



Department
of Health &
Social Care

Form of Contract

HPVValidate: Validation of high-risk (hr) HPV test system using self-collected vaginal samples – Cervical screening laboratory selection
Contract Number: C50753

This Contract is made between:

Department of Health and Social Care, Office for Health Improvement and Disparities (formerly **Public Health England**), 39 Victoria Street, London SW1H 0EU

and

Norfolk and Norwich University Hospital NHS Foundation Trust, Cytology Department, Cotman Centre, Colney Lane, Norwich, NR4 7UB (the "Contractor")

The following is agreed:

1. The Contract is made up of the following documents:

a) This Form of Contract for HPV Self-Sampling Test Validation

b) PHE Conditions of Contract (as included in the tender documents and subsequently amended by the parties). For the purposes of the PHE Conditions of Contract, this Form of Contract constitutes the only Order (as defined in the PHE Conditions of Contract).

c) The Contractor's tender response (including prices as detailed in the Commercial Envelope of the tender response and subsequently amended).

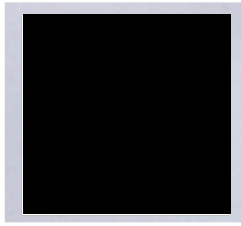
d) Confirmation of the allocated self-sample device/s and the laboratory study lead

e) Specification for PHE - Corporate - HPV Self-Sampling Test Validation as included in the tender documents.

(all of the above documents taken together (as amended in accordance with this Contract) being referred to as the "Contract")

2. If there is an inconsistency between any of the documents listed above, a higher listed document shall prevail over a lower listed document, i.e. document (a) shall prevail over all other documents; document (b) shall prevail over documents (c) and (d).
 3. The Contract will commence on the date that signatures are added by both the Authority and the Contractor.
 4. The duration of the Contract will be until completion of the project, but in any case, no later than the 31st March 2022.
-

Signature:



For and on behalf of the Authority

Name: 

Job Title: Procurement Manager

Date: 1st December 2021

Signature:



For and on behalf of the Contractor

Name: 

Job Title: Chief Finance Officer

Date: 30th November 2021



Department
of Health &
Social Care

PUBLIC HEALTH ENGLAND

CONDITIONS OF CONTRACT FOR THE PURCHASE OF SERVICES

**INCLUSIVE OF INTELLECTUAL PROPERTY CLAUSES SPECIFIC
TO RESEARCH CONTRACTS**



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1. Defined Terms and Interpretation

1.1 In these terms and conditions the words and expressions below will be interpreted to have the meanings adjacent to them:-

- 1.1.1 **"Affected Party"** means, in the context of Clause 47 the Party whose obligations under the Contract have been affected by the Force Majeure Event;
- 1.1.2 **"Authorised Officer"** means a person designated as such by the Authority from time to time as notified in writing to the Contractor to act as the representative of the Authority for all purposes connected with the Contract, including any authorised representative of such person;
- 1.1.3 **"Authorised Sub-Processors"** means:
 - (a) any member of the Contractor's Group which assists the Contractor in providing the Service;
 - (b) persons who provide information technology services that the Contractor uses in the course of providing the Services; and
 - (c) any Sub-Processor referred to in Schedule 2.
- 1.1.4 **"Authority"** means the Beneficiary placing the Order or, if a Third Party Beneficiary places the Order, the Beneficiary to which the Third Party Beneficiary supplies goods and/or services;
- 1.1.5 **"Beneficiary"** means any or all of:
 - (a) Public Health England, an executive agency of the Department of Health (hereafter referred to as "Public Health England" or "PHE", also referred to as "the Authority")
 - (b) the Department of Health and all agencies thereof;
 - (c) any statutory successor to any of the above;and **"Beneficiaries"** shall be construed accordingly;
- 1.1.6 **"Commencement Date"** means the date agreed by the Parties in writing or detailed in the Specification, on which the provision of the Services is to start;
- 1.1.7 **"Confidential Information"** means any information, which has been designated as confidential by either Party in writing or that ought reasonably to be considered as confidential however it is conveyed, including information that relates to the business, affairs, developments, trade secrets, know-how, personnel and suppliers of the Contractor, including IPRs, together with all information derived from the above, and any other information clearly designated as being confidential (whether or not it is marked as 'confidential') or which ought reasonably to be considered to be confidential. For the avoidance of doubt, Confidential Information does not include the content of this Contract:



- 1.1.8 **"Contract"** means the agreement between the Authority and the Contractor comprising the Order, these terms and conditions and schedules hereto, and the Specification, and for the avoidance of doubt all other terms, conditions or warranties other than any terms, conditions or warranties implied by law in favour of the Authority or the Beneficiaries are excluded from the agreement between the Authority and the Contractor unless expressly accepted in writing by the Authorised Officer;
- 1.1.9 **"Contractor"** means the provider of the Services pursuant to the Contract;
- 1.1.10 **"Contract Manager"** means a person designated as such by the Contractor from time to time as notified in writing to the Authority to act as the duly authorised representative of the Contractor for all purposes connected with the Contract, including any authorised representative of such person;
- 1.1.11 **"Contract Period"** means (subject to earlier termination in accordance with its terms or by operation of law) the duration of the Contract, starting on the Commencement Date, as set out in the Order and/or the Specification (or if the Order and/or the Specification does not set out such a duration, the period from the date of the Order until the Authority terminates by giving not less than 1 month's notice in writing to the Contractor);
- 1.1.12 **"Contract Price"** means the monies payable by the Authority or any Beneficiaries to the Contractor for the provision of the Services as set out in the Order. In the absence of agreement by the Parties to the contrary, the Contract Price shall be inclusive of all taxes, duties, expenses and disbursements save for VAT (if applicable) and shall include the costs of all equipment and materials including uniforms, training and radio-equipment supplied by the Contractor, all travelling expenses involved and all royalties, licence fees or similar expenses in respect of the making, use or exercise by the Contractor of any Intellectual Property or Intellectual Property Rights for the purpose of performance of the Contract.;
- 1.1.13 **"Contract Standard"** means such standard as complies in each and every respect with all relevant provisions of the Contract;
- 1.1.14 **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);
- 1.1.15 **"Convictions"** means other than in relation to minor road traffic offences, any previous or pending prosecutions, convictions, cautions and binding-over orders (including any spent convictions as contemplated by Section 1(1) of the Rehabilitation of Offenders Act 1974 by virtue of the exemptions specified in Part II of Schedule 1 of the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (SI 1975/1023) or any replacement or amendment to that Order);



- 1.1.16 **"Costs"** includes costs, charges, outgoings and expenses of every description;
- 1.1.17 **"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;
- 1.1.18 **"Data Subject Request"** means a request made by a data subject to exercise any rights of data subjects under Data Protection Laws;
- 1.1.19 **"Deliverable"** means any data, report, drawing, specification, design, invention, plan, program, document, contract, and/or other material produced by or to be produced by or acquired by or to be acquired by the Contractor in the course of the performance of the Services;
acquired by The Secretary of State for Health and Social Care acting as part of the Crown for the Department of Health and Social Care
- 1.1.20 **"Dispute Resolution Procedure"** means the procedure set out in Clause 24;
- 1.1.21 **"Electronic Trading System(s)"** means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
- 1.1.22 **"Employees"** means, for the purpose of Clause 29, the employees assigned to the Services by the incumbent contractor or, as the case may be, by the Authority or any Beneficiaries prior to the Commencement Date;
- 1.1.23 **"Force Majeure Event"** means one or more of the following to the extent that it is not attributable to the Contractor or the Contractor's staff: war, civil war (whether declared or undeclared), riot or armed conflict; radioactive, chemical or biological contamination; pressure waves caused by aircraft or other aerial devices travelling at sonic or supersonic speed; acts of terrorism; explosion; fire; flood; extraordinarily severe weather conditions which are both unforeseen and for which precautions are not customarily taken by prudent business organisations so as to avoid or mitigate the impact thereof; industrial action which affects the provision of the Services, but which is not confined to the workforce of the Contractor or is site specific; pestilence; the actions of governmental authorities to the extent that such actions are implemented either pursuant to emergency powers or otherwise outside the usual course of governmental business; or Act of God, or other event which is beyond the reasonable control of the Party in question and could not have been avoided or mitigated by the exercise of all reasonable care by that Party and further provided that such event materially affects the ability of the Party seeking to rely upon it to perform its obligations under the Contract;



“Framework Agreement” means any agreement which defines, in broad terms, the scope and terms and conditions under which supply contracts will be entered into should the need arise;



- 1.1.25 **"Good Industry Practice"** means the exercise of that degree of skill, diligence and foresight which would reasonably and ordinarily be expected from a skilled and experienced service provider engaged in the provision of services similar to the Services under the same or similar circumstances as those applicable to the Contract and which are in accordance with any codes of practice published by relevant trade associations;
- 1.1.26 **"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).
- 1.1.27 **"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;
- 1.1.28 **"Insolvent"** means:
- (a) if the Contractor is an individual, that individual or where the Contractor is a partnership, any partner(s) in that firm becomes bankrupt or shall have a receiving order, administration order or interim order made against him, or shall make any composition or scheme of arrangement with or for the benefit of his creditors, or shall make any conveyance or assignment for the benefit of his creditors, or shall purport to do so, or any application shall be made for sequestration of his estate, or a trust deed shall be granted by him for the benefit of his creditors;
 - (b) if the Contractor is a company, the passing by the Contractor of a resolution for its winding-up or the making by a court of competent jurisdiction of an order for the winding-up of the Contractor or the dissolution of the Contractor, or if an administrator is appointed, or documents are filed with the court for the appointment of an administrator or notice of intention to appoint an administrator is given by the Contractor or its directors or by a qualifying floating charge holder (as defined in paragraph 14 of Schedule B1 to the Insolvency Act 1986), or the appointment of a receiver over, or the taking possession or sale by an encumbrancer of any of the Contractor's assets, or if the Contractor makes an arrangement with its creditors generally or makes an application to a court of competent jurisdiction for protection from its creditors generally; and
 - (c) any event in any jurisdiction other than England and Wales which is analogous to any of the above;
- 1.1.29 **"Intellectual Property"** means any and all patents, trademarks, service marks, domain names, registered designs, utility models, applications for and the right to make applications for any of such rights, inventions, Know-How (as defined below), unregistered trademarks and service marks, trade and business names, including



rights in any get-up or trade dress, copyrights, (including rights in computer software and in websites) unregistered design rights and other rights in designs and rights in databases, subsisting anywhere in the world; the right for the maker of a database to prevent extraction or reutilisation or both of the whole or a substantial part of the content of that database, as described in Directive 96/9/EC on the legal protection of databases; rights under licences, consents, orders, statutes or otherwise in respect of any rights of the nature specified in this definition "Intellectual Property"; and rights of the same or similar effect or nature as or to those above in each case in any jurisdiction;

- 1.1.30 **"Intellectual Property Right"** includes the right to exploit any Intellectual Property or any right which is similar or analogous to any Intellectual Property; any moral right; 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;
- 1.1.31 **"Background Intellectual Property"** means any Intellectual Property and Intellectual Property Rights, other than Foreground Intellectual Property, that is used in connection with any part of the services.
- 1.1.32 **"Foreground Intellectual Property"** means any Intellectual Property and Intellectual Property Rights that arises or is obtained or developed by, or by the Contractor on behalf of, either party in the course of or in connection with the performance of the services.
- 1.1.33 **"In writing"** shall be interpreted to include any document which is recorded in manuscript, typescript, any electronic communication as defined in Section 15 of the Electronic Communications Act 2000 but excluding mobile telephone text messages;
- 1.1.34 **"Know How"** means all information not publicly known which is used or required to be used in or in connection with the Services existing in any form (including, but not limited to, that comprised in or derived from engineering, chemical and other data, specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and circuit diagrams, brochures, catalogues and other descriptions) and relating to the design, development, manufacture or production of any products; the operation of any process; the provision of any Services; the selection, procurement, construction, installation, maintenance or use of raw materials, plant, machinery or other equipment or processes; the rectification, repair or service or maintenance of products, plant, machinery or other equipment; the supply, storage, assembly or packing of raw materials, components or partly manufactured or finished products; quality control, testing or certification of any person;
- 1.1.35 **"Laboratory Guide"** means the Contractor's Laboratory Guide current at the date of this Agreement, as supplied to the Authority and/or any Beneficiary or, if not so supplied, available on request from the Contractor, including any updates or supplements issued by



the Contractor;

- 1.1.36 **"Loaned Equipment"** means equipment owned by the Authority or any Beneficiary which is loaned to the Contractor for the purposes of the Contract;
- 1.1.37 **"Location"** means the location for the provision of the Services as set out in the Contract or as otherwise agreed in writing between the Authority or any Beneficiary and the Contractor;
- 1.1.38 **"Loss"** includes losses, liabilities, claims, costs, charges and outgoings of every description (including legal expenses), compensation payable under contracts with suppliers and/or customers, loss of normal operating profits, loss of opportunity, loss of goodwill, loss of revenue from related contracts and pure economic loss;
- 1.1.39 **"Month"** means a calendar month;
- 1.1.40 **"Order"** means any order placed on the Contractor by an Authority or any Beneficiary for the provision of the Services whether or not such order is placed pursuant to a Framework Agreement concluded between the Contractor and any Beneficiary or Beneficiaries as the case may be;
- 1.1.41 **"Party"** means any party to the Contract individually and "Parties" refers to all of the parties to the Contract collectively. A Party shall include all permitted assigns of the Party in question. All persons who are not a Party to the Contract are third parties;
- 1.1.42 **"Person"** includes any individual, partnership, firm, trust, body corporate, government, governmental body, authority, agency, unincorporated body of persons or association and a reference to a person includes a reference to that person's successors and permitted assigns;
- 1.1.43 **"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;
- 1.1.44 **"Privacy Notice"** means the Contractor's privacy notice available at <https://www.hslpathology.com/>
- 1.1.45 **"Protected Data"** means personal data provided to the Contractor by the Authority, any Beneficiary or a third party on the instructions of the Authority or any Beneficiary, or collected or generated by the Contractor in the course of the Services;
- 1.1.46 **"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;



- 1.1.47 **"Receipt of Order"** means, if personally delivered, at the time of delivery; if sent by facsimile, at the time of transmission; if posted, at the expiration of 48 hours or (in the case of airmail seven days) after the envelope containing the same was delivered into the custody of the postal authorities; and if sent by electronic mail, provided that a telephone call is made to the recipient warning the recipient that an electronic mail message has been sent to him (as evidenced by a contemporaneous note of the Party sending the notice) and a hard copy of such notice is also sent by first class recorded delivery post (airmail if overseas) on the same day as that on which the electronic mail is sent;
- 1.1.48 **"Recruits"** means any new employees engaged by the Contractor to work on the Services to which this Contract relates (and any amendment to those Services);
- 1.1.49 **"Replacement Contractor"** means any contractor engaged to replace the Contractor or any sub-contractor of the Contractor;
- 1.1.50 **"Service Information"** means information concerning the Services provided by the Contractor to the Authority in accordance with Clause 32.1 for inclusion in the Authority's catalogue and/or any Beneficiary's catalogue from time to time;
- 1.1.51 **"Services"** means the services provided by the Contractor pursuant to, and in accordance with, the Contract;
- 1.1.52 **"Sites"** means those areas at the Location for the use of the Contractor and his staff in the provision of the Services, as set out in the Specification;
- 1.1.53 **"Specification"** means the description of the Services together with (where applicable) a brief description of Deliverables to be provided pursuant to such Services as referred to, set out in or attached to the Order (or, if no such description is set out in or attached to the Order, as set out in or attached to any documentation inviting the Contractor to tender for the appointment to provide the Services, including any documentation issued, or made available, to the Contractor by any Beneficiary);
- 1.1.54 **"Third Party Beneficiary"** means each of the bodies set out in the list attached at Schedule 1, as supplied from time to time by the Authority to the Contractor;
- 1.1.55 **"TUPE"** means the Transfer of Undertakings (Protection of Employment) Regulations 2006 and Council Directive 2001/23/EC on the approximation of the laws of the Member States relating to the safeguarding of employees rights in the event of transfer of undertakings, businesses or parts of undertakings or businesses;
- 1.1.56 **"UKAS"** means the United Kingdom Accreditation Service, or any successor to it;
- 1.1.57 **"Year"** means during the Contract Period, any 12 month period commencing on the Commencement Date or an anniversary thereof.



- 1.2 In these terms and conditions, all references to any statute or statutory provision shall be deemed to include references to any statute or statutory provision which amends, extends, consolidates or replaces the same and shall include any orders, regulations, codes of practice, instruments or other subordinate legislation made thereunder and any conditions attaching thereto. Moreover, where relevant, references to English statutes and statutory provisions shall be construed as references also to equivalent statutes, statutory provisions and rules of law in other jurisdictions.
- 1.3 Any headings to Clauses, together with the front cover and the Index are for convenience only and shall not affect the meaning of these terms and conditions. Unless the contrary is stated references to Clauses shall mean the Clauses of these terms and conditions.
- 1.4 Unless otherwise expressly defined in these terms and conditions, the words used in these terms and conditions shall bear their natural meaning. The Parties have had equal opportunity to take legal advice and the *contra proferentem* rule shall not apply to the interpretation of these terms and conditions.
- 1.5 Where a term of these terms and conditions provides for a list of items following the word "including" or "includes" then such list is not to be interpreted as being an exhaustive list. Any such list shall not be treated as excluding any item which might have been included in such list having regard to the context of the contractual term in question. The *ejusdem generis* principle is not to be applied when interpreting these terms and conditions. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
- 1.6 In these terms and conditions, words importing any particular gender include all other genders.
- 1.7 In these terms and conditions, words importing the singular only shall include the plural and vice versa.
- 1.8 In these terms and conditions "staff" and "employees" shall have the same meaning.
- 1.9 Subject to the contrary being stated expressly or implied from the context in these terms and conditions, all communication between the Parties shall be in writing.
- 1.10 All monetary amounts are expressed in pounds sterling but in the event that pounds sterling is replaced as legal tender in the United Kingdom by a different currency then all monetary amounts shall be converted into such other currency at the rate prevailing on the date such other currency first became legal tender in the United Kingdom.
- 1.11 Except where an express provision of these terms and conditions states the contrary, each and every obligation of a Party under the terms and conditions is to be performed at that Party's cost.



Any reference to a Party "procuring" another person to act or omit to act in a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.

- 1.13 All references to the Contract include (subject to all relevant approvals) a reference to the Contract as amended, supplemented, substituted, novated or assigned from time to time.

2 Appointment

- 2.1 The Authority appoints the Contractor to provide the Services:
- 2.1.1 promptly (and in any event within any time targets as may be set out in the Specification) and in a professional and courteous manner so as to reflect and promote the image of the Authority and any Beneficiary;
 - 2.1.2 strictly in accordance with the Specification and all provisions of the Contract; and
 - 2.1.3 in accordance with all applicable UK and European laws and regulations and Good Industry Practice; and
 - 2.1.4 in accordance with the policies (including, when on any premises of the Authority or any Beneficiary or on any other premises where it works alongside the Authority's or any Beneficiary's staff, any racial discrimination and equal opportunities policies), rules, procedures and the quality standards of the Authority and any Beneficiary as amended from time to time.
- 2.2 The Contractor accepts the terms of appointment as provided in Clause 2.1 in consideration of the Contract Price.

3 Performance of the Services

- 3.1 Subject to Clause 15.1, the Contractor shall provide at its own expense all staff, equipment, tools, appliances, materials or items required for the provision of the Services to the Contract Standard.
- 3.2 To the extent that the Specification includes the date, format and method of delivery of the Services and Deliverables and/or the applicable performance measures, performance due-by dates, minimum performance levels and methods of performance measurement in respect of the Services, the Contractor will abide by the same.
- 3.3 Time shall be of the essence with regard to the obligations of the Contractor under the Contract.
- 3.4 If the Specification provides for performance of the Services in stages, the Contractor undertakes to perform the Services in strict compliance with the timetable for stages as provided in the Specification.
- 3.5 The Authority and the Contractor will co-operate with each other in good faith



and will take all reasonable action as is necessary for the efficient transmission of information and instructions and to enable the Authority, or as the case may be, any Beneficiary to derive the full benefit of the Contract. At all times in the performance of the Services, the Contractor will co-operate fully with any other contractors appointed by the Authority or any Beneficiary in connection with other services at the Location.

- 3.6 In addition to any more specific obligations imposed by the terms of the Contract, it shall be the duty of the Contractor to notify the Authorised Officer of all significant changes to staffing, rates of pay or conditions of employment, or hours of work or other technological changes at least one month prior to the implementation of any such revised arrangements.
- 3.7 The Contractor shall provide information in a format, medium and at times specified by the Authority, related to the performance of the Services as may be reasonably required.
- 3.8 In providing the Services, the Contractor shall use Good Industry Practice to ensure that any computer systems and/or related hardware and/or software it uses are free from corrupt data, viruses, worms and any other computer programs which might cause harm or disruption to the Authority's or, as the case may be, to any Beneficiary's computer systems.
- 3.9 If at any time the Contractor becomes aware of any act or omission or any proposed act or omission by the Authority or any Beneficiary or by any member, official or employee of the Authority or any Beneficiary which prevents or hinders or may prevent or hinder the Contractor from providing the Services in accordance with the Contract then the Contractor shall immediately inform the Authorised Officer of that fact. For the avoidance of doubt, the Contractor's compliance with this Clause shall not in any way relieve the Contractor of any of its obligations under the Contract.
- 3.10 The Authority and any Beneficiary shall provide the Contractor with copies of its policies, rules, procedures and quality standards (and shall promptly inform the Contractor of any amendments to such documents) to enable the Contractor to comply with its obligations under the Contract.
- 3.11 The Authority may, where necessary, require the Contractor to set up and maintain appropriate policies, rules, procedures and quality standards in relation to the employment of his own staff whilst carrying out their duties in relation to the Contract at the Location. This shall include, but not be limited to, disciplinary and grievance procedures. The Contractor shall provide the Authority and any Beneficiary with copies of such policies, rules, procedures and quality standards (and shall promptly inform the Authority and any Beneficiary of any amendments to such documents).
- 3.12 The Contractor will immediately notify the Authorised Officer of any actual or potential problems relating to the Contractor's own suppliers that affects or might affect his ability to provide the Services.
- 3.13 The Contractor will be responsible for providing and maintaining the Services to the Contract Standard at all times and will ensure continuity of supply (at no extra cost to the Authority and any Beneficiary) in accordance with the Specification. The Contractor must have in place contingency plans and



arrangements which are approved by the Authority to ensure continuity of supply.

- 3.14 The Contractor will immediately notify the Authorised Officer of any actual or potential industrial action, including strike action, whether such action be of his own staff or others, that affects or might affect his ability at any time to provide the Services.
- 3.15 The Contractor will be responsible for providing and maintaining the Services to the Contract Standard during industrial action, at no additional cost to the Authority and any Beneficiary. The Contractor must have in place contingency plans and arrangements which are approved by the Authority.
- 3.16 In the event of the Contractor being unable to maintain the Services to the Contract Standard, the Contractor shall without prejudice to the remedies of the Authority and any Beneficiary permit the Authorised Officer and his staff, to have access to and unrestricted use of such machinery, equipment and materials which being the property of the Contractor deemed necessary to maintain the Services by the Authorised Officer during industrial action, or any other such occurrence, without additional charge.
- 3.17 In the event of a major incident (as defined in the Authority's major incident policy) the Contractor shall perform the Services in accordance with the relevant section of the Specification.

4 Deliverables

- 4.1 Wherever the Services require the Contractor to provide a Deliverable:
 - 4.1.1 such Deliverable will be delivered in the form prescribed and in accordance with the Specification. If no such form is prescribed in the Specification, the Contractor will provide Deliverables in a professional form to the requirements (including as to time of delivery) notified to the Contractor by the Authorised Officer;
 - 4.1.2 the Authority or any Beneficiary may accept such Deliverable or reject it in its reasonable discretion on the grounds that such Deliverable is (in whole or in part) not of satisfactory quality and/or does not meet the brief set out in the Specification or the requirements otherwise made known to the Contractor by the Authority or any Beneficiary pursuant to clause 4.1.1;
 - 4.1.3 the Authority or any Beneficiary will not reject any Deliverable (wholly or in part) without providing written reasons to the Contractor as to why such Deliverable has been rejected;
 - 4.1.4 any dispute as to whether the Authority or any Beneficiary has exercised its right to reject any Deliverable reasonably shall be resolved by the Dispute Resolution Procedure; and
 - 4.1.5 any Deliverables which are rejected shall be replaced by the Contractor (at no extra charge to the Authority or any Beneficiary) by Deliverables which are reasonably satisfactory to the Authorised Officer.



5 Performance Measurement

- 5.1 In addition to any more specific obligations imposed by the terms of the Contract, it shall be the duty of the Contractor to provide the Services to the Contract Standard which in all respects shall be to the reasonable satisfaction of the Authorised Officer.
- 5.2 The Contractor shall institute and maintain a properly documented system of quality control as set out in the Specification and which is to the reasonable satisfaction of the Authorised Officer to ensure that the Contract Standard is met.²¹
- 5.3 In addition to any other rights of the Authority and any Beneficiary under the Contract, the Authorised Officer shall be entitled to inspect the Contractor's quality control system referred to in Clause 5.2 above.
- 5.4 During the Contract Period, the Authorised Officer may inspect and examine the provision of the Services being carried out at the Location without notice at any time. The Contractor shall provide to the Authority all such facilities as the Authority may require for such inspection and examination.
- 5.5 The Contractor shall allow the Authority and any person, firm or organisation authorised by the Authority to have access to and to audit all records maintained by the Contractor in relation to the supply of the Services. The Contractor shall assist the Authority or any party authorised by the Authority (as the case may be) in the conduct of the audit.
- 5.6 If any part of any Service is found to be defective or different in any way from the Specification or otherwise has not been provided to the Contract Standard other than as a result of a default or negligence on the part of the Authority or any Beneficiary, the Contractor shall at its own expense re-perform the Services in question (without additional remuneration therefor) within such time as the Authority or any Beneficiary may reasonably specify failing which the Authority or any Beneficiary shall be entitled to procure performance of the defective Services from a third party or to execute the tasks in question itself.
- 5.7 If the performance of the Contract by the Contractor is delayed by reason of any act or default on the part of the Authority or any Beneficiary or, by any other cause that the Contractor could not have reasonably foreseen or prevented and for which it was not responsible, the Contractor shall be allowed a reasonable extension of time for completion of the Services so affected.
- 5.8 For each Service, the Authority or any Beneficiary shall, acting reasonably, ascertain whether the Contractor's provision of the Service in question meets any performance criteria as specified in the Specification or, if the criteria are not so specified, meets the standards of a professional provider of the Services. On or before the fifteenth working day of each calendar month during the Contract Period and within 14 days after termination of the Contract, the Authority or any Beneficiary may in their reasonable discretion:
- 5.8.1 in respect of each of the Services during the preceding calendar month, provide to the Contractor a notice (each called a "**Performance Notice**") which shall set out a statement of the



Authority's or any Beneficiary's dissatisfaction with the Contractor's performance and provision of the Services;

- 5.8.2 each Performance Notice issued by the Authority or the Beneficiary shall include a proposed rebate of the Contract Price commensurate to the under-performance of the Contractor as recorded in the Performance Notice;
- 5.8.3 if the Contractor disputes any matter referred to in any Performance Notice and/or the proposed rebate of the Contract Price, the Contractor may raise this objection with the Authority or the Beneficiary and if this matter is not resolved within 7 days the matter shall be referred to the Dispute Resolution Procedure; and
- 5.8.4 if the Contractor has not raised any objection to the Performance Notice within 7 days of receipt (or such other period as agreed between the Parties) then that Performance Notice shall be deemed to have been accepted by the Contractor and the rebate on the Contract Price referred to therein shall become immediately effective.
- 5.9 The Authority and any Beneficiary's rights under Clause 5.8 are without prejudice to any other rights or remedies the Authority or any Beneficiary may be entitled to.
- 5.10 On request, the Contractor shall submit to the Authority and any Beneficiary progress reports detailing its adherence to the timetable (if any) as set out in the Specification in a format approved by the Authority or any Beneficiary. The submission and acceptance of such reports shall not prejudice any other rights or remedies of the Authority or any Beneficiary under the Contract.
- 5.11 If required by the Authority or any Beneficiary, the Parties shall co-operate in sharing information and developing performance measurement criteria with the object of improving the Parties' efficiency. Any such agreements shall be fully recorded in writing by the Authority or Beneficiary as the case may be.

6 Contract Price and Payment

- 6.1 In consideration of the Contractor's due and proper performance of its obligations under the Contract, the Contractor may charge the Authority or, as the case may be, any Beneficiary the Contract Price in accordance with this Clause 6.
- 6.2 The only sums payable by the Authority or any Beneficiary to the Contractor for the provision of the Services shall be the Contract Price. All other costs, charges, fees and expenses of whatever kind arising out of or in connection with the Contract shall be the responsibility of the Contractor.
- 6.3 In accordance with the Contract, where the Contractor is required to provide Deliverables, the Authority or any Beneficiary shall be entitled to withhold payment of the Contract Price pending receipt and acceptance of the Deliverables in accordance with the Specification.
- 6.4 Unless otherwise agreed in writing by the Authority or any Beneficiary and the



Contractor, within 15 days of the end of each calendar month, the Contractor shall invoice the Authority or, as the case may be, any Beneficiary for any Services provided by the Contractor in that calendar month. Such invoices shall be rendered on the Contractor's own invoice form clearly marked with the Authority's or the Beneficiary's order number (if any). Invoices must show the period to which they relate and the aspects of the Services for which payment is claimed together with the agreed charging rates and any other details the Authority or the Beneficiary may require. Failure to provide such information will entitle the Authority or the Beneficiary to delay payment of the Contract Price until such information is provided.

- 6.5 Subject to Clauses 6.3 and 6.6, the Authority or any Beneficiary shall pay any invoice submitted by the Contractor in accordance with Clause 6.4 within 30 days of receipt by the Authority or the Beneficiary of such invoice. The Authority or the Beneficiary shall pay such invoice(s) by BACS (Bank Automated Clearing System) if it so chooses or any alternate means as agreed between the Authority or the Beneficiary and the Contractor.
- 6.6 The Authority and any Beneficiary shall be entitled to deduct from any monies due or to become due to the Contractor any monies owing to the Authority or the Beneficiary from the Contractor.
- 6.7 Where the performance of the Contractor does not meet the required standard then a deduction as set out in the Specification or as agreed by the Parties may be made.
- 6.8 Except where otherwise stated in the Order, the Contract Price is exclusive of VAT which shall be payable, if applicable, by the Authority or any Beneficiary in addition to such Contract Price. The invoice provided to the Authority or any Beneficiary by the Contractor in accordance with Clause 6.4 shall show the VAT calculations separately.
- 6.9 The Contractor will keep accurate books and records in relation to the provision of the Services in accordance with sound and prudent financial management. All such books and records shall be made available to the Authority at regular intervals of not less than quarterly.
- 6.10 In the event of the Authority or any Beneficiary breaching Clause 6.5, the Contractor shall be entitled to charge interest on the outstanding amount owed by the Authority or such Beneficiary in accordance with the Late Payment of Commercial Debts (Interest) Act 1998.
- 6.11 Subject to Clauses 6.12 and 6.13, the Contract Price shall not be subject to any increase whatsoever by the Contractor during the Contract Period.
- 6.12 In the event that the Contract is varied under Clauses 22 or 23 in such a way as to affect the Contract Price and if agreement between the Parties cannot be reached on the adjustment to the Contract Price within 3 months both Parties shall jointly act to resolve the dispute in accordance with Clause 24.
- 6.13 If the adjusted Contract Price is not so agreed or certified until after such variation has taken effect, the Authority or any Beneficiary shall continue to pay the Contractor at the rate current prior to the variation but shall pay to the Contractor or be entitled to recover from the Contractor as the case may be such sum if any as is equal to the difference between the amount which should



have been paid in accordance with the adjusted Contract Price and the amount which was actually paid.

- 6.14 In the event that the Contract ends or is terminated otherwise than at the end of a complete year, the sum payable by the Authority or any Beneficiary under Clause 6 shall be one twelfth of the annual sum which would otherwise have been payable for the complete year for each completed month.

7 Resources

- 7.1 The Contract Price includes payment in full for all facilities and resources required by the Contractor to provide the Services in accordance with the Contract. Any facilities or resources needed or used by the Contractor to perform the Services shall be provided by the Contractor without additional cost to the Authority or any Beneficiary.
- 7.2 The Contractor confirms its satisfaction of its abilities and experience in all respects to perform the Services pursuant to the Contract to the reasonable satisfaction of the Authority.

8 Contract Period

- 8.1 The Contract shall commence and (subject to any earlier lawful termination) remain in force for the Contract Period.
- 8.2 The Authority may, by notice in writing, extend the Contract Period, provided that the said notice shall have been given to the Contractor no later than 12 weeks before the end of the Contract Period.

9 Authorised Officers

- 9.1 Any notice, information or communication given to or made by an Authorised Officer shall be deemed to have been given or made by the Authority.
- 9.2 The Contractor shall decline from providing the Services to any of the Authority's or Beneficiary's staff who are not Authorised Officers.

10 Employees

- 10.1 The Contractor shall be entirely responsible for the employment and conditions of service of his staff employed in the Contract.
- 10.2 The Contractor will employ sufficient employees to ensure that all of the Services are provided at all times and in all respects in complete conformity with the Specification. This will include, but not be limited to, the Contractor providing a sufficient reserve of trained and competent staff to provide the Services during staff holidays or absence due to sickness or voluntary absence. In relation to the Services, the Contractor will employ only such persons as are careful, skilled and experienced in the duties required of them, and will ensure that every such person is properly and sufficiently trained and instructed (at the Contractor's expense) and carries out the Services with regard to
- 10.2.1 the task or tasks that person has to perform;



- 10.2.2 all relevant provisions of the Contract and the Specification;
- 10.2.3 all relevant policies, rules, procedures and standards of the Authority and any Beneficiary (including any racial discrimination and equal opportunities policies);
- 10.2.4 the need for those working in an health service environment to observe the highest standards of hygiene;
- 10.2.5 the need to keep confidential all information marked as confidential howsoever acquired whether relating to the Authority or any Beneficiary and its business;

11 Control and Supervision of Staff

- 11.1 Any notice, information, instruction or other communication given or made to the Contract Manager shall be deemed to have been given or made to the Contractor.
- 11.2 The Contract Manager shall be suitably qualified in accordance with the Specification. In addition a work history/biography will be submitted to the Authorised Officer for approval prior to interview.
- 11.3 The Contractor shall forthwith give notice in writing to the Authorised Officer of the identity of the person appointed as Contract Manager and of any subsequent appointment. Until notice of a subsequent appointment shall have been given the Authority and any Beneficiary shall be entitled to treat as Contract Manager the person last notified to the Authorised Officer as being the Contract Manager.
- 11.4 The Contractor shall ensure that the Contract Manager, or a competent deputy who is duly authorised to act on his behalf, is available to the Authority and any Beneficiary at all times when any employee of the Contractor is on duty for the provision of the specified Services.
- 11.5 The Contractor shall inform the Authorised Officer of the identity of any person authorised to act for any period as deputy for the Contract Manager before the start of that period.
- 11.6 The Contract Manager or his deputy shall consult with the Authorised Officer and such other of the Authority's or any Beneficiary's own supervisory staff as may from time to time be specified by the Authorised Officer as often as may reasonably be necessary for the efficient provision of the Services in accordance with the Contract.
- 11.7 The Contractor shall provide a sufficient complement of supervisory staff in addition to the Contract Manager, to ensure that the Contractor's staff engaged in and about the provision of the Services at the Location are adequately supervised and properly perform their duties at all times.
- 11.8 All persons appointed to managerial and supervisory positions in accordance with the Specification must be to the acceptance of the Authorised Officer



who will have the right to veto the appointment of any candidate who is deemed to be unsuitable provided that (i) the Authorised Officer acts reasonably in exercising this right to veto and (ii) the Contractor's staff who were notified to the Authority and/or any Beneficiary as part of the Contractor's tender response are deemed to be suitable and are therefore not subject to the Authorised Officer's right to veto.

- 11.9 The Contractor's staff engaged in and about the provision of the Services shall primarily be under the control and direction of the Contractor's own supervisory staff but nevertheless while on the Authority's and any Beneficiary's premises will obey all reasonable instructions given to them by the Authority's or any Beneficiary's supervisory staff in any matter occasioned by the operational needs of the relevant Service or the health, safety or welfare of anyone.
- 11.10 The Contractor shall ensure that his staff carry out their duties and behave while on the Authority's or any Beneficiary's premises in an orderly manner and in as quiet a manner as may reasonably be practicable having regard to the nature of the duties being performed by them. The Contractor's staff shall not cause any unreasonable or unnecessary disruption to the routines, practices, and procedures of the Authority's or any Beneficiary's staff, patients or visitors, or any of the staff of any other contractors.

12 Health and Safety

- 12.1 While at the Location, the Contractor shall comply, and shall ensure that its employees comply with, the requirements of relevant Health and Safety and other relevant legislation, including regulations and codes of practice issued thereunder, and with the Authority's and any Beneficiary's own policies and procedures.
- 12.2 The Contractor shall at all times maintain a specific Health and Safety at Work policy relating to the employment of his own staff whilst carrying out their duties in relation to the Contract on the Authority's or any Beneficiary's premises.
- 12.3 The Contractor will be required to nominate a Health and Safety Representative to liaise with the Authorised Officer on all Health and Safety matters.
- 12.4 The Contractor's staff shall follow a system of accident recording in accordance with the Authority's or any Beneficiary's accident recording procedure and the Contractor's own accident reporting procedures.
- 12.5 All notifiable accidents shall immediately be brought to the attention of the Authorised Officer.
- 12.6 The Contractor shall ensure the co-operation of its employees in all prevention measures designed against fire, or any other hazards, and shall notify the Authority of any change in the Contractor's working practices or other occurrences likely to increase such risks or to cause new hazards.
- 12.7 The Contractor's staff shall be trained to recognise situations which involve an actual or potential hazard including:
- 12.7.1 danger of personal injury to any person on the Authority's or



Beneficiary's premises and

- a) where possible, without personal risk, make safe any such situation; or
 - b) report any such situation to the Authorised Officer;
- 12.7.2 fire risks and fire precautions and procedures including attendance at fire lectures/drills in accordance with the Authority's or any Beneficiary's policies;
- 12.7.3 security;
- 12.7.4 risk management;
- 12.7.5 major incident;
- 12.8 The Contractor shall provide such first aid facilities and ensure that his staff abide by such first aid procedures as shall be required by the Authority or any Beneficiary as detailed in the Specification.
- 12.9 The Contractor shall at any time ensure that the equipment used and procedures operated conform to the Authority's or any Beneficiary's Fire Policy as detailed in the Specification.
- 12.10 The Contractor shall co-operate with the Authority's or any Beneficiary's Fire, Security and Safety Advisors and shall comply with their reasonable instructions.
- 12.11 The Contractor will comply with the Control of Substances Hazardous to Health (COSHH) Regulations (as amended) and COSHH hazard management and control.

13 Location

- 13.1 Subject to satisfactory agreement between the Parties on price, the Authority reserves the right to increase or reduce the number of Locations under the Contract at any time during the Contract Period.
- 13.2 Without prejudice to any other right or remedy the Authority will endeavour to give as much notice as possible of increases or reductions to the number of Locations under the Contract, although a minimum period of time is not specified in these conditions.
- 13.3 Upon completion of this Contract the Authority and any Beneficiary shall grant a non exclusive and revocable licence to the Contractor to enter upon the Locations for the sole purpose of providing the Services to the Authority and any Beneficiary, subject to the provisions of Clauses 5 and 26, for the term of the Contract. The licence thereby granted shall be subject to the conditions of the Contract and shall not be deemed to create a relationship of Landlord and Tenant as between the Authority or any Beneficiary and the Contractor.



14 Use of Authority Sites

- 14.1 The Authority and any Beneficiary shall during the Contract Period permit the Contractor to use in connection with the provision of the Services certain Sites at the Location as set out in the Specification.
- 14.2 The Contractor shall use the Sites only in connection with the provision of the Services and shall ensure that the Contractor's staff use the Sites only for that purpose.
- 14.3 The Contractor shall ensure that the Sites have a clean, tidy and professional appearance at all times.
- 14.4 The permission given to the Contractor to use the said Sites is personal to the Contractor and the Contractor's staff and shall cease immediately the Contract ceases to be in force. Only the Contractor's own staff and persons making deliveries to the Contractor in connection with the provision of the Services may enter or use any part of the Sites without the prior written permission of the Authorised Officer.
- 14.5 For the avoidance of doubt it is hereby declared that the permission to enter and use the said Sites is not the grant of a tenancy of any part of the Sites. The Authority and any Beneficiary retains full possession and control over such Sites at all times and the Contractor shall not receive exclusive possession of, or any estate or interest in, any such Sites.
- 14.6 The Authority and any Beneficiary reserves the right at all times to permit third parties to use the Sites, subject to the rights granted to the Contractor pursuant to the Contract.
- 14.7 The Contractor shall keep the said Sites clean, tidy and properly secure.
- 14.8 The Authority and any Beneficiary will provide a sufficient supply of water, gas and electricity to operate equipment used to provide the Services.
- 14.9 The Authority and any Beneficiary will arrange for the disposal of refuse from authorised collection points as set out in the Specification.
- 14.10 The Contractor will not alter or modify any part of the Sites without the written permission of the Authorised Officer, unless alteration or modification is part of the Services to be provided by the Contractor. If alteration or modification of the Sites is to be provided by the Contractor, Clause 27.4 will apply.

15 Equipment and Materials

- 15.1 The Contractor shall be responsible for the provision and installation of all equipment and materials used in connection with the Contract except where these are loaned to the Contractor by the Authority or any Beneficiary in accordance with Clause 16 or transferred into the ownership of the Contractor under Clause 15.13 and 15.14.



- 15.2 Where equipment and materials are supplied by the Authority or any Beneficiary these will be serviced and maintained by the Authority or that Beneficiary.
- 15.3 The Contract Manager shall forthwith inform the Authorised Officer of any defects appearing in or losses of, or damage, occurring to the Authority's or any Beneficiary's equipment. The Contractor shall be liable to pay to the Authority or that Beneficiary the cost of any replacement necessary as a result of loss or damage caused deliberately or negligently by the Contractor's staff.
- 15.4 In accordance with the Specification, the Contractor will, at his own expense, install all necessary equipment for the provision of the Services.
- 15.5 The Contractor shall ensure that all equipment used in connection with the Contract is maintained in good working order in compliance with manufacturer's instructions and current legislation.
- 15.6 All equipment and materials used by the Contractor shall comply with latest relevant British Standard or European equivalent specifications where such exist and the Contractor shall upon request furnish the Authorised Officer with evidence to prove that such equipment and materials comply with this condition.
- 15.7 The Contractor shall:
- a) establish effective planned maintenance programmes; and
 - b) make adequate arrangements for emergency remedial maintenance, to ensure continuity of the Services; and
 - c) ensure compliance with all regulations covering the inspection and testing of all equipment used at the Location in the provision of the Services; and
 - d) maintain records, open for inspection by the Authority of maintenance testing and certification.
- 15.8 Any communication or electrical equipment used by the Contractor in connection with the Contract shall not cause any interference with or damage to any equipment used by the Authority or any Beneficiary.
- 15.9 Any communication or electrical equipment proposed to be used by the Contractor in connection with the Contract shall, at the discretion of the Authority be tested and approved by the Authority before use on the Authority's or any Beneficiary's premises.
- 15.10 Notwithstanding Clause 15.9 the Contractor shall be liable for any damage caused by any communication or electrical equipment used in connection with the Contract.



15.11 [INTENTIONALLY LEFT BLANK]

15.12 The Authority or any Beneficiary shall not be responsible, charged or chargeable for any equipment or materials brought on site by the Contractor.

15.13 [INTENTIONALLY LEFT BLANK]

15.14 [INTENTIONALLY LEFT BLANK]

16 [INTENTIONALLY LEFT BLANK]

17 Assignment

17.1 The Contractor shall not assign the whole or any part of the Contract without the prior written consent of the Authority.

17.2 Subject to 17.1 if consent to assign is requested from the Authorised Officer:

17.2.1 the Authority may insist upon the production to it (inter alia) of all reasonable information and documentation relevant to

- a) the financial liability;
- b) competence; and
- c) relevant experience of the proposed assignee
- d) as reasonable and valid conditions of their consent under Clause 17.1;

17.2.2 the contractor must warrant that the contractor and assignee will fully comply with Clause 20;

17.2.3 the Contractor must engage the most appropriate and qualified assignee to undertake the supply of the Services.

18 Sub-Contractors

18.1 The Contractor shall not sub-contract the supply of any Services without the previous consent in writing of the Authorised Officer (such consent not to be unreasonably withheld), except that the Contractor is deemed to have such consent to sub-contract the supply of any Services to members of the Contractor's Group and, in respect of the Contractor's Group, will not be subject to Clause 18.2.

18.2 Subject to Clause 18.1 if consent to sub-contract is requested from the Authorised Officer:

18.2.1 the Authority may insist upon the production to it (inter alia) of all reasonable information and documentation relevant to

- a) the financial liability;
- b) competence; and



c) relevant experience of the proposed sub-contractor

as reasonable and valid conditions of their consent under Clause 18.1;

18.2.2 the contractor must warrant that appropriate and adequate insurance is in place for the life of the sub-contract and that the contractor and sub-contractor will fully comply with Clause 20;

18.2.3 the Contractor must engage the most appropriate and qualified sub-contractor to undertake the supply of the Services.

19 Limitation of liability

19.1 Neither Party shall be liable to the other Party for any loss or damage, costs or expenses incurred or suffered by the other Party as a result of any breach of the terms of the Contract, unless the same were in the reasonable contemplation of the Parties at the time when they entered into the Contract.

19.2 Except in the case of death or personal injury caused by negligence, and fraudulent misrepresentation or in other circumstances where liability may not be so limited under any applicable law, the liability of either Party under or in connection with the Contract, whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall not exceed the sum of £5 million in any one Year.

19.3 The Contract Price of the Services under the Contract has been negotiated and agreed on the basis that the Parties may limit their liability to each other as set out in the Contract and the Parties each confirm that they will themselves bear or insure against any loss for which the other Party has limited its liability under the Contract.

20 Insurance

20.1 The Contractor shall insure against its liability under Clause 19.2 with a minimum limit of indemnity of £5 million per annum or such other sum as may be agreed between the Authority and the Contractor in writing. The Contractor shall maintain professional indemnity insurance to cover all liability under the Contract and provide evidence of such professional indemnity insurance as the Authority may reasonably request from time to time.

20.2 The Contractor shall hold employer's liability insurance in respect of the Contractor's staff in accordance with any legal requirement for the time being in force.

21 Review

21.1 The Contractor shall attend formal, minuted review meetings (each such meeting being a "**Review**"), as required by the Authorised Officer, to discuss the Authority's levels of satisfaction in respect of the Services provided under the Contract and to agree any necessary action to address areas of dissatisfaction. The Contractor will not obstruct or withhold its agreement to any such necessary action. Such Reviews shall be attended by duly authorised and sufficiently senior employees of both the Authority and the Contractor together



with any other relevant attendees. The Parties shall agree a standing agenda for such Reviews.

22 Variation of the contract

- 22.1 Any variation to the terms of the Contract must be recorded in writing and executed by a director or company secretary (if the Contractor is a company) or an authorised signatory of the Contractor (if the Contractor is not a company) and the Authorised Officer. Such record of the variation in question must address all consequential amendments required to be made to the Contract as a result of such variation, including adjustment to the Contract Price.
- 22.2 Variations will take effect as from the date specified in the signed record of variation and shall not have retrospective effect unless expressly provided for in such record.
- 22.3 Each record of variation must be dated and sequentially numbered. Each of the Authority and the Contractor will be entitled to an original executed counterpart of the record of variation.
- 22.4 Save as provided in any such record of variation, the Contract will continue in full force and effect.

23 Variation of the Specification

- 23.1 The Authority may at any time propose to the Contractor any reasonable variation or addition to the Specification and the Contractor shall not unreasonably withhold or delay its consent to such variation.
- 23.2 No such variation or addition shall affect the continuation of the Contract.

24 Dispute Resolution Procedure

- 24.1 During any dispute, including a dispute as to the validity of the Contract, it is mutually agreed that the Contractor shall continue its performance of the provisions of the Contract (unless the Authority or any Beneficiary requests in writing that the Contractor does not do so).
- 24.2 If a dispute arises between the Authority or any Beneficiary and the Contractor in relation to any matter which cannot be resolved by the Authorised Officer and the Contractor Manager either of them may refer such dispute to the Dispute Resolution Procedure.
- 24.3 In the first instance each of the Authority or such Beneficiary and the Contractor shall arrange for a more senior representative than those referred to in Clause 24.2 to meet solely in order to resolve the matter in dispute. Such meeting(s) shall be minuted and shall be chaired by the Authority or such Beneficiary (but the chairman shall not have a casting vote). Such meeting(s) shall be conducted in such manner and at such venue (including a meeting conducted over the telephone) as to promote a consensual resolution of the dispute in question at the discretion of the chairman.
- 24.4 If the meeting(s) referred to in Clause 24.3 does not resolve the matter in question then the Parties will attempt to settle it by mediation in accordance



with the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure or any other model mediation procedure as agreed by the Parties. To initiate a mediation the Parties may give notice in writing (a "Mediation Notice") to the other requesting mediation of the dispute and shall send a copy thereof to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator. The mediation shall commence within 28 days of the Mediation Notice being served. Neither Party will terminate such mediation until each of them has made its opening presentation and the mediator has met each of them separately for at least one hour. Thereafter paragraph 14 of the Model Mediation Procedure will apply (or the equivalent paragraph of any other model mediation procedure agreed by the Parties). Neither Party to the mediation will commence legal proceedings against the other until 30 days after such mediation of the dispute in question has failed to resolve the dispute. The Parties will co- operate with any person appointed as mediator providing him with such information and other assistance as he shall require and will pay his costs, as he shall determine or in the absence of such determination such costs will be shared equally.

25 Environmental Considerations

- 25.1 The Contractor shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Services. Where the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Contractor shall comply with such agreements or codes of practices as if they were incorporated into English law subject to those voluntary agreements being cited in tender documentation.
- 25.2 Without prejudice to the generality of the foregoing, the Contractor shall:
- 25.2.1 comply with all reasonable stipulations of the Authority or any Beneficiary aimed at minimising packaging in which any products supplied by the Contractor to the Authority or any Beneficiary, as part of the performance, of the Services are supplied;
 - 25.2.2 promptly provide such data as may reasonably be requested by the Authority or any Beneficiary from time to time regarding the weight and type of packaging according to material type used in relation to all products supplied to the Authority or any Beneficiary under or pursuant to the Contract;
 - 25.2.3 comply with all obligations imposed on it in relation to any products supplied to the Authority or any Beneficiary as part of the performance of the Services by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (or any other equivalent legislation giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive 94/62/EC);
 - 25.2.4 label all products supplied to the Authority or any Beneficiary by the Contractor under the Contract and the packaging of those products, to highlight environmental and safety information as required by applicable UK and EU legislation;



- 25.2.5 unless otherwise agreed with the Authority or any Beneficiary, insofar as any products supplied under the Contract comprise or include electrical or electronic equipment, manage the said equipment and associated consumables at end of life to facilitate recovery, treatment, recycling and provide any information which the Authority or any Beneficiary may reasonably require from time to time regarding the costs of such activity;
- 25.2.6 promptly provide all such information regarding the environmental impact of any products supplied or used under the Contract as may reasonably be required by the Authority or any Beneficiary to permit informed choices by end users;
- 25.2.7 where goods are imported in to the UK then for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 the Contractor shall assume the rolled-up obligations for all activities performed outside the United Kingdom in relation to the goods and the packaging which is used for the containment, protection, handling, delivery and presentation of the goods in addition to any other obligations he may have pursuant to the said regulations.
- 25.3 The Contractor shall meet all reasonable requests by the Authority or any Beneficiary for information evidencing the Contractor's compliance with the provisions of this Clause.

26 Termination

- 26.1 The Authority may terminate the Contract (in whole or in part) by serving written notice on the Contractor in any of the following circumstances:-
- 26.1.1 a material failure (in whole or in part) by the Contractor to perform any material obligation of the Contractor under Clauses 2, 3, 4, 10, 11, 12, 17 18, 20, 22, 25, 29, 30, 35, 36, 37, 38, 39, 41 and 42 provided that (if capable of remedy) such failure has not been remedied to the Authority's reasonable satisfaction within a period of 30 days following written notice demanding remedy of the failure in question being served by the Authority on the Contractor; or
- 26.1.2 the Contractor fails (in whole or in part) to perform any material obligation of the Contractor owed to the Authority or any Beneficiary on more than 3 occasions; or
- 26.1.3 the Contractor becomes Insolvent or otherwise ceases to be capable of providing the Services; or
- 26.1.4 the Contractor is in default of any duty of care or any fiduciary or statutory duty owed to the Authority and/or any Beneficiary and/or any patient, employee or agent of the Authority or, as the case may be, any Beneficiary; or
- 26.1.5 there is a change of ownership or control of the Contractor which, in the reasonable opinion of the Authority will have a material impact



- on the provision of the Services or the image of the Authority; or
- 26.1.6 the Contractor purports to assign the Contract in breach of Clause 17; or
- 26.1.7 the Contractor shall have offered or given or agreed to give to any person any gift or consideration of any kind as an inducement or reward for doing or forbearing to do, or for having done or forborne to do, any action in relation to the obtaining or execution of the Contract or any other contract with the Authority or, as the case may be, any Beneficiary, or for showing or forbearing to show favour or disfavour to any person in relation to the Contract or any other contract with the Authority or, as the case may be, any Beneficiary; or similar acts have been done by any person employed by it or acting on its behalf (whether with or without the knowledge of the Contractor); or
- 26.1.8 if in relation to the Contract or any other contract with the Authority or, as the case may be, any Beneficiary the Contractor or any person employed by it or acting on its behalf shall have committed any offence under the Prevention of Corruption Acts 1889 to 1916, or shall have given any fee or reward to any officer of the Authority or, as the case may be, Beneficiary which shall have been exacted or accepted by such officer under colour of his office or employment and is otherwise than such officer's proper remuneration.
- 26.1.9 by giving the Contractor 3 months notice of its' intention to terminate the contract.
- 26.2 The Authority and any Beneficiary shall be entitled to recover from the Contractor the amount of any Loss resulting from termination under Clause 26.1 only where such Loss is a result of the Contractor's deliberate or negligent breach of this Contract. For the purpose of this Clause, Loss shall include reasonable cost to the Authority and any Beneficiary of the time spent by its officers in terminating the Contract and in making alternative arrangements for the provision of the Services.
- 26.3 The Contractor may terminate the Contract in the following circumstance, by giving 1 month's written notice:
- 26.3.1 if the Authority or any Beneficiary has committed a material breach of the Contract; and
- 26.3.2 the Contractor has brought the breach of Contract to the attention of the Authorised Officer; and
- 26.3.3 the Authority or such Beneficiary has not corrected the said breach of Contract within a reasonable period of time.
- 26.4 [INTENTIONALLY LEFT BLANK]
- 26.5 The Authority and the Contractor agree that termination (in whole or in part) or expiry of the Contract shall not affect either Party's obligations which the Contract provides shall survive the termination or expiry of the Contract or the continuance of the part or parts not terminated where the Contract is terminated



- 26.6 Any termination (in whole or in part) of the Contract will not prejudice the rights, obligations and duties of each Party arising prior to such termination taking effect.

27 Arrangements on Termination

- 27.1 The Authority and the Contractor agree that termination or expiry of the Contract shall not affect either Party's obligations which the Contract provides shall survive the expiration or termination of the Contract.
- 27.2 After termination or expiry all data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the Services ('**Services Information**') (including any Deliverables which remain to be completed as at the date of termination or expiry) and all other items provided on loan or otherwise to the Contractor by the Authority or, as the case may be, any Beneficiary shall be delivered by the Contractor to the Authority or, as the case may be, any Beneficiary provided that the Contractor shall be entitled to keep copies thereof to the extent that the information contained therein does not relate solely to the Services or to the extent that the Contractor is required by law to maintain copies thereof or to the extent that the Contractor was possessed of such data documents and records prior to the date of the Contract. This Clause 27.2 shall not apply to the extent that the Contractor is required to retain any Services Information in order to comply with any applicable laws (including without limitation any applicable data protection laws), regulations and guidelines (including without limitation any UKAS accreditations and guidelines of the Royal College of Pathologists for the retention and storage of pathological records and specimens).
- 27.3 The Contractor shall retain all papers, files, records and vouchers relating to the provision of the Services as provided for under Clause 27.2 for the period of 12 years after the date of the termination of the Contract and thereafter shall not destroy them but deliver them to the Authority or, as the case may be, any Beneficiary.
- 27.4 [INTENTIONALLY LEFT BLANK]
- 28** [INTENTIONALLY LEFT BLANK]
- 29** [INTENTIONALLY LEFT BLANK]



31 Intellectual Property

- 31.1 All Foreground Intellectual Property (excluding any intellectual property arising in the results from the pathology tests performed as part of the Services ("**Results IP**")) shall vest in and be owned absolutely by the Contractor and the Authority agrees to execute all documents and assignments and do all such things as may be necessary to perfect the Contractor's title to the Intellectual Property or to register the Contractor as owner of registrable rights. The Results IP shall vest in and be owned absolutely by the Authority and the Contractor agrees to execute all documents and assignments and do all such things as may be necessary to perfect the Authority's title to the Results IP or to register the Authority as owner of registrable rights. The Authority grants to the Contractor an irrevocable royalty free licence to use the Results IP for the purpose of performing its obligations under this Contract and complying with any applicable laws (including without limitation any applicable data protection laws), regulations and guidelines (including without limitation any UKAS accreditations and guidelines of the Royal College of Pathologists for the retention and storage of pathological records and specimens).
- 31.2 The Contractor hereby grants to the Authority an irrevocable royalty free licence to use the Foreground Intellectual Property for academic teaching and research purposes, including but not limited to academic publications, but not for commercial exploitation.
- 31.3 All Background Intellectual Property owned by either Party shall remain the property of that Party but the Contractor shall, where it has the right to do so, grant the Authority and any Beneficiary a non-exclusive, perpetual, royalty free, global license to use any Background Intellectual Property to the extent necessary for the purpose of the Services.
- 31.4 Should the grant of a licence of any of the Contractor's Background Intellectual Property be necessary in order for the Authority to exploit any Results IP, then the Contractor, in so far as it is able, may on request consent to grant a non-exclusive licence to the same to the extent necessary, such consent not to be unreasonably withheld or delayed, and on agreement of a reasonable royalty rate.
- 31.5 The Parties shall, in connection with each individual Order, be entitled to negotiate and agree provisions for the ownership of Intellectual Property Rights which deviate from Clauses 31.1 and 31.2 to the extent that the Parties agree that such other provisions are more suitable for the services under that Order.
- 31.5.1 Subject to Clause 19, the Contractor agrees to indemnify and keep indemnified the Authority and any Beneficiary against any costs, claims, proceedings, expenses and demands arising from the use, application, supply or delivery of any Deliverable, process, article, matter or thing supplied under the Contract that would constitute or is alleged to constitute any infringement of any person's Intellectual Property Rights, provided that the actual or alleged infringement does not arise in connection with any action or omission of the Authority and/or



- 31.6 The Contractor may publish details relating to the work undertaken pursuant to this Contract with the prior written permission of the Authority (such permission not to be unreasonably withheld or delayed). Title to and the right to determine the disposition of any copyrights or copyrighted material in journals, theses, dissertations or other such published materials produced in connection with this clause 31.7 shall remain with the publishing party.
- 31.7 Where the Contractor's liability under the indemnity in clause 31.5.1 arises out of or in connection with an actual or threatened third party claim against the Authority or any Beneficiary (the '**Claim**'), the Contractor's liability is conditional upon the Authority or the Beneficiary (as the case may be):
- 31.7.1 notifying the Contractor in writing of the Claim as soon as reasonably practicable, setting out particulars of the Claim;
 - 31.7.2 not making any admission of liability or settle the Claim or do anything which would prejudice the defence of the Claim without the prior written consent of the Contractor (such consent not to be unreasonably withheld);
- 31.8 giving the Contractor conduct of the Claim, and (at the Contractor's cost) providing such co-operation and assistance as the Contractor may reasonably require in the conduct of the claim.

32 Electronic Product Information

- 32.1 The Contractor shall provide the Authority or, as the case may be, any Beneficiary the Service Information in such manner and upon such media as agreed between the Contractor and the Authority or, as the case may be, any Beneficiary from time to time for the sole use by the Authority and any Beneficiary.
- 32.2 The Contractor warrants that the Service Information is complete and accurate as at the date upon which it is delivered to the Authority or, as the case may be, any Beneficiary and that the Service Information does not contain any data or statement which gives rise to any liability on the part of the Authority or, as the case may be, any Beneficiary following publication of the same in accordance with this Clause 31.1.
- 32.3 In the event the Service Information ceases to be complete and accurate, the Contractor shall promptly notify the Authority or, as the case may be, any Beneficiary in writing of any modification or addition to or any inaccuracy or omission in the Service Information.
- 32.4 The Contractor grants the Authority or, as the case may be, any Beneficiary a non-exclusive royalty free licence in perpetuity to use and exploit the Service Information and any Intellectual Property therein for the purpose of illustrating the range of goods and services (including, without limitation, the Services) available pursuant to the Authority or any Beneficiary contracts from time to time. No right to illustrate or advertise the Product Information is granted to the Contractor by the Authority or any Beneficiary as a consequence of the licence conferred by this Clause 32.4 or otherwise under the terms of this Contract.
- 32.5 The Authority or, as the case may be, any Beneficiary may reproduce for its



- 32.5 The use of the Service Information provided by the Contractor in the Authority's catalogue and/or any Beneficiary's catalogue from time to time which shall be made available on the National Health Service internal communications network in electronic format or made available on the Authority's external website and/or any Beneficiary's external website or any other electronic media of the Authority or any Beneficiary (as the case may be) from time to time.
- 32.6 Before any publication of the Service Information (electronic or otherwise) is made by the Authority or, as the case may be, any Beneficiary, the Authority or, as the case may be, any Beneficiary will submit a copy of the relevant sections of the Authority's catalogue or any Beneficiary's catalogue (as the case may be) to the Contractor for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Contractor shall have no right to compel the Authority or any Beneficiary to exhibit the Product Information in any product catalogue as a result of the approval given by it pursuant to this Clause 32.6 or otherwise under the terms of this Contract.
- 32.7 If requested in writing by the Authority or, as the case may be, any Beneficiary, the Contractor and the Authority or, as the case may be, any Beneficiary shall forthwith negotiate in good faith an agreement to use the Electronic Trading Systems.

33 Sales Information

- 33.1 If requested by the Authority or any Beneficiary, the Contractor shall provide the Authority or, as the case may be, any Beneficiary with statements giving accurate and complete details of the quantity and value of the Services provided by the Contractor to the Authority pursuant to the Contract. The frequency, format and level of detail to be included in such statements shall be as specified by the Authority in the Order (or, if no such description is set out in or attached to the Order, as set out in or attached to any documentation inviting the Contractor to tender for the appointment to provide the Services, including any documentation issued, or made available, to the Contractor by any Beneficiary).
- 33.2 The Contractor shall keep at its normal place of business detailed, accurate and up to date records of the quantity and value of the Services provided by it to any Authority or, as the case may be, any Beneficiary, on or after the date of the Contract and pursuant to the Contract together with accurate details of the identity of the Authority or, as the case may be, any Beneficiary to which such Services were provided. Subject to any other auditing process being agreed between the Authority or, as the case may be, any Beneficiary and the Contractor in writing, the Authority or, as the case may be, any Beneficiary shall be entitled by prior appointment to enter the Contractor's normal place of business during normal office hours and to inspect such records in order to verify whether any statement supplied by the Contractor to the Authority or, as the case may be, any Beneficiary pursuant to Clause 33.1 is accurate and complete.

34 Audit and Accounts

- 34.1 For the purpose of:
- 34.1.1 the examination and certification of the Beneficiary's accounts; or



- 34.1.2 any examination pursuant to section 6(1) of the National Audit Act 1983 or any re-enactment thereof of the economy, efficiency and effectiveness with which the Beneficiary has used its resources,
- 34.2 the Comptroller and Auditor General and the Beneficiary or its auditors may examine such documents as he may reasonably require which are owned, held or otherwise within the control of the Contractor and may require the Contractor to produce such oral or written explanation as he considers necessary. The Contractor acknowledges that it will fully cooperate with any counter fraud policy or investigation, whether carried out by the NHS Counter Fraud and Security Management Service, or any equivalent body, successor or function, at any time. For the avoidance of doubt it is hereby declared that the carrying out of an examination under Section 6(3)(d) of the National Audit Act 1983 or any re-enactment thereof in relation to the Contractor is not a function exercisable under this contract.

35 Confidentiality

- 35.1 The Authority, any Beneficiaries and the Contractor acknowledge that the content of this Contract is not Confidential Information. Notwithstanding any other term of this Contract, the Contractor hereby gives consent for the Authority and any Beneficiaries to publish the Contract in its entirety, including from time to time agreed changes to the agreement, to the general public. Limited redactions of specific contractual text on the grounds of national security, protection of personal privacy, IT security and the prevention of fraud are permitted.
- 35.2 Nothing in this Clause 35 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable law or as required by any governmental or regulatory authority or any relevant accreditation body or as necessary or, where the Contractor is the Recipient, (i) as necessary for the performance of the Contractor's obligations under this Contract or (ii) to the Contractor's immediate or ultimate holding company or any of the Contractor's Group, provided that the Contractor procures that such holding company or Group company complies with this clause 35 as if any reference to the contractor in this Clause 35 were a reference to such holding company.
- 35.3 The Contractor authorises the Authority and any Beneficiary to disclose the Confidential Information to such person(s) as may be notified to the Contractor in writing by the Authority from time to time to the extent only as is necessary for the purposes of auditing and collating information so as to ascertain a realistic market price for the Goods supplied in accordance with the Contract, such exercise being commonly referred to as "benchmarking". Subject to the provisions given in clause 35.1 above, the Authority and any Beneficiary shall use all reasonable endeavours to ensure that such person(s) keeps the Confidential Information confidential and does not make use of the Confidential Information except for the purpose for which the disclosure is made. The Authority and any Beneficiary shall not without good reason claim that the lowest price available in the market is the realistic market price.



35.4 The Contractor acknowledges that the Authority and Beneficiaries are or may be subject to the FOIA. The Contractor notes and acknowledges the FOIA and both the respective Codes of Practice on the Discharge of Public Authorities' Functions and on the Management of Records (which are issued under section 45 and 46 of the FOIA respectively) and the Environmental Information Regulations 2004 as may be amended, updated or replaced from time to time. The Contractor will act in accordance with the FOIA, these Codes of Practice and these Regulations (and any other applicable codes of practice or guidance notified to the Contractor from time to time) to the extent that they apply to the Contractor's performance under the Contract.

35.5 The Contractor agrees that:

35.5.1 without prejudice to the generality of clause 35.2, the provisions of this Clause 35 are subject to the respective obligations and commitments of the Authority and any Beneficiary (as the case may be) under the FOIA and both the respective Codes of Practice on the Discharge of Public Authorities' Functions and on the Management of Records (which are issued under section 45 and 46 of the FOIA respectively) and the Environmental Information Regulations 2004;

35.5.2 subject to Clause 35.5.3, the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for the Authority or a Beneficiary (as the case may be);

35.5.3 where the Authority or a Beneficiary is managing a request as referred to in Clause 35.5.2, the Contractor shall co-operate with the Authority or Beneficiary making the request and shall respond within five (5) working days of any request by it for assistance in determining how to respond to a request for disclosure.

35.6 The Contractor shall and shall procure that its sub-contractors shall:

35.6.1 transfer any request for information, as defined under section 8 of the FOIA, to the Authority or a Beneficiary as soon as practicable after receipt and in any event within five (5) working days of receiving a request for information;

35.6.2 provide the Authority or a Beneficiary with a copy of all information in its possession or power in the form that the Authority or a Beneficiary requires within five (5) working days (or such other period as the authority or a Beneficiary may specify) of the Authority or a Beneficiary requesting that information; and

35.6.3 provide all necessary assistance as reasonably requested by the Authority or a Beneficiary to enable the Authority or a Beneficiary to respond to a request for information within the time for compliance set out in section 10 of the FOIA.

35.7 The Authority or Beneficiary (as the case may be) may consult the Contractor in relation to any request for disclosure of the Contractor's Confidential Information in accordance with all applicable guidance.

35.8 This clause 35 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a



patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in the Contract, this Clause 35 shall remain in force for a period of 3 years after the termination or expiry of this Contract.

- 35.9 In the event that the Contractor fails to comply with this Clause 35, the Authority reserves the right to terminate the Contract by notice in writing with immediate effect.

36 Data Protection

- 36.1 When the Contractor processes Protected Data on behalf of the Authority and/or the Beneficiary in providing the Services the parties agree that the Authority will be the data controller and the Contractor will be the data processor. Schedule 2 to this Contract sets out when the Contractor processes Protected Data on behalf of the Authority. Clause 36.12 describes the circumstances where the Contractor will use Protected Data on its own behalf as data controller.
- 36.2 When the Contractor processes Protected Data as the data processor, clauses 36.4 to 36.11 (inclusive) will apply in relation to the Protected Data. Where the Contractor processes Protected Data as data controller, Clause 36.12 will apply instead.
- 36.3 The Authority will comply with the Data Protection Laws in relation to the Protected Data, and ensure that all instructions given by it to the Contractor in respect of Protected Data will at all times be in accordance with Data Protection Laws.
- 36.4 Processing instructions.
- 36.4.1 When the Contractor processes Protected Data as the data processor, the Contractor will comply with the obligations of data processors under Data Protection Laws.
- 36.4.2 Unless required to do otherwise by applicable law, the Contractor will (and will take steps to ensure each person acting under its authority will) process the Protected Data only in accordance with the Authority's documented instructions as set out in this Contract, Schedule 2 and any relevant Pathology Request (the "**Processing Instructions**").
- 36.4.3 If applicable law requires the Contractor to process Protected Data other than in accordance with the Processing Instructions, the Contractor will notify the Authority of any such requirement before processing the Protected Data (unless applicable law prohibits the Contractor from doing so).
- 36.4.4 The Contractor will promptly inform the Authority if the Contractor becomes aware of a Processing Instruction that, in the Contractor's opinion, infringes Data Protection Laws. The Contractor will have no liability for any processing in accordance with those Processing Instructions after giving the notice. The Contractor obligations under this clause 36.4.4 do not limit the Authority's obligations under clause 36.3.



36.5.1 In relation to the processing of the Protected Data, the Contractor 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.

36.6 Using staff and other processors.

36.6.1 The Contractor will not engage any data processor to process the Protected Data on the Authority's behalf (a "**Sub-Processor**") without the Authority's authorisation of that specific Sub-Processor. The Authority will not unreasonably withhold, condition or delay such consent. The Authority hereby authorises the appointment of the Authorised Sub-Processors.

36.6.2 The Contractor will ensure that each Sub-Processor that is appointed under clause 36.6.1 is appointed under a contract containing materially the same obligations as clauses 36.4 to 36.11 (inclusive).

36.6.3 The Contractor 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 the Contractor will, where practicable and not prohibited by applicable law, notify the Authority of any such requirement before such disclosure).

36.7 Assistance with the Authority's compliance and data subject rights.

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

36.7.2 The Contractor will provide such assistance as the Authority reasonably requires (taking into account the nature of processing and the information available to the Contractor) to the Authority in ensuring compliance with the Authority'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 Authority in response to any Personal Data Breach. The Authority will pay the Contractor's charges for providing the assistance in this clause 36.7, such charges to be calculated on a time and materials basis



at the Contractor's applicable daily or hourly rates in force from time to time.

36.8 International data transfers.

36.8.1 The Authority agrees that the Contractor may transfer Protected Data to countries outside the United Kingdom for the purpose of providing the Services, provided all transfers by the Contractor 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 Authority agrees that the Contractor may implement such safeguards by entering into standard data protection clauses authorised under the Data Protection Laws, which the Contractor may do as agent on behalf of the Authority. The provisions of clauses 36.4 to 36.11 (inclusive) will constitute the Authority's instructions with respect to transfers in accordance with clause 36.4.2.

36.9 Records, information and audit.

36.9.1 The Contractor will maintain, in accordance with Data Protection Laws binding on the Contractor, written records of all categories of processing activities carried out on behalf of the Authority.

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

- (a) giving the Contractor reasonable prior notice of such information request, audit and/or inspection being required by the Authority;
- (b) ensuring that all information obtained or generated by the Authority 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);
- (c) ensuring that such audit or inspection is undertaken during normal business hours, with minimal disruption to the Contractor's business, the Sub-Processors' business and the business of other customers of the Contractor.

36.10 Breach notification. the Contractor will, without undue delay notify the Authority of the Personal Data Breach involving the Protected Data, and provide the Authority with details of the Personal Data Breach.

36.11 Deletion or return of protected data and copies. the Contractor will, at the Authority's written request, either delete or return all of the Protected Data to



the Authority in such form as the Authority 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, the Contractor will inform the Authority of any such requirement). Where the Contractor will process that Protected Data as data controller under Clause 36.12, the Contractor may retain the Protected Data.

36.12 Protected Data that the Contractor processes as data controller.

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

- (a) 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
- (b) 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.

36.12.2 When the Contractor 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 Contract.

37 The Human Rights Act 1998

37.1 The Contractor shall, and shall use reasonable endeavours to ensure that its employees or agents and/or sub-contractors shall, at all times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998.

37.2 Subject to Clause 19, the Contractor agrees to indemnify and keep indemnified the Authority and any Beneficiary against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Contractor of its obligations under Clause 37.1.

38 Warranty

38.1 The Contractor warrants to the Authority that it has all necessary corporate standing and authorisation to enter into and be bound by the terms of the Contract. At all times in connection with the Contract, the Contractor shall be an independent contractor and nothing in the Contract shall create a relationship of agency or partnership or a joint venture as between the Contractor and the Authority or, as the case may be, any Beneficiary and accordingly the Contractor shall not be authorised to bind the Authority or, as the case may be, any Beneficiary.



39 Relationship of the Parties

- 39.1 The Contractor shall not incur any liabilities on behalf of the Authority or, as the case may be, any Beneficiary; or, make any representations or give any warranty on behalf of the Authority or, as the case may be, any Beneficiary; or, enter into any contract or obligation on behalf of the Authority or, as the case may be, any Beneficiary.

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41 Inducements to Purchase

- 41.1 The Contractor shall not offer to the Authority or any of its employees or agents or, as the case may be, any Beneficiary or any of its employees or agents as a variation of the Contract, or as an agreement collateral to it, any advantage other than a cash discount against the Contract Price or training of the employees of the Authority or, as the case may be, any Beneficiary in connection with the Services.

42 General

- 42.1 Save as required by law and/or the requirements of any relevant stock exchange and Clause 31.1, no publicity shall be made by any of the Parties relating to any matter in connection with the Contract without the prior written consent of the other Party.
- 42.2 The Contractor shall from time to time upon the request of the Authority, execute any additional documents and do any other acts or things which may reasonably be required to implement the provisions of the Contract.
- 42.3 Any provision of the Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.
- 42.4 The Contractor acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of the Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the Authority for any misrepresentation (whether made carelessly or not) or for breach of any warranty unless the representation relied upon is set out in the Contract or unless such representation was made fraudulently.
- 42.5 The failure by the Authority, the Contractor or, as the case may be, any Beneficiary to insist upon the strict performance of any provision, term or condition of the Contract or to exercise any right or remedy consequent upon the breach thereof shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.
- 42.6 Each Party shall bear its own expenses in relation to the preparation, execution and implementation of the Contract including all costs legal fees and other



expenses so incurred.

- 42.7 The Contractor warrants represents and undertakes to the Authority that there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Contractor and that there are no material contracts existing to which the Contractor is a party which prevent it from entering into the Contract; and that the Contractor has satisfied itself as to the nature and extent of the risks assumed by it under the Contract and gathered all information necessary to perform its obligations under the Contract and all other obligations assumed by it.
- 42.8 The rights and remedies provided in the Contract are cumulative and not exclusive of any rights or remedies provided by the general law, or by any other contract or document. In this provision "general law" includes the law of a country other than England, and "right" includes any power, privilege, remedy, or proprietary or security interest.

43 Third Party Rights

- 43.1 The Authority and the Contractor acknowledge that they have entered into the Contract for the benefit of each of the Beneficiaries and each of the Third Party Beneficiaries. Accordingly, the Authority and the Contractor agree that (in addition to the Authority's right to enforce the Contract) each of the Beneficiaries and each of the Third Party Beneficiaries may enforce any term of the Contract.
- 43.2 Save as provided in Clause 43.1 of the Contract, a person who is not a Party to the Contract shall have no rights pursuant to the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Contract.
- 43.3 All or any of the provisions of the Contract may be rescinded or varied by the Parties in their entirety or in part without the consent of or the need to give any notice to any person not a Party to it.

44 Third Party Beneficiaries

- 44.1 In the event that any Third Party Beneficiary wishes to enforce its rights under Clause 43.1 the following provisions shall apply:
- 44.1.1 the Third Party Beneficiaries shall have the same rights as the Beneficiaries under the Contract and shall comply with all the terms of the Contract which apply to the Beneficiaries;
- 44.1.2 the Third Party Beneficiaries shall not enter into any obligations in the name of the Authority or any Beneficiary and shall not make any representations or give any warranties on behalf of the Authority or any Beneficiary;
- 44.1.3 where Services are ordered by any Third Party Beneficiary the Contractor agrees that it shall supply such Services to such Third Party Beneficiary and invoices for the Services supplied to such Third Party Beneficiary shall be issued by the Contractor to, and in



the name of, such Third Party Beneficiary and such Third Party Beneficiary shall be liable for settlement thereof;

44.1.4 the Authority shall not be liable to any Third Party Beneficiary for any acts or omissions of the Contractor or for any loss, damage or other expenses incurred or suffered by any Third Party Beneficiary as a result of such Third Party Beneficiary exercising its rights under the Contract;

44.1.5 each Third Party Beneficiary undertakes to indemnify and keep indemnified the Authority and any Beneficiary from and against all costs, claims, demands, liabilities, damages, losses and expenses (including all legal expenses) incurred or suffered by the Authority or any Beneficiary:

a) arising out of or in connection with any act or omission of the Third Party Beneficiary or any breach of any term of the Contract by the Third Party Beneficiary;

b) as a result of any claim, loss, injury, damage, expense or delay suffered or incurred by the Contractor or any third party arising directly or indirectly from or in any way connected with the acts or omissions of the Third Party Beneficiary in enforcing its rights under the Contract, whether wilful, reckless, fraudulent, negligent, dishonest or otherwise;

and the Third Party Beneficiary shall at its own expense take out and maintain adequate insurance in respect of such liabilities and provide evidence of such insurance as the Authority may reasonably request from time to time;

44.1.6 in the event of any dispute:

a) between the Contractor and any Third Party Beneficiary relating to any act or omission of such Third Party Beneficiary or any breach of any term of the Contract by such Third Party Beneficiary;

b) between the Authority and any Third Party Beneficiary relating to the supply of goods and/or services by the Third Party Beneficiary to the Authority or any Beneficiary;

the Authority reserves the right to suspend such Third Party Beneficiary's rights under the Contract until such dispute has been resolved;

44.1.7 if the Contractor makes a claim against any Third Party Beneficiary for any act or omission of such Third Party Beneficiary or any breach of the Contract by such Third Party Beneficiary the Contractor agrees that it shall not include the Authority or any Beneficiary as a party to any proceedings against such Third Party Beneficiary;

44.1.8 the Authority shall notify any Third Party Beneficiary which is removed from the list set out in Schedule 1 and such Third Party



45 Equality and Non-discrimination

45.1 The Contractor shall not:

45.1.1 discriminate directly or indirectly or by way of victimisation or harassment against any person within the meaning of the Equality Act 2010;

45.2 The Contractor shall notify the Authority immediately of any investigation of or proceedings against the Contractor under the 2010 Act and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.

45.3 The Contractor shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under the 2010 Act due directly or indirectly to any act or omission by the Contractor, its agents, employees or sub-contractors.

45.4 The Contractor shall impose on any sub-contractor obligations substantially similar to those imposed on the Contractor by this Clause 45.

45.5 In addition to its obligations under this clause 45 relating to equality, the Contractor shall:

45.5.1 ensure that it complies with all current employment legislation and in particular, does not unlawfully discriminate within the meaning of the Equality Act 2010, or any other relevant legislation relating to discrimination in the employment of employees for the purpose of providing the Services. The Contractor shall take all reasonable steps (at its own expense) to ensure that any employees employed in the provision of the Services do not unlawfully discriminate within the meaning of this clause 45.5 and shall impose on any sub-contractor obligations substantially similar to those imposed on the Contractor by this Clause 45.5; and

45.5.2 in the management of its affairs and the development of its equality and diversity policies, the Contractor shall co-operate with the Authority in light of the Authority's obligations to comply with statutory equality duties. The Contractor shall take such steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age.

46 Notices

46.1 Any notice to be given under the Contract shall either be delivered personally, sent by facsimile or sent by first class recorded delivery post (airmail if



(overseas) or electronic mail. The address for service of each Party shall be its registered office or such other address as either Party may previously have notified to the other Party in writing. A notice shall be deemed to have been served:

- 46.1.1 if personally delivered, at the time of delivery;
 - 46.1.2 if sent by facsimile at the time of transmission;
 - 46.1.3 if posted, at the expiration of 48 hours or (in the case of airmail seven days) after the envelope containing the same was delivered into the custody of the postal authorities; and
 - 46.1.4 if sent by electronic mail, a telephone call is made to the recipient warning the recipient that an electronic mail message has been sent to him (as evidenced by a contemporaneous note of the Party sending the notice) and a hard copy of such notice is also sent by first class recorded delivery post (airmail if overseas) on the same day as that on which the electronic mail is sent.
- 46.2 In proving such service it shall 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 facsimile was transmitted on a tested line or that the correct transmission report was received from the facsimile machine sending the notice as the case may be.

47 Force Majeure

- 47.1 No Party shall be entitled to bring a claim for a breach of obligations under the Contract by the other Party or incur any liability to the other Party for any Loss or damages incurred by that party to the extent that a Force Majeure Event occurs and it is prevented from carrying out obligations by that event of force majeure.
- 47.2 In the occurrence of a Force Majeure Event, the Affected Party shall notify the other Party as soon as practicable. The notification shall include details of the Force Majeure Event, including evidence of its effect on the obligations of the Affected Party and any action proposed to mitigate its effect.
- 47.3 As soon as practicable, following such notification, the Parties shall consult with each other in good faith and use all reasonable endeavours to agree appropriate terms to mitigate the effects of the Force Majeure Event and facilitate the continued performance of the Contract.

48 Law

- 48.1 The Contractor submits to the jurisdiction of the English courts and agrees that the Contract is to be governed and construed according to English law.



SCHEDULE 1

Third Party Beneficiaries

[INTENTIONALLY LEFT BLANK]



SCHEDULE 2

1 Subject matter and nature of processing

1.1 The subject matter and nature of the Contractor's processing of the Protected Data are:

- 1.1.1 the people who have provided pathology samples using self-sampling cervical screening devices (the "**Subjects**"); and
- 1.1.2 test results from the Subjects who provided pathology samples analysed by the Contractor,

for the purpose of assisting the Authority with testing the operational and clinical performance of self-sampling cervical screening testing.

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 Gender
- 3.1.3 Age
- 3.1.4 Address
- 3.1.5 Phone number
- 3.1.6 Type of pathology tests conducted
- 3.1.7 Results of pathology test
- 3.1.8 Type of self-sampling device used

4 Categories of data subjects

4.1 The Protected Data concerns the Subjects and the clinicians who receive the Subjects' test results.

SCHEDULE 3

NNUH Cytology Costs & Budget for self sampling validation

[REDACTED]

Detailed breakdown of budget costs in page 2 and 3

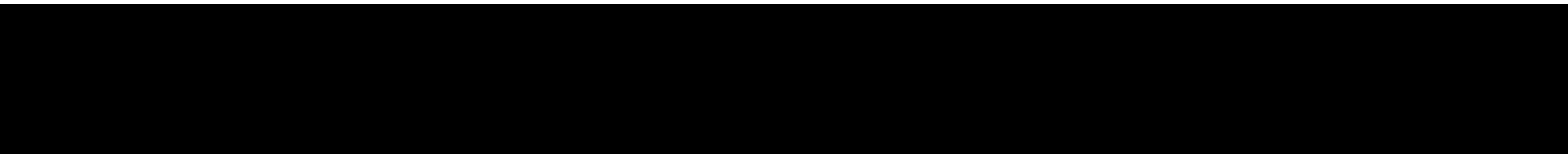
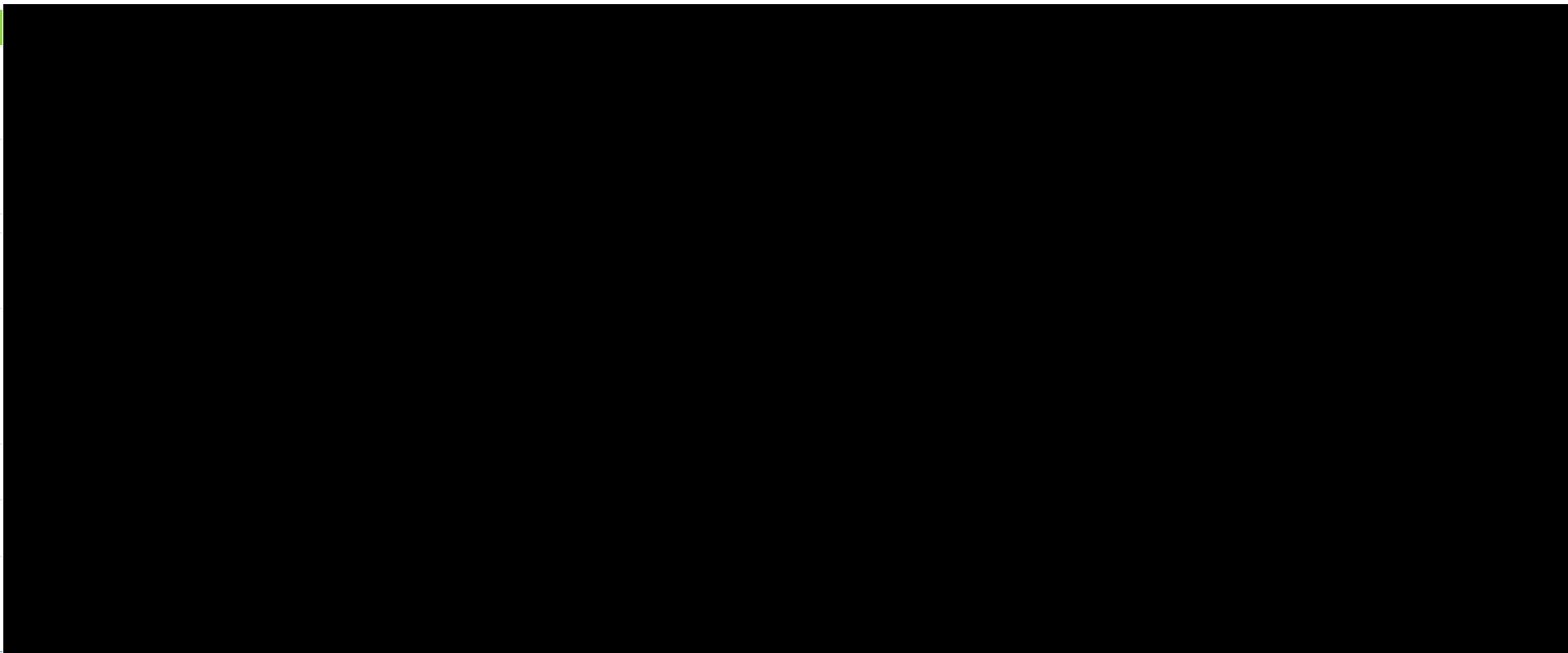
Summary of costs:

11

114

114







SCHEDULE 4

Confirmation of the allocated self-sample device/s and the laboratory study lead

Laboratory:	Cytology Laboratory
Site address:	Norfolk & Norwich University Hospitals NHS Foundation Trust Cytology department, Cotman Centre Colney Lane Norwich NR4 7UB
Self-sample device:	Rovers Medical Evalyn Brush
Platform:	Roche
Study Lead:	[REDACTED]
Costs: [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]



Validation of high-risk (hr) HPV test system using self-collected vaginal samples – Cervical screening laboratory selection

Purpose

Public Health England (PHE) is seeking to commission laboratories providing cervical screening testing to the NHS Cervical Screening Programme to:

1. Test the operational and clinical performance of self-sampling devices on their existing HPV test platform
2. Collate the test result and associated relevant data for analysis and transfer securely to PHE
3. Engage and communicate with PHE on the progress and issues relating to the execution of the study protocol. Provide a report at the end of the study on the operational performance of the self-sampling devices in combination with the HPV test platform
4. Where possible *support* in the creation of a sample archive that will facilitate evaluation of new HPV-associated technologies in the future, through the supply of samples residual to the validation

Background

Public Health England (PHE) is the expert national public health agency which fulfils the Secretary of State for Health's statutory duty to protect health and address inequalities and executes his power to promote the health and wellbeing of the nation.

PHE supports local authorities, and through them clinical commissioning groups, by providing evidence and knowledge on local health needs, alongside practical and professional advice on what to do to improve health, and by taking action nationally where it makes sense to do so.

Outline of Work

Up until December 2019, cervical screening was based on cytology, but the fundamental role of the Human Papillomavirus (HPV) high risk strains in the aetiology of cervical cancer, along with the introduction of the HPV vaccination programme



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presented a strong rationale for implementing primary HPV screening across England, reserving cytology testing for HPV positive women. Following a [recommendation from the UK NSC](#); a national programme of primary HPV screening was [fully implemented in England in December 2019](#).

Primary HPV screening is when the first test carried out on the sample looks for the human papillomavirus which can cause abnormal cells on the cervix. If HPV is detected a cytology test is used as a triage, to check for any abnormal cells. Please refer to the [cervical screening primary HPV screening implementation guide](#).

The move to primary HPV screening provides an opportunity to change the method of sample collection and allow women to self-collect a vaginal sample at home via a self-sampling device. Despite a [small increase in cervical screening coverage](#) over the last two years, it remains below the required standard especially in young women. Self-sampling provides opportunities to engage eligible women in the programme, reduce inequalities, increase participation and continue to reduce the incidence of cervical cancers.

An external review of HPV self sampling commissioned by the NHS National Screening Committee was published in March 2017¹. This was in response to a proposed recommendation that self sampling as a strategy to address non-attendance for cervical screening requires further study in well organised pilots and research projects. An additional consideration is whether self sampling should be an approach to routine screening in the national programme delivery.

The external review reported that;

- test performance is reasonable and may be useful as a failsafe for women who do not respond to screening invitations
- there is a low rate of inadequate samples for HPV testing
- there was an improvement in screening uptake, in most studies of between 10% and 20%
- some women did not use the kits but were prompted to attend for clinician testing

The review highlighted some limitations;

- cost effectiveness of self sampling has not been evaluated
- more information is needed on the circumstances in which this approach should be used, for example the length of time following an initial invitation the self screen should be offered
- more information is needed on how to offer the kit, for example by direct mailing

¹ UK NSC (2017), Cervical cancer screening – HPV self sampling, Costello Medical Consulting Ltd



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- to the home address compared to an offer to collect or order a kit
- the potential for a negative impact on the usual clinician offered screen was not explored

The NHS Cervical Screening Programme response is to conduct an evaluation of HPV self-sampling as a primary screening option for eligible women. Scotland and Wales are also interested in investigating how HPV self-sampling can improve engagement and efficiencies in their respective programmes. All evidence gathered will be reported back to the UK NSC.

In line with above, Kings College London in partnership with the North Central and East London cancer alliance will be offering HPV self-sampling to women who have not responded to their screening invitation and whose appointments are more than 6 months overdue. This is a study named YouScreen² and it aims to start engaging eligible women from December 2020 and will provide evidence to the UK NSC on the impact HPV self-sampling has on non-responders.

Studies on HPV self-sampling

Much of the evidence gathered so far comes from international studies, hence the call from the UK NSC for more information in the UK. Studies and evaluations conducted in Holland, Denmark, Australia and Sweden provide strong evidence for the use of HPV self-sampling in increasing programme coverage and addressing barriers to attending screening appointments based within clinical settings. The Netherlands, Malaysia and Australia all include HPV self-sampling in their national screening programmes, with Denmark due to follow later this year.

Several projects have reported on the uptake and performance of HPV self-sampling as a primary screening tool and on the performance of HPV self-sampling devices compared to clinician taken samples which have been synthesized into meta-analysis. However, at the time of preparation of this document, there is no manufacturer of a clinically validated HPV test to formally offer/approve a device for self collection to be used in combination with its particular HPV assay. Current evidence and practice indicate that many of the self-sampling devices and tests are currently being used off-protocol. This is one of the key issues that will be addressed for the purposes of this evaluation. It is important to assure the quality of the sampling and test so that women can be managed safely.

² <https://www.kcl.ac.uk/research/cptu>



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The English Cervical Screening Programme Approach

The evaluation will be completed in 3 phases:

- Phase 1: Clinical validation of an hrHPV test system based on self samples in NHS England commissioned laboratories
- Phase 2: Evaluation of HPV self-sampling in the English cervical screening programme
 - 2a) Design the pathway and processes for evaluation
 - 2b) Implementation of the evaluation
- Phase 3: A report of recommendations to inform the UK NSC on feasibility of full roll out across the programme

PHE will be responsible for detailed planning and management of the project from conception to delivery, working with a range of existing and new stakeholders to deliver this strategy, including NHS England who commission the laboratory services currently providing HPV primary screening testing across England.

Engagement with partner nations Scotland and Wales will also be maintained throughout the project so they can consider their contribution to the evaluation, its design and wider evidence gathering across the UK population.

Phase 1 Deliverables

To test the performance of self-sample devices they need to be compared with results obtained by a “gold standard” validated biospecimen, formally approved by the manufacturer for use with a particular HPV assay. For the purpose of the present validation, this will be a clinician taken cervical liquid-based cytology (LBC) sample. This will provide important information to the programme on the accuracy of self-sampling devices relative to existing, standard bio-specimens currently used by the programme.

Three self-sample devices have been selected after consideration by the laboratory technology subgroup :

- [Aptima Multitest](#) Swab (Hologic)
- [Evalyn Brush](#) (Rovers)
- [FLOQswab](#) (Copan)

Documents included that should be read in conjunction with this specification:

- Clinical validation protocol and laboratory workflows
- Protocol for sites taking part in this study
- The original expression of interest sent on 5 August 2020



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Please note the self-sample devices will be provided by PHE.

Please provide responses to the following questions:

1. Please state your preferred self-sample device
2. Please confirm the HPV test platform you intend to use in this study
3. Please confirm that you would be willing to assess a device that may not be your stated preferred option, but will be compatible with the HPV platform you use
4. Please state if you would be willing to test more than one self-sample device on your current platform
5. Please note that for the purpose of the validation self-samples cannot be requested electronically through an order comms method. Confirm that you are happy to take part in the study on this basis
6. Confirm you can provide an assessment of the operational performance of the chosen hrHPV test system after the required number of samples has been processed. To include:
 - pre-analytical aspects and ease of processing
 - environmental monitoring of the pre-analytical process
 - reliability of testing self-samples on hrHPV test system - sample/run failure rates
 - percentage of adequate self-sampling specimens
7. Provide an overview of capacity (existing or potential) for frozen storage of residual samples before transfer to a central archive at PHE
8. Provide a brief description of research and development the laboratory has been involved with in the last 5 years
9. PHE are planning to commence the validation no later than 31 March 2021. Please provide any relevant information that may impact on your preparations and readiness between now and 31 March 2021. This should include commentary on current delivery against national standards and the plans and timelines for addressing any areas where performance is not in line with national guidance. Please provide detail how you plan to mitigate against potential risks and issues



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Costs

The provider will need to give a detailed breakdown of their costs. Please note that applicants will need to demonstrate value for money. Please provide the following costs, exclusive of VAT:

Commercial envelope

1. Please provide a full breakdown of costs associated with any required set-up costs.

Please note items agreed will need to be purchased and invoiced by 31 March 2021.

Activity	Reason activity for	Grade of staff responsible	Cost
Total			

2. Please provide a full breakdown of costs associated with processing the self-samples. This may include but is not exclusive to:

- Additional equipment required to prepare and process samples
- Additional time/resource to check, prepare and process samples
- Logging and transfer of results for data analysis
- Preparation of samples for storage
- Stability testing of 50 samples (see clinical validation protocol)

As a guide we are expecting costs to fall between £10.00 - £20.00 per sample.

Activity	Reason activity for	Grade of staff responsible	Cost
Total cost per sample			



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3. Please provide full breakdown of costs associated with providing monitoring and feedback regarding, including an end of study report on the operational performance of the self-sampling device in combination with the HPV test platform throughout the contract period

Activity	Reason for activity	Grade of staff responsible	Cost
		Total	

Risk Management

Applicants should submit, as part of their application, a summary explaining what they believe will be the key risks to delivering this work, and what contingencies they will put in place to deal with them.

A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a project objective. All risks should be identified. The summary should include an assessment of each risk, together with a rating of the risk's likelihood and its impact on the key deliverables (using a high, medium or low classification for both). The risk assessment should also identify appropriate actions that would reduce or eliminate each risk, or its impact.

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Application Process

Applications should be submitted electronically to:

corporate.procurement@phe.gov.uk

and include the following documentation:

- A document setting out the responses to all the questions and data as described
- A document containing full cost breakdown for all required costs elements (exclusive of VAT)
- Supporting statement setting out and establishing suitability to undertake the required activities. If you have already submitted an expression of interest only submit additional relevant information you would like us to know
- Budget (including breakdown of spend)
- A document explaining what you believe will be the key risks to delivering this work, and what contingencies you will put in place to deal with them
- 1-page CVs of core team who will be responsible for the coordination, delivery and quality management of the work
- Word count (excluding Team CVs) is a max of 2,500 words per document.

Selection Criteria

Responses will be assessed on:

- strength of the application to fulfil all requirements
- quality of the responses
- ability to deliver without adversely affecting routine screening activity. This will include an assessment of data provided routinely to the Screening QA service.
- value for money (justification of the proposed costs)

All questions will be marked out of 20 with the following scoring definitions applied:

- 00-03 Unacceptable
- 04-08 Weak
- 09-12 Satisfactory
- 13-17 Good
- 18-20 Excellent



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Applications will be reviewed by an internal PHE panel and successful bidders will be informed electronically of the result.

Evaluators:

[REDACTED]

Delivery Timescale

	Target dates
Tender live	16/12/2020
Bidder questions and answers	21/12/20 – 08/01/21
Close applications	15/01/2021 at 4pm
Review applications	18/01/2021

Contract Period

The contract will aim to start on 1 February 2021 until 1 February 2022 as per the commissioning timetable below.

Standard break clauses for each contract will be enforced prior to the contract renewal.

Contact Point(s)

It is expected that the supplier will appoint a named, suitably qualified evaluation lead Manager who will be the main point of contact with Public Health England.

The key contact points at PHE will be:

[REDACTED]

Members of staff will be available for telephone or face to face advice throughout the contract period. PHE can facilitate discussions with other topics experts from within PHE and other key partners.