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Planning

Nucleic Acid Amplification Testing Services (NAT)

NHS Blood and Transplant

F01: Prior information notice
Prior information only
Notice identifier: 2023/S 000-007842
Procurement identifier (OCID): ocds-h6vhtk-03b3e3
Published 17 March 2023, 1:40pm

Section I: Contracting authority

I.1) Name and addresses

NHS Blood and Transplant

500 North Bristol Park

Bristol

BS34 7QH

Contact

Tennille Madigan

Email

tennille.madigan@nhsbt.nhs.uk

Telephone

+44 7795483583

Country

United Kingdom

Region code

UKK11 - Bristol, City of

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

Nucleic Acid Amplification Testing Services (NAT)

II.1.2) Main CPV code

- 33124130 - Diagnostic supplies

II.1.3) Type of contract

Supplies

II.1.4) Short description

This Prior Information Notice (PIN) is a call for competition and is separate to any tender opportunity. Its purpose is to inform the market of an up-and-coming tender opportunity. NHSBT are looking for a fully integrated high throughput testing solution for automated Nucleic Acid Amplification Technology (NAT) Testing which is the screening of blood, tissue and stem cell donations for the detection of hepatitis C (HCV) RNA, Human Immunodeficiency virus 1 and 2 (HIV-1 and HIV-2) RNA, hepatitis B (HBV) DNA, hepatitis E virus (HEV) RNA, and West Nile Virus (WNV) RNA.

Organisations who express an interest must declare this by 17th April 2023 including a statement confirming their current participation in a Kit Evaluation Group (KEG) evaluation, or their intention to join the KEG process, or confirmation that their testing solution has previously been KEG approved. Any organisations wishing to participate in the KEG evaluation process must also submit their relevant assay Instructions For Use (IFU) by 17th April 2023 to tennille.madigan@nhsbt.nhs.uk
Organisations who express an interest to participate will be invite to future engagement sessions in March/April 2023.

II.1.5) Estimated total value

Value excluding VAT: £45,000,000

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
- 48921000 - Automation system
- 33141625 - Diagnostic kits
- 33696500 - Laboratory reagents
- 71900000 - Laboratory services
- 33124110 - Diagnostic systems
- 33140000 - Medical consumables
- 33696200 - Blood-testing reagents
- 33127000 - Immuno-analysis devices
- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

Manchester & Bristol (Filton)

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. The intended use of the assays must include use on human blood, stem cell, and living tissue donors.
Great Britain (GB) will continue to recognise CE marking under the IVDD or IVDR until 30 June 2024 and from 1 July 2024 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 (PULSE) without the need for changes to PULSE. NHSBT are looking for a fully

integrated, high throughput, automated Nucleic Acid Amplification Testing (NAT) screening system which can detect HCV RNA, HIV-1 RNA, HIV-2 RNA, HBV DNA, HEV RNA, and WNV RNA.
NAT Screening will be performed by NHSBTs two testing sites in England at Manchester and Bristol (Filton). Samples from blood donors donations will be pooled prior to screening therefore pooling equipment is also required as part of the solution. Samples from stem cell and living tissue donors will be screened as individual donations and therefore not pooled.
Throughput requirements:

HCV RNA, HIV-1 RNA, HIV-2 RNA, HBV DNA, HEV RNA: 1,520,000 samples per year
WNV RNA: 48,000 samples per year
At a minimum, HCV, HIV, and HBV must be multiplexed

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 KEG. Any organisations wishing to participate in the KEG evaluation process must also submit their relating assay IFUs by 17th April 2023 to tennille.madigan@nhsbt.nhs.uk
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 April/May 2023. I Expressions of interest should be e-mailed to tennille.madigan@nhsbt.nhs.uk by 17th April 2023.

II.3) Estimated date of publication of contract notice

23 June 2023

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: No