Planning

QF-PCR Assay for the Rapid Aneuploidy Testing of Prenatal, Fetal Tissue and Neonatal Blood Samples

NHS Wales Shared Services Partnership-Procurement Services (hosted by Velindre University NHS Trust)

F01: Prior information notice
Prior information only
Notice identifier: 2021/S 000-004371
Procurement identifier (OCID): ocds-h6vhtk-029868
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Section I: Contracting authority

I.1) Name and addresses

NHS Wales Shared Services Partnership-Procurement Services (hosted by Velindre University NHS Trust)

2nd Floor, Woodland House, Maes-Y-Coed Rd

Cardiff

CF14 4TT

Email

rhian.lye@wales.nhs.uk

Telephone

+44 2921836446

Country

United Kingdom

NUTS code

UK - UNITED KINGDOM

Internet address(es)

Main address

http://nwssp.nhs.wales/ourservices/procurement-services/

Buyer's address

https://www.sell2wales.gov.wales/search/Search_AuthProfile.aspx?ID=AA0221

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

Additional information can be obtained from the above-mentioned address

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

QF-PCR Assay for the Rapid Aneuploidy Testing of Prenatal, Fetal Tissue and Neonatal Blood Samples

II.1.2) Main CPV code

- 33696000 - Reagents and contrast media

II.1.3) Type of contract

Supplies

II.1.4) Short description

NHS Wales Shared Services Partnership, Procurement Services on behalf of the All Wales Genomics Laboratory wishes to invite suppliers with the capability of supplying a commercial QF-PCR assay for the rapid aneuploidy testing of prenatal, fetal tissue and neonatal blood samples to discuss their solution.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKL - WALES

Main site or place of performance

All Wales Genomics Laboratory, University Hospital of Wales, Cardiff

II.2.4) Description of the procurement

The Reproductive and Neonatal Genomics Services team at the All Wales Genomics

Laboratory offers a range of specialist tests as part of investigations performed on prenatal, postnatal and post-mortem tissue samples.

The team currently offers a rapid aneuploidy testing service using an in-house QF-PCR assay with considerable staff time required to prepare kits and set-up the testing.

The following tests are performed;

-Rapid aneuploidy testing for trisomy 13, 18 and 21 and triploidy as a front-line test for all prenatal and pregnancy loss samples and for neonatal samples referred due to a clinical suspicion of a common trisomy

-Sex chromosome testing to detect evidence of sex chromosome aneuploidy in prenatal and pregnancy loss samples referred with evidence of fetal cystic hygroma (monosomy X), and for male patients with suspected Klinefelter syndrome (XXY)

-A rapid service to determine genotypic sex for foetuses at risk of an X-linked condition or congenital adrenal hyperplasia (CAH) and for neonates with ambiguous genitalia

-Maternal cell contamination (MCC) testing of prenatal samples prior to onward testing

The laboratory receives approximately 170 prenatal samples, 240 pregnancy loss samples and 75 neonatal samples per annum.

The laboratory team intends to procure a commercial QF-PCR assay for the rapid aneuploidy testing of prenatal, fetal tissue and neonatal blood samples on a 3-5 year contract.

We anticipate that the tender will be out by late Spring/early Summer 2021, with a view to begin service delivery by January 2022.

The main drivers for change are:

-To reduce the analysis time by the procurement of a solution with a low requirement for repeat testing

-To reduce the hands-on time required for both the technical and analytical aspects of the testing.

-To future proof ahead of CE-IVD Directive requirements coming into force for genetic testing

Please create a 1-1.5 hour presentation to be delivered remotely via Teams/Skype/Zoom on a mutually convenient time/date between Monday 29th March to Friday 9th April 2021. The presentation should detail how your solution may best meet our needs with time for questions at the end. It should cover the points below as well as giving an overview of the

functionality of the assay that would be of benefit to the laboratory:

1.The application of the assay to a range of sample types including; amniotic fluid/prenatal fluids, chorionic villi, fetal tissue/products of conception, neonatal bloods

2.The assay performance on chelex-based DNA preps and sub-standard samples

3.The ability of the assay to detect low level cell lines indicative of mosaicism or maternal cell contamination

4.The microsatellite marker content and chromosome coverage of the available test kits

5.An overview of the technical procedure with an estimation of hands-on time for the PCR set-up

6.Expected failure rate for different sample types and the repeat reflex options which are available

7.The software solutions available and their compatibility with the 3730 genetic analyser and Genemapper v6

8.The ability to mask data within the software solution to reduce identification of incidental findings

9.Costing for each of the test kit options (inclusive of reflex kits)

10.The shelf-life/expiry date of the kits

11.Lead-in time from ordering to receipt of goods

II.2.14) Additional information

Please contact Sarah.Anderson@wales.nhs.uk and elle.mcneil@wales.nhs.uk to arrange a meeting to discuss our requirement and present your solution.

II.3) Estimated date of publication of contract notice

1 June 2021

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

Section VI. Complementary information

VI.3) Additional information

NOTE: To register your interest in this notice and obtain any additional information please visit the Sell2Wales Web Site at https://www.sell2wales.gov.wales/Search/Search_Switch.aspx?ID=108764.

(WA Ref:108764)