DHSC Terms and Conditions for the Supply of Goods

The Authority	Secretary of State for Health and Social Care 39 Victoria Street, Westminster, London SW1H 0EU, UK
The Supplier	INNOVA MEDICAL GROUP INC., 800 E. Colorado Blvd., Suite 288, Pasadena, CA91101, USA. with NV company registration number: E5628270202-1

Date	13th March 2021
Type of Goods	INNOVA SARS-CoV-2 Antigen Rapid Qualitative Test Kits
Domestic/Overseas Supplier	Overseas supplier
Document Created by	[redacted]

This Contract is made on the date set out above subject to the terms set out in the Order Form and schedules ("**Schedules**") below. The Authority and the Supplier undertake to comply with the provisions of the Order Form and the Schedules in the performance of this Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of this Contract. For the avoidance of doubt, the Contract consists of the terms set out in the Order Form and the Schedules, together with the annexes as stated.

The Definitions in Schedule 3 apply to the use of all capitalised terms in this Contract.

Schedules

Schedule 1	Key Provisions (attached)
Schedule 2	General Terms and Conditions – as per Schedule 2 attached to the contract between the Authority and the Supplier dated 17 September 2020 ("**Original Contract**")
Schedule 3	Definitions and Interpretations – as per Schedule 3 attached to the Original Contract
Schedule 4	Additional Special Conditions – as per Schedule 4 attached to the Original Contract
Schedule 5	SARS Covid 2 variants of concern (attached)

Order Form

1. Contract Reference	500
2. Date	[ ] March 2021
3. Authority	Secretary of State for Health and Social Care 39 Victoria Street, Westminster, London SW1H 0EU, UK
4. Supplier	INNOVA MEDICAL GROUP INC., 800 E. Colorado Blvd., Suite 288, Pasadena, CA91101, USA. with NV company registration number: E5628270202-1
5. The Contract	The Supplier shall supply the Goods described below on the terms set out in this Order Form and the Schedules. Unless the Contract otherwise requires, capitalised expressions used in this Order Form have the same meanings as in Schedule 3. In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail. Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Authority and may delay conclusion of the Contract.
6. Goods to be Supplied	**Test kits** [redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

Note on colours: NHS logo must use pantone 300 blue

[redacted]

The artwork files and documents referenced in the table above shall be separately provided by the Authority to the Supplier.

[redacted]

Delivery

[redacted]

[redacted]			

	[redacted] The Supplier shall be responsible for obtaining China customs clearance for the Goods such that they are available to be shipped to the UK from the above date of delivery. All units of the Goods shall be packaged in accordance with Annex 1_Innova SARS-Cov-2 Antigen test IFU (as attached to the Original Contract and as varied by this Order Form) and shall be supplied with the batch documentation set out in this Contract or as otherwise reasonably required by the Authority. [redacted]
7. Specification	The specification of the Goods is as set out in Annex 1_Innova SARS-Cov-2 Antigen test IFU (as attached to the Original Contract) and Annex 2 Clinical Trial

[redacted]

8. Term

The Term shall commence on the date of this Order Form.

This Contract shall expire on 28 April 2021 (and the period from commencement until such expiry date shall be the total Contract term), unless this Contract is otherwise extended or terminated in accordance with the terms and conditions of the Contract.

9. Charges

The Charges for the Goods shall be as set out below:

Description	Price per test kit unit (exc. VAT)	Total # items	Total Price (exc. VAT)	Currency
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total Price	**GBP £1,212,000,018.18 (excluding VAT)**			

10. Payment

[redacted]

	[redacted]	
11. Authority's Authorised Representative(s)	For general liaison your contact will be [redacted]	
12. Supplier's Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]	
13. Address for notices	**Authority:** Department of Health and Social Care, 39 Victoria Street, Westminster, London SW1H 0EU, UK [redacted]	**Supplier:** INNOVA MEDICAL GROUP INC., 800 E. Colorado Blvd., Suite 288, Pasadena, CA91101, USA [redacted]
14. Key personnel	**Authority:** [redacted]	**Supplier:** [redacted]
15. Procedures and Policies	No additional policies	

[redacted]

16. Insurance	[redacted]

Signed by the authorised representative of THE AUTHORITY

Name:	[redacted]	Sign	[redacted]
Position:	[redacted]	Date	13th March 2021

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]		
Position:	[redacted]	Date	13 March 2021

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 2 of this Schedule 1 shall apply to this Contract.

1.2 The optional Key Provisions at Clauses 3 to 12 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.

1.3 Extra Key Provisions shall only apply to this Contract where such provisions are set out at the end of this Schedule 1.

2 Order of precedence

2.1 Subject always to Clause 1.9 of Schedule 3 should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

2.1.1 Order Form;

2.1.2 Schedule 1: Key Provisions;

2.1.3 Any annexes referred to in the Order Form or the Key Provisions;

2.1.4 Schedule 2: General Terms and Conditions;

2.1.5 Schedule 3: Definitions and Interpretations; and

2.1.6 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

2.2 For the avoidance of doubt, the Order Form shall include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Supplier's responses, proposals and/or method statements to meet those requirements, and any clarifications to the Supplier's responses, proposals and/or method statements as included in this Contract. Should there be a conflict between these parts of the Order Form, the order of priority for construction purposes shall be (1) the Authority's requirements; (2) any clarification to the Supplier's responses, proposals and/or method statements, and (3) the Supplier's responses, proposals and/or method statements.

3 Quality assurance standards ☒ (only applicable to the Contract if this box is checked and the standards are listed)

3.1 The following quality assurance standards shall apply, as appropriate, to the manufacture and/or supply of the Goods:

3.1.1 ISO134852016(CN 1742021) (Annex 3 as attached to the Original Contract)

3.1.2 Internal process control documentation regarding Quality Control Procedures (Annex 4 as attached to the Original Contract)

4 [redacted] ☐ [redacted]

[redacted]

5 [redacted] ☒ [redacted]

[redacted]

5.2 The Supplier acknowledges and accepts that the Authority intends to incur costs to arrange international transportation for Goods based on the delivery schedule in this Contract and the Authority may not be able to avoid incurring such costs in respect of any scheduled delivery that is delayed.

6 Specific time periods for inspection ☒ (only applicable to the Contract if this box is checked and Clause 6.1 of this Schedule 1 is completed)

6.1 The Authority (or one or more third parties appointed by it) shall have the right to inspect the Goods at their place of manufacture or storage prior to shipment and, if necessary, the Supplier shall store the Goods during such inspection at no cost to the Authority. The Supplier shall not be liable for any delay in the delivery of any shipment of the Goods if such delay results from any inspection by the Authority pursuant to this Clause 6.1.

7 Specific time periods for rights and remedies under Clause 4.6 of Schedule 2 ☐ (only applicable to the Contract if this box is checked and Clause 7.1 of this Schedule 1 is completed)

7.1 The Authority's rights and remedies under Clause 4.6 of Schedule 2 shall cease **[*insert period – e.g. 12 months*]** from the date of delivery of the relevant Goods.

8 Termination for convenience ☒ (only applicable to the Contract if this box is checked)

8.1 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

where:

(i) "**Delivered Kits**" means the number of units of test kits which are delivered by the Supplier and paid for by the Authority under the Contract; and

(ii) "**Cancelled Kits**" means the number of units of test kits which were ordered under the Contract but are no longer required to be delivered following the termination.

8.4 [redacted]

[redacted]

9 Right to terminate ☐ (only applicable to the Contract if this box is checked)

9.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12)

month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice.

10 Consigned Goods ☐ (only applicable to the Contract if this box is checked)

10.1 Provided that such Consignment Request is consistent with the forecast requirement for the Goods (as set out in the Order Form and/or as calculated in accordance with any relevant processes set out in this document and/or as otherwise agreed by the Parties in writing), the Supplier shall deliver the Consigned Goods in accordance with Clause 2 of Schedule 2 in response to a Consignment Request for their eventual purchase and use by the Authority in accordance with the terms set out in this Contract.

10.2 For the avoidance of doubt, Clause 4 of Schedule 2 shall apply to the inspection, rejection, return and recall of the Consigned Goods.

10.3 The Authority shall, or shall procure that its third party provider shall, maintain any storage facilities throughout the term of this Contract where the Consigned Goods are to be stored in such manner that such storage facilities remain suitable to store the Consigned Goods.

10.4 Prior to the Consigned Goods being taken into use by the Authority, the Authority shall ensure that:

10.4.1 the Consigned Goods are stored at the storage facilities in such a manner as to protect them from damage or deterioration;

10.4.2 the Consigned Goods in its possession remain readily identifiable as the Supplier's property;

10.4.3 any identifying marks or packaging on or relating to the Consigned Goods are not removed, defaced or obscured; and

10.4.4 the Consigned Goods are kept in satisfactory condition in accordance with any reasonable and necessary instructions from the Supplier from time to time.

10.5 The Authority shall keep accurate stock records in relation to any Consigned Goods and shall provide the Supplier with a sales report ("**Sales Report**") each **[week/month/quarter/other agreed period]** detailing current stock levels and the Consigned Goods taken into use by the Authority. For the avoidance of doubt, a sale will take place at the point any Consigned Goods are taken into use by the Authority.

10.6 On receipt of the Sales Report, the Supplier may invoice the Authority the Contract Price for all of the Consigned Goods taken into use by the Authority (as set out in that Sales Report).

10.7 Each ***[week/month/quarter/other agreed period]*** the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Order Form for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by the Authority (including, without limitation, where the Authority obtains substitute goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to

supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:

10.7.1 the Contract Price of the Minimum Quantity in the relevant period; and

10.7.2 the Contract Price for Consigned Goods purchased by the Authority in that period.

10.8 The Authority (on a first in first out basis) may return to the Supplier any Consigned Goods that it is unable to use ("**Returned Goods**") by giving written notice to that effect ("**Returns Notice**"). Upon receipt of a Returns Notice, the Supplier shall collect the Returned Goods at the Supplier's risk and expense within ten (10) Business Days of the date of the Returns Notice. If the Supplier requests and the Authority accepts that the Returned Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority may invoice the Supplier for the costs associated with the disposal of the Returned Goods and the Supplier shall pay any such costs.

10.9 Risk in respect of any Returned Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier; or (b) immediately following the expiry of ten (10) Business Days from the date of the Returns Notice related to such Returned Goods. If Returned Goods are not collected within ten (10) Business Days of the date of the relevant Returns Notice, the Authority may return the Returned Goods to the Supplier at the Supplier's risk and expense and/or charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of the relevant Returns Notice. The Authority may invoice the Supplier for such return expenses and/or storage costs and the Supplier shall pay any such expenses or costs.

10.10 The Consigned Goods shall at all times be subject to the direction and control of the Supplier, and the Supplier may (at the Supplier's risk and expense), upon (10) Business Days written notice to the Authority, collect (on a first in first out basis) any Consigned Goods that have not been taken into use by the Authority within [***insert period***] of their delivery to the Authority and/or which have a remaining shelf life of less than [***insert period***].

10.11 The Authority acknowledges that it holds Consigned Goods in its possession as bailee for the Consignor until such time as ownership passes in accordance with Clause 3.2 of Schedule 2.

10.12 On the termination or expiry of this Contract for whatever reason, all Consigned Goods not taken into use by Authority as at the point of such termination or expiry shall be deemed Returned Goods. Such Returned Goods shall be deemed the subject of a Returns Notice that shall be deemed to have been received by the Supplier with a notice date the same as the date of the expiry or earlier termination of this Contract. Clauses 10.8 and 10.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 10.8 and 10.9 of this Schedule 1, shall survive the expiry or earlier termination of this Contract for these purposes.

11 Electronic product information ☐ (only applicable to the Contract if this box is checked)

11.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

11.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same.

11.3 If the Product Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information.

11.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods) available pursuant to the Authority's contracts from time to time.

11.5 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval.

11.6 If requested in writing by the Authority, and to the extent not already agreed as part of writing, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System

12 Additional provisions ☒ (only applicable to the Contract if this box is checked)

12.1 In the event that the Supplier becomes aware that it may not be able to meet any of the delivery dates set out in this Contract, it shall notify the Authority in writing as soon as possible of the issue and likely impact on delivery timescales.

12.2 [redacted]

[redacted]

[redacted]

12.4 [redacted]

[redacted]

12.6 The Authority continues to test the SARS-CoV-2 Antigen Rapid Qualitative Test Kits against new virus strains to confirm the efficacy of the Goods. The confirmatory protocol is as follows:

12.6.1 [redacted]

[redacted]

[redacted]

12.7 [redacted]

12.7.1 [redacted]

[redacted]

[redacted]

12.8 [redacted]

[redacted]

[redacted]

12.9 [redacted]

12.10 [redacted]

[redacted]

[redacted]

[redacted]

12.10.4 the Supplier shall provide such technical and other support and assistance to the Authority in relation to the Authority's regulatory obligations with regard to the Goods or any investigations required as a result of the Authority's post-market surveillance or other regulatory activities. This may include technical investigations of the Goods, production/supply chain investigations, recalls, the provision of associated reports and updates to the Goods to address issues arising, patient complaints or requirements to enhance usability. If a patient complaint arises and investigation is needed, the Supplier shall provide such support to enable the investigation to commence within the timelines required by the MHRA or other relevant regulatory body; and

12.10.5 the Supplier shall, on written request from the Authority, promptly make any changes to the Goods (including the test kits, the IFU and/or the packaging) which are necessary to meet the requirements of the MHRA or other relevant regulatory body.

12.11 The Supplier shall, or where appropriate shall procure that the manufacturer of the Goods shall:

12.11.1 [redacted]

12.11.2 regularly assess (including using wet lab or in silico evidence) the Goods in relation to detection of any established, new or emerging SARS-CoV-2 virus variants and any known or potential risk of failure to perform in accordance with the Authority's requirements. The Supplier shall inform the Authority in writing immediately on becoming aware that the performance of the Goods may be compromised by any identified variants of the SARS-CoV-2 virus.

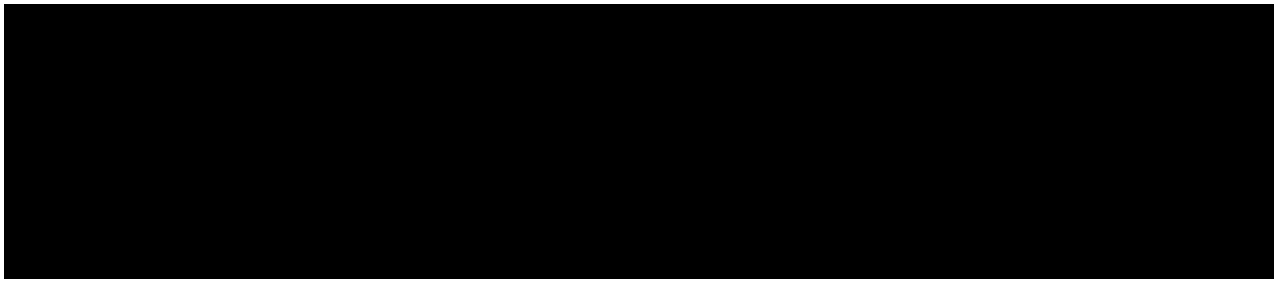
12.12 [redacted]

12.13 The Supplier warrants on an ongoing basis that it shall comply with paragraphs 12.11 and 12.12 and further warrants that on the basis of that compliance it is not aware of any variants which would adversely affect the effective performance of the Goods in detecting any of the variants of the SARS-CoV-2 virus identified in Schedule 5, identified in accordance with its obligations under paragraph 12.11 or otherwise notified to the Supplier.

12.14 The Supplier warrants that the Goods will be effective to the Authority's required level of sensitivity in detecting the variants of the SARS-CoV-2 virus which are identified in Schedule 5, identified (or should have been identified) by the Supplier acting in accordance with its obligations under paragraph 12.11, or which have otherwise been notified to the Supplier prior to the date of delivery of the Goods. The Supplier shall inform the Authority in writing immediately on becoming aware at any time that the performance of the Goods may be adversely affected in relation to any identified variants of the SARS-CoV-2 virus.

12.15 The Authority may request at any time that a sample of the Goods is submitted by the Supplier, at the Supplier's cost, to a testing institution designated by the

Authority for testing of sensitivity in the detection of established, new or emerging



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