Appendix 1

National Microbiology Framework Agreement
Order Form

FROM

Authority:	The Secretary of State for Health and Social Care as part of the Crown through the UK Health Security Agency of Nobel House, 17 Smith Square, London, SW1P 3HX (the "Authority").
Invoice address:	Address: United Kingdom Health Security Agency, Financial Operations and Control, Porton Down, Salisbury, Wiltshire, SP4 0JG Email: [redacted]
Contract Manager:	Name: [redacted] Phone: E-mail:
Secondary Contact: e.g. business operational contact, project manager	Name: [redacted] Phone: E-mail:
Procurement lead	Name: [redacted] Phone: E-mail:
Name and address for notices:	Name: [redacted] Address: UK Health Security Agency Nobel House, 17 Smith Square, London, SW1P 3HX
Internal reference (if applicable):	C77969

TO

Supplier:	Don Whitley Scientific Limited
Contract Manager:	[redacted]
Secondary Contact:	[redacted]
Account Manager:	[redacted]

	[redacted]
Name and address for notices:	[redacted] Address: Victoria Works, Victoria Street, Bingley, West Yorkshire, BD16 2NH. Company registration number: 01342672

Applicable terms and conditions

The following terms and conditions are applicable to the Contract for this Order:

Appendix A	Call-off Terms and Conditions for the Supply of Goods and the Provision of Services	**Applicable to this Contract**
Appendix B	Optional Additional Call-off Terms and Conditions for Installation and Commissioning Services	☒ **(only applicable if this box is checked)**
Appendix C	Optional Additional Call-off Terms and Conditions for Maintenance Services	☐ **(only applicable if this box is checked)**
Appendix D	Optional Additional Call-off Terms and Conditions for Bespoke Research, Development and Manufacturing Requirements	☐ **(only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))**
Appendix E	Optional Additional Call-off Terms and Conditions for Reagent Rental	☐ **(only applicable if this box is checked)**
Appendix F	Optional Additional Call-off Terms and Conditions for Managed Equipment Services	☐ **(only applicable if this box is checked)**
Appendix G	Optional Additional Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services	☐ **(only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))**
Appendix H	Further Optional Additional Call-off Terms and Conditions Each of the following clauses in Appendix H is only applicable to this Contract if the relevant box is checked:	**(only applicable if one or more boxes are checked)**
	1. TUPE applies at the commencement of the provision of Services ☐	
	2. TUPE on exit ☐	
	3. Different levels and/or types of insurance ☐	
	4. Induction training for Services ☐	
	5. Further Authority obligations ☐	

	6. Assignment of Intellectual Property Rights in deliverables, materials and outputs of the Services	☐	
	7. Inclusion of a Change Control Process	☐	
	8. Authority step-in rights	☐	
	9. Guarantee	☐	
	10. Termination for convenience	☒	
	11. Pre-Acquisition Questionnaire	☐	
	12. Time of the essence (Goods)	☐	
	13. Time of the essence (Services)	☐	
	14. Specific time periods for inspection	☐	
	15. Specific time periods for rights and remedies under Clause 3.6 of Schedule 2 of Appendix A	☐	
	16. Right to terminate following a specified number of material breaches	☐	
	17. Expert Determination	☐	
	18. Consigned Goods	☐	
	19. Improving visibility of Sub-contract opportunities available to Small and Medium Size Enterprises and Voluntary, Community and Social Enterprises	☐	
	20. Management Charges and Information	☐	
	21. COVID-19 related enhanced business continuity provisions	☐	
	22. Buffer stock requirements	☐	
	23. Modern slavery	☒	
The additional Order Specific Key Provisions set out at Annex A (Order Specific Key Provisions) to this Order Form shall also apply to this Contract.			**x**

1. CONTRACT DETAILS

(1.1) Commencement Date: 23 May 2022

(1.2) Services Commencement Date (if applicable): 23 May 2022

(1.3) Contract Price ((i) breakdown and (ii) payment profile):

1.3.1. The Contract Price is a maximum of Fifty-one thousand, seven hundred and seventy-seven pounds and fifty-nine pence (£51,777.59) (Excl. VAT), full details of which are contained in (Appendix B – Summary of Contract Price). For the avoidance of doubt, the Authority is not committed to pay the Contract Price.

1.3.2. Following execution of the Contract, the Authority shall submit to the Supplier a purchase order for the Contract Price, the amount of which shall be the maximum value of services which can be ordered during the Contract Period (the "Purchase Order").

1.3.3. For the installation and commissioning charges detailed in the table below, the Supplier may invoice the Authority upon completion of the Services as set out below during the period starting on the Commencement Date and ending at the end of the term. Daily labour charges shall only be invoiced as incurred by the Supplier.

1.3.4. The Supplier shall inform and obtain approval from the Authority for any additional costs relating to this Service.

Descriptions	Qty	Unit Price	Total Price
Engineers (4 days each, 8 hours per day) Includes Travel and Subsistence costs	[redacted]		[redacted]
Field Application Specialist (5 days) Excludes accommodation, travel and subsistence costs	[redacted]		[redacted]
Collection and Transportation of WASP Lab equipment (collection and transportation to take place at the same time as the conveyor and pallets, if not additional costs will apply)	[redacted]		[redacted]
		Total	**£25,935.30**

1.3.5. For the instruments charges detailed in the table below, the Supplier may invoice the Authority upon the delivery of the Goods as set out below during the period starting on the Commencement Date and ending at the end of the term.

Descriptions	Item No	Qty	Total Price
[redacted]			

1.3.6. For the invoicing process and associated terms see Section 2 of Annex A (Order Specific Key Provisions) of this Order Form.

(1.4) Term of Contract:

1.4.1 This Contract shall commence on 23 May 2022 ("Commencement Date") and shall, subject to clause 1.5 and unless terminated earlier in accordance with its terms, expire on 23 November 2022 (the "Term").

1.4.2 Without prejudice to any other right of termination set out in this Contract, the Authority may terminate this contract, in whole or in part, for convenience by giving the Supplier not less than six (6) weeks' notice in writing.

1.4.3 Any contractual terms included in the quotations do not form part of this contract.

(1.5) Term extension options:

Not applicable.

2. GOODS AND/OR SERVICES REQUIREMENTS

(2.1) Description of the Goods / Services:

This Contract covers the transportation, installation, and commissioning of WASPlab equipment at Manchester Royal Infirmary (MRI).

The Services and Goods to be provided by the Supplier under this Contract shall be (the "Services"). Equipment details together with location of equipment is set out in Appendix C (Equipment to be transported and installed).

The Services to be covered under this contract are as follows:

- Transportation of WASP Lab equipment and other associated equipment from Epsom St. Helier, London to MRI
- Installation and commissioning of equipment
- Handover to MRI laboratory team

2.2 The Supplier shall provide the Services in accordance with the following specification

(the "Specification"):

Transportation of WASP Lab equipment

2.2.1 Transport existing WASP Lab equipment including conveyor T section and pallets at the same time from St Heliers to MRI. Separate deliveries may incur additional costs. Details of equipment is set out in Appendix C.

2.2.2 Ensure the WASP Lab equipment is appropriately packaged for transportation.

2.2.3 Liaise with both St Helier site and MRI to ensure smooth transition of equipment between the two sites.

Installation and commissioning of equipment

2.2.4 Installation qualification (IQ) – follow documented verification process to ensure the equipment has been correctly installed and configured according to standards agreed with the lab team. This shall include, but not be limited to:

- Install the WASP lab equipment in designated area as agreed with the MRI lab team. Details of the installation location as set out in the lab drawing in Appendix F
- Connect the new processing module to the existing WASP lab system
- Transfer all the WASP protocols to the new machine and ensure all the other elements of the WASP lab protocols link into this from the WASP lab servers
- Test the WASP in cycle to check that automation and software works properly
- Carry out routine cycle tests, verification and undertake corrective actions where necessary.

2.2.5 Operational qualification – follow documented testing process to ensure the equipment meets all operating ranges as agreed with the lab team.

- Apply the correct WASP core settings and verify all communications with the Laboratory Information System (LIS)
- Re-test the WASP in routine cycle to ensure correct operation
- Provide report detailing overall assessment of the system's efficiency and performance.

Handover to MRI lab team

2.2.6 Provide Installation qualification certificate and other relevant documents following commissioning of the WASP lab equipment.

(2.3) Premises and Location(s) at which the Goods / Services are to be delivered / provided:

2.3.1 The Supplier shall complete agreed Services at the following location:

Manchester Royal Infirmary (MRI)
Microbiology Department

Oxford Road, Manchester
M13 9WL.

2.3.2 All planned Services shall be pre-advised by the Supplier to the Authority's primary delivery contact and the additional delivery contact stated below (individually or collectively be known as the "Delivery Contact") at least 48 hours prior to attendance:

2.3.3 Primary delivery contact: [redacted]

2.3.4 Additional delivery contact: [redacted]

2.3.5 The Supplier shall provide the following data when notifying the Delivery Contact:

- Supplier name
- Authority's Order Number
- Item reference, Supplier's part code, description and quantity
- Item / pallet / carton reference for multi-pallet / carton shipments
- Full detailed despatch / pack list at item level and any special instructions originally entered for Authority's Order (e.g., project).

2.3.6 The Delivery Contact will confirm:

- Booking reference number
- Date and time of delivery slot (where applicable); and
- Delivery address.

2.3.7 Delivery of the Goods/Services shall be considered to have occurred when the Delivery Contact or other authorised representative of the Authority at the Authority's nominated location has signed the delivery note confirming receipt.

(2.4) Key personnel of the Supplier to be involved in the Goods / Services:

[redacted]

(2.5) Performance standards:

The Supplier shall deliver the Services to the standard set out within Clause 2.1, and Appendices of this Order Form.

(2.6) Quality standards:

The Supplier shall ensure the accreditations set out in Appendix D – ISO Certification shall be maintained throughout the Contract Period.

(2.7) Contract monitoring arrangements:

The Authority Contract Manager and Supplier Contract Manager shall meet Monthly and no less than quarterly (unless otherwise notified by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of the Contract (unless otherwise requested by the Authority).

(2.8) Management information and meetings:

At the Authority's request, within five (5) Working Days of such request, the Supplier shall provide such management information to the Authority as the Authority may reasonably request from time to time (including without limit any information about the Supplier's supply chain and its compliance in relation to sustainability requirements). On a monthly basis the Supplier will provide a MI report that includes:

Key Performance Indicators (the "KPIs")

1) Installation qualification (IQ) - documented verification process to ensure the equipment has been correctly installed and configured according to standards set by the original equipment manufacturer or as agreed with the lab team.

2) Operational qualification (OQ) documented testing process to ensure the equipment meets all operating ranges as specified by the original equipment manufacturer or as agreed with the lab team.

3) The KPIs for installation and commissioning will be covered by the qualification Certificate. The team at the Manchester will receive this and the Contract Manager will log this information in the overall contract folders.

4) The KPIs should commence at the same time.

3. CONFIDENTIAL INFORMATION (if applicable)

(3.1) The following information shall be deemed Confidential Information:

Pricing and individual contact details.

(3.2) Duration that the information shall be deemed Confidential Information:

For a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

4. DATA PROCESSING (if applicable)

(4.1) Personal Data to be processed by the Supplier:

In accordance with the Data Protection Protocol.

5. LEASE / LICENSE (if applicable)

(5.1) The Authority is granting the following lease or licence to the Supplier:

Not applicable.

Signature: [redacted]

For and on behalf of the Authority

Name: [redacted]

Job title: [redacted]

Date: 20 May 2022

Signature: [redacted]

For and on behalf of the Supplier

Name: [redacted]

Job title: [redacted]

Date: 30/5/22

Annex A

Order Specific Key Provisions

1.0 Introduction

This Annex A includes any supplemental requirements and any other relevant details, information, provisions and terms, forming part of this Order Form, as envisaged by the Framework Agreement, the Ordering Procedure, the other parts of this Order Form, the Call-Off Term and Conditions for the Supply of Goods and the Provision of Services and/or as required by the Authority (as applicable to this Contract and to the extent not addressed elsewhere as part of this Order Form). For the avoidance of doubt, any further annexes, appendices, schedules or other documents referred to in this Annex A shall be deemed part of this Annex A and part of this Order Form.

2.0. Delivery and Risk:

2.1. The Supplier shall deliver the services to the locations set out in section 2.2 of the Order Form.

2.2. The Supplier will ensure that provision of the services are made in accordance with the terms of this Order Form including Annex A, Appendix 1 and the Call-Off Terms and Conditions, except that any contractual terms included in any quotations included in Appendix 1, 2, 3 or 4 do not form part of this contract.

3.0. Invoicing Process:

3.1. Payment terms are net 30 days from receipt of a valid monthly invoice.

3.2. Within 10 Business Days of receipt of the Supplier's countersigned copy of the Contract, the Authority will send a unique purchase order ("PO") number. The Supplier must be in receipt of a valid PO number before submitting an invoice.

3.3. The Supplier shall provide a consolidated monthly invoice to the Authority for all Services received and accepted by the Authority each month.

3.4. All invoices should be sent for approval and must include the proof of delivery to the Authority's designated finance mailbox e-mail: [redacted] and their agreed representative (to be confirmed at first Supplier meeting) before being submitted for payment.

3.5. All invoices must be sent quoting a valid purchase order number. The Supplier shall provide a current statement of accounts on a monthly basis; this is a standard commercial process and should show all invoices raised and amounts outstanding.

3.6. To avoid delay in payment it is important that the Supplier provides a compliant invoice

that includes, as a minimum, a valid PO number, PO line-item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non – compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.

3.7. In support of Goods/Services being delivered the Supplier shall provide to the Authority a signed delivery note confirming receipt of the Goods/Services at the Authority's nominated Delivery Locations.

3.8. Supplier queries regarding payment must be forwarded to the Authority's Account Payable section by email to: [redacted]

4. Access to Premises and Location

4.1. Supplier staff shall hold the relevant security clearance for the Premises and Location where the Services shall be performed, where appropriate.

4.2. The Authority's authorised representative at the Premises and Locations shall provide to the Supplier such reasonable access to the Premises and Locations as may be required, in accordance with clause 4 (Operation of the Services) of the Call-Off Terms and Conditions, to provide the Services.

Appendix B – Summary of Contract Price

Installation and commissioning

Descriptions	Service	Qty	Unit Price	Total Price
Engineer Callout (4 days each, 8 hours per day)	Uninstall and package up of WASP DT (serial no 086-060-0546) for transportation. Price includes travel, hotel, and meal expenses. Work will commence from 9:00 to 17:00.	[redacted]	[redacted]	[redacted]
Field Application Specialist Costs	FAS will ensure that test protocols are correctly installed on the new WASP and that it works in conjunction with the existing equipment. Price excludes travel, accommodation and subsistence costs. This shall be charged at reasonable rates.	[redacted]	[redacted]	[redacted]
Transportation	Collection and transportation of WASP DT (serial no 086-060-0546) located at St Heliers, London	[redacted]	[redacted]	[redacted]
Equipment	WASP Lab Conveyor and T Section (Including 8 pallets)	[redacted]	[redacted]	[redacted]
			Total	£51,777.59

Appendix C – Equipment

Descriptions	Item No	Qty
WASP Lab Conveyor	W087-010	1
WASP Lab Conveyor T Section	WO087-1500	1
Pallets	TBD4NET	8

Appendix D - ISO Certificate

bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: Don Whitley Scientific Limited
Victoria Works
Victoria Street
Bingley
BD16 2NH
United Kingdom

Holds Certificate Number: FM 32849

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, development, manufacture, installation and service of instrumentation and associated products for microbiological applications.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1995-11-28
Latest Revision Date: 2021-12-17

Effective Date: 2022-01-14
Expiry Date: 2025-01-13

Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract
An electronic certificate can be authenticated online
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Appendix E - Declaration of Conformity

5 GQ12.1 rev05 of 02 February 2022

Copan
innovating together

EU-DECLARATION OF CONFORMITY
WASPLab®

Manufacturer: *Copan WASP S.r.l.*
Via Achille Grandi, 32
25125 Brescia (Italy)

SRN number: *IT-MF-000012489*

PRODUCT LIST

PRODUCT CODE	*PRODUCT NAME*
W087	WASPLab®
W087-010	WASPLab® Conveyor
W087-011	WASPLab® Single Incubator
W087-012	WASPLab® Double Incubator
W087-013	WASPLab® Server

Under our own sole responsibility, we hereby declare that the listed products meet the provisions of the following Regulation and Directives and following amendments:

- *Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR), according to the conformity assessment procedure described in the Annex IX*
- *Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, according to the conformity assessment procedure described in the Annex VIII*
- *Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)*
- *Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (LVD)*
- *Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility (EMC)*
- *Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED)*

SGQ12.1 rev05 of 02 February 2022

Copan
innovating together

Products Data:

BASIC UDI-DI	*805014821IP040AAUTOM01UB*
Intended Purpose	*WASPLab® is an automated device intended to be used for the incubation and the digital imaging of agar culture plates streaked with microbiological specimens derived by the human body for microbiological investigations.*
Risk Class according to IVDR 2017/746 (Annex VIII)	*Class A according to Rule 5b*

Applied standards:

Ref. No. /Date	Title
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk reduction
EN 62304:2006/A1:2015	Medical device software. Software life-cycle processes
IEC 62366-1:2015/COR1:2016	Medical devices – Part 1: Application of usability engineering to medical devices
ETSI EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-3 V1.6.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
ETSI EN 300 330 v2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

SGQ12.1 rev05 of 02 February 2022

Copan
innovating together

Valid Until: 07/02/2027

This declaration is supported by the Technical Documentation, that is compiled by the Regulatory Department and retained under the premises of the Manufacturer. The Manufacturer has a Quality Management System that is certified according to the standards EN ISO 13485:2016 *Medical devices - Quality management systems – Requirements for regulatory purposes* and EN ISO 9001:2015 *Quality Management System – Requirements.*

Place, Date of Issue: Brescia, 07/02/2022

Mario Savarese
CEO

Page 3 of 3

Appendix F – Lab Drawing

The Supplier shall install the equipment as per the layout agreed in the lab drawing below.

Manchester Rev07.pdf