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Contract

EQA for the National Genomic Test Directory

NHS England

F03: Contract award notice

Notice identifier: 2021/S 000-025500

Procurement identifier (OCID): ocds-h6vhtk-02eb09

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Section I: Contracting authority

I.1) Name and addresses

NHS England

Quarry House

Leeds

LS2 7UE

Contact

Anita Pannu

Email

anita.pannu@nhs.net

Country

United Kingdom

NUTS code

UKE - Yorkshire and the Humber

Internet address(es)

Main address

<https://www.england.nhs.uk//>

Buyer's address

<https://www.england.nhs.uk//>

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

EQA for the National Genomic Test Directory

Reference number

C30160

II.1.2) Main CPV code

- 85100000 - Health services

II.1.3) Type of contract

Services

II.1.4) Short description

This procurement relates to external quality assurance of the samples and the DNA material taken at NHS Genomic Laboratory Hubs as part of the new Genomic Medicine Service. Such sequencing requires high quality DNA and to ensure these samples are provided by the NHS Genomic Medicine Centres (GMCs), a range of external quality assessment (EQA) schemes are required. An assured lab network of GLHs will provide the required assurance to the wider GMS (including for clinical genetics services and Genomic Medicine Centres established as part of the 100,000 Genomes Project).

II.1.6) Information about lots

This contract is divided into lots: No

II.1.7) Total value of the procurement (excluding VAT)

Value excluding VAT: £1,500,000

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKI - London

Main site or place of performance

NHS England

II.2.4) Description of the procurement

Building on the 100,000 Genomes Project and existing genetic services, In October 2018 NHS England announced the launch of the NHS Genomic Medicine Service (GMS) which will be mobilised as part of a transition period to take place over 18 months. The long term aims of the Genomic Medicine Service are to:

- o Provide consistent and equitable care for England's 55 million population
- o Operate to common national standards, specifications and protocols
- o Deliver to a single national genomic testing directory – covering use of all technologies from single gene to whole genome sequencing initially for rare disease and cancer
- o Give all patients the opportunity to participate in research (for individual benefit and to inform future care)
- o Build a national genomic knowledge base providing real world data

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sequencing requires high quality DNA and to ensure these samples are provided by the NHS Genomic Medicine Centres (GMCs), a range of external quality assessment (EQA) schemes are required. An assured lab network of GLHs will provide the required assurance to the wider GMS (including for clinical genetics services and Genomic Medicine Centres established as part of the 100,000 Genomes Project). The quality assurance measures are concentrated on 5 major areas below. NHS England are obligated to provide a quality assurance service to ensure samples collected are of high enough quality to extract a full genome. The required EQA service is as follows:

- EQA for DNA extraction from blood samples
- EQA for DNA extraction for formalin fixed paraffin embedded (FFPE) tissue samples
- EQA for the measurement of DNA quality
- EQA for the assessment of tumour content and cellularity
- EQA for the National Genomic Testing Directory

II.2.5) Award criteria

Price

II.2.11) Information about options

Options: No

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Award of a contract without prior publication of a call for competition in the cases listed below

- The services can be provided only by a particular economic operator for the following reason:
 - absence of competition for technical reasons

Explanation:

A full list of the UKAS accredited suppliers able to provide a quality assurance service for the testing of DNA samples can be found

here: <https://www.ukas.com/browse-ukas-accredited-organisations> The NHS England Genomics Unit has assessed the UKAS-accredited supplier market by use of the link above to identify which are able to meet the service requirements. Based on this assessment, the Genomics Unit has ascertained that: • UK NEQAS (hosted by NHS Lothian) are the only provider qualified and ISO17043 or equivalent accredited for the DNA extraction EQA schemes and related molecular pathology schemes as described above; • No other single provider has the ability to provide the range of medical laboratory tests across Haematology, Blood Coagulation, Immunophenotyping and Histocompatibility and Immunogenetics disciplines. The list of centres with their corresponding EQAs listed can be accessed here Centres - UK NEQAS. The UK NQEAS centres involved are: GenQA/UK NQEAS Genomics – <https://www.genqa.org/UK> NEQAS Leucocyte Immunophenotyping - <http://www.uknegasli.co.uk/UK> NEQAS Haematology – <https://www.uknegash.org/>

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: No

Section V. Award of contract

A contract/lot is awarded: Yes

V.2) Award of contract

V.2.1) Date of conclusion of the contract

13 July 2021

V.2.2) Information about tenders

Number of tenders received: 1

Number of tenders received from SMEs: 0

Number of tenders received from tenderers from other EU Member States: 0

Number of tenders received from tenderers from non-EU Member States: 0

Number of tenders received by electronic means: 0

The contract has been awarded to a group of economic operators: No

V.2.3) Name and address of the contractor

Lothian Health Board

Waverly Gate 2nd Floor 2-4 Waterloo PLace Edinburgh

Edinburgh

EH1 3EG

Email

accountsreceivable@nhslothian.scot.nhs.uk

Country

United Kingdom

NUTS code

- UKM - Scotland

Internet address

<https://www.nhslothian.scot/Pages/default.aspx>

The contractor is an SME

Yes

V.2.4) Information on value of contract/lot (excluding VAT)

Initial estimated total value of the contract/lot: £1,500,000

Total value of the contract/lot: £1,500,000

Section VI. Complementary information

VI.3) Additional information

The required EQA services are as follows and are all mandatory as part of the contract:

- Annual provision of the tests listed in the National Genomic Testing Directory which will be implemented during the transition phase of the Genomic Medicine Service
- Annual provision of one assessment run for DNA extraction from blood samples
- Annual provision of one assessment run for DNA extraction from FFPE tissue samples
- Annual provision of one assessment run for DNA extraction from fresh frozen tissue samples
- Annual provision of one assessment run for DNA extraction from saliva tissue samples
- Annual provision of one assessment run for tissue histopathology assessments
- Annual provision of one assessment run for DNA quality measurement
- Capability to develop other EQAs for any other aspect of laboratory work involved delivery of whole genome sequencing of clinical samples.
- Evidence of scientific advice appropriate to these EQA schemes.
- Delivery of these EQA schemes to all laboratories deemed appropriate by NHS England including Genomic Laboratory Hubs and associated Local Genomic Laboratories.
- Established process for independent, anonymised assessment of results and unbiased reporting of participant performance against NHS England ratified criteria and integration into appropriate National Quality Assurance Advisory Panels.
- Ability to interact with participants with performance issues and support the identification of the causative issues and aid improvement; including the monitoring of the participant in future EQA runs.

The output from the above is to ensure NHS England is assured that the DNA material collected by NHS laboratories is fit for purpose and the genomic tests performed are accurate and appropriately reported. Without a Quality Assurance service in place there is a high risk of NHS GLHs being regularly paid for

samples and tests of sub-standard quality leading to an unachievable genomic testing for the NHS. Laboratory work undertaken as part of the NHS Genomic Medicine Service must be covered by the industry standard - ISO 17043 for the appropriate EQA schemes. UK National External Quality Assessment Service (UK NEQAS) consortium member.

VI.4) Procedures for review

VI.4.1) Review body

NHS England

Skipton House, 80 London Road

London

SE1 6LH

Country

United Kingdom

Internet address

<https://www.england.nhs.uk//>

VI.4.2) Body responsible for mediation procedures

NHS England

Skipton House, 80 London Road

London

SE1 6LH

Country

United Kingdom

Internet address

<https://www.england.nhs.uk//>

VI.4.4) Service from which information about the review procedure may be obtained

NHS England

Quarry House

Leeds

LS2 7UE

Country

United Kingdom

Internet address

<https://www.england.nhs.uk//>