



DRF/P-SAC/JACOB/CNRGH

**SPECIFICATIONS
PROJECT VERSION**

Pages : 1 / 16
Indice : O
Date : 16/05/2025

Réf : 20250401CReFI_X_CDC05





Objet : Supply of a 2nd generation high throughput sequencer

**SUPPLY OF A 2ND GENERATION HIGH THROUGHPUT
SEQUENCER**

**FOR THE REFERENCE, INNOVATION, EXPERTISE AND
TRANSFER CENTER (CREFI_X)**

DIFFUSION :

KEY WORDS: SUPPLY SEQUENCER, NGS , HIGH THROUGHPUT

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Centre de Référence, d'Innovation, d'Expertise, et de transfert (CReFI_X)

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1 OBJECTIVE

These specifications define the conditions under which the Contractor will supply a 2nd generation high-throughput NGS sequencer to CREFIX, based at the CNRGH of the Institut de Biologie François Jacob at the CEA Fontenay-aux-Roses center in Evry (91).

2 CONTEXT

2.1 Presentation of the CEA

The CEA is a public industrial and commercial establishment whose mission is research and development in energy, defense, information technologies, and health. The professions practiced at the CEA cover a wide range of fields and are classified into several major professional families, which include both research and management activities: physics, chemistry, mathematics and scientific computing, material science and technology, security, safety, life sciences, earth and environmental sciences, quality, finance, international relations, technical assistance to programs...

For more information about the CEA, please visit the website www.cea.fr.

2.2 Presentation of the François Jacob Institute of Biology

The François Jacob Institute of Biology, located primarily at the CEA Paris-Saclay sites in Fontenay-aux-Roses and Evry, aims to strengthen fundamental research and develop translational and technological research in three domains:


- ⇒ Radiobiology and radiotoxicology,
- ⇒ Human health (neurodegenerative, infectious, and immuno-hematological disorders),
- ⇒ Medical and environmental genomics.

The François Jacob Institute of Biology includes:

⇒ **Five departments** focused on:

- Medical genomics (CNRGH: [National Center of Human Genomics Research](#)),
- Environmental genomics and metabolic function exploration (Genoscope: [National Center of Sequencing](#)),
- Radiobiology and radiotoxicology (IRCM: [Institute of cellular and molecular radiobiology](#)),
- Prevention and treatment of infectious diseases (IDMIT: [Infectious Diseases Models for Innovative Therapies](#)),
- Diagnosis and treatment of neurodegenerative diseases (MIRCen: [Molecular Imaging Research Center](#)),

⇒ **Three services** involved in research and technological innovations:

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- Prion-related conditions (SEPIA: [Unit of Prion Disorders and Related Infectious Agents](#)),
- Immuno-hematology (SRHI: [Immuno-Hematology Research Unit](#)),
- Development of innovative therapies (STI: [Innovative technology service](#)).

2.3 Presentation of the National Center of Human Genomics Research (CNRGH) of the CEA

Based in Evry, the National Center of Human Genomics Research (CNRGH, previously known as the National Center for Genotyping, CNG) is a department attached to the François Jacob Institute of Biology. This department is one of the national research platforms in genomics dedicated to genome sequencing and genotyping of human diseases.

The National Center of Human Genomics Research aims to develop and apply genotyping, sequencing, and genomic technologies related to these activities, particularly for identifying morbid genes involved in genetic diseases, common diseases, and population studies. The CNRGH is also a large facility serving the scientific community nationally, at the European level, and internationally, conducting DNA and RNA sequencing operations on a very large scale, based on an industrial organization that reduces costs and conducts cohort studies on hundreds, thousands, or even tens of thousands of individuals. The CNRGH has a substantial panel of tools and techniques associated with genotyping and sequencing: DNA banks, cutting-edge technologies for gene variant identification and detection, genetic markers and maps, genotyping platforms for microsatellite and bi-allelic markers called "SNPs," high-throughput sequencing platform, tools for physical mapping and gene cloning, statistical analysis, genetic epidemiology, and bioinformatics.

- The expertise developed by the CNRGH has led to its selection to co-lead the CReFIX in the context of the structural plan for genomic medicine.

2.4 Presentation of the Reference, Innovation, Expertise, and Transfer Center (CReFIX)

Genomic medicine is profoundly changing patient care. To ensure that everyone can access the new technologies of genomic medicine fairly across the country, France is implementing a plan: the France Genomic Medicine Plan 2025. Its aim is to evolve by 2025 and beyond the way patients are diagnosed, prevented, and treated. The plan responds to a request from the Prime Minister addressed to the Aviesan Alliance in April 2015, to examine the conditions for access to genetic diagnosis in our country.

The CReFIX (Reference, Innovation, Expertise, and Transfer Center) is a Mixed Service Unit (US39 created in early 2019) among the CEA, INSERM, and Inria. It is, along with diagnostic sequencing platforms and the data analysis collector (CAD), one of the 3 key structures of the device set up by the France Genomic Medicine 2025 Plan (PFMG2025) to deploy genomic analysis in healthcare.



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Its dual mission is, across the entire value chain of genomic medicine (from biology to data analysis), to 1) establish standards to ensure data and structure reproducibility and interoperability and 2) innovate and accelerate technology transfer in connection with private actors to offer the most recent and effective approaches while developing a national industrial sector.

The CReflX is currently located on the premises of the National Center of Human Genomic Research (CNRGH) and the Genopole in Évry, which allows for synergies, sources of skills transfer, collaborations, as well as budget optimization.

As UMS-type structures do not have legal personality, the CReflX relies on its members (CEA, Inserm, and Inria) for administrative support, including purchasing activities.

2.5 Context

Thanks to the implementation of the FMG2025 plan, whole genome sequencing for diagnostic purposes is now accessible to patients. In this clinical and healthcare reimbursement context, the growth of this new form of medicine, known as genomics, will be further boosted by a reduction in sequencing costs, a reduction in sequencing times and a lower error rate, enabling the detection of low allele frequency variants involved in pathologies (rare diseases, cancer).

New high-throughput 2nd generation sequencers have appeared on the market in recent years, and their suppliers are announcing a reduction in whole-genome sequencing costs (for 100 Gb per sample – 30X depth), this price including the cost per sequencing consumable unit (flow cell or wafer type).


CReflX, in the context of its missions for the FMG2025 plan, would like to acquire a high-throughput 2nd generation sequencer, with the features mentioned above and detailed below, in order to evaluate the sequencer's performance.

This evaluation will provide advice to existing (SeqOIA and Auragen) and future sequencing platforms, as well as to other partners, so that they can maintain their high level of competitiveness and be able to evolve towards any new technology likely to bring an economic advantage while maintaining high data quality and flexibility of use (run loading capacity (multiplexing), i.e. the number of WGS 30X – 100Gb that can be multiplexed on a sequencing substrate) or a major technical breakthrough (reduction of run duration, detection of low allelic frequency variants).

2.6 Structure of the need

The need is structured as follows:

The services are divided into a fixed part and an estimated part.

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Fixed part

The fixed price includes the following services:

- Firm part :
 - Supply of the sequencer,
 - Delivery, installation and commissioning on CEA site,
 - Testing on CEA site,
 - Training of CEA staff,
 - Delivery of all documentary deliverables,
 - Warranty for 36 months from receipt of the sequencer,
- Optional part :
 - Option n°1: Preventive and corrective maintenance for 12-months from the end of the first 36-month warranty period.
 - Option n°2: Preventive and corrective maintenance for 12 months from the end of the first maintenance option (option n°1 or option n°3);
 - Option n°3 : Preventive maintenance for 12 months from the end of the first 36 months of warranty;
 - Option n°4: Preventive maintenance for 12 months from the end of the first maintenance option (option n°1 or option n°3).

Estimated part:

The estimated part covers the services, on preliminary price lists, relating to the consumables required to produce 10,000 “WGS human genome 30X” (300bp, 30X i.e. 100 Gb per genome). In order to guarantee flexibility in the sequence production flow, a minimum of 2,500 genomes must be sequenced on sequencing substrates (Flow Cell or other) with a loading capacity as close as possible to 25 genomes (WGS at 30X, i.e. 100 Gb).


3 DESCRIPTION OF THE NEED

The supply of a 2nd generation high-throughput NGS sequencer enabling access to a production rate of at least 10,000 genomes per year at the lowest possible unit price per genome, hereinafter referred to as the Equipment. As the Equipment is to be used over several years, CReflX wishes to obtain the lowest possible cost per genome, without having to modify the Equipment.

3.1 Services related to the Equipment


The CEA expects the Equipment to meet the following requirements:

- The price of the Equipment included in the fixed part and the price of the associated consumables included in the estimated part must be as low as possible (full-cost analysis). Any significant reduction in cost will be a plus.
- Sequencing of any type of sample, with no limitation on the type of application (whole genome sequencing, exome sequencing, low pass whole genome

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sequencing, whole transcriptome analysis, expression profiling, cfDNA analysis, etc.).

- minimized operator intervention time (preparation of the flow cell or other suitable support and the various sequencing reagents, equipment initialization and start-up phases),
- Access to a range of production rates, from 3,000 to 3,600 Gigabases of sequences per day, up to 32,000 Gigabases per week. Details of consumable costs according to production rate will be included in the documents to be supplied,
- primary analysis of generated data automatically integrated into the Equipment system. Output data retrieval time will be detailed in the tender,
- Secondary analysis must be possible using pipelines developed at the CNRGH or commercialized and implemented for sequencing data analysis (open source),
- software updates provided by the Contractor at no additional cost to CEA throughout the lifetime of the Equipment,
- The Equipment must be compatible with the environment and protocols currently in use at the CNRGH,
- The Equipment must carry out the basecalling and validate the sequences obtained according to their quality criteria (Qscore), whether in the case of libraries starting from DNA or RNA,
- The equipment must enable the simultaneous sequencing of at least 96 bar-coded samples (indexes), in a simple way (simplified combinatorial capacity, whatever the number of samples to be multiplexed),
- The equipment must enable 300bp reads to be obtained without loss of quality,
- The reads obtained should achieve a quality score (Qscore) above Q30 in at least 85% of cases. Higher quality would be a plus,
- The sequencing time of a run should not exceed 24h. A shorter run duration would be a plus,
- The equipment and/or data processing system must enable the operator to view, store and use the raw sequencing data (sequencing signal acquisition output files in FASTQ format),
- The equipment must be compatible with libraries prepared with kits from different companies (no captive markets), or failing that, offer a library conversion kit,


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- All the sample preparation systems proposed with the Equipment will guarantee its optimal operation by achieving the performance levels set out above,
- The sample preparation and sequencing consumables will ensure that the Equipment operates optimally by achieving the performance levels set out above, even when converting libraries initially produced for another sequencing instrument,
- The Equipment must allow for a simple washing system after each run to eliminate any risk of contamination between the different runs. Automatic post-run wash would be a plus,
- The equipment should automatically recognize the loading of sequencing reagents, and check that they correspond to the reagents required for the run to be launched,
- The equipment should not require any user intervention while sequencing is in progress,
- The Equipment will have to write the generated data to the Equipment, or directly to a local server. The possibility of a double copy locally and on a local server would be a plus,
- The Equipment must ensure the preservation of data generated or being generated, even in the event of hardware, software or even network problems.

In addition to the technology's ability to meet the constraints of productivity and read length, CEA will be particularly attentive to the price of the equipment, the price of the maintenance and the cost of the consumables per gigabase.

3.2 Equipment interface

- The Equipment interface should be in English and as simple as possible. French would be a plus.
- The Equipment interface should alert the user to incorrect positioning or reagent type before the run is launched.
- The Equipment interface should allow the user to vary the read parameters as desired within the limits imposed by the consumables used.
- The user interface must clearly warn the user of any hardware or software malfunction as soon as it is detected. If this malfunction occurs during sequencing and does not cause any hardware degradation or safety problems, it will not stop

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the sequencing in progress, unless the sequencing can be resumed at the stage that caused the problem, without any loss of quality.


- The Equipment and its interface must allow file transfers between the instrument and a LIMS in order to import and export information.
- The Equipment interface must enable the Equipment to be restarted and shut down.
- The Contractor undertakes to supply the latest version of the operating system and future updates, within 5 working days of their release.

3.3 Services relating to the Contractor

- The Equipment will be delivered with the hardware and software necessary for its operation.
- An Installation Qualification (IQ) with a validation and acceptance report (PV) will be issued to the user by the Contractor.
- After installation, the Contractor undertakes to carry out, at his own expense, at least one validation run of the Equipment in order to obtain sequences of 300 nucleic bases on the highest-capacity sequencing support. The data generated must correspond to the expectations (length, quality, number of bases generated etc.) set out above. If this is not the case, the Contractor will have to make the modifications necessary for the proper operation of the Equipment, and carry out any new validation runs required, until these expectations are met.
- Any new validated update shall be proposed and supplied free of charge by the Contractor to the user within 5 working days.
- A training course for 10 people, divided into two courses for 5 people, will be provided by the Contractor, to enable the user to become autonomous. A training certificate will then be issued. The Contractor will supply the consumables needed for the training course. The kit(s) used will preferably be for WGS PCR Free from human gDNA standard samples that will be provided by the CEA.
- A written intervention report must be provided by the Contractor after each intervention (installation, maintenance, repair, etc.).

3.4 Confidentiality

- The Equipment must not enable the retrieval of sequencing data, or any other information that would allow the samples to be identified, either by the Contractor or by a third party not authorized by the user.

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4 PRICES AND CONSUMABLES

The financial appendix must be completed in accordance with the following points.


4.1 Fixed price

- The fixed-price part includes the Equipment and the 36-month warranty.
- The lump-sum part includes two options for preventive and corrective maintenance of twelve months (option n°1 and n°2) and two options for preventive maintenance of twelve months (option n°3 and n°4).

4.2 Estimated part: consumables

- Consumables must be single-use in order to avoid contamination.
- Consumables must contain as few toxic products as possible.
- Consumables must be able to be disposed of without risk of release into the environment (closed containers or, failing that, sealable to prevent spillage or volatility).
- Consumables must take up minimum of space, so that they can be received, moved and disposed of manually, without the need for transport tools.
- The supply of consumables will be subject to a Price List detailed as follows:
 - Sequencing substrate (flow cell or other type) suitable for very high throughput: quantity to produce per year 7500 "WGS human genomes 30X i.e. 100 Gb" without constraint of loading/multiplexing capacity (minimum or maximum) on the sequencing substrate.
 - Sequencing substrate (flow cell or other type) adapted for high throughput with maximum loading/multiplexing capacity: quantity to produce 2500 per year "WGS human genome 30X i.e. 100 Gb" (as close as possible to 25 "WGS human genome 30X i.e. 100 Gb" per substrate).
 - Consumables required for the proper operation of the Equipment (e.g. washing reagents); the tenderer is requested to indicate all captive consumables.
 - The tenderer is asked to indicate any other consumables suitable for the Equipment (examples: library preparation kit, index plate, adapter, library conversion kit, etc.).

The Contractor guarantees that consumables, in particular sequencing substrates, will be sold at the lowest retail prices when tenders are submitted,

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with no commitment to a minimum number of consumables or a minimum annual order price. The Contractor also undertakes to update the prices indicated in the BPU, at least on the anniversary date, and if possible as soon as new, less expensive consumables are marketed by the Contractor.


5 COMPLIANCE AND SAFETY

5.1 Compliance with standards

- The Equipment must comply with electrical safety standards (electrification and overheating). It must be absolutely safe to operate and reliable, given its intended use.
- The Equipment must be fitted with the necessary electrical protection devices to isolate the operator from any direct or indirect electrical contact (electrification).
- Meet CE standards.
- Voltage 220-230 V at a frequency of 50-60 hertz. Electrical outlets must be compatible with the European Union electrical network (CE standards).

5.2 User safety

- The Equipment shall be fitted with a safety system preventing access to its working area when in operation.
- The Equipment must not allow the release of toxic products, either by projection or evaporation.
- The Equipment must not allow opening or access to reagents while sequencing is in progress, unless it allows several runs to be launched in parallel or sequentially. In this case, opening and access to reagents must be limited to the minimum necessary to launch the new run, and must not have any impact on the run already in progress.
- The Equipment must have a switch to cut off the power supply. This switch must not be located where it could be activated by mistake.
- Safety devices must not cause any additional risk.
- Safety devices must not be easily retracted or rendered inoperative.
- The absence or failure of one of the safety devices, depending on the degree of danger, will prevent start-up or make it impossible to launch a run (positive safety).

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- Insofar as their function permits, accessible parts of the equipment must not contain any sharp edges, sharp corners or rough surfaces likely to injure the user.

6 DELIVERY, INSTALLATION, TESTING

6.1 Place of delivery

Unless otherwise specified by CEA, the Equipment is delivered to the following address:

Commissariat à l'Energie Atomique et aux Energies Alternatives
Institut de Biologie François Jacob
Centre National de Recherche en Génomique Humaine
CREFIX
Bâtiment G2 – 1st or 2nd floor
To the attention of Mme Christine Michel / Mme Violette Turon / Mme Zuzana Gerber
31 Boulevard des Coquibus
91000 Evry Cedex
France

6.2 Delivery and installation constraints

The Equipment and any devices required for its operation, which are the subject of these specifications, are to be delivered and installed for CNRGH at the CReFIX laboratory, on the first or second floor of the CEA/CNRGH G2 building, located at 2, rue de Gaston Crémieux in Evry Courcouronnes. The Contractor must find a suitable solution for this delivery.

The limiting factors are the dimensions of the elevator:

- Landing doors: width 1000mm; height 2000mm
- Cabin: width 1100; depth 1550mm

At his own expense, the Contractor will install the new sequencer and any equipment required for its operation (also new) on site, using suitable lifting equipment (cranes, scaffolding) that complies with regulations. The Contractor may call on a subcontractor to deliver and transport the equipment upstairs to the premises. This subcontracting will be at the Contractor's expense and under his responsibility.

Loading and unloading of the sequencer and any equipment required for its operation are the responsibility of the Contractor.

The Contractor will be responsible for

- ⇒ the packaging of the Equipment, adapted to the means of transport used and allowing easy handling in existing access conditions,
- ⇒ protection of the equipment for storage, to avoid any deterioration, in particular by :
 - impact during transport,
 - bad weather,



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- temporary storage on unprotected areas outside the premises,
- ⇒ transport to the CEA's equipment facilities, taking into account the constraints involved in getting on the premises (elevator or crane and scaffolding required),
- ⇒ the unloading, handling and installation of the Equipment in the premises provided.
- ⇒ checking the conformity of the installations to which the Equipment is attached,
- ⇒ assembly and adjustment in preparation for on-site tests: During this stage, the Contractor will connect the Equipment to all the building's networks required (electricity, water, gas, drainage, etc.). In the event that handling equipment belonging to the CEA is to be used, the Contractor must provide proof that its personnel are authorized to use such equipment, which must be the subject of a prior loan request. The Contractor must comply with the safety conditions applicable on site. During installation, the Contractor will be responsible for any damage to any equipment not supplied by the Contractor.
- ⇒ the cleanliness of the premises occupied.

The Contractor is strongly advised to request a visit on site in order to provide the necessary equipment (cranes, scaffolding) to move the equipment to the planned premises (on the first or second floor of the G2 building at CEA/CNRGH, located at 2, rue de Gaston Crémieux in Evry Courcouronnes).

5.3. On-site testing

On-site tests will be carried out by the Contractor in the presence of CEA employees who will be working on the Equipment.

The on-site acceptance tests will validate the technical specifications of the Equipment.

During these tests, a validation run with a reference provided by the Contractor is required.


5.4. Documentation

The documentation associated with all the Equipment will include :

- ⇒ operating and user manuals in paper and pdf format, or available on a website with updates
- ⇒ a complete backup of the software associated with the operation of the Equipment,
- ⇒ all drawings, circuit diagrams and cabling required for maintenance,
- ⇒ a certificate of compliance with French and European standards,
- ⇒ licenses for all software supplied.

5.5 Training

After installation and conclusive on-site tests, two training sessions for CEA employees called upon to work on this Equipment will be provided by the Contractor as soon as possible

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at the CNRGH premises (for 2 * 5 people). These training sessions must include a presentation of the documents supplied by the Contractor. For the practical part of the training, the Contractor will supply the necessary kits for WGS PCR Free library preparation and sequencing 300bp, and the CEA will provide reference samples.

7 WARRANTY

The warranty period is 36 months, from the date of receipt of the Equipment. The warranty must cover any failure that is not due to a handling error on the part of the CEA.

The Contractor must guarantee the availability of spare parts for a period of at least 5 years after the Equipment has been commissioned.

In addition, the Contractor will provide the CEA with a detailed description of what is covered by the warranty in its offer.

The warranty must include at least parts, labor and travel as required, with an on-site intervention within 5 working days from the request made by the CEA (telephone confirmed by e-mail), and a preventive annual maintenance.


8 MAINTENANCE (OPTIONAL)

- Optional (option n°1 and n°2): the provision of a 12-month period of preventive and corrective maintenance (including parts, labor, software support and travel), with a maximum on-site response time of 5 working days from the request made by the CEA (by telephone, confirmed by e-mail).
- Optional (options n°3 and n°4): the supply of a 12-month preventive maintenance service (parts, labor, software support and travel included) with a maximum on-site response time of 5 working days from the request made by the CEA (telephone confirmed by e-mail).

9 DOCUMENTARY DELIVERABLES

When submitting tenders, the tenderer must provide the CEA with the following information:

- The cost of consumables and an estimate for 10,000 genomes per year, with a minimum of 2,500 genomes to be sequenced on "Flow cell" or other substrates with a loading capacity as close as possible to 25 "WGS 30X human genomes, i.e. 100 Gb".
- A description of the company's organization and local structure.

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- A description of the company's commitment to promoting sustainable development.

As part of the performance of the service, the Contractor will provide the following documents:

- On delivery of the Equipment and any devices required for its operation to the CEA/EVRY site, the Contractor shall provide the CEA with the following documents, in English or French:
 - Instructions for use, including precautions to be taken by operators.
 - Maintenance specifications, detailed technical documentation of the Equipment and any devices required for its operation, and its accessories, in English or French, specifying as a minimum the performance guaranteed by the Contractor.
- After training, the Contractor will provide an individual training certificate and training materials, preferably in French.
- After installation, commissioning and operating tests, the Contractor will issue an acceptance and validation report.
- After each warranty or maintenance intervention, the Contractor will submit an intervention report and a validation report.