

1 Introduction

1.1 Brief Description.

The purified recombinant hemagglutinin reagent is critical for a number of research projects including the one to [REDACTED]. We will not be able to buy these specific HA reagents from any other supplier. These are influenza reagents for research into [REDACTED]. These reagents are required for work with a broader perspective around [REDACTED], which also includes [REDACTED] and other [REDACTED] may emerge in the future.

All the reagents that we buy from eEnzyme LLC are of a single type i.e they are recombinant purified influenza hemagglutinin from different strains.

1.2 Commercial notes.

- **Why is the item the only one that can meet your requirement?** These are purified recombinant antigen produced in specific expression system and HA antigens produced by other suppliers are made in other expression systems and are for different strains as such the antibodies we have developed only work optimally on antigens from E Enzymes.
- **What could potential alternatives be? And why can't you use them?** Antibodies used for assays have been tested and calibrated using antigens from E -Enzymes having to change to other antigens would generate extra work and antibodies may not bind
- **What would be the effect/implications if we bought an alternative item?** Antibodies don't bind with same affinity and specificity
- **What are the risks to the Agency if we don't buy the item? (please be a bit more specific than 'the project will stop'. How will that impact the business? Will the project stopping cause to Agency not to meet the corporate objectives? If so, which one?** The performance of antibodies will not match that we have already reported and publicly disclosed

These specific reagents are crucial for the research project. There is published research manuscripts (please read page 4 of the attached published paper) that reference the reagents purchased from eEnzyme LLC;



gaiotto Hufton
2016.pdf

Experimental Procedures

Reagents and influenza antigens

Recombinant HA antigens from A/Solomon Islands/3/2006 (H1N1), A/South Carolina/1/1918 (H1N1), A/California/07/2009 (H1N1)pdm09, A/Brisbane/59/2007 (H1N1), A/New Caledonia/20/1999 (H1N1) and A/Vietnam/1194/2004 (H5N1) (eEnzyme) and A/Christchurch/16/2010 (H1N1) (Immunotech) were used. The virus antigen standard used in this study was derived from A/California/07/2009 (H1N1)pdm09 (National Institute for Biological Standards and Control, NIBSC). Expression and purification of single domain antibodies (sdAbs) R1a-G6, R1a-F5, R2b-D9, R2a-G8, R1a-B6, R1a-A5 and R2b-E8 was as described previously [8]. All sdAbs were also fused to a C-terminal c-Myc tag for detection. Commercial IgG antibodies FC41 (Ab00149-1.1) (Absolute Antibodies), RM10 (1055-RM10) (Sino Biologicals) and MIA-H7-334 (eEnzyme) were used as controls for correctly folded hemagglutinin (HA).

These sole source products are manufactured in US and are sold exclusively in UK by eEnzyme LLC. See Sole Supplier letter attached.

An online search did not find any other supplier for these reagents.

Taking all the points into consideration regarding these niche and exclusive reagents, a direct award is requested for this supplier to facilitate our research projects.

2 Justification for use of the negotiated procedure without prior publication

It is proposed to direct award this contract under the following section of the PCR2015, Regulation 32

~~Delete the sections that do not apply. The Commercial Team will assist with this.~~

- ~~• 32(2)(b) Where the works, supplies or services can be supplied only by a particular economic operator for any of the following reasons:
 - ~~(i) the aim of the procurement is the creation or acquisition of a unique work of art or artistic performance,~~
 - ~~(ii) competition is absent for technical reasons,~~
 - ~~(iii) the protection of exclusive rights, including intellectual property rights~~~~



SUCCESS IS EASY WITH THE RIGHT TOOLS

SOLE SOURCE LETTER

To Whom It May Concern:

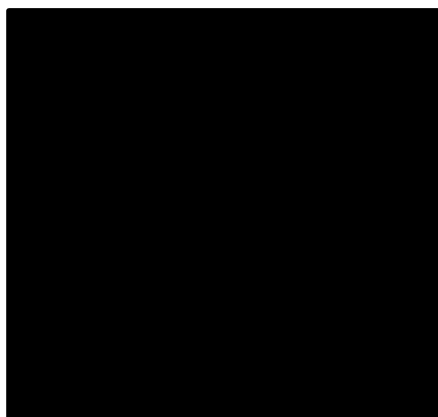
This letter is to confirm that the items listed below that we have supplied to your Institute since August of 2017 are sole source products, manufactured in US and sold exclusively in UK by us, eEnzyme LLC.



Thank you for your interest in our products.

List of Items:

IA-003W-005P
IA-0042W-005P
IA-0053W-005P
IA-0091W-005P
IA-BR10-0100
IA-H7-009P
IA-H7-HK017P
IA-H7-HK017P
IA-SW-12P
MIA-H3-501
MIA-H3-B07



3 Costings

Item	Cost	Years Required	Total	Notes
Cost of Purchase (Capital Cost)				
Maintenance / Servicing				
Operate Costs / Consumables	£10,000	3 (1+1 possible extensions)	£30,000.00	Total excluding possible extensions.

4. Approvals

4.1. Agency approvals

What approvals have already been made through Agency business processes.	n/a
Business Case Ref number	
Financial limits and restrictions	

4.2. Cabinet Office Controls

Do CO Controls apply? (See SOP on INsite)	no
If yes which control applies?	
Control Ref number	
Financial limits and restrictions	

4.3. Proposed Length of Contract

Initial Contract: 3 years

Potential Extensions: none

4.4. Terms and Conditions of Contract

Standard PO T&C's

5. Savings

6.

Savings Type

Operational Transformation Benefits Definition				Equivalent Definition(s) in Bravo
Benefit Type	Benefit Category	Ref	Investment in the project or programme will ...	
Non-cashable	Risk Mitigation	NC4	... measurably reduce the likelihood or impact of documented risks	<ul style="list-style-type: none"> • Quality increases • Rationalisation Savings

7. Approvals

Name	Position	Signature	Date
			
			
			
			
			