Planning

Enhanced Chemical Analysis for Copper Sulphate

NHS Blood & Transplant

F01: Prior information notice
Prior information only
Notice identifier: 2021/S 000-002850
Procurement identifier (OCID): ocds-h6vhtk-029289
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Section I: Contracting authority

I.1) Name and addresses

NHS Blood & Transplant

North Bristol Park

Filton, Bristol

BS34 7QH

Email

Jo.Murphy@nhsbt.nhs.uk

Telephone

+44 1179217218

Country

United Kingdom

NUTS code

UK - UNITED KINGDOM

Internet address(es)

Main address

https://www.nhsbt.nhs.uk/

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

Enhanced Chemical Analysis for Copper Sulphate

Reference number

NHSBT1491

II.1.2) Main CPV code

- 71900000 - Laboratory services

II.1.3) Type of contract

Services

II.1.4) Short description

NHSBT are seeking an enhanced analysis of Copper Sulphate solution which is an in

vitro, semi-quantitative reagent used for investigation on the acceptance of blood donor minimum haemoglobin levels when taken from a capillary blood sample. The reagent is used to test a droplet of blood from a donor's finger, following the use of a lancet, which will be transferred into the solution using a pipette.

NHSBT must update the product conformity profile for this device and must understand the impact when exposed to different variables throughout its formulation process, transportation, use and storage. The profile is to be produced through a number of studies for visual, chemical and therapeutic analysis. In current practice, NHSBT Copper Sulphate solutions are used professionally for male and female specific testing to ensure only suitable donors are bled. Therefore, all studies must be conducted for scenario 1) Female Donation and Scenario 2) Male Donation.

II.1.6) Information about lots

This contract is divided into lots: Yes

Maximum number of lots that may be awarded to one tenderer: 6

II.2) Description

II.2.1) Title

Study 1 - Assessment of products useful life

Lot No

1

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 1 - Assessment of products useful life

This is to be determined through the maximum number of drops of blood that can be added to the copper sulphate before the product returns an inaccurate result under varying conditions.

II.2) Description

II.2.1) Title

Study 2 - Assessment of the device’s stability during shelf life

Lot No

2

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 2 - Assessment of the device’s stability during shelf life

During routine storage at what point does the device start to fail:

(a) Visually

(i) Photostability storage study

(ii) Integrity of the labels when exposed to routine use, light.

(b) Chemically

(i) Chemical analysis storage study

(ii)Theoretical analysis of formula to outline potential chemical interactions that may degrade over time.

II.2) Description

II.2.1) Title

Study 3 - Bacterial contamination

Lot No

3

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 3 - Bacterial contamination

(a) During routine storage, at what point does bacterial ingress occur – Bacterial storage study to be conducted on fresh and end of shelf life product.

(b) If the product is challenged with routine environmental microbiological contaminants does this result in proliferation of the contaminants? - Controlled bacterial challenge study conducted on fresh and end of shelf life product.

II.2) Description

II.2.1) Title

Study 4 – Packaging

Lot No

4

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 4 – Packaging

Study to challenge the packaging to address the impact and potential for:

(a) Product leakage

(b) Product damage – Physical and degradation of the bottles and or seal

(c) Product evaporation

(d) Electrostatic impacts (from packaging material)

II.2) Description

II.2.1) Title

Study 5 – Health and Safety

Lot No

5

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 5 – Health and Safety

Health and safety evaluation in accordance with Directive:

(a) Risk to individuals

(b) Appropriate method of discard

(c) Shipping and Transportation recommendations

II.2) Description

II.2.1) Title

Study 6 – Impacts to Specific Gravity

Lot No

6

II.2.2) Additional CPV code(s)

- 71900000 - Laboratory services

II.2.3) Place of performance

NUTS codes

- UK - UNITED KINGDOM

II.2.4) Description of the procurement

Study 6 – Impacts to Specific Gravity

Assessment of the impact of temperature on the specific gravity of the device:

(a) Theoretical analysis of the device to calculate in the potential changes in Specific gravity that could occur under routine storage conditions

(b) Study protocol to test the male and female device for specific gravity under a range of routine storage temperatures and in use parameters

II.3) Estimated date of publication of contract notice

17 March 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