Kent and Medway Pathology Network

Service Specification for Pathology/Laboratory Medicine

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FOREWORD

1. The Kent & Medway Pathology Network (KMPN) was formed to implement the national pathology modernisation strategy, by developing a shared vision for pathology services across the county, delivering both local and national priorities and imperatives. It is also responsible for ensuring the implementation and monitoring compliance with the national pathology Quality, Innovation, Productivity and Prevention (QIPP) programme across Kent & Medway (K&M).

2. The Network is a commissioning led partnership between the K&M Primary Care Trusts, Dartford & Gravesham and Maidstone & Tunbridge Wells NHS Trusts and East Kent Hospitals University, Medway Hospital and Queen Victoria Hospital NHS Foundation Trusts. It currently delivers services from its laboratories to these five Trusts, three PCTs and their Practice Based Commissioning (PBC) teams, as well as the K&M NHS and Social Care Partnership Trust. It covers a population of 1.73 million, employs around 800 staff, performed more than 20 million tests in 2008/09 with an annual budget in the region of £50 million.

3. The purpose of this service specification for the KMPN is to:

    a. Define the service and quality objectives, remit and reporting arrangements for the delivery of pathology across the Network in order to provide clear direction for local services.

    b. Commission pathology as a consolidated service across the whole of the Network against a single service specification.

    c. Ensure that the provision of pathology services across the whole of the Network are conducted consistently and effectively through achieving a set of agreed core standards, performance indicators and reporting arrangements.

    d. Ensure value for money, reduce cost and improve efficiency of services through standardisation.

    e. Set a framework for monitoring the effectiveness of pathology services within the Network against the delivery of these key service specifications.

    f. Provide for a quality commission framework for the delivery of pathology services in K&M.

4. The aims of the Network are also recognised as:

    a. To support the commissioning of the highest value and quality services that meet national and clinical guidance.

    b. To support the delivery of national targets.

    c. To deliver financial efficiencies

    d. To deliver continuous service improvement

5. The Network will achieve its aims through:

    a. Population based demand assessment.

b. Pathway development.

c. Determining clinical standards and protocols across pathways.

d. Assessment of clinical outcomes.

e. Facilitate service redesign and reconfiguration to improve pathways and maximise use of available resources and quality of patient care through multi-disciplinary care models.

f. Agreeing the quality standards for the delivery of pathology services within K&M.

6 The above approaches will support the wider health economies to:

a. Achieve financial balance.

b. Ensure patients receive the appropriate levels of care commensurate to their need at the earliest point in the pathway.

c. Ensure patients have timely access to services.

d. Ensure demand for services is appropriate.

e. Provide services through evidenced based medicine and patient focus.

f. Ensure optimum use of resources and capacity.

g. Ensure patients are central to service design and are provided with a high standard of information about the services they can receive.

h. Implement relevant national polices.

7. A key objective of the Pathology Network is the development of local strategies for the modernisation and delivery of pathology services in a managed network across Kent and Medway, which will deliver both national priorities and local imperatives.

8. Each Trust within the Network agrees that it will:

a. Co-operate with the other Trusts on the modernisation agenda for pathology services, acting in good faith and in the best interests of the Network;

b. Not commit any act or omission deliberately to hinder or delay the effective and efficient working of the Network;

c. Collaborate together to provide the best service for the benefit of all patients and users, and to meet the strategic policy needs of the local health economies.

d. Collaborate to ensure best value in procurement and delivery of services across all organisations party to this agreement;

e. Co-operate together to ensure that services are delivered from the best locations that meet the strategic needs of the Network.

f. Share relevant information within and between the Trusts and respond to requests for information promptly;

9. The Trusts acknowledge and agree that it is intended that the Network will operate in accordance with the following general principles:

   a. It is expected that the benefits resulting from the Trusts working within a network will include improved services for patients and users, significant economies of scale and optimal scope for service development and modernisation, compared with the likely benefits that would apply to pathology departments working individually and independently.

   b. The Trusts will agree not to impede the development of common standards and procedures and to implement consistent and/or compatible systems and solutions.

10. The Network will comply at all times with the aim of providing optimal care for patients and the Trusts will seek clinical advice in this regard from NICE, CPA and other relevant bodies.

Kent and Medway Pathology Network

SERVICE SPECIFICATION

1 Summary

1.1 The purpose of this service specification is to define the service quality and standards required for the delivery of a complete, end to end pathology service across the pathology network. This service specification consists of a general service specification and discipline specific service specifications. It is anticipated that the service provider shall meet the requirements of all elements of the total service specified, including quality measures (key performance indicators) embedded in this agreement.

1.1.1 The service shall be provided within a secure, sustainable framework with appropriately agreed savings reinvested in service development after national and pre agreed local savings targets have been met.

1.1.2 A system shall be in place to ensure the clinical effectiveness and efficient clinical utility of individual and groups of tests.

1.1.3 The service model shall meet or exceed national guidelines on delivery and satisfy standards laid down by relevant accreditation and/or regulatory bodies.

2 Service Description

2.1 Pathology or laboratory medicine services play an important role in the delivery of modern, evidence-based healthcare. The service is a key enabler for commissioning care pathways leading to better, more effective outcomes. Services can be accessed at various points in a patient's care pathway including screening of disease, diagnosis of and monitoring disease, as well as optimising treatment.

2.2 Currently, pathology services are provided in response to a request from a clinician who may be working in primary, secondary, tertiary care or the community.

2.3 Services are also provided to private contractors (including Category 2) as well as clinical and research organisations. All pathology testing undertaken is restricted to human subjects.

2.4 Pathology is a consultant-led service which has developed individual areas of specialism and expertise. In addition to providing expertise and knowledge in terms of laboratory medicine many pathologists are also involved in direct patient care and/or providing clinical advice.

2.5 Standardisation of pathology service delivery across organisational boundaries and integration into care pathways will result in a high quality end-to-end service wherever it is accessed in Kent & Medway (K&M).

3 Clinical Specialties

The main clinical specialties or disciplines within pathology are as follows:

3.1 **Cellular Pathology (Including Histology, Cytology and Mortuaries) -** The diagnosis of disease based on analysis at a cellular level of samples of tissue: biopsy, post-mortem, cervical screening.

3.2 **Clinical Biochemistry –** A study of the chemical and biochemical mechanisms of the body in relation to disease. It provides a link between medicine and the basic sciences, and employs analytical and interpretative skills to aid in the prevention, diagnosis and treatment of disease.

3.3 **Immunology -** Analysis and treatment of immunological disease, allergy, transplant compatibility.

3.4 **Haematology & Blood Transfusion -** Diagnosis and treatment of blood diseases, transfusion services, including specialist investigations for Haemophilia and Thrombophilia.

3.5 **Microbiology -** Bacteriology, Virology and Mycology. Analysis of micro-organisms found in samples. Responsible for infection control surveillance and for the detection and control of disease outbreaks and incidents and employs analytical and interpretative skills to aid in the prevention, diagnosis and treatment of disease.

4 Other Clinical Services

4.1 Direct clinical care. (Consultant Chemical Pathologists, Haematologists and Microbiologists).

4.2 Provision of specialist information and advice to professionals in primary and secondary care as well as public health

4.3 Control of infection prevention and control.

4.4 Participation in multidisciplinary team meetings.

4.5 Provision of specialist advice both on ward rounds and over the telephone.

4.6 Provision of guidance and advice, quality assurance and support for Point of Care Testing (PoCT).

4.7 Specialist advice on Blood Transfusion.

4.8 Specialist advice on Health and Safety (H&S).

4.9 Specialist advice on Information Management and Technology (IM&T).

4.10 Mortuary services, including Post Mortem examinations.

4.11 Education and training for pathologists, undergraduate and postgraduate doctors and other healthcare professional.

4.12 Research and development, including involvement with clinical trials and evaluation of new technology.

4.13 Population/public health medicine.

5 Service Model

5.1 The Service Provider shall deliver a network model that provides:

5.1.1 An integrated, high quality, consistent level of service to patients and other users wherever they access pathology services in K&M.

5.1.2 A service model that is sufficiently flexible in delivery, patient-focused but at the same time provides efficiencies and economies through appropriate standardisation and consolidation.

6 Service Objectives

6.1 The Service Provider shall:

6.1.1 Provide a best value patient-focused service that fulfils the clinical needs of patients and other users.

6.1.2 Provide safe, efficient, responsive, comprehensive and effective services which meet National guidelines, accreditation requirements and statutory regulations.

6.1.3 Provide flexible and appropriate services that respond to changes in patient care and organisational requirements.

6.1.4 Ensure the service supports all NHS and local programme priorities, including those required to deliver quality and fiscal improvements.

6.1.5 Ensure that service standards are met through the appropriate use of qualified and registered staff. Maintain a balanced skill mix that provides the best value service and ensure all staff are developed and trained to be competent for the work to be undertaken.

6.1.6 Provide clinical support and advice throughout the pathology patient pathway, including not only during the testing phase but also during the pre and post analytical phases.

6.1.7 Ensure effective use of equipment, facilities and estate through consolidation of services and essential standardisation through joint procurement within the Network or beyond.

6.1.8 Work within, and meet the standards of a quality management system, ensuring all standard operating procedures comply with CPA accreditation requirements, National minimum standards and regulatory bodies such as MHRA and HTA.

7 General Service Description

7.1 The Service Provider shall:

7.1.1 Provide a pathology service including diagnostic tests to support patient clinical management, interpretation and reporting of results as well as clinical advice on further investigation and treatment of patients, in respect of tests

relating to Cellular Pathology (including post mortem and mortuary services), Clinical Biochemistry, Haematology (including specialist coagulation services) Blood Transfusion, Immunology, Microbiology, infection control and any other related specialities.

7.1.2 Provide advice on the most appropriate use of pathology testing within clinical pathways and agree protocols with users to ensure appropriate test requesting.

7.1.3 Provide appropriate support services including: compatible technology for data, information management, logistics and non patient transport.

7.1.4 Provide services as required 24 hours a day, every day of the year including bank holidays and public holidays. The laboratories operated by the service provider must meet the demands specified for the various service users. These are given in the sections in this document dealing with individual disciplines.

7.1.5 Provide at the most appropriate location for each acute hospital in K&M, where a full pathology service is not otherwise provided, those tests detailed in Appendix 1. They are to be provided 24 hours a day, 7 days a week, during the year. The provision of this service shall include pre analytical, analytical and clinical interpretative advice and meet all the applicable requirements of this specification.

7.1.6 Ensure the volume and range of tests over the life of the contract is met and responds to demand management arrangements. The service must be capable of responding to future changes in clinical demand, new technologies and changes in national guidance and quality standards.

7.1.7 Ensure that all laboratories within the Kent & Medway Pathology Network (KMPN) work in partnership and cooperation to deliver an integrated, high quality, consistent level of service to patients, users and commissioners.

7.1.8 Support the provision of specified test result reporting, direct to the individual patient or requestor, as required or requested, via a secure method.

7.1.9 Support the provision of facilities, staff and equipment for a range of clinically urgent tests, on all hospital sites where it is deemed clinically necessary and ensures efficient use of facilities.

7.1.10 Ensure that test result reports are only authorised by an appropriately trained individual.

7.1.11 Provide professional advice to develop and design patient care pathways to ensure high quality, cost effective patient-focused care.

7.1.12 Support the provision of PoCT at acute hospital locations and other clinical settings which are informed by clinical need (i.e. community based provision) with full IM&T connectivity where possible to the pathology laboratory information management system (LIMS).

7.1.13 Provide all facilities (including specialised category 3 facilities) and equipment to meet the requirements of the Pathology Service Specification throughout the life of the contract.

7.1.14 Agree naming conventions in line with current and any future National Laboratory Medicine Catalogue.

7.1.15 Ensure that test profiles, scientific units, methodologies and in as many cases as possible, reference ranges are standardised across the Network.

7.1.16 Provide a robust plan to ensure service continuity across all pathology disciplines, in the event of an untoward service failure.

7.1.17 Ensure that a joint process between providers, users and commissioners is in place to agree the use of new tests, previously not provided under contract, and for the removal and decommission of obsolete and redundant tests.

7.1.18 Where NICE Guidance, National Service Frameworks, or their equivalent exist, ensure processes for the appropriate use and pattern of testing to meet these guidelines and frameworks are identified and the results reported.

8 Transport Services

8.1 The Service Provider shall:

8.1.1 Provide an integrated transport and logistics service to support the delivery of pathology services. This will include inter-site movements, transportation of specimens from specified collection points including hospital sites, GP surgeries, and transport to the relevant analytical laboratories; as well as supplies and confidential data.

8.1.2 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.

8.1.3 Ensure that samples are collected on a regular, timely basis from specified collection points, including hospital sites and GP surgeries that meet the agreed clinical requirements for their collection and the viability of individual samples.

8.1.4 Ensure that samples are transported in accordance with best practice, statutory and contract requirements to ensure compliance with H&S regulations and maintain sample integrity and data confidentiality.

8.1.5 If required, to ensure sample integrity, facilities should be made available for on-site pre analytical processing prior to the sample being transported.

8.1.6 Work toward identifying and utilising a solution that allows the continuous tracking and identification of location, from production to final disposal, of samples.

9 Information Technology

Information Technology shall be provided as described in the general specification as an integral part of service delivery, in addition –

9.1 The Service Provider shall:

9.1.1 Meet agreed national messaging standards (i.e. HL7v3, Snomed CT NLMC) for all inbound and outbound traffic.

9.1.2 Ensure standards-based, open interoperability between NHS clinical and laboratory systems as appropriate to the clinical requirements of the service.

9.1.3 Work with their users to deliver a “paperless” pathology requesting and reporting service.

9.1.4 Conform to NHS Information Governance Standards, including DPA and Caldicott.

9.1.5 Ensure that all internal knowledge driven processes conform to NHS standards and use NHS evidence based best practice guidelines.

9.1.6 Support open data access to all information to support clinical, audit, research and business intelligence functions as needed by the service users.

9.1.7 Ensure that the patient NHS Number is used as a primary identifier in all cases. Any exceptions are to be agreed with service commissioners.

9.1.8 Provide an appropriate IM&T laboratory to laboratory messaging service across the trusts within the Kent and Medway Pathology Network (KMPN). This will enable each laboratory in the Network to be electronically linked to one another to facilitate the referral of work across the Network.

9.1.9 Work with their users to deliver a “paperless” pathology requesting and reporting service using NHS informatics standards for information exchange.

9.1.10 Ensure systems are appropriate to support routine care, chronic disease management, mandatory infectious diseases and other disease monitoring and screening services if required.

9.1.11 Support the provision of pathology electronic requesting and reporting from acute hospital locations, GP practices and other clinical settings, which are informed by clinical need.

10 Specimen Reception

10.1 The Service Provider shall ensure that:

10.1.1 Each specimen reception area attached to a laboratory has a dedicated supervisor. This shall be operated by staff trained and competent in all reception duties, including the safe handling of samples and how to respond to any inadvertent exposure to hazardous materials.

10.1.2 Reception staff must work in accordance with the agreed standard operating procedures and be trained to check the integrity of samples and request forms (or electronic equivalent) and establish and maintain a system to record discrepancies, resolve and record resolutions.

10.1.3 It develops and maintains protocols that specify the type of specimen required for each investigation and the conditions under which the sample should be collected and transported to the laboratory and processed/handled thereafter.

10.1.4 It ensures the provision of a specialised reception arrangement for Cellular Pathology and Blood Transfusion services in recognition of the nature of the samples received.

11 Anticoagulation Services

11.1 The Service Provider shall:

11.1.1 Supply an anticoagulation service to support the patient pathway including the delivery of clinics staffed by specialist nurses, on hospital sites or at locations nominated by the commissioner.

12 Point of Care Testing Service

12.1 The Service Provider shall ensure that a Point of Care Testing Committee (PoCT) is established and operated on behalf of each acute Trust to:

12.1.1 Ensure that PoCT is undertaken in accordance with professional, national and regulatory guidance to meet best practice.

12.1.2 All testing is performed within a quality management system.

12.1.3 Results wherever possible are integrated with the LIMS.

12.1.4 Work with Practice Based Commissioners (PBC) to provide safe, effective and quality PoCT service in the community.

12.1.5 Advise PoCT co-ordinator(s) and the supporting management structure(s) established by the provider, for PoCT services.

12.1.6 Ensure all PoCT complies with professional, national and regulatory guidelines (Appendix 2).

13 Tests Sent to a Third (Tertiary) Party

13.1 For requested tests which cannot be provided by K&M laboratories, the service provider must:

13.1.1 Contract these with a CPA accredited (or equivalent) third party laboratory.

13.1.2 Ensure that where a specific test is not provided within the Network, all Network Acute Trusts should contract with the same “tertiary” provider for those individual tests.

13.1.3 Ensure that if a requested test requires a second clinical opinion or analytical qualification, the tests shall be sent to a designated reference laboratory designated or approved by the Service Provider and supported by a Consultant Pathologist (or equivalent) of the relevant pathology discipline.

13.1.4 Ensure that the performance targets outlined within this specification also apply to third party tests.

13.1.5 Ensure that the contracts for esoteric analysis are reviewed on an annual basis and quality standards are maintained to ensure compliance with national accreditation requirements and best practice.

14 Storage and Retrieval of Samples, Organs and Paper Based Records

14.1 The Service Provider must:

14.1.1 Ensure that there are mechanisms in place for the proper handling, storage and security of all samples and documentation at all times. This will be carried out in accordance with the acute Trusts' guidelines, national guidelines and regulatory/legal requirements.

15 Handling and Disposal of Waste

15.1 The Service Provider must:

15.1.1 Ensure that mechanisms are in place for the proper handling and disposal of waste at all times, meeting at least the minimum national standards for their handling and disposal.

16 Pathology Service Accreditation

16.1 The Service Provider must:

16.1.1 Be CPA accredited (or any replacement accreditation body) across all the services provided and meet regulatory requirements of MHRA and HTA.

16.1.2 Be compliant with full CPA accreditation standards (or any replacement accreditation body) and demonstrate adherence to quality management systems. If, following assessment by an accrediting regulatory body a service, or part of that service, does not meet the required standard, an action plan with timescales for achieving full compliance, must be produced for review. Failure to achieve full compliance within the agreed timeframe will result in the contract being terminated for the whole or part of the service, unless extenuating circumstances can be demonstrated and agreed between both parties.

16.1.3 Ensure that quality standards, procedures and policies are consistent with professional, national and regulatory guidelines.

17 Quality Assurance

17.1 The Service Provider shall:

17.1.1 Ensure that Quality Assurance Systems are developed and maintained for the service in accordance with CPA (or any replacement accreditation system) and Clinical Governance requirements.

17.1.2 Supply details of the Quality Assurance Framework for the provision of pathology service of high quality.

17.1.3 Subject all results to internal quality control procedures to ensure their suitability in terms of accuracy and precision prior to reporting.

17.1.4 Participate in at least one external quality assessment scheme for each analyte where a relevant UK scheme is available. The utility of tests not included in an external quality assessment scheme must be assessed and if the test is deemed to be clinically necessary, an alternative solution shall be sought for accessing quality.

17.1.5 Make available on request to all, summaries and/or the detailed results of their Quality Assurance Scheme reports.

17.1.6 Detail what actions they are taking, over an agreed timescale, if a report from a Quality Assurance Scheme shows persistent poor performance for any one analyte.

18 Health & Safety

18.1 The Service Provider must:

18.1.1 Comply with Health and Safety legislation and NHS requirements.

18.1.2 Ensure that a senior member of staff is responsible for all H&S within the pathology service. Delegated responsibility can be given to other individuals to attend appropriate H&S committee meetings to advise on H&S issues within the acute Trusts.

18.1.3 Operate robust comprehensive security and confidentiality procedures including laboratory facilities, management of samples, reports, staff, equipment, patient information and access to laboratory facilities.

18.1.4 If agreed, advise on H&S for the siting of PoCT devices, and any equipment for pre-analytical sample processing occurring outside of the laboratory.

19 Patient Safety

19.1 The Service Provider shall:

19.1.1 Actively participate in clinical audit programmes, adverse incident reporting and complaints monitoring, analysis of these events must be demonstrated and shared with the service user and purchaser with an agreed action plan.

20 Education & Training

20.1 The Service Provider must:

20.1.1 Ensure that all staff are trained (in a Health Protection Council (HPC) registered training laboratory) and competent to carry out their designated duties and are registered with the HPC or other appropriate regulatory and/or professional body, e.g. IBMS, RCPath.

20.1.2 Ensure that all staff are trained (in a HPC registered training laboratory) to perform their duties safely including the training of specialist registrars in accordance with national standards/training programmes.

20.1.3 Ensure that it continues to review and provide the most appropriate and efficient skill mix of staff to meet the current and future service provision and to achieve maximum efficiency and safety.

20.1.4 Ensure that in-house staff training and assessment of competency is undertaken to meet professional, national and regulatory standards.

20.1.5 Comply with professional and national standards for regulatory training for new and existing staff to ensure consistency of service delivery and patient safety.

20.1.6 Ensure that training records and assessment of competency are recorded.

20.1.7 Provide education and training to all clinical users and managers on service delivery and specialist clinical services.

20.1.8 Ensure that all Consultant and clinical scientist staff have sufficient time in their job plans to provide clinical interpretation and advice to laboratories, users and patients and to undertake the professional activities needed to support their clinical roles.

21 Research & Development

21.1 The Service Provider shall:

21.1.1 Ensure that relevant and appropriate research and development is undertaken to facilitate service development and staff training.

21.1.2 Support clinical trials.

21.1.3 Establish links with local academic institutions and other centres for Research & Development.

21.1.4 Ensure that staff, who participate in research projects, have been properly resourced and the project has been agreed by local and other appropriate clinical research ethics committees.

21.1.5 Ensure that evidence based research findings that are generated locally and from other evidence, are evaluated for future service development.

21.1.6 Ensure that senior K&M pathology staff develop recommendations for pathology testing using evidence based practice and national guidance where available in relation to the service.

22 User Relationships

22.1 The Service Provider shall:

22.1.1 Make available to all clinical users of the service contract, a comprehensive pathology ‘User Handbook’.

22.1.2 Produce regular updates for clinical users.

22.1.3 Participate in user group meetings to improve and develop service delivery and patient care.

22.1.4 Provide clinical advice on the appropriateness of laboratory testing to assist demand management.

22.1.5 Continue to collaborate closely with clinical teams within the acute Trusts, primary and community care.

22.1.6 Ensure that service users are trained and updated on the appropriate use of the pathology service.

23 Performance Monitoring

23.1 The Service Provider shall:

23.1.1 Be responsible for monitoring the Pathology Service.

23.1.2 Provide monthly activity as detailed in Appendix 3, Key Quality Indicators as detailed in Appendix 4, and other agreed performance indicator data, when required, as detailed in Appendix 5.

23.1.3 Provide monthly turnaround time ("TAT") reports, showing actual TATs against those agreed in the contract. (See Appendix 6). It is anticipated that these turnaround times will be met in 95% of cases unless an amendment to the contract has been agreed with the commissioner for financial or clinical reasons.

23.1.4 Produce exception reports and action plans, where performance is at variance with the standards.

23.1.5 Provide annually, or in exceptional circumstances when requested, full pathology activity and costing data as defined by the KMPN.

24 Performance Management

24.1 The Service Provider shall:

24.1.1 Provide at least quarterly, information to users to ensure that the service is being used effectively and efficiently. This shall include:

24.1.1.1 Test utilisation.

24.1.1.2 Workload statistics.

24.1.1.3 Turnaround time.

24.1.1.4 Appropriateness of testing.

24.1.1.5 Service audits.

24.1.1.6 Recommendations on new and obsolete tests.

24.1.1.7 Reflex testing.

24.1.1.8 Adverse incidents.

24.1.1.9 Quality measures.

24.1.1.10 Key Performance Indicators.

25 Knowledge Management

25.1 The Service Provider shall:

25.1.1 Provide a consultant-led clinical liaison, interpretation and advice service. This must include information on pre-analytical components of the laboratory service, up-to-date guidance on the use of appropriate tests as well as advice on the meaning of results, access to a specialist opinion and participation in multidisciplinary case meetings.

25.1.2 Provide specialist advice on PoCT to provide consistency and continuity to patient care irrespective of site of testing.

26 Quality Management

26.1 The Service Provider shall:

26.1.1 Be compliant with CPA accreditations standards and demonstrate adherence to quality management systems.

26.1.2 Produce an action plan with timescales that is updated at regular intervals if the service is at any time not fully compliant with any accreditation standards.

26.1.3 Ensure that all aspects of quality assurance are undertaken as described in paragraph 17.

26.1.4 Ensure all equipment, reagents and facilities for laboratory and PoCT, shall comply with standards issued by CPA or other regulatory bodies and comply with H&S legislation.

27 Clinical Governance

27.1 The Service Provider must:

27.1.1 Adhere to the elements of good clinical governance and comply with the relevant reporting arrangements within the Network and the acute hospitals.

28 Audit

28.1 The Service Provider shall:

28.1.1 Undertake, in all specialities, a schedule of witness, horizontal and vertical audits and any consequent actions arising from these audits as part of its quality management system.

28.1.2 Undertake clinical audits in all specialities, in conjunction with service users to demonstrate continuing clinical service improvement.

28.1.3 Audit the effectiveness of elements of patient care pathways and ensure any changes and improvements in service delivery identified as part of the audit, are implemented.

29 National Screening

29.1 The Service Provider shall:

29.1.1 Ensure that it meets the testing and reporting requirements of all national screening programmes. These services, e.g. Chlamydia or Cervical Cytology screening, are to be provided from the least number of locations appropriate to clinical and service requirements.

30 Phlebotomy & other sample collection

30.1 The Service Provider shall:

30.1.1 Ensure phlebotomy services are provided in designated areas to ensure safe delivery of care outside the analytical areas of the laboratory in accordance with national guidelines.

30.1.2 Ensure patients must be given an opportunity to pre book their phlebotomy appointment where appropriate, e.g. the provision of a “choose and book” or telephone booking service.

30.1.3 Ensure blood collection is undertaken by staff trained and competent in this procedure in accordance with an agreed standard operating procedure. Guidance and advice on blood collection shall be provided to GP practices where phlebotomy is undertaken.

30.1.4 Provide users with guidance and advice on the correct sample to collect, timing of sample, and special patient preparation as well as the type of specimen container.

30.1.5 Provide sample tubes, bottles, containers and blood collection kits etc, to users as part of the service contract.

30.1.6 Utilise a standardised Network-wide test request form, until the full provision of electronic ordering is in place.

31 Provision of Consumables and Supplies to Service Users

31.1 The Service Provider shall:

31.1.1 Supply all request forms, or electronic requesting documentation and necessary consumables as part of the service provided.

32 Advice on Choice of Test and Sampling

32.1 The Service Provider shall:

32.1.1 Give advice in the form of a user guide to the service on the appropriateness and timeliness of tests to be requested in various clinical circumstances.

32.1.2 Ensure that advice is available by telephone during normal and outside normal working hours to supplement that provided in the user guide and to deal with specific clinical enquiries.

32.1.3 Ensure that a single K&M wide, General Practice "out of hours" protocol is available and agreed for the handling of urgent results that require action out of normal working hours.

32.1.4 Ensure that guidance is available on the choice of sample and container for its collection to maintain specimen integrity and validity of results.

32.1.5 Provide professional advice to develop and design patient care pathways to ensure high quality, cost effective patient-focused care.

32.1.6 Audit the effectiveness of elements of patient care pathways and ensure any changes in service delivery identified as part of the audit are implemented.

32.1.7 Provide expert, professional advice and guidance on the commissioning of new tests.

32.1.8 Provide expert, professional advice and guidance on the withdrawal of those tests considered to be obsolete.

33 Blood Sciences

33.1 The Service Provider shall:

33.1.1 Provide a consultant led clinical and laboratory service for Clinical Biochemistry, Immunology, Haematology, Haemophilia and Blood Transfusion.

33.1.2 Co-locate the Clinical Biochemistry, Immunology and Haematology services to provide integrated blood sciences laboratories.

33.1.3 Provide the service from a maximum of two integrated cold blood sciences laboratories, one integrated Haemophilia clinical and laboratory service and one Immunology laboratory in K&M with an appropriate number of "hot" (core) laboratories to support acute and community care provision where required.

33.1.4 Support the provision of facilities, staff and equipment for an agreed range of clinically urgent tests, on all acute hospital sites.

33.2 Clinical Biochemistry – the Service Provider will ensure that it provides:

33.2.1 Support for acute and planned care, as well as the monitoring of long term conditions.

33.2.2 Diagnostic lipid testing in assessment of cardiovascular risk in high risk groups of patients and in 40-75 year age group.

33.2.3 Monitoring and assessment in support of patients with lipid disorders.

33.2.4 Diagnosis, management and cascade testing of patients and relatives with familial hypercholesterolaemia.

33.2.5 Support for the diagnostic pathway in patients with inborn errors of metabolism, including access to detailed specialist testing from external laboratories on complex and rare metabolic conditions including inborn errors or metabolism and endocrinopathies.

33.2.6 Metabolic dynamic function testing in support of endocrine disorders.

33.2.7 Assessment and monitoring of patients in the care pathway of metabolic bone disorders eg osteoporosis.

33.2.8 Supporting the diagnosis and monitoring of patients with malignancy, including comprehensive and appropriate tumour marker service for screening, diagnosis and monitoring cancers in accordance with National and International best practice guidelines.

33.2.9 Biochemical assessment of patients admitted to the emergency department, including those with acute coronary syndrome.

33.2.10 Therapeutic drug monitoring, including lithium monitoring, in accordance with NPSA (NPSA/2009/PSA005) and NICE guidance. Regular audits as required by the guidance are to be undertaken to ensure compliance.

33.2.11 Detailed protein biochemistry service to include Consultant interpretative comments for Immunofixation and provide appropriate guidance on patient referral for treatment or monitoring.

33.2.12 Support for patients receiving total parenteral nutrition.

33.3 Immunology - the Service Provider will:

33.3.1 Ensure there is an availability of all routine autoimmune serology tests including anti-nuclear antibody, liver auto antibodies, coeliac disease screen, thyroid peroxidase antibody, ANCA, GBM antibody, skin antibodies, rheumatoid factor.

33.3.2 Ensure there is availability of all routine protein investigations including IgG, IgA, IgM, serum protein electrophoresis, urine Bence Jones Protein, complement C3 and C4, alpha-1 antitrypsin where not provided by a centralised biochemistry laboratory.

33.3.3 Ensure there is availability of total IgE measurement plus specific IgE to a wide range of allergens including house dust mite, common pets, pollens, foods, insect venoms.

33.3.4 Ensure there is a documented protocol, set up by consultant or consultant clinical scientist in immunology, for addition of appropriate follow on investigations from initial autoantibody tests.

33.3.5 Ensure there is a documented protocol, set up by consultant or consultant clinical scientist in immunology, for the cancellation of requested investigations that are not indicated by the clinical details.

33.3.6 Ensure there is a documented process for analysing urgent requests (same day turnaround) for ANCA and GBM antibodies, by arrangement with the laboratory.

33.3.7 Ensure there is a process for referring samples to specialist laboratories for neurological antibodies and other specialist investigations.

33.4 Haematology and Haemophilia - the Service Provider will:

33.4.1 Provide a full Haematology medical interpretation and clinical service, including, automated analysis, Microscopy, Blood coagulation, PoCT, anticoagulation monitoring and dosing, specialist investigations and the review of abnormal blood films and results.

33.4.2 Ensure that clinical advice in relation to the Haematology service is provided as soon as is practicable and according to clinical need.

33.4.3 Haematologists in their role as physicians need to ensure that they provide patient consultation and treatment, as well as providing laboratory support.

33.4.4 Where possible patients requiring haematological referral are to be referred to the clinical staff responsible for producing the interpretation of their results.

33.4.5 Ensure that a single integrated Haemophilia clinical and laboratory service is available.

33.4.6 Specialist haemostasis investigations are to be co-located with the specialist clinical unit to facilitate close monitoring; for example during acute inpatient stays.

33.5 Blood Transfusion - the Service Provider will:

33.5.1 Provide blood grouping, red cell antibody screening and antibody identification.

33.5.2 Provide blood products, including red cells, platelets, fresh frozen plasma and cryoprecipitate.

33.5.3 Provide specialist blood products: Anti D, Coagulation factors e.g. Beriplex, factor 8 and Albumin.

33.5.4 Provide urgent clinical advice for users of blood and blood products, antibody identification and quantitation as necessary and establish a maximum blood ordering schedule in agreement with users.

33.5.5 Provide an antenatal antibody screening service.

33.5.6 Maintain stock and issue blood bank fridges, freezers and incubators.

33.5.7 Provide full traceability of blood and blood components for 30 years as per blood safety and quality regulations.

33.5.8 Provide specialist red cell, platelet and white cell haematoimmunology investigations on patient samples in conjunction with the NHS Blood and Transplant (NHSBT).

33.5.9 Provide a full blood transfusion service to all the acute trusts and other clinically appropriate sites within K&M.

33.5.10 Work to provide a remote electronic issuing of blood and blood products system.

33.5.11 There is a system is in place to allow identification of samples for blood transfusion which should be sent to the laboratory for processing at the site where the blood is to be required, if electronic issue of blood is not available at that site.

33.5.12 Patients with trauma, obstetrics, major surgery and those in Intensive care have full 24/7 blood transfusion services available, provided by appropriately qualified and experienced staff in compliance with Blood Safety and Quality Regulations (BSQR).

33.5.13 Ensure laboratory staff maintain documentation, which provides Quality Assurance and an audit trail of all aspects of blood and blood usage and comply with any legal requirements to store records or fate of transfused blood products, communication to the trusts and users will be via the providers Blood Transfusion Committee.

33.5.14 Maintain adequate stocks of blood, blood components and blood products to meet the needs of patients subject to availability and within constraints from the NHSBT.

33.5.15 Manage wastage and participate in the National Blood Stocks Management scheme.

33.5.16 Promote blood conservation methods such as cell salvage and pre surgical anaemia assessment.

33.5.17 Provide blood product storage facilities that are alarmed to a manned area and monitored for temperature on a 24 hours a day, 365 days per year basis and store blood and blood products according to blood transfusion best practice and follow the appropriate blood transfusion policy of the acute trust.

33.5.18 Report any adverse reactions, adverse events or other relevant clinical incidents to the appropriate body; eg SABRE or SHOT.

33.5.19 Ensure policies and practices are in accordance with:

33.5.19.1 Blood Safety and Quality Regulations 2005: statutory instrument 2005/50.

33.5.19.2 National Patient Safety Agency safer practice notice *'Right Patient Right Blood'.*

33.5.19.3 Health service circulars: HSC 1998/224 '*Better Blood Transfusion'.*

33.5.19.4 HSC 2002/009 *'Better Blood Transfusion appropriate use of blood'.*

33.5.19.5 HSC 2007/001 'Better Blood Transfusion, UK Transfusion Laboratory Collaborative recommendations on minimum standards for hospital transfusion laboratories 2009'.

33.5.19.6 British Committee for Standards in Haematology.

33.5.19.7 Guidelines for the Blood Transfusion services in the UK, (the red book) 7th edition, 2005.

34 Cellular Pathology Service

34.1 The Service Provider will:

34.1.1 Ensure there is a Cellular Pathology Service providing urgent and routine analysis for inpatient, outpatient and GP referrals and supporting Multidisciplinary teams in patient management decisions from a maximum of two laboratories in K&M.

34.1.2 Ensure that all reports are compliant with the latest Royal College of Pathologists Guidelines including minimum data sets.

34.1.3 Ensure that all practices and procedures are in line with the Code of Practice for Histopathologists and Histopathology Services as issued by the Royal College of Pathologists (2009) and any subsequent later editions.

34.1.4 Ensure there is effective face to face review of complex pathological cases at cut up for orientation purposes if required.

34.1.5 Ensure there are specified arrangements in place for review of complex benign and malignant cases, all cancers at MDT via videoconferencing with occasional face to face, if not on site.

34.1.6 Ensure that MDM attendance is in line with IOG peer review, expected to be at least 66% for core members for the all MDM meetings.

34.1.7 Ensure provision of a consistent (named) pathologist or deputy to support and attend each cancer MDT.

34.1.8 Ensure that for site based MDTs, a pathologist attends the meeting on site unless proven technology available is on site.

34.1.9 Ensure there are adequate handover arrangements for cases when Consultants take planned leave.

34.1.10 Ensure that MDT pathologists are contactable by telephone for advice.

34.1.11 Ensure there is a flexibility of service provision, in order to meet any current or future Government Initiatives which would affect IOG compliance activities.

34.1.12 Make use of video conferencing for offsite MDT's as far as possible.

34.1.13 Ensure there is the ability for a clinician to meet with the Histopathologist on site, to orientate complex specimens prior to cut up if this falls outside the Kent & Medway Cancer Network (KMCN) agreed orientation protocols.

Alternatively where available, the use of videoconferencing links to relay live macroscopic images of specimens to the clinician for orientation if not on site should be used. If the Histopathologist available on the day is not the reporting Histopathologist, arrangements will be made for direct handover of the specimen from that pathologist to the reporting pathologist.

34.1.14 Ensure there will be the ability for appropriate pre-fixation preparation as required to optimise sample preservation.

34.1.15 Ensure that specimen orientation protocols are defined and agreed between Pathologists and clinical colleagues within the KMCN.

34.2 Frozen Section Service – The Service Provider must :

34.2.1 Ensure that booked cases are guaranteed a maximum 30 minute turnaround from receipt, by using on site frozen section processing facility.

34.2.2 Ensure that ad hoc or non-booked cases, using a Rapid Response Protocol for urgent cases, are couriered to the laboratory and the results are telephoned back to theatres.

34.2.3 Ensure there is a booked frozen section reporting service on acute hospital sites, where required, 9:00 am to 5:00pm, Monday to Friday (excluding Public Holidays).

34.2.4 Ensure there is clear guidance for clinicians on how to book elective frozen section requests and how to arrange ad hoc or non-booked frozen sections within the hours detailed above.

34.2.5 Ensure that the appropriate pathology staff are on site to undertake booked frozen sections, which require a minimum of 48 hours notice.

34.3 Non Gynae Cytology Service – the Service Provider must:

34.3.1 Ensure that there is a Biomedical Scientist available to attend, within a reasonable time frame, scheduled Head and Neck, Thyroid and any other specialist clinics where fine needle aspiration is required, together with imaging sessions involving Fine Needle Aspiration (FNA), on site between 9:00 am and 5:00 pm Monday to Friday (excluding Public Holidays) to check the adequacy of cellularity of samples taken by clinicians / radiologists.

34.3.2 If funded, ensure attendance at designated FNA clinics, run by a appropriately qualified cellular pathologist, where patients can be referred on an urgent basis for Fine Needle Aspiration Cytology (FNAC).

34.3.3 Ensure that very urgent cytology is reported verbally to clinician on the same day, in line with IOG requirements.

34.3.4 Ensure that urgent (high suspicion malignancy) cytology is reported verbally to clinician within 48 hours.

34.4 Gynae Cytology Service – the Service Provider will:

34.4.1 Provide, from a single centre, the Gynae Cytology service as described in the service specification at Appendix 7.

34.5 **Mortuary Service –** the Service Provider shall:

34.5.1 Provide mortuary services that comply with HTA requirements.

34.5.2 Comply with the Department of Health's good practice guide for NHS mortuary staff "Care and respect in death" in that they balance delivery of an effective and efficient service which follows stringent procedures for ensuring safety and security, with the need to demonstrate respect and sensitivity for bereaved and meet the needs of clinical staff.

34.5.3 Provide facilities for coroner led post-mortem services that meet national and local requirements.

34.5.4 Provide a consultant led post-mortem service that meets national and local standards.

34.5.5 Encourage the Coroner to refer to a specialist tertiary consultant all post mortems that require a specialist to carry them out e.g. maternal, infant or child deaths. Provide advice for the Coroner about appropriate referral.

35 Microbiology Service

35.1 The Service Provider shall:

35.1.1 Provide a clinically led Microbiology service to support clinical services in the acute trusts and the community.

35.1.2 Provide onsite specialist medical advice through telephone discussions or visiting ward based patients.

35.1.3 Provide laboratory support and infection control medical advice for individual organisations infection control and prevention services.

35.1.4 Ensure there is a fully functional Microbiology Service provided by a maximum of two laboratories in K&M; that provide urgent and routine diagnostic and screening analysis for inpatient, outpatient and GP referrals. Test repertoires are to be determined by clinical need and agreed with commissioners.

35.1.5 Ensure the service provides a 24 hour, 7 day week laboratory service for urgent requests and a suitable service response to unplanned operational demand variations e.g. communicable disease outbreaks.

35.1.6 Provide an appropriate and fair use of consultant time across the K&M acute hospitals, providing a clinically appropriate level of support for the laboratories and a full clinical service to the acute trusts.

35.1.7 Provide a medical and infection control "out-of-hours" on-call service for K&M acute trusts and meet the needs of the laboratory service for clinically important specimens on Sundays and Bank Holidays, as well visits to wards as necessary.

36 Analytical Service

36.1 The Service Provider shall:

36.1.1 Deliver an analytical service from the laboratory or alternatively support PoCT (where it has been agreed to be appropriate) to ensure safe and effective patient outcomes.

36.1.2 Provide a repertoire of investigations and support patient care (screening, diagnosis, monitoring and optimising treatment).

36.1.3 Ensure that urgent requests arising from locations outside the acute hospitals are subject to similar turnaround times on receipt.

36.1.4 Ensure that users of the service are advised of any disruption to normal service provision, alternative arrangements to support weekends, bank holidays and any contingency.

36.1.5 Repatriate tests sent to laboratories outside K&M if justified, on a clinical, scientific, logistical or cost effectiveness basis.

36.1.6 Assume responsibility for the range and quality of in vitro medical devices used for blood sciences and microbiology tests undertaken by PoCT in acute hospitals. All other specialties will be responsible for their own PoCT devices. In addition, with appropriate agreement and resources the provider may manage PoCT in settings outside the hospital i.e. GP practices, primary care clinics, pharmacies and community hospitals. If management of these devices is not agreed, the service shall provide guidance on standards and quality assurance.

37 Interpretative Service/ Results Provision

37.1 The Service Provider shall:

37.1.1 Ensure that the results of pathology tests produced by a laboratory are authorised after technical validation and clinical validation if appropriate, this may involve the addition of comments to aid clinical interpretation.

37.1.2 Ensure that individual results or groups of results shall be combined and issued as a final report.

37.1.3 Ensure that reports containing provisional results or interim reports are marked accordingly.

37.1.4 Inform and update requestors about their responsibility for taking any clinical decision or action as a consequence of receiving the test results.

37.1.5 Inform and update requestors about the need for results to be incorporated into the patient health care record.

37.1.6 Ensure that pathology results are reported electronically, as part of a paper report or to the requestor by telephone.

37.1.7 Ensure that results of tests requested urgently or abnormal results are reported to the requesting clinician within the required timeframe, if the requesting clinician is unavailable these results must be reported to a designated alternate.

37.1.8 Ensure that provisional results are reported, in circumstances when it is judged their immediate availability may affect patient management, users must be made aware that such results could change.

37.1.9 Ensure that any provisional results are confirmed as soon as possible. Any changes to a provisional or final report which will alter patient management must be notified to the user by telephone and an amended report issued.

37.1.10 Ensure that interim reports are issued in lieu of a final report waiting for one or more test results; this shall be superseded by a final report once all results are available.

37.1.11 Ensure that amended reports are issued if provisional results change, if results previously reported are subsequently found to be erroneous or to add/delete results or clinical comments, all amended reports must be clearly labelled and include the reason for the amendment.

38 Interpretation and Advice

38.1 The Service Provider shall:

38.1.1 Offer clinical interpretation of results and advice on further tests/patient management.

38.1.2 Ensure that further tests relevant to the initial request/consultation shall be added where appropriate.

38.1.3 Ensure that clinical liaison, interpretation of results and advice on pathology specialties shall be provided by a dedicated advice line during normal working hours.

38.1.4 Ensure that advice for Blood Sciences and Microbiology Services is available 24 hours a day, 7 days a week throughout the year by a registered clinical scientist or consultant Pathologist.

38.1.5 Ensure that specialist knowledge and expertise is provided to other clinical Networks and to multidisciplinary teams throughout K&M as appropriate.

Appendix 1 (To be confirmed by local agreement)

Rapid Response Laboratory

Repertoire of tests to be available in acute hospital laboratories

Serum/Plasma
Alanine transaminase (ALT)
Albumin
Alkaline phosphatase
Ammonia
Amylase
Aspartate transaminase
Bilirubin *(total and conjugated)*
Blood gases and lactate *(use ward-based instruments)*
Bicarbonate
Calcium
[Cortisol]
Carboxyhaemoglobin *(use ward-based instruments)*
Chloride
C-reactive protein
Creatine kinase
Creatinine
Digoxin
Ethanol (alcohol)
Glucose
Human chorionic gonadotrophin
[Iron]
Lithium
Magnesium
Osmolality
Paracetamol
Phosphate
Salicylate
[TFTs]
Total protein
[Transferrin]
Troponin
Urate
Urea

CSF
Glucose
Total protein
Xanthochromia screen

Urine
Creatinine
Osmolality
Potassium
PBG
Sodium

Haematology
Urgent FBC, coagulation for inpatients and urgent outpatients
Sickle screens
Malaria investigations
Coagulation samples including investigations such as D-Dimer, reptilase times
Bone marrow staining and examination
Full Blood Transfusion service

Appendix 2

Point of Care Testing (PoCT)

1. Guidelines for Implementation of Near Patient Testing, 1993. Available from the Association of Clinical Biochemists, 130-132 Tooley Street., London SE1 2TU, UK
2. Near-Patient Testing: A Statement of best practice for Scotland. Edinburgh: Scottish Office Department of Health, National Advisory Committee for Scientific Services, 1996.
3. Point-of-Care In Vitro Diagnostic (IVD) Testing: Approved Guideline. CLSI Document AST2-A. Wayne, PA: CLSI, 1999.
4. Joint Working Group on Quality Assurance Guidelines for Near to Patient or Point of Care Testing, 1999
5. Management of In Vitro Diagnostic Medical Devices. MDA DB 2002(02), March 2002. www.mhra.gov.uk
6. Management and Use of IVD Point of Care Test Devices. MDA DB 2002(03), March 2002. www.mhra.gov.uk
7. Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities: Approved Guideline, 2nd ed. CLSI Document C30-A2. Wayne, PA: CLSI, 2003.
8. Guidelines on point-of-care testing. The Royal College of Pathologists, October 2004. www.rcpath.org/resources/pdf/point-of-caretesting-updatedoct04.pdf
9. International Standard ISO 22870(E). Point-of-Care Testing (POCT) – Requirements for Quality and Competence. Switzerland: International Organization for Standardisation, 2006
10. Point of Care Testing for Managers and Policymakers. CP Price & A St. John. AACC Press, 2006.
11. Standards for the Medical Laboratory Clinical Pathology Accreditation (UK) Ltd. www.cpa-uk.co.uk
12. Management and Use of IVD Point of Care Test Devices MHRA DB 2010 (02), February 2010.
13. Best Practice Recommendations for Point of Care Testing (PoCT) Ruth Lapworth, on behalf of the Kent & Medway Pathway Network, January 2009.
14. Buyer's Guide. Point of Care testing for cholesterol measurement. CEP09020 NHS Purchasing and Supply Agency, September 2009.
15. Buyer's Guide. Blood Glucose Systems. Purchasing and Supply Agency, May 2008.
16. Point of Care Testing Cholesterol Testing. Top 10 Tips, MHRA 2005.

Appendix 3

Reporting Requirements

The K&M service providers will, by the 15th of the month, or in exceptional cases, when requested, provide an electronic report in database or spreadsheet form with the following data field completed with the pathology activity for the previous month and the year to date, for each Commissioning organisation and the KMPN:

Commissioning Organisation code
Requesting Consultant/GP
Date sample requested
Date sample received in lab
Date reported
Discipline
Patient DOB
Practice Code
NHS number
Hospital Number (if NHS number not available)
HRGC (where available)
Patient post code
Patient sex
Test Name
Test Code

Appendix 4

Key Quality Indicators for K&M Pathology Service

Aspect of Service Quality	Measure	Data Collection Method	Structure, Process or Outcome	Test 1 Utility	Test 2 Feasibility	Test 3 Comparability	Test 4 Differentiation	Test 5 Diagnosis	Test 6 Authority	Test 7 Credibility
A. Maintain specimen integrity	Number specimen repeats due to wrong container or handling									
B. Reflex costing index	Change in cost due to reflex tests									
C. Access	Ease of access by user/patient to results, advice, information									
D. User Satisfaction	User satisfaction rating									
E. Follow-up	% results acted on									
F. Clinically relevant responsiveness	Variation from target turnaround times for various tests and purposes									
G. Directive reporting	Presence of instructions for follow up and audit									
H. Use of national reference ranges	Continuous improvement in use of national reference ranges (once agreed)									
I. Appropriate repeat testing	% following agreed pathway or protocol									

J. Appropriate testing	Using the agreed test									
K. Appropriate sampling	% appropriately submitted samples									
L. Contribution to patient record	% results on electronic system									
M. Waiting times	Waiting times for phlebotomy									
N. Error logging	Presence of error logging process									
O. Patient ID	Penetration of NHS number on requests									
P. Contribution to pathway performance	Breaches of national waits for other services contributed to by pathology									
Q. Performance management	Existence of performance management measures									
R. Safe systems	Safe systems for amended and updated interim reports									

Explanations of Measures

A. Number specimen repeats due to wrong container or handling or inadequate ID. Wrong container may include no container suitable for request made. Handling may include time to lab, temperature of initial storage etc
[DN – should these be 3 separate quality indicators – can we estimate the cost to the lab and to the overall health system of informing requester and getting a further sample (data will be useful in cost/benefit analysis for order comms system)]
B. Change in cost due to reflex tests – may include frequency of reflex testing, range of clinical indications, cost of additional assays v cost of repeat sample for the additional tests reflexed

C. Ease of access by user/patient to results, advice, and information – information may be from lab 'handbook' or other referenced source. [DN – should patient and user criteria be separate criteria; does advice infer person to person eg by phone or e-mail?]
D. User satisfaction rating – [DN - does this include patient as well as clinician? Requires a questionnaire to be designed]
E. % results acted on – [DN – does this break down into results opened/acknowledged (if electronic reporting); ?lab ability to access and count unopened results; Acted upon is more difficult without access to notes and is subjective – GB suggested that if critical results added a set of additional tests within a time frame then this may be a proxy for this criterion]
F. Variation from target turnaround times for various tests and purposes – [DN requires local conversations with clinicians to set targets]
G. Presence of instructions for follow up and audit – [DN requires some agreement on when such instructions should be given]
H. Continuous improvement in use of national reference ranges (once agreed) – national audit of uptake of published and agreed reference ranges from Harmony project
I. % following agreed pathway or protocol – [DN – may need to concentrate on areas with national recommendations eg frequency of requests for tumour markers]
J. Using the agreed test – [DN – requires lab participation in protocol development? – does this overlap with I.]
K. % appropriately submitted samples
L. % results on electronic system – [DN – includes POCT – should this be limited to LIMS where there is an EPR?]
M. Waiting times for phlebotomy – [DN – requires targets to be set but could be done by patient satisfaction survey – the KMPN have a questionnaire used in their Choose & Book Phlebotomy project]
N. Presence of error logging process – [DN and how used to improve performance?]
O. Penetration of NHS number on requests – [DN – defined as the ability to obtain all patient pathology data through single entry of NHS number?]
P. Breaches of national waits for other services contributed to by pathology – includes A&E trolley waits and cancer targets [DN – requires more than a single criterion]
Q. Existence of performance management measures – to demonstrate how pathology enhances the overall quality of care; timeliness of sample transport
R. Safe systems for amended and updated interim reports – need to ensure that such reports are acknowledged and acted upon [DN major concern re missed cancer diagnosis]

<u>Definitions of Terms</u>

Three categories of *measure:*

- outcome measures
- process measures (such as waiting times)
- structure measures (the presence or prevalence of specific capability)

Appendix 5

Quality Measures and Indicators

QUALITY INDICATORS	CPA Standard
Accessibility	H
AI (not RIDDOR)	
Appraisal (inc CPD)	B
Appropriate testing	
Appropriate repeat testing	
Appropriate reflex testing	
Audit	H
Audit - Calendar / Outstanding Non Compliances	H
Audit - Infection Control Audit results for Mortuary	
Audit - Microbiology Audit completion against audit calendar expectation	
Audit - MRSA Screening Audit	
Average Cost per Test	
Blood Culture Positivity Rate by Ward - Includes reporting of data on presumed contaminants to ward managers	
Blood Wastage	D
CDT Positivity Rate (by Ward and Commissioning Organisation)	
Complaints response rate	H
CPA Status	
Ease of access by user/patient to results, information, advice	
Effect of advice/testing on outcomes	
Failure to act on priority*	E
Failure to do requested test*	F
Failure to identify required test*	E
Failure to provide telephone – critical report*	G
Failure to select priority*	E
H&S safe waste disposal	C
H&S secure waste containment	C
HTA	
Incidents	
Infection Control, Hand Washing Compliance	C
Lost & found' sample - (found the next day after reported as missing)	E
Lost Samples	E
Maintain specimen integrity	
Mandatory training rates	B
MHRA	
National Guidelines	
Performance - EQA & NEQAS	G
Performance - IQA	G
Performance - QC	F
Progress against agreed quality / cost improvement schemes	
Reduction in referred tests	
RIDDOR	
Risk Assessments	
Sample disclaimer rate – (processed with disclaimer)	E
Sample rejection rate – (with multiple cause analysis)	E
SOP Review Status	A

Staffing, Sickness Rate, Staff Turnover, Vacancy	B
Traceability	D
Turnaround Time	H
Unlabelled or incomplete requests by Ward/GP	
User Surveys/Satisfaction	

PERFORMANCE INDICATORS	**CPA Standard**
Attendance at Clinical Governance	B
Budget Report with details on over/under expenditure	
Compliments	
Performance Management	
Reducing Agency Staff Costs	B
Reduction in Non Pay Spend	
Value for money	
Volume of work by specimen type. – This is also shown by requesting organisation – wards for the hospital, GUM, ANC, Commissioning Organisation and GP surgeries	
Weekend work costs (excluding On-Call) – Saturday, Sunday and Bank Holiday morning work is not included in our staff pay budget	
Workload - Bench area	
Workload - Per WTE	
Workload - Tests	
Workload - Weighted per WTE	
Workload – Weighted Units	

Appendix 6

CLINICAL BIOCHEMISTRY & IMMUNOLOGY TURNAROUND TIMES

Clinical Biochemistry has set a target of delivering the results for the following tests located from –

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
	of a suitable sample being received by the laboratory					
17-hydroxy progesterone						√
5' hydroxyindole acetic acid (HIAA)						√
Adrenaline						√
Adrenocorticotrophic hormone (ACTH)						√
Alanine transaminase (ALT)	√	√	√			
Albumin	√	√	√			
Albumin (urine)				√		
Aldosterone						√
Alkaline phosphatase (ALP)	√	√	√			
Alkaline phosphatase isoenzymes						√
Allergy testing (RAST)					√	
Alpha-1-antitrypsin				√		
Alpha-1-antitrypsin phenotyping						√
Alpha-fetoprotein (maternal)				√		
Alpha-fetoprotein (tumour marker)				√		
Aluminium						√
Amino acids (plasma and urine)						√
Ammonia	√	√	√			
Amylase	√	√	√			
Androstenedione						√
Angiotensin converting enzyme (ACE)					√	
Anti-acetylcholine receptor Ab						√
Anti-dsDNA Ab					√	

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
Anti-GBM Ab		by arrangement		√		
Anti-neutrophil cytoplasmic Ab (ANCA)		by arrangement		√		
Anti-thyroid peroxisomal Ab				√		
Aspartate transaminase (AST)	√	√	√			
Autoantibody screen				√		
Bence Jones protein					√	
Bicarbonate	√	√	√			
Bilirubin (conjugated)	√	√	√			
Bilirubin (total)	√	√	√			
BNP					√	
C1 esterase inhibitor						√
C1 esterase inhibitor function						√
CA 12-5					√	
CA 15-3					√	
CA 19-9					√	
Caeruloplasmin				√		
Calcitonin						√
Calcium (serum)	√	√	√			
Calcium (urine)				√		
Calculi (renal)						√
Carbamazepine *	√	√	√	√		
Carcinoembryonic antigen (CEA)					√	
Chloride	√	√	√			
Cholesterol (high density lipoprotein)	√	√	√			
Cholesterol (total)	√	√	√			
Cholinesterase (phenotype)						√
Cholinesterase (pseudo-)						√
Cholinesterase (RBC)						√
Citrate (urine)						√
Coeliac Disease Screen				√		
Complement C3				√		
Complement C4				√		
Copper (serum and urine)						√

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
Cortisol (serum) *				√		
Cortisol (urine)						√
C-peptide						√
C-reactive protein	√	√	√			
Creatine kinase (CK)	√	√	√			
Creatinine (serum)	√	√	√			
Creatinine (urine)				√		
Cryoglobulin					√	
Cyclosporin				√		
Cystic fibrosis mutations						√
Cystine						√
Dehydroepiandrosterone (DHEAS)						√
Digoxin *	√	√	√			
Dopamine						√
Drug screen						√
Electrophoresis (serum and urine protein)					√	
Ethanol	√	√	√			
Ethosuximide						√
Extractable nuclear antigen Ab's (ENA)					√	
Ferritin				√		
Folic acid				√		
Follicle stimulating hormone (FSH)				√		
Gamma glutamyl transferase	√	√	√			
Gastrin						√
Globulin	√	√	√			
Glucagon						√
Glucose	√	√				
Glucose (Plasma)		√	√			
Glycated haemoglobin (HbA1c)				√		
Growth hormone						√
Gut hormone screen						√
Haptoglobin				√		

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
Homovanillic acid (HVA)						√
Human chorionic gonadotrophin (according to ectopic pregnancy protocol)	√	√	√			
Human chorionic gonadotrophin (HCG, tumour marker)				√		
Immunoglobulin A (IgA)				√		
Immunoglobulin E (IgE)				√		
Immunoglobulin G (IgG)				√		
Immunoglobulin G subclasses (IgG1-4)						√
Immunoglobulin M (IgM)				√		
Insulin						√
Insulin-like growth factor (IGF)						√
Intrinsic factor Ab					√	
Iron	√	√	√			
Lactate (plasma)	√	√	√			
Lactate (plasma and CSF)	√	√				
Lactate dehydrogenase (LDH)	√	√	√			
Lamotrigine						√
Lead						√
Lithium	√	√	√			
Luteinising hormone (LH)				√		
Magnesium	√	√	√			
Mucopolysaccharides						√
Neuron specific enolase						√
Noradrenaline						√
Occult blood				√		
Oestradiol				√		
Oligoclonal bands (CSF & serum)						√
Organic acids (urine)						√
Osmolality (serum and urine)	√	√	√			
Oxalate						√
Paracetamol	√	√	√			
Paraquat			√			

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
Parathyroid hormone (PTH)					√	
Pemphigus/oid Ab					√	
Phenobarbitone				√		
Phenytoin				√		
Phosphate	√	√	√			
Porphobilinogen			√			
Porphyria screen						√
Potassium	√	√	√			
Pro-collagen III						√
Progesterone				√		
Prolactin *				√		
Prostate specific antigen (PSA)				√		
Protein (total, serum and CSF)	√	√	√			
Protein (total, urine)				√		
Reducing substances						√
Renin						√
Salicylate	√	√	√			
Sodium	√	√	√			
Steroid profile						√
Stone analysis (renal)						√
Sugar chromatography						√
Tacrolimus (FK506)				√		
Testosterone					√	
Theophylline				√		
Thyroid stimulating hormone				√		
Thyroxine (T4, free)				√		
Toxicology screen						√
Transferrin	√	√	√	√		
Transferrin iron-binding capacity	√	√	√	√		
Triglyceride (fasting)	√	√	√			
Triiodothyronine (T3, free)				√		
Triiodothyronine (T3, total)				√		

	A&E, ECC, CDU, ITU, CCU & NICU	All Other Inpatient requests	All GP and Outpatient Work	All locations	All locations	All locations
Investigation	**Within 1 Hour**	**Within 4 Hours**	**Within 1 Day**	**Within 7 Days**	**Within 14 Days**	**Within 6 Weeks**
Troponin I	√	√	√			
Urea (serum)	√	√	√			
Urea (urine)				√		
Uric acid (serum)	√	√	√			
Uric acid (urine)				√		
Very long chain fatty acids (VLCFA)						√
Vitamin A						√
Vitamin B2 (riboflavin)						√
Vitamin D (25-hydroxy)						√
Vitamin E						√
Xanthochromia Screen				√		
Zinc						√
β-2-microglobulin						√

***** *following requesting consultant to duty biochemist approval*

These turnaround times are from receipt by the laboratory to report issued, including weekends but not bank holidays. It is anticipated that these turnaround times will be achieved for 95% of specimens. In some cases results can be undertaken & reported urgently if the laboratory or duty Biochemist is contacted directly.

Histopathology Turnaround Times

- All turnaround times are assumed to be from receipt in laboratory
- All verbal reports to be recorded in final report
- Urgent biopsies/small specimens: 24-72 hours from receipt in laboratory (interim report if additional laboratory investigations are indicated)
- Cancer biopsies to be reported to clinician within 5 working days (written or electronic)
- Cancer resections requests reported to clinician within 10 working days (written or electronic)
- Non cancer cases to be reported to clinician within 10 working days (written or electronic)
- Large specimen routine reported to clinician maximum 15 working days (written or electronic)
- Additional laboratory investigations, e.g. special stains, immunohistochemistry etc to be reported to clinician within 5 working days (written or electronic) from original report
- All cancers, and all lesions where it is sometimes difficult to distinguish between benign and malignant lesions (or other serious illness) to be reported or reviewed by a Cellular Pathologist who is a member of the specialist team – this to be noted on report.
- Requests for tests not available in the laboratory's repertoire or requiring an expert opinion from another laboratory may take up to 4 weeks for a final report to be issued. In these cases an interim report is to be issued to enable the clinician to counsel the patient appropriately pending the final report.

HAEMATOLOGY, HAEMOSTASIS & TRANSFUSION TURNAROUND TIMES

	Urgent (h)	Routine Wards (h)	Routine OPD/GP (h)	Complex (weeks)	Referral (weeks)
Haematology					
ESR	4	24	24		
FBC	1	4	24		
FBC with manual film	4	72	72		
Glandular Fever Test		48	48		
Haematinics		7 days	7 days	7 days	
Antenatal Haemoglobinopathy Screen		3 working days	3 working days		
Other haemoglobinopathy		7 days	7days		
Malaria Screen	4	24	24		
Sickle Cell Test	4	24	72		
Haemostasis					
Anti-Xa	1	72			1
APTT	1	4	4		
Coagulation Screen	1	4	4		
D Dimer	1	4			
Factor Assays	4	24	7 days		3 weeks
Fibrinogen	1	4	24		
Prothrombin Time or INR	1	4	4		
Thrombophilia Screen				4	4
Urgent antithrombin	4				
Transfusion					
Blood Group and Antibody Screen	1	24			
Cross-match*	1	24			
Direct Antiglobulin Test	1	24	24		
FFP	1				
Issue of Anti-D	4	24	24		
Kleihauer		24	24		
Platelets	4	24			

* Un-crossmatched group compatible blood can be available in 15mins and O Negative blood is available immediately

Microbiology Turn Around Times

The following turnaround times are from receipt by the laboratory to report issued, including weekends but not bank holidays. It is anticipated that these turnaround time will be achieved for 95% of specimens.

The service shall provide, if appropriate, the ability to undertake & report urgently those tests marked with an *, if the laboratory or on call Biomedical Scientist is contacted directly.

Investigation	Turnaround Time
AAFB culture	7-10 weeks
AAFB microscopy	1-3 days *
Blood cultures	1-7 days
Chlamydia PCR	1-7 days
CSF microscopy & culture	1-3 days *
CSF PCR	7-14 days
Ear, nose & throat culture	1-3 days
Faecal Clostridium difficile toxin	1-2 days
Faecal culture	3-5 days
Faecal OCP	1-3 days
Faecal rota/adeno	1-3 days
Genital culture	2-3 days
Legionella urinary antigen	1 day
MRSA screen	1-4 days
Mycology culture	1-8 weeks
Mycology microscopy	1-2 days
Pneumococcal urinary antigen	1 day
Pus, fluid & tissue culture	2-6 days
Sputum & respiratory culture	2-3 days
Urine microscopy & culture	1-2 days
Wound culture	2-6 days
Antenatal serology	1-7 days
Hepatitis A serology	1-3 days
Hepatitis B immunity	1-7 days
Hepatitis B serology	1-7 days
Hepatitis C PCR	7-14 days
Hepatitis C serology	7-14 days
HIV PCR/viral load	7-14 days
HIV serology	7-14 days *
Rubella immunity	1-7 days
Syphilis serology	1-7 days
Toxoplasma serology	7-14 days
Varicella Zoster immunity	1-3 days *
Viral PCR	7-14 days

Appendix 7

SERVICE SPECIFICATION FOR KENT AND MEDWAY LABORATORY BASED CERVICAL SCREENING SERVICE

BACKGROUND

The Cervical Screening Programme has undergone major changes in the last few years as a result of the implementation of new technology, rescheduling call/recall and falling coverage. Further declines in the numbers of women entering the scheme, through the introduction of the HPV vaccination programme and additional technological advances such as the introduction of semi-automated screening instrumentation are anticipated.

The net effect is that increasing numbers of screening and medical staff in cervical cytology laboratories fail to meet the national minimum workload to maintain competence. This represents a significant risk to the programme and change to the configuration of cervical cytology laboratory services within Kent is required to ensure a high quality, cost effective service.

The Kent and Medway Pathology Network (KMPN) have commissioned two management consultancy reviews as part of the modernisation initiative.

Hub and spoke arrangements of sample preparation have existed since 2006 in Kent between William Harvey Hospital (hub) and Medway Hospital and Preston Hall (hub) and Darent Valley Hospital.

SERVICE AIMS

- To provide a cost efficient, effective, robust high quality cervical screening service that meets and/or exceeds national standards as defined by the NHSCSP.
- To reconfigure the provision of cervical cytology screening services, to include Colposcopy samples from gynaecology clinics, in Kent and Medway (K&M) in line with the recommendations from the KMPN (one centre for Kent).

Objectives

- All women should receive the results of their cervical screening tests within two weeks by the end of December 2010.
- Electronic result download between the provider and all call/recall offices to which the results are sent shall be established if not already in place.
- The annual workload figures of all primary screening and checker staff should meet or exceed the national workload minimum targets.
- All medical staff undertaking cytology reporting should have a weekly time allocation of at least one PA in respect of this work and examine in excess of 750 samples per annum.
- The total laboratory workload for cervical screening samples should meet or exceed 35,000 samples per year.
- Regular Multidisciplinary meetings should be convened and formally recorded. Participants should attend at least 75% of these meetings in a year.
- All trained medical and non-medical staff should participate in the External Quality Assessment Scheme for Gynaecological Cytopathology.
- Liquid-based cytology shall be the technology used in the cervical screening laboratories.

- Semi-automated screening technology shall be introduced as soon as practicable after the publication of the MAVARIC trial.

LOCATION

The screening service shall be provided from one laboratory site within Kent. An indication of the number of current locations from which the cervical cytology samples are collected from for each commissioning organisation is given in the table and the map below. The KMPN transport system provides two delivery / collection runs per day.

Current PCT	Approximate Number of Collection Points
East Kent	127
West Kent (MTW)	70
East Sussex (MTW)	7
Medway (MFT)	126
West Kent (DVH)	40
TOTAL	**370**

LABORATORY AND INDIVIDUAL STAFF WORKLOADS

Service Providers should ensure that all non-medical staff achieves at least the minimum annual workload(s) appropriate to their respective function(s) within the unit. All medical staff should have a weekly time allocation of at least 1PA for cervical cytology.

ACTIVITY MEASUREMENTS AND ACTIVITY FORECASTS

The activity undertaken by each of the current NHS Provider Laboratories in 2007/2008 and 2008/9 is given in the table below. Although declines in cervical screening numbers are anticipated because of the impacts of new technologies in automated screening, vaccination and HPV testing, the screening programme is very sensitive to major fluctuations in demand when public interest is stirred by media interest.

Cervical Cytology Screening

Trust	2007/8	2008/9	2009/10
Medway NHS Foundation Trust	23302	25486	24082
Dartford and Gravesham NHS Trust	16256	17706	
Maidstone and Tunbridge Wells NHS Trust	31125	35244	36337
East Kent Hospitals University NHS Foundation Trust	38565	41681	43168
Total	**109248**	**120117**	

Non Screening Colposcopy Samples

Trust	2007/8	2008/9	2009/10
Medway NHS Foundation Trust	1097	1479	1219
Dartford and Gravesham NHS Trust	642	732	

Maidstone and Tunbridge Wells NHS Trust	966	1246	
East Kent Hospitals University NHS Foundation Trust	2881	3095	3233
Total	**5586**	**6552**	

PERFORMANCE AND SERVICE QUALITY MONITORING

Clinical Leadership

Each laboratory shall be under the supervision of a lead consultant pathologist who shall have overall responsibility for the reporting standards of all LBC slides signed out by non-medical staff. They shall be contractually responsible for ensuring adequate governance arrangements are in place to deliver a quality service to the agreed specification.

Workload

- Each laboratory that provides the service shall undertake a minimum of 35,000 samples per annum.
- All pathologists participating in the cervical screening programme shall report at least 750 cases per year. This figure should include all cervical cytology, where the pathologist issues a report.
- All medical staff who report cytology samples shall have a minimum time allocation to this work of 1PA per week and undertake this minimum workload.
- There shall be an appropriately qualified and experienced person to act as a Hospital Based Programme Coordinator).
- All primary screeners shall screen at least 3,000 cases per annum based on current manual techniques.
- All staff that undertakes both primary screening and checking shall meet the minimum standard of 1000 primary screens and 750 checks per annum.
- Primary screening staff shall not screen for more than five hours per day and shall spend no more than two hours at a microscope without a break.
- All primary screeners should cover a similar casemix.

Laboratory Accreditation

- Each laboratory participating in the cervical screening programme shall currently hold CPA accreditation and shall retain CPA accreditation, or its equivalent.
- Each laboratory participating in the cervical screening programme shall demonstrate and maintain strong key performance indicators by participating in regular assessment processes by the South East Coastal Quality Assurance Reference Centre.

Staff Responsibilities

- Each laboratory shall be under the supervision of a consultant pathologist who shall have overall responsibility for the reporting standard of all LBC slides signed out by non-medical staff.

- The consultant pathologist shall be contractually responsible for ensuring adequate governance and quality system arrangements are in place to deliver a quality service to the agreed specification.
- There shall be clear documented lines of responsibility and accountability.
- Only suitably trained medical staff, BMSs and Cytoscreeners shall undertake the screening role.
- The checking role shall ordinarily be undertaken by staff that are Health Professions Council registered and have a minimum of three years experience in cytology post completion of the NHSCSP Certificate in Cervical Cytology.
- Competent trained laboratory staff shall sign out cervical cytology reports.
- All LBC slides considered borderline, dyskaryotic, malignant or are a third inadequate case shall be reported by a Consultant Pathologist or suitably qualified Advanced Cytology Practitioner or Consultant biomedical Scientist.

Staff Training

- All screening and medical staff shall be trained and competency assessed on the relevant technology used to produce LBC slides.
- All Cytoscreeners who undertake the reporting of negative and inadequate cervical samples should hold the Certificate in Cervical Cytology, the C&G Diploma in Cervical Cytology (3165-03) or equivalent.
- All Biomedical staff who undertakes the reporting of negative and inadequate cervical samples should be registered with the Health Professions Council and should preferably hold the Certificate in Cervical Cytology, the C&G Diploma in Cervical Cytology (3165-03) or equivalent.
- Existing and new Advanced Consultant Bio-Medical Scientists (Advanced Cytology Practitioners) shall hold all relevant national qualifications including the Certificate in Advanced Practice in Cervical Cytology.
- Existing and new medical staff shall be on the specialist register or have equivalent experience.
- Provision shall be made for continuing education for all scientific and medical staff in non-training grades.
- All staff shall receive and take part in continual update training.
- All non-medical staff participating in the NHSCSP shall undertake a formal update course at least every three years.
- All Consultant Medical staff to have successfully completed the conversion training to LBC or passed the FRCPath Part 2 examination in LBC or hold the Certificate of Higher Cervical Cytology Training (CHCCT).
- Regular educational sessions shall be held for the discussion of interesting and problem cases and new developments. All grades of staff shall participate.
- Service providers shall provide dedicated time for ‘in house’ updating of screening staff.
- If staff return to cervical cytology after an absence exceeding 3 months, they should undertake a formal, documented in-house assessment programme; if the absence exceeds 6 months, attendance at an external update course may be required.

- Relevant and up to date journals and text books shall be available to all staff in all laboratories.

Staff Performance

- The performance of all laboratory staff shall be monitored and documented, along with action taken to address problems – please refer to SEC QA Screener Poor Performance Guidelines (February 2009).
- All performance outwith standards shall be dealt with in a sensitive and caring fashion. Anonymity shall not outweigh consideration of the action to be taken
- Remedial action, such as retraining and re-testing, shall always take place, when necessary to correct substandard performance.
- Persistent substandard performance, or an unwillingness to accept advice on retraining, shall result in the suspension of the individual concerned from the screening programme. This applies equally to primary screeners, checkers and consultants.
- All trained medical and non-medical staff who sign out or report cervical cytology samples should participate in the External Quality Assessment Scheme for Gynaecological Cytopathology.

Quality Control and Quality Assurance

- All laboratories shall have appropriate IQC arrangements.
- All laboratories shall have, and shall follow, standard operating procedures, which document every laboratory process.
- All laboratory procedures shall be routinely monitored and their monitoring recorded.
- All laboratories shall rapid review/preview all negative and unsatisfactory slides, on a daily basis.
- The integrity of all laboratory data shall be validated and audited.
- All cervical cytology staff shall participate regularly in a NHSCSP Gynaecological Cytology EQA scheme and any deficiencies shall be corrected. A record shall be kept of all deficiencies and corrective actions undertaken.
- All laboratories that process or stain cervical samples should participate in the External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology.
- Laboratory KC61 data should fall within the Achievable Standards range as published annually in the National Statistics Bulletin.

Reporting

- All laboratories shall use the British Society for Cervical Cytology, BSCC reporting terminology.
- All laboratories shall be monitored against current standard reporting ranges based on KC61 returns as published in the Annual NHSCSP Statistical Bulletin (England) for 2008-09 these are:
    - Moderate and severe: 0.8% - 1.45%
    - Mild and borderline: 4.0% - 7.45%
    - Positive Predictive Value (PPV): 75.3 – 88.6%

- All laboratories shall be monitored against achievable standards as detailed below:
    - Sensitivity (all grades dyskaryosis): >90%
    - Sensitivity (high grade dyskaryosis): >95%
- All performance outside these standard reporting ranges and achievable standards for screening cytology shall be fully investigated in accordance with internal policies on the identification and control of non-conformities, SEC QA Early Warning Guidelines (February 2008) and if deemed appropriate following consultation with the QA team, the NHSCSP Guidelines for Managing Incidents in the Cervical Screening Programme (NHSCSP publication number 11).

Multi-Disciplinary Team and Performance Management Meetings

- Multidisciplinary team meetings, to review individual cases and correlate patient care, particularly with regard to cytology/histology discrepancies, and should be held every 2-4 weeks in accordance with the guidance given in Guidance for Cytology, Histology and Colposcopy Multi-Disciplinary Team Meetings (September 2007), SEC QA Colposcopy MDT Guidance (July 2008) and Colposcopy and Programme Management (NHSCSP publication number 20)

- In addition, steering group meetings to discuss operational issues and performance of the screening service shall be held bi-annually and should include laboratory personnel, Primary Care Trusts Directors of Public Health, South East Coast Cervical Screening Quality Assurance Reference Centre.

Laboratory Accommodation and Facilities

- Laboratory accommodation and facilities must meet the requirements of HBN 20, CPA and should comply with the BSCC Code of Practice and Medical Devices Agency recommendations.

Records

- All LBC slides shall be filed accurately to facilitate retrieval for review.
- 99% of LBC slides selected for review shall be retrievable by the laboratory within two working days
- All LBC slides shall be kept for a minimum of 10 years.
- Documentation relating to laboratory IQC shall be retained for a minimum of 10 years.
- Slide disposal after 10 years shall be documented.

Audit of Invasive Cancer

- All women who develop invasive or micro-invasive adenocarcinoma or squamous carcinoma of the cervix shall have their screening histories reviewed, and all available slides from these women shall be included in the review in accordance with the guidelines set out in the NHSCSP Audit of Invasive Cervical Cancers (NHSCSP publication number 28).

INFORMATION TECHNOLOGY REQUIREMENTS

The provider shall use computer laboratory information management software (LIMS), which will maintain a database including a register of all local women within the NHSCSP, for failsafe purposes, and is easily auditable. Data collection for trend analysis shall be required, statistical quality returns (KC61), as well as the capability to transfer information to the call/recall agency.

The provider shall be expected to demonstrate how such LIMS will be used and how training will be delivered, as well as the logistics around the use of the system and its accuracy. The software would be required to meet the local and national Information Governance requirements and NHS Connecting for Health compatibility.

Additionally, each individual member of screening staff must have access to the NHAIS 'Open Exeter' system in order to access the screening history of all women registered in the local area, regardless of whether previous samples were screened at the provider laboratory.

The provider shall be required to implement and manage a system for the electronic order communications from GP practices as soon as practicable.

The provider shall be required to provide a system for the electronic communication with NHS Cellular Pathology Laboratories within K&M and to Colposcopy clinics to provide a direct route of referral

The provider shall comply with National data requirements including Caldicott guidelines and relevant Data Set Control Notices and Commissioning Data Set Manual.