NHS Standard Contract 2021/22

Particulars (Shorter Form)

Contract title / ref: ***NIPT Service***

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Contract Reference	**NIPT Service Project_6321**
DATE OF CONTRACT	**30 July 2021**
SERVICE COMMENCEMENT DATE	**01st July 2021**
CONTRACT TERM	**2 years 11 months commencing 01st July 2021**
COMMISSIONERS	**Public Health England**
CO-ORDINATING Commissioner	**Public Health England**
PROVIDER	**North Thames Genomic Laboratory Hub (GLH)**

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Definitions and Interpretation

CONTRACT

Contract title: NIPT Service

Contract ref: Project_6321

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**;
2. the **Service Conditions (Shorter Form)**;
3. the **General Conditions (Shorter Form)**,

as completed and agreed by the Parties and as varied from time to time in accordance with GC13 (*Variations*).

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by	[redacted] ..... **Signature**
[INSERT AUTHORISED SIGNATORY'S NAME] for and on behalf of Public Health England	[redacted] Health Improvement Directorate ..... **Title** 07/09/21 ..... **Date**
[INSERT AS ABOVE FOR EACH COMMISSIONER]	
SIGNED by	[redacted] ..... **Signature**
[redacted] **for and on behalf of GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST**	**CFO** ..... **Title** **06/09/21** ..... **Date**

SERVICE COMMENCEMENT AND CONTRACT TERM	
Effective Date	01st July 2021
Expected Service Commencement Date	01st July 2021
Longstop Date	Not Used
Service Commencement Date	01st July 2021
Contract Term	2 years 11 months commencing 01st July 2021
Option to extend Contract Term	NO
Notice Period (for termination under GC17.2)	6 months
RE NIPT DPIA.msg SERVICES	
Service Categories	**Indicate all that apply**
Continuing Healthcare Services (including continuing care for children) (CHC)	Not Applicable
Community Services (CS)	Not Applicable
Diagnostic, Screening and/or Pathology Services (D)	Yes
End of Life Care Services (ELC)	Not Applicable
Mental Health and Learning Disability Services (MH)	Not Applicable
Patient Transport Services (PT)	Not Applicable
Co-operation with PCN(s) in service models	
Enhanced Health in Care Homes	NO
Service Requirements	
Essential Services (NHS Trusts only)	NO
Is the Provider acting as a Data Processor on behalf of one or more Commissioners for the purposes of the Contract?	YES

PAYMENT	
National Prices apply to some or all Services (including where subject to Local Modification or Local Variation)	**NO**
Local Prices apply to some or all Services	**YES**
Expected Annual Contract Value agreed	**YES for Year 1 (11 months ending 31st May 2022) only, with no maximum cap**
GOVERNANCE AND REGULATORY	
Provider's Nominated Individual	[redacted] Email: [redacted] Tel: [redacted]
Provider's Information Governance Lead	[redacted] Email: [redacted] Tel:
Provider's Data Protection Officer (if required by Data Protection Legislation)	[redacted] Email: [redacted] Tel:
Provider's Caldicott Guardian	[redacted] Email: [redacted] Tel:
Provider's Senior Information Risk Owner	[redacted] Email: [redacted] Tel:
Provider's Accountable Emergency Officer	[redacted] Email: [redacted] Tel: [redacted] Mob: [redacted]
CONTRACT MANAGEMENT	
Addresses for service of Notices	**Commissioner: Public Health England** **Address: Wellington House, 133-155 Waterloo Road, London, SE1 8UG** **Email:** [redacted] **Provider:** Great Ormond Street Hospital for Children NHS Foundation Trust **Address:** Great Ormond Street, London WC1N 3JH **Email:** notices@gosh.nhs.uk
Commissioner Representative(s)	[redacted] **Address: Wellington House, 133-155 Waterloo Road, London, SE1 8UG** **Email:** [redacted] **Tel:** [redacted]
Provider Representative	[redacted]

	Address: Great Ormond Street Hospital for Children NHS Foundation Trust, London WC1N 3JH Email: [redacted] Tel: [redacted]

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents and complete the following actions:

1.	Not applicable

C. Extension of Contract Term

To be included only in accordance with the Contract Technical Guidance.

NOT USED

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service specification set out below

SCHEDULE 2 – THE SERVICES

B. Service Specifications

Service Specification No.	Final 3.0
Service	Genomic Laboratory Non-invasive prenatal testing ("**NIPT**") Service
Commissioner Lead	[redacted] Public Health England ("**PHE**")
Provider Lead	[redacted], Medical Director, NHS North Thames Genomic Laboratory Hub
Period	01/07/2021 – 31/05/2024 (Evaluative Rollout)
Date of Review	*As detailed throughout specification and TBC*
Definitions	"**NIPT Service Provider**" means the contract holder for the NIPT service. In this agreement this is the Genomic Laboratory Hub (GLH). "**NIPT Laboratory Provider**" means the laboratory providing the testing, analysis and reporting of the NIPT sample, where this is different from the NIPT Service Provider.

1 Population Needs

1 Context and evidence base

1.1.1 The UK National Screening Committee ("**UK NSC**"), through the NHS Fetal Anomaly Screening Programme ("**NHS FASP**") has recommended that NIPT be assessed as an additional option to the current screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome for women with chance results greater than or equal to 1 in 150 (1 in 2 to 1 in 150).

1.1.2 The recommendation from the UK NSC is to undertake an evaluative approach to introducing the offer of NIPT, as an additional option, for those women with a higher chance result of 1 in 2, to 1 in 150 following combined or quadruple screening.

1.1.3 The UK NSC commissioned a full review of the published scientific and cost evidence (systematic review) relating to NIPT. This was presented to the UK NSC in June 2015. A formal announcement following the UK NSC recommendations was made by the Department of Health on 29 October 2016. Please see the PDF at the following hyperlink for a brief summary on the purpose of non-invasive prenatal testing from the UK NSC; https://legacyscreening.phe.org.uk/policydb_download.php?doc=602.

1.1.4 A further review was undertaken in 2019 to include the offer of NIPT screening in twin pregnancies as part of the evaluation roll-out. In addition, the UK NSC also updated the approved technology for use in NIPT screening as an additional option to the current screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome for women with chance results greater than or equal to 1 in 150 (1 in 2, to 1 in 150). The NIPT Laboratory Provider must supply the class of tests which were evaluated in the two Warwick reviews. These were based on sequencing and microarray methodologies. Elements of the test process may be modified but the overall methodology must remain sequencing and microarray based. This will be effective for the duration of the Contract.

1.1.5 NIPT is a technique that can be used to screen for Down's syndrome, Edwards' syndrome and Patau's syndrome during pregnancy. It involves taking a sample of blood from the pregnant woman. The mother's blood contains a mixture of her DNA and the placental DNA. This is known as the total cell free DNA ("**cfDNA**"). In most cases, the placental DNA will be the same as the baby's DNA. The contribution of DNA from the placenta is called cffDNA.

1.1.6 cffDNA can be detected in maternal plasma as early as 5 to 7 weeks gestation. However, test results are more accurate after 10 weeks because the amount of cffDNA increases over time. cffDNA remains in the maternal circulation for only a few hours after each pregnancy, making it suitable for pregnancy-specific testing.

1.1.7 The evaluative roll-out will last for three years after which recommendations will be made by the UK NSC about the future commissioning arrangements for NIPT.

2 Outcomes

2.1 Public Health England Responsibilities

2.1.1 PHE is the expert national public health agency, providing the evidence, support and advice needed locally, nationally and internationally. PHE fulfils certain key Secretary of State for Health and Social Care duties and remains responsible for four critical functions (1) protecting the public's health; (2) improving the public's health; (3) improving population health by supporting sustainable health and care services; and (4) supporting the capacity and capability of the public health system in England. PHE's broader priorities include support and advice on the Government's prevention and levelling up priorities, specifically including work on childhood obesity, mental health, smoking, health inequalities and the needs of the most vulnerable groups in society, and NHS-led national screening programmes. These priorities are set out in an annual strategic remit letter: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/882570/PHE_Remit_Letter_from_Jo_Churchill_to_Duncan_Selbie.pdf.

2.2 Specific defined outcomes

2.2.1 For clarity the service will be an evaluative roll-out. The NIPT Service Provider will be expected to provide feedback and information reporting as set out in paragraph 8 (Data Reporting) of this Service Specification, as well as adapting the Services as required by PHE throughout the Term of the Contract. This will enable the programme leads to evaluate the roll-out at the stage identified in paragraph 8 (Data Reporting) of this Service Specification; ensuring any required changes to the pathway and/or screening process can be made efficiently and effectively. If it becomes necessary, the UK NSC would also be able to make a recommendation to cease use of NIPT as part of the screening pathway.

3 Scope

3.1 Aims and Objectives of Services

3.1.1 In delivering the aims and objectives of the Services the NIPT Laboratory Provider will meet all the key indicators (e.g. sample turnaround times) as set out in paragraph 3.7.1 of this Service Specification.

3.1.2 Based upon the UK NSC recommendation in 2016, the overall aims and objectives of the Services are described below.

3.1.3 Pregnant women are already offered a screening test for Down's syndrome, Edwards' syndrome and Patau's syndrome from 10-14 weeks of pregnancy (the combined test, involving an ultrasound scan and blood test), or a screening test for Down's syndrome only (the quadruple test, involving a blood test alone) if booking between 14-20 weeks.

3.1.4 If the screening test shows that the chance of having a baby with Down's syndrome, Edwards' syndrome and Patau's syndrome is higher than 1 in 150, this is called a higher- chance result. Currently, women who have a higher chance result have the option of having an invasive diagnostic test (amniocentesis or CVS).

3.1.5 The proposed change is for Non-Invasive Prenatal Testing to be offered to women who are deemed at higher chance following the current primary screen. NIPT is not diagnostic and an invasive diagnostic test is still required to receive a definitive diagnosis.

3.1.6 Key findings supporting the UK NSC recommendation:

i. an invasive diagnostic test carries a small risk of miscarriage. The evidence suggests that NIPT will reduce the number of women being offered an invasive test.

ii. however, while we know that the accuracy of NIPT is good, we don't yet know how it will perform in an NHS screening programme pathway (hence the evaluative roll-out service commissioned here).

iii. for women who choose to have NIPT, this will add in an extra step in the screening programme. The impact of this, and the choices women

make at different points in the pathway, is something that we hope to gain a better understanding of through further evaluation.

3.1.7 A recommendation has therefore been made to evaluate the introduction of NIPT to Down's syndrome, Edwards' syndrome and Patau's syndrome screening. This will include scientific, ethical and user input to better understand the impact on women, their partners and the screening programme around the offer of NIPT or invasive testing following a screening test result where:

i. the screening test chance result for trisomy 21 (T21) is greater than or equal to 1 in 150;
ii. the combined test chance result for trisomy 18 (T18) and trisomy 13 (T13) is greater than or equal to 1 in 150.

3.1.8 The main aims and objectives of this laboratory service are:

i. To allow women to access the NIPT Services with rapid turnaround times to enable appropriate clinical decisions to be taken, at an appropriate time during pregnancy. For clarity, access will be via maternity services if the patient is confirmed as meeting the eligibility criteria which is a screening chance result from combined or quad test of ≥1 in 150.
ii. Support the model for the NHS FASP, as recommended by UK NSC for evaluation as an additional option to the current screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome for women with chance results greater than or equal to 1 in 150 (1 in 2 to 1 in 150).
iii. To provide evidence and feedback to the NHS FASP to enable developments and changes to be made during the term of the contract to facilitate the evaluative roll-out. Further details regarding what evidence is required and the frequency it should be sent is detailed in paragraph 8 of this Service Specification.
iv. To provide the evidence to allow the UK NSC to assess the evaluation of the NIPT Services. Further details regarding what evidence is required and the frequency of submission is detailed in paragraph 8 (Data Reporting) of this Service Specification.
v. Set out the roles and responsibilities of the NIPT Service Provider in delivering the Services and meeting the key performance indicators regarding data requirements specified in paragraph 8 (Data Reporting) of this Service Specification. The NIPT Service Provider agrees, as further detailed in the description of the NIPT Services below, to be responsive to the findings of the evaluative roll-out as it proceeds. The NIPT Laboratory Provider commits to working with the NHS FASP to develop, adapt and modify the laboratory pathways, ordering systems, sample management processes and data requirements as the evaluative roll-out progresses. Developments of the pathways and processes would happen as and when required during the evaluative roll-out period.

3.1.9 Further, this Service Specification sets out the NIPT Service Provider's need to comply with data reporting requirements to fulfil both the on-going

quality assurance of laboratory services for NHS FASP and shorter-term reporting to inform and support the evaluative roll-out of NIPT as part of the screening pathway.

3.2 Laboratory Service description

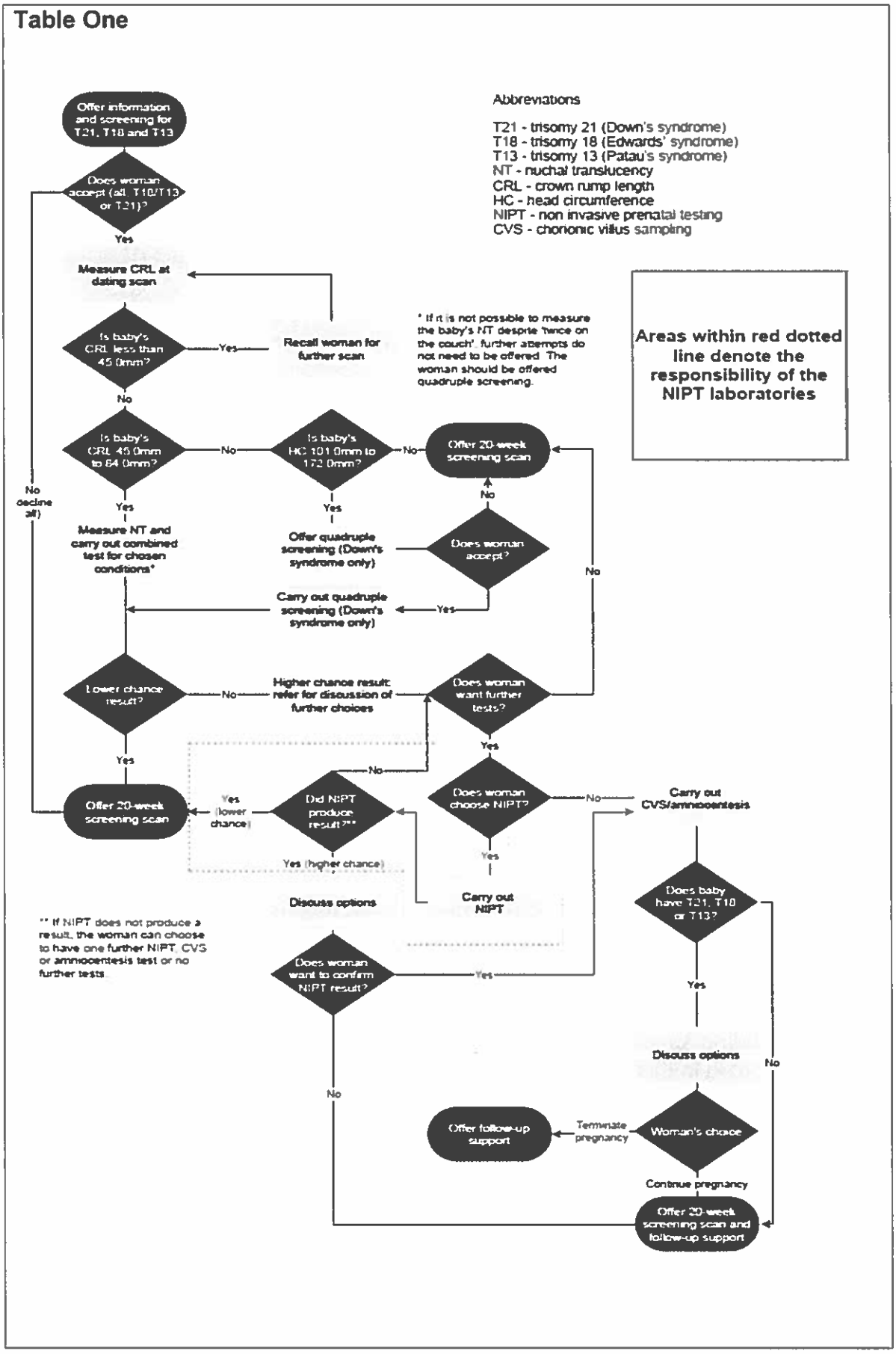
3.2.1 Genomic testing for the NHS in England is commissioned by NHS England and NHS Improvement and undertaken through the National Genomic Testing Service and outlined in the National Genomic Test Directory. The National Genomic Testing Service consists of seven Genomic Laboratory Hubs ("**GLH**") and subcontracted Local Genomic Laboratories ("**LGL**") and Designated Provider(s). The GLH National Network, working collaboratively, operates a world class resource for the NHS in England to underpin an NHS Genomic Medicine Service and works to a nationally agreed set of standards, quality management and assurance of all processes and data. In order to ensure that the genomic testing element of the NIPT service is an integrated part of the National Genomic Testing Service the NIPT Laboratory Provider provides the Services under a chain of formal sub-contracting agreements to the NIPT Service Provider. Evidence should be provided as to how its provision, governance and quality management of NIPT sits in the context of the overall services provided by the NIPT Service Provider. The NIPT Laboratory Provider must also be ISO 15189:2012 accredited for NIPT and must participate in an ISO 17043 NIPT accredited EQA scheme. Accreditation for NIPT as part of NHS FASP shall be assessed.

3.2.2 Where NIPT Services are sub-contracted by a NIPT Service Provider the sub-contractor responsible for delivering the laboratory services should be defined as a NIPT Laboratory Provider, or NIPT Subcontracted Service Provider, and will comply with the requirements set out in this specification. For clarity, it is the responsibility of the NIPT Service Provider as the Contract holder to ensure Service Specification compliance of any sub-contractor (NIPT Laboratory Provider) and the NIPT Service Provider shall be fully responsible for the delivery of the Services and this Service Specification, irrespective of its contractual relationship with the NIPT Laboratory Provider where the Services are in whole or in part sub-contracted.

3.2.3 Where such NIPT Services have been sub-contracted out the NIPT Service Provider shall ensure the NIPT Laboratory Provider complies with the provisions and requirements as set out in this Service Specification in their entirety.

3.2.4 The following diagram (Table One) is the applicable Screening Programme Pathway which clearly lays out the process that must be followed. The NIPT Laboratory Provider is responsible for carrying out the activities illustrated within the red dotted line, but not the other activities illustrated in Table One.

Table One


Offer information and screening for T21, T18 and T13
Does woman accept (all, T18/T13 or T21)?
Yes
No decline all)
Measure CRL at dating scan
Is baby's CRL less than 45.0mm?
Yes
Recall woman for further scan
No
Is baby's CRL 45.0mm to 84.0mm?
No
Is baby's HC 101.0mm to 172.0mm?
No
Offer 20-week screening scan
No
Yes
Measure NT and carry out combined test for chosen conditions*
Yes
Offer quadruple screening (Down's syndrome only)
Does woman accept?
No
Yes
Carry out quadruple screening (Down's syndrome only)
No
Lower chance result?
No
Higher chance result: refer for discussion of further choices
Does woman want further tests?
Yes
Yes
Offer 20-week screening scan
Yes (lower chance)
Did NIPT produce result?**
No
Yes (higher chance)
Does woman choose NIPT?
No
Carry out CVS/amniocentesis
Yes
Carry out NIPT
Discuss options
Does woman want to confirm NIPT result?
Yes
No
Does baby have T21, T18 or T13?
Yes
Discuss options
No
Woman's choice
Terminate pregnancy
Offer follow-up support
Continue pregnancy
Offer 20-week screening scan and follow-up support
* If it is not possible to measure the baby's NT despite 'twice on the couch' further attempts do not need to be offered. The woman should be offered quadruple screening.
** If NIPT does not produce a result, the woman can choose to have one further NIPT, CVS or amniocentesis test or no further tests.
Abbreviations
T21 - trisomy 21 (Down's syndrome)
T18 - trisomy 18 (Edwards' syndrome)
T13 - trisomy 13 (Patau's syndrome)
NT - nuchal translucency
CRL - crown rump length
HC - head circumference
NIPT - non invasive prenatal testing
CVS - chorionic villus sampling
Areas within red dotted line denote the responsibility of the NIPT laboratories

3.3 Testing repertoire

3.3.1 The NIPT Laboratory Provider shall perform NIPT and FASP reporting on T21, T18 & T13 only in singleton and twin pregnancies with no inclusion of fetal sex or other chromosomal findings.

3.3.2 The NIPT Laboratory Provider shall only undertake NIPT as part of the NHS screening programme:

- 3.3.2.1 for those women with a higher chance result of 1 in 2 to 1 in 150 from combined or quadruple testing offered, as evidenced by the referring maternity services; and
- 3.3.2.2 where there is evidence provided by the referring maternity services to the NIPT Laboratory Provider that the woman been offered the clinical options as described in the NHS FASP pathway (Table One at paragraph 3.2.4 above) prior to their sample being taken (the **"NIPT Eligibility Criteria"** – paragraph 3.3.3 below).

3.3.3 Women who have received a higher chance result (1 in 2 to 1 in 150) from either combined or quadruple tests who choose to have NIPT may accept the offer of screening for:

i. Down's syndrome only,
ii. Edwards' syndrome and Patau's syndrome only, or
iii. All 3 conditions.

3.3.4 The initial NIPT Eligibility Criteria check will be performed by the maternity services that refer the service user to the NIPT Laboratory Provider. The NIPT Laboratory Provider will be required to check that the information provided by the maternity service in the pathology test request indicates that the sample meets the Eligibility Criteria prior to processing the sample.

3.4 Sample collection, handling and processing

3.4.1 The NIPT Laboratory Provider must create, maintain and comply with ISO 15189 and Human Tissue Act 2004 compliant Standard Operating Procedures (**"SOPs"**) setting out processes in respect of sample receipt, storage, extraction, preparation, sequencing, microarray, analysis (including bioinformatics), transportation, and a reporting protocol for NIPT (including specific sample requirements) and the further details required as set out in in this Service Specification.

3.4.2 The NIPT Laboratory Provider will follow the flow chart as defined in Table One (area within red dotted line only) at paragraph 3.2.4 of this Service Specification and meet all the key indicators as specified in paragraph 8 (Data Reporting) of this Service Specification.

3.4.3 The NIPT Laboratory Provider will purchase sample kits and distribute these to the Ordering Entities (i.e the referring services); these sample kits will not be chargeable to the Ordering Entities.

3.4.4 All timings referred use Day 0 definition as the day the NIPT Laboratory Provider receives the sample as evidenced by the Provider logging the sample in its laboratory information management system up on receipt;

Day 0 is NOT the day the NIPT Laboratory Provider receipts the sample if samples are not receipted immediately upon receiving.

3.4.5 Samples are not able to be refrigerated and storage should comply with the Human Tissue Act 2004.

3.4.6 The Ordering Entity will notify the NIPT Laboratory Provider that a sample is being sent; the NIPT Laboratory Provider should develop (during mobilisation) and provide (during the Contract term) a means of communication for this to occur and a record to be maintained.

3.4.7 If samples are delayed, exception reporting will be undertaken to determine the cause and an appropriate action plan will be agreed with the NIPT Laboratory Provider.

3.4.8 The NIPT Laboratory Provider must provide evidence of and report in the Monthly Performance Report on its compliance with such SOPs.

3.4.9 The SOPs for NIPT shall detail:

a. the provision of specialist cell stabilising blood tubes by the NIPT Laboratory Provider as applicable to Ordering Entities;
b. the provision of appropriate standardised request forms (paper and/or electronic) by the NIPT Laboratory Provider as applicable to Ordering Entities, which meet NHS FASP minimum data requirements;
c. the provision of transportation and storage of samples from Ordering Entities to the NIPT Laboratory Provider as applicable;
d. the competency/grade level of staff which will be required at each step of the NIPT process (which must meet requirements of UKAS);
e. processing times for each stage of the workflow which are consistent with the NIPT Turnaround Times (see paragraph 3.7.1 of this Service Specification);
f. all manual processing of NIPT within the NIPT pathway of the NIPT Laboratory Provider including Quality Control ("**QC**") laboratory protocol for each step of the NIPT process;
g. the processes designed should minimise cross contamination:
    i. processes to ensure that if there is a single test failure in a particular sample run that: only the sample which failed will need to be re-tested or a repeat sample obtained; and none of the other samples tested in that run are affected. These processes should include stop points and re-start points which allow for the repeat of certain steps in the process should a technical failure in the laboratory process occur;
    ii. the number of re-tests that can be run on a single patient sample (minimum of 10 ml sample) without requiring a new sample to be taken;
h. the policy for informing NHS FASP, Ordering Entities and PHE of any downtime in test availability (for example extended holiday periods, instrumentation failure or equipment maintenance). This policy should include a requirement to notify Ordering Entities in advance (where technically possible) of any of the foregoing and advise NHS FASP and PHE of any impact on NIPT Turnaround Times. The NIPT Laboratory Provider will be required to have contingency plans in place to cover such eventualities;

i. procedures for monitoring, labelling and tracking samples from sample receipt to reporting results back to Ordering Entities, including details of expected timeframes which shall be in line with the NIPT Turnaround Times. The procedure should include a process for cross-referencing samples received against results reported;
j. all consumables required to run NIPT from receipt of patient sample to reporting the result to Ordering Entities and include information as to whether a "kit" is used or separate elements;
k. the quality assurance processes which build in robust QC fail safes into the laboratory pathway for NIPT and set out how samples that fail to meet the QC thresholds are identified;
l. all instruments and equipment used in the screening process;
m. the technology method used for NIPT;
n. the process to collect and follow up outcomes for all NIPT performed as part of the NHS FASP including to confirm screening results by either following up interpupillary distance ("**IPD**") results or assessment of baby at birth for confirmation (this will be collected in collaboration with NCARDRS);
o. the number of DNA samples it can process in a single batch and processes demonstrating that:
    i. DNA samples will be run regularly in batches of scalable numbers; and
    ii. the analysis protocol is able to adjust to scaling up in numbers in order to meet the NIPT Turnaround Times; and
p. a mechanism for the NIPT Laboratory Provider to obtain ordering information and other data where NIPT Services have been subcontracted to a NIPT Laboratory Provider to provide NIPT so that the NIPT Service Provider and the NIPT Laboratory Provider (where applicable) can fulfil their reporting obligations in accordance with this Service Specification.

3.4.10 The NIPT Laboratory Provider shall:

a. receive and acknowledge receipt of the NIPT order in accordance with the SOPs;
b. only process orders which meet the NIPT Eligibility Criteria stated within paragraph 3.3.3 of this Service Specification;
c. check that all the NIPT Minimum Data has been supplied and submitted correctly alongside the complete sample;
d. check that the sample and accompanying patient referring card/specimen labels provided is complete; if the information is not complete, the NIPT Laboratory Provider must seek this correct information whilst storing and holding the sample(s) provided;
e. check that the choices made regarding conditions that the screening offer is accepted for are clearly documented on the request form. If they are not clear or the relevant parts of the form have been left blank it is the responsibility of the laboratory to clarify the screening required with the requestor before the sample is analysed;
f. perform the relevant QC on the sample at all steps of the pipeline to determine if the sample is of sufficient quality to proceed to NIPT and at all steps of the procedure;

g. perform NIPT in accordance with the applicable standards for NIPT as set out in this Service Specification; and
h. return the complete results to Ordering Entities in accordance with the NIPT Turnaround Times (see paragraph 3.7.1 of this Service Specification),

3.5 Technical and Analytical platforms and Capability

3.5.1 The Business Continuity Plan and procedures which both the NIPT Service & Laboratory Provider is to have in place, maintain and comply with in accordance with Clause 5 of Schedule 2 (General Terms and Conditions) of the Contract must include a contingency procedure to mitigate disruption to the NIPT service so far as reasonably practicable, but until such time as the NIPT Laboratory Provider enters into the reciprocal disaster recovery agreement of the sort contemplated by paragraph 3.5.2 the NIPT Laboratory Provider shall not (despite anything to the contrary in the Contract) be required to ensure continuity of NIPT in the event of service failure.

3.5.2 The NIPT Service Provider will facilitate a reciprocal disaster recovery contingency arrangement between the NIPT Laboratory Provider and other laboratory operators delivering NIPT for the National Genomic Testing Service such that the NIPT Laboratory Provider may refer samples to those other laboratories in the event that the NIPT Laboratory Provider is unable to provide the Service from its own laboratories.

3.5.3 The NIPT Service Provider should report to PHE if it proposes to make any upgrades to current technology methodology in development of laboratory equipment, consumables and software for analysis or other similar items used in the performance of NIPT, what the upgrade is for, and an estimated launch date to NHS FASP and PHE.

3.6 Bioinformatics, Annotation and Validation

3.6.1 The NIPT Laboratory Provider shall set out in the SOPs required under paragraph 3.4.9:

a. full details of the process for validation/verification of NIPT results using the ISO 15189:2012 guidance. This must include as a minimum the "ISO 15189:2012 Standard 5.5.1 Selection, Validation and Verification of Examination Procedures" document for NIPT;

b. the specific parameters used to generate final NIPT results. This must include parameters (for example, a priori risk) used to determine the lower and higher chance result;

c. the key quality parameters used in their analysis of NIPT results to pass or fail each sample (for example, minimum/maximum library

yield QC, minimum samples for analysis, specific sequencing data quality control, minimum fetal fraction); and

d. the auditing processes and procedures on reporting of NIPT Turnaround Times (see paragraph 3.7.1 of this Service Specification).

3.7 Clinical interpretation, reporting, returning of results and measuring outcomes

3.7.1 The NIPT Laboratory Provider shall, ensure that they perform the NIPT and return the result to the Ordering Entity (the maternity service that will provide the service user(s) with the test result(s)) within five (5) days of receipt of the sample at the NIPT Laboratory Provider, as evidenced by the NIPT Laboratory Provider logging the sample in its laboratory information management system ("NIPT Turnaround Times").

3.7.2 If there is a sample testing failure, the NIPT Laboratory Provider shall, report this immediately to the Ordering Entity, advise if a second sample needs to be obtained from a patient, and advise of any impact of such failure on NIPT Turnaround Times.

3.7.3 The NIPT Service Provider must provide, as part of its regular report to PHE and NHS FASP such information as necessary to fulfil the NIPT Service Provider's obligations) and shall report directly to NHS FASP:

i. examples of NIPT reports (include 'higher chance', 'lower chance' and 'no result');
ii. details of current NIPT 'no result' numbers and reasons for 'no result' and provide evidence for both first sample and re-sample requests;
iii. information on the NIPT Laboratory Provider's false positive and false negative rate;
iv. details on the NIPT Laboratory Provider's performance against the NIPT Turnaround Times and any failures to meet the NIPT Turnaround Times and the reason for such failure;
v. instances where samples require to be repeated, where additional samples need to be obtained due to test failure, and the impact on the overall NIPT Turnaround Times; any failures to meet the laboratories' QC thresholds.

3.7.4 NIPT Laboratory Provider shall regularly communicate with NIPT Service Provider on evaluation, reporting and auditing activities, performed as part of their accreditation requirements, to assess screening safety and performance as defined by NHS FASP requirements, these communications shall be documented. This will include providing returns to Down's syndrome screening quality assurance support service ("**DQASS**") and National Congenital Anomaly and Rare Disease Registration Service ("**NCARDRS**") and providing to PHE, NHS FASP :

i. details of such returns to DQASS and NCARDRS; and
ii. other requirements during the evaluative roll-out as defined by NHS FASP, all within the timescales specified by NHS FASP.

3.7.5 The Maternity Unit is responsible for providing the necessary privacy notices to the patient. This statement overrides GC21.8. This is not the responsibility of the NIPT Laboratory Provider.

3.8 Population covered

3.8.1 The population covered will be eligible women registered for care with a NHS Maternity provider in England who have a higher chance result from a combined or quadruple screening test. Eligibility will be checked and confirmed by the Ordering Entity. See Eligibility Criteria stated within paragraph 3.3.3 of this Service Specification. The NIPT Laboratory Provider will be required to check that the information supplied by the Ordering Entity with the pathology test request indicates that the sample meets the Eligibility Criteria prior to processing the sample.

3.9 Any acceptance and exclusion criteria and thresholds

3.9.1 As per paragraph 3.8 above.

3.10 Interdependence with other services/providers

3.10.1 The Services will be interdependent with the referring healthcare services, which may include, but not limited to, maternity services where the patient is registered with their GP or where they have chosen to receive treatment.

3.10.2 The interdependencies with PHE, NHS FASP and NHS England and NHS Improvement ("**NHSE&I**") are described throughout this document and will not be repeated here.

3.11 Activity & Tariff

3.11.1 Activity is anticipated to be between 10,000 to 12,000 tests per annum based on historical activity however this is not guaranteed. This activity will be split between providers.

3.11.2 Payment will be on a tariff basis. The tariff applicable to this service is set out in Schedule 3.

4 Applicable Service Standards

4.1 Applicable national standards

4.1.1 The NIPT Laboratory Provider if a sub-contractor must be ISO 15189:2012 accredited for NIPT and participate in ISO 17043 accredited EQA NIPT scheme for aneuploidies.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

4.2.1 No standards are applicable at the time of tender publish however this may be varied throughout the evaluative roll-out.

4.3 Applicable local standards

4.3.1 No standards are applicable at the time of tender publish however this may be varied throughout the evaluative roll-out.

5 Applicable quality requirements

5.1 Applicable Quality Requirements

5.1.1 See paragraph 8 (Data Reporting) below.

5.2 Quality Assurance

5.2.1 The NIPT Laboratory Provider will provide evidence on request to PHE and NHS FASP of its UKAS accreditation.

5.2.2 The NIPT Laboratory Provider must evidence to NHS FASP, when requested by either party, that their quality management system incorporates all the requirements of the screening pathway as set out in both Table One (at paragraph 3.2.4 above) and the NHS FASP Guidance as may be updated from time to time. The NIPT Laboratory Provider shall manage incidents in accordance with the NHS Screening Safety Incidents Framework and the PHE Managing Safety Incidents in NHS Screening Programmes guidance (https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes).

5.2.3 The NIPT Laboratory Provider shall participate in the ISO 17043 accredited EQA NIPT scheme for aneuploidies. The NIPT Laboratory Provider shall, on request, share its data on EQA performance and the reports on the outcomes of the screening samples set to them via the NEQAS scheme, with NHS FASP, NCARDRS and PHE. If the NIPT Service Provider has subcontracted NIPT to a NIPT Laboratory Provider, it shall obtain the performance data and reports relating to such NIPT Laboratory Provider and provide this to the aforementioned parties.

5.2.4 Both the NIPT Service Provider and the NIPT Laboratory Provider will be responsive to the findings of the evaluative roll-out as it proceeds, usually communicated by NHS FASP. Therefore, the NIPT Service Provider commits (and shall ensure the commitment of any NIPT

Laboratory Provider) to working with NHS FASP to adapt and modify the laboratory pathways, processes and data requirements and SOPs created by the NIPT Laboratory Provider in accordance the evaluative roll-out, as it progresses in accordance with PHE and NHS FASP instructions. The NIPT Laboratory Provider shall also be required to perform data reporting to fulfil both the on-going quality assurance of laboratory services for NHS FASP in the long term and in the shorter term to inform and support the evaluative roll-out of NIPT as part of the screening pathway. **If either the NIPT Service Provider or NIPT Laboratory Provider fail to develop or change the Services as required throughout this evaluative roll-out, upon instruction from NHS FASP, PHE, PHE reserves the right to terminate the Contract due to failure to provide the contracted service.**

6 Governance and organisational structure

6.1 The NIPT Laboratory Provider shall be fully compliant, with the NHS FASP specific requirements and standards. These requirements and standards will be more fully described in the NHS FASP operational guidance ("**NHS FASP Guidance**"). The NIPT Laboratory Provider shall work with PHE and NHS FASP to develop the NHS FASP Guidance following the signature date of the Contract.

6.2 The NIPT Service Provider shall provide evidence on request to PHE and NHS FASP of its laboratory organisational structure for performing NIPT and how its provision of NIPT sits in the context of the overall Services provided by the NIPT Service Provider. On receipt of such evidence, NHS FASP shall assess whether to approve such organisational structure or require changes prior to engaging the NIPT Service Provider to perform the Services. In the event of any changes to the organisational structure of the NIPT Service Provider and/or the NIPT Laboratory Provider during the Term of the Contract, the NIPT Service Provider shall provide details of such changes and shall determine whether to approve the same or request further changes. This organisational structure shall include details of:

i. the named clinical lead for the NIPT Service Provider (and where NIPT has been subcontracted the clinical lead for the NIPT Laboratory Provider) as further detailed in paragraph 6.3, who shall form part of the Service Delivery Team; and
ii. the management and governance structure.

6.3 The named clinical lead referred to in paragraph i6.2i for NIPT screening for T21,T18 and T13 must be a suitably qualified clinician or clinical scientist who:

i. is either at the level of a laboratory director or is directly responsible thereto;
ii. has management oversight and responsibilities; and
iii. is FRCPath qualified,

referred to as the "NIPT Screening Lead" ("**NIPT Screening Leads**").

6.4 The NIPT Service Provider shall participate, and shall procure the participation of any NIPT Laboratory Provider, in cross-organisational and multi-disciplinary arrangements for the governance, management, communication and development of the screening pathway. This will include the sharing of data and information, as specified by NHS FASP on its and any NIPT Laboratory Provider's performance and quality in respect of NIPT (which shall include the submission of Monthly Performance Reports), with NHS FASP, NCARDRS, PHE, and PHE Screening Quality Assurance Services. If NIPT has been subcontracted in accordance with paragraph 6.5, the NIPT Service Provider shall require the NIPT Laboratory Provider to provide it with sufficiently detailed information on its performance and quality in order for the NIPT Service Provider to fulfil its obligations under this paragraph 6.4.

6.5 The NIPT Service Provider and/or the NIPT Laboratory Provider can only subcontract NIPT to a NIPT Laboratory Provider (providing NHS services) or other LGL or Designated Provider (providing NHS services), with the prior written approval of PHE prior to any service commencement or entering into contract(s), or as set out in paragraph 6.8. Where a NIPT Laboratory Provider is used, the NIPT Service Provider shall ensure that the relevant NHS NIPT Laboratory Provider Subcontract contains:

6.5.1 details of service level agreements and risk assessed protocols between the NIPT Service Provider and such NIPT Laboratory Provider;

6.5.2 provisions that set out the responsibilities and working arrangements for screening samples sent by Ordering Entities to the NIPT Laboratory Provider;

6.5.3 arrangements and obligations on the NIPT Laboratory Provider in respect of:

- confirming sample receipt;
- meeting NIPT Turnaround Times;
- ensuring all screening results reach the responsible Ordering Entity and the instructing NIPT Laboratory Provider (as further detailed in the NHS FASP Guidance);
- reporting to the NIPT Service Provider all the information that the NIPT Service Provider is required to provide to PHE in accordance with this Service Specification;
- performing the NIPT Gateway Services;
- complying with the SOPs created by the NIPT Laboratory Provider in accordance with paragraph 3.4.1 above and the NHS FASP Guidance;

6.5.4 performance monitoring and reporting mechanisms to enable the NIPT Service Provider to monitor the compliance of the NIPT Laboratory Provider; and

6.5.5 a requirement on the NIPT Laboratory Provider to be ISO 15189:2012 accredited for NIPT, and participate in ISO 17043 accredited EQA NIPT schemes,

and all such provisions and arrangements must align with the SOPs set by the NIPT Laboratory Provider in accordance with Paragraph 3.4.1.

6.6	The NIPT Service Provider must provide details to PHE of their information governance processes (including those of all NIPT Laboratory Providers).
6.7	The NIPT Service Provider shall comply, and shall procure the compliance of all NIPT Laboratory Providers, with the screening policy and pathways of NHS FASP, as will be set out in the NHS FASP Guidance to support the evaluative roll-out of NIPT as an additional option within NHS FASP.
6.8	The NIPT Laboratory Provider may appoint the Sub-contractors referred to in Schedule 5.

7 Workforce Development and Personnel

7.1. The NIPT Laboratory Provider must ensure, and evidence on request, that all its staff participating in NIPT undertake Continuing Professional Development ("**CPD**") and revalidation, including the recommended eLearning modules relevant to laboratory staff for the NHS FASP programme. The NIPT Laboratory Provider must ensure that all staff participating in NIPT shall complete the Down's, Edwards' and Patau's Screening e-Learning Resource (https://phescreening.blog.gov.uk/2017/03/24/new-e-learning-module-for-screening-for-downs-edwards-and-pataus-syndromes/) module by the end of the Mobilisation Period. Such e-Learning Resource should be completed by each member of staff (within the NIPT Laboratory Provider) every 24 months. Any other specific courses which PHE or NHS FASP requires staff participating in NIPT to complete during the Term of the Contract shall be advised to the NIPT Service Provider from time to time. The NIPT Service Provider shall thereafter advise any NIPT Laboratory Providers of any such additional courses and ensure that the NIPT Laboratory Providers' staff participate in such courses.

8 Data Reporting

Data requirements from genomic laboratories to support NIPT evaluation questions

The following information must be provided in line with the timescales stipulated and will be a requirement of the ongoing contractual agreement.

Data title	Data source	Data collection system	Data collection frequency
What is the impact (if any) of maternal age, demographics (post code), geography, ethnicity, gestational age, any differences between singleton and twins numerical chance result value or other morphology e.g. USS findings on the above choices?	Maternity provider Genomics laboratory	NCARDRS	Quarterly Annual
Test arrival in laboratory (time from sample draw to receipt in the genomic laboratory	Genomics laboratory	NIPT experimental metric 3 -agreed single process with NCARDRS (See NIPT 3 standard below)	Surveillance-monthly Quarterly Annual
Test turnaround time (receipt of sample to NIPT result)	Genomics laboratory	NIPT experimental metric- 4 agreed single process with NCARDRS (see NIPT 4 standard below)	Surveillance-monthly Quarterly Annual
What is the 'no result' rate of the NIPT test? *(UK NSC question)* Singleton and twins Defined as a no result from first or second NIPT sample	Genomics laboratory	Agreed single process with NCARDRS	Surveillance-monthly
Number of higher chance NIPT results	Genomics laboratory	NCARDRS	Monthly Quarterly Annual
Positive and negative predictive values for T21, T18 and T13 in the tested population	Genomics laboratory	NCARDRS	Annual
Training log Evaluation of training- e learning and face to face sessions	Maternity/ biochemistry laboratory providers/ genomics	IEPP	Monthly Quarterly Annual

	laboratory providers			

Surveillance

PHE aim to set up a surveillance system during the evaluative period where real time learning can occur about NIPT tests that do not produce a result- no result and inconclusive or indeterminate results. Inconclusive or indeterminate results happen when the result is in a middle range which is neither positive nor negative. The rate of indeterminate results was found to range from 0 to 11%. The Warwick evidence review estimated that offering NIPT as a second stage screening test following combined screening would result in 385 initial test failures. These no results and inconclusive results potentially delay the screening pathway and we would need to understand the extent and impact of this on women.

Getting a 'no result' can occur at any stage of the following process

- problems with sample collection (inadequate blood volume, haemolysis, incorrect labelling) or transportation (delayed arrival of sample in laboratory) [estimated rate of 0.03 to 11.1%]
- low fetal fraction -usually below 4% [estimated rate of 0.5 to 6.1%] assay failure for a variety of reasons- failure at DNA extraction, amplification or sequencing [estimated rate of 0 to 12.2%]

No result NIPT pathway

PHE aim to collect information regarding the above steps, how these are managed in the laboratory, whether rates are technology dependent or not, by how long does a no result extend the pathway for the woman and how do factors like gestational age, BMI and a fetus with a confirmed trisomy contribute to no results. This will require matching each no result with pregnancy outcomes. Genomics laboratories would report no result cases to PHE screening via the NCARDRS process using a web-based portal. For this surveillance arm we require monthly reporting.

Data fields required for reporting on surveillance *(this would be in the form of a drop-down menu)*

Case identifier
Maternal BMI

NIPT no result/indeterminate result	1st NIPT sample (need gestational age at	2nd NIPT sample
		IPD
		No further testing

	sampling)		
	2nd NIPT sample (need gestational age at sampling)	IPD	
		No further testing	

Reasons for no results/indeterminate results	Sampling problems	Sample not received	Free text	
		Sample in wrong tube	Free text	
		Sample lacks identifiers or has incorrect identifiers eg mislabelling	Free text	
		Sample insufficient blood volume	Free text	
		Sample haemolysed	Free text	
		Too long in transit/ delayed arrival in lab	Free text	
	Internal quality control processes	DNA extraction	Free text	
		Library prep	Free text	
		Sequencing	Free text	
	Analysis	Low fetal fraction	Value of fetal fraction	Free text
		Equipment failure	Free text	
		Technical failure	Free text	
	Results	Communication failure eg problem with email	Free text	
		Automated report problems	Free text	
	Other reasons	Free text		

Singleton pregnancy

Twin pregnancy – chorionicity – mono, di and zygosity if available

Add to results – failure to select the correct testing algorithm for the pregnancy.

The following key performance indicators (KPI) must be met on an ongoing basis by all NIPT Laboratory providers and will be a contractual requirement. NIPT Laboratory Providers must report on their performance against these key performance indicators (KPI) in the manner stipulated to comply with Contract terms and conditions.

If a provider does not meet the 'Acceptable level' stated in each of the Key Performance Indicators (KPIs) below Public Health England (PHE) will work with the NIPT Laboratory

provider to agree an action plan and timescales with the provider in which they must adhere to rectify performance levels.

During the first six months after the Service Commencement Date (the 'Grace Period'), if the NIPT Laboratory Provider fails to meet the 'Acceptable level' stated in each of the Key Performance Indicators below, the NIPT Laboratory Provider will work with the Commissioner to agree and action plan and timescales which the NIPT Laboratory Provider will implement to rectify the performance levels, but a KPI failure during the Grace Period shall have any other consequences under the Contract.

DRAFT FASP NIPT-S02: test: timely receipt of NIPT sample

Description

The proportion of all NIPT samples received in the genomic laboratory ≤ 2 working days.

Rationale

To enable timely reporting of screening results to women so they can make personal informed choices. Delays in sample receipt increases the chances of deterioration and the need for a repeat sample.

Definition

Numerator: number of NIPT samples received by the laboratory ≤ 2 working days of sample collection/draw

Denominator: number of NIPT samples received by the laboratory in the reporting period

Sample received is when the sample is recorded as received on the laboratory information management system

For the purposes of this standard, day of sampling is day 0

We calculate performance by dividing numerator by denominator and multiplying by 100 to give a percentage.

Performance thresholds

Acceptable level: ≥90.00%

Achievable level: ≥95.00%

Caveats

None

Data collection and reporting

Data source: genomic laboratories

Responsible for data quality and completeness: genomic laboratories

Responsible for submission: NCARDRS

Reported by: maternity service

Published by: maternity service

Reporting period

Monthly

DRAFT FASP NIPT-S03: test: turnaround time NIPT

Description

The proportion of NIPT screening test results reported ≤ 5 calendar days of sample receipt (evidenced by the sample being receipted into the NIPT Laboratory Provider's laboratory information management system).

Rationale

To enable timely reporting of screening results to women so they can make personal informed choices.

Definition

Numerator: number of NIPT screening results reported by the genomic laboratory to maternity service ≤ 5 calendar days of sample receipt

Denominator: number of NIPT screening samples received in the genomic laboratory in the reporting period excluding samples received:

- that are not fit for analysis and a repeat sample is requested
- with missing information required for calculating the result

The denominator and numerator include samples that are analysed where the result is 'no result'

Date of sample receipt in the laboratory is counted as day 0.

We calculate performance by dividing numerator by denominator and multiplying by 100 to give a percentage.

Performance thresholds

Acceptable level: ≥85.00%

Achievable level: ≥95.0%

Caveats

None

Data collection and reporting

Data source: genomic laboratory

Responsible for data quality and completeness: genomic laboratory

Responsible for submission: NCARDRS

Reported by: genomic laboratory

Published by: genomic laboratory

Reporting period

Monthly

SCHEDULE 2 – THE SERVICES

C. Indicative Activity Plan

Guaranteed 70% activity for Year 1 is for 2,832 tests (11-month activity). Range between 3,090 to 4,414 for 12-month period.

D. Essential Services (NHS Trusts only)

Not Applicable

G. Other Local Agreements, Policies and Procedures

Not Applicable

J. Transfer of and Discharge from Care Protocols

Not applicable

K. Safeguarding Policies and Mental Capacity Act Policies

Not Applicable

SCHEDULE 3 – PAYMENT

A. Local Prices

Price per test in Year 1 is £341.26 with a guaranteed Annual payment equivalent to 2,832 tests (£966,448.32).
An upfront payment of £289,934.50 (equivalent to 30% of the guaranteed Annual activity) will be made on the commencement date followed by 10 monthly payments of £67.651.38.
A reconciliation exercise will be carried out after 4 months, 8 months and 11 months respectively. Any activity above the 2,832 tests will be reconciled at month 11 and will be paid at a price per test of £341.26.

Price per test in Year 2 is £345.57 paid monthly in arrears for the number of tests performed.

Price per test in Year 3 is £349.90 per test paid monthly in arrears for the number of tests performed.

B. Local Variations

For each Local Variation which has been agreed for this Contract, copy or attach the completed publication template required by NHS Improvement (available at: www.england.nhs.uk/pay-syst/national-tariff/locally-determined-prices) – or state Not Applicable. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

C. Local Modifications

For each Local Modification Agreement (as defined in the National Tariff) which applies to this Contract, copy or attach the completed submission template required by NHS Improvement (available at: www.england.nhs.uk/pay-syst/national-tariff/locally-determined-prices). For each Local Modification application granted by NHS Improvement, copy or attach the decision notice published by NHS Improvement. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

D. Expected Annual Contract Values

Range between 3,090 – 4,414
We guarantee payment of 2,832 tests in year one only. Tests over and above 2,832 in year one will be paid at the prevailing tariff stated below for year 1.
Base Tariff equals:
Tariff for Year 1 is £341.26 (includes MFF)
Tariff for Year 2 is £345.57 (includes inflation and MFF)
Tariff for Year 3 is £349.90 (includes inflation and MFF)

Expected Annual Value for Year 1 is £966,448.32 - £1,506,321.64. An upfront payment equivalent to 30% of the guaranteed Annual activity of £289,934.50 will be made on the commencement date followed by 10 monthly payments of £67,651.38.

A reconciliation exercise will be carried out after 4 months, 8 months and 11 months respectively. Any activity above the 2,832 tests will be reconciled at month 11 and will be paid at a price per test of £341.26.

Expected Annual Value for Year 2 is £1,067,811.30 - £1,525,345.98 invoiced monthly in arears based on actual activity.
Expected Annual Value for Year 3 is £1,081,191 - £1,544,458.60 invoiced monthly in arears based on actual activity.

Please note the tariffs set out above are fixed for the duration of the contract.

(Specify the proportion of the Expected Annual Contract Value to be invoiced each month, in accordance with SC36.21.)

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards and National Quality Requirements

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Period over which the Standard / Requirement is to be achieved	Applicable Service Category

The Provider must report its performance against each applicable Operational Standard and National Quality Requirement through its Service Quality Performance Report, in accordance with Schedule 6A.

SCHEDULE 4 – QUALITY REQUIREMENTS

C. Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Applicable Service Specification
As per the service specification			

SCHEDULE 5 - GOVERNANCE

B. Provider's Material / Permitted Sub-Contracts

Sub-Contractor [Name] [Registered Office] [Company number]	**Service Description**	**Start date/expiry date**	**Processing Personal Data – Yes/No**	**If the Sub-Contractor is processing Personal Data, state whether the Sub-Contractor is a Data Processor OR a Data Controller OR a joint Data Controller**
University College London Hospitals NHS Foundation Trust Euston Road London NW1 2PG	Service provider	01st July 2021 – 31st May 2024 (unless the Contract is terminated earlier)	No	N/A
HSL Pathology LLP The Halo Building 1 Mabledon Place London WC1H 9AX Company number OC401483	Service provider – pathology services	01st July 2021 – 31st May 2024 (unless the Contract is terminated earlier)	Yes – Patient Data and clinician data	Refer to Schedule 6
Central & South Genomic Laboratory Hub (GLH) Birmingham Women's and Children's Hospital NHS Foundation Trust Mendelsohn Way Edgbaston Birmingham B15 2TGZ	Alternative provider in the case of service failure.	As and when required. Arrangements in place for duration of contract.	Yes – Patient Data and clinician data	Refer to Schedule 6
South East GLH Guy's and St Thomas' NHS Foundation Trust Trust Offices, St Thomas' Hospital Westminster Bridge Road London	Alternative provider in the case of service failure.	As and when required. Arrangements in place for duration of contract.	Yes – Patient Data and clinician data	Refer to Schedule 6

SE1 7EH				
HSL (Analytics) LLP The Halo Building 1 Mabledon Place London England WC1H 9AX Company number OC391046	Service provider – pathology services	01st July 2021 – 31st May 2024 (unless the Contract is terminated earlier)	Yes – Patient Data and clinician data	Data processor
HSL (FM) LLP The Halo Building 1 Mabledon Place London England WC1H 9AX Company number OC391023	Service provider – laboratory facility services	01st July 2021 – 31st May 2024 (unless the Contract is terminated earlier)	Yes – Patient Data and clinician data	Data processor
Any laboratory engaged in a reciprocal disaster recovery referral laboratory service of the kind described in Schedule 3	Service provider - referral laboratory services	For the duration of the relevant business continuity event	Yes – Patient Data and clinician data	Data processor

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report
National Requirements Reported Centrally			
1. As specified in the DCB Schedule of Approved Collections published on the NHS Digital website at https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance
National Requirements Reported Locally			
1. Activity and Finance Report *(note that, if appropriately designed, this report may also serve as the reconciliation account to be sent by the Provider under SC36.22)*	[For local agreement]	[For local agreement]	[For local agreement]
2. Service Quality Performance Report, detailing performance against Operational Standards, National Quality Requirements, Local Quality Requirements, Never Events and the duty of candour	[For local agreement]	[For local agreement]	[For local agreement]
3. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	[For local agreement]	[For local agreement]	[For local agreement]
4. Summary report of all incidents requiring reporting	[For local agreement]	[For local agreement]	[For local agreement]
Local Requirements Reported Locally			
Insert as agreed locally			The Provider must submit any patient-identifiable data required in relation to Local Requirements Reported Locally via the dedicated email address [PHE.NCARDRS@nhs.net]
As per the service specification			

	Reporting Period	Format of Report	Timing and Method for delivery of Report

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

C. Incidents Requiring Reporting Procedure

Procedure(s) for reporting, investigating, and implementing and sharing Lessons Learned from: (1) Serious Incidents (2) Notifiable Safety Incidents (3) Other Patient Safety Incidents
As set out in the service specification

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

F. Provider Data Processing Agreement

Data Processing Services

Processing, Personal Data and Data Subjects

1. The Provider must comply with any further written instructions with respect to processing by the Co-ordinating Commissioner.

2. Any such further instructions shall be incorporated into this Annex.

Description	Details
Subject matter of the processing	All patient information obtained and held in any clinical or administrative system relating to service delivery.
Duration of the processing	As per contract expiry
Nature and purposes of the processing	To enable full processing of patient information relating to the delivery of services being commissioned.
Type of Personal Data	Full patient information required for delivery of contract.
Categories of Data Subject	Co-ordinating commissioner's patients.
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	The NIPT Laboratory Provider shall retain the laboratory records in line with its retention policies based on the guidance published by the Royal College of Pathologists. Where those policies require the retention of such records beyond the termination or expiry of the Contract the NIPT Laboratory Provider shall retain those records in accordance with those policies and the Data Protection Legislation as a Data Controller.

Please see attached Schedule 6F Data Processing Agreement

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SCHEDULE 7 – PENSIONS

Not Applicable

SCHEDULE 8 – TUPE*

1. The Provider must comply and must ensure that any Sub-Contractor will comply with their respective obligations under TUPE and COSOP in relation to any persons who transfer to the employment of the Provider or that Sub-Contractor by operation of TUPE and/or COSOP as a result of this Contract or any Sub-Contract, and that the Provider or the relevant Sub-Contractor (as appropriate) will ensure a smooth transfer of those persons to its employment. The Provider must indemnify and keep indemnified the Commissioners and any previous provider of services equivalent to the Services or any of them before the Service Commencement Date against any Losses in respect of:

   1.1 any failure by the Provider and/or any Sub-Contractor to comply with its obligations under TUPE and/or COSOP in connection with any relevant transfer under TUPE and/or COSOP;

   1.2 any claim by any person that any proposed or actual substantial change by the Provider and/or any Sub-Contractor to that person's working conditions or any proposed measures on the part of the Provider and/or any Sub-Contractor are to that person's detriment, whether that claim arises before or after the date of any relevant transfer under TUPE and/or COSOP to the Provider and/or Sub-Contractor; and/or

   1.3 any claim by any person in relation to any breach of contract arising from any proposed measures on the part of the Provider and/or any Sub-Contractor, whether that claim arises before or after the date of any relevant transfer under TUPE and/or COSOP to the Provider and/or Sub-Contractor.

2. If the Co-ordinating Commissioner notifies the Provider that any Commissioner intends to tender or retender any Services, the Provider must within 20 Operational Days following written request (unless otherwise agreed in writing) provide the Co-ordinating Commissioner with anonymised details (as set out in Regulation 11(2) of TUPE) of Staff engaged in the provision of the relevant Services who may be subject to TUPE. The Provider must indemnify and keep indemnified the relevant Commissioner and, at the Co-ordinating Commissioner's request, any new provider who provides any services equivalent to the Services or any of them after expiry or termination of this Contract or termination of a Service, against any Losses in respect any inaccuracy in or omission from the information provided under this Schedule.

3. During the 3 months immediately preceding the expiry of this Contract or at any time following a notice of termination of this Contract or of any Service being given, the Provider must not and must procure that its Sub-Contractors do not, without the prior written consent of the Co-ordinating Commissioner (that consent not to be unreasonably withheld or delayed), in relation to any persons engaged in the provision of the Services or the relevant Service:

   3.1 terminate or give notice to terminate the employment of any person engaged in the provision of the Services or the relevant Service (other than for gross misconduct);

   3.2 increase or reduce the total number of people employed or engaged in the provision of the Services or the relevant Service by the Provider and any Sub-Contractor by more than 5% (except in the ordinary course of business);

   3.3 propose, make or promise to make any material change to the remuneration or other terms and conditions of employment of the individuals engaged in the provision of the Services or the relevant Service;

3.4 replace or relocate any persons engaged in the provision of the Services or the relevant Service or reassign any of them to duties unconnected with the Services or the relevant Service; and/or

3.5 assign or redeploy to the Services or the relevant Service any person who was not previously a member of Staff engaged in the provision of the Services or the relevant Service.

4. On termination or expiry of this Contract or of any Service for any reason, the Provider must indemnify and keep indemnified the relevant Commissioners and any new provider who provides any services equivalent to the Services or any of them after that expiry or termination against any Losses in respect of:

4.1 the employment or termination of employment of any person employed or engaged in the delivery of the relevant Services by the Provider and/or any Sub-Contractor before the expiry or termination of this Contract or of any Service which arise from the acts or omissions of the Provider and/or any Sub-Contractor;

4.2 claims brought by any other person employed or engaged by the Provider and/or any Sub-Contractor who is found to or is alleged to transfer to any Commissioner or new provider under TUPE and/or COSOP; and/or

4.3 any failure by the Provider and/or any Sub-Contractor to comply with its obligations under TUPE and/or COSOP in connection with any transfer to any Commissioner or new provider.

5. In this Schedule:

COSOP means the Cabinet Office Statement of Practice *Staff Transfers in the Public Sector* January 2000

TUPE means the Transfer of Undertakings (Protection of Employment) Regulations 2006

**Note: it may in certain circumstances be appropriate to omit the text set out in paragraphs 1-5 above or to amend it to suit the circumstances - in particular, if the prospect of employees transferring either at the outset or on termination/expiry is extremely remote because their work in connection with the subject matter of the Contract will represent only a minor proportion of their workload. However, it is recommended that legal advice is taken before deleting or amending these provisions.*