

## INTERNATIONAL BLOOD GROUP REFERENCE LABORATORY TERMS AND CONDITIONS FOR MOLECULAR DIAGNOSTICS

The Purchaser's attention is particularly drawn to the provisions of clause 9.

### 1 Definitions

1.1 In these Terms and Conditions, the following definitions shall apply:

**"Agreement"** means the agreement between NHSBT and the Purchaser for the provision of the Services, comprising these Terms and Conditions; the Request Form; and the Specification;

**"Bribery Act"** means the Bribery Act 2010 and any subordinate legislation made under that Act from time to time together with any guidance or codes of practice issued by the relevant government department with respect to such legislation;

**"Business Day"** means a day (other than a Saturday, Sunday or public Holiday) when banks in London, UK are open for business;

**"Charges"** means the charges payable by the Purchaser to NHSBT in respect of the provision of the Services, in accordance with clause 4;

**"Commencement Date"** has the meaning set out in clause 2.2;

**"Confidential Information"** means all information, data and material of any nature not in the public domain which either party may receive or obtain in connection with the operation of the Agreement, Personal Data and/or Special Category Data as defined in Data Protection Legislation" and: (i) data which is designated as confidential by either party or that ought reasonably to be considered as confidential

(however it is conveyed or on whatever media it is stored); or (ii) which is a trade secret;

**"CEDR"** means the Centre for Effective Dispute Resolution – a London based mediation and alternative dispute resolution body;

**"Data Controller"** has the meaning given to it in Data Protection Legislation;

**"Data Processor"** has the meaning given to it in Data Protection Legislation;

**"Data Protection Legislation"** means all applicable data protection and privacy legislations and guidance including but not limited to the "General Data Protection Regulation" or "GDPR", the Data Protection Act 2018, and any relevant guidance or codes or legislation transposed into UK law under the European Union (Withdrawal) Act 2018 or any codes of relevant codes of practice issued by the European Data Protection Board or the Information Commissioner from time to time (all as amended, updated or re-enacted from time to time);

**"Disclosing Party"** has the meaning set out in clause 13.1;

**"FOIA"** means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner in relation to such legislation;

**"Force Majeure Event"** shall have the meaning set out in clause 20.1;

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### **"Information Disclosure Requirements"**

means the requirements to disclose information under:

- (a) the FOIA;
- (b) the Environmental Information Regulations 2004; and
- (c) any applicable code of practice;

**"Intellectual Property"** means any and all patents, trademarks, service marks, domain names, registered designs, inventions, Know How, unregistered trademarks and service marks, trade and business names, including rights in any get up or trade dress, and all copyright in any item delivered to the Purchaser pursuant to the Agreement, or used by NHSBT in performance of the Services or otherwise used by NHSBT in connection with the Agreement or the Services as well as all confidential information, experience, drawings, or other technical information and information concerning anything done by NHSBT pursuant to or for the purposes of the Agreement;

**"Intellectual Property Rights"** means the right to exploit any Intellectual Property or any right which is similar or analogous to any Intellectual Property throughout the world; any moral rights; any licence, right or interest of any kind arising out of or granted or created in respect of any Intellectual Property; any right to bring an action for passing off or any similar or analogous proceeding anywhere in the world;

**"Joint Controllers"** means where two or more Data Controllers jointly determine the purposes and meaning of Processing. This could include Processing for the same purpose, using the same personal database (i.e. one database);

**"Know How"** means all Confidential Information which is used or required to be used in or in connection with the Services existing in any form

(including, but not limited to technical and clinical knowhow and that is comprised in or derived from engineering, chemical and other specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and diagrams, brochures, catalogues and other descriptions) and relating to the operation of any process and/or the provision of the Services;

**"Law"** means:

- (i) any applicable statute or proclamation or any delegated or subordinate legislation or Regulation;
- (ii) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;
- (iii) any applicable code of practice; in each case as applicable in England and Wales;
- (iv) any applicable EU Law transposed into UK law under the European Union (Withdrawal) Act 2018;

**"NHSBT"** means NHS Blood and Transplant, a Special Health Authority established under SI 2005 No 2529 of 500 North Bristol Park, Filton, Bristol, BS34 7QH, and which organisation shall supply the Services to the Purchaser pursuant to the Agreement;

**"NHSBT Employees"** means all persons employed or engaged by NHSBT from time to time in connection with the Services;

**"NHSBT Facility"** means the premises from which the Services are performed by NHSBT;

**"Order"** means the Purchaser's order for the Services as set out in the Request Form;

**"Request Form"** means a request form that is completed by the Purchaser in respect of the Purchaser's order for the Services, and to which these Terms and conditions are embedded;

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**"Personal Data"** has the meaning given to it in Data Protection Legislation;

**"Processing"** has the meaning given to it in Data Protection Legislation;

**"Prohibited Act"** means any of the following actions:

- (a) to directly or indirectly offer, promise or give any person working for or engaged by NHSBT a financial or other advantage to:
  - (i) induce that person to perform improperly a relevant function or activity; or
  - (ii) reward that person for improper performance of a relevant function or activity;
- (b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for improper performance of a relevant function or activity in connection with the Agreement;
- (c) commit any offence:
  - (i) under the Bribery Act;
  - (ii) under legislation creating offences concerning fraudulent acts;
  - (iii) at common law concerning fraudulent acts relating to the Agreement or any other contract with NHSBT; or
  - (iv) defrauding, attempting to defraud or conspiring to defraud NHSBT;

**"Purchaser"** means the party who purchases Services from NHSBT pursuant to the Agreement

and whose details are set out in the Request Form;

**"Purchaser Default"** has the meaning set out in clause 3.5;

**"Purchaser Personnel"** means all employees, agents, consultants and contractors of the Purchaser, including any sub-contractors and all personnel of such contractors or sub-contractors;

**"Receiving Party"** has the meaning set out in clause 13.1;

**"Request for Information"** shall have the meaning set out in the FOIA or any apparent request for information under the FOIA, the Environmental Information Regulations 2004 or any applicable code of practice;

**"Sample"** means materials, substances, products or other similar items provided by the Purchaser to NHSBT and which are to be analysed by NHSBT pursuant to the Agreement;

**"Services"** means the testing services to be performed by NHSBT as set out in the Request Form and as further detailed in the Specification;

**"Special Category Data"** has the meaning given to it in Data Protection Legislation;

**"Specification"** means the specification embedded as Schedule 1 of this Agreement; and

**"Terms and Conditions"** means these terms and conditions as may be amended from time to time in accordance with clause 18.1.

## 2 **Basis of Agreement**

- 2.1 The Order constitutes an offer by the Purchaser to purchase the Services in accordance with these Terms and Conditions.

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2.2 The Order shall only be deemed to be accepted when the Purchaser sends the completed and signed Request Form to NHSBT and on which date the Agreement shall come into existence (the "**Commencement Date**").

2.3 Subject to early termination in accordance with these Terms and Condition, the Agreement shall continue until the later of:

- (a) completion of the Services; or
- (b) payment by the Purchaser for all Services performed by NHSBT.

2.4 The Agreement constitutes the entire agreement between the parties. The Purchaser acknowledges that it has not relied on any statement, promise, representation, assurance or warranty made or given by or on behalf of NHSBT (whether written or oral), which is not set out in the Agreement.

2.5 These Terms and Conditions apply to the Agreement to the exclusion of any other terms that the Purchaser seeks to impose or incorporate, or which are implied by trade, custom, practice or course of dealing.

2.6 **Order of Precedence:** If there is any ambiguity or inconsistency in or between the documents comprising the Agreement, the priority of the documents is in accordance with the following sequence:

- (a) these Terms and Conditions;
- (b) the Specification;
- (c) the Request Form; and
- (d) any other document forming part of the Agreement and/or referred to in the Agreement.

## 3 Services

3.1 NHSBT shall perform the Services in accordance with the Specification.

3.2 NHSBT shall perform the Services using reasonable skill and care.

3.3 NHSBT shall use all reasonable endeavours to meet any turnaround times and/or performance dates specified in the Specification, but any such dates shall be estimates only and time shall not be of the essence for the performance of the Services. Accordingly, any failure by NHSBT to meet any such turnaround times and/or performance dates shall not be deemed to be a breach of the Agreement.

3.4 NHSBT shall have the right to make any changes to the Services which are necessary to comply with any applicable Law or safety requirement, or which do not materially affect the nature or quality of the Services, and NHSBT shall notify the Purchaser in any such event.

3.5 If NHSBT's performance of any of its obligations is prevented or delayed by any act or omission by the Purchaser or failure by the Purchaser to perform any relevant obligations as set out in the Agreement (in particular, as set out in these Terms and Conditions and the Specification) including, without limitation, any delay caused or contributed to by the Purchaser, or any defects in any Sample or failure of any Sample to meet the requirements set out in the Specification ("**Purchaser Default**"):

- (a) NHSBT shall, without limiting its other rights or remedies, have the right to suspend performance of the Services until the Purchaser remedies the Purchaser Default, and to rely on the Purchaser Default to relieve it from the performance of any of its obligations to the extent the Purchaser

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- Default prevents or delays NHSBT's performance of any of its obligations;
- (b) NHSBT shall not be liable for any costs or losses sustained or incurred by the Purchaser arising directly or indirectly from NHSBT's failure or delay to perform any of its obligations as set out in this clause 3; and
- (c) the Purchaser shall reimburse NHSBT on written demand for any costs or losses sustained or incurred by NHSBT arising directly or indirectly from the Purchaser Default.
- 3.6 NHSBT shall only provide those Services detailed within the Request Form.
- 4 Charges and Terms of Payment**
- 4.1 The Charges payable for the Services shall be calculated on a cost per unit basis.
- 4.2 NHSBT shall invoice the Purchaser immediately following and in respect of each calendar month in which the Services were provided.
- 4.3 The Purchaser shall pay each invoice submitted by NHSBT within thirty (30) days of the date of the invoice by BACS, cheque or credit card and in Pounds Sterling and in full and cleared funds to a bank account nominated in writing by NHSBT. Time for payment shall be of the essence for the Agreement. NHSBT may at its sole discretion require payment in advance of the Services.
- 4.4 All amounts referred to in the Agreement are expressed net of any form of tax, levy or duty of any kind (including, without limitation, value added tax (VAT)) which may be chargeable and which shall be payable by the Purchaser in addition to the sum in question at the rate for the time being prescribed by Law on delivery by NHSBT to the Purchaser of a valid tax/VAT invoice.
- 4.5 If the Purchaser fails to pay any invoice submitted by NHSBT under the Agreement by the due date for payment, NHSBT shall be entitled (without prejudice to any other right or remedy it may have) to:
- (a) charge interest on any amount outstanding at the rate of three per cent (3%) per annum, above the annual base lending rate of the Bank of England from time to time. Such interest shall accrue on a daily basis from the due date for payment until actual payment of the invoice amount, whether before or after judgment. The Purchaser shall pay the interest with the overdue amount; and/or
- (b) suspend provision of the Services until all outstanding sums are paid in full, and any additional costs incurred by such suspension shall be paid by the Purchaser; and/or
- (c) terminate the Agreement pursuant to clause 11.3.
- 4.6 The Purchaser shall pay all amounts due under the Agreement in full without any set-off, counter-claim, deduction or withholdings.
- 5 Purchaser's Obligations**
- 5.1 The Purchaser shall:
- (a) ensure the terms of the Order (and any information it provides in the Request Form) are/is complete and accurate;
- (b) fulfil all its obligations as set out in the Agreement, including, without limitation:
- (i) providing each Sample to NHSBT in the manner, and to the quality so specified in the Specification and so far as possible within the timescales

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specified in the Specification and the relevant User Guides;

(ii) providing NHSBT with such information and materials as set out in these Terms and Conditions and in the Specification and as NHSBT may otherwise reasonably require in order to perform the Services, and ensure that such information is accurate in all material respects;

(iii) without prejudice to clause 5.2, obtaining and maintaining all necessary licences, permissions, approvals and consents as set out in these Terms and Conditions and/or the Specification and as NHSBT may otherwise require before the date on which the Services are to be performed; and

(c) co-operate with NHSBT in all matters relating to the Services.

5.2 Where consent is required for an investigation or to comply with the Human Tissue Act 2004 or other Law, it is the responsibility of the Purchaser to ensure that any person from whom Samples have been provided to NHSBT (including any patient or donor) has been informed of, and has consented in writing to, the tests being requested. The Purchaser shall provide a copy of this information to NHSBT on request. If one or more tests are declined the Purchaser must properly record the refusal of consent, including specifying which tests are declined, on the accompanying test request form. NHSBT shall not be required to perform any test on any Sample to which an individual has refused consent. The Purchaser shall ensure that any person providing any Sample is informed that Samples may be stored by NHSBT as part of required archiving protocols or to enable further investigation for the benefit of

the individual and that each person provides explicit consent in writing to such storage.

5.3 The Purchaser shall be responsible for arranging the packaging and transportation of Samples to NHSBT, and accordingly shall:

(a) comply with all relevant Law and comply with any laws, regulations and/or other governmental policy or guidance in any relevant jurisdiction, and

(b) have all relevant licences, permissions, approvals and consents required and necessary to transport the Samples to the NHSBT.

5.4 The Purchaser shall remain responsible at all times for any and all risk relating to Sample condition, maintenance during transport, compliance with guidance or law in any relevant jurisdiction and requirements under these Terms and Conditions.

5.5 The Purchaser shall be responsible for all costs related to the packaging and transport of the Samples to NHSBT.

## **6 Audits and Visits**

6.1 The Purchaser will have the right to audit and inspect any NHSBT Facility during normal business hours by giving NHSBT at least fourteen (14) days prior written notice on the condition that the Purchaser:

(a) does not unnecessarily or unreasonably interfere with or cause any delay to the Services or any other services or projects;

(b) is liable for all acts and omissions of all Purchaser Personnel whilst they are at any NHSBT Facility;

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- (c) has appropriate insurance in place to cover the risks created by the Purchaser in the carrying out of the audit; and
- (d) shall ensure and procure that all Purchaser Personnel whilst they are at any NHSBT Facility will comply with NHSBT's policies and procedures.

6.2 NHSBT will have the right to audit and inspect any premises of the Purchaser that is used for the provision of the Services during normal business hours by giving the Purchaser at least fourteen (14) days prior written notice.

### **7 Samples**

7.1 Subject to clause 7.2 NHSBT will return all Samples and written information provided by the Purchaser to NHSBT pursuant to the Agreement to the Purchaser (at the Purchaser's cost) or destroy such Samples and written information upon expiry or termination of the Agreement or on receipt of reasonable written notice.

7.2 The Purchaser confirms and agrees that NHSBT may retain sufficient quantities of the Samples supplied by the Purchaser, and copies of associated written information for quality testing purposes and archive Samples for regulatory compliance requirements.

### **8 Warranties and Representations**

8.1 The Purchaser warrants, represents and undertakes to NHSBT that:

- (a) it has obtained all necessary approvals, consents, licences and permissions relating to the Agreement;
- (b) it will comply with all relevant Law and comply with any laws, regulations and/or other governmental policy or guidance in any relevant jurisdiction;

(c) it has all necessary corporate standing and authorisation to enter into and be bound by the terms of the Agreement;

(d) prior to providing any Sample or any related information to NHSBT it will undertake a full risk and safety assessment (compliant with all appropriate regulatory and health and safety legislation in England and Wales and any other relevant jurisdiction) of such Sample and related information and, where appropriate, it will obtain all necessary clearances, licences and consents in relation to the use of each Sample by NHSBT in accordance with the Agreement, including such consents as may be required pursuant to the Data Protection Legislation for the Services to be performed. The Purchaser will provide NHSBT with copies of such clearances, licences and consents as is reasonably requested by NHSBT;

(e) it has provided, or will at the appropriate time provide, to NHSBT in writing all relevant health and safety information required for the correct storage, handling and use of any Sample provided to NHSBT by the Purchaser, including without limitation, all information regarding known or potential hazards which may arise from such storage, handling and use of the Samples;

(f) that it shall use all reasonable efforts to ensure that any Samples supplied to NHSBT pursuant to the Agreement will not cause any loss of or damage to the property of NHSBT nor to NHSBT Employees, agents, contractors or sub-contractors, save to the extent that such loss or damage is caused by the negligent act of NHSBT or due to a failure by NHSBT to comply with any written information provided to NHSBT by the Purchaser pursuant to clause 8.1(e);

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- (g) if any Purchaser Personnel has cause to visit any NHSBT Facility, the Purchaser shall ensure such Purchaser Personnel comply with any policies and procedures that may from time to time operate at any such NHSBT Facility; and
- (h) it shall only use the results of the Services as shall be permitted by any relevant Law or law and guidance relating to the use of test results, issued by any governmental authority or agency in any relevant jurisdiction.

### **9 Limitation of Liability: The Purchaser's attention is particularly drawn to this clause**

9.1 Nothing in the Agreement shall in any way exclude or limit either Party's liability for:

- (a) death or personal injury caused by its negligence, or the negligence of its employees, agents and subcontractors; or
- (b) fraud or fraudulent misrepresentation.

9.2 Subject to clause 9.1:

- (a) NHSBT shall under no circumstances whatever be liable to the Purchaser, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss of profit, revenue, goodwill, business opportunity or loss of or cost of restoration of data or any other indirect or consequential loss or damage arising under or in connection with the Agreement, and/or arising under or in connection with the Purchaser's use of the results of the Services, including, without limitation, any clinical decisions made by the Purchaser and/or care pathways designed by the Purchaser using the results of the Services; and

- (b) NHSBT's total liability to the Purchaser in respect of all other losses arising under or in connection with the Agreement and/or arising under or in connection with the Purchaser's use of the result of the Services, whether in contract, tort (including negligence), breach of statutory duty or otherwise shall in no circumstances exceed the Charges paid in respect of the Services.

9.3 The Purchaser shall at all times indemnify and keep NHSBT indemnified from and against all costs, losses, claims, demands, liabilities, expenses (including legal expenses), judgments, awards, orders, proceedings and findings of any nature sustained or incurred by or made against NHSBT, NHSBT Employees or NHSBT agents to the extent caused by or contributed to by (whether directly or indirectly) the Purchaser's failure to comply with the Agreement or any other act or omission of the Purchaser including, without limitation, any costs and losses sustained or incurred by NHSBT pursuant to clause 3.5.

9.4 Except as otherwise set out in these Terms and Conditions, all conditions, warranties, terms and undertaking express or implied, whether by statute, common law, trade practice, custom, course of dealing or otherwise (including without limitation, as to quality, performance or fitness or suitability for purpose) in respect of the provision of the Services and the results of the Services are, to the fullest extent possible by Law, excluded from the Agreement.

9.5 This clause 9 shall survive termination of the Agreement.

### **10 Intellectual Property**

10.1 All Intellectual Property Rights in or arising out of or in connection with the Services shall be owned by the Purchaser.



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10.2 In relation to Intellectual Property, nothing in the Agreement will result in the Purchaser acquiring any Intellectual Property Rights in the Services or the methods or Know How or other information used by NHSBT in providing the same or owned by NHSBT before or during the term of the Agreement.

10.3 The Purchaser shall not without NHSBT's prior written consent publish or disclose any information relating to the Services supplied by NHSBT to the Purchaser if to do so would result in disclosure of any Intellectual Property Rights belonging to or used by NHSBT or any NHSBT Confidential Information.

### **11 Termination**

11.1 Without limiting its other rights and remedies, NHSBT may terminate the Agreement by giving the Purchaser six (6) months' written notice.

11.2 Without limiting its other rights and remedies, either party may terminate the Agreement with immediate effect by giving written notice to the other party if:

(a) the other party commits a material breach of any term of the Agreement and (if such breach is remediable) fails to remedy that breach within thirty (30) days of that party being notified in writing to do so; or

(b) the other party enters into liquidation, receivership or administrative receivership or otherwise becomes insolvent or ceases to trade or do business.

11.3 Without limiting its other rights and remedies, NHSBT may terminate the Agreement with immediate effect by giving written notice to the Purchaser if the Purchaser fails to pay any amount due under the Agreement on the due date for payment and fails to pay all outstanding

amounts within fifteen (15) days of being notified in writing to do so.

### **12 Consequences of Termination**

12.1 On expiry or termination of the Agreement for any reason:

(a) the Purchaser shall immediately pay to NHSBT all of NHSBT's outstanding unpaid invoices and interest and, in respect of Services provided but for which no invoice has been submitted, NHSBT shall submit an invoice, which shall be payable by the Purchaser immediately upon receipt;

(b) all rights and licences granted by either party to the other shall automatically cease and the parties shall cease all and any use of the other's Intellectual Property Rights and any Confidential Information;

(c) clauses which expressly or by implication survive termination or expiry shall continue in full force and effect; and

(d) the accrued rights, remedies, obligations and liabilities of the parties as at expiry or termination shall be unaffected, including the right to claim damages in respect of breach of the Agreement which existed at or before the date of expiry or termination.

### **13 Confidentiality**

13.1 The party receiving Confidential Information ("**Receiving Party**") will treat it as secret and confidential and will not use it for its own benefit or for the benefit of any other party or for any purpose other than those required or permitted by the Agreement. The Receiving Party will not disclose any part of the Confidential Information to any third party without the express prior written consent of the party making the Confidential Information available ("**Disclosing Party**"), other

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than to such of the Receiving Party's employees or consultants who reasonably require such disclosure and who are bound by similar confidentiality provisions.

13.2 The provisions contained in clause 13.1 shall not apply:

- (a) to any information, which is in or enters the public domain other than as a result of a breach of the Agreement or where the Receiving Party receives the information from a third party which is not under any obligation of confidence to the Disclosing Party; or
- (b) where the information has been developed by the Receiving Party independently of the disclosure; or
- (c) to any information, which is required to be disclosed by Law, its transparency obligations, governmental policy (as may apply from time to time to public bodies), any governmental or regulatory authority or by a court of competent jurisdiction; or
- (d) to information already known by the Receiving Party prior to the Commencement Date, the prior knowledge of which the Receiving Party can evidence by written records.

13.3 Each party shall apply to the Confidential Information of the other party no less security measures and degree of care as it applies to its own Confidential Information, but in no event less than a reasonable degree of care.

13.4 Upon termination of the Agreement or upon the Disclosing Party's written request, the Receiving Party will return all the Confidential Information supplied to the Receiving Party by the Disclosing Party within twenty-eight (28) days of such request. Each party may retain copies of

Confidential Information to the extent specified in the Specification or to the extent that it is required to hold such information to ensure legal compliance with its obligations under the Agreement, including regulatory compliance.

13.5 This clause 13 survives termination of the Agreement.

## **14 Freedom of Information and other disclosure requirements**

14.1 The Purchaser acknowledges that NHSBT is subject to the Information Disclosure Requirements and shall assist and cooperate with NHSBT to enable NHSBT to comply with those requirements.

14.2 Where the Purchaser or any Purchaser Personnel receives a Request for Information which relates to NHSBT or the Agreement or the Services, the Purchaser shall:

- (a) as soon as reasonably practicable after receipt and in any event within five (5) days of receipt, forward the Request for Information to NHSBT; and
- (b) provide all necessary assistance as reasonably requested by NHSBT to enable NHSBT to respond to a Request for Information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the Environmental Information Regulations 2004, as applicable.

14.3 Subject to the notification and consultation provisions of clauses 14.2 to 14.4, NHSBT shall be responsible for determining at its absolute discretion whether other information contained in a Request for Information:

- (a) is exempt from disclosure in accordance with the provisions of:

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- (i) the FOIA; or
  - (ii) the Environmental Information Regulations 2004; or
  - (iii) any applicable code of practice; or
- (b) is to be disclosed in response to a Request for Information and in no event shall the Purchaser respond directly to a Request for Information which relates to NHSBT or the Agreement or the Services unless expressly authorised to do so by NHSBT in writing.
- 14.4 If the Purchaser is subject to the Information Disclosure Requirements, then should the Purchaser receive a Request for Information that relates to NHSBT and/or the Agreement and/or the Services the parties shall jointly agree a response to such Request for Information complying at all times with all relevant statutory time limits.
- 14.5 The Purchaser acknowledges that NHSBT may nevertheless, acting in accordance with the Information Disclosure Requirements, be obliged to disclose information following consultation with the Purchaser.
- 14.6 The Purchaser shall ensure that all information produced in the course of the Agreement or relating to the Agreement is retained for disclosure and shall permit NHSBT to inspect such records as requested from time to time.
- 14.7 Where the Purchaser or any Purchaser Personnel receives a request for information under any laws, regulations and/or guidance in any relevant jurisdiction, which relates to NHSBT, the Agreement, or the Services, the Purchaser shall:
- (a) as soon as reasonably practicable after receipt and in any event within five (5) days of receipt, forward the request for information to the NHSBT;
  - (b) provide all necessary assistance as reasonably requested by NHSBT to enable NHSBT to:
    - (i) respond to the request for information within the time for compliance; or
    - (ii) do a joint response to the request for information with the Purchaser PROVIDED NHSBT shall determine at its absolute discretion what information is to be disclosed in respect of the request for information; and
  - (c) under no circumstance respond directly to the request for information which relates to NHSBT and/or the Agreement and/or the Services unless specifically authorised to do so by NHSBT.
- 15 Publicity**
- 15.1 Except with the written consent of the other party, neither party shall make any press announcements or publicise the Agreement in any way.
- 15.2 Subject to any consent provided pursuant to clause 15.1, the Purchaser shall not advertise, publish or use NHSBT's name in any way, including without limitation use of NHSBT's name in the Purchaser's own marketing and promotional material.
- 16 Health and Safety**
- 16.1 Both parties shall comply, and will ensure that its employees will comply, with the requirements of relevant Health and Safety at Work Act etc. 1974 and all regulations and codes of practice issued thereunder, as well as all other laws governing health and safety in any relevant jurisdiction whilst performing their obligations hereunder.
- 16.2 The Purchaser shall ensure that all Samples are packaged and transported to NHSBT in

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accordance with all relevant health and safety requirements and regulations including but not limited to use of approved transport containers and to comply with all relevant carriage of dangerous goods legislation and regulations to prevent breakage or spillage in transit or usage in order to avoid any and all risk of injury or damage to any individual or property.

### **17 Data Protection**

- 17.1 Both Parties will comply with all the legal requirements of the Data Protection Legislation. This clause is in addition to, and does not relieve, remove or replace, a Party's obligations under the Data Protection Legislation.
- 17.2 The Parties acknowledge that for the Purposes of the Data Protection Legislation, the Purchaser is the Data Controller and NHSBT is the Data Processor.
- 17.3 There may be some occasions where the Purchaser undertakes the role of Data Processor for NHSBT as Data Controller. In such cases the Purchaser will use reasonable endeavours to ensure that personal information will only be processed in accordance with the specific instruction of NHSBT (as Data Controller for such information) and to ensure that the established policies and procedures for security of data will be applied.
- 17.4 Without prejudice to the generality of this clause, the Data Controller will ensure that it has all the necessary appropriate consents and notices in place to enable lawful transfer of the Personal Data and/or Special Category Data Processor for the duration and Purposes of the Agreement.
- 17.5 Without prejudice to the generality of this clause, the Data Processor shall, in relation to any Personal Data and/or Special Category Data processed in connection with the performance by

the Data Processor of its obligations under the Agreement:

- 17.5.1. Process that Personal Data and/or Special Category Data only on the written instructions of the Data Controller unless the Data Processor is required by applicable laws to otherwise process that Personal Data and/or Special Category Data. Where the Data Processor is relying on laws as a member of the European Union or European Union Law as the basis for processing Personal Data and/or Special Category Data, the Data Processor shall promptly notify the Data controller of this before performing the processing required but the applicable laws unless those applicable laws prohibit the Data Processor from so notifying the Data controller;
- 17.5.2. Ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the Data Controller, to protect against unauthorised or unlawful processing of Personal Data and/or Special Category Data, and against accidental loss of destruction of, or damage to, Personal Data and/or Special Category Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising and encrypting Personal Data and/or Special Category Data, ensuring confidentiality, integrity, availability and resilience of its systems and services), ensuring the availability of access to Personal Data and/or Special Category Data can be restored in a timely

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- manner after an incident, and regularly assessing and evaluating the effectiveness of technical and organisational measures adopted by it;
- 17.5.3. Ensure that all personal who have access to and/or process Personal Data and/or Special Category Data are obliged to keep the personal Data and/or Special Category Data confidential; and
- 17.5.4. Not transfer any Personal Data and/or Special Category Data outside the European Economic Area unless the prior written consent of the Data Controller has been obtained and the following conditions are fulfilled:
- I. The Data Controller or Data Processor has provided appropriate safeguards in relation to the transfer;
  - II. The Data Subject (as defined in the Data Protection Legislation) has enforceable rights and effective legal remedy;
  - III. The Data Processor complies with reasonable instructions notified to it in advance by the Data controller with respect to the processing of the Personal Data and/or Special Category Data.
- 17.5.5. Assist the Data Controller at the Data Controllers cost in responding to any request from a Data Subject, as such term is defined in the Data Protection Legislation, and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
- 17.5.6. Notify the Data Controller without undue delay, and in any event no later than twenty-four (24) hours on becoming aware of Personal Data Breach, as such term is defined in the Data Protection Legislation;
- 17.5.7. At the written direction of the Data Controller, delete or return Personal Data and/or Special Category Data and copies thereof to the Data Controller on termination of the Agreement unless required by applicable law to store the Personal Data and/or Special Category Data/ and
- 17.5.8. Maintain complete and accurate records and information to demonstrate its compliance with this clause.
- 17.6. Unless approved in writing by the Data Controller, the Data Controller does not consent to the Data Processor appointing any third-party processor of Personal Data and/or Special Category Data under the Agreement.
- 17.7. The Data Processor shall allow for audits of its data processing activity by the Data Controller's designated auditor.
- 17.8. Either Party may, at any time, on less than thirty (30) days' notice, revise this Clause 17 by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an appropriate certification scheme (which shall apply when replaced by attachment to the Agreement).
- 18 Variation**
- 18.1 No variation of the Agreement, including the introduction of any additional terms and conditions, will be effective unless it is agreed in writing and signed by both parties.

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### 19 Assignment

19.1 Neither party may assign or otherwise transfer all or any part of its duties or obligations under the Agreement to any other third party without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except in the case of a statutory reorganisation of all or part of NHSBT.

### 20 Force Majeure

20.1 Neither Party shall be liable to the other for its inability or delay in performing any of its obligations hereunder if and to the extent that such inability or delay is caused by or arises as a result of circumstances beyond the reasonable control of the relevant Party and which results in or causes the failure of that Party to perform its obligations hereunder (with the exception of any obligation to make payment to NHSBT for the Services), including but not limited to: war, fire, flood, pandemic, riot, act of God, lightning, explosion, storm, terrorism or act of Government or other regulatory authority, industrial action or default of suppliers or sub-contractors ("**Force Majeure Event**").

20.2 The Party affected by a Force Majeure Event will as soon as it is reasonably practicable give full particulars in writing to the other Party, and shall take all reasonable steps to mitigate the effect of such Force Majeure Event.

20.3 If a Force Majeure Event persists for a period of one hundred and twenty (120) days, then either party shall have the right to terminate the Agreement upon written notice to the other.

### 21 Notices

21.1 Any notice to be given under the Agreement will be delivered personally or sent by email or sent by first class recorded delivery post (airmail if overseas). The address for service of each party

is the address set out in the Request Form or such other address as either party may previously have notified to the other party in writing. A notice will be deemed to have been served:

- (a) if personally delivered, at the time of delivery;
- (b) if sent by email, at the time of sending; and
- (c) if posted, at the expiration of forty-eight (48) hours or (in the case of airmail seven (7) days) after the envelope containing the same was delivered into the custody of the postal authorities.

21.2 In proving such service it will be sufficient to prove that personal delivery was made, or that the envelope containing such notice was properly addressed and delivered into the custody of the postal authority as prepaid first class, recorded delivery or airmail letter (as appropriate) or that the email was received with an acknowledgement of receipt, as the case may be.

### 22 Dispute Resolution

22.1 In the event of any dispute or difference between the parties arising in connection with the Agreement, the parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) days of being requested in writing by the other party to do so.

22.2 If the parties are unable to settle a dispute arising out of or in connection with the Agreement in the manner set out in clause 22.1 above within seven (7) days of one party requesting resolution, the dispute shall be referred to the parties' Chief Executive Officers (or equivalent) or their nominated deputies.

22.3 If the Chief Executives (or equivalent) or nominated deputies, are unable to resolve the dispute within seven (7) days of the dispute being

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referred to them the dispute will be referred to an independent third party for resolution. In the event that the Parties cannot mutually agree on the identity of an independent third party, the parties will seek resolution by requesting the CEDR to appoint an independent third party. The decision of the independent third party (including as to costs) shall be final and binding on both parties.

22.4 Except as otherwise specified by the independent third party, the parties shall each bear their own costs and expenses in relation of settlement of any disputes and shall share equally the costs of the independent third party.

### **23 Prevention of Bribery**

23.1 The Purchaser:

- (a) shall not, and shall procure that any Purchaser Personnel shall not, in connection with these Terms and Conditions commit a Prohibited Act;
- (b) warrants, represents and undertakes that it is not aware of any financial or other advantage being given to any person working for or engaged by NHSBT, or that an agreement has been reached to that effect, in connection with the entry into the Agreement, excluding any arrangement for which full details have been disclosed in writing to NHSBT before entry into the Agreement.

23.2 The Purchaser shall:

- (a) if requested, provide NHSBT with any reasonable assistance, at NHSBT's reasonable cost, to enable NHSBT to perform any activity required by any relevant government or agency in any relevant jurisdiction for the purpose of compliance with the Bribery Act;

- (b) within ten (10) days of receiving a request from NHSBT, certify to NHSBT in writing (such certification to be signed by an officer of the Purchaser) compliance with this clause 23 by the Purchaser and all persons associated with it or other persons who are purchasing goods or services in connection with the Agreement. The Purchaser shall provide such supporting evidence of compliance as NHSBT may reasonably request.

23.3 If any breach of clause 23.1 is suspected or known, the Purchaser must notify NHSBT immediately.

23.4 If the Purchaser notifies NHSBT that it suspects or knows that there may be or has been a breach of clause 23.1, the Purchaser must respond promptly to NHSBT's enquiries, co-operate with any investigation, and allow NHSBT to audit books, records and any other relevant documentation.

23.5 NHSBT may terminate the Agreement by written notice with immediate effect if the Purchaser or Purchaser Personnel (in all cases whether or not acting with the Purchaser's knowledge) breaches clause 23.1.

23.6 Notwithstanding clause 22 (Dispute Resolution), any dispute relating to:

- (a) the interpretation of this clause 23; or
- (b) the amount or value of any gift, consideration or commission,

shall be determined by NHSBT and its decision shall be final and conclusive.

23.7 Any termination under clause 23.5 will be without prejudice to any right or remedy which has already accrued or subsequently accrues to NHSBT.

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### 24 Law and Jurisdiction

- 24.1 The Agreement and any disputes or claims arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
- 24.2 Each party irrevocably agrees, for the sole benefit of NHSBT that, subject as provided below, the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with the Agreement or its subject matter or formation (including non-contractual disputes or claims).
- 24.3 Nothing in this clause 24 shall limit the right of NHSBT to take proceedings against the Purchaser in any other courts of competent jurisdiction, nor shall the taking of proceedings in any one or more jurisdictions preclude the taking of proceedings in any other jurisdictions, whether concurrently or not, to the extent permitted by the law of such jurisdiction.

### 25 General

- 25.1 **Severance:** If and in so far as any part or provision of the Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed not to be or never to have been or formed a part of, the Agreement and the remaining provisions of the Agreement shall continue in full force and effect.
- 25.2 **No partnership or agency:** Nothing in the Agreement and no action taken by the parties pursuant to the Agreement shall constitute, or be deemed to constitute between the parties a partnership, association, joint venture or other co-operative entity nor constitute either party the agent of the other for any purpose.
- 25.3 **Waiver:** The failure of either party to exercise or enforce any right conferred on that party by the Agreement shall not be deemed to be a waiver of any such right or operate to bar the exercise or enforcement thereof at any time or times thereafter.
- 25.4 **Third parties:** A person who is not party to the Agreement shall have no rights pursuant to the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Agreement.



## **SCHEDULE 1 – SPECIFICATION**

### **International Blood Group Reference Laboratory (IBGRL) Molecular Diagnostics**

NHSBT International Blood Group Reference Laboratory (IBGRL) Molecular Diagnostics is part of NHSBT and provides specialist diagnostic services for NHS hospitals, and other health service and commercial customers (“Molecular Diagnostics”).

The IBGRL Molecular Diagnostics department is a UKAS accredited medical laboratory (No 9765) Details of accredited tests are available at <https://ibgri.blood.co.uk/services/licensing-and-accreditation/> and all work is carried out within the framework of a documented quality system. The department participates in external quality assurance exercises for blood group genotyping. All information provided to NHSBT about patients and donors is held in compliance with the Data Protection and Freedom of Information Acts.

<https://www.nhsbt.nhs.uk/privacy/>

The department undertakes:

1. Blood group specific genetic investigations to identify women with antigen-positive fetuses who are at risk of haemolytic disease of the fetus and newborn (HDFN).
2. A fetal sex typing service for pregnancies affected by X-linked genetic conditions or when early treatment of the fetus differs according to fetal gender.
3. Blood group genotyping to predict the most clinically important blood groups of patients who have been multi-transfused or where serological phenotyping is not possible, and patients with haemoglobinopathies.

The User guides, INF1135 with further details on service provision and sample requirements are available on the IBGRL website: <http://ibgri.blood.co.uk/>

#### **1 SERVICE AVAILABILITY**

1.1 The IBGRL Molecular Diagnostics laboratory is open:

- Monday to Friday 09:00-17:00 (all services),
- Closed on Saturday, Sunday and Christmas Day, Boxing Day, New Year's Day and Public Holidays.

Answer phone and email services are in place to take requests outside normal working hours. We will endeavour to respond to the request on the next business day.

#### **2. SERVICE USER RESPONSIBILITIES**

The Purchaser is responsible for ensuring that samples referred to IBGRL for testing meet the following specifications:

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- 2.1. **Consent:** All genetic testing requires informed consent. It is the responsibility of the test requester to ensure that appropriate patient consent has been obtained. The laboratory assumes that, on receipt of a clinical sample and a completed referral form, consent has been obtained.
- 2.2. Where appropriate, extracted DNA is stored for possible future (consented) testing and for quality assurance purposes. This includes DNA from patients where no genetic test is currently available or required
- 2.3. **Provision of correct request form:** The Purchaser is responsible for providing suitable samples (including minimum sample volume) as specified on the IBGRL request forms and in the User Guide INF1135. Request forms are available for printing. The current version of the request form must be used.
- 2.4. **Provision of correct sample and volume:** See the User Guide for referring samples to IBGRL Molecular Diagnostics (INF1135)

### 3 SAMPLE QUALITY

- 3.1 The requester is responsible for providing a sample of suitable quality for testing as the quality of test results will be compromised if samples are not of an adequate standard.
- 3.2 Samples in the following sub-standard conditions will not be accepted. The report will state why the sample was not and will incur a charge:
  - 3.2.1 Samples taken at gestational ages less than stated in the User Guide INF1135
  - 3.2.2 Haemolysed samples (for fetal genotyping from maternal plasma)
  - 3.2.3 Leaking, broken or samples contaminated by leaking samples
  - 3.2.4 Inadequate blood volume (see User Guide INF1135 for sample volumes)
  - 3.2.5 Sample sent in incorrect type of tube (see User Guide INF1135)
  - 3.2.6 Inadequate labelling of sample tube / or referral form
  - 3.2.7 Maternal blood samples (from women with anti-D, -C, -c or -E) must not be older than 3 days from date of venepuncture for fetal RhD/C/c and E genotyping on arrival at NHSBT
  - 3.2.8 Maternal blood samples must not be older than 2 days from date of venepuncture for fetal Kell genotyping on arrival at NHSBT
  - 3.2.9 Maternal blood samples for fetal sex typing must not be older than 7 days from date of venepuncture on arrival at NHSBT
  - 3.2.10 Samples sent too early in gestation unless it has been pre-agreed with IBGRL (see User Guide INF1135)
  - 3.2.11 Samples suspected of being used for any testing prior to being sent to NHSBT
  - 3.2.12 Samples with addressograph labels as detailed in clause 3.7 of this schedule.
  - 3.2.13 Hand written alterations on either the sample or request form – see 3.7 of this schedule

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3.2.14 Samples of amniotic fluid or CVS DNA which have been in transit more than seven days.

3.3 Sample labelling and request form completion.

3.3.1 Information regarding sample labelling requirements and request forms is also detailed within the IBGRL User Guide found at <http://ibgri.blood.co.uk/>. In the event the requester fails to adhere to the labelling and sample requirements, NHSBT reserves the right to charge the Purchaser a fee as detailed within clause 3.2. These charges apply for samples where:

3.3.1.1 A sample has been rejected on receipt

3.3.1.2 A concession for testing has been requested by the Purchaser following the rejection on receipt, or IBGRL has accepted the sample for testing under concession.

3.3.1.3 A sample has been tested on a concession, requested by the Purchaser, but subsequently rejected by IBGRL during the testing process

3.4 When the Purchaser requires Services, they will provide a request form to NHSBT for each sample to be analysed. Samples must be accompanied by the appropriate signed and completed request form (FRM4674, FRM4738, FRM4739) as outlined in the department User Guide INF1135. Each request form has a guide for completion of the form (INF1341, INF1342, INF1343) available at <http://ibgri.blood.co.uk/>. Request forms are the basis of the correct identification of the patient. The points of identification provided on the request form must match the information provided on the sample. IBGRL will not accept referrals with an inadequate request form or sample labelling. Samples must be labelled with 3 or more identical points of identification, one of which is the NHS/CHI/HCS/Hospital number if available.

Minimum patient identification: (Surname and first name are one identifier)

- Surname
- Forename or forenames in full
- Date of birth
- NHS number, hospital number or unique identification number (the same number must be on both the tube and the form)
- Date of venepuncture
- Estimated delivery date (by scan) or gestational age (for the appropriate test requests)
- Samples MUST be labelled, dated and signed by the person taking the sample.

3.5 The form must also identify the requester including contact details, the reason for the test and relevant diagnosis. The reverse of the request form and / or user guide explains sample labelling requirements, sample volumes and request form completion. This information can be found at <http://ibgri.blood.co.uk/>.

3.6 Labels pre-printed prior to phlebotomy e.g. Addressograph labels are not acceptable on samples. They are, however, acceptable on request forms providing they do not obscure other vital details. Samples must have

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handwritten labels unless demand printed labels are produced at the time of phlebotomy. NHSBT must be informed in writing if demand printed labels are in use.

3.6.1 Handwritten alterations on either the sample or request form may make the sample invalid for testing.

3.6.1.1 Any minor alterations must be initialled by the person taking the sample to be acceptable for testing.

3.6.1.2 The request form must be completed with clinical information as requested and the expected date of delivery where applicable.

3.7 Packaging of samples.

3.7.1 It is the responsibility of the sender to ensure that all samples are packaged in accordance with the Carriage and Packaging of Dangerous Goods Health and Safety DAT2132

<https://nhsbtbe.blob.core.windows.net/umbraco-assets-corp/14357/dat2132-carriage-packaging-of-dangerous-goods-health-and-safety.pdf>

to prevent breakage or spillage in transit. The outside of the box or package containing the samples must be clearly addressed to the appropriate department.

## 4. TRANSPORT OF SAMPLES

4.1 The sender/referring unit is responsible for arranging transport of samples to IBGRL. Samples should be sent by courier or first class post direct to IBGRL.

4.2 The outer container must be addressed to:

Molecular Diagnostics  
International Blood Group Reference Laboratory  
NHS Blood and Transplant  
500 North Bristol Park  
Northway  
Filton  
BS34 7QH

4.3 Sample box labels are available on the IBGRL website. The outer container should state:

4.3.1 The date sent

4.3.2 The sender's address

4.3.3 Sample box labels are available on the IBGRL website <https://ibgri.blood.co.uk/> Please ensure the correct address labels are used.

4.4 The container must be stored and transported at room temperature

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- 4.5 Samples must reach the laboratory in Filton in time to be processed during laboratory working hours (Monday to Friday 09:00 to 17:00) within set time limits after venepuncture. Sample reception is open at all times, but samples must arrive so that they can be opened and processed within the time limits below:
- 4.5.1 Maternal blood referrals for fetal RhD, RhC, Rhc and RhE status: must be processed within 3 days of venepuncture
  - 4.5.2 Maternal blood referrals for fetal K status: must be processed within 2 days of venepuncture
  - 4.5.3 Maternal blood referrals for fetal sex: must be processed within 7 days of venepuncture
  - 4.5.4 Referrals of amniotic fluid must be processed within 7 days of sampling and CVS DNA within 7 days of transportation.
  - 4.5.5 Blood group genotyping: blood samples should be received within 14 days of sampling but may be tested up to 3 months post-venepuncture depending on sample condition.
- 4.6 Samples not of an adequate standard or quality, and incorrectly identified samples will not be tested and will incur a charge. Please refer to section 2 of this schedule for full information.
- 4.7 Urgent samples should be sent directly to IBGRL via courier or 1st class Post.

## **5 IBGRL RESPONSIBILITIES**

- 5.1 Testing in accordance with current guidelines and standards: Samples will be tested in accordance with current published guidelines and standards as given in the IBGRL user guides and documented in the departmental quality manual.
- 5.2 The implementation of appropriate Quality Systems as described in the IBGRL user guide:
- 5.2.1 IBGRL will maintain appropriate laboratory accreditation and will participate in relevant external quality assurance schemes
  - 5.2.2 IBGRL will provide a schedule of accreditation and a quality declaration (INF1438) to enable other laboratories evidence compliance to ISO 15189 on the IBGRL website <https://ibgri.blood.co.uk/>
- 5.3 Customer complaints and suggestions.
- 5.3.1 IBGRL Molecular Diagnostics is committed to continuously improving the quality and range of services provided and welcomes any comments or suggestions from users. Please contact your NHSBT Customer Services representative, or the Laboratory Manager or Head of Department regarding complaints and suggestions. Complaints are managed via our Quality Management system or Customer Services as appropriate. We always strive to provide a satisfactory response to any complaint. In the unlikely event that your complaint is not resolved to your satisfaction please refer to the NHSBT complaints procedure which is available upon request and described in the user guide.
- 5.4 IBGRL reporting and test turnaround times.

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- 5.4.1 The turnaround time for samples is based on those stages of the process which the department can control and measure, i.e. from the date of receipt of sample at IBGRL Molecular Diagnostics to the date of authorisation of the report.
  - 5.4.2 All written reports of investigations referred to IBGRL will be sent to the requester (originator) by Royal Mail post. A single report will be posted to the address of the requester, or other nominated address as specified on the referral form. The responsibility for acting on the results of such investigations rests with the requester (originator)
  - 5.4.3 Urgent reports can be sent by email on request. The Purchaser must provide secure email details. In addition, it is also the responsibility of the Purchaser to ensure details provided for the return of this information are accurate. IBGRL is not responsible for failure of this information to be transmitted if the information is not accurate, legible, or relevant at the time of being actioned.
  - 5.4.4 The requester will be notified by email or telephone if a significant delay in reporting the test result is anticipated.
- 5.5 Turnaround times will depend on the complexity of the test required. IBGRL normally issues 85% of reports within the following times:
- 5.5.1 Fetal genotyping tests within 7 business days
  - 5.5.2 Fetal sex typing within 5 business days
  - 5.5.3 Genotyping of amniotic fluid and chorionic villus samples within 10 business days
  - 5.5.4 Standard and extended patient genotyping (excluding haemoglobinopathy array) within 10 business days
  - 5.5.5 Extended haemoglobinopathy array genotyping within 12 weeks of referral
  - 5.5.6 Standard patient genotyping requests can be performed within 48 hours (Monday to Friday during normal working hours) of arrival at IBGRL, if required, for an added premium, provided that the sample is received by mid-day Monday to Friday before testing is required.
  - 5.5.7 Turnaround times for standard and extended patient genotyping may be longer if samples need to be referred for specialist reference investigations.

## **6 LIMITATIONS OF TESTING**

- 6.1 Full details of the limitations of testing are contained in the IBGRL User Guide.
- 6.2 Blood group genotyping: The molecular biology of blood groups, and particularly of the Rh system, is complex and genetic differences may be found in ethnic groups. It remains a possibility that on very rare occasions genotyping results may not correspond to serological phenotype. Clinical decisions should not therefore rest solely on genotyping results. People who have received a transplant following which incomplete engraftment has taken place may exhibit chimerism in their blood cell populations and therefore in their DNA; this may give incorrect genotyping results or prevent a conclusive result being issued. Clinical history of transplantation should be recorded on the request form.

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- 6.3 Non-Invasive Fetal Genotyping: Please note that we cannot confirm the presence of fetal DNA in a maternal blood sample. There is a possibility that failure to detect the fetal gene of interest may be due to undetectable levels of fetal DNA in the sample and may not indicate that the fetus is negative for that blood group or lacks the Y chromosome. There is a theoretical possibility that in a very small number of pregnancies we may detect fetal DNA from a fetus that has subsequently been lost as a result of the 'vanishing twin' phenomenon (Landy & Keith, 1998). In addition, due to the complexity of some blood group systems, there remains the possibility that on very rare occasions, genotyping results may not correspond to phenotype by conventional serology.

## **7 OUR REQUIREMENTS OF THE REQUESTER**

- 7.1 In order to ensure the standards of our service are maintained and to aid improvement, we try to monitor the accuracy of our testing procedures. We appreciate receiving information on the infant's blood group or sex after delivery. If there is a discrepancy between the baby's phenotype at birth and the predicted phenotype or baby's sex, please inform the IBGRL laboratory as soon as possible.
- 7.2 If samples are referred for fetal genotyping before the recommended gestation, and an antigen negative or female gender result is predicted, the requester should send a repeat sample after the recommended gestational age (and at 28 weeks gestation for Kell genotyping requests). This will reduce the small chance of a false negative genotyping result being undetected during the pregnancy.

## **8 WEB BROWSER**

- 8.1 Results will be available on Sp-ICE within 1 hour of authorisation. Not available for international customers

## **9 SERVICE VARIATION**

- 9.1 Every effort is made to provide diagnostic services as detailed in relevant user information documents, including but not limited to, the service specific user guides. However, NHSBT may have to alter the range or specification of services on offer due to technological or scientific advances, or changes in national quality or safety requirements. All changes, which might arise from such circumstances, will be notified in writing to Purchasers or Users in advance.

**SCHEDULE 2 – PRICE**

For pricing and payment, please contact NHSBT's Molecular Diagnostics department on [molecular.diagnostics@nhsbt.nhs.uk](mailto:molecular.diagnostics@nhsbt.nhs.uk).



**SCHEDULE 3 - DATA PROCESSING PARTICULARS**

Purpose for processing the Data	Each Party will process personal data in the course of working together according to the terms of this Contract.
Type of Personal Data being processed	Surname, Forename or forenames in full, Date of birth, NHS number, hospital number or unique identification number, expected data of delivery (EDD), MedicalHistory where required for further investigation.
Categories of Data Subjects	Patients
Duration of processing	As long as medically and legally required in accordance with this Contract, Law and Regulation. Duration of processing is outlined in the IBGRL User Guides INF1259 and INF1135.
Retention Periods (detail)	<p>As long as medically and legally required in accordance with this Contract, Law and Regulation.</p> <p>30-year minimum retention period (after which a review is to be performed to establish whether retention is required for a longer period) for Name, Date of Birth, NHS Number, Hospital Number and Expected Date of Delivery including results on Hematos and Sp-ICE.</p> <p>Retention period is 9 Months for Request Forms and samples.</p>
Details of Storage	<p>Cloud based, local server, shared server Third Party Server where agreed by the Parties.</p> <p>Electronic data will be stored securely with restricted access.</p> <p>Hardcopy to be stored securely where appropriate to do so in line with each Parties policies.</p>

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	Sample storage at local IBGRL facilities
Destruction and/or request for erasure	<p>Any data shared between the Parties must be returned or securely destroyed as specified by the Contract, NHSBT policies and/or applicable law and regulation.</p> <p>Data on Hematos and Sp-ICE can be destroyed by NHSBT IT (via service now &gt; service request catalogue &gt; RFC data base amendment).</p> <p>Request Forms are destroyed after 9 months of receipt. Sample storage is destroyed after 9 months of receipt.</p> <p>Data on the shared drive or email correspondence can be destroyed on request by the contracting Parties.</p>