

DNA analysis at King's
Faculty of Life Sciences &
Medicine

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TERMS AND CONDITIONS

Please read this document carefully. It contains important information about this **CONTRACT** between the Liverpool Womens NHS Foundation Liverpool Womens NHS Foundation Trust and DNA analysis at King's [King's College London]'. This contract is annually reviewable.

1 THESE TERMS

- 1.1 These are the terms and conditions on which we will supply these services to you.
- 1.2 Please read these terms carefully. These terms tell you who we are, how we will provide products to you, how you and we may change or end the **CONTRACT**, what to do if there is a problem and other important information. If you think that there is a mistake in these terms [or require any changes], please contact us to discuss.

2 INFORMATION ABOUT US AND HOW TO CONTACT US

- 2.1 King's College London is a body incorporated by Royal Charter in England and Wales. Our principal address is Strand, London, WC2R 2LS. Our registered VAT number is GB 627 4035 51. DNA analysis at King's is the trading name of a non-profit making service run within King's College London and where all the business is conducted.
- 2.2 The testing laboratory is located at our Waterloo Campus. You can contact us by telephoning our customer service team at 0207 848 4130 (fax 0207 848 4129) or by writing to us at DNA analysis at King's, King's College London, Franklin Wilkins Building, 150 Stamford Street, London SE1 9NH, or emailing us at dna.analysis@kcl.ac.uk
- 2.3 If we have to contact you we will do so by telephone or by writing to you at the email address or postal address you provided to us.
- 2.4 When we use the word 'writing' or 'written' in these terms, this includes emails.

3 OUR CONTRACT WITH YOU

- 3.1 Our acceptance of a case will take place when you have registered your case with us and we have responded verbally and/or in writing. Our formal **CONTRACT** with you comes into existence once samples have been received.
- 3.2 If we are unable to accept your case, we will inform you of this in writing and will not charge you for the service. This might be because the client has been unable to supply the necessary identification documents with the samples that we require in order that we meet the requirements of the Human Tissue Act 2004. The latter makes it a criminal offence to hold human cellular material with the intention of analysing the DNA in it without informed **CONSENT**.

3.3 We do everything we can to meet reasonable specified deadlines, but sometimes we are unable to do so for reasons that we cannot control such as a) samples that have been poorly taken and do not contain enough material for us to analyse, b) delays in transit of samples or sampling kits or c) cases that require more extensive analysis than normal. In all cases we will attempt to resolve problems, which may involve us undertaking additional tests, requesting and waiting for additional family samples, or resampling an individual in the case.

4 OUR RIGHT TO MAKE CHANGES

4.1 We may change the product: (a) to reflect changes in relevant laws and regulatory requirements and (b) to implement minor technical adjustments and improvements. These changes will not detriment the outcome of the case.

4.2 In addition we may make changes to our terms, but if we do so we will notify you. You may then contact us to end the CONTRACT before the changes take effect. All received case samples will be completed.

5 YOUR RIGHT TO MAKE CHANGES

5.1 If you wish to make a change to your requirements please contact us and we will let you know if that change is possible and give you an idea of any timelines. If we cannot make the change or the consequences of making the change are unacceptable to you, you may want to end the CONTRACT.

6 OUR SERVICE

6.1 This Service provides information about a person's identification in the form of DNA. Its main purpose is to compare this genetic information in order to seek, confirm or refute a familial relationship with another individual on the Donor Conceived Register (the REGISTER).

6.2 We are registered on the Ministry of Justice list of approved laboratories that can carry out DNA tests to solve a legal dispute about whether someone is the parent of a child.

6.3 We are a body accredited by the United Kingdom Accreditation Service (UKAS) for relationship testing services (UKAS No: 7850) and meet the international standards set out in ISO17025 for a testing laboratory. We follow industry standards recommended to us by the International Society of Forensic Genetics and the UK Human Genetics Commission.

6.4 For ethical and privacy reasons we will not undertake whole autosomal DNA testing.

6.5 We will hold a secure database of the genetic results of all individuals who have been sampled and analysed by us as part of the REGISTER and any other genetic information that has been forwarded to us by the LIVERPOOL WOMENS NHS FOUNDATION TRUST or individuals on the REGISTER.

6.6 On completion of the initial tests in a case we will compare the DNA profiles with all others on the REGISTER and communicate the outcome to the LIVERPOOL WOMENS NHS FOUNDATION TRUST administrator for follow on consideration relating to the credibility of the finding and further instructions to us.

6.7 In consultation with the LIVERPOOL WOMENS NHS FOUNDATION TRUST possible familial links will not be revealed unless a likelihood of that relationship in comparison with another (LR) is numerically less than 50 (times more likely). LRs approaching 50 will be examined further using both genetic and non-genetic tools in order to examine the credibility of a potential link.

7 DEFINITIONS

- 7.1 CONTRACT** – a binding **CONTRACT** for the Service between the Client and us (DNA analysis at King's) in accordance with and subject to these terms and conditions.
- 7.2 CLIENT** – the individual or organisation using the Service.
- 7.3 LIVERPOOL WOMENS NHS FOUNDATION TRUST** – the **CLIENT** organisation – and regulated by the Human Fertilisation and Embryology Authority (HFEA)
- 7.4 REGISTER** – the Donor Conceived Register
- 7.5 SERVICE** – the DNA testing service offered by DNA analysis at King's.
- 7.6 LABORATORY** - the physical location where we conduct the tests and associated administration.
- 7.7 CONSENT** - the giving of informed consent by the **DONOR** or a person acting legally on behalf of a **DONOR** who is a minor, or who lacks mental capacity, in accordance with the Mental Capacity Act 2005, or in relation to material from a deceased, in accordance with the Human Tissue Authority (HTA) publication 'Code of Practice 1: Consent' – the **CONSENTEE**.
 - 7.7.1** No sample will be tested without a valid **CONSENT** form accompanied by appropriate identification for all **DONORS** being sampled and any **CONSENTEE** recording **CONSENT**.
 - 7.7.2** Appropriate identification is official photographic identification, such as a passport or photographic driving licence. Identification for minors without a passport requires their full birth certificate, naming the mother, and the NHS 'Red Book' or NHS Medical Card, for a child born in the UK, or the birth document issued in the country of birth.
- 7.8 DONOR** - the person providing a biological sample for DNA testing in accordance with these terms and conditions. This is in contrast to gamete donors who are registrants on the **REGISTER**
- 7.9 SAMPLER** – the individual who collects the sample from the **DONOR**, an accredited medical or legal practitioner or individual who has received appropriate training
- 7.10 STATUTORY DECLARATION** – a written statement of fact that is signed in the presence of a Solicitor, a Notary of the Public, a Justice of the Peace, or a Commissioner for Oaths.
- 7.11 TEST** – the series of DNA tests that we undertake in order to answer the question posed
- 7.12 TEST REPORT** – the written document that summarises or details the **TESTS** that have been undertaken and provides an answer (inconclusive or not) to the question being asked.

8 PAYMENT

- 8.1** All fees quoted are exclusive of VAT and will be at the level of £80 per sample from 1 November 2017 and invoiced on a monthly basis.
- 8.2** Sampling within our sampling clinic at King's College London will be charged at £35 per individual. Clients who attend our clinic and for whom we have to collect additional samples will be sampled free of charge. Travelling, if requested, to collect samples elsewhere will be charged separately. External samplers may charge an additional and separate fee for their service.
- 8.3** We take all reasonable care to ensure that the fees advised to you are correct. If we discover an error in the fee for the services you order we will contact you for additional payment, if that is due, or to make arrangements to refund monies if you have overpaid.
- 8.4** We will not charge extra for any additional tests that we consider will help to provide a satisfactory answer to the service you are requesting.

- 8.5 DNA analysis at King's will provide sampling kits free of charge to yourselves or any designated independent sampler but will not provide sampling kits to, or test samples received directly from any person taking part in the test (unless this sampling is required to collect additional material from a previous independently collected sample). Clients requesting kits to be sent overseas will be charged an additional fee to cover the relevant courier cost, dependent on location. Clients will be informed of the expected courier fees current at the time.
- 8.6 We will not be responsible for sampling fees charged by independent parties.
- 8.7 Provision of a sample accompanied with a valid CONSENT form and appropriate identification gives rise to a CONTRACT with us to conduct the agreed tests and will be deemed to give authority to commence the process and incur the agreed fees.
- 9 PROVIDING THE SERVICE**
- 9.1 All tests will be conducted in duplicate prior to provision of the TEST REPORT.
- 9.2 If our performance of the service is affected by an event outside our control then we will contact you as soon as possible to let you know and we will take steps to minimize the effect of the delay. Provided we do this we will not be liable for delays caused by the event but if there is a risk of substantial delay (other than for genetic reasons) you may contact us to end the contract and receive a refund for the services have been paid for, but not received.
- 9.3 Testing times are variable but we will take all reasonable steps to produce a report as soon as possible. There are several reasons why reports may take extended periods of time:
- 9.3.1 Delays in receipt of samples from an external provider.
- 9.3.2 Receipt of poor quality samples from an outside provider. We will make special efforts to extract DNA of a suitable quality before requesting new samples in order to limit additional fees for repeat sampling and courier fees, as needed.
- 9.3.3 DNA testing that involves testing relationships other than a donor-donor-conceived relationship.
- 9.3.4 DNA testing that that has revealed one of more genetic inconsistencies, such that a conclusion cannot be reached without additional testing.
- 9.3.5 DNA testing that has not resolved the question being asked to our satisfaction without additional testing being undertaken.
- 9.3.6 Specialist DNA tests being required: X and Y chromosome tests, mitochondrial DNA, single nucleotide polymorphisms.
- 9.4 TEST REPORTS, consisting of a letter of explanation and any genetic results, will be provided only in writing and sent by first class post and/or by email (as advised) to the address provided in the consent form or the instructing client otherwise requesting the report.
- 9.5 Genetic information will be provided only to the adult parties involved in the TEST and not the LIVERPOOL WOMENS NHS FOUNDATION TRUST unless consent is provided by the individuals concerned, or for essential confidential reasons as agreed between the LIVERPOOL WOMENS NHS FOUNDATION TRUST and DNA analysis at King's. A summary of the test results will be provided to the LIVERPOOL WOMENS NHS FOUNDATION TRUST for them to authorize release of the TEST REPORT.
- 9.6 Consent can be withdrawn and both files and/or samples will be destroyed on receipt of a written request at any time from any party providing the original CONSENT. We reserve the

right to request provision of certain information in order for us to gauge the validity of the request.

10 SUSPENSION OF SERVICES

- 10.1 The normal service will be suspended from two working days prior to December 25th in any year until the next working day after Jan 1st in any year.
- 10.2 We may have to suspend the services at other times to:
 - 10.2.1 Deal with technical problems or make minor technical changes;
 - 10.2.2 Update the services to reflect changes in relevant laws and regulatory requirements;
 - 10.2.3 Make changes to the services as requested by you or notified by us to you.
- 10.3 We will contact you in advance to tell you we will be suspending the services (other than detailed in clause 10.1), unless the problem is urgent or an emergency. You may contact us to end the contract if we suspend the services or tell you we are going to suspend them, in each case for a period of more than one week and we will refund any sums you have paid in advance for services not provided to you.
- 10.4 We reserve our right to suspend the service to you for non-payment.

11 YOUR RIGHTS TO END THE CONTRACT

- 11.1 You have 12 weeks after the day of your contract with us to end the contract. However, once we have completed the services you cannot change your mind, even if the period is still running. If you cancel after we have started the services, you must pay us for the services provided up until the time you tell us that you have changed your mind.
- 11.2 Your request to end the contract must be provided in writing, by post or email and we will acknowledge your request in writing, by post or email.
- 11.3 We will make any refunds due to you as soon as possible. If you are exercising your right to change your mind then your refund will be made within 14 days of your telling us that you have changed your mind.

12 OUR RIGHTS TO END THE CONTACT

- 12.1 We may end the contract at any time by writing to you if:
 - 12.1.1 You do not make any payment to us when it is due and you still do not make payment within 60 days of us reminding you that payment is due.

13 ENDING THE CONTRACT

- 13.1 Retained sample, files and genetic information will be forwarded to the LIVERPOOL WOMENS NHS FOUNDATION TRUST, or any agency appointed by the LIVERPOOL WOMENS NHS FOUNDATION TRUST as directed and within three months of the CONTRACT end.

14 IF YOU WITH TO COMPLAIN ABOUT THE SERVICE

- 14.1 If you have any questions or complaints about the services, please contact us. You can contact us by telephoning our service team at +44 (0)207 848 4130 or by writing to us at dna.analysis@kcl.ac.uk or DNA analysis at King's Franklin Wilkins Building, King's College, 150 Stamford Street, London SE1 9NH.
- 14.2 Please detail your complaint in writing and this will be considered under our complaints policy which is provided as Appendix A.

- 15 OUR RESPONSIBILITY FOR LOSS OR DAMAGE SUFFERED BY YOU YOUR CLIENTS**
- 15.1** DNA analysis at King's aims through its quality management and double testing processes to provide tests that are highly accurate but, as with any testing, there is always the possibility of error or omission. In the event of the client being able to establish a claim for damages resulting from any act of DNA analysis at Kings', whether negligent or otherwise, our liability will not exceed £1000, or the cost of the test if higher.
- 15.2** According to the CME Unfair Terms Guidance, fairness is more likely to be achieved by excluding liability for:
- 15.2.1** Losses that were not foreseeable to both parties when the contact was formed;
- 15.2.2** Losses that were not caused by any breach on the part of the trader;
- 15.2.3** Business losses, and/or losses to non-consumers
- 15.3** The rights of the client will be subject to the client notifying us in writing of any error of omission within thirty days of the test report
- 15.4** These terms and conditions do not seek to exclude liability in relation to person injury or death caused by our negligence or the negligence of our employees, agents or subcontractors; for fraud or fraudulent misrepresentation; for breach of your legal rights including the right to receive services which are as described and supplied with reasonable skill and care.
- 15.5** Audits are conducted by DNA analysis at King's on a regular basis and if these reveal any subsequent error then the clients will be informed in writing and, depending on the impact of these errors, the laboratory may offer a full or partial refund of the test fee.
- 16 JURISDICTION**
- 16.1** Which laws apply to this contract and where you may bring legal proceedings.
- 16.1.1** These terms are governed by English law and you can bring legal proceedings in respect of the services in the English courts.
- 16.1.2** If you live in Scotland you can bring legal proceedings in respect of the services in the either the Scottish or the English courts.
- 16.1.3** If you live in Northern Ireland, you can bring proceedings in respect of the services in either the Northern Irish or the English courts.

Dated: 1 June 2019

For review: 31 May 2020

APPENDIX A

COMPLAINTS

1.0 POLICY

The Laboratory will respond to all complaints in a timely and appropriate fashion. A complaints form will be used to record any pertinent information relating to the complaint and give details of dates and outcome. Forms are available on all computers and in a folder in the scientist's writing area. Forms will be retained, with copies of all correspondence, within the complaints file and a reference placed to this on the client's blue sheet.

Complaints made in writing must be responded to in writing (or email) within two working days of receipt, or as soon as possible if the Head of Section is absent in circumstances where the letter is directed to the Head, setting out the expected timeline for investigation of the complaint and letting the client know when they will expect a reply.

If complaints are received by telephone, or in person, the nature of the complaint should be recorded on the complaints form and referred to the Head of Section, who will telephone, email, or speak personally to the client as soon as possible after this. In the absence of the Head of Section either of the Senior Scientists or a member of the administration team will be responsible for making the initial response until the Head of Section's return.

The client will be offered the opportunity to put the complaint in writing, to be dealt with on a formal basis.

If the response to the client is not accepted, the case will be referred to the Divisional Head for advice and direction.

Consideration must be given to all complaints as to whether or not they are the consequence of a non-conforming issues. Such complaints must be escalated using the non-conforming issues policy.

2.0 BACKGROUND

There may be occasions when the laboratory is contacted by clients who wish to raise concerns or complaints about the service they have received. This document details the procedures and processes that the laboratory should undertake in order to investigate and clarify any problems, resolve any issues and identify what corrective actions should follow.

3.0 RESPONSIBILITY

This procedure may be undertaken by members of staff who have undergone a period of training where that is required. The operator has the responsibility of performing the task strictly in accordance with this quality document. Deviation from this without prior consultation with the Head of Section is not permitted.

4.0 TRAINING

The supervisor must ensure that the operator has received adequate training in all aspects of the procedure. The operator must ensure that all training given has been understood and has been received at a level sufficient to enable working to a high standard without supervision.

5.0 CLIENT COMPLAINT PROCEDURE

5.1 There is a multiplicity of reasons why a client may contact a laboratory with a concern or complaint. Compliance with the requirements detailed in the quality manual will minimise these.

Regardless of fault the client should be made aware that this will be taken seriously and they should be dealt with in a professional and compassionate manner. All issues must be detailed in the client's case file, logged on a complaints form and referred to the Head of Section (or appropriate person).

5.2 All complaints will be investigated by the Head of Section (Quality Manager) or one of the Deputy Quality Managers on the direction of the Head of Section. Complaints against the Head of Section will be referred to the Head of Department.

5.3 Customers disputing a reported result will be offered further testing or re-testing for re-assurance. Such action should only become necessary following consultation with the customer to ensure that the report has been correctly interpreted.

Extra testing may be offered if the results reported are believed correct, but it is also thought that the clients are unduly stressed by the result and would be re-assured by further testing. This is done under the discretion of the Head of Section.

Extra or re-testing will be offered or undertaken if an element of reasonable doubt becomes apparent from quality tests recorded at the time of testing.

Re-testing of fresh samples will be offered if it is believed that samples have become degraded as a result of failure in sampling, delay in sample arrival, failure of laboratory procedures, or failure of equipment in use during the processing period.

Retests or additional testing will always be undertaken free of charge in the above circumstances.

The laboratory will inform the client concerning the possibility of obtaining a second opinion from another accredited laboratory and be offered a list of contact details of laboratories within the UK that provide an accredited service.

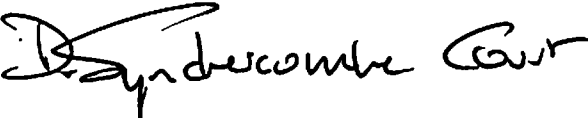
5.4 Customers complaining of excessive waiting time before the release of test results should be assured that we endeavour to meet our estimated time of testing, but these are not guaranteed. Delays due to unforeseen circumstances will not be compensated, provided the client is kept appropriately informed of the delay. Compensation, at the discretion of the Head of Section, should be considered in cases where it is considered that the laboratory is at fault. Typically this may involve a refund of 25 - 50% of the relevant client costs.

5.5 The Head of Section is responsible for communicating with the client in order to resolve any issues that have been raised. The Head of Section will offer the client an opportunity for a face to face meeting. Ideally the results of any investigation of a complaint and the corrective actions that will be taken should be communicated in writing to the client, although it is acknowledged that some clients will not wish to receive a written report and would prefer to discuss this over the telephone

or at a meeting. Regardless, the issues and action taken should be detailed within the complaints file and the reasons for not providing the client with a written report provided here also.

5.6 All complaints will be discussed at routine staff meetings and reviewed at the annual management meeting.

 DANIEL NASH DIVISIONAL MANAGER 10.9.2019.
GYNAECOLOGY


D. SINDERCOMBE COURT, Professor of
Forensic Genetics, King's Forensic 16.9.19