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Planning

Microbiology Serology Testing Managed Service

NHS Blood and Transplant

F01: Prior information notice
Prior information only
Notice identifier: 2023/S 000-011542
Procurement identifier (OCID): ocds-h6vhtk-03c346
Published 21 April 2023, 3:24pm

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

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

Microbiology Serology Testing Managed Service

Reference number

C166166 (Project Ref)

II.1.2) Main CPV code

- 71900000 - Laboratory services

II.1.3) Type of contract

Services

II.1.4) Short description

The purpose of this Prior Information Notice is to:
• Alert potential suppliers that NHS Blood and Transplant intends to let a managed service contract which supports the delivery of Microbiology Serological screening/ testing of blood and non-blood donations. NOTE: The estimated total value below is based on a maximum 10-year contract duration.
• Develop NHSBTs understanding of the capabilities, dependencies and competitiveness of the marketplace and the ability of industry to provide the required level of support and innovation.
• Make potential suppliers aware of the Kit Evaluation Group (KEG) and their assessment process for assays

An expression of interest must be e-mailed to Daniel.Kirkbride@nhsbt.nhs.uk by no later than Monday 29 May 2023, which includes the following:
• Company Name and Address
• Company point of contact details (Name, role, email and contact number)
• Copies of the relevant assay Instructions for Use

Upon expressing an interest, potential suppliers will be sent a further request for information, to aid discussions at supplier engagement events to be arranged for June 2023. The formal publication of the procurement is planned for August/ September 2023.

II.1.5) Estimated total value

Value excluding VAT: £50,000,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 33190000 - Miscellaneous medical devices and products
- 33124100 - Diagnostic devices
- 33141625 - Diagnostic kits
- 33124110 - Diagnostic systems
- 33696200 - Blood-testing reagents
- 33696500 - Laboratory reagents
- 71900000 - Laboratory services
- 33140000 - Medical consumables
- 33127000 - Immuno-analysis devices
- 33124130 - Diagnostic supplies

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

Main site or place of performance

NHSBT Filton, 500 North Bristol Park Northway, Filton, Bristol BS34 7QH
NHSBT Manchester, Plymouth Grove, Manchester M13 9LL
NHSBT Colindale, Charcot Road, Colindale, London NW9 5BG

II.2.4) Description of the procurement

NHSBT undertakes Microbiology Serology testing across three testing sites, the largest being Manchester and Filton testing laboratories. These test approximately 1.7 million donations per annum, which includes tests on blood, tissue and stem cell donations.

The third site, Microbiology Services Laboratory (MSL) in Colindale, tests approximately 5k donations per annum. MSL tests non-blood donations (tissue and stem cell), including those from deceased (not heart beating) tissue donors as well as undertaking confirmatory testing of screen reactive blood donations

Donation testing laboratories in Manchester and Filton perform the following tests:
· Hepatitis B (HBsAg) *
· Hepatitis B core (anti-HBc) **
· Hepatitis B antibody (anti-HBs) ***
· Human immunodeficiency virus (HIV 1&2 Ab/Ag) *
· Hepatitis C (anti-HCV) *
· Syphilis antibodies *
· Human T-lymphotropic virus I/II (anti-HTLV) *
· Cytomegalovirus (CMV) IgG or Total antibody **
· Malarial antibody (anti-malaria) **
· Trypanosome cruzi (anti-T. cruzi) **

The Microbiology Services Laboratory (MSL) in Colindale performs the following tests:
· Hepatitis B (HBsAg) *
· Hepatitis B antibodies (anti-HBc) **
· Human immunodeficiency virus (HIV 1&2 Ab/Ag) *
· Hepatitis C (anti-HCV) *
· Syphilis antibodies *
· Human T-lymphotropic virus I/II (anti-HTLV) *
· Cytomegalovirus (CMV) IgG or Total antibody **
· Malarial antibody (anti-malaria) **
· Trypanosome cruzi (anti-T. cruzi) **
· Cytomegalovirus (CMV) IgM ***
· Hepatitis B antibodies (anti-HBs) ***
* Mandatory requirement
** On selected donations
*** Where required

Deceased (non-heart beating) donor screening is performed at Microbiology Services Laboratory (MSL), Colindale and therefore the assays used in MSL must be suitable for deceased donor screening.

Automated instrumentation is required to enable high throughput testing of mandatory and additional testing for blood and non-blood donors. Archiving and long-term storage of plasma samples is also required. Consideration will be given to all efficiency and innovation opportunities, including, but not limited to, middleware and sample presentation technology.

The end-to-end solution must be capable of producing test results in a format that can be

utilised by NHSBT's host IT systems without the need for development to NHSBT host IT systems.

All Microbiology Serology testing requirements must be in accordance with the Guidelines for the Blood Transfusion service in the United Kingdom (www.transfusionguidelines.org/red-book).

In accordance with the Guidelines for the Blood Transfusion service in the United Kingdom, Kit Evaluation Group (KEG) approval of the assays must be obtained prior to the award of contract. The submission of your assay Instructions for Use will allow a desktop review of high-level mandatory requirements. If the high-level mandatory requirements are met during the desktop review, organisations will be invited to participate in the KEG process and be asked to formally submit FRM51 "Application for NHSBT Evaluation of Microbiology Test Kit", a copy of which will supplied by NHSBT following a successful desktop review.

All in-vitro diagnostic medical devices, for example: instruments, consumables and reagents must be CE/UKCA marked. GB will continue to recognise CE marking under the IVDD or IVDR until 30 June 2024 and from 01 July 2024 devices placed on the GB market must be UKCA marked under the UK MDR 2002 as amended.

II.3) Estimated date of publication of contract notice

31 August 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