge to be easier and less risky, and can open up for alternative replacement systems if they cannot be combined into one big LIMS.

Today, the laboratory has three different LIMS; Swisslab (Nexus), a homemade LIMS based on FileMakerPro (internally called “Lipidregisteret”), and Clarity LIMS (Illumina). FileMakerPro is used in Unit for Cardiac and Cardiovascular Genetics, and Swisslab is used in all other laboratory units in Section for Laboratory Diagnostics. Both systems are handling the entire workflow in DMGs laboratories, despite the integration and monitoring of to DMGs next generation sequencing instruments and workflow, which is covered by the Clarity LIMS. The new system shall replace Swisslab and the laboratory managing part of the FileMakerPro application. It should also have modules for Next generation sequencing, aiming to also replace Clarity LIMS.

Our department also embrace extensive policlinic activity with genetic counselling of individuals and families. It will therefore be an advantage if the LIMS also has a clinical module supporting the needs for this activity. If so, we aim to replace three system today used for handling genetic counselling. In Unit for Cardiac and Cardiovascular Genetics uses FileMakerPro and Cyrillic to cover their needs in the clinic. Hereditary cancer section is using an Oracle-based system developed in-house; internally called “CGEN”. Clinical Genetic Section is using MedInsight for the same purpose. Ideally, the new LIMS can replace all these clinical systems. The FileMakerPro application holds the highest priority to be replaced also for its clinical module, thereafter “CGEN”, and desirable; MedInsight. It should be noted that DIPS is used as the hospital’s electronic patient journal system (EPJ), and integration between this EPJ and the new LIMS will be needed.

Historical data from the replaced systems will need to be converted into the new LIMS. This applies both to the laboratories LIMS and the clinical systems.

More than one system can be selected to cover the functionalities, given the possibility of an integration between them.

2.5.2 Desired functionality and possibilities in the solution

1. A new Laboratory Information Management System that should be flexible and user-friendly and that meets the following needs for the department:
   - Efficient workflow handling to save time and reduce risk of errors
   - Allow for integration with instruments and ICT systems in use at the hospital

- High degree of traceability throughout the work flow, with particular emphasis on DNA indexing for sequencing methods that require library preparation
- Sample registration, from numbering and marking of received samples to test completion and reporting of results for efficient and quality assured processing of samples.
- Biobank functionality
- Customization of user interfaces and workflows
- Automatic registration of user information and time stamp throughout the process from sample registration through technical and medical validation steps and reporting.
- Advanced and flexible tools for statistics and reporting
- Efficient and clear solution for multidiscipline follow up of genetic testing of families and family screening when pathogenic variant is discovered preferably through the use of pedigree functionality

2. Migration of data from various existing systems into new LIMS
3. User manuals and user training
4. Support during and after implementation of new system

2.5.3 Scope

Oslo University Hospital Trust intends to enter into agreements with one Contractor.

Section of Medical Genetics at Telemark Hospital Trust is included in the procurement with an option for purchasing.

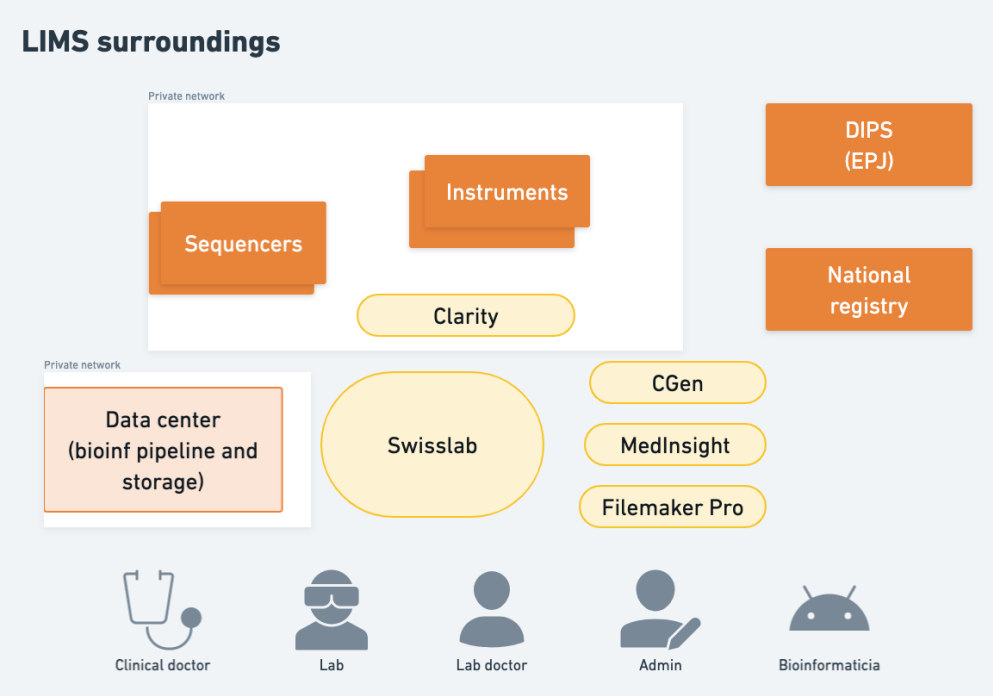
2.6 Agreement form and duration

The Customer plans to use the following agreements;

- Development and Customisation Agreement (SSA-T)
    - Agreement governing the delivery of software that is developed or customised for the Customer
- Maintenance Agreement (SSA-V)
    - Agreement governing the maintenance and servicing of software and equipment

The agreements are based on The Norwegian Government's Standard Terms and Conditions for IT Procurements.

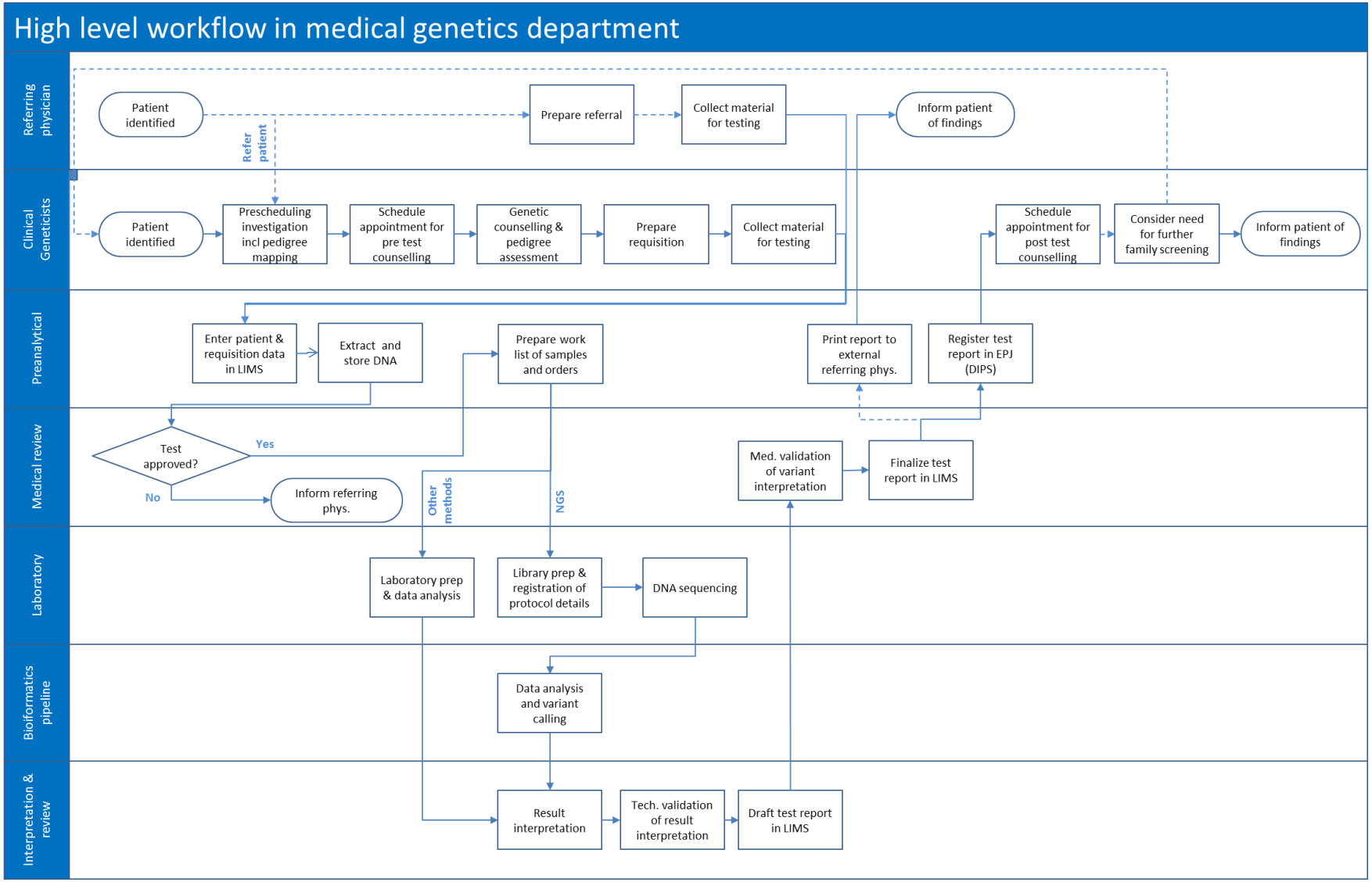
Figure 2. Overview of the LIMS surroundings.



2.7 Workflow

The document “Current workflow NGS trio sample” illustrates current workflow for a trio sample for NGS.
The document “Flowchart_Integrations LIMS AMG” describes integrations related to the current LIMS.

Figure 3. Flowchart of current workflow of all the department’s methods (high-level).


High level workflow in medical genetics department
Referring physician
Clinical Geneticists
Preanalytical
Medical review
Laboratory
Bioinformatics pipeline
Interpretation & review
Patient identified
Refer patient
Prepare referral
Collect material for testing
Inform patient of findings
Patient identified
Prescheduling investigation incl pedigree mapping
Schedule appointment for pre test counselling
Genetic counselling & pedigree assessment
Prepare requisition
Collect material for testing
Schedule appointment for post test counselling
Consider need for further family screening
Inform patient of findings
Enter patient & requisition data in LIMS
Extract and store DNA
Prepare work list of samples and orders
Print report to external referring phys.
Register test report in EPJ (DIPS)
Test approved?
Yes
No
Inform referring phys.
Other methods
NGS
Med. validation of variant interpretation
Finalize test report in LIMS
Laboratory prep & data analysis
Library prep & registration of protocol details
DNA sequencing
Data analysis and variant calling
Result interpretation
Tech. validation of result interpretation
Draft test report in LIMS

3 Terms and Definitions

Term	Description
Analysis	Diagnostic test
Anonymize	Anonymization is a type of data sanitization whose intent is privacy protection. It is the process of either encrypting or removing personally identifiable information from data sets to that the people the data describe remain anonymous.
API	Application Programmer interface is a set of routines, protocols and tools for building software applications.
Architecture	Can be divided into business architecture, information architecture, application architecture (solution architecture), technology architecture, security architecture. These areas together define the structure of the solution and how it interacts with its surroundings.
Bioinformatic pipeline	**Bioinf pipeline**: Computational processing of raw (sequencing) data into something interpretable (identfied variants, reports). The processing is typically run on a series powerful computers in a data center.
Client	Client defines both the client part of the application (user interface) ad the equipment on which the client part is run (PC, laptop, tablet, mobile phone etc)
Consumer Electronics	Electronic equipment intended for the private market such as tablets, smartphones, digital cameras etc.
Data controller	Data controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purpose and means of the processing of personal data; where the purposes and means of such processing are determined by law
Data processor	Data processor means a natural or legal person, public authority, agency or other body which process personal data on behalf of a data controller.
Data Protection Authority	This Norwegian Government Agency is an independent body set up to protect the individual's right to privacy. The main legislation directing the work of Datatilsynet is the Personal Data Act. Norway is bound by the GDPR in the same manner as EU member states
D-number	Temporary identity number given to foreign citizens who stay only a short time or periodically in Norway
Electronic Signature	A unique signature for everyone accessing the system. The signature is predefined by an administrative hospital system
Ella	Software for clinical analysis of genetic data developed by the department of medical genetics at Oslo University Hospital
FH-number	Common support number, FH-number is a national unique identification of a person who does not have a social security number or D-number or where this is not known
Healthcare Regions	The specialist healthcare in Norway is divided into 4 different regions; North, Mid-Norway, Vest and SouthEast.
H-number	Emergency Social Security Number allocated internally within a specific hospital trust to provide a unique identifier for a patient who does not have a social security number or D-number or where this is not knows.
Hospital	A hospital or location is part of a Hospital Trust
Hospital Trust / Regional	A hospital trust Ts organized with one or more hospitals offering medical assistance. There are some health trusts that do not provide

Term	Description
Health Authorities	medical assistance, but are owned by the regional health authorities and offers services to the various regions
Information model/Data model	An information model in software engineering is the representation of concepts and the relationships, constraints, rules and operations to specify data semantics for a chosen domain of discourse
Legal entity	Each Hospital Trust is a separate legal entity with its own board and is directly responsible for medical assistance provided within their organization and for fulfilling all relevant legal requirements
Metadata	Information about the data including but not limited to description, structural and reference
MTD	Medical Technical Devices
Patient Demographics	Non-clincial information about the patient such as patient ID, name, gender, etc
Patient ID	Unique patient identification. In Norway this can be social security number, FH-number, D-number, H-number
Regional Health Authorities	Regional health authorities own the various different Hospital Trusts. The regional health authorities do not offer medical assistance but are responsible for ensuring that the various hospitals in the region performs their duties in a satisfactory manner.
Role	A role is an umbrella term for a set of users of an application that needs the same functionality and has the same user rights, such as doctor, engineer and interpreter. Roles are used to simplify the linking of an individual user to a set of functionality and rights in the application/solution
Sample	The biologic material
Single Sign On	Single Sign-On is a centralized session and user authentication service in which on set of login credentials can be used to access multiple applications.
Social security number	Social Security Number is a unique identifier for persons residing in Norway on a permanent or temporary basis. Norwegian social security numbers consist of the persons birth date (6 digits - ddmmyy) and a personal number (5 digits)
Specialized application/system	A specialized clinical end user application, often associated with a specialized medical discipline or function
Version Handling	How the offered solution handles storing of changes and at the same time secures historic data in the system.

4 Project Management and Support

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:

F-1	Tenderer must have a clear strategy for execution of projects of this type.	AC		
F-2	Tenderer is asked to describe in detail their process for execution of the project, including, but not limited to: - Project management - Timelines, included milestones and risks - Testing and communication with the users - User training	BC		
F-3	The Tenderer should describe the functionality and structure of their LIMS. Include information about relevant modules for a medical genetics laboratory, including NGC and other relevant methods, clinical work (for example pedigree functionality and family relations), invoicing, reagent tracking, instrument integrations etc.	BC		
F-4	The tenderer should describe their strategy for solving errors, bugs and change request, including time limits and support.	BC		

5 User configuration and self service

Our departments, our processes and the technology in the field of genetics are constantly evolving. We therefore have a great need to be able to make changes and adjustments in our LIMS. We desire a system that supports high level of self service, where we can do a lot of the configurations and customization ourselves. It is important that we easily can test new config./changes before put in to production.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
	The system must enable a high degree of self service without involving the tenderer or the hosting partner	A		
	The system should support testing configuration and customization on the system, to prevent undesirable side effects. .	BDC		
	Customization and configuration of workflows should be able to be copied and used as base for modification I.e. a new workflow is created by adding or deleting one or more process steps from an existing workflow.	B		
	The customers should be able to configure the user interface to limit or add information.	B		

6 Flexible data model

The LIMS must adapt to new requirements and need to handle new type of data and relationships between key concepts. Ideally such customization can be done by trained users without little involvement by Tenderer or the hosting partner. New datatypes and concepts should naturally be integrated into various parts of the LIMS like the user interface, workflows, API, searching and dashboards. Examples of new datatypes are genetic variant described in HGVS nomenclature with classification 1-5 and ACMG-criteria like PS1 and BP4 and bioinformatics pipeline (type of pipeline, date started/completed, result, error messages). The LIMS's API should then be extended to allow for receiving status information from a run of the pipeline. And any general search functionality should enable searching all patients with a certain genetic variant.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
	The Tenderer is asked to elaborate on how the LIMS can adjust to new data types	BC		

7 System updates

Regular maintenance of the system, such as version upgrades and bug fixes is required.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-5	License renewal and maintenance in general must operate smooth with absolute minimal downtime of the system. In the case of planned downtime this must always be announced and accepted by purchaser	AC		
F-6	Software updates must be compatible with older versions of the system. I.e., upon updates customization and configuration is still functioning in the newer version. Software updates must preserve data, configuration and customization.	A		
F-7	The solution should have mechanism for alerting users of any updates or downtimes; and prevent data loss from any unsaved user changes	BD		
F-8	A software update should first be tested in a production like environment before being applied to production.	BD		
F-9	The system must be able to get updated to follow changes in technology, methods, instruments, protocols, reagents etc. The updates might be updated by the Tenderer or by the custom using the building blocks of LIMS	A		
F-10	The tenderer is asked to elaborate on the LIMS development process and it's timeline. It is evalated positively that the time between updates is short	BC		
F-11	Changes to the LIMS should be driven by our needs, and not be imposed by the Tendered or other customers	BD		

8 User Forums

Our department sees the value of having an active and easily accessible user forum where we can exchange experiences, knowledge and discuss any change requests

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-12	Describe how tenderer facilitates and support the users need to meet, to learn and help each other, including any physical and online training and other user forums.	C		

9 Manuals and Documentation

The operating language in our department is ether Norwegian or English. Our department is accredited to the standard ISO 15189:2012 which means the system must be fully documented.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-13	The Tenderer must provide electronic user, administrator and installation manuals in English.	A		
F-14	The Tenderer should confirm if manuals can be also provided in Norwegian	B		
F-15	The Tenderer shall provide updated manuals together with future releases of the LIMS as required	A		
F-16	The Tenderer must provide full and updated documentation for the product	A		

10 Language Support

The operating language (both read and written) in our department is ether Norwegian or English.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-17	The offered solution's user interface shall be in either English or Norwegian. The tenderer should state whether the system support multiple languages in the user interface.	A		

F-18	The offered solution's use of Norwegian (if applicable) should be based on recognized Norwegian terminology and standard spelling	B		
F-19	The offered solution must support Norwegian characters (æ/ø/å) and Norwegian sorting sequence	A		
F-20	Describe the formatting options of dates, numbers, currencies and other data that typically have language specific formatting	AC		

11 LIMS Database

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-21	The database must be read-accessible from outside the system environment and can be queried by external software	A		
F-22	The database content must be owned by the purchaser at all times	A		
F-23	The purchaser requires access to read the database tables and make extracts from there. There should be no ban on extracting raw data from the database.	BD		

12 Regulatory Compliance

There are several national and international regulations that our lab must follow. There are several national frameworks for electronic message exchange that must be followed. Unfortunately, these documents are not available in English.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-24	The system must comply with the EU GDPR law	A		

F-25	The system must support procedures in an DS/EN ISO 15189:2013 accredited laboratory.	A		
F-26	Electronic messages sent from the system must comply with the ebXML framework for electronic message exchange - HIS 1037:2011 (see appendix 1)	A		
F-27	The system must handle application receipt as described HIS 80415:2012 (see appendix 2)	A		
F-28	When registering electronic addresses in the address register and when addressing messages, service-based addressing shall be used, in accordance with the requirements in HIS 1153-1:2016, HIS 1153-2:2016 and HIS 1153-3:2017 (see appendix 3, 4 and 5)	A		
F-29	Use of contact information in electronic messages should be in comply with the framework HIS 1174:2017 (See appendix 6)	A		
F-30	Linking related messages using identifiers shall be in accordance with the requirements in HIS 1218:2019 (see appendix 7)	A		
F-31	The system should support structure phenotype information according to The Human Phenotype Ontology (HPO)	BD		
F-32	The system should comply with ISO/TS 202428:2017 Health informatics - Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records	B		

13 Auditability

Out see it as a great advantage if there is functionality for audit in the system. We carry out many internal audits and have several external bodies that perform major audits.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-33	The system should contain a complete audit trail. Audit of a given sample must be able to be presented in an easily	B		

	accessible form. I.e. it must at all times be possible for authorized users to access data for any given process and its data in the system.			

14 Scalability and Performance

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-34	Tenderer should elaborate on how the increase on number of ongoing processes affects the overall performance of the system while fetching, displaying, processing and registering information. By numbers of ongoing processes we mean e.g: - number of samples/patients registered in the system - number of created workflows - number of simultaneous connected users - number of simultaneous processing jobs - increase on the size of the database - number of API calls - number of integrations - number of searches Please also give a description on how searches initiated by the users (e.g for statistics) impact the performance of the offered solution.	BC		
F-35	The performance of the system should not be affected by demanding searches/queries	BD		

15 User-Friendliness and Information Access

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-36	The Tenderer shall elaborate on how the offered solution supports efficient work processes e.g. without unnecessary use of time, mouse clicks or keystrokes for the user.	C		
F-37	The offered solution's user interface should follow principles for universal design, such as support for hearing impairment, visual impairment or color blindness or other disabilities	B		
F-38	The offered solution should provide a help function that covers all functionality available to the user	BD		
F-39	The offered solution should provide informative error messages on English or Norwegian in any error situation that the user can encounter. Where it is not possible to provide sufficient information in an error message, the offered solution must provide details on where this can be found.	BD		
F-40	The tenderer should elaborate on how the patient information (name, social security number, gender, sample ID) is visible in the different user interfaces.	BC		
F-41	The offered solution should provide easy access to relevant information, such as family relations, patient information and sample information, from anywhere in the workflow. The tenderer should describe how users easily can switch between different interfaces and modules. It is evaluated positively that the system supports easily navigation between interfaces and modules.	BD		
F-42	The user interface should adapt to the users screens, such as large screens, dual screens or a tablet.	BD		
F-43	The system should have keyboard shortcuts for common actions or navigation to various part of the system.	B		
F-44	The system should enable hyperlinking to external documents and web pages, like hospital procedures and omim.org	B		

F-45	The system should support user specific bookmarks to various parts of the system			
F-46	The system should support plain text pasting into text fields by removing formatting from the original text			
F-47	The system should allow for text formatting like bold and underlining in text fields			
F-48	The system should allow the user to turn autocorrect on and off			

16 Logging in

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-49	The solution should support a centralized way of preventing logins (i.e. during maintenance)	B		
F-50	The Tenderer should describe how often a login in required	BD		
F-51	The solution should allow for the user to manually log out	BD		

17 Master Data Management

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-52	The Tenderer shall elaborate on how master data is entered, updated and managed in the offered solution. This should include a description of the need for involvement of Tenderer or data handler in this process, and what management of masterdata the purchaser can do themselves. It is weighted positively that the purchaser can manage masterdata themselves.	CD		
F-53	The offered solution shall support various different types of	A		

	master data such as: a. Indications and diagnoses b. Analysis and test panels c. Disease groups d. Patient type (inpatient, outpatient etc.) e. Referring physician f. Referring institution g. Billing type h. Types of material			
F-54	The tenderer should elaborate on the possibility for categorizing different data in the system. For example registration and categorization of results (variants), disease groups, methods used, sample types and more. It is evaluated positively that the system supports categorization of data that are searchable for statistics.	BD		
F-55	The Tenderer should describe how the solution supports international medical standard, e.g. NPU codes, ICD10 codes, HPO terms, OMIM codes, orphan.net and SNOMED codes	BC		

18 Electronic Signature

The final reports/results generated in the system must be validated and signed by competent personnel before released.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-56	The offered solution shall support advanced electronic signature functionality that meets the requirements of EU regulation number 910/2014.	A		
F-57	The offered solution shall automatically include electronic signature and time stamp based on user data for key validation steps in the process (technical and medical validation)	A		

19 Communication between Users

The staff in our department is located in several different sites. It is important for our operations that he staff can communicate with each other during the whole process.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-58	The Tenderer shall elaborate on how the offered solution supports efficient communication between users of the system, such as various comment fields or messages between users/user groups in the system.	AC		
F-59	The offered solution should allow the user to add predefined standard comments to analysis/work orders for internal use.	B		
F-60	The offered solution should be able to automatically add standard comments based on the analysis or indication selected	BD		
F-61	The offered solution should allow the user to set notifications/flags/prioritization/comments for different concepts/entities in the workflow.	BD		

20 Document management

The department desires a simple document archive that should take care of scanned documents such as requisitions, images from cytogenetic analysis, screen dumps or reports from bioinformatic pipeline. The documents should be linked to relevant items in the LIMS.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-62	The offered solution must be able to link documents to relevant items in the LIMS	A		
F-63	The offered solution must support the import and storage of files in multiple different formats. The Tenderer shall elaborate on any limitations to the number of documents or file formats that can be stored with each work order.	AC		
F-64	The offered solution must be able to save the finalized report as a separate document that can be exported or printed.	A		

F-65	The offered solution must be able to save revised final reports in as a separate document together with previous versions of finalized reports.	A		
F-66	The offered solution should be able to use/import an external ID that later on is searchable in the system. E.g external requisition number or other external identifier.	BD		
F-67	The solution should support OCR scanning for extracting information in to the LIMS (e.g from paper requisitions)	BC		

21 Inventory Management

We want to keep track of such things as reagents and kits in the LIMS. Both to help order new products and know which samples and analyses used the various products. Since the department is spread across several buildings and floors the LIMS should ideally also know the location of the products.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-68	The system must keep track of inventory, such as reagents, kits, flow cell and control material. The tenderer is asked to elaborate on the systems functionality regarding control with inventory.	AC		
F-69	The inventory section should be adaptable for different locations.	B		
F-70	All reagents/kits/consumables should be directly linked to various data such as its vendor, catalogue number, lot number, expiration date and amount of stock. It should also be traceable which lot is used for which sample/project.	BD		
F-71	The solutions inventory section should be able to monitor the stock of reagents (amount, volume and expiration date). It is evaluated positively that the system can monitor and send out warnings to users when the reagent count reach a defined threshold.	B		

F-72	Reagents should only be able to be chosen in processes configured hereto. I.e., it must not be possible to choose reagents that do not apply for a given process.	B		
F-73	The system should support that reagents are 1) registered manually 2) or automatically in batches via a spreadsheet or barcode scanning.	B		
F-74	The system should track the link between a reagent and dilutions hereof	B		

22 Scheduling samples and instruments

The system should have an overview of the instruments and their status to help efficient use and timely maintenance of them.

Analyses have various priorities and urgent ones should be started before others. The system should help schedule the samples on the instruments.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-75	The system should allow users to schedule samples for a given process. I.e. the user can determine when a given sample or pool is to be run on the sequencing instruments The tenderer is asked to describe how the users can schedule samples. It is evaluated positively that the scheduling is easily managed	BD		
F-76	The Tenderer is asked to elaborate on how the system supports managing of instruments, such as scheduling of instruments, status of service and maintenance, calibration/service dates, control runs and more. Please also give information about what kind of warning system are available, e.g notifying users when the service date is approaching.	AC		

23 Patient demographics

All Norwegians are registered in a national register ("Folkeregisteret"/ National Population Register) which the LIMS must integrate with. There are several instances of this register with different update delays. It's not yet decided which one our LIMS should use. This register contains items as an identifier, name, date of birth, address and gender. It does not contain health related information like phenotypes and allergies. Apart from finding a patient in the register, the LIMS must also enable updating some of the items. As "Folkeregisteret» holds the master information, the LIMS must avoid working with old data items. There is also some patient information that is only relevant for the LIMS and that needs to be stored and by managed the LIMS.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-77	The solution must integrate with "Folkeregisteret"	A		
F-78	The offered solution should support automatic update of patient information from "Folkeregisteret".	BD		
F-79	The offered solution shall support all past and current standards for Norwegian social security numbers/patient identification	A		
F-80	The offered solution should allow for entry of multiple patient contact addresses in addition to the National Population Register address	B		
F-81	The offered solution should automatically check the format of patient identification such as: a. Ordinary social security number b. D-number c. H-number d. FH-number e. Emergency number	B		
F-82	The offered solution must support registration of patient demographic data through scanning of 1D and 2D bar codes in accordance with applicable ISO/IEC standards.	A		
F-83	The offered solution shall support manual update of patient information	A		
F-84	The offered solution must support the possibility of defining and storing:	A		

	- Inpatient/outpatient - Payer type (claim for refund or not) - Gender of the patient - Additional patient contact details apart from the ones in the register			
F-85	The solution must support lookup of patients using either patient ID, or first name/last name	A		

24 Requisition Management

Patient analyses are requisted by a doctor by sending either a digital requisition or be sending a paper form. The LIMS must thus support both manual and automatic reqistration of the information in the requisition.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-86	The offered solution shall support electronic requisitions. The tenderer is asked to specify if there are any limitations regarding electronic requisition.	A		
F-87	The offered solution must allow for the manual entry of information from the requisitions directly in the system.	A		
F-88	The offered solution should allow integration with the National Population Register for automatic lookup of patient name and contact details based on a patient identifier (e.g. social security number)	B		
F-89	The offered solution must allow for the entry of patient family details such as: a. Family number b. Family member c. Family relationship	A		
F-90	The Tenderer must elaborate on how family relations and details are registered and visualized. It is evaluated positively that the system has functionality for pedigree mapping and	BCD		

	family details.			
F-91	The offered solution must allow the registration of multiple physicians for each patient. The Tenderer shall provide details on the maximum number of physicians that can be registered. And information about main requester and copy requester	A		
F-92	The Tenderer should describe how the offered solution can enable the structured entry of indication information through the use of HPO (Human Phenotype Ontology) terms	BCD		
F-93	The offered solution should allow for an approval step by a lab doctor before the requested analysis can be included in work orders	BCD		
F-94	The offered solution must provide an overview of all prior analyses that have been performed for each patient.	A		
F-95	The Tenderer should provide information on how the offered solution can be customized for cascading of analyses based on preset criteria.	BD		
F-96	The offered solution shall allow the user to select various levels of urgency/priority for each analysis.	A		
F-97	In the offered solution it should be possible to mark orders that should be reanalyzed when new/updated analyses are available	B		
F-98	All work orders/requisitions and samples must be registered with a unique ID (either a ID generated by the LIMS or an external ID). The solution should prevent the same number from being used again.	A		

25 Sample Management

With increasing number of genetic analyses in healthcare the LIMS must be able to efficient handle a large number of samples. More use of robots and automatic biobanks, requires the LIMS to integrate with those and support a high level of automation. There is however a need to also support manual registration.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-99	The Tenderer shall elaborate on how the offered solution	A		

	allows the manual registration of sample information such as: a. Material type b. Tube type c. Volume d. Concentration e. Collection date			
F-100	The offered solution must support 1D and 2D code scanning to automatically register sample information	A		
F-101	The offered solution should support generation of archive positions for storing/bio banking of the sample	BD		
F-102	The offered solution must allow editing of sample information if sample information changes.	A		
F-103	The offered solution must allow the use of one sample for multiple requisitions and analysis. It should be clear that a sample has been used in several work orders.	A		
F-104	The solution must support derived samples and linking between the master sample (e.g. blood or tissue) and the derived samples (e.g. DNA)	B		
F-105	The offered solution should be able to generate sample destruction date for each sample based on predefined criteria. The solution should allow for manual editing of destruction date for individual samples.	B		
F-106	The offered solution should be able to provide full overview of the department's biobank inventory. Note: The department use Hamilton Verso S1-SE DNA storage system for DNA samples. It is evaluated positively that the LIMS can integrate with this system for updated archive positions.	B		

26 Work Order generation

A work order initiates many of regular activities in the lab. The laboratory personnel are dependent on having lists/overviews of all work orders to be processed. Work order lists for a specific activity should be usually the same method execution (like DNA extraction) is done for all the entries in the list.

A work order list can also function as a communication tool between lab engineers and prevent a person from doing work others already have started. Some work orders are only relevant for specific persons or persons with certain roles.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-107	The offered solution must be able to generate work order lists using a flexible set of criteria and include results with different type of information.	A		
F-108	The offered solution must be able to generate work order lists for DNA extraction from various materials with information about: a. sample number (and/or 2D-barcode) b. material type c. Extraction protocol d. DNA measurement protocol	A		
F-109	The offered solution must be able to generate work orders for laboratory preparation and sequencing which includes information such as: a. Project number/name b. Family number c. Identifier for relationship within a family d. Order number e. Sample number f. Patient social security number g. Patient gender h. DNA concentration	A		
F-110	The offered solution should be able to generate work order for analysis interpretation generally and for individual users	BD		
F-111	The offered solution should be able to generate work orders for technical and medical validations generally and for	BD		

	individual users			
F-112	The offered solution should be able to generate work orders for genetic counselling and general patient follow up	B		
F-113	The offered solution shall allow for the manual update of work orders to accommodate for changes such as: a. Inclusion of additional tests b. Removal of samples c. Change of indication	A		
F-114	The Tenderer shall describe work order version control in the offered solution.	AC		
F-115	The offered solution should support working on a work order in a collaborative fashion (I.e multiple simultaneous editing, chat functionality).	B		

27 Workflow Support in the Laboratory

Workflows describe the various steps that analyses, samples or other resources are guided through. For both efficiency and high quality the LIMS should have strong strong and flexible support of complex workflows. There will be workflows of different types and they will be regularly updated and made obsolete. The LIMS should support easy creation and editing workflows. The workflows will be handled both manually and automatically.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-116	The offered solution must be able support a variety of workflows in the laboratory including, but not limited to: a. Next Generation Sequencing b. Sanger Sequencing c. MLPA Analysis d. Fragment analysis e. Array CGH analysis f. SNP-ID Fingerprinting analysis	BC		
F-117	The system should support the complete workflow for NGS and other methods, including, but not limited to, QC, index sequence allocation to samples, planning, comparing results, pooling of samples, capture of samples, dilution for sequencing,	BC		

	run on sequencing instruments, incl. sample sheet generation. Alternatively, describe experience with integration to Clarity LIMS (Illumina)			
F-118	The Tenderer should elaborate on the offered solutions ability to support workflow automation.	C		
F-119	The system should offer a powerful tool for creating and editing workflows. I.e workflow templates or subworkflows.	BC		
F-120	All ongoing processes should be able to be processed simultaneously by other users and are not locked by the user who began the process	B		
F-121	The Tenderer shall describe how the offered solution provides flexibility and control to experiment planning and flowcell configuration.	AC		
F-122	The system should be able to pool samples and pools. Upon pooling there must be a check for index uniqueness and in case two index sequences differ by less than three base pairs, the system must display a warning for the user. After pooling, all information about the individual samples and pools must be accessible to the user.	BD		
F-123	Pools can be processed, i.e go through processes and have values, such as measurements, attached to it.	BD		
F-124	The offered solution must support full traceability tracking throughout the laboratory workflow including the following: a. Multiple reagent/kit numbers for each work order b. Reagent/kit lot numbers c. Reagent kit expiry date d. Instrument number e. Instrument calibration date	A		
F-125	The offered solution must support the registration of time stamp and user information for each process step.	A		
F-126	The offered solution should make it easy to see the log of the process steps.	B		

F-127	The offered solution should allow users to create and editworkflows.	BD		
F-128	The offered solution must support the upload of files in various formats. Please specify any limitations.	BD		
F-129	The Tenderer shall describe work flow version control in the offered solution.	C		

28 Technical and Medical Validation

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-130	The offered solution shall provide functionality that records the technical and medical validation of diagnostic results by automatically registering the user ID and timestamp for the user performing the validation activity.	A		
F-131	The offered solution shall provide functionality that makes it possible to control which users can perform technical and medical validation of samples/orders.	A		
F-132	The offered solution shall prevent already validated results from being edited by users.	BD		

29 Test report Generation

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-133	The Tenderer shall elaborate on how the offered solution supports efficient report generation.	A		
F-134	The Tenderer should provide an overview of any pre-configured report templates available in the offered solution.	BC		

F-135	The Tenderer shall describe any limitations on the number of customized report templates that can be stored in the LIMS	BCD		
F-136	The Tenderer shall describe the degree to which reports can be configured and the involvement required by Tenderer and/or administrator in setting up customized reports	BCD		
F-137	The offered solution must allow for the incorporation of both hospital logos and accreditation marks in the various reporting templates	A		
F-138	The Tenderer shall describe how elements such as accreditation marks and/or specific data fields can be switched on and off for a specific test report.	AC		
F-139	The Tenderer shall elaborate on the text formatting capabilities of the report and incorporation of report elements such as: a. Tables b. Graphs c. Headers with patient information d. Footers with page numbers e. Different fonts	BCD		
F-140	The Tenderer shall describe the capability to include results from mulitiple analyses into a single report	BCD		
F-141	The offered solution must be able to provide report preview and printing.	A		
F-142	The offered solution should allow the user to select specific attachments to be included in the final report file.	BD		
F-143	The offered solution must allow for the registration of sequencing data interpretation information for each order including; a. Variant information b. Variant class c. Interpretation details d. Transcript information It is evaluated positively that this information is searchable.	BD		

F-144	The offered solution shall allow the user to access variant classification tools and requisition details throughout the various workflows. The tenderer is asked to elaborate on how the system can facilitate to reach other systems / applications from the LIMS	BD		
F-145	The Tenderer shall describe how version control of test report templates is handled in the offered solution	A		
F-146	Describe the possibility of automated merging of a validated test report with an appendix, before sending it electronically to the referring doctor. E.g. merging of results with method limitations, coverage reports or other.	C		

30 Quality Assurance

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-147	The offered solution should support registration of controls, and the generation of trend analysis based on quality control data. The Tenderer is asked to describe how the system handles Quality control samples and data.	AC		
F-148	The system should support addition of control samples either manually or automatically. Whether the controls are added manually or automatically is decided either through configuration or by the user of the system. All controls are specific to process(es) meaning that a control for e.g. Qubit cannot be added to processes other than Qubit measurements. It is evaluated positively that controls can be added to single processes as well as complete workflows	BD		
F-149	Controls should have the option to be linked to a lot number and total amount of stock	BD		

31 Clinical Work Processes

Our department embrace extensive policlinic activity with genetic counselling of individuals and families. It will therefore be an advantage if the LIMS also has a clinical module supporting the needs for this activity. If so, we aim to replace three system today used for handling genetic counselling. In Cardio- and Cardiovascular Genetic Unit, FileMakerPro and Cyrillic together are used to cover their needs in the clinic. Hereditary cancer section is using an oracle-based systems developed in-house; internally called “CGEN”. Clinical Genetic Section is using MedInsight for the same purpose. Ideally, the new LIMS can replace all these clinical systems.

32 Planning of genetic counselling activities

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-150	In the offered solution it should be possible to generate family numbers with relations. The tenderer is asked to elaborate on how family information is handled in the system.	A		
F-151	The offered solution should support the use of family ID from the current LIMS (Swisslab/Lipidregisteret/CGen/Medinsight)	B		
F-152	The Tenderer should elaborate on the offered solutions medical appointment management capabilities. Please include information on possibility to register multiple appointments per patient.	BC		
F-153	The offered solution should be able to generate worklists for genetic counselling activities and patient follow up.	BD		
F-154	The offered solution should enable the structured registration of phenotype information, and fenotype information as free text.	BDC		
F-155	The offered solution should allow for the tracking of missing test samples in particular for trio tests.	B		

33 Dynamic Pedigree Mapping

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:

F-156	The offered solution should ha a module for dynamic pedigree charting function that allows the clinicians to design and record links and pathologies for all the members of a family. Please elaborate on this functionality with screenshots of sample pedigree chart. The Tenderer should also elaborate on how details such as patient ID and diagnosis status in the pedigree map can be enabled/disabled when printing or showing the map in counselling sessions. Examples of sample pedigree maps with different levels of detailing should be included. It is evaluated positively that the pedigree charts is automatically generated/updated when new family information is entered	BCD		
F-157	The offered solution should allow clinicians to look up family members through the dynamic pedigree chart or via the family number	B		
F-158	The offered solution should allow for the use of “dummies” to show not yet registered family members in the dynamic pedigree chart	B		
F-159	The offered solutions dynamic pedigree map should show both the diagnostic status and the counselling status for each member of a family	BD		

34 Query Capabilities and Performance Reporting

Both administrators and medical staff need to gather information from the LIMS outside of the usual workflows and work order lists. The solution should offer a general search/query functionality.

No:	Requirement text:	Requirements:	Answer:	Elaboration:

		(A/B/C/D)	(Y/N/E)	
F-160	The system must support searches/queries for patients, samples, analyses, work order lists, test reports, bioinformatic pipelines and other custom data types	A		
F-161	Searches/queries should include single or multiple fields, dates, Booleans, regular expressions and from/to values	BD		
F-162	The search should allow for sorting the results	BD		
F-163	The fields shown in the results should be customizable	BD		
F-164	The search criteria should be saved for easy re-use	BD		
F-165	The search should support auto-suggest for key	B		
F-166	The result should be able to export to a PDF or a CSV file	BD		

35 Dashboard Capabilities and Performance Reporting

A dashboard helps track, analyze, and present key data from the LIMS to gain deeper insight into the work of the department.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-167	The Tenderer shall elaborate on the offered solutions pre-configured dashboard capabilities, including information on pre-configured KPIs, metrics and other key data points relevant for the laboratory. Please include screen prints as examples of this.	AC		
F-168	The Tenderer shall describe the degree to which dashboards can be configured and the involvement required by Tenderer and/or administrator in setting up customized dashboards	AC		
F-169	The Tenderer shall elaborate on how the system can be set up to provide customized role/user specific dashboards. Please include screen prints with examples of role/user specific	BCD		

	dashboards.			
F-170	The Tenderer shall elaborate on how the offered solution can be configured to extract data to support regular reporting to hospital management and authorities such as: a. Number of samples received per year b. Number of analysis performed per disease group c. Number of analysis performed per patient type d. Number of analysis performed per analysis type e. Number of analysis performed versus disease causing variants found f. Number of analysis per referring health institution	BCD		

36 Integrations

Integrations will be important as the surroundings of the LIMS will keep changing at a rapid pace. More instruments and collaborations with other labs will be introduced. It's crucial that the offered solutions allows for several methods for integrations and the integrations are efficiently and naturally part of the LIMS.

36.1 General

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-171	The offered solution must integrate with systems using exchange of files	AC		
F-172	The offered solution must provide a powerful and standards based API	AC		
F-173	The offered solution must integrate with systems using messaging (standard and custom)	AC		

36.2 Systems

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:

F-174	The offered solution must integrate with other patient administrative systems such as the hospitals electronic patient journal, DIPS. The offered solution must support integration with the hospitals electronic patient journal (EPJ), DIPS, to import patient's personal data. This includes the following: : a. Name b. Social security number c. Address information d. Contact details (phone numbers and email address)	A		
F-175	The offered solution should be able to integrate with Illumina's Clarity LIMS	BD		
F-176	The offered solution should be able to integrate with other LIMS such as Unilab (Siemens) and Swisslab.	B		
F-177				
F-178	The Tenderer should describe any experience with integration to the following software, or how it can be done: provide priced options for the following software applications: a. (QiaConsole) Qiasymphony Management System (QMC) (File transfer software for QiaSymphony) b. Labelmark Plus (Label maker for slides)	BC		

36.3 External registries

See also section «22 Patient demographic» for related requirements.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-179	The offered solution must integrate with the National Population Register to find patients and update patient	A		

	demographic data			
F-180	The offered solution should integrate with the Norwegian Health Professional Registry to be able to find contact details for referring physicians and other copy recipients of analyses results	BD		

36.4 Instruments

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-181	The offered solution shall support the use of handheld 1D and 2D code scanners	A		
F-182	The Tenderer should describe any experience with integration to the following instruments, or how it ca be done: provide priced options for the following instruments: a. Hamilton Verso S1-SE biobanking b. Qiasymphony (Qiagen) DNA extractionQiaxpert *(QIagen) Measures DNA concentration and impurities)* c. Biomek FXP *(Liquid handling)* d. Hamilton Star *(Liquid handling))* e. Agilent DNA microarray scanner *(arrayCGH)* f. Covaris *(DNA fragmentation)* *g.* Tapestation *(Concentration and fragment size measurements)* h. Spectramax M3 *(Absorbance and fluorescence measurement)* i. Lightcycler 480 *(Real-time PCR)* *j.* cBot2 *(Hybridize and amplify DNA to flow cell)* k. QuantStudio 12K Flex *(SNP-ID genotyping)*	BC		
F-183	The offered solution should be able to integrate with Hamilton Verso S1-SE for output files for biobanking. Two-way integration is preferred	BD		

F-184	The Tenderer should provide priced options for integration with the following sequencing instruments: a. 3730 DNA analyzer (DNA Sequencing, Sanger and fragments) b. MiSeq (DNA Sequencing) c. NextSeq (DNA Sequencing) d. NovaSeq (DNA Sequencing)¨ e. BioNano, Oxford Nanopore	BC		

36.5 API

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-185	The Tenderer shall provide a description of the APIs provided with the LIMS	A		
F-186	All information registered in the LIMS shall be available through the APIs	A		
F-187	The APIs must be flexible and expandable to ensure that they always adapt to the current data model.	BC		
F-188	The APIs shall use industry standard, machine readable formats such as Jason or XML to ensure that information from the LIMS can be utilized by any programming language /protocol. If these formats are not supported, please elaborate on available formats.	BCD		
F-189	The LIMS should provide traceability of which client uses the API. (client can be both individual and application) Also, the LIMS should register and provide traceability on what changes were made to the database and why API client initiated/performed the change.			
F-190	The API shall help drive workflows			

F-191	The API should allow for efficient update of masterdata			
F-192	The API should support integration with external bioinformatic processing.			

36.6 Bioinformatic processing

Many analyses requires computation in dedicated and external data centers and the LIMS should integrate with such processing

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-193	The system should generate metadata needed by the computation	B		
F-194	The system should be able to initiate data processing	B		
F-195	The system should receive status from processing and present to users. Both individual and batch status should be presented	B		

37 Invoicing

See also section “12 Regulatory Compliance” for requirements regarding electronic message exchange.

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-196	The system provides a function for keeping track of the prices of individual processes and/or workflows. Each sample or batch of samples should be linked to a price depending on which process / workflow it has completed. Tenderer is asked to describe the billing feature in column G	AC		
F-197	The offered solution must allow for the registration of payer	A		

	details and payer type (i.e. no refunding, differentiating paying models) and for each order			
F-198	The offered solution should keep a track of historic price information	BD		
F-199	The offered solution should allow for a current set of prices and a future set to become active on a given date	B		

38 Other

No:	Requirement text:	Requirements: (A/B/C/D)	Answer: (Y/N/E)	Elaboration:
F-200	The Tenderer is encouraged to include any additional information about the offered solutions functionality that is relevant for the buyer in the evaluation tenders for a new LIMS	B		