

**DATED**

**2021**

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**(1) THE DOCTORS LABORATORY LIMITED**

**and**

**(2) .....**

**(CLIENT / CLINIC)**

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**AGREEMENT FOR THE PROVISION OF  
GENOME SEQUENCING SERVICES AS PART  
OF GOVERNMENT DAY 2 TESTING FOR  
INTERNATIONAL ARRIVALS**

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## AGREEMENT DETAILS

<b>Agreement date:</b>	
<b>Client (full company name, company number and registered address):</b>	
<b>Client's address for notices:</b>	Name: Title: Email: Telephone: Postal Address:
<b>TDL:</b>	The Doctors Laboratory Limited (Company No. 02201998)
<b>TDL's registered office:</b>	The Halo Building, 1 Mabledon Place, London, WC1H 9AX
<b>TDL's address for notices:</b>	Name: Annette Wilkinson Title: Director of Business Development & Service Email: TDLtravel@tdlpathology.com Telephone: 020 7307 7373 Postal Address: The Halo Building, 1 Mabledon Place, London, WC1H 9AX
<b>Services Start Date OR The date the Agreement is entered into by the parties:</b>	/ /
<b>Notice period:</b> (see clauses 4.2 and 8.1)	7 days
<b>Services:</b>	The Day 2 and Day 8 Testing service, as described in the Services Description, provided by TDL pursuant to the Agreement.
<b>Type of test required:</b>	SARS CoV-2 genome sequencing, meeting the relevant Department of Health and Social Care (DHSC) standards
<b>Fees:</b>	The fees detailed in the Services Description.

- 1 This agreement is made up of the following:
  - 1.1 The Agreement Details.
  - 1.2 The Agreed Terms.
  - 1.3 The Services Description.
  - 1.4 The Annex.  
(together the "**Agreement**").
- 2 If there is any conflict or ambiguity between the terms of the documents listed in paragraph 1 above, a term contained in a document higher in the list shall have priority over one contained in a document lower in the list.
- 3 Except where expressly provided otherwise words and phrases used in the Agreement have the meaning defined in clause 1 of the Agreed Terms.

This Agreement has been entered into on the date stated at the beginning of it.

Signed by ANNETTE WILKINSON for and on behalf of THE DOCTORS LABORATORY LIMITED	) ..... ) Director	
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Signed by:	Signature:
..... )	.....
for and on behalf of:	) Job Title:
.....	.....

## SERVICES DESCRIPTION

### I. Services:

- a. TDL is providing the Client with the genome sequencing element of the government's Day 2 and Day 8 Testing scheme (detailed below).
- b. The Test that TDL is providing is the type of test referred to in the Agreement Details. TDL will communicate the results of the Test to the Client as described below.
- c. TDL will refer the Test to the relevant member of the TDL Group. The UKAS accreditation number of the TDL Group laboratory issuing the Test result and PHE notification is contained in the Test result issued to the Client.
- d. The Client shall ensure that all information provided to TDL is accurate and up to date.
- e. TDL has the right to prioritise Priority Testing over this Service, as further set out in clause 3.5. This may impact turnaround times and provision of the Service.

### II. Ordering a Test:

- a. The Client shall order Tests by submitting a request form provided by TDL (a '**Pathology Request Form**') in accordance with any instructions circulated by TDL from time to time (a '**Pathology Request**'). Any Sample received that is not accompanied by a Pathology Request Form (complete with at least the minimum information requested by TDL from time to time) will not be accepted for analysis and will be discarded.
- b. Where a Pathology Request Form sent to TDL does not include the Sample collection date and time, the Test will be rejected and the Sample discarded without analysis.

### III. Sending Samples to TDL:

- a. The Client is responsible for arranging appropriate courier transport of the Samples to the TDL Sample reception facility accordance with any instructions circulated by TDL from time to time. The Client must ensure that Samples are packaged and labelled in accordance with Applicable Law and good clinical practice.

### IV. Reporting Pathology Results to the Client:

- a. TDL will report Test results to the Client using the wording currently used by TDL for clinical or general Testing (a '**Report**'). The Client will be responsible for relaying the Test results using any wording dictated by Applicable Law and government guidance to the traveller and within the timeframe dictated by Applicable Law and government guidance. TDL will not communicate the Test result directly to the traveller.
- b. Where the Client is reproducing a Report, the Client must also include on the reproduced Report a reference to the TDL Group UKAS number using the wording: 'This assay is UKAS (ISO15189) accredited. Results produced by HSL Analytics (LLP) UKAS no.8059', or such other wording as TDL informs the Client from time to time.
- c. TDL will report the Test results to the Client in accordance with the method of communication agreed between the Client and TDL from time to time. The Client will be responsible for ensuring that their contact details are correct.

### V. Turnaround times:

- a. Subject to clauses 3.4 and 3.6, the turnaround time for a Test conducted on a Sample is 48 hours.
- b. The turnaround time is measured from the time TDL logs the Sample in its laboratory information management system at its Sample reception facility, until the time TDL releases the Test result to the Client or PHE (as required) in accordance with this Agreement.

**VI. Fees:**

- a. For this Service, the Client will pay a fee that is the most recent price that TDL has communicated to the Client in writing prior to the date of the Pathology Request.

**VII. The obligations of the parties:**

**COVID-19 TESTING FOR IN-BOUND INTERNATIONAL TRAVEL – ‘DAY 2 AND DAY 8 TESTING’**

BACKGROUND: All international arrivals to England from are required to take a test on or before Day 2 and, unless they are arriving from what the government has listed as a ‘green country’, a test on or after Day 8. Private providers may provide tests for Day 2 and Day 8 testing for international arrivals travelling from countries that are not on the government’s ‘red list’ of countries. References to ‘Day 2’ and ‘Day 8’ in this Annex 3 shall be interpreted in accordance with Applicable Law and government guidance. For ‘Day 2’ tests, the government has required that genome sequencing is carried out on Samples which tested positive for Covid-19. For the avoidance of doubt, TDL is not the end-to-end provider of this testing service. TDL only carries out the genome sequencing element of the service.

The following obligations are included in order for the parties to comply with the responsibilities set out in the government’s guidance and the Applicable Law.

<b>1</b>	<b>TDL’s Obligations:</b> TDL shall fulfil the obligations set out in this table in accordance with Applicable Law and government guidance.
1.1	TDL shall have a GMC-registered medical director for oversight and approval of medical practices and reporting any medical issues relating to the Testing aspect of the Service and shall have an HCPC-registered healthcare scientist for oversight and reporting any clinical scientific issues relating to the Testing aspect of the Service. TDL shall also have a bioinformatician supervising genome sequencing.
1.2	Have an effective system of clinical governance in place which includes appropriate standard operating procedures in relation to the carrying out of appropriate tests.
1.3	Have a system in place to report adverse incidents or quality control issues to the relevant regulatory body, in relation to the Testing only.
1.4	Hold UKAS ISO 15189 or ISO/IEC17025 accreditation as required by Applicable Law.
1.5	Report to Public Health England or any public health body that takes on the functions of or replaces PHE (collectively <b>PHE</b> ) the information, so far as it is known to the operator of the TDL laboratory, which that operator is required to report (as defined in the Applicable Law) and in accordance with the timeframes set out in Applicable Law.
1.6	Inform the Client of the VOC / VUI label for each Sample.
1.7	Perform genome sequencing on the Samples using the methods and meeting the requirements set out in the Applicable Law and government guidance. Ensure that the coverage of genome sequencing requirements set out in the Applicable Law and government guidance are met.

1.8	Preserve and transport Test material to support and enable genome sequencing from the point at which the Sample is received in TDL's (or the appropriate TDL Group member's) Sample reception area.
1.9	Have a process in place to remove human reads from any data submitted to a public repository.
1.10	Make Samples available for dual sequencing on the request of NHS Test and Trace or the COVID-19 UK Genomics Consortium (COG-UK) or as otherwise required by Applicable Law, and partake in assurance processes on request.

<b>2</b>	<b>The Client's Obligations:</b> the Client shall fulfil the obligations set out in this table in accordance with Applicable Law and government guidance.
2.1	Only provide TDL with Samples which are appropriate for Testing (e.g. the Samples have been taken in accordance with Applicable Law and government guidance, have been tested positive for Covid-19 following a PCR Test and which have a cycle threshold (CT) value of less than 30).
2.2	Provide TDL with the Sample specimen ID number reported by the Client to PHE within the timeframes that TDL notifies to the Client from time to time, and in any event in time to allow TDL to meet its reporting obligations to PHE.
2.3	Provide TDL with the Sample within any timeframe dictated by Applicable Law or government guidance.
2.4	If required by Applicable Law and government guidance, the Client shall have provided the DHSC with all relevant information prior to the date that TDL starts to perform the Services.
2.5	Have an appropriately registered clinician for oversight and approval of clinical practices and oversight and reporting of any clinical issues.
2.6	Have an effective system of clinical governance in place.
2.7	Provide PHE with all information (and within the required timeframes) required under the Applicable Law and government guidance, except for that information which TDL has agreed in writing with the Client (email to suffice) to provide.
2.8	Have a system in place to report adverse test incidents or quality control issues to the relevant regulatory body with the exception of those involving the Testing aspect of the Service, which TDL will report.
2.9	Comply with all legal and regulatory requirements for Sample collection, processing and sharing Samples and Test results, including data protection legislation as applicable and/or as set out in this Agreement.
2.10	Preserve and transport Test material to support and enable genome sequencing from Sample collection up to the point at which the Sample is received in TDL's (or the

	appropriate TDL Group member's) Sample reception area.
2.11	Comply with, or ensure the end-to-end provider complies with, any other obligation required by Applicable Law or government guidance in relation to the Day 2 and Day 8 testing scheme that is not expressly an obligation on TDL set out in this Services Description.
2.12	<b>Ensure that travellers are aware and understand that they should contact the Client with any comments or queries they have relating to the Service and that travellers should not contact TDL directly with any such comments or queries.</b>

## **AGREED TERMS**

### **1 INTERPRETATION**

#### **1.1 Definitions:**

'Agreed terms' means these terms and conditions set out in clause 1 to clause 20 (inclusive).

'Applicable Law' means the laws, regulations, judgments, binding on the relevant party, as amended from time to time.

'Authorised Sub-Processors' means: a) Health Service Laboratories LLP and any other member of the TDL Group which provides the applicable Test or Service; b) persons who provide information technology services that TDL uses in the course of providing the Services; and c) any Sub-Processor referred to in the Annex.

'Business Day' means a day other than a Saturday, Sunday, or public holiday in England when the banks in London are generally open for business.

'Client' means the client identified in the Agreement Details.

'Consumables' means the Sample Collection Kit and any other commodity provided by TDL in order for the Client to benefit from the Services.

'controller, data subject, personal data, process and processor' have the meanings given to those terms in Data Protection Laws (and terms related to 'process' such as 'processing' have corresponding meanings).

'Data Protection Laws' means the UK GDPR, the Data Protection Act 2018, and any other Applicable Law having effect in the United Kingdom concerning privacy or the use of personal data.

'Data Subject Request' means a request made by a data subject to exercise any rights of data subjects under Data Protection Laws.

'Device' means an in vitro diagnostic medical device within the meaning given in regulation 2(1) of the Medical Devices Regulations 2002.

'Good Industry Practice' means the standard of skill and care reasonably to be expected from a professional provider of the Services.

'Group' in respect of any undertaking, means such undertaking and its group undertakings ('undertaking' and 'group undertaking' having the meanings given in s1161 of the Companies Act 2006).

'Health Authority' means (i) a department of the UK government or of a devolved administration, (ii) an executive agency of such department, or (iii) a body exercising statutory functions in relation to public health in the UK or any part of the UK.

'Laboratory Guide' means TDL's Laboratory Guide current at the date of this Agreement, as supplied to the Client or, if not so supplied, available on request from TDL, including any updates or supplements issued by TDL.

'Pathology Request' means a request for a Test which the Client submits in accordance with the process set out in the Services Description.

'Personal Data Breach' means any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, any Protected Data.

'Privacy Notice' means TDL's detailed Privacy Notice available at [tdlpathology.com](http://tdlpathology.com).

'Processing Instructions' has the meaning given to that term in clause 11.2.

'Protected Data' means personal data provided to TDL by the Client or a third party on the instructions of the Client, or collected or generated by TDL in the course of the Services.

'Public Health Programme' means a programme administered by a Health Authority to monitor or analyse health data for the purpose of public health or for statistical, scientific or



research purposes in the public interest.

'Sample' means a sample provided by the Client to TDL for Testing.

'Sample Collection Kit' means a kit provided to the Client for the Services and used to collect the Samples.

'Sub-Processor' has the meaning given in clause 13.1.

'TDL Group' means The Doctors Laboratory Limited and its Group and Health Service Laboratories LLP and its Group

'Test' means a pathology test of the type referred to in the Agreement Details to be carried out by TDL on a Sample, and 'Testing' means the process of conducting that Test and reporting the results to the Client.

'UKAS' means the United Kingdom Accreditation Service, or any successor to it.

## 1.2 Interpretation:

1.2.1 References to the singular include the plural and vice versa.

1.2.2 Clause headings and paragraph headings are for ease of reference only and are not part of this Agreement for the purpose of construction.

1.2.3 References to paragraphs are to paragraphs of the Schedules, unless otherwise indicated.

1.2.4 Words following the terms 'including', 'include', 'in particular', 'for example' or any similar expression shall be construed as illustrative and shall not limit the sense of the words, preceding those terms.

1.2.5 A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

1.2.6 All references to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time.

## 2 COMMENCEMENT AND TERM

The Agreement shall commence on the Services Start Date and shall continue until terminated in accordance with clause 8.

## 3 THE SERVICES

3.1 The Services shall consist of:

3.1.1 the services selected in the Agreement Details and described in the Services Description;

3.1.2 such other services as TDL agrees in writing to supply to the Client from time to time.

3.2 The Client shall request the Test by completing and submitting a Pathology Request.

3.3 TDL will provide the Services under the Agreement:

3.3.1 in accordance with Good Industry Practice;

3.3.2 in accordance with the UKAS medical laboratory accreditation standard (ISO 15189); and

3.3.3 using suitably skilled and experienced staff.

3.4 TDL will use reasonable efforts to achieve the Test turn-around times set out in the Services Description. TDL does not warrant that it will achieve Test turn-around times in the case of any particular Sample.

3.5 TDL may prioritise over the Services any laboratory testing services (which are not Tests) provided in relation to medical diagnoses, medical care or treatment which patients are undergoing (not including care or treatment related to the Services) ('**Priority Testing**'). If TDL considers it necessary in order to ensure the provision of Priority Testing by a member of the TDL Group, TDL may:

3.5.1 suspend or restrict the provision of the Services, and/or

3.5.2 extend the Test turn-around times;

and TDL may restrict the supply of the Consumables if it considers this necessary in order to manage stock levels.

- 3.6 The Laboratory Guide sets out Sample rejection criteria. If the Sample meets those criteria, or if TDL considers that the Sample is otherwise unsuitable for Testing (including for any reason set out in the Services Description) or TDL is unable to conduct the Testing then TDL may decline to carry out the Testing under the Agreement and will be entitled to dispose of the Sample.
- 3.7 TDL may destroy or dispose of a Sample after completing the Testing or on termination of the Agreement, unless otherwise agreed in writing with the Client.
- 3.8 TDL shall make reasonable efforts to supply the Sample Collection Kits to the Client in the manner indicated in the Agreement Details.

#### 4 **PRICE AND PAYMENT TERMS**

- 4.1 The fees payable by the Client for the Services will be the fees set out at the Services Description (subject to clause 4.2).
- 4.2 TDL may amend the fees set out in the Services Description by giving the Client prior written notice. The notice period given by TDL will be no shorter than the period specified in the Agreement Details.
- 4.3 As at the date of this Agreement many of TDL's services are VAT exempt. All of TDL's prices are stated exclusive of VAT and where VAT is chargeable on the Services the Client will pay it at the applicable rate.
- 4.4 Invoices are normally issued to the Client on a monthly basis, but TDL reserves the right to issue them more frequently. The Client will pay TDL's invoices within 30 days of the date of the invoice, without any deduction or set off. At TDL's option interest may be charged on late payment at the statutory rate prescribed from time to time by regulations under the Late Payments of Commercial Debts (Interest) Act 1998. Invoices paid from outside the UK must be paid by either direct bank transfer or by cheque drawn on a UK branch. All payments will be made in pounds sterling.
- 4.5 Without affecting any of its other rights, TDL may suspend provision of the Services if the Client fails to pay an invoice due to TDL.
- 4.6 The Client acknowledges that there is no 'fee-to-patient' payment option available for this Service. This means that the Client cannot request that TDL seeks payment from the traveller of the fees owed by the Client in respect of the Test and Sample Collection Kit.

#### 5 **CONFIDENTIALITY**

- 5.1 A party (the "**Receiving Party**") shall hold and maintain the confidence of all information of a confidential nature which it receives from the other party (the "**Disclosing Party**").
- 5.2 The Receiving Party may disclose the Disclosing Party's confidential information:
  - 5.2.1 to the employees, officers, representatives, contractors, subcontractors or advisers of the Receiving Party or the Receiving Party's Group who need to know such information for the purposes of exercising the Receiving Party's rights or carrying out its obligations under or in connection with this Agreement. The Receiving Party shall ensure that its and its Group's employees, officers, representatives, contractors, subcontractors or advisers to whom it discloses the other party's confidential information comply with this clause 5;
  - 5.2.2 as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority, or accreditation body; or
  - 5.2.3 as necessary for the performance of the Receiving Party's obligations under this Agreement.
- 5.3 The Receiving Party shall not use the Disclosing Party's confidential information for any purpose other than to exercise its rights and perform its obligations under or in connection with

this Agreement, or as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority, or accreditation body.

- 5.4 The restrictions in clause 5 will not apply to information which: (i) was in The Receiving Party's possession prior to disclosure by the Disclosing Party; or (ii) is now or hereafter comes into the public domain other than by default of the Receiving Party; or (iii) was lawfully received by the Receiving Party from a third party acting in good faith having a right of further disclosure; or (iv) is required by law to be disclosed by the Receiving Party; or (v) which is required by a regulatory or accreditation body to be disclosed to it for the purpose of regulating or accrediting the Receiving Party.

## **6 CLIENT RESPONSIBILITIES**

- 6.1 The Client will ensure that all necessary consents and permissions are obtained and all necessary information provided to the traveller, which is required under Applicable Law or good clinical practice in order to permit the Testing, the performance of any other Services, and the use of the Protected Data as contemplated in the Agreement.
- 6.2 The Client will provide TDL with any information reasonably necessary for performing the Services, including by ensuring that the Pathology Request contains sufficient information regarding the Sample, the relevant traveller, and the Client details of where the Test results are to be reported, and will ensure that any information the Client provides to TDL in connection with the Services is accurate and complete.
- 6.3 The Client will comply with its obligations set out in the Services Description.
- 6.4 The Client will comply with any reasonable instructions which TDL provides about the use of the Service from time to time, including instructions about the collection, preparation, and transportation of Samples submitted to TDL.

## **7 LIABILITY**

- 7.1 Nothing in this Agreement will limit or exclude liability for death or personal injury caused by negligence or any other liability that cannot be limited or excluded under Applicable Law.
- 7.2 In this Agreement, 'liability' means any liability whether in contract, tort (including negligence), misrepresentation, breach of statutory duty or otherwise, which arises in connection with the Services or under or in connection with this Agreement.
- 7.3 The aggregate liability of TDL and the Client will each be limited to £2,000,000 in total.
- 7.4 Neither TDL nor the Client will have any liability for:
- 7.4.1 loss of profit or revenue;
  - 7.4.2 loss of anticipated savings;
  - 7.4.3 loss of reputation or goodwill; or
  - 7.4.4 indirect, special or consequential loss.
- 7.5 TDL will have no liability for any delay or failure in performance of the Services arising from the Client's delay or failure in performing its obligations under clause 6.
- 7.6 All of the warranties which TDL gives in relation to the Services are expressly set out in this Agreement. All other warranties, whether implied or express, are excluded from this Agreement where it is lawful to exclude them.
- 7.7 In this clause 7 references to TDL include the members of TDL's Group, and for the purpose of the limit in clause 7.3 the liabilities of TDL and the TDL Group Members will be counted in aggregate. The members of TDL's Group may enforce this clause 7.

## **8 TERMINATION**

- 8.1 Either party may terminate this Agreement for convenience by giving the other party prior written notice of at least the period specified in the Agreement Details.

- 8.2 Without affecting any other right or remedy available to it, either party may terminate this Agreement with immediate effect by giving written notice to the other party if:
- 8.2.1 the other party commits a material breach of any term of this Agreement which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of 30 days of receipt of a notice identifying the breach and requiring its remedy;
- 8.2.2 the other party takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), applying to court for or obtaining a moratorium under Part A1 of the Insolvency Act 1986, being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;
- 8.2.3 the other party suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business; or
- 8.2.4 the other party's financial position deteriorates to such an extent that in the terminating party's reasonable opinion the other party's capability to adequately fulfil its obligations under this Agreement has been placed in jeopardy.
- 8.3 Without affecting any other right or remedy available to it, TDL may terminate this Agreement with immediate effect by giving written notice to the Client if the Client fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than 14 days after being notified to make such payment;
- 8.4 Termination of this Agreement shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination, including the right to claim damages in respect of any breach of the agreement which existed at or before the date of termination.
- 8.5 Following termination of this Agreement for any reason TDL may submit its invoice for any Services provided but not yet invoiced up to the date of termination, and the Client shall pay such invoice in accordance with clause 4.
- 8.6 Any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination of this Agreement shall remain in full force and effect, including clauses 7 (LIABILITY), 8 (TERMINATION), 18 (DELETION OR RETURN OF PROTECTED DATA AND COPIES), 19 (PROTECTED DATA THAT TDL PROCESSES AS A DATA CONTROLLER) and 20 (GENERAL).
- 9 FORCE MAJEURE**
- 9.1 If the performance of any obligation under the Agreement (except for an obligation to pay) is prevented, restricted or interfered with by reason of circumstances beyond the reasonable control of that party obliged to perform it (a "**Force Majeure Event**"), the party so affected will be excused from any resulting failure or delay in performance, and the time for performance will be extended by an amount of time equal to the duration of the Force Majeure Event. The party so affected will use reasonable endeavours to mitigate the effect of the Force Majeure Event on its performance of its obligations. If the Force Majeure Event delays or prevents performance of a party's obligations for more than three months, either party may terminate the agreement on written notice to the other.
- 10 DATA PROCESSOR AND DATA CONTROLLER**
- 10.1 When TDL processes Protected Data on behalf of the Client in providing the Services the parties agree that the Client will be the data controller and TDL will be the data processor. The Annex to this Agreement sets out when TDL processes Protected Data on behalf of the Client. Clause 19 describes the circumstances where TDL will use Protected Data on its own behalf as data controller.
- 10.2 When TDL processes Protected Data as the data processor, clauses 11 to 18 (inclusive) will apply in relation to the Protected Data. Where TDL processes Protected Data as data controller, clause 19 will apply instead.

10.3 The Client will comply with the Data Protection Laws in relation to the Protected Data, and ensure that all instructions given by it to TDL in respect of Protected Data will at all times be in accordance with Data Protection Laws.

## 11 DATA PROCESSING INSTRUCTIONS

11.1 When TDL processes Protected Data as the data processor, TDL will comply with the obligations of data processors under Data Protection Laws.

11.2 Unless required to do otherwise by Applicable Law, TDL will (and will take steps to ensure each person acting under its authority will) process the Protected Data only in accordance with the Client's documented instructions as set out in this Agreement, the Annex and any relevant Pathology Request (the "**Processing Instructions**").

11.3 If Applicable Law requires TDL to process Protected Data other than in accordance with the Processing Instructions, TDL will notify the Client of any such requirement before processing the Protected Data (unless Applicable Law prohibits TDL from doing so).

11.4 TDL will promptly inform the Client if TDL becomes aware of a Processing Instruction that, in TDL's opinion, infringes Data Protection Laws. TDL will have no liability for any processing in accordance with those Processing Instructions after giving the notice. TDL's obligations under this clause 11.4 do not limit the Client's obligations under clause 10.3.

## 12 DATA SECURITY MEASURES

12.1 In relation to the processing of the Protected Data, TDL will implement and maintain, at its cost and expense, appropriate technical and organisational measures to ensure for the Protected Data a level of security appropriate to the risks presented by the processing, taking into account the state of the art, the cost of implementation and the nature, scope, context and purpose of the processing of the Protected Data as well as the risk of varying likelihood and severity of the rights and freedoms of natural persons.

## 13 USING STAFF AND OTHER PROCESSORS

13.1 TDL will not engage any data processor to process the Protected Data on the Client's behalf (a "**Sub-Processor**") without the Client's authorisation of that specific Sub-Processor. The Client will not unreasonably withhold, condition or delay such consent. By accepting this Agreement the Client authorises the appointment of the Authorised Sub-Processors.

13.2 TDL will ensure that each Sub-Processor that is appointed under clause 13.1 is appointed under a contract containing materially the same obligations as clauses 11 to 18 (inclusive).

13.3 TDL will ensure that all persons authorised to process Protected Data are subject to a binding obligation to keep the Protected Data confidential (except where disclosure is required in accordance with Applicable Law, in which case TDL will, where practicable and not prohibited by Applicable Law, notify the Client of any such requirement before such disclosure).

## 14 ASSISTANCE WITH THE CLIENT'S COMPLIANCE AND DATA SUBJECT RIGHTS

14.1 Taking into account the nature of the processing, TDL will implement and maintain reasonable measures to assist the Client to respond to Data Subject Requests relating to the Protected Data that TDL processes on the Client's behalf. TDL will refer such Data Subject Requests it receives to the Client promptly, and in any event within five Business Days of receipt of the request.

14.2 TDL will provide such assistance as the Client reasonably requires (taking into account the nature of processing and the information available to TDL) to the Client in ensuring compliance with the Client's obligations under Data Protection Laws with respect to: (i) security of processing, (ii) data protection impact assessments (as such term is defined in Data Protection Laws), (iii) prior consultation with the relevant regulator regarding high risk processing, (iv) and notifications to the regulator and/or communications to data subjects by the Client in response to any Personal Data Breach. The Client will pay TDL's charges for providing the assistance in

this clause 14, such charges to be calculated on a time and materials basis at TDL's applicable daily or hourly rates in force from time to time.

## **15 INTERNATIONAL DATA TRANSFERS**

15.1 The Client agrees that TDL may transfer Protected Data to countries outside the United Kingdom for the purpose of providing the Services, provided all transfers by TDL of Protected Data to such recipients are in accordance with such safeguards or other mechanism(s) for transfers of personal data as may be permitted under Data Protection Laws from time to time. The Client agrees that TDL may implement such safeguards by entering into standard data protection clauses authorised under the Data Protection Laws, which TDL may do as agent on behalf of the Client. The provisions of clauses 11 to 18 (inclusive) will constitute the Client's instructions with respect to transfers in accordance with clause 11.2.

## **16 RECORDS, INFORMATION AND AUDIT**

16.1 TDL will maintain, in accordance with Data Protection Laws binding on TDL, written records of all categories of processing activities carried out on behalf of the Client.

16.2 TDL will, in accordance with Data Protection Laws, make available to the Client such information as is reasonably necessary to demonstrate TDL's compliance with its obligations as a data processor under this Agreement and the Data Protection Laws, and allow for and contribute to audits, including inspections, by the Client (or another auditor mandated by the Client) for this purpose, subject to the Client:

16.2.1 giving TDL reasonable prior notice of such information request, audit and/or inspection being required by the Client;

16.2.2 ensuring that all information obtained or generated by the Client or its auditor(s) in connection with such information requests, inspections and audits is kept strictly confidential (save for disclosure to the relevant regulator or as otherwise required by Applicable Law);

16.2.3 ensuring that such audit or inspection is undertaken during normal business hours, with minimal disruption to TDL's business, the Sub-Processors' business and the business of other customers of TDL.

## **17 BREACH NOTIFICATION**

17.1 TDL will, without undue delay notify the Client of the Personal Data Breach involving the Protected Data, and provide the Client with details of the Personal Data Breach.

## **18 DELETION OR RETURN OF PROTECTED DATA AND COPIES**

18.1 TDL will, at the Client's written request, either delete or return all of the Protected Data to the Client in such form as the Client reasonably requests within a reasonable time after the end of the provision of the relevant Services related to processing, and delete existing copies (unless storage of any data is required by Applicable Law and, if so, TDL will inform the Client of any such requirement). Where TDL will process that Protected Data as data controller under clause 19, TDL may retain the Protected Data.

## **19 PROTECTED DATA THAT TDL PROCESSES AS A DATA CONTROLLER**

19.1 TDL may process Protected Data as data controller in the circumstances and for the purposes set out in TDL's Privacy Notice. In particular TDL may:

19.1.1 retain and submit Protected Data to a Health Authority in the United Kingdom for the purposes of a Public Health Programme operated by that Health Authority, or to regulator for the purpose of complying with regulatory obligations; and

19.1.2 retain and process Protected Data in its laboratory records in order to meet the requirements of the UKAS medical laboratory accreditation standard (ISO 15189) and implement the guidelines of the Royal College of Pathologists for the retention and storage of pathological records and specimens.

19.2 When TDL processes personal data on its own behalf as data controller, it will do so in accordance with the obligations of data controllers under Data Protection Laws and with the applicable terms of the Agreement.

## 20 GENERAL

### 20.1 Dispute resolution.

20.1.1 If any dispute arises relating to this Agreement or any breach or alleged breach of this Agreement, the parties will make a good faith effort to resolve such dispute without recourse to legal proceedings. If, notwithstanding such good faith efforts, the dispute is not resolved either party may submit the dispute to the jurisdiction of the English Courts.

20.1.2 Except to the extent clearly prevented by the area of dispute, the parties will continue to perform their respective obligations under this Agreement while such dispute is being resolved.

20.2 **Variation.** Any amendments to this Agreement will not be effective unless in writing and signed by an authorised signatory on behalf of each of the parties. The terms of this Agreement may be varied by agreement of the parties but without the consent of any third party whether or not the rights of such third party are affected by such variation. Notwithstanding the foregoing, TDL may at any time amend this Agreement by written notice to the Client in order to reflect changes to the Applicable Law and government guidance which relate to the Services.

20.3 **Rights and waiver.** All rights granted to either of the parties will be cumulative and not exhaustive of any rights and remedies provided by law. The failure of either party to enforce (or delay in enforcing) at any time for any period any one or more of the terms of this Agreement will not be a waiver of such term or of the right of such party at any time subsequently to enforce all the terms of this Agreement.

20.4 **Severability.** If any provision of this Agreement is or becomes invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions will not be in any way affected.

20.5 **Assignment.** TDL may assign or sub-contract the performance of this Agreement (in whole or in part) or any one or more of the Tests to be performed hereunder to suitably accredited laboratories including those listed in the Laboratory Guide. The Client may not assign, transfer, or declare a trust over, this Agreement or any of its rights or obligations hereunder without the prior written approval of TDL.

20.6 **Relationship of the parties.** It is acknowledged and agreed that TDL and the Client are independent contractors and nothing in this Agreement will create or be construed as creating a partnership or (except as provided in clause 15 and the Annex) a relationship of agent and principal between the parties. The Client acknowledges and agrees that, in requesting Services from TDL, it is not acting as agent for any traveller or travellers to which the Services relate.

### 20.7 Notices.

20.7.1 All notices given under this Agreement will be in writing and will be delivered by hand or sent by prepaid first class post or by prepaid first class recorded delivery or by email transmission. All notices will be delivered at or sent to the postal or email address of the relevant party set out in the Agreement Details (or such other address as that party will notify in writing to the other for this purpose).

20.7.2 A notice sent by post will be deemed to be served at 9.00 am on the second Business Day following the date of posting; a notice sent by email transmission will (provided the sender receives no error message indicating that delivery has been unsuccessful) be deemed to have been served at the time it is transmitted if transmitted within business hours (9.00 am to 6.00 pm, London time) on a Business Day or, if transmitted outside such business hours on a Business Day or on a day which is not a Business Day as soon thereafter as such business hours commence.

### 20.8 Entire agreement.

20.8.1 This Agreement constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, terms implied by custom or

course of dealing, warranties, representation and understandings between the parties, whether written or oral, relating to its subject matter.

- 20.8.2 Each party acknowledges that it has not entered into the Agreement in reliance on, and will have no remedies in respect of, any representation or warranty that is not expressly set out in the Agreement except in the case of fraudulent misrepresentation.
- 20.9 **Third parties.** The Agreement is not intended to create any rights for, nor be enforceable by, any third party except as set out in clause 7.
- 20.10 **Governing law and jurisdiction.** The Agreement and any dispute arising out of or in connection with it (including non-contractual disputes and claims) will be governed by and construed in accordance with English law and each of the parties submits to the exclusive jurisdiction of the English Courts.



## ANNEX

### 1 Subject matter and nature of processing

- 1.1 TDL processes Protected Data as data processor on behalf of the Client:
  - 1.1.1 in the case of Testing, when TDL receives a Pathology Request and Sample and processes the corresponding Protected Data to carry out the Test and report the Test results in accordance with the Client's documented instructions; and
  - 1.1.2 in the case of any other Services, when TDL is required to process the Protected Data on the Client's behalf to fulfil the Client's instructions.
- 1.2 The subject matter and nature of TDL's processing of the Protected Data are:
  - 1.2.1 pathology samples and test results for the purpose of providing clinical pathology services;
  - 1.2.2 information about clinicians who order pathology tests, for the purposes of reporting the Test results to the Client.

### 2 Duration of processing

- 2.1 The duration of the processing is the time necessary to carry out the Services.

### 3 Types of personal data

- 3.1 The Protected Data comprise the following types of personal data:
  - 3.1.1 Name
  - 3.1.2 Sex
  - 3.1.3 Date of birth
  - 3.1.4 Home address (including postcode)
  - 3.1.5 Address being used as residence in the UK, if the traveller is not a UK resident
  - 3.1.6 NHS number (if known and applicable)
  - 3.1.7 Date Sample was taken
  - 3.1.8 Identity numbers assigned by TDL or the Client
  - 3.1.9 Types of pathology tests conducted
  - 3.1.10 Results of pathology tests
  - 3.1.11 The types of data referred to in the TDL Laboratory Guide
  - 3.1.12 Sample type
  - 3.1.13 Reporting date
  - 3.1.14 Requesting clinician details
  - 3.1.15 Details of any variant of concern or variant under investigation identified
  - 3.1.16 Raw data from the Test
  - 3.1.17 Information about the Sample and Test
  - 3.1.18 The traveller's medical history

### 4 Categories of data subjects

- 4.1 The Protected Data concerns travellers in respect of whom TDL conducts pathology Testing, and clinicians who request pathology tests.