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Planning

Molecular Screening

NHS Blood and Transplant

F01: Prior information notice

Prior information only

Notice identifier: 2022/S 000-024061

Procurement identifier (OCID): ocds-h6vhtk-0363be

Published 26 August 2022, 9:16pm

Section I: Contracting authority

I.1) Name and addresses

NHS Blood and Transplant

500 North Bristol Park

Bristol

BS34 7QH

Contact

Daniel Kirkbride

Email

daniel.kirkbride@nhsbt.nhs.uk

Telephone

+44 7764280366

Country

United Kingdom

Region code

UKK11 - Bristol, City of

National registration number

NHS Blood and Transplant

Internet address(es)

Main address

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

Buyer's address

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

I.3) Communication

Additional information can be obtained from the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

<https://health-family.force.com/s/Welcome>

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

Molecular Screening

II.1.2) Main CPV code

- 33100000 - Medical equipments

II.1.3) Type of contract

Supplies

II.1.4) Short description

This Prior Information Notice (PIN) is separate to any tender opportunity and its purpose is to consult the market to improve NHSBT's knowledge of current assays and high throughput non-blood donor nucleic acid testing systems available in the marketplace and gauge market interest. It is the intention of NHSBT to further consult those organisations who express an interest to identify preparatory work which may need to take place ahead of any future tendering opportunities.

II.1.5) Estimated total value

Value excluding VAT: £7,000,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 33124000 - Diagnostics and radiodiagnostic devices and supplies
- 85111800 - Pathology services

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Colindale (London)

II.2.4) Description of the procurement

NHSBT requires a direct contractual relationship with either the manufacturer or any other economic operator for a complete end-to-end integrated solution, which must include all the necessary equipment, installation, maintenance, consumables, reagents, software, including an inter-operability provision with NHSBT's existing IT infrastructure, and an overall on-going support mechanism that may be required to carry out the necessary testing as stated below. All in vitro diagnostic medical devices, for example, instruments, consumables, and reagents must be CE/UKCA marked. Great Britain (GB) will continue to recognise CE marking under the IVDD or IVDR until 30 June 2023 and from 1 July 2023 devices placed on the GB market must be UKCA marked under the UK MDR 2002 as amended. The end-to-end solution must be capable of producing test results in a format that can be utilised by NHSBT's host IT system.

NHSBT are looking for a fully integrated, high throughput, automated Nucleic Acid Testing (NAT) screening system which can detect HBV DNA, HIV-1 RNA, HIV-2 RNA, HCV RNA, HEV RNA in EDTA plasma samples from non-blood (e.g. stem cell, tissue) donors including deceased (non-heart beating) donors.

Molecular Screening will be performed by NHSBT's Microbiology Services Laboratory in Colindale (London) with the following approximate number of samples per marker per year for both donation screening and confirmatory testing:

- ~ HBV DNA: 7,381 screening tests (see note) & 1,082 discriminatory/ID tests per year.
- ~HIV-1 RNA/ HIV-2 RNA: 7,381* screening tests & 652 discriminatory/ID tests per year.
- ~HCV RNA: 7,381 screening tests (se note) & 640 discriminatory/ID tests per year.
- ~HEV RNA: 7,126 tests per year.

NOTE:HBV/HIV1&2/HCV tested as a multiplex screen.

It is important that interested parties respond to this PIN, as prior KEG approval will be a mandatory requirement for any associated future tender opportunity, in-line with the requirements of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book - <https://www.transfusionguidelines.org/red-book>).

NHSBT will seek to understand the status of assays which would be offered with regards to NHSBT's Kit Evaluation Group (KEG).

Further details on KEG and the process will be provided during Supplier Engagement.

The format of Supplier Engagement will be communicated to those organisations that respond to this PIN; however, this is likely to be virtual meetings conducted via Microsoft Teams during the second half of September 2022.

Expressions of interest should be e-mailed to daniel.kirkbride@nhsbt.nhs.uk by 1200hrs on 12 September 2022.

II.3) Estimated date of publication of contract notice

6 May 2024

Section IV. Procedure

IV.1) Description

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

The procurement is covered by the Government Procurement Agreement: Yes