This is a published notice on the Find a Tender service: https://www.find-tender.service.gov.uk/Notice/007839-2023

Planning

Hepatitis A virus (HAV) RNA & Parvovirus B19 DNA Testing Services

NHS Blood and Transplant

F01: Prior information notice
Prior information only
Notice identifier: 2023/S 000-007839
Procurement identifier (OCID): ocds-h6vhtk-03b3e0
Published 17 March 2023, 1:28pm

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

Hepatitis A virus (HAV) RNA & Parvovirus B19 DNA Testing Services

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 the detection of hepatitis A virus (HAV) RNA and Parvovirus B19 DNA in partnership with NHSBT. Additionally, the solution must also be able to test for HBV DNA, HIV-1 RNA, HIV-2 RNA, HCV RNA, HEV RNA as contingency during a business continuity need for NHSBTs Molecular Screening Service located in Colindale London. The solution must have the relevant UKCA marking to support this ability.

Organisations who express an interest must declare this by 17th April 2023 date including a statement confirming their current participation in a Kit Evaluation Group (KEG) evaluation or their intention to join the KEG process. 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

II.1.5) Estimated total value

Value excluding VAT: £5,600,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 33124130 - Diagnostic supplies
- 33124130 - Diagnostic supplies
- 33124000 - Diagnostics and radiodiagnostic devices and supplies
- 33127000 - Immuno-analysis devices
- 71900000 - Laboratory services
- 33696200 - Blood-testing reagents
- 48921000 - Automation system
- 33124110 - Diagnostic systems
- 33141625 - Diagnostic kits
- 33696500 - Laboratory reagents
- 33140000 - Medical consumables
- 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

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 for EDTA plasma drawn from blood donors. Other specific requirements are outlined below.
The solution:
A s Fully integrated high throughput testing solution is required for screening blood and plasma donors for HAV RNA and Parvovirus B19 DNA. Samples will be pooled prior to screening therefore pooling equipment is also required as part of the solution.
The HAV RNA and Parvovirus B19 DNA testing solution must have the ability to test EDTA plasma samples from blood & plasma donors that have been stored frozen for up to 2 years at minus 20 degrees (-20).
In addition, the solution will be required to support NHSBT's Microbiology Services Laboratory, a small specialist laboratory based in Colindale, solely in a contingency role to support NHSBT business continuity for essential screening services, therefore the testing solution MUST also have the ability to test the following as individual donations ie not pooled) using the same analyser as for HAV and B19: 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 those from deceased (non-heart beating) 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 (PULSE) system.
HAV RNA and Parvovirus B19 DNA testing will be performed at an purpose built NHSBT laboratory based in Manchester with the following approximate number of samples per marker per year for donation screening:
Throughput: Approx: 146,000 samples per month until July 2024; July 2024 onwards 95,000 samples per month
Molecular Screening Throughput Contingency
The HAV & B19 laboratory will act as a contingency laboratory for the Molecular Screening service. As this is a contingency requirement due to a business continuity need, the numbers of tests required will be variable depending on the business continuity response. We anticipate the numbers to be relatively low compared to HAV and B19 and NHSBT will manage the work flow during a business continuity response working in partnership with the supplier to execute.

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 March/April 2023. 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

4 May 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