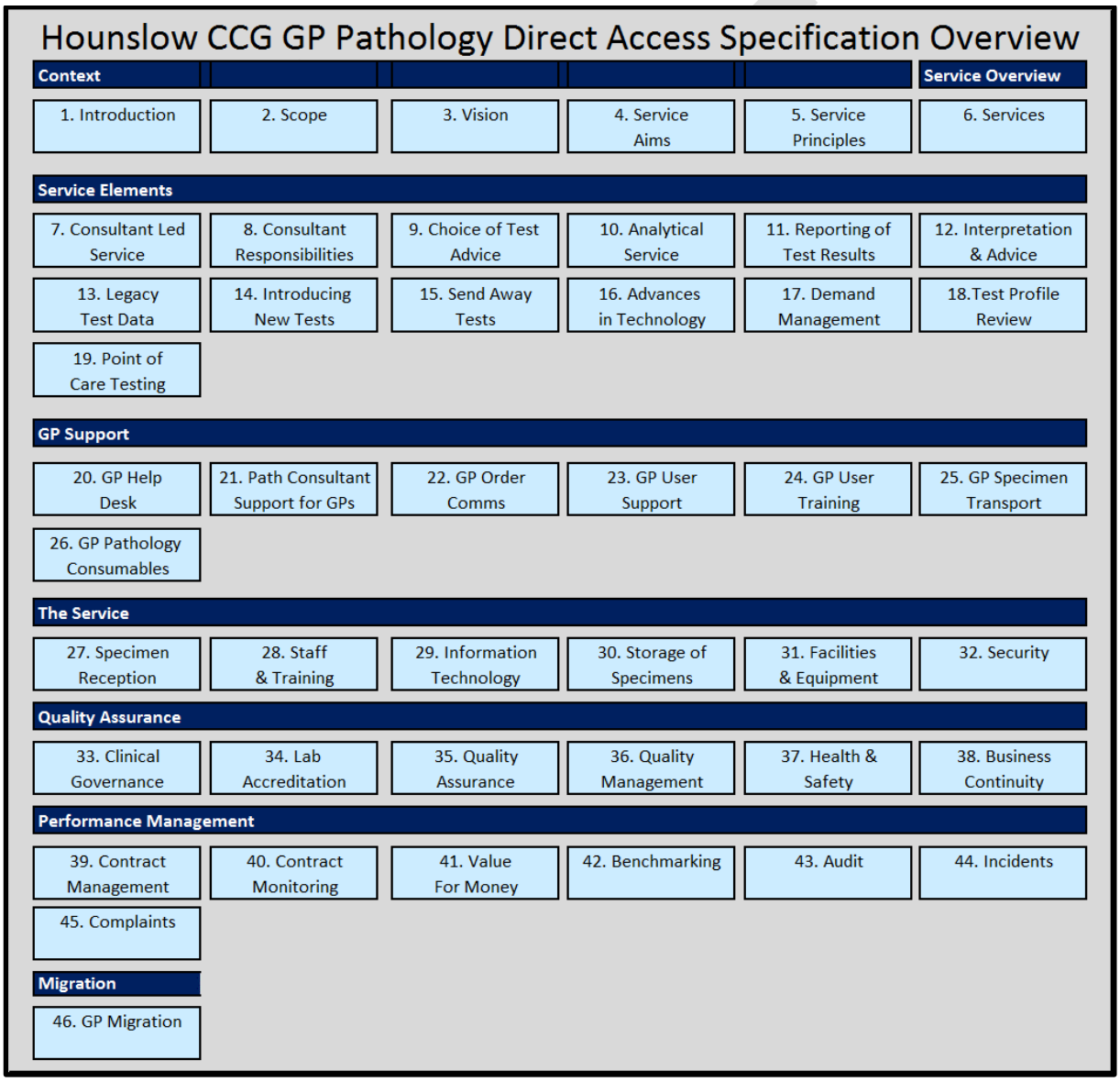
Hounslow CCG

GP Direct Access Pathology Service

Draft Specification



Context	
1	**Introduction**
1.1	Pathology is concerned with the study of the cause of disease and the ways in which they affect the body. Pathology tests examine changes in tissues, blood and other body fluids. GP pathology tests can be broadly categorised into three areas as follows: **(i)** **Blood Sciences:** the examination of blood and urine, which includes haematology, clinical biochemistry and immunology. **(ii)** **Infection:** the examination of disease, detection of viruses and problems with the immune system which includes microbiology, virology and immunology. **(iii)** **Cellular Pathology:** the examination of tissues and organs including histopathology and cytology.
1.2	Pathology is complex and highly technical service, covering a range of disciplines, with a range of response times, and a variety of delivery locations. Pathology services are a critical enabler in diagnosis, informing treatment and preventing infection in a very high percentage of patient conditions. It is also an essential element of research into the causes of disease and illness, their prevention and treatment.
1.3	Pathology services involve the collection of specimens, laboratory processing and analysis, reporting the results to the originating clinician along with interpretation and clinical advice. A key element of many pathology services is the involvement of consultant pathologists in assessing a patient and their related pathology test results and giving clinical advice on treatment.
2	**Scope**
2.1	Hounslow CCG require the Contractor to deliver a comprehensive Consultant Led GP Direct Access pathology service including: 1. Analysis and reporting of blood sciences, microbiology and histology tests 2. Test facilities and equipment 3. All associated staffing including lab technicians and bio medical scientists 4. Consultant leadership, advice and reporting support 5. Clinical governance 6. IT systems, Laboratory Information Management Systems (LIMS) and mandated user of electronic Order Comms test requesting at all 49 GP practices in Hounslow 7. Specimen collection consumables 8. Specimen transport 9. Storage of slides and samples where required 10. GP contact/help desk

	11. GP engagement and pathology skill development 12. Urgent Test request premium service for GPs 13. Monthly Performance Reporting 14. Order Comms IT support GPs with CQC guidelines, including QOF points 15. Lab Supplies, reagents and consumables 16. Service management, administration 17. Andrology services analysing seminal fluids. These services should be provided from facilities which are both accessible to patients and meet best practice guidelines. 18. Point of Care Testing (POCT) support, including advice and support for POCT devices owned and operated by GP practices and community health services 19. Pathology services to Corals Barracks, Hounslow Community Clinics (specialist skin service) and WMUH outreach anticoag services Phlebotomy Services are outside the scope of this service. Cytology screening is outside the scope of this contract as these are commissioned by NHS England with screening performed by at St Marys hospital and Frimley Park hospital.
2.2	The Consultant led GP Direct Access Pathology Service will support 49 GP practices, and other primary care facilities including GP managed care homes, in the London Borough of Hounslow. Samples are taken at GP managed care homes but taken back to the GP practices for transport to the laboratory. The CCG serves a diverse population with a comprehensive range of services. These services are provided from a range of locations that are likely to undergo change in the future. While services are focused on local needs specific to the population served, the CCG is also driven by national priorities.
2.3	The GP Direct Access Pathology service needs to be future proofed, to support GPs working together with NHS Hounslow's evolving primary care model including supporting 0800 to 2000 GP practice openings and 7 days working. Order Comms systems need to accommodate the needs of GPs working at several locations and locum doctors to ensure test results are delivered to the correct GP registered with a Hounslow patient.
2.4	Demand management will be a key feature of the requirement to drive out inappropriate test requesting. The Contractor will lead on GPs pathology skills development and support and develop existing monthly test ordering performance reporting at a practice level. The Contract KPI's will include targets for the Contractor to deliver effective demand management campaigns including associated incentives and penalties linked to demand management performance.
2.5	The Contractor will need to ensure that GP practices continue to use electronic test requesting and provide test results sharing between primary and secondary care by cooperating with the North-West London Diagnostics Cloud initiative. Currently Hounslow GPs achieve this test result sharing functionality, through the SunQuest Open Net system.

3	**Vision**
3.1	The overall vision is to provide the GPs with a robust, safe and reliable pathology service that meets their needs and achieves the target outcomes.
3.2	The standard of the service should satisfy the requirements of: a) Requesting GP Clinicians; b) Accreditation agencies including UKAS and ISO c) Hounslow Clinical Commissioning Group Clinical Governing Body
3.3	There will be a focus on efficient use of pathology testing through supporting GPs request the right test, for the right patient, at the right time. Electronic Order Communications usage, demand management and effective test profile configurations will be key to achieving this aim.
3.4	There is a key requirement that the service is supported by an effective IT system which enables efficient requesting and reporting of test results including functionality to share patients acute and GP requested test results. Refer to Section 4.1 for more details.
4	**Service Aims**
4.1	The key aims of the Contractors service are to deliver: 1. A Consultant led pathology service providing clinically safe, reliable results at the required Turnaround Times (TAT's) 2. Services which meet or exceed national guidelines and satisfy standards set by relevant accreditation and regulatory bodies 3. Consultant Pathologist support to GPs, to advise them about abnormal test reports, support them with ordering appropriate tests and support GPs by advising how to treat patients conditions 4. Effective engagement with GPs during both the mobilisation and delivery of contracted services 5. Rapid mobilisation with existing lab capacity and staff within a reasonable geographic distance which will not impact the integrity of sample quality 6. Partnership working with the GPs and commissioners to drive out unnecessary tests through demand management, with processes in place to ensure the clinical effectiveness and clinical utility of individual and groups of tests 7. Provision of proven and robust common IT Order Comms platforms, which are capable of integrating with patient results from local acute systems via the North-West London Diagnostic Cloud and facilitate exchange of information. IT systems should support extended GP practice opening hours and the provide the flexibility for GPs to request tests for other GP's patients and their test results to be received by the GP that the patient is registered with. 8. A safe and seamless transition to the new service whilst meeting the handover deadlines and enhancing to the quality of the existing service 9. Provision of monthly practice test ordering performance reports which provides transparency of cost of tests ordered

	10. Cooperation with the Department of Health's Modernising Pathology Agenda and NWL Diagnostics Cloud Initiative to implement standardised test ranges, test formulae's and test ordering rules 11. As the CCG expects that there will be further reduction in test prices over the contract term, the provider will agree to an annual benchmarking of a basket of tests to establish whether prices should be further reduced to reflect advances in technology, analyser efficiency and economies of scale driven by laboratory consolidation. 12. Provider end to end responsibility for a full pathology service, seamlessly integrating all elements and taking total responsibility for the service 13. Value for Money through competitive pricing which reflects the benefits of economies of scale for high volume automated tests and future advancements in lab technology 14. Flexible specimen transport arrangements which support future 08.00 to 20.00 GP practice opening and future weekend GP practice opening requirements Advanced IT enabled systems are a key requirement, allowing GP's to request tests efficiently including an IT Order Comms systems which facilitates: • Seamless interoperability with Sunquest OpenNet to facilitate test sharing of acute and primary care test results for Hounslow patients • Functionality to facilitate bulk test ordering periodically for multiple patients which require repeated batches of tests for defined conditions on a regular frequency • Maintaining the current high levels of GP satisfaction with efficient electronic test requesting, to maximise GP's time in face to face patient consultations • Having automated demand management tools included to alert GP's to minimum test repeat intervals (eg: Vitamin D) • The functionality for GP's requesting tests to ask the lab to copy results to other clinicians. This is important for a GP hub model where GPs may be requesting tests for patients not registered with their practice • Creating unique sample barcode labels to track, trace and identify samples • Advanced ordering of tests allowing tests to be scheduled in advance • Capture time of sample taken by phlebotomists
5	**Service Principles**
5.1	The Contractor will become the CCGs and GPs trusted partner by: • providing excellent clinical advice and guidance to GPs • support the high levels of GP test requesting via electronic Order Comms • effectively supporting the CCG to manage pathology testing demands • be flexible to deal with new demands from primary care • able to realise the benefits of future changes in lab technology • continually work towards improving the service

Service Overview	
6	**Services**
6.1	The Contractor will carry out the range of tests listed in the test activity volume baseline and within the turnaround times listed stated (or the specific turnaround times agreed by the CCG and the Contractor as clinically appropriate). The service will support all 49 GP practices in Hounslow listed in the Hounslow GP practice baseline. For the avoidance of doubt, gynaecological cytology screening for the CCG will continue to be performed at both St Mary's hospital Paddington and Frimley Park Hospital. The Contractor will provide the services from a laboratory on the xxxxxx Site. The xxx Laboratory will operate 24hrs a day, 7 days a week, 365 days a year. The Contractor will ensure that contracted Turnaround Times (TATS) are met and implement processes for monitoring overdue and pending tests. For those tests performed in house, 'Pending' test lists are produced several times each day by the laboratory to monitor throughput and TATs. The over-riding factor which determines whether a test is performed by the laboratory is clinical need, associated benefit and cost. The Contractor anticipates the test repertoire to be developed and reviewed following discussions between the CCG GP clinical leads for pathology and the Contractors Consultant Pathologists. The Contractor will have consultant led best practice teams which are specialist groups from all the individual disciplines. These groups look at the latest technology/methodologies and report on their suitability for test production and new advances in the field of laboratory medicine. The CCG will benefit from these groups for test demand management and keeping up to date with the latest technology. The Contractor will use a fleet of vehicles for transporting specimens from the CCG sites to the laboratory. Each vehicle will be fitted with all appropriate health and safety equipment to ensure safe and secure transit of specimens. All Contactors laboratory services must be meet the requirements of data protection legislation.
6.2	The Contractor must be capable of expanding both the volume and range of tests over the period of the contract to respond to likely future demand. The Contractor will continually review its test repertoire in response to clinical demand and greater effectiveness from advanced technology. This means that, should the CCG decide to add a specific test, the evaluation and correlation will already have been completed, allowing speedier implementation and benefits realisation. Any changes in test menu, method or testing site would be agreed with the CCG prior to implementation. The XYZ lab facility has capacity for an annual volume of xm tests. The laboratory will be configured to allow for variability and fluctuation in workload and will therefore also be capable of accommodating additional volume. To cope with increases in demand, the Contractor will purchase additional and/or larger clinical analysers and, where appropriate, add additional staff.

Service Elements	
7	**Consultant Led Service**
7.1	While a Contract will exist between the Contractor and the CCG, the pathology service will remain a Consultant-led and directed service. All Consultant Pathologists within each speciality will lead and manage of the service. The CCGs pathology service will be directed by a lead clinician from pathology appointed by the Contractor. The function of this individual is to manage the contract, in conjunction with the CCG, for the contracted pathology laboratory services, to ensure that the pathology service provided is in line with the strategic direction of the CCG and meets contractual commitments.
7.2	The CCG will monitor and manage the contract via the contract management Meetings, comprising senior GP clinical and managerial staff, who will liaise with the Contractors Consultant Pathologists to ensure that the agreed procedures and standards are maintained. Issues requiring discussion at the contract management meetings will be presented by the CCGs lead GP clinician for pathology.
7.3	When conducting discussions with CCG staff, the Contractor will communicate with the appropriate CCG staff as indicated by the CCG's management structures. The importance of definition of clear lines of accountability for all staff involved in provision of pathology services for the CCG and other users is recognised. In addition any such new management arrangement will be expected to satisfy the following requirements: • Full UKAS ISO15189 Accreditation status, or subsequent relevant accreditation body • Recognition and acceptance by the relevant professional bodies (e.g. RCPath, HPC (Health Professions Council), ACB). • Fulfilling contractual service provision obligations
7.4	The Contractors consultant pathologists are integral to the entire laboratory process. Their role ensures that all aspects of the service (pre-analytical/analytical/post analytical) conform to the highest attainable standards. The Contractors Consultant Pathologists will issue reports to the CCG highlighting the quality, appropriateness and efficiency of the service delivered to clinicians and GPs.
7.5	Contract management meetings will monitor all operational and service aspects of the contract. All service changes that entail amendments to the contract price can only be agreed in accordance with the change control process. Where the Contractors Consultant Pathologists require a change to be made to the Services, such change shall be proposed and approved through the contract management meeting.

7.6	The Contractors Consultants will set the standards for the total quality system and assist with the design of the system. Quality Management will produce reports for review at the contract management meetings. All Consultant Pathologists will monitor quality measures on a regular basis in their disciplines and take action when performance falls short of agreed standards (non-conformance). Consultant Pathologists decide when remedial action is sufficient to resolve a problem raised through the quality system and have the right to request quality improvement initiatives.
7.7	The Contractor will establish a documented system for registering and responding to serious clinical or laboratory incidents. Specifically the CCG requires near misses and Serious Untoward Incidences to be flagged and reported to them within one working day by writing in an email and then also be reported formally in the next quarterly contract meetings.
7.8	The Consultant Pathologist will be responsible for assessing quality measures (internal and external quality control data) and work practices related to analytical services performed for GP patients. Where deficiencies are identified, the Consultant Pathologist will lead the Contractors response with corrective actions. Resolution of these issues will depend on the signed acceptance from the Consultant Pathologist.
8	**Consultant Responsibilities**
8.1	The Consultant Pathologist will be responsible for both the clinical and laboratory aspects of the service relating to their speciality.
8.2	The Contractors relevant Consultant Pathologist(s) will consider and agree the selection of equipment.
8.3	The Contractors Consultant Pathologist(s) will consider and agree the selection of analytical methods. The Consultant Pathologists signature will be required before any new or amended SOPs can be accepted by the CCG.
8.4	Consultant Pathologists will be responsible for the interpretation of test results and for providing clinical advice to users of the laboratory service.
8.5	The Consultant Pathologists will advise on the test repertoire for the GPs patients. The Contractor will establish a documented process for the introduction of new tests and the withdrawal of retired tests. The Consultant Pathologist will agree the validation strategy to be used to assess the new procedure through method comparison studies. The Consultant Pathologist has the right to review the results of the evaluation and request further experimentation as necessary. A new procedure cannot enter service unless the relevant Consultant Pathologist has approved the results of this verification procedure. The Consultant Pathologist will work closely with the CCG to ensure that the test repertoire is in accordance with agreed formulae of approved tests and minimum repeat intervals for tests. The North West London Diagnostic Cloud project and usage of electronic Order Comms will support the enforcement of the agreed test formulae and implementation of demand management initiatives/campaigns.
8.6	The Consultant Pathologist has the right to request alterations in service delivery. All such changes should be approved by the contract management meeting and signed off by the Authorised Officer if it requires a change to the Contract. The agreement of the CCG is a pre-requisite before any changes are implemented.

8.7	The Consultant Pathologist will ensure that procedures and tests performed for the CCG are carried out by technical staff that have appropriate training and expertise. Their responsibilities will include supporting the recruitment of senior new lab staff and agreeing ongoing training.
8.8	The responsibilities of the Consultant Pathologist will include: 8.8.1 Review of Quality Control and Quality Assurance data. 8.8.2 Liaising with the GP users of pathology services, including establishing the respect of GPs, to become their trusted advisor for technical pathology advice and guidance through dealing promptly with Hounslow GPs queries and requests for additional information. 8.8.3 Provision of clinical advice on specimens at all stages from initial processing to final reporting. 8.8.4 Determination of action limits for telephone reporting of abnormal results. 8.8.5 Determination of which staff can authorise or telephone laboratory results. 8.8.6 Determination of clinical priorities in the work of the department. 8.8.7 Requesting repeat analysis of any patient test or tests. 8.8.8 Determining the protocols of all dynamic function or reflex tests 8.8.9 Ensuring the carrying out of additional investigations as a consequence of results found on specimens. 8.8.10 Appropriateness of test requests and specimens. 8.8.11 Supporting GPs to request tests appropriately through advice and guidance and working with the CCG to implement demand management campaigns. 8.8.12 Teaching and training of medical and non-medical laboratory staff. 8.8.13 Participation in the selection and suitability of laboratory staff. 8.8.14 Participation in the strategic direction of the CCG's Pathology service. 8.8.15 Ensuring Standard Operating Procedures are in place. 8.8.16 Audit. 8.8.17 Research and Development
9	**Choice of Test Advice**
9.1	The Contractor will give advice in the form of an electronic User Guide to the service users, on the appropriateness and timeliness of tests to be requested in various clinical circumstances. The User Guide will detail turnaround times and special pre analytical requirements. The electronic User Guide will be accessible from both the Order Comms system and the CCG extranet. The Contractor will work with the CCG to introduce GP user friendly algorithm tools to support the selection of appropriate tests for patient's conditions.

9.2	The Contractor will ensure that advice is available by telephone via the single point of contact GP Help Desk to supplement that provided in the User Guide and to deal with specific clinical enquiries.
9.3	The Contractor will ensure that guidance is available on the choice of sample and container for its collection to maintain specimen integrity and validity of results.
9.4	The Contractor will provide professional advice to develop and design patient care pathways to ensure high quality, cost effective patient-focused care, where pathology tests are an integral part of the patient pathway.
9.5	The Contractor will participate in a joint process with GP and community pathology service users, to provide expert, professional advice and guidance to agree the provision of new tests, previously not provided, and for the removal and decommissioning of obsolete and redundant tests.
10	**Analytical Service**
10.1	The Contractor will deliver an analytical service from the laboratory and support Point of Care Testing (PoCT) provided by GP's in their practices, to ensure safe and effective patient outcomes.
10.2	The Contractor will deliver an end to end analytical service which includes the full range of activities from the pickup of samples from GP practices, to the issue of the validated electronic result and must include relevant interpretive clinical advice to the requestor when appropriate.
10.3	The Contractor will provide a repertoire of investigations that support patient care including screening, diagnosis, monitoring and optimising treatment.
10.4	The Contractor will ensure that urgent GP requests are subject to urgent turnaround times, these requests will be flagged by the Order Comms as "Urgent", and will be picked up from GPs promptly and are prioritised upon receipt at the laboratory reception.
10.5	The Contractor will have appropriate facilities and equipment for the safe, effective, efficient and timely delivery of the analytical service.
10.6	The Contractor will ensure that users of the service are advised of any disruption to normal service provision; e.g. adverse weather conditions or traffic incidents impacting specimen collection times.
10.7	The Contractor will have robust plans in place to ensure service continuity and service resilience across all pathology disciplines, in the event of an unexpected service failure and or transportation issues
11	**Reporting of Test Results**
11.1	The Contractor will take complete responsibility for the provision of pathology test results to all GP users and for responding to queries from all parties about obtaining the results. This includes providing test reports to GPs in an agreed electronic formats and Hounslow CCG commissioners with all associated queries, including results not received, queries on the results etc.
11.2	The Contractor will provide reports in the form agreed with the CCG. All reports are user definable, the Contractor will work with the CCG and relevant groups to design

	and create the required report formats. The Contractor will agree the presentation and appearance of all reports with the relevant Consultant Pathologists or other managers in order to ensure that the report is appropriate for the recipient. The test results report will comply with the Royal College of Pathology best practice guidelines regarding standard formats
11.3	The Contractor will make available electronic results to the GP test requestors by the contracted turnaround times by a direct link into GP practice systems and update. the Order Comms system with the test results. The Contractor must respect and maintain practice system links when migrating the service and support practices during the migration to update them if necessary. The Contractor must have robust procedures in place to ensure the results are electronically sent directly to the original GP requestor, this is especially important when setting up new GP requestors.
11.4	The Contractor must have robust processes in place in their Order Comms systems to set up locum GPs and GPs who work in several practices including the NHS Hounslow network hub practices, to ensure that patient test results are returned to the right practice and GP clinician who is responsible for acting on the patients results. The Contractor will work with the practices to ensure GPs are trained how to request electronic copy results are automatically forwarded to relevant GPs.
11.5	The Contractor must setup new locums on the Order Comms system within two days of the request. The Service Contract will include KPI's for timely set of new GP starters and locums on Order Comms.
11.6	The Contractor will obtain the approval of the CCG to any changes to the electronic pathology request forms.
11.7	The Contractor will report all test results to users as follows: • Reporting abnormal results, which includes reporting of serious adverse results. Results that fall outside the normal range or within the alert range will be flagged as such and will appear automatically within the central system "to be phoned" queue. This will enable the single point of contact GP Help Desk to ensure that urgent and abnormal results are issued to the requesting clinicians as early as possible. Clinically dangerous results will be telephoned, slightly abnormal results are flagged on the report. • Reporting serious adverse results to GPs between 18.30 and 08.00. During out of hours, defined as between 18.30 to 08.00 Monday to Friday and 08.00 Saturday to 08.00 Monday plus Bank Holidays, the following procedures will apply to communicating seriously adverse results where clinical intervention may be required urgently. The laboratory will be responsible for communicating the seriously adverse result to 111 call centre, where the result will be reviewed by the 111 Doctor. Dependent on the 111 doctors interpretation of the result, the 111 Doctor may decide to either contact the patient directly with the contact phone number included on the result or otherwise contact and instruct NHS Hounslow's CCGs out of hours provider, Care UK, to make a house visit to contact the patient.

	The laboratory can reference the patients contact numbers in instances when they are included in the original electronic test request. The laboratory will also be responsible for phoning through the seriously adverse patients result to the relevant practice when the practice is next open to see patients. This could either be the next working day morning or a time at the weekend or bank holiday if the practice offers weekend and or bank holiday surgery sessions. • Checking and authorising completed reports prior to release to the user. Laboratory Information Management System (LIMS) results are only available for export to third party result reporting systems once they have passed through the clinical authorisation phase and have been signed out for release by an appropriate authoriser. • Determining which results should be reported to a Consultant Pathologist. The Consultant Pathologist can specify which test results require their authorisation. Whether results need to be reviewed by an authoriser or automatically authorised, signed out and released by the system, depends upon the individual record and result and whether any background LIMS rules have been configured to act. The Contractor will configure user definable authorisation queues and assign security so that only approved users may access certain areas and results for authorisation. • Signing reports Most report transfer is done electronically. In all cases the name of the person who released the report, date of releasing and laboratory where the releasing took place would be tagged electronically to the report for audit purposes. • Telephoning results There should be a procedure for logging these calls, so that an audit trail is created. The Contractor will have Standard Operating Procedures (SOPs) on the telephoning of results that incorporate UKAS ISO15189 guidelines. • How incomplete request forms or specimen labels will be handled. A SOP for the processing of incomplete requests and mislabelled specimens that meets the Contractor's corporate, legal and UK compliance issues controls the handling of these cases. • Providing guidance to laboratory staff on the urgency of cases. As a general principle, if the request is marked urgent, then that is the laboratory response. Any change to that status would only be made by a clinician. The experience and expertise of the Contractor's technical staff mean that it would turn a routine case into an urgent one as the situation demanded.
11.8	Out of Hours results will be provided as follows: • Normal Results on site at the laboratory site – the laboratory team will release results from the laboratory system via GP System link and then populate the Order Comms system.

	• Urgent or abnormal results for GPs – the laboratory team will notify the GP using contact details provided by the practice prior to the start of the contract. If the GP is not contactable through this route, the laboratory team will contact the appropriate out of hours service as specified in Section 11.7 above.
11.9	The Contractor will report a provisional result without delay when it is considered that its immediate availability may impact on the management of a GPs patient whilst making clear that this result may change in the final report. Any significant change to a provisional or final report that is likely to alter the management of the patient must be notified to the requestor by telephone followed up by the issue of a clearly marked amended report.
11.10	The Contractor will agree the type of communication to be used to alert the Consultant Pathologists and the CCG GPs to urgent results.
11.11	The GP Help Desk team will call through urgent results to designated contact numbers. Should such an occurrence occur outside core hours, the technical team will assume this responsibility. The Contractor will ensure written protocols are agreed with GPs for communicating results which are of a serious or life threatening potential and require urgent clinical action and or emergency referral to secondary care.
11.12	The Contractor will be able to produce histopathology reports to support the reporting of minimum data sets to local and national databases, including SNOMED CT codes, and other codes as agreed from time to time with Consultant Histopathologists as per national and regional guidelines. The Contractor will need to support multi-disciplinary teams ("MDT"s) reviews of cases and investigations. Where the contractor cannot review the specimen in house it will need to send away the case to a specialist referral centre.
12	**Interpretation and Advice**
12.1	The Contractor must produce clinical interpretation notes to accompany results as required.
12.2	The Contractor must flag clearly any abnormal results and provide interpretive comments in addition to reference ranges, where appropriate, on all issued reports.
12.3	The Contractor will ensure that further reflex tests relevant to the initial request/consultation shall be added where appropriate and possible from the sample available.
12.4	The Contractor will ensure there is prompt access to clinical liaison, interpretation of results and advice on pathology specialties shall be provided by a dedicated single point of contact GP Help Desk operating between 0800 and 2000 Monday to Friday.
12.5	The Contractor will also arrange out of hour consultant advice and guidance cover as required. There will be contracted turnaround times for providing advice and guidance, this will be within three working days of original request for routine requests and within two hours for urgent requests (check with Clinicians). GPs will first contact the single point of contact GP Help Desk to contact consultants for advice and guidance.

13	**Legacy Test Data**
13.1	The Contractor will access off line databases for interrogating legacy data to reference patient test result data for the previous two years There is no requirement to transfer this data into the Contactors LIMS system. The offline data base should include at least two years patient test data. Access to legacy test results should ideally be achieved by interrogation of an offline database file or contacting incumbent providers for test results details
13.2	The Contractor will work with the incumbent providers to obtain the historical data and will report back to the CCG if there are constraints caused by an incumbent provider, the CCG will use its reasonable endeavours to assist the Contractor in obtaining any required assistance from the incumbent provider in connection with obtaining data bases of historical test data.
13.3	Additionally, the Contractor will also liaise with incumbent providers on an adhoc basis to obtain historic results and recall histology samples if required.
14	**Introducing New Tests**
14.1	The Contractor will respond appropriately to requests for changes in the services; for example, changes in the TATs, the repertoire of tests and testing methods. The Contractor's approach acknowledges that it is in the best interests of all contracting parties to maintain and develop the service so that it is as the forefront of pathology service delivery. This is important for the CCG because they need to be able to respond quickly to local needs, changes in government policy and to developments in technology. It is important for the Contractor because the company wishes to maintain its reputation and commitment to patients, growth, and people. Any change will go through the Change Control procedure. The Contractor will develop a close working relationship with the CCG, so it can ensure any change optimises the service provided to patients and GP clinicians.
14.2	A regular six monthly newsletter update will be produced by the Contractor and distributed electronically to the CCG and GP users informing them of the availability of new tests and technology. Informing clinicians of changes in Reference Ranges will be included in the technical update section of the quarterly newsletter update, which will be reviewed by the Consultant Pathologist before distribution to the larger group. Under no circumstance will a reference range change go into effect without Consultant Pathologist notification and sign off before it goes live in production. Reference range changes will also be communicated as a message on the reports.
14.3	The Contractor will maintain clearly defined procedures for costing and implementing new tests, in conjunction with the relevant Consultant Pathologists and in accordance with the terms of this contract; for example, where these represent an improvement on previous methodologies. A clearly defined cost of testing exercise is undertaken for tests to price the individual elements of an assay e.g.: Labour cost – direct/indirect Material cost – direct/indirect

	Instrument costs – capital/lease considerations Overheads IT Transport and Logistics Before a new instrument or test methodology comes into routine production a validation procedure is undertaken to guarantee valid results.
14.4	The Contractor will satisfy the requirements of the DH Pathology Modernisation Programme and support the CCG to meet their requirements. The Contractor will maintain a positive relationship with professional bodies, industry leaders and government departments. The development of networks with their standardisation and streamlining of processes to improve efficiency and productivity is absolutely in line with the Contractor's way of working.
14.5	The Contractors Consultant Pathologists will discuss with the CCG how/whether and to what extent the laboratory services should respond to pathology modernisation initiatives.
15	**Send Away Tests**
15.1	The Contractor will maintain adequate procedures for the management of third party "send away" tests, referring them to UK Accreditation Service (UKAS) ISO15189 accredited laboratories and follow ISO15189 guidelines. The Contractor must ensure that the third party esoteric test provider meets the same quality criteria and performance standards set out in this specification. A full list of tests that would be referred to third party laboratories and the referral site is given at Attachment A; however this list may be expanded or reduced depending upon the volume of testing actually received by the CCG and market conditions. The Contractor must ensure that contracts for esoteric or send away tests are reviewed on an annual basis and quality standards are continually met to ensure compliance with national and ISO accreditation requirements and best practice. Records are kept of all referred specimens and pending list reports are made to monitor the return of referral results in a timely manner. The Contractor monitors referral laboratories quality on an on-going basis. For those tests referred to third party laboratories an 'Overdue' test list is prepared on a daily basis with any test that becomes overdue being followed up by the Contractor's single point of contact GP Help Desk. Audits of referral laboratories can be undertaken by the Contractors pathologists and third party laboratories will be routinely audited by the Contractors QA department. Samples for referral tests will be sent to third party laboratories. The CCG would wish to be charged the same rate or lower, as other NHS laboratories for this work and for other referred tests not listed in this specification that are referred to other NHS laboratories for testing. Should the provider laboratory for the tests listed above charge the Contractor the commercial rate, the CCG will work with the Contractor to obtain the NHS charges from such providers.
15.2	The Contractor will ensure that access to specialist clinical advice is available for third party tests, including immunology and virology tests. The Contractors

	Consultant Pathologists must be aware of requests for advice from the GP clinicians at the CCG. Should specialist clinical advice be required for third party tests, the initial contact will be through the GP Help Desk. The GP Help Desk will then contact the appropriate Consultant Pathologist, as agreed, if requested by them and either provide the contact details of the third party specialist clinical adviser, or arrange for the specialist clinical adviser to contact the Consultant Pathologist.
16	**Advances in Technology**
16.1	In the event of any advances in pathology services technology in terms of the test methodology, then the Contractor and the CCG shall meet together with a view to assessing whether such new technology should be introduced within the services.
16.2	This review will include an agreement as to the adjustments that should be made to fees payable to cover the additional costs or as the case may be, or the costs savings that would be attributable to the new technology. Subject to agreement being reached on these matters, the Contractor shall introduce the new technology into the services as soon as reasonably practicable.
17	**Demand Management**
17.1	The CCG wants to work with the Contractor to establish mechanisms to ensure that the current duplication of tests (for example by a GP and then at a specialist community clinic) are managed down. The integration of the Contractors Order Comms System with the North West London Diagnostics Cloud will be key to eliminating unnecessary duplicated tests.
17.2	The Order Comms systems will have the functionality to prompt primary care staff, during the test request preparation stage, to query the database for the recent test results of a particular patient, within a particular timeframe. The Order Comms system will interface with the results database before a request is confirmed, alerting the user if the same test has been conducted to avoid the ordering of duplicate tests. The Order Comms system will support requestors to select the most appropriate and effective tests for their patients.
17.3	The Contractor will work with GPs to define formulae for agreed authorised test repertoires, protocols for minimum repeat intervals, algorithms and other similar schemes to ensure the appropriateness of test requesting. Implementing agreed demand management automated controls on electronic ordering systems where appropriate.
17.4	The Contractor will make available test requesting trend reports to support clinical peer review of requesting behaviours.
17.5	The Contractor will support the GPs to further develop their appropriate test requesting skills, enabling them to request the right tests for the right potential symptom or condition at the right time. Every six months a demand management campaign will be agreed jointly between the CCG and the Contractor to support appropriate test requesting.
17.6	The Contractors Order Comms system must display the relevant cost of tests during the requesting process to make the costs of all tests transparent to the requesting GP.

18	**Test Profile Review**
18.1	The Contractor will work with the CCG to review the bundle of tests contained within standard profiles (such as a Liver Function Test "LFT") to ensure that all tests are clinically necessary and ensure the tests include in profiles reflect the most up to date tests and clinically relevant and effective tests based on pathology consultant advice and guidance This could result in the constituent tests of profiles being changed. Additional test profiles to meet GPs needs to managed patient conditions may be introduced by agreement with the CCG. The CCGs GP clinical leads will meet on a six monthly basis to review and make amendments to existing and introduce new condition based profiles by agreement.
19	**Point of Care Testing**
19.1	The Contractor will provide a Point of Care Testing (PoCT) support service to the GPs, which will include the provision of advice and guidance to GPs. This service will include Quality Assurance for the GP and community owned PoCT devices in the patch.
19.2	The Contractor will support GPs to: • Help ensure that PoCT is undertaken by GPs in accordance with professional, national and regulatory guidance to meet best practice. • Support integration of PoCT with electronic Order Comms systems wherever practical and possible, this involves mainly Roche anticoagulation devices. • Provide independent advice and guidance on the suitability and appropriateness of third party PoCT equipment and the process used to deliver the PoCT service.
GP Support	
20	**GP Help Desk**
20.1	The Contractor will provide 24 hour support (365 days per year). Such 24 hour cover will include a dedicated GP Help Desk service operating 0800-2000 Monday to Friday, excluding public holidays. Outside these hours there will be support from the duty technical team via a dedicated mobile or land line. The Contractor shall ensure that the Help Desk is responsive to GP needs, with the responsiveness being monitored against agreed response time KPIs and an annual GP service satisfaction survey. The GP Help Desk will provide a single point of contact for GPs and other CCG pathology service users. The GP Help Desk will receive and log all customer calls for orders, progress chasing, clinical enquiries, technical enquiries and faults. The GP Help Desk will manage and monitor enquiries, faults and orders until resolution is achieved The GP Help Desk will be operated by a team of well trained staff, dedicated to answering service users' queries about results, specimen types, courier collections, supplies, Consultant Pathologist advice and similar queries. They will have an in-depth knowledge of the pathology services being provided.

	The initial point of contact for all GP service issues is the GP Help Desk. When a service issue, which cannot be resolved by the GP Help Desk occurs, it will be escalated through to the department head and then to the pathology manager. The standard of good practice for help desk and support services shall be good industry practice. If the CCG wish to extend the help desk service hours as defined in this specification, they shall be entitled to do so at an agreed cost. The GP help desk team will provide support functions using established procedures, which outline core processing, handling orders, and escalations procedures. Copies of these are available from the Contractor on request The GP Help Desk will co-ordinate the majority of queries which occur during normal working hours. Regular feedback is sought from users of this service, both GPs and the Contractors lab staff and Consultant Pathologists.
20.2	The GP Help Desk shall conduct such processes and procedures as are appropriate to support and manage the services, including order management, clinical and technical support, change management and customer help.
20.3	The GP Help Desk will be staffed with trained personnel and the telephony solution will allow for multiple calls to be dealt with. A full list of contractors help desk staff, including those in a supervisory position, will be provided to the CCG. A protocol for referring calls to Consultant Pathologists will be agreed prior to the service commencement date.
20.4	The GP Help Desk will also provide GP service users with IT and data systems support. IT support will be available out of hours and on weekends through dedicated 'on call' staff. Mobile telephone numbers of Contractor key executives and supervisors will also be provided to the CCG.
20,5	The Contractor will provide the CCG on request, reports detailing GP Help Desk usage including number and time of call profiles throughout the day and week, which GPs are using the service and what are the type of enquiries made.
21	**Pathology Consultant Support for GPs**
21.1	The Contractor will be committed to supporting the CCG's consultant led service. Liaison with Consultant Pathologists will be regular and frequent, formal and informal, reflecting current close working relationships between laboratory and GP clinical staff.
21.2	The Contractor will preserve or enhance close collaboration between the CCG's GPs the Consultants and the pathology disciplines. A key element of the Contractor's service to clients is the GP Help Desk. The Contractor will be able to access to consultant advice via the GP Help Desk. The Contractor will supply each Consultant Pathologist with a mobile phone for their use in and outside normal working hours and for people to contact them for advice. In addition to this, there will be normal office contact numbers and the Contractor's e-mail system. The Consultant Pathologists will have access to the laboratory database and the databases of all the Contractor's referral labs, the quality information and all technical and scientific information of the Contractor. This will allow the provision of data

	promptly to a Consultant Pathologist to assist them in evaluating and interpreting the laboratory's work subject to appropriate information governance constraints. The Contractor will ensure a seamless distribution and production of results for the Consultant Pathologist. All Consultant Pathologists will have access to all results/reports, whether interim or waiting for final review, and, if directed by the Consultant Pathologist, all efforts will be made to prioritise/expedite the production of results for specific cases. Reviewing test utilisation and inappropriate requesting will be achieved by regular reviews of workload analyses between Consultant Pathologists and the Contractors staff. If inappropriate testing is noticed on specific patients from guidelines previously given by the Consultant Pathologist, then the Consultant Pathologist will be informed at their next department meeting or on an individual basis if directed to do so. The Contractors Consultant Pathologists will work with the CCG to understand what is required and support the development of the CCG's demand management policies. The Contractor will proactively support the CCG with data and IT solutions where ever and whenever possible.
22	**GP Order Comms**
22.1	The CCG has mandated the use of an electronic Order Comms solution and the Contractor must procure at their cost, the relevant licenses to operate this end to end service The Order Comms system need to interfaces seamlessly with the practice systems currently utilised by the GP's (SystmOne and EMIS web).54 of Hounslow GP practices use SystmOne and one practice uses EMIS web.
22.2	The Contractor is responsible for deploying the functionality for electronic test ordering through the use of an Order Comms system. All interfaces will be fully tested by the contractor before being transferred to the live environment. Additionally the contractor will be responsible for refreshing Order Comms and GP interfaces to meet evolving software standards and refreshes.
22.3	The Contractor will provide a system for bar coding of samples received from the GPs, via Order Comms and at the point of requesting. The barcoding of samples will facilitate track and trace. The Contractor will include an interface between their LIMs (Laboratory Information Management System) to the Order Communications System ("OCS"). The laboratory system to be used at the xxx Laboratory is the xxx system. The Order Comms System must fully support the production of user definable barcode labels, which can include a host of eye readable patient demographics for positive patient ID and a barcode. These labels are produced automatically during request entry by the GP practice printers and/or as the samples are booked in within the laboratory environment. The Contractor will be responsible for the provision, maintenance and training related to GP order comm label printers, this includes the provision of specialist paper to create the labels. The Order Comms system enables this functionality at the point of requesting.
22.4	Any communication or electrical equipment used by the Contractor in connection with the Contract shall not cause any interference with or damage to any equipment used by GP Practices.

23	GP User Support
23.1	The Contractor must implement a process for GP's to contact the relevant pathology consultants in case of queries. A one page summary of all pathology consultants must be included on the Order Comms system including name, title, speciality, pictures and contact phone numbers and email addresses. The Contractor should meet the KPIs for responding to GPs queries by consultants and work together with the CCG to introduce an electronic chat room to deal with GPs queries. Routine queries in the chat room should be responded by the relevant consultant in 48 hours, and the system should allow for the responses to be downloaded directly into the patient record.
23.2	The Contractor will have a dedicated GP Liaison Manager who will be responsible for resolving any GPs issues with the service including dealing with transport arrangements, specimen collection consumables supplies, training and usage of Order Comms and access to advice and guidance.
23.3	The Contractor will publish a comprehensive User Handbook in an electronic format accessible by all clinical users of the services. This will include details of senior pathology staff and how they can be contacted, the Contractor's policy on handling complaints from users, and guidelines on the appropriate use of tests and their interpretation. A directory of services, both in electronic format, will be produced by the Contractor. In addition, the CCG will be provided with information to place on the North West London Diagnostic Cloud OpenNet system, in consultation with CCG users, clinicians and pathologists.
23.4	The User Handbook will include as a minimum: (i) key contact information; (ii) sampling instructions; (iii) guidance on choice of appropriate container; (iv) reference ranges for tests; (v) advice on maintaining sample integrity; (vi) advice on common interferences; (vii) guidance on availability, appropriateness and timeliness of tests (including Turnaround Times) (viii) any special handling needs (ix) listing send away tests that are not performed directly by the Contractor and state sample required (x) referral laboratory names and addresses for esoteric send away tests
23.5	The Contractor will ensure that appropriate staff attend all meetings that they have been designated to attend with the CCG and the GPs.
23.6	The Contractor will undertake annual GP user satisfaction surveys as required by UKAS ISO15189 and demonstrate how the Service will respond to this information. The Contractor will achieve this requirement by holding user feedback sessions, regular meetings with users to identify up and coming areas of need, and via user satisfaction surveys. The information gathered from these sources will be incorporated into the Contractor's Quality Management planning and used to develop proposals and action plans to be taken through the appropriate process for approval and implementation.

23.7	The Contractor will set up and participate in user group meetings. It is expected that these groups will involve CCG GP clinicians, managers and patients.
23.8	The Contractor will design all test request screens, liaising with the CCG Clinical leads so that they meet the needs of requesting GP clinicians. To support safe and efficient data entry and processing, certain elements of the test request screens are standard. The part of the test requesting screen which is user definable to the individual GP clinician and request forms will be developed in conjunction with the Consultant Pathologists and clinical GP users.
23.9	The Contractor will design test selection screens with safe data entry in mind. Certain elements of the request form will be standardised to support bar coding, standard demographics layout, accession labelling, and document imaging and storage.
23.10	The Contractor will establish and keep up-to-date a list of the CCGs GPs, with telephone numbers in electronic format.
24	**GP User Training**
24.1	The Contractor after consultation with the CCG, will participate in the training and development of GPs and any other CCG staff who access the pathology service. The details of this training and development activity will be discussed and agreed via the contract management meeting.
24.2	The Contractor will provide opportunities and support for in the training and development of GPs, practice staff and any other CCG staff accessing the service. Specifically the contractor will be responsible for training new Order Comms users and deliver refresher training programmes and support the Order Comms system by providing a user manual.
24.3	The Contractor will provide regular training to GP clinicians in the correct use of all the services. There should be particular emphasis as to how trainee GPs and newly appointed GPs will have induction sessions to use the system. This will include use of electronic Order Comms, the directory of services, the GP Help Desk and effective use of the pathology service (for example, requesting urgent results and demand management).
25	**GP Specimen Transport**
25.1	The Contractor will provide GP specimen pickups in accordance with the pickup requirements set out in the route schedule in the GP practice baseline.
25.2	Prior to the service commencement date, the Contractor shall liaise with each GP practice receiving services under the Contract to discuss and agree their pick up requirements and to finalise the attached schedules. For the avoidance of doubt, such schedules shall be finalised in agreement with the CCG.
25.3	The GP specimen transport service will also deliver pathology consumables and other pathology service related materials to GPs. The GP specimen transport service will not be responsible for delivering non pathology consumables and other non-pathology related records and supplies to GP practices under this specification.

25.4	The Contractor will provide a transport service to pick up GP specimens, appropriate to the location of the tests and which meets or exceeds the standard of the CCG's existing GP transport arrangements. All GP practices require two daily collections of samples. The GP practice baseline specifies the transport services which will be provided by the Contractor. The Contractor will work with the CCG to review current pickup times to see whether they meet the needs of GP practices and make modifications where operationally possible. The practices require one morning pickup and one early evening pickjup between 1700 and 20.00. Hub practices and may require an additional collection in the day. Going forward practices and hubs may require specimen pickups and test analysis at weekends, from service commencement it is anticipated that five practices will require a weekend specimen pickup service. The precise specimen pick up requirements are set out in the GP Practice baseline. Couriers for GP collections will follow route sheets designed to make collections from GP practices at convenient times, ensuring that specimens are delivered to the laboratory with minimum delay. Route sheets will detail the actual time of collection, number of specimens collected and time of delivery to the laboratory. The number of specimens collected and delivered will be reconciled to ensure that all specimens are accounted for and records kept for audit purposes. Any delayed or missed pick-ups will be logged and the Transport Supervisor will take corrective action. All courier staff, including third party contractors, will be trained in specimen transport and training in line with UKAS ISO15189 accreditation. The courier service will be audited regularly using Courier Logs. These are used by the Contractor's couriers to track sample collections and delivery times, along with sample numbers. A report of courier performance will be provided to the CCG at agreed intervals.
25.5	Where capacity allows, the Contractor's dedicated couriers will handle emergency urgent pick-up requests. The Contractor will work with the CCG to agree an urgent pick-up request transport service which may either entail samples being picked up from a practice with a late collection or a one-off service which entails a one off pick-up fee. To support the effective management of some patients, the Contractor needs to provide a priced option for GPs to request an urgent pickup of a sample and rapid analysis. The response times for urgent requests are samples to be picked up are within one hour after the request and then the result being available two hours afterwards resulting in a total three-hour request to reported result turnaround time. It is envisaged the urgent specimen pickup and report service will only be used infrequently by Hounslow GPs on an exceptional basis. The urgent specimen and report service would be priced as a cost per each request service, which will be an additional charge to the price per test. If capacity is not available, an external contractor will be used. This courier contractor will be validated and meet UKAS ISO15189 accreditation standards.
25.6	The Contractor will ensure that samples are transported in accordance with best practice, statutory and contract requirements for their collection to ensure compliance with Health and Safety regulations and maintain sample integrity and data confidentiality. The Contractor will monitor and report incidents during sample

	transportation that may have affected the quality of the sample. The Contractor will monitor numbers of lost samples and issues with raised potassium's and report these issues on a quarterly basis. The Contractor will take corrective action if issues relating to lost or non processable samples are more than agreed tolerances.
25.7	The Contractor will ensure that all vehicles used for specimen transport satisfy all legal requirements. Drivers of vehicles will be suitably trained to handle biological specimens in accordance with best practice and statutory legislation. The drivers will be trained in maintaining specimen integrity relevant to testing needs; for example, room temperature, frozen samples, etc. Training and competency assessments will be in line with UKAS ISO15189 accreditation. Standard Operating Procedures ("SOPs"), training manuals, etc. will available for inspection by the CCG.
25.8	The Contractor will transport specimens in suitable vehicles with the appropriate temperature controlled environments in the event of extreme temperatures.
26	**GP Pathology Consumables**
26.1	As part of the service provision, the Contractor will supply all electronic requesting specialist stationary and necessary specimen collection consumables, including blood collection systems and needles including butterfly needles where required by the CCG.
26.2	The Contactor will monitor stocks of pathology consumables; ensuring sufficient supplies are always available to the GPs.
26.3	The Contractor will ensure that guidance is available on choice of sample and container for its collection, to maintain specimen integrity and validity of results and make this information is available in the user guide.
26.4	The Contractor will provide a supply of request forms and necessary consumables as part of the contingency plan for failure of Order Communications.
Lab Support Processes	
27	**Specimen Reception**
27.1	Urgent samples will be prioritised in order of their urgent nature. Samples are to be handled, both during working hours and out-of-hours.
27.2	The Contractor will provide a supervisor dedicated to the reception area of each site carrying out pathology tests.
27.3	The Contractor will maintain Standard Operating Procedures ("SOPs") detailing the training of reception staff. These will include safe handling of dangerous samples and how to respond to inadvertent exposure to infected materials.
27.4	The Contractor will train reception staff to check the integrity of samples and request forms. If discrepancies are found, these will be logged onto the database. The Contractors help desk resolves discrepancies in consultation with the ordering GP clinician. Resolution will be documented in the database.

27.5	The Contractor will train and supervise reception staff, so that a competent person deals with queries appropriately.
27.6	The Contractor will maintain protocols that specify the type of specimen required for each investigation and the conditions under which the specimen should be collected and transported to the laboratory.
27.7	The Contractor will provide specialised reception arrangements for histopathology in recognition of the precious nature of the specimens.
27.8	Members of the Contractor's technical team providing the Out of Hours service will deal with these samples received after the reception staff have left the premises.
27.9	The Contractor will ensure specimens from all disciplines are treated with equal importance, irrespective of the site of processing.
28	**Staff and Training**
28.1	The Contractor will provide appropriate numbers and skill mix of staff to provide the services required by the CCG. Appropriate management roles will be defined for managing Laboratory services including specimen reception.
28.2	The Contractor will ensure that all staff are appropriately qualified for the work they are performing. .
28.3	The Contractor will involve their relevant Consultant Pathologists in the appointment of all senior staff to be deployed in the provision of the Services. This will include, for example, involving them in short-listing and interviewing candidates.
28.4	The Contractor will have a full-time HR/Training Coordinator and in addition designated Training Officers in each laboratory discipline who oversee the training requirements and training documentation for the department. The Contractor will deliver and document operational training and will implement Standard Operating Procedures ("SOP") regarding training to ensure that the Contractor provides adequate training to all staff, which meets the requirements of the relevant professional bodies where appropriate. The Contractor's laboratory facilities will meet the HPC and IBMS training requirements. The Contractor will support lab-based reports as part of the requirements for employees taking BSc or MSc qualifications. Furthermore, the Contractor will maintain a library, with internet access, providing access to technical books and journals for employees. The Contractor will undertake regular competence assessments. The Contractor will deliver ongoing training and development of its employees. All departments in the laboratory will have a designated Training Officer to ensure that team member's skills and training are maintained on an ongoing basis. The Contractor will also maintain a pathology technical library, with access to technical books and journals for employees, including Internet access. The Contractors employees will attend external conferences and seminars. The cost of training courses, conferences and seminars is covered by the Contractor.

	The Contractor should conduct an on-going rolling programme of competency assessment, which ensures the periodic assessment of job skills, proficiency and overall competence
28.5	The Contractor will meet the Health Professions Council (HPC) training requirements and have trainer status for microbiology (bacteriology), histopathology, haematology and biochemistry. The Contractor's training policy and procedure will ensure that the Contractor meets the training/education requirements of the relevant professional bodies and provides opportunities for all staff for further education and training.
29	**Information Technology**
29.1	The information system requirements are seen as a key component of the success of Service delivery. The Contractor will operate a Laboratory Information System and an electronic Order Comms system. The Contractor must ensure that the systems, interfaces and information flows it is implementing can meet the requirements of the CCG from the agreed service commencement date. For the avoidance of doubt, this includes ensuring continuity of the IT services, and minimising any IT downtime.
29.2	In providing the IT services, the Contractor shall use Good Industry Practice to ensure that any computer systems and/or related hardware and/or software it uses are free from corrupt data, viruses, worms and any other computer programs which might cause harm or disruption to the CCGs' and GP practice computer systems.
29.3	It is a requirement that information systems are in place and ready for testing at least four weeks before the service commencement date.
29.4	The Contractor will monitor its IT performance on a monthly basis, and shall provide a monthly report to the CCG, within 15 working days of the end of the relevant month, detailing any downtime and fix and response times.
29.5	It is essential that systems and interfaces enable the efficient flow of orders and results for the GP's. The CCG will not accept persistent and continual IT downtime.
29.6	The Contractor shall be responsible for all IT failures including downtime, irrespective of the cause of such failures. All information system downtime or faults, relating to the Contractor networks, interfaces, software or hardware which prevent the CCGs or GP practices carrying out their planned workload must be rectified by the Contractor.
29.7	Both the Order Comms and LIMS systems need to provide for 99.8% user availability. It will be the Contractor's responsibility for ensuring continuity of the Services during periods of downtime and for reloading and updating records and data when the systems are in operation again.
29.8	The CCG requires the contractor to interface their LIMS with the Order Communications solution. It is the responsibility of the Contractor to achieve the necessary interfaces. The Contractor needs to ensure that all the necessary interfaces to operate an end to end full pathology service are included in the contract price.
29.9	The Contractor must provide the necessary hardware to deliver the service; costs for hardware system refresh must be included in the contract price. All software used by

	the Contractor in the provision of the services will be supported on a contract which provides full software upgrades. For the avoidance of doubt the Contractor is responsible for the costs of both the LIMS and Order Comms software.
29.10	The Contractor will supply the network required to connect the peripheral devices and remote system links to the pathology system. All connections should be sized so they operate efficiently. The Contractor must ensure that their analysers are interfaced with their LIMS system.
29.11	The Contractor will ensure that test orders are processed using machine readable technology, e.g. samples being bar-coded rather than hand written.
29.12	The Contractor will have a comprehensive Laboratory Information Management System (LIMS) including systems supporting biochemistry, haematology, immunology, microbiology and histology disciplines.
29.13	The Contractor will ensure, that where requested by the relevant consultant, verified data can be made “read only”, so that it cannot be altered subsequently. Each record, once passing through the clinical authorisation process, will be marked as authorised and will be locked for editing. Users, subject to security level, are able to unlock these records and make amendments; these amendments will invoke the LIMS audit trail and force the record through clinical authorisation again.
29.14	The Contractor will ensure security, confidentiality and ongoing availability of data held on behalf of the CCG.
29.15	The NHS Number, with check digit can be configured to be a mandatory field within the LIMS request entry screen. This field is a fully searchable and indexed field within the LIMS system.
29.16	The Contractor and its IT sub-contractors selected to service the contract fully support the design objectives of relevant NHS IT regulators.
29.17	The Contractor will provide information in the form and at the times required by the CCG to support: o Contract payments o Clinical audit o National requirements to collect a minimum data set o Statutory returns The CCG will require monthly activity data by test and by cost for each general practice within 15 working days of the end of each month. The CCG will require monthly activity data to show where tests have been duplicated in primary and secondary care.
29.18	The Contractor will provide means for the Consultant Pathologists to access previous test results. The LIMS system will allow a full and complete history lookup on screen for any and all patients at any time. This history view can be filtered to show previous results from the patient within a specific LIMS workgroup or pathology discipline or can display all relevant history across all workgroups.

29.19	The Contractor will incorporate within their pathology system the ability to produce a consolidated list of all previous specimen results/reports for histology cases, for any specific patient. The list should include, for each item, the laboratory reference number, the patient's name and age sex, SNOMED code, the referring clinician, the reporting pathologist, the macroscopic and microscopic findings and conclusions.
29.20	The Contractor will retain pathology data for at least the minimum time set down by UKAS ISO15189 standards or future accreditation standard such as relevant ISO standards. All data backups are retained for a minimum of 30 years. Data residing on magnetic media must be held at a secure off-site location, in conditions that will ensure security and the integrity of the media.
29.21	The Contractor will make available in electronic format all pathology test data and results.
29.22	The Contractor will comply with the messaging standards as defined by the relevant NHS IT regulators. The Contractor will be able to encode according to the SNOMED classification, with look up tables for ease of use. Ideally, it should incorporate an automatic SNOMED facility.
29.23	The Contractor will provide IT support staff through a dedicated team of IT professionals will provide support for the systems and applications. In addition, all systems are monitored 24/7 365 days a year by staff at the Contractor's data centre. Remote insight tools enable staff to provide troubleshooting and user support at and from all locations. Out of business hours, on-site support is available by telephone from a nominated member of the support staff team. On-site support response times to reported problems will be within 2 hours. The Contractor's IT staff will fully support all hardware and software/applications under their responsibility, wherever required.
30	**Storage of Specimens**
30.1	The Contractor will manage the handling and storage of specimens in a safe and secure manner in accordance with national guidelines, biosecurity, regulatory and legal requirements. The Contractor will store samples for appropriate times and temperatures to comply with the storage requirements of the Royal College of Pathologists Guidance and UKAS ISO15189 standards for the specific type of sample. Samples storage management must be achieved through the LIMS software system. Additionally the Department of Health Code of Practice on Records Management must be met.
30.2	The Contractor will store samples, reports and request forms, and associated worksheets and documentation, for the length of time defined by the Royal College of Pathologists guidelines and the Department of Health Code of Practice on Records Management. All documentation concerned with analysis of patient samples with be stored locally at the respective site for one month and then will be archived to a commercial storage facility for a minimum of 15 years. Histology documents and blocks will be stored indefinitely. The Contractor will maintain all histopathology, and post-mortem records relating to patients indefinitely.

30.3	The Contractor will provide a computer-based system of logging archived samples, with procedures to ensure rapid and reliable later access to any stored sample.
30.4	The Contractor will store blood samples for a sufficient period of time, whilst respecting contracted turnaround times and under appropriate conditions to reduce the need for re-sampling GP patients: (i) to enable the addition of further tests (termed as reflex tests) by the requestor or other clinicians; (ii) in the case of errors and shall analyse repeat samples in this case without charge where the error was caused by the Contractor; (iii) for a sufficient period to deal with necessary retrospective tests in accordance with national guidelines.
30.5	The Contractor will retrieve from storage films and other relevant media against agreed criteria as requested by Consultant Pathologists and other CCG GP clinicians. Haematology blood films will be stored for a time agreed with the Consultant Pathologists and CCG GP clinicians.
31	**Facilities and Equipment**
31.1	The Contractor will provide sufficient facilities and all laboratory pathology equipment which are accredited to UKAS ISO15189 standards or relevant future accreditation body, to carry out the required volume and range of tests and other services. For the avoidance of doubt, all equipment costs, including equipment refresh costs should be included in the contract price. UKAS ISO15189 full accreditation or relevant subsequent future accreditation body must be maintained at the laboratory site. The Contractor will have in place maintenance and support arrangements for all its equipment and facilities
31.2	The Contractor shall ensure that all equipment and materials used in connection with the Contract is maintained in good working order in compliance with the manufacturer's instructions and current legislation. This shall include the Contractor preparing a regime for the maintenance and calibration of the laboratory equipment.
31.3	The Contractor shall ensure that all facilities and equipment are covered by adequate insurance in the event of damage to, or loss.
31.4	The Contractor will ensure that sufficient stocks of reagents and other consumables are held to support the lab analysers and avoid the risk of service interruption.
31.5	All equipment used by the Contractor shall comply with the latest relevant British Standard or European equivalent specifications where such exist.
31.6	The Contractor shall establish effective planned maintenance programmes and make adequate arrangements for emergency remedial maintenance, to ensure continuity of the services; The Contractor will ensure compliance with all regulations covering the inspection and testing of all Equipment used at the laboratory facility in the provision of the services; and The Contractor will maintain records, open for inspection by the CCG (on giving reasonable prior notice to the Contractor), of maintenance, testing, calibration and

	certification. Any information obtained by the CCG during such inspection shall be treated as confidential information.
31.7	The CCG shall be permitted to inspect the laboratory facilities and lab equipment, on giving reasonable prior notice to the Contractor. Any information obtained by the CCG during such inspection shall be treated as confidential information and the CCG shall comply with the Contractor's policies in force at the laboratory facility.
32	**Security**
32.1	The Contractor will provide its staff with identification security badges complete with photograph and name badges at induction and ensure that these are worn at all times when on CCG or GP practice sites.
32.2	The Contractor needs to operate password controlled or swipe card security access at all of its current operational sites. The Contractor will ensure that there is no unauthorised access to the laboratory and that all visitors are properly identified and wear ID badges.
Quality	
33	**Clinical Governance**
33.1	The Contractor will support the CCG's clinical governance policies, in particular, through the provision of data, and staff development procedures.
34	**Lab Accreditation**
34.1	The Contractor will provide and maintain SOP's for all the tests provided and all associated procedures, as required to achieve and maintain UKAS ISO15189 accreditation or any future relevant Accreditation relating to pathology services.
34.2	UKAS ISO15189 accreditation or any future accreditation relating to pathology services will be maintained at all sites delivering the service throughout the contract period.
34.3	The Contractor will, unless specifically agreed otherwise, conform to the guidelines set out in the current UKAS ISO15189 accreditation handbook.
34.4	The Contractor will provide the laboratory facility with a complete functional quality system including a set of operational SOP's and a quality manual.
35	**Quality Assurance**
35.1	The Contractor will appoint a dedicated Quality Assurance (QA) Manager and maintain an effective QA system.
35.2	The Contractor will provide an annual quality report based on performance metrics. A lab-focused review will be carried out by the Quality Assurance Team. Items and metrics will include: issues arising from audit and customer satisfaction surveys/complaints, review for trends in customer complaints, EQA performance, performance metrics (such as turnaround time), amended reports and sample handling errors.

35.3	The Contractor will have formal procedures for change management within the laboratory.
35.4	The Contractor will have well defined processes for implementation and change of internal quality control processes. Defined procedures include: • Laboratory Quality Control • Control Materials - Establishing Ranges • Repeat Analysis • Entering and Reporting Results Staff will be trained on these procedures, so that a standardised process is carried out.
35.5	The Contractor will ensure that it has sufficient stocks to meet the requirements of the Service. This will be supported by effective stock control systems.
35.6	The Contractor will participate in external quality assurance schemes. The Contractor will handle effectively reports from EQA schemes. Reports will be promptly approved by the team leader, Consultant Pathologist for the discipline and QA manager, and signed/dated. If there is a non-conformance, the issue is investigated to establish cause, wherever possible, and corrective/preventative action taken.
35.7	The Contractor will ensure that all EQA results are reviewed by the relevant Consultant Pathologist and will use EQA reports for training purposes.
35.8	The Contractor will ensure that any other laboratory or facility that is used to undertake work related to this Contract meets the specified QA standards. Laboratories used for referral testing must be accredited by UKAS ISO15189 or future relevant accreditation body.
35.9	The Contractor will provide regular information to clinical users upon the performance within the external and internal QA schemes.
35.10	The Contractor led by the Consultant Pathologist is responsible for resolving quickly and appropriately any issues raised by an EQA organisation about test non-conformances.
35.11	The Contractor will maintain a database listing all the analytes measured. For each entry, the database must show the details of the method, which reagent lot is currently in use, which calibrator is currently in use and which analytical platform is being used for the assay.
35.12	The Contractors QA Manager will co-ordinate a programme of quality improvement initiatives which cover all aspects of the Service (pre-analytical, analytical and post-analytical). The QA Manager must ensure that as many staff as possible are involved in this process and that the Contractor's management provides the resources for this aspect of the quality programme to take place. The Contractor will be responsible for monitoring Laboratory quality issues and quality improvement are coordinated and monitored.

35.13	The Contractor will have a procedure for checking the correlation between different analysers performing the same tests; this includes separate analytical platforms performing the same tests on the same site and separate analytical platforms performing the same tests at different locations.
36	**Quality Management**
36.1	The Contractor must ensure compliance with national accreditation standards and demonstrate adherence to quality management systems, ensuring all aspects of quality assurance are undertaken.
36.2	The Contractor must implement laboratory policies and procedures to meet appropriate quality standards and to ensure operational consistency. These will include a Quality Policy and Manual, Standard Operating Procedures and policies such as sample labelling, sample storage and disposal, result authorisation and reporting.
36.3	The Contractor shall have a robust quality management system (QMS) in place to monitor and learn from laboratory based errors which shall include, but not be limited to: (i) Logging of all errors based on Good Industry Standards; (ii) Analysis of significant errors by root cause analysis with timescales agreed with Service users for corrective / preventative actions; (iii) Engagement with CCG contract managers to investigate significant laboratory errors and agree actions taken to reduce the subsequent risk of repeating the error for the same reasons
37	**Health and Safety**
37.1	The Contractor will nominate a senior manager with the responsibility for all aspects of Health and Safety (H&S) within the laboratory. The Contractor's H&S Co-ordinator will provide front line leadership to ensure a safe environment is provided to all employees. H&S is a key part of every new employee's induction process. H&S training records are contained in each employee's training file. The Contractor's H&S officer will regularly interact with the CCG on any relevant issue. Training on risk assessment will also be undertaken.
37.2	Whilst providing the services, the Contractor shall comply, and shall ensure that its employees comply, with the requirements of relevant health and safety legislation and other relevant legislation, including regulations and codes of practice issued thereunder, and, whilst at the CCG premises and GP practice premises, with the CCG's own policies and procedures.
37.3	The Contractor shall at all times maintain a specific health and safety at work policy relating to the employment of its own staff whilst carrying out their duties in relation to the Contract.
37.4	The Contractor's staff shall follow a system of accident reporting.

37.5	The Contractor's staff shall be trained to recognise situations which involve an actual or potential risk or the need for risk management including: • danger of personal injury to any person on the contractors premises, and either, where possible, without personal risk, make safe any such situation or report any such situation; • fire risks and fire precautions and procedures including attendance at fire lectures and drills in accordance with the Contractor's policies; • security; and • major incidents.
37.6	The Contractor will provide adequate white coats and all other protective clothing and equipment for any on-site clinical staff or visitors.
38	**Business Continuity**
38.1	The Contractor will maintain an effective business continuity plan detailing how, in the event of a major failure of the services, facilities, plant or equipment the service can continue without disruption to the CCG and GP practices. This will include developing a relationship with local alternative backup laboratories to provide this Service.
38.2	The Contractor will have robust plans in place to ensure the continuity of transport arrangements for sample pickups.
38.3	The Contractor will ensure that contingency arrangements are in place to ensure adequate available cover in the case of any planned or unplanned increases in workload and staff absences caused by sickness or travel disruptions.
38.4	Contingency arrangements are required for periods of IT system downtime which cannot be fixed within the contracted fix time standard and will subsist and therefore require alternative temporary arrangements to be put in place to ensure that the CCG can still request tests and access test results.
38.5	The Contractor will use IT systems that are designed and configured to provide a high level of fault tolerance. The Contractors Information Technology department are required to constantly monitor system performance and service disruption on all systems.
38.6	The Contractor must have backup plans and processes for manual steps that would be taken by the laboratory to maintain service in the event of a lengthy period of system downtime. Manual reporting SOP documents will be required defining the steps required to report results via hard-copy to the relevant GP. When the system is back up, the data for these manually run samples is entered into the database and electronic reports are produced as required.
38.7	In the event of an IT system failure, a manual process for ensuring urgent results are communicated to the relevant GP will be deployed.

Performance Management	
39	**Contract Management**
39.1	The contract management meeting shall include representation from: The CCG: (one of whom shall be appointed as the chair), including representatives from GP Users, Contract Management, IT, Governance and Risk Departments; The Provider: including the Lab Manager, Contracts Manager and relevant laboratory staff and Pathology Consultants where required The contract management meeting shall meet monthly for the first nine months of the contract and then on a quarterly basis unless agreed on a different basis by the Parties.
39.2	The functions of the contract management meeting shall include: 1. Providing a means for the joint review of any issues relating to day-to-day aspects of the performance of the contract; 2. Receiving monitoring information from both the Contractor and the CCGs contract management team; 3. Reviewing the providers operational performance including clinical consultants performance; 4. Reviewing and agreeing new tests and respective pricing; 5. Agreeing to the range of tests to be monitored by the Contractor and the relevant TATs applicable to such tests; 6. Ensuring user satisfaction surveys are carried out at least annually, with the results used to improve the services; 7. Providing a forum for joint strategic discussion, considering actual and anticipated changes in demand from the CCG and technical and clinical factors influencing the operation of the contract (for example, new technology, new tests and requesting patterns) 8. Demand management initiatives performance 9. Considering possible variations of the contract to reflect such changes and for the more efficient performance of this contract. 10. A forum for providing a means of resolving disputes or disagreements amicably between the contracting parties
39.3	Where the members of the contract management meeting agree it is appropriate, meetings may be held by telephone or video conference. Minutes of all meetings and recommendations of the contract management meetings shall be kept by the Contractor who shall circulate copies within five working days. of the holding of the meeting or the making of the recommendation. The Contractor shall ensure that a full set of minutes are open to inspection by the CCG at any time, upon request.
39.4	In addition, the Contractor and the CCG, will use one contract management meeting every six months to include several CCG GP pathology service users to discuss new tests, agree demand management campaigns, identify any GP training needs and discuss any issues with the service.

40	**Contract Monitoring**
40.1	Monitoring will be carried out in accordance with the relevant terms as detailed in the contract. Should the problem not be resolved to the satisfaction of the CCG, the matter will be escalated through the CCG's internal process and/or the contract management meeting, and the Contractor will co-operate with such process.
40.2	The Contractor will provide regular management information in electronic and paper form showing the level of activity undertaken during the period and associated charges/credits. This data must reconcile with the invoices and credit notes from the Contractor.
40.3	The Contractor will work closely with the CCG's finance department to ensure the data meets their requirements by providing meaningful management information.
40.4	The Contractors billing system must only pass tests for billing once the results have been reported. All tests are costed separately in the Contractor's billing system, but can be presented as profiles where appropriate.
41	**Value for Money**
41.1	The Contractor will actively encourage the reduction in unnecessary, clinically inappropriate or duplicate tests. As pathology is a consultant-led service, the Consultant Pathologists have a fundamental role in leading the process to reduce unnecessary, clinically inappropriate or duplicate tests. The Contractor will work closely with the CCG to develop and support test utilisation management programmes, providing data and information to supplement the leadership of the Consultant Pathologists. The benefits that accrue will be shared between the CCG and the Contractor, based on a number of criteria: • the input of each party into identifying and developing an area to be addressed • associated benefits • success rate
42	**Benchmarking**
42.1	If at any time during the contract a National and or London Tariff is introduced in respect of any test which, when applied to this contract, would mean that the CCG is paying more for that test than it would be paying if the National and or London Tariff was applied to the services, the CCG and the Contractor shall meet and in good faith agree the changes to be made to the test prices so that the CCG is not paying any more under this Contract than it would be paying if it appointed a contractor to provide the Services on the basis of the National and or London Tariff. The parties shall have one month from the introduction of the National and or London Tariff in which to agree the revised test prices, after which either party shall have the right to refer such matter to the dispute resolution procedure.
42.2	At the end of month 9, 21, 33, and 45 of the contract, the CCG has the option to select a basket of up to 35 tests (approximately up to 10% of the total test repertoire) to be benchmarked against the average prices of up to five London CCG prices. If the overall basket value of tests is lower than the average of comparable CCG test prices, the relevant tests with prices higher than the average unit test price of the benchmarked CCG's will be adjusted downwards for the next contract year.

	Hounslow CCG will establish a panel of CCGs who collaborate with the annual test benchmarking.
42.3	In addition to annual price benchmarking the CCG can request a test price to benchmarked at the end of month 9, 21, 33, and 45 of the contract, in the event they are aware of a technology advancement in the analysis of a test or there is as significant uptake in demand for a test than was include in the baseline. Increases in demand could occur where an expensive test (such as a genetic molecular test) is requested by GPs rather than acute clinicians as part of patient pathway redesign initiatives.
42.4	Once agreement is reached or a determination is made pursuant to the dispute resolution procedure, the Contractor shall introduce the revised test price(s) within two months from the date of such agreement or determination as appropriate.
43	**Audit**
43.1	The Contractor will actively participate in clinical audit programmes for the laboratories and support audit projects of the CCG. The Contractor will provide information and data to support the clinical audit programme and projects implemented by the CCG.
43.2	An annual plan of end to end process including specimen collection to result delivery audits will be drawn up by the Contractors Consultant Pathologists to cover each discipline performed by a member of the Quality Assurance department. More frequent, focused, vertical audits and record reviews will be performed by laboratory department scientific staff following training on an agreed protocol.
44	**Incidents**
44.1	The Contractor will maintain procedures for reporting incidents to the Consultant Pathologists and the nominated CCG management staff, and taking agreed follow up action. Procedures must be in place to show how this is achieved and who will accept the final result of remedial work. Procedures will define the scope, responsibilities and process for incident reporting, corrective action/ preventive action and closure of the incident. If necessary, a for cause audit will be undertaken.
45	**Complaints**
45.1	The Contractor will maintain procedures for handling GP and CCG complaints and taking agreed follow up action. A record of all complaints received by the Contractor of whatever nature regarding any of the services shall be kept by the Contractor to include, but not limited to, the number and classification of complaints received.
45.2	Within ten working days of receipt of a complaint, the Contractor shall provide the CCG with a copy of the written response to such complaint. The Contractor's response shall include: • a full description of the investigation which the Contractor has conducted in respect of the complaint; • the outcome of the Contractor's investigation; and • details of the Contractor's proposed remedial action plan to address the matters raised in the complaint.

45.3	The Contractor shall supply the CCG and present at the contract management meeting with a copy of the record of complaints as part of the monthly management reports.
45.4	Serious complaints shall be notified by the Contractor to the CCG as soon as reasonably practicable but in any event within two working days of receipt.
45.5	The Contractor (including all the Contractor's staff) shall co-operate fully with the CCG in investigating and resolving complaints made, and every endeavour shall be made to improve the services in the light of valid complaints received and to minimise complaints so far as possible.
45.6	In respect of any complaints arising out of this Contract which fall within the terms of the CCGs' complaints procedure, the Contractor shall also comply with the relevant CCGs' complaints procedure, as notified to the Contractor in writing from time to time, to the extent it applies to such complaints.

GP Practice Migration

46	**Migration Plan**
46.1	Hounslow CCG needs to consolidate their pathology provision from two existing main providers to a single provider. It is envisaged that consolidation of service provision will deliver clinical, quality and value for money benefits.
46.2	The Contractor will work closely with the CCG by frequent face to face weekly migration meetings to plan and implement the service change.
46.3	The Contractor will work closely together with the clinical commissioners and incumbent providers to agree a plan to migrate the services within a safe but limited time. A detailed migration plan will be agreed by the Contractor and the CCG. The CCG agrees to provide such co-operation and assistance as may reasonably be required to enable the Contractor to achieve this.
46.4	The Contractor must achieve a safe and seamless transition to the new service to the agreed milestones. The Contractor needs to carefully manage the migration of services to mitigate the risk of service interruption. The Contractor will engage effectively with GPs both during the transition and throughout the contract.
46.5	The CCGs obligations to support the migration plan are to: • Use reasonable endeavours to ensure that the incumbent providers complies with all of its obligations relating to the handover of the services, as set out in the CCG's current contract with the incumbent providers. This will include providing databases of legacy test data • Allowing access to GP practices, as required by the Contractor, on receiving reasonable prior notice.
46.6	The migration plan contains key dates for monitoring the progress of the migration activities and enabling both the CCG and the Contractor, to assess the need for additional actions in order to complete the migration activities by the target service commencement date.

46.7	The Contractor will take prime responsibility for delivering and managing the agreed migration plan. It will manage and co-ordinate the activities of third parties involved in the migration including its subcontractors, the CCG and the incumbent providers.
46.8	All appropriate resources will be supplied by the Contractor to facilitate a smooth migration of the service and full service testing will take place before go live. The Contractor's project management must incorporate rigorous testing and internal handover procedures to ensure the smooth progress of the migration plan.
46.9	A joint migration assurance team will be set up between the Contractor, CCG and incumbent providers. It is the responsibility of the Contractor to notify the migration assurance team of any tasks which are delayed or at risk of delay and notify the migration assurance team of the actions that need to be taken to rectify these. If the delays are outside the control of the Contractor, the migration assurance team will decide the action that will be taken.
46.10	The Contractor and CCG representatives will attend migration assurance meetings which will be scheduled to convene immediately after the Contract Signature.