



Tendering Instructions for procurement of 1 instrument:

Next generation sequencing/ massive parallel sequencing instrument with analysis software and consumable items

to

University Hospital of North-Norway HF (UNN)





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1 Introduction

The University Hospital of North-Norway (UNN), Department of Medical Genetics, covers the medical genetic services provided for the region of North-Norway and also provides genetic services for specific groups of patients both nationally and internationally. The Department is involved in diagnostics in a wide spectrum of diseases and we offer genetic tests when appropriate. We are currently using Sanger sequencing for a large number of different genes which is time consuming and leads to a long response time.

The need for low cost sequencing has driven the development of high-throughput second-generation sequencing technologies that parallelize the sequencing process, producing hundreds of thousands of sequences at once.

We are now requesting an instrument for massive parallel sequencing or next generation sequencing (hereafter named next generation sequencing instrument in this tender) to expand our analyses of genes involved in human disease. The instrument shall primarily be configured for analysis of genes involved in genetic disorders, but will to a certain degree also be open for other users with other needs.

The instrument should be a low-to-medium throughput platform for the more routine and smaller scale sequencing projects of the departmental laboratory. It has to meet the high quality standard for mutation/variant detection in human genomic DNA, as well as in whole human exomes, with respect to sensitivity and specificity. Furthermore, it should provide a user- friendly interface for operating the instrument and analysis of the data. It must be able to detect single base pair substitutions that occur in a mosaic state -less than 10 %, and small deletions and insertions. The instruments performance on correctly determining the number of bases in homo-polymer runs must be specified. Correct detection of a minimum of a 10base-pair homo-polymer is a requirement. The unit must be a bench top instrument and specific localization demands must be specified. Other specific requirements are listed in the appendix no. 1.

All equipment necessary for amplification, quality check of any step, sequencing and analysis of a subset of known human genes must be specified and included in the tender. Equipment necessary for quality check of DNA prior to analysis must also be included.

1.1 Software

In addition to providing software for producing FASTQ files or similar file types, the offer must also include software for variant calling towards a human reference sequence, using integrated software, or recommended third-party software.

1.2 Consumable items

A framework agreement will be entered for delivery of consumable items and reagents. Tenderers must thus estimate the costs covering everything in the way of consumable items that would be necessary for a consumption level of 55 runs per year. The machine should be flexible with regards to number of samples run at the same time, and we want the offer to include price calculations for running the machine with three different scenarios, as stated in





appendix no. 3.

Tenderers are obligated to supply consumable items for as long as UNN is utilising the equipment that is encompassed by this procurement. The obligation will last for 5 years. UNN is not obligated to purchase a definite quantity of consumable items. It is UNN's need for analyses that will always determine the quantities.

Shelf life of consumable must be specified.

1.3 Warranty

The offer shall include a warranty period of 3 years. A warranty period, exceeding the period of standard warranty, can be offered as a service contract. The price of the warranty period must be specified on the appended price form, appendix no 2.

1.4 References

A reference list of maximum three customers using the instrument should be provided, especially laboratories using the instrument for diagnostic purposes. The references will most likely be contacted during the evaluation to verify the information and description in the offer.

2 Administrative provisions

2.1 Rules and procedure for the competition

Entry into a contract is encompassed by the Norwegian Act relating to Public Procurements of 16 July 1999 No. 69 and the Norwegian Regulations relating to Public Procurements of 7 April 2006 No. 402 with later amendments. The procurement procedure that will be utilised is "Open procedure" according to § 14-1 (1). The tender will be announced in the Mercell, TED- and Doffin-databases.

2.2 Language in tender

The tender and additional information can be written in either English or Norwegian.

2.3 Submission of offer

The deadline for submitting the offer is **30 December 2013 at 12:00.** Offers that are received late will be rejected. All offers should be entered electronically through the Mercell-portal, www.mercell.no,

Any questions regarding the tender must be placed through the communicative module in Mercell. All communication is logged.

If you are unknown to Mercell or have questions on how to import the tender, please contact Mercell Support: Tlf.: + 47 21 01 88 60.

We recommend that the offer is submitted well within the due time, however the offer can be edited until the deadline.





The offer requires an electronic signature. Information about this is found at www.buypass.no, www.bankid.no or www.commfides.no.

It should be noted that it may take a few days to receive the electronic signature.

2.4 Prices

The price of the instrument and the consumable items etc. must be specified on the appended price form, appendix no. 2.

The prices shall be offered in **Norwegian kroner (NOK)** excluding VAT.

The price must be specified inclusive delivery, complete installation and start up.

The price shall also include commissioning.

A warranty period of 3 years shall be included.

Alternative models for warranty, they must be specified in separate offers (see 1.3).

All responses must be given under the respective points and not in the form of cross-references. The prices must be fixed and not in the form of list prices and discounts.

2.5 Opening

There will be no public opening of the offers received.

2.6 Expenses

Costs that are incurred by the tenderer will not be refunded by University Hospital of North-Norway.

2.7 Period of validity

The offers must be valid until 11 July 2014.

2.8 Alternative offers

Alternative offers will not be accepted.

2.9 Deadline for questions

All questions regarding the competition must be placed no later than 10 days before the deadline.

2.10 Public access to competition documents

With respect to the Norwegian "Act relating to the right of access to documents held by public authorities and public undertakings", the procurement records and tenders received will be blocked from public inspection until the supplier has been selected.

The tender documents will subsequently become available to the public. An exception to public access will be made however for information that by law is subject to a non-disclosure obligation. Information that is typically subject to non-disclosure obligations includes information on personal situations (but usually not place of birth, birth date, National Insurance number, citizenship, civil status, occupation and place of abode), and competition-





sensitive operating or business conditions (for example production methods, products under development, customer lists, strategies, analyses, prognoses, but usually not total prices).

Tenderers are thus requested to also include a "censored" version of their offers. For any possible request for public access, the Client will, regardless of this, assess whether the information is of such a nature that the Client is obligated to exempt it from disclosure.

2.11 Requirements specifications

Offers that do not satisfy our minimum requirements in the requirements specification will be rejected.

2.12 Reservations by a tenderer

If the offer has deviated from the tendering instructions, it must appear clearly in the offer. The deviations must appear in the offer letter, possibly with a reference to where in the offer the deviation is described. They must be precise and unambiguous, and must be described such that the client is able to assess the deviations without contact with the supplier. Significant reservations against criteria in the tendering instructions may be able to cause the offer to be rejected.

2.13 Precedence of documents

The following order of precedence for documents will underlie the agreement:

- 1. Tendering instructions with appendixes.
- 2. The offer.

3 Required qualifications

Documentations on the required qualifications must be imported into Mercell – qualifications.

Alternative documentation can be accepted. Please contact UNN for clarification.

The supplier must satisfy the following requirements:

Organisational and legal position:

Requirement	Documentation
The tenderer must be a lawfully established	Registration in the register of companies or
company.	industry register as per national statutes
	(official business registration certificate).





Tax certificates:

Requirement	Documentation
The tenderer must be up-to-date with their	Tax certificate for taxes.
payment of taxes and duties. Norwegian	Tax certificate for VAT.
tenderers must document this using	Both certificates must have been issued on
certificates that are no more than 6 months	form RF-1244 from chief municipal
old.	treasurers.

HSE self-declaration:

Requirement	Documentation
The tenderer shall submit a self-declaration stating that the tenderer fulfils, or upon any possible award of a contract will fulfil, legally mandated requirements in Norway as regards health, safety and the environment.	HSE self-declaration with obligatory signature of the general manager.
For foreign contractors, the following shall apply:	
It is hereby confirmed that in the preparation of the offer regard has been paid to the health, safety and environmental legislation following from the Norwegian Regulations relating to systematic health, safety and environmental work in undertakings (Internal Control Regulations), established by Royal Decree of 6 December 1996 pursuant to the Act of 4 February 1977 No. 4 relating to worker protection and the working environment, etc. It is accepted that upon request the client will be	
given the right to review and verify the company's system for taking care of work with health, safety and the environment.	

Economic and financial capacity:

Economic and imancial capacity.	
Requirement	Documentation
The tenderer must have satisfactory capital	The company's report from the previous
adequacy.	year, as well as more recent information
	that is of relevance to the company's
	financial figures, including the auditor's
	report.
	Submission of the company's annual
	accounts or excerpts from such.





Technical qualifications:

Requirement	Documentation
The tenderer must have experience from	Overview of the most important deliveries
corresponding procurements.	during the past three years for the type of
	equipment the competition basis
	encompasses, including the value of the
	procurement, the point in time and the
	recipient.

If these values are regarded as confidential, approximate numbers can be given.

4 Training

The following requirements are posed for training and the training plan:

4.1 Training for users

The equipment ordered will not be deemed to have been delivered and taken over before the requisite training has been carried out and we have ensured that the instrument is functioning satisfactory. It will be necessary to train minimum three employees of the Department of Medical Genetics in order to ensure the correct use of the instrument and a detailed description of a training plan for the users must be included from the supplier with the respect to all steps in process.

The points in time for the training must be agreed upon. The training will commence on-site after the equipment has been installed. The users must be allowed to request a follow-up session on site with personnel from the company within the first year after the purchase.

5 Criteria for awarding the contract

The offers that meet the minimum requirements (MR1 and MR2) will be further evaluated. The evaluation of offer will be carried out with respect to minimum requirements 2 (MR2), additional requirements (AR) and the documentation requirements in the requirements specification, appendix no. 1, together with appendix no. 3 "Analysis quality and capacity".

Award of the contract will occur based upon the most financially advantageous offer using the following criteria:

5.1 Computed lifecycle cost, weighted at 40 %

The calculation will be based on an estimated quantity of 55 runs/ year for a period of 5 years.





The calculation includes:

- Price of the instrument
- Price of analysis software and consumable items
- Price pr. run as specified in appendix 3
- Price of additional equipment as specified
- Prices of service agreements including telephone support, travel, daily allowance, repair service and spare parts
- Price of training program on-site

5.2 Functionality, analysis quality and capacity, weighted at 60 %

- Ref. to appendix no. 1 "Requirement specifications"
- Ref. to appendix no. 3 "Analysis quality and capacity"

6 Formulation of the offer

The offer must include the following information and be included with the following structure:

Folder name:	Content:
Folder1 – Offer letter	Tenderers must enclose an offer letter signed by an authorised representative of the tenderer and containing a confirmation that the tenderer accepts the requirements and conditions that have been established in the basis for the competition.
Folder2 – Fulfilment of requirements specification	With respect to requirements specification, appendix no. 1.
Folder3 – Product	Document requirements, according to the requirements
information	specification, appendix no. 1.
Folder4 – Prices	Price form, appendix no. 2, ref. point 2.4.
Folder5 – Training plan	User training, ref. point no. 4.
Folder6 – Reference list	Reference list, ref. point 1.4.
Folder7 – Other	Possible other information/other documentation.
Folder8 – Censored offer	Censored offer, ref. point 2.10.

Offers that do not contain this information may be rejected.





7 Appendix

The tender consists of the above document and the following appendixes

Appendix

Appendix no. 1: Requirements specification

Appendix no. 2: Price form

Appendix no. 3: Analysis quality and capacity Appendix no. 4: Purchasing terms instrument

Appendix no. 5: Purchasing terms for delivery of consumable materials