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Tender

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

THE UNIVERSITY OF BIRMINGHAM

F02: Contract notice

Notice identifier: 2024/S 000-010057

Procurement identifier (OCID): ocds-h6vhtk-044da5

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](mailto:k.samsonik@bham.ac.uk)

#### **Country**

United Kingdom

#### **Region 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

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## 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

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## **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

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## **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