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Opportunity

TENDER FOR THE DEVELOPMENT AND SUPPLY OF A SALIVA-BASED LATERAL FLOW IMMUNOASSAY

THE UNIVERSITY OF BIRMINGHAM

F02: Contract notice
Notice reference: 2024/S 000-010057
Published: 27 March 2024, 1:44pm

Section I: Contracting authority

I.1) Name and addresses

THE UNIVERSITY OF BIRMINGHAM

Edgbaston

BIRMINGHAM

B152TT

Contact

Kseniya Samsonik

Email

k.samsonik@bham.ac.uk

Country

United Kingdom

NUTS code

UKG31 - Birmingham

Companies House

RC000645

Internet address(es)

Main address

https://www.birmingham.ac.uk/

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

https://in-tendhost.co.uk/universityofbirmingham/aspx/Home

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

https://in-tendhost.co.uk/universityofbirmingham/aspx/Home

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

TENDER FOR THE DEVELOPMENT AND SUPPLY OF A SALIVA-BASED LATERAL FLOW IMMUNOASSAY

Reference number

SC12346/24

II.1.2) Main CPV code

- 38000000 - Laboratory, optical and precision equipments (excl. glasses)

II.1.3) Type of contract

Supplies

II.1.4) Short description

The University of Birmingham invites tenders for the development and supply of lateral flow immunoassay. The lateral flow is intended to be used to detect antibodies in human saliva samples. Specifically, the lateral flow assay needs to be able to detect IgG-class anti-tetanus antibodies. The lateral flow immunoassay will need to be developed to meet the following key target specifications:

High sensitivity detection that can differentiate protective antibody status. To enable its use with saliva specimens, the test will need to have a low limit of detection. The test positivity threshold needs to be equivalent to the WHO protective threshold of 0.1 IU/mL in serum. Proof of concept studies at the University of Birmingham estimate that the protective cut-off in serum is equivalent to ~ 0.0024 IU/mL in saliva.

Minimal time to perform, able to be completed with a small number of simple steps and return a result within 15 minutes.

Reader-free and return a qualitative (positive or negative) result.

The method of saliva sample collection to accompany the test needs to be suitable for use in young children and infants.

The test should be able to be completed by a non-specialist and in a community or field setting.

The test should have no linked required cold chain, able to withstand hot/humid temperatures on land and able to withstand conditions associated with transport by both aeroplane and drone.

The test needs to be stable, with a long-term stability time equivalent to existing commercial lateral flow tests.

The design of the test needs to be as low-cost as possible. This is to enable its use in low-middle income countries or low resource settings.

The test design also needs to strongly reflect environmental considerations. Specifically, an unhoused test strip is desirable. The sample collection and application, and any other test components, should be designed and utilised with the objective of using as little plastic as possible and minimal packaging.

The project will require developing the test to meet these desired specifications, evaluating the test performance (for example performance around the cut-off, reproducibility, stability and any other relevant domains, as informed by international guidelines on test evaluation e.g. CLSI) and supplying UoB with devices. Small batches of devices (~ 200) will need to be supplied to UoB at various points in the development to assess clinical accuracy. On completion of the project, the CRO will need to be able to supply UoB with up to 1000 devices suitable for use at the point of care as part of an in-field evaluation study.

The development needs to be carried out within appropriate Quality Management Systems and in accordance with regulatory requirements for medical devices. The supplier should be certified to ISO 13485 and able to develop test to be compliant with IVDR 2017/746 requirements. The project should include the compiling and supply of relevant documentation and files to support future submission for regulatory approval. Post-project, the CRO should be able to support any future manufacture, scale-up and distribution of the test.

II.1.5) Estimated total value

Value excluding VAT: £230,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKG3 - West Midlands

II.2.4) Description of the procurement

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II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months

12

This contract is subject to renewal

No

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

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

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

26 April 2024

Local time

12:00pm

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.7) Conditions for opening of tenders

Date

26 April 2024

Local time

12:01pm

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.4) Procedures for review

VI.4.1) Review body

University of Birmingham

Edgbaston

B15 2TT

Country

United Kingdom