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Title	|	Quality Manual
Author	|	Bryan Smith (Inactive), Harlovleen Bhachu, and John Auld (Inactive)
Authorised By	|	Harlovleen Bhachu
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Procedure Amendments

	Date	Page	Amendment	Authorized By
1	29 Nov 17		Introduction of amendment page	JA
2	29Nov 17	21	Quality Policy is now a standalone document referenced in this manual	JA
3	29 Nov 17	Appendices	Various changes in Cell Path management structure	JA
4	29 Nov 17	11	Addition of reference to mortuary services	JA
5	29 Nov 17	53	Addition of reference to mortuary services TNT as a carrier	JA
6	29 Nov 17	23	Slight amendment to wording about quality objectives	JA
7	29 Nov 17	30	Clarification of the SLA procedure	JA
8	29 Nov 17	33	Clarification of the complaints procedure	JA
9	1 Aug 18	Various	Review document-Minor grammatical changes, updated departmental profiles and patient stats, updated quality policy.	JA
10	18 Oct 18	Various	Minor amendments and additions required by UKAS assessors following the Haem/BT SU visit. No material change to content	JA
11	05.11.19	Various	Minor amendments and additions required by UKAS assessors following the Histo visit.	JA
12	06.11.19	40	Cellular pathology TAT updated to reflect RCPath guidelines.	JA

All staff must be made aware of the change(s)

Procedure Amendments

	Date	Page	Amendment	Authorised by
13	29.5.2020	11	Responsibility for Antenatal Screening Programme & reference to organogram added	JA
14	29.5.2020	83	Change to named individual with responsibility for Pre-Analytics	JA
15	11.6.2020	13	Removal of role of Consultant Microbiologist as Associate Director of Infection Prevention & Control for WHAT.	JA
16	11.6.2020	77	Addition of Associated Document for Haematology (Audit Procedure)	JA
17	11.6.2020	12	Removal of Helena Aggram analyser from Haematology	JA
18	19/11/2020	12	Added HM-Jackarc analyser to Biochem,	LH
19	19/11/2020	23	Removed reference to GP locality meetings, added reference to user feedback form on website	LH
20	24/08/2021	14	Fine needle aspirate procedure within cellular pathology temporarily suspended	AP
21	24/08/2021	82	Organisational Chart updated	AP
22	29/09/2021	22	In the event of vacant laboratory director role	MC
23	29/09/2021	25	Updated quality policy 12.4 added Updated line …. and conforms to the standard and regulations of BS EN ISO 15189:2012	LKB
24	29/09/2021	12	4 DxH 900s 2 DxH 900s at the Alex rather than DxH800s	BBJ
25	29/09/2021	13	refers to TOSOH - should be SEBIA	BBJ
26	07/10/2021	24	Quality Policy Version number amended to 12.5	LKB

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27	12/01/2022	81	Dr B Sethi lab director cellular pathology	A.Philo
28	31/01/2022	11,12 80,81	Update to Biochemistry instrumentation. Organisational chart updated.	NP
29	01/02/2022	80, 81	Update to both organisational charts Biochemistry – recent updated incorrect Replacement of Dr Sethi in Cellular Pathology	HKB
30	29/7/2022	80, 81	Update to cellular pathology organisational chart – DG lab manager, SWL deputy laboratory manager, KW training officer. Update to Biochemistry organisational chart: Jessica Patel laboratory manager. Update to pathology organisational chart: Helen Jarvie divisional director of operations.	A.Philo
31	29/7/2022	29	HTA DI updated	A.Philo

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1. Introduction and scope

This document, together with the specified documents, represents the Quality Management System (QMS) of the Pathology Directorate of Worcestershire Acute Hospitals NHS Trust (WAHT). It has been compiled to meet the requirements of UKAS (ISO 15189 2012), NHSLA, Human Tissue Authority and the Blood Safety and Quality Regulations 2005, Statutory Instrument 2005 No. 50. BSQR 2005 as amended.

The QMS is the process developed to support the generation of an efficient and effective, high quality and appropriate laboratory advice, testing and recommendation service. It encompasses all elements of quality delivery, including management systems, quality assurance and quality control.

Throughout the text of the Quality Manual, there are references to the ISO Standard (ISO 15189 2012) and supplementary documents and to policies or procedures [indicated in square brackets].

This Quality Manual (ISO 15189 2012:4.2.2.2) [PO-U-GEN-QualityManual] fulfils two functions:-

(a) It describes the Quality Management System for the benefit of the Directorate management and staff.

(b) A copy of it is available on the pathology website to provide information for users and for external assessors.

The **scope of the service** provided by the Pathology Service is as follows:

An in-house routine diagnostic service for Haematology & Blood Transfusion and Clinical Biochemistry, Microbiology and Cellular Pathology services**.** All disciplines across the sites come under the same senior management and use the same quality management system. Pathology at Worcestershire Royal Hospital operates as the main facility where all routine primary care work is handled with the facilities at the Alexandra Hospital operating as a satellite facility for inpatient, outpatients at the Alexandra and urgent work from this location. Some testing in Blood Sciences is done on a countywide basis either at the Redditch or Worcester site and in these cases the samples analysed would be from a variety of sources, both inpatient and outpatients. The service provided is of a routine nature with none of the facilities acting as a designated referral centre.

There are body stores on both sites with a post-mortem suite at WRH.

1.1 Laboratory background

Worcestershire Acute Hospitals NHS Trust Pathology Service
The Pathology Directorate is part of the Worcestershire Acute Hospitals NHS Trust. It has laboratories on two of the three Trust sites, located at Worcestershire Royal Hospital and Alexandra Hospital, Redditch. Any work from Kidderminster Hospital is transported by courier to the Worcester site.

The Pathology service is provided to Worcestershire Acute Hospitals NHS Trust, the three CCG's which exist across Worcestershire and Worcestershire Health and Care NHS Trust. Other organisations are free to approach us to see if we are able to offer them specific elements of our service and these would be considered in line with our policy for Establishment and review of agreements, [MR-U-GEN-SLA], in order to assess capacity, skills and expertise. Currently we have specific SLAs with Spire-Southbank Hospital for pathology services including the supply of cross matched and flying squad blood components. Services are also provided to St Richards Hospice. The two local prisons, HMP Hewell and HMP Long Lartin, also send us samples from their clients.

Phlebotomy is not within Pathology, this being within the Outpatient Department and managed as such by the relevant Outpatients manager on each of the three sites.

Transport services are provided by two separate organisations and are managed by their transport manager in each case. Samples from the South of Worcestershire and Wyre Forest including from Kidderminster Hospital are collected by a fleet of Acute Trust vehicles while those from the Bromsgrove and Redditch areas are collected by Health and Care Trust vehicles. Samples and pathology supplies are transported between the three sites by a different set of Acute Trust vehicles which constantly rotate between the three acute sites transporting a wide variety of items.

The four disciplines within the Pathology Directorate provide a high quality evidence based service described below. Expert interpretation and advice from Consultant medical and scientific staff enhance the analytical service.

1.2 Mission statement

To provide a high-quality Pathology service including Cellular Pathology, Clinical Biochemistry, Haematology & Blood Transfusion and Microbiology that meets the expectations agreed with its users, and conforms to the standard and regulations laid down by UKAS (ISO 15189: 2012) and other relevant legislation and regulatory bodies.

1.3 Service scope

The service for Haematology, Blood Transfusion and Biochemistry is provided from two different Acute Trust sites. The IT system in use is common across both sites and information about any sample can be accessed from either site. As far as possible common analytical platforms are in use across the sites and where this is not the case progress is being made towards this. Comparison studies are done where tests are offered on both sites

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in order to ensure comparability of results irrespective of site of analysis. For those disciplines which operate from multiple locations staff are nominally assigned to the Worcestershire Royal Hospital site and the other site is staffed by rotating staff from this site. (Ref: GEN-1 Appendix C)

Worcestershire Royal Hospital
Charles Hastings Way
Worcester
WR5 1DD
Tel. 01905 763333

Alexandra Hospital
Woodrow Drive
Redditch
B98 7UB
Tel. 01527 503030

Kidderminster Hospital
Bewdley Road
Kidderminster
DY11 6RJ
Tel. 01562 823424

Information on the services provided and contact telephone numbers are available on the Pathology Website, http://www.worcsacute.nhs.uk/pathology

1.3.1 Clinical Biochemistry

The Clinical Biochemistry service has its main site at Worcester with a satellite site at Redditch.

The Worcester Royal hospital site has pre-analytical, automated, semi-automated and POCT sections. The automated section consists of Beckman Coulter chemistry and immunoassay analysers providing results on serum, plasma, urines and fluids for a variety of common biochemical tests. The Semi-Automated section of the laboratory performs HbA1c analysis, electrophoretic, immuno-fixation techniques, quantitation of serum free light chains and CSF spectrophotometry. All primary care samples are processed here as well as the Worcester hospital inpatient and outpatient work. The service is available 24 hours, 7 days per week, and is contacted via switchboard during out of routine hours. For a full test repertoire please consult the pathology website http://www.worcsacute.nhs.uk/pathology.

The laboratory is also involved in the countywide management of Point of Care Testing (POCT) including test/equipment selection, training and external quality assurance for blood gas and glucose analysis. The Pathology wide multidisciplinary POCT committee meets quarterly, and reports to the Trust Medical Devices Committee which is attended by one of the Clinical Scientists.

The Alexandra hospital site at Redditch has Pre-Analytical, automated and manual sections. The automated section consists of Beckman Coulter chemistry and immunoassay analysers providing results on serum, plasma, urines and fluids for a variety of common biochemical

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tests. The manual section provides a countywide weekly quantitative urine catecholamine metabolites service and countywide faecal calprotectin and faecal haemoglobin (FIT) analysis on the HM-Jackarc analyser is also performed at the Redditch laboratory. Other than for the countywide services only the Redditch hospital inpatient and outpatient samples are processed here as well as any urgent Primary care samples which are specifically delivered by local doctors/nurses. If there are any tests required on these samples that are not offered at this site then the samples are sent on the next available transport to the Worcester site following analysis of the tests which are offered at this site. For a full test repertoire please consult the pathology website http://www.worcsacute.nhs.uk/pathology. The service is available 24 hours, 7 days per week, and is contacted via switchboard out of routine hours.

POCT for this site is monitored daily by the laboratory staff but managed by the Worcester site.

All staff are based at the Worcester hospital and the Redditch laboratory is covered by a pool of cross site trained personnel.

Each biomedical scientist section lead has a team of staff under their control on both sites who ensure that all relevant tasks are completed. Further information is provided in the Biochemistry Department Organisational Chart. AD-U-CHM-Organisational chart chemistry

1.3.2 Haematology

Haematology has its main site at Worcester with a satellite site at Redditch providing haematology and coagulation testing. The Worcester site processes all the GP samples as well as inpatient and out-patient samples. The Redditch site analyses only the Redditch hospital inpatient and outpatient samples as well as any urgent Primary care samples which are specifically delivered by local doctors/nurses. The service at both Worcester and Redditch is available 24 hours, 7 days per week, and is contacted via switchboard out of routine hours. For a full test repertoire please consult the pathology website http://www.worcsacute.nhs.uk/pathology

At WRH the routine haematology section has 4 connected Beckman Coulter Unicel DxH 900 analysers for full blood count analysis, white (5 cell) differential and reticulocyte counting; with a connected Beckman coulter DxH (Automated) slidemaker stainer for blood samples. A semi-automated Hematek 3000 slide stainer is available for blood films requiring urgent examination. Bone marrow slides are stained manually for Consultant examination. Automated ESR results are processed by one of two Alifax test1 BCL analysers using capillary stopped kinetic analysis.

The coagulation section provides routine INR, PTTR, Fibrinogen and D-Dimer results using two IL TOP 550 analysers, as well as Factor assays and screening for Lupus Thrombophilia, Factor VIII RCOF Antigen , Thrombophilia, Von Willebrand Factor Antigen..

The Haemoglobinopathy section has a Sebia Capillarys 3 Tera for identification of haemoglobin variants. The Countywide Antenatal Screening Service for Sickle Cell and

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Thalassemia is provided on the WRH site with referrals for counselling made to the Clinical Genetics Unit at Birmingham Women's Hospital, if necessary. Identified haemoglobin variants are referred for confirmation to Sandwell Hospital and suspected thalassemia's sent to the National Haemoglobinopathy Reference Laboratory at Oxford. The Screening Service is overseen by the Clinical Lead Haematologist and organised on a daily basis by the Haematology Screening Lead BMS (ED-U-HAE-SCT Screening Organisation Chart).

The combined haematology and coagulation section at Redditch provides full blood count analysis, white (5 Cell) differential and reticulocyte counting using two Beckman Coulter Unicel DxH 900 analysers. Routine INR, PTTR, Fibrinogen and D-Dimer tests are carried out on the IL TOP 350 analysers. Blood films are stained using the Hematek 3000 Slide stainer. Bone marrow slides are stained manually. Automated ESR results are obtained using the Alifax test1 BCL analyser

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1.3.3 Blood Transfusion Services

A full acute blood transfusion service is provided from both Worcester and Alexandra sites with a Blood Issue fridge being housed at Kidderminster.

Electronic Issue (EI) is utilised at both the Worcester and Redditch sites and manual techniques are used for red cell compatibility testing when the rules for EI are not met. Platelets, plasma and cryoprecipitate are issued on named patient basis. The departments also issue other blood products including Human Albumin Solution, Anti-D immunoglobulin, Prothrombin complex (Beriplex), Fibrinogen concentrate (Riastap) and FEIBA(Factor VIII) for haemophilia. Kleihauer testing is done manually on the WRH site only with any identified positive foetal bleeds above 2 ml being referred to Heartlands Hospital (weekdays) or NHS BT Liverpool (weekends) for quantitation by flow cytometry. The department also performs manual transfusion reaction investigations.

Both the Worcester and Redditch departments each have 2 Ortho Clinical Diagnostic Vision analysers for processing group & screen samples, direct agglutination tests , performing antibody identification panels and red cell phenotyping.An Antenatal blood group serology screening service is provided with sample referral to NHS Blood and Transplant if antibody titration is required. HLA tissue typing, HLA B27 and Fetal Genotyping tests are sent to the NHS Blood and Transplant service for processing.

There is a blood issue fridge at KTC which contains 6 units of emergency O Rh D negative red cell units which are supplied from WRH. The laboratory at Worcester also sends blood and platelets to KTC on a named patient basis, primarily to support oncology and community transfusion services (approximately 10 patients per week). All blood transfusion samples from KTC are sent to WRH for processing.

The lead consultant for Transfusion chairs the Transfusion Team Meetings and Trust Transfusion Committee. The implementation of National Guidelines and development of service provision are agreed at these meetings.

The Blood Transfusion department also supplies blood and blood products on a supply only basis to community and private hospitals within the locality.

1.3.4 Cellular Pathology Service

Cellular Pathology has its main site at Worcestershire Royal Hospital, with a satellite facility for frozen sections (must be pre-booked) at the Alexandra Hospital Redditch. There is no Cellular Pathology service at Kidderminster. It also manages Mortuary services at both Redditch and Worcester.

The Worcestershire Royal Hospital site provides a full Histology service, from dissection of formalin fixed tissue through processing, sectioning and staining. A limited range of tinctorial special stains are carried out on this site and all immunohistochemistry and Breast HER2 slides are prepared and stained here using the Roche Ultra immunostaining platform.

Frozen section facilities exist within the laboratory for rapid diagnosis where necessary and specialist investigations such as immunofluorescence sectioning.

MOHS:

This service is managed by the Dermatology department. Cellular Pathology offers technical assistance – BMS assistance for specimen preparation and Consultant assistance for reporting the samples. The samples are processed within the Dermatology area and the sections are brought to the Cellular Pathology Laboratory for reporting. The reporting procedure involves one consultant pathologist from Cellular Pathology alongside the consultant dermatologist.

Fine Needle Aspiration assistance (FNA)

The laboratory assists with FNA procedures. This is primarily located within the Laboratory and is managed by the lead consultant for the day, however this is temporarily suspended. We also offer laboratory assistance with preparation of slides to any clinics on request.

One Stop Clinic for head and neck – the laboratory assists one morning a week at the Worcester one stop head and neck clinic. The laboratory provides assistance to prepare and assess adequacy of sample at the clinic

All Cytology preparation takes place at Worcester. Thin Prep is used for the preparation of the majority of samples, using the T2000.

Mortuary Services

The mortuary services are HTA accredited on both sites. The Worcester site has facilities for post mortems and body storage. The Redditch site acts as a body store only.

One of the Consultant Pathologists acts as the HTA Designated Individual for the Trust.

For more details see website http://www.worcsacute.nhs.uk/pathology

1.3.5 Microbiology

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The Microbiology laboratory is situated at Worcestershire Royal Hospital. It provides a diagnostic service for Bacteriology and Virology. The department has a wide repertoire of tests that are listed on the Pathology Website. Wherever possible these assays are performed on automated systems but where limitations exist conventional manual cultures, manual identification and antimicrobial susceptibility testing are performed.

The automated identification system used by the department is Matrix assisted laser desorption/ionization technology (MALDI-TOF) and the automated identification / antimicrobial susceptibility system is a VITEK 2 using micro dilutions and an advanced expert system.

The department also deploys an automated optical system combining bright-field and phase contrast microscopy and Mast Uri semi- automated identification and sensitivity system to assist in the analysis of urinary tract infections.

Tuberculosis screening is also undertaken by bacteriology under Containment Level 3 conditions using an automated liquid methodology in conjunction with a manual solid media culture method allowing for greater sensitivity. The Cepheid GeneXpert is available for rapid confirmation of the presence of *Mycobacterium Tuberculosis*.

Virology provides a wide range of serological and molecular tests using a variety of automated and manual methods as stated on the pathology website.

There are automated molecular methods for the detection of viral loads for HIV and HCV viruses and Sexual health screening for HSV, Chlamydia and Neisseria gonorrhoeae that are carried out on Roche and Cepheid platforms.

Molecular detection for SARS-COV2 is performed using a variety of platforms, using Roche, Perkin Elmer, Cepheid, Biofire and Qiagen platforms.

All routine serological analytical processing has recently been re-patriated into Microbiology and is performed on the Diasorin Liaison , Biomerieux VIDAS and DS2 platforms.

Microbiology also maintains links with outside bodies including Public Health England and has an active role in monitoring patterns of infection in the community.

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2 Normative references

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000: 2004, *Conformity assessment —Vocabulary and general principles*
ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories* (Currently under revision-June 17)
ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing schemes
ISO/IEC 22870:2016, Point of care testing (POCT) – Requirements for quality and competence
ISO/IEC Guide 2: 2004, *Standardization and related activities — General vocabulary*
ISO/IEC Guide 99: 2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
Various UKAS documents found under either the LAB, TPS or GEN series on the UKAS website.

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

3.1 Accreditation
Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks

3.2 Alert interval or critical interval
Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

3.3 Automated selection and reporting of results
Process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention

3.4 Biological reference interval reference interval
Specified interval of the distribution of values taken from a biological reference population EXAMPLE The central 95 % biological reference interval for sodium ion concentration values in serum from a population of presumed healthy male and female adults is 135 mmol/l to145 mmol/l.

3.5 Competence
Demonstrated ability to apply knowledge and skills

3.6 Documented procedure
Specified way to carry out an activity or a process that is documented, implemented and maintained

3.7 Examination
Set of operations having the object of determining the value or characteristics of a property

3.8 Interlaboratory comparison
Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3.9 Laboratory director
Person(s) with responsibility for, and authority over, a laboratory

3.10 Laboratory management
Person(s) who direct and manage the activities of a laboratory

3.11 Medical laboratory clinical laboratory
Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

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3.12 Nonconformity
Nonfulfillment of a requirement

3.13 Point-of-care testing POCT near-patient testing
Testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

3.14 Post-examination processes or post analytical phase
Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results

3.15 Pre-examination processes or Pre-Analytical phase
Processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins

3.16 Primary sample or specimen
Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

3.17 Process
Set of interrelated or interacting activities which transform inputs into outputs

3.18 Quality
Degree to which a set of inherent characteristics fulfils requirements

3.19 Quality indicator
Measure of the degree to which a set of inherent characteristics fulfils requirements
EXAMPLE If the *requirement* is to receive all urine samples in the laboratory uncontaminated, the number of contaminated urine samples received as a % of all urine samples received (*the inherent characteristic of the process*) is a measure of the quality of the process.

3.20 Quality management system (QMS)
Management system to direct and control an organization with regard to quality

3.21 Quality policy
Overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management

3.22 Quality objective
Something sought, or aimed for, related to quality

3.23 Referral laboratory
External laboratory to which a sample is submitted for examination

3.24 Sample
One or more parts taken from a primary sample
EXAMPLE: A volume of serum taken from a larger volume of serum.

3.25 Turnaround time

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Elapsed time between two specified points through pre-examination, examination and post-examination processes

3.26 Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

3.27 Verification

Confirmation, through provision of objective evidence, that specified requirements have been fulfilled

Confirmation can comprise activities such as

— performing alternative calculations,
— comparing a new design specification with a similar proven design specification,
— undertaking tests and demonstrations, and
— reviewing documents prior to issue.

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4 MANAGEMENT REQUIREMENTS

4.1 Organization and management responsibility

4.1.1 Organization

4.1.1.1 General

Worcestershire Acute Hospitals NHS Trust provides hospital-based services from three main sites, Worcestershire Royal Hospital, Kidderminster Hospital and Treatment Centre and the Alexandra Hospital in Redditch. The Trust is responsible for providing high-quality acute healthcare services across Worcestershire, serving a population of more than 580000 as well as caring for patients from surrounding counties and further afield.

In 2018 the Trust cared for more than 231,000 different patients 156,180 people in A&E and 641,486 outpatient visits. More than 5,200 babies are born in our Trust every year.

Worcestershire Royal Hospital (WRH) is the latest of the Trust's three sites. The main hospital was built under the private finance initiative (PFI) and opened in 2002. The hospital has 500 beds and nine operating theatres including four laminar theatres. It has a level 2 neo-natal intensive care unit and a cardiac catheterisation laboratory as well as an Oncology Centre. The 24/7 Primary Percutaneous Coronary Intervention (PPCI) service began in October 2013. Equipment, facilities and estates are mainly processed by our PFI partners, Engie and Siemens.

Pathology comprises of Cellular Pathology, Clinical Biochemistry, Haematology & Blood Transfusion, and Microbiology providing a comprehensive routine pathology service. There are mortuaries at both Worcester and Redditch offering body storage for the trust and a post mortem facility used by our own Histopathologists for both routine and coroners post mortems at the Worcester site only.

The facility has an extensive air tube system used for the transport of samples, suitable for transportation in this way; from around the hospital site which comes under the authority of the PFI partner and so is managed by them[ED-U-W-WRH Pneumatic Tube Policy] Bulk deliveries of samples from around the site are delivered by portering staff while those from outside of the site are delivered by the transport services of the Acute or Health and Care Trusts as appropriate. Details on services provided on each site are available on the pathology website. http://www.worcsacute.nhs.uk/pathology

The Alexandra Hospital in Redditch was opened in 1985. The hospital is the centre for the county's Urology service. The hospital has over 300 beds, eight operating theatres, MRI and CT scanners and cancer unit status for breast, lung, urology, gynaecology and colorectal cancers. Pathology comprises of Clinical Biochemistry and Haematology and Blood Transfusion satellite laboratories for inpatient, outpatient and urgent work. Cellular Pathology offer a frozen section (must be pre booked) service at this site The Mortuary service is a body store only on this site. The facility has an extensive air tube system which is used for the transport of samples, suitable for transportation in this way, from around the hospital site which comes under the authority of the estates department and so is managed by them. Bulk deliveries of samples from around the site are delivered by portering staff.

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Samples for Microbiology, Cellular Pathology, or blood sciences tests within our repertoire but not offered on this site are transported on a regular basis to the Worcester site by either Acute or Health and Care Trust vehicles.

Kidderminster Hospital houses the Kidderminster Treatment Centre (KTC) which offers clinical facilities and patient accommodation for a wide range of day case, short stay and inpatient procedures on patients from across the county and surrounding areas. The nurse-led minor injuries services are open 24 hours a day and treat more than 24,000 patients every year. It can deal with a wide variety of injuries including simple fractures, soft tissue injuries, lacerations, bites, burns and scalds.

Other facilities at the Kidderminster site include a full range of outpatient clinics – including outpatient cancer treatment in the Millbrook Suite – MRI and CT scanners and a renal dialysis unit. Pathology samples are transported on a regular basis to the Worcester site by Acute Trust vehicles.

While the Trust manages all the acute sites the actual building and supporting infrastructure at Worcestershire Royal Hospital comes under the jurisdiction of the PFI partner. In the interests of best value there are items of equipment in use on these sites which form part of countywide procurements either through the Trust or our PFI partners.

Pathology provides its services to Worcestershire Acute Hospitals NHS Trust, the three CCG's which exist across Worcestershire and Worcestershire Health and Care NHS Trust. Other organisations are free to approach us to see if we can offer them specific elements of our service and these would be considered in line with our policy for Establishment and review of agreements, [MR-U-GEN-SLA], in order to assess capacity, skills and expertise. Currently we have specific SLAs with BMI Droitwich Spa hospital and Spire-Southbank Hospital for pathology services including the supply of cross matched and flying squad blood components. Services are also provided to St Richards Hospice. The two local prisons, HMP Hewell and HMP Long Lartin, also send us samples from their clients.

The four disciplines within the Pathology Directorate provide a high-quality evidence based service described below. Expert interpretation and advice from Consultant medical and scientific staff enhance the analytical service.

4.1.1.2 Legal entity

Relationship to the Host Organisation and Legal Entity

The Pathology Directorate is part of the Specialised Clinical Services Division (SCSD) for Worcestershire Acute Hospitals NHS Trust which can be held legally responsible for its actions. (ISO 15189:2012: 4.1.1.2) The Trust Establishment Order can be found at http://www.legislation.gov.uk/uksi/1999/3473/made

The management relationships with the Trust are through the Specialised Clinical Services Division which is led by the Divisional Medical Director and Divisional Director of Operations and is represented in the Trust organisational charts available on the Trust Intranet. The

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board members and a list of executive and non-executive directors can be found on the hospital website at: http://www.worcsacute.nhs.uk/about-us/trust-board-whos-who/

4.1.1.3 Ethical conduct

There are arrangements in place to ensure the ethical conduct of staff at all times.

a) A contractual commitment for both staff and the organisation through the commissioners of service ensures that there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement, or operational integrity.

b) All staff are governed by the Trust's policy on Standards of Business Conduct-Declaration of interests and acceptance of gifts and hospitality [ED-U-GEN-Declaration of interests and acceptance of gifts and hospitality] to ensure that management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.

c) Where potential conflicts in competing interests may exist, they are openly and appropriately declared;

d) Staff always follow the retention and storage of pathological records and specimens (5th edition, 2015). Joint publication between the RCPath and IBMS [ED-U-GEN-The retention and storage of pathological records and specimens (5th edition, 2015)] when dealing with human samples, tissues or remains.

e) Confidentiality of information is maintained by strict adherence to the Trust's Code of Conduct in respect of Confidentiality [ED-U-GEN-Code of Conduct in respect of Confidentiality]

4.1.1.4 Laboratory director

The Pathology Directorate is led by the Directorate Clinical Director and Directorate Manager who are both responsible to the Divisional Medical Director and Divisional Director of Operations for all aspects of the pathology service.

Each individual Department of the Directorate is directed by a Clinical Lead who has executive accountability and the competence to assume responsibility for the services provided.

- The duties and responsibilities of both the Clinical and individual laboratory directors are documented.
    - In the event that a post is temporarily unfilled responsibility for the role will be covered by the positions line manager.

4.1.2 Management responsibility

4.1.2.1 Management Commitment

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Laboratory Management through the Pathology Executive Management Committee is committed to the development, implementation and continual improvement of its quality management system (QMS). This requirement is achieved by:

- Ensuring that all laboratory personnel are aware of and comply with regulatory and accreditation requirements.
- Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users.
- Establishment of the Directorate Quality Policy (see below).
- Ensuring that quality objectives and plans to achieve these objectives are in place.
- Defining the responsibilities, authorities and interrelationships of all personnel
- Establishment of effective communication processes with staff and also with the service stakeholders.
- Establishment and appointment to the role of Quality Manager
- Ensuring that management reviews are carried out on a regular basis to the depth required by the ISO 15189 standard.
- Ensuring that staff are competency assessed to provide assurance that they are competent to perform their assigned activities.
- Ensuring that there are adequate resources to enable the proper conduct of pre-examination, examination, and post-examination activities.

4.1.2.2 Needs of users

Within pathology we recognise that an essential prerequisite of a quality service is that the organisation and management of Pathology relates to the needs and requirements of its users. (ISO 15189 2012:4.4 and 4.14.3)

The needs and requirements of users are identified both at Department level and by the Pathology wide User Interaction Groups. The GP user group meets at least three times per year. Activities include: -

- Satisfaction surveys
- User Group Meetings
- MDTs
- Patient feedback from FNAs

There is also a user feedback form available on the Pathology website

User interaction feedback forms the focus of the quality (ISO 15189 2012:4.1.2.3) and objective setting and planning by the Pathology Executive Management Committee. Consideration of the findings form part of each departments management review.

4.1.2.3 Quality policy

The Laboratory management has described the purpose of its quality management system in the following quality policy.

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The quality policy:

a) includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of ISO 15189, and continual improvement of the quality of laboratory services.

b) provides a framework for establishing and reviewing quality objectives.

c) is communicated to and understood by all staff via i-passport and the pathology website as well as being displayed in all areas of the department.

d) is reviewed bi-annually or more frequently if required, by the Pathology Executive Management Committee (PEMC) using feedback from departmental management review meetings for continuing suitability.

Each discipline establishes specific quality objectives which allow their department to meet the needs and requirements of the users, and these are approved at PQAC. The quality objectives are measurable and consistent with achieving the aims of the quality policy.

The Quality Policy (ISO 15189:2012: 4.1.2.3) of the Pathology Directorate is described below and a copy is displayed within each laboratory, the general Pathology office at WRH and Specimen Reception at WRH.

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Quality Policy (Vn 12.5)

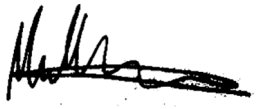
Our Aim: To provide a high quality Pathology service including Cellular Pathology, Clinical Biochemistry, Haematology & Blood Transfusion and Microbiology that meets the expectations agreed with its users, and conforms to the standard and regulations of BS EN ISO 15189:2012 and other relevant legislation and regulatory bodies.

This will be achieved by:

- Operating a high quality service that takes account of and meets the needs and requirements of users.
- Setting quality objectives and plans in order to implement this quality policy in conjunction with its users.
- Ensuring that all Pathology personnel understand the needs of users and are familiar with the contents of the Quality Manual, including this policy, and all procedures relevant to their work.
- Provision of a quality management system that integrates the processes required for the conduct of its examinations, documents these processes and keeps records that provide evidence of the proper conduct of its activities, while also being committed to achieving continual quality improvement.
- Providing adequate resources for the provision of this service including the health, safety, respect and welfare of all staff, visitors and patients including compliance with relevant environmental legislation.
- Upholding professional values in accordance with Trust Policies and relevant Professional regulations and be committed to good professional practice and conduct.

The Pathology Directorate will comply with the ISO 15189: 2012 standards, the requirements of the Blood Safety and Quality Regulations 2005, (BSQR 2005, as amended), and Human Tissue Authority (Human Tissue Act 2004). In doing so it is committed to:

- Recruitment, training, development and retention of staff at all levels in a manner that ensures that they are competent to perform the tasks they are contracted to do.
- Procurement and management of all external services, equipment and consumables in a manner that ensures the quality of its examination results.
- Handling of all patient samples is a way that ensures the correct performance of laboratory investigations.
- Only use examination procedures that ensure the highest achievable quality of all examinations performed
- Reporting of results of examinations in ways that ensure the timeliness, accuracy and clinical usefulness while at all times maintaining confidentiality
- Reviewing the Quality Policy for suitability and effectiveness at the annual management review.



Dr Mike Cornes
Consultant Clinical Scientist & Pathology Clinical Director

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4.1.2.4 Quality objectives and planning

The Trust decides upon its strategic objectives on an annual or biennial basis. These are fed through the Division of Specialised Clinical Services (of which Pathology is a part) to the Pathology Executive Group who then ensure that Departmental objectives which are measurable, consistent with achieving the aims of the quality policy and link to these are then determined. The individual departments conduct their management reviews in sufficient depth to meet the requirements of ISO 15189 throughout the year in a manner that ensures all topics are covered on at least an annual basis. They also determine whether the objectives have been successfully completed which provides an opportunity for revising such objectives and plans and the on-going functioning and integrity of the QMS.

4.1.2.5 Responsibility, authority, and interrelationships

Directorate organisational chart structures are shown at the end of this document [AD-U-GEN-DirectorateOrgChart]. (ISO 15189:2012: 4.2.2.2c)

Each individual department within Pathology is responsible for the maintenance and storage of a current department specific organisational chart. (BSQR 2005, as amended 4.b.i) These are linked in i-passport to the Directorate organisational chart [AD-U-GEN-DirectorateOrgChart].

- A Biomedical Scientist (BMS) for each individual department acts as laboratory manager and as such has Trust wide managerial responsibility for non-medical staff of that department and manages and co-ordinates services between laboratories within their discipline. This managerial responsibility covers the areas of personnel, quality and Health and Safety as well as being the budget manager for their area. The Laboratory Director is the Budget Holder for that discipline while budgetary and finance issues are dealt with on a day to day basis by the Laboratory Manager in their role as budget manager. (See post holder form at end of this document for more detail including deputies)
- Each department has its own Quality Manager/Lead who is supported by several staff within each area.
- There are deputies for all key functions of the Laboratory Director role as detailed on the Post Holder form at end of this document.

Non-medical staff are accountable to the Pathology General Manager (PGM) through the Departmental Manager. Clinical scientist staff are accountable to the Laboratory Director.

Pathology medical staff are accountable directly to the Pathology Clinical Director who is then accountable to the Trust Medical Director.

Departmental Quality Managers/Leads are responsible to the PGM and their Departmental Manager for issues relating to quality and the maintenance of the QMS.

Departmental H&S Officers are responsible through their Departmental Manager to the Pathology General Manager who has ultimate responsibility for ensuring the Health, Safety and Welfare of staff and visitors within Pathology.

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Departmental Training Officers are responsible through their Departmental Manager to the Pathology General Manager who has ultimate responsibility for ensuring compliance with National and Trust training requirements.

All senior Biomedical Science staff have proven technical and managerial competencies appropriate to the post held. They are registered with the HCPC and have relevant qualifications such as Licentiate, Member or Fellowship of the Institute of Biomedical Sciences (IBMS) or be HCPC registered Clinical Scientists

In the absence of key managerial staff, the appropriate appointed deputy fulfils the role of the absent member of staff.

All staff are issued with a job description detailing the general extent and limitations of their responsibilities. These are reviewed annually at Personal Development Reviews (PDR) meetings for laboratory and clerical staff and at appraisals for medical staff.

On a day-to-day basis, specific duties relating to these responsibilities are discharged through the member of staff with direct responsibility for the supervision of any given individual.

- It is the responsibility of all employees to become familiar with and participate in Quality Management and the requirements of the Pathology QMS.
- Staff must at all times follow documented and approved SOPs.
- Staff must become familiar with the contents of this Quality Manual.
- Staff must record non-conformances on i-passport (PR-U-GEN-Recording of Non-Conformances on i-passport) as soon as possible after they arise and if patient/staff harm or potential harm has been caused this must also be recorded on the Trust Datix system in order that prompt and appropriate action can be taken to control the problem.
- Staff must participate in annual appraisal.
- BMS staff must record self-assessments and Continuing Professional Development (CPD) activities within their personal portfolios and ensure that their competency records are kept up to date.

4.1.2.6 Communication

- Laboratory management communicates with staff through a variety of means including departmental staff meetings and daily huddles, e-mails, notice boards and one to one meetings. Staff suggestions are actively encouraged (ISO 15189 2012:4.14.4). Records are kept of items discussed in communications and meetings. Minutes of all pathology wide meetings are readily available for all staff to read.

- Laboratory management ensures that appropriate communication processes are established between the laboratory and its stakeholders through a variety of mechanisms including user interaction meetings, surveys, e-mails and individual interactions ensuring that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination, post-examination processes and quality management system.

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4.1.2.7 Quality manager

Each department has a Quality Manager and or quality lead(s) that have, irrespective of other responsibilities, delegated responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented, and maintained.

They also submit detailed reports to laboratory management through PQAC, on the performance of the quality management system and any need for improvement. If necessary, these can be raised to PEMC.

User needs and comments are fed through PQAC to PEMC ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.

4.2 Quality Management System (QMS)

4.2.1 General requirements

The following groups/committees are responsible for the creation, implementation, review and amendment of the QMS used across Pathology in Worcestershire.

Documentation is controlled through the use of an electronic document control system supplied by Genial Genetics called i-passport.

4.2.1.1 Pathology Directorate Management Meetings:

4.2.1.1.1 Pathology Executive Management Committee (PEMC)

The Pathology Executive Management Committee meetings are held monthly. There is a defined constitution and terms of reference [MR-U-GEN-ExeMeetConst]. Its principal function is to define the strategy for Pathology and monitor performance.

The Committee includes the Clinical Director, Directorate Manager, Directorate Support Manager, Laboratory Directors, Laboratory Managers, Pathology IT Manager, other Band 8 pathology staff and a finance representative.

Chairman: Clinical Director / Directorate Manager

Secretary: Directorate Support Manager or suitable deputy

4.2.1.1.2 Pathology Quality and Accreditation Committee (PQAC)

The Directorate Quality & Accreditation Committee meets monthly. It has a defined constitution and terms of reference [MR-U-GEN-PQACMeetConst]. Its principal function is to

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oversee and steer the quality management system and accreditation issues for Pathology. This group reviews risk reporting incidents and advises on clinical governance. PQAC is also responsible for the management of pathology wide documents including the development and updating of the pathology web pages.

The Committee includes the Directorate Manager, Individual Laboratory managers, Quality Managers/Quality Leads, IT Lead and Directorate Support Manager.

Chairman: Directorate Manager

Secretary: Directorate Support Manager or suitable deputy

PQAC oversee subgroups which deal with specific aspects of the quality agenda

4.2.1.1.3 User Interaction Groups

This group co-ordinates interaction, consultation and feedback with users. It has a defined constitution and terms of reference [MR-U-GEN-PQACMeetConst]. Because of the differing needs of internal and external users the group meets with Hospital staff and Primary Care representatives separately, 3 times per year

The group includes User representatives which may be clinical or managerial, Pathology General Manager, Individual Laboratory Managers, Pathology IT Manager, Laboratory Directors and Pathology Consultant staff, Directorate Support Manager as well as specific individuals relevant to the agenda items.

Chairman: Principal Clinical Scientist.

Secretary: Directorate Support Manager or suitable deputy

In addition to the User Interaction Group, additional subgroups are formed as appropriate, i.e. Policies & Procedures and report to the PQAC on the specific areas they have been set up to deal with.

4.2.1.2 HTA Governance committee

The HTA Governance committee meets quarterly. Its purpose is to ensure the HTA DI is aware of any issues across the two sites, raise awareness of HTA and make the staff groups aware of any new legislation. It is also a forum for mortuary / hospital staff to raise any suggestions.

The committee includes: HTA DI (chair), Mortuary manager, Laboratory manager or deputy, Mortuary staff – all or representative, Hospital representatives – Women's division, A &E

Chairman: Dr W Haddadin, Consultant Histopathologist

Secretary: Minutes are taken by the lab manager

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4.2.1.3 HTC committee

The Hospital Transfusion Committee (HTC) meets quarterly and acts as an expert forum of the Clinical Governance Group. It has been established to ensure safe and appropriate transfusion practice within the organisation through the use of local protocols based on national guidelines.

Its remit includes:

- Implementation of national guidelines into trust practice
- Implementation of Serious Hazards Of Transfusion recommendations into the trust
- Monitoring transfusion incidents and risk
- Monitoring blood usage and wastage within the trust and benchmarking against other trusts usage and wastage
- Monitoring training of staff involved in transfusion practise
- Developing contingency plans in case of blood shortages
- Ensuring compliance with Blood Safety and Quality Regulations 2005.

The committee includes: Lead Consultant Haematologist, Blood Bank manager, Lead Transfusion Practitioner, Consultant physician, Consultant anaesthetist, Consultant surgeon, Consultant paediatrician, Consultant Obstetrics and Gynaecology, A&E consultant, Worcester Health and Care trust (HACW) representative.

Chairman: The Lead Consultant Haematologist will chair the meetings. In the absence of the chair an alternative consultant haematologist will be nominated.

Secretary: Secretarial support will be through the Transfusion Practitioners and pathology.

4.2.1.4 Implementation of the Quality Management System: Laboratory management is committed to the development and implementation of the quality management system and continually improves its effectiveness.

This is achieved through;

- Each department having a Quality Manager and quality lead(s) that have, irrespective of other responsibilities, delegated responsibility and authority as detailed previously above.
- User needs and comments being fed through PQAC to PEMC ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.
- The roles which are responsible for the quality management system (QMS) are described below, and defined within Departmental/discipline specific individual Job Descriptions (see AD-U-GEN-DirectorateOrgChart and post holder form)
- The Quality Manager/Lead has responsibility for implementation and maintenance of the QMS but not for undertaking all the tasks involved. They may be engaged full-time or part-time on quality management.
- Laboratory management through PQAC ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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- Quality manual: The Pathology Quality Manual is reviewed at least annually by PQAC, updated as required and any changes communicated to all personnel concerned. This document includes the Quality Policy, description of the scope of the QMS, organisational structure, roles and responsibilities of laboratory management, quality management structure and documentation and is accessible to all staff. (ISO 15189 2012:4.2.2.2)

4.2.2 Documentation requirements

4.2.2.1 General

The quality management system documentation includes:

a) statements of a quality policy (see 4.1.2.3) and

b) a quality manual (see 4.2.2.2);

c) quality objectives (see 4.1.2.4); determined by each individual department to align with the achievement of the above.

d) procedures, documents and records determined by the laboratory as required to comply with both ISO 15189 and to ensure the effective planning, operation and control of its processes;

e) copies of applicable regulations, standards and other normative documents.

4.2.2.2 Quality manual

The laboratory management have established and maintain this quality manual that includes:

a) the quality policy (4.1.2.3);

b) a description of the scope of the quality management system;

c) a presentation of the organization and management structure of the laboratory and its place in the parent organization including a description of the roles and

responsibilities of laboratory management (including the laboratory director and quality manager)

d) Information about the structure and relationships of the documentation established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff have access to and are instructed on the use and application of the quality manual and the referenced documents.

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4.3 Document control

Documents are prepared both on a pathology wide basis and within individual departments. Every opportunity is taken to harmonise these documents across pathology to reduce duplication and ensure single ways of working. Irrespective of whether the document is department specific or pathology wide the same process is followed so that both the preparation and control of documents is in accordance with the document control policy and procedure [MO-U-GEN-Document Control]. The first 3 parts of the title of any document thus prepared indicate the type of document, site or 'U' if universal and department or 'GEN' if pathology wide. Authorisation of these documents is carried out by senior staff within the discipline for department specific documents while pathology wide ones are authorised by the Pathology General Manager, if non-clinical, and the Clinical Director, if clinical. Once authorised, documents are available for everybody to use on i-passport and reading records are stored on the system. Superseded protocols are then not widely visible but are retained by the system.

a) All documents issued as part of the quality management system are reviewed and approved by authorized personnel before issue.

b) All documents are identified to include:

— a title;
— a unique identifier on each page;
— the date of the current edition and/or edition number;
— page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5,");
— authority for issue.

c) Current authorized editions and their distribution can be identified on demand by producing a list from i-passport.

d) The minimum amounts of hard copy documents are used but where this is the case only current, authorized editions of applicable documents are available at points of use.

e) Where documents are amended by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is issued within a specified time period in compliance with [MO-U-GEN-Document Control].

f) Changes to documents are identified either by change sheets attached to each document and or with change information attached to each version of the document within i-passport.

g) Documents remain legible.

h) Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.

i) Obsolete controlled documents are removed and made inaccessible to all but senior staff on i-passport.

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j) All previous versions of obsolete controlled documents are retained in i-passport for as long as the system is live.

4.4 Service agreements

4.4.1 Establishment of service agreements

The laboratory has documented procedures for the establishment and review of agreements for providing medical laboratory services both internally to the Trust and externally to other healthcare organisations. [MR-U-GEN-SLA] [MR-U-GEN-Service agreement internal]

By following these we ensure compliance with the ISO 15189 standard as outlined below.

Agreements to provide medical laboratory services consider the complete sample pathway including the request, examination and the report. The agreement specifies the information needed on the request to ensure appropriate examination and result interpretation.

Each request accepted by the laboratory for examination(s) is considered to constitute an agreement.

The following conditions are met when the laboratory enters into an agreement to provide medical laboratory services.

- The requirements of the customers and users, and of the laboratory services, including the examination processes to be used, are defined, documented, and understood (see ISO 15189 2012: 5.4.2 and 5.5).
- The laboratory management ensures that it has the capability and resources to meet the specified requirements including:
- The laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.
- Examination procedures selected are appropriate and able to meet the customer's needs (see ISO 15189 2012:5.5.1).
- Customers and users are informed of deviations from the agreement that impact upon the examination results.
- Reference is made to any work referred by the laboratory to a referral laboratory or consultant.

4.4.2 Review of service agreements

Service agreements are reviewed both as part of the wider management review and on a regular basis as appropriate to the length of the agreement or whenever a material change occurs which could impinge on the agreement.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process would be repeated and any amendments would be communicated to all affected parties.

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4.5 Examination by referral laboratories

4.5.1 Selection and evaluation of referral laboratories and consultants:

The laboratory has a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline. [MR-U-GEN-Examination by referral labs and consultants]

- The procedure ensures that the following conditions are met.
- The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.
- Arrangements with referral laboratories and consultants are reviewed and evaluated periodically using the scheduled review process in i-passport where appropriate documentation and evidence can be recorded in i-passport to ensure that the relevant parts of ISO 15189 are met.
- A register of all referral laboratories and consultants from whom opinions are sought along with approval status can be obtained by discipline from i-passport on demand at any time.
- Requests and results of all samples referred are kept for a pre-defined period as defined in the control of records and control of clinical material policies. PO-U-GEN-ControlProcessQualRec; PO-U-GEN-CtrlClinMat

4.5.2 Provision of examination results

Unless otherwise specified in the agreement, we as the referring laboratory (and not the referral laboratory) accept responsibility for ensuring that examination results of the referral laboratory are provided to the person making the request.

Reports from referral laboratories include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation and indicate which examinations were performed by a referral laboratory or consultant with the author of any additional remarks also being clearly identified.

Where possible both requests and results are transmitted electronically to and from the referral laboratories using N-PEX to reduce both the risk associated with transcription processes and turnaround times. In all other cases, there are processes in place to ensure the efficient and accurate transcription or onward transmission of referred results to the requestor in order to avoid any unnecessary delays.

Where collaboration is needed between clinicians and specialists from both referring and referral laboratories for the correct interpretation and application of examination results, this process is not hindered by commercial or financial considerations.

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4.6 External services and supplies

A policy exists [MR-U-GEN-External Services and supplies] that defines how the laboratory selects and approves suppliers using relevant criteria that have been established, based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's and end user's requirements. This is done in collaboration with the supplies department who ensure that purchasing information describes the requirements for the product or service to be purchased. Reviews are carried out regularly using the scheduled review process in i-passport where appropriate documentation and evidence can be recorded to ensure that the relevant parts of ISO 15189 are met.

A list of selected and current approved suppliers of equipment, reagents and consumables along with their review status can be obtained by discipline from i-passport on demand at any time.

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4.7 Advisory services

The laboratory has various established arrangements for communicating with users as detailed earlier in the section about the needs and requirements of users on the following:

- advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination:
- advising on individual clinical cases:
- professional judgments on the interpretation of the results of examinations:
- promoting the effective utilization of laboratory services:
- consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

These arrangements work in a variety of ways: formal and informal, extending from formal user group meetings through informal lunchtime meetings to individual conversations between clinical staff and senior laboratory staff or Consultants.

Clinical advice and interpretation can be obtained directly from a relevant Pathology Consultant during normal working hours or outside of these hours via switchboard as part of the on-call Pathology service.

4.8 Resolution of complaints

Feedback received from clinicians, patients, laboratory staff or other parties is dealt with in pathology following the pathology wide policy, [PO-U-GEN-Userfeedback] or in the event of a specific complaint this would be dealt with by the pathology wide complaints policy [MR-U-GEN-Complaints]. As detailed in that policy anything that was a formal complaint would then be managed using the Trust Complaints Process flowchart, [ED-U-GEN-Trust Complaints Process flowchart]. Records are maintained in the complaints section of i-passport of all complaints, formal or informal, their investigation, including investigation of the root cause, and the action taken by both the laboratory and the Trust complaints department, where appropriate. Any other feedback would be dealt with by the Laboratory Director/Lab manager who would investigate, raise non-conformances as appropriate and take what action was possible to resolve the highlighted issues.

4.9 Identification and control of nonconformities

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There is a procedure for Identification and control of non-conformities (PR-U-GEN-Non-conformance procedure) which includes determining appropriate Preventive and Corrective Action and ensures that nonconformities identified from pre-examination, examination or post-examination processes are effectively managed. There is also a procedure for recording these and any necessary actions on i-passport (PR-U-GEN-Recording of Non-Conformances on i-passport)

It is appreciated that nonconforming examinations or activities occur in many different areas and can be identified in many ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, inter-laboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews.

The procedure therefore ensures that the requirements of the ISO 15189 standard are met in that:

- the responsibilities and authorities for handling nonconformities are designated:
- the immediate actions to be taken are defined:
- the extent of the nonconformity is determined:
- examinations are halted and reports withheld as necessary:
- the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed:
- the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary:
- the responsibility for authorization of the resumption of examinations is defined:

- each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

There are also procedures for recalling blood components associated with internal and external notification and reporting of adverse transfusion incidents and events to the MHRA via SABRE and where appropriate SHOT.

4.10 Corrective action

As per the above named procedure all nonconformities are reviewed as soon as possible after they are found by a senior member of staff to determine the severity and effect which then helps to determine the management route for that particular non-conformance. Once any immediate remedial action felt to be needed has been carried out then:

- The root cause is determined using one of the standard techniques, i.e. 5 whys, fishbone analysis or any other system felt to be appropriate to the particular circumstance. Once this is done it is then possible to:
- evaluate the need for corrective action to ensure that nonconformities of this sort do not recur and then:
- the appropriate corrective action needed is determined, implemented and recorded: Once this has all been done:
- the effectiveness of the corrective action taken is reviewed and modified as necessary.

4.11 Preventive action

It is recognised that preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). For this reason, it can result from several sources, in addition to review of the operational procedures, including analysis of data, trend and risk analyses and external quality assessment (proficiency testing).

The detail of how this is carried out can be found in the procedure: PR-U-GEN-Non-conformance procedure

The laboratory determines actions to eliminate the causes of potential nonconformities to prevent their occurrence ensuring that any preventive actions taken are appropriate to the effects of the potential problems and are fully documented on i-passport

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Once this has all been done the effectiveness of the preventive action taken is reviewed and modified as necessary.

4.12 Continual improvement

The department has a procedure: [PO-U-GEN-Continuous Quality Improvement] which identifies the many ways that we as a provider of laboratory services strive to ensure that we aim for continual improvement in everything we do.
Individual disciplines within pathology carry out management and other reviews on a regular basis covering all aspects of the service provided. These other reviews include such things as corrective and preventive actions resulting from non-conformances, evaluation of IQC and EQA, staff suggestions as well as changes imposed upon us by methodology or system changes. The purpose of these reviews is to ensure that there is continual improvement in the way we perform and a constant strive to maintain a service of the highest quality as stated in our quality policy. Improvement activities are prioritised at senior staff meetings based on the effect of the issue(s) identified obviously giving issues affecting patient outcome the highest priority and communicated to staff through the daily huddles that occur in each department. As per: [PR-U-GEN-Non-conformance procedure] all non-conformances are recorded on i-passport where the action plans are developed, documented, and implemented as appropriate. The procedure also identifies that: *In all cases it is vital that any corrective actions are determined, implemented and along with any remedial or preventive actions which were put into place are monitored by subsequent re-audit or by other appropriate means to ensure the actions have corrected the cause of the non-compliance and have not resulted in any deleterious effects elsewhere.* This whole process is monitored by Laboratory management at the monthly Pathology Quality and Accreditation (PQAC) meetings where data is submitted by discipline of outstanding non-conformances, audits and documents due for review. As well as these other issues are also reviewed including compliments/complaints, NICE guidance, items on risk register or anything else which has the potential to affect our ability to provide a high-quality service

4.13 Control of records

- The control of process and quality records is governed by the Pathology wide policy [PO-U-GEN-ControlProcessQualRec] and similar departmental procedures which cover those items specific to individual areas are linked in i-passport to this policy.

- Notice is taken of current legislation, regulations and guidelines including those provided by the IBMS/Royal College of Pathologists [ED-U-GEN-The retention and storage of pathological records and specimens (5th edition, 2015)] in determining which process and quality records (including quality records of external origin) are to be retained and for how long.

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- The control of clinical material is governed by the Pathology wide policy [PO-U-GEN-CtrlClinMat] and similar departmental procedures which cover those items specific to individual areas are linked in i-passport to this policy.

- One of the Consultant Pathologists is the HTA Designated Individual for the Trust. (ISO 15189 2012: 5.2.3/5.7.2/5.7.2/5.7.3)

4.14 Evaluation and audits

4.14.1 General

There are a number of ways in which we as Pathology and individual disciplines demonstrate that the pre-examination, examination, post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users. This helps to ensure conformity to the quality management system and where deficiencies are identified allows us to continually improve the effectiveness of the quality management system.

These include but are not limited to:

- Assessment of user satisfaction and complaints
- Internal audit of the quality management system
- Internal audit of examination processes
- External quality assessment
- Reports from external assessment bodies.
- Quality improvement, including corrective and preventive action and the monitoring of quality indicators
- Identification and control of nonconformities

The results of these evaluations and subsequent improvements are made available to staff through the daily huddles or staff meetings and to users through the minutes of meetings as required. This information is also analysed and entered into the management review process.

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

As part of the review process authorised personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. As well as looking at the clinical significance other areas are also reviewed including sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither

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insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.

4.14.3 Assessment of user feedback

The laboratory seeks information relating to user perception as to whether the service has met their needs and requirements through a variety of means including regular user group meetings, surveys and individual meetings ensuring confidentiality is maintained to other users at all times. Records are kept of this information collected and actions taken. [PO-U-GEN-UserFeedback]

4.14.4 Staff suggestions

Laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service. [LF-U-GEN-Staff Suggestion for Improvement Form]. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained within each individual department. There is also a facility on i-passport whereby any member of staff who wishes to suggest an amendment to a policy, procedure, SOP, etc. can register this on passport at any time and this is then passed to the document owner who can do one of three things:

1) Reject it as not appropriate,

2) Accept it for immediate incorporation into the document,

3) Accept it to be incorporated into a future version of the document.

This information is then fed back to the sender so that they know what has happened with their suggestion.

4.14.5 Internal audit

The laboratory has a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records. [PO-U-GEN-Audit policy and procedure]

The audit programme considers the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits.

Audit training forms part of the programme identified within this document. All such training is carried out by competent peer auditors within departments.

The audit criteria, scope, frequency and methods are defined in individual departments audit calendars.

Audit activities, nonconformities found and time scales for corrective and preventive actions are recorded.

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The results of internal audit are regularly evaluated by departmental quality managers, quality leads and by the PQAC and escalated to the Pathology Executive Management Committee (if appropriate). Decisions and actions taken are documented, monitored and communicated to personnel as appropriate.

Internal audit of quality management system:

Internal audit of the quality management system is conducted as part of the Pathology audit policy, [PO-U-GEN-Audit policy and procedure], planned and scheduled as part of the audit calendar and conducted against agreed criteria.

Internal audit of examination processes:

The internal audit processes for pre-examination, examination and post examination processes are as part of the scheduled internal audit calendar which is specific to each discipline. As with internal audits of the quality management system, audit is conducted against agreed criteria and performed by individuals with appropriate training.

Personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when nonconformities are identified. Any necessary remedial actions are taken and then corrective action is taken without undue delay to eliminate the causes of the detected nonconformities, once the root cause analysis has been conducted. These are then recorded and any further changes needed implemented and the process re-audited.

4.14.6 Risk management

The laboratory evaluates the impact of work processes and potential failures on examination results as they may affect patient safety. [MR-U-GEN-Process Risk management] Processes are then modified as appropriate to reduce or eliminate the identified risks and decisions and actions taken are documented.

4.14.7 Quality indicators

Key Performance Indicators; the Directorate uses an agreed template for monitoring departmental performance indicators as described below.

The following KPI’s are reported to the Specialised Clinical Services Division quarterly Performance and Planning meeting.

Turn Around Time performance against target for:

Cellular Pathology

All Cellular pathology requests (80% within 7 days and 90% within 10 days)

All Cytology requests (80% within 7 days and 90% within 10 days)

Clinical Biochemistry

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- Creatinine for Emergency Department (90% within 1 Hour)
- Creatinine for GP (90% within 24 Hours)
- Troponin-T for Emergency Department (90% within 90 minutes)

Haematology

- Full Blood count for Emergency Department (both sites) (90% within 1 hour)
- Full Blood Count for GPs (both sites) (90% within 24 hours)

- **Blood Transfusion**

  Foetal Genotyping 95% in 10 working days

  Kleihauer testing 95% in 24 hours

Microbiology

- MRSA for Acute Trust (95% within 2 Days)
- Urine M&CS for GP (95% within 3 Days)
- Covid-19 urgent tests (within 4 hours)

The above turnaround times have been chosen as they provide assurance that Pathology supports patient flow within the Trust (A&E times and MRSA reporting), meets standards for Bowel Cancer screening programme and provides timely reports for primary care.

Accreditation status with UKAS, MHRA and HTA are reported together with IBMS portfolio Training status for all Departments.

The numbers of incidents which require reporting to SABRE or HTA are monitored.

These performance indicators provide the Trust with information on a range of key areas. (ISO 15189 2012:4.14.7)

In addition to this the disciplines within pathology can record other quality indicators which can be used internally to facilitate continuous quality improvement. LP-U-HAE.TRA Procedure for Establishing and Monitoring Quality Indicators; MR-U-HIS-Quality Indicators Procedure; LP-U-CHM-Performance Indicators; DP-U-MIC-QPIProcedure

Laboratories have established turnaround times for each examination that reflects clinical needs. These are monitored through PQAC where remedial or corrective action is discussed. Other performance indicators which are regularly audited include IQA and EQA performance, sickness absence, mandatory training and complaints. Departments and the Directorate participate fully in the evaluation of clinical effectiveness, audit, and risk management activities of the parent organisation, and have close links with the Risk and Clinical Governance team. The PQAC reviews clinical incidents and any high risks are added to the Trust Risk Register. (ISO 15189 2012:4.14.3/4.15.2/4.8)

4.14.8 Reviews by external organizations

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Pathology is subject to several reviews by external organisations including but not limited to UKAS, MHRA, HTA, CQC, and Health & Safety Executive. When any of these reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory takes appropriate immediate actions and produces an action plan, as appropriate, indicating what corrective action or preventive action is required to ensure continuing compliance with the requirements of the appropriate body. Records are kept of these reviews and of the corrective actions and preventive actions taken. The effect of any changes made is also reviewed to show that there have been no deleterious effects to any other part of the system.

Additionally to this the blood transfusion department submits an annual report to the MHRA SABRE and where appropriate SHOT.

4.15 Management review

4.15.1 General

Each department in Pathology conducts regular reviews of the laboratory's quality management system to ensure its continuing suitability, adequacy and effectiveness and support of patient care. LF-U-HAE.TRA-Quality management meeting TOR; LP-U-HIS-QMRTOR; LP-U-CHM-QMRTOR; MP-U-MIC-MQAC MeetiConst

4.15.2 Review input

The review includes all that is required by ISO 15189 and key quality objectives identified from this review are defined and plans formulated for their implementation with agreed timeframes (ISO 15189 2012:4.1.2.4). These documents are then stored on i-passport.

In addition to the above, the blood transfusion department submits an annual report to the MHRA that includes a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with BSQR 2005, as amended, and provides details of how these systems ensure such compliance. (BSQR 10.1.a/b). These documents are also stored on i-passport.

4.15.3 Review activities

The review analyses the input information for causes of nonconformities, trends and patterns that indicate process problems particularly where these could or have affected the laboratory's contribution to patient care.
Once identified these issues are used as opportunities for improvement [PO-U-GEN-Continuous Quality Improvement] and if necessary the need for changes to the quality management system, including the quality policy and quality objectives.

4.15.4 Review output

The output from the management review is incorporated into a record documenting any decisions made and actions taken during the management review related to:

a) improvement of the effectiveness of the quality management system and its processes;
b) improvement of services to users;

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c) resource needs.

Any findings and actions arising from management reviews are recorded and reported to laboratory staff through the various methods detailed earlier in this document and are also made available on i-passport for all to see at any time.

Laboratory management also ensures that any actions arising from management review are completed within a defined and reasonable timeframe which is appropriate to the importance of the issue identified and that these are reviewed at subsequent review meetings.

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5 TECHNICAL REQUIREMENTS

5.1 Personnel

5.1.1 General

The laboratory has a documented procedure for personnel management [PR-U-GEN-PersonnelManagement: Personnel Management Procedure] which details how personnel are managed and what records are maintained to indicate compliance with requirements.

5.1.2 Personnel qualifications

The personnel qualifications required for each position are identified in the person specification used during the selection process. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed.

Any personnel in a position to make judgments with reference to examinations carry suitable qualifications and have registration by appropriate professional/legal bodies.

5.1.3 Job descriptions

Job descriptions and contracts: Every member of staff is issued with a contract, which includes terms and conditions of service and complies with current legislation along with a job description including job title, location, accountability, purpose, main duties and responsibilities and the requirement for participation in staff annual joint review (ISO 15189 2012:5.1.7). A copy is stored with the contract in personal files which are kept in locked cabinets by the relevant line manager. In addition, staff are aware that they are also expected as part of their contract of employment to adhere to the Trust policies and procedures, which are updated from time to time and these can be found on the Trust intranet.

5.1.4 Personnel introduction to the organizational environment

All staff are required to attend a Trust induction prior to or at commencement of post. [PO-U-GEN-PathologyindPolicy] Staff also undergo a departmental induction which starts on their first day in the department. The documents' describing this process are linked to the above named policy in i-passport and once completed and signed a copy of this induction checklist is stored in the individual's personal file, held by the department manager and a copy sent to the Trust Training Manager.

5.1.5 Training

There is a Pathology Training Committee which meets quarterly to address and prioritise training needs for staff in line with the objectives of the service and within available financial resources. Training needs are identified at Personal Development Reviews and the Pathology Training Plan is produced which is submitted on an annual basis to the Trust Training Department which then produces a Trust wide training plan.

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Training and education is provided in accordance with Trust policies and guidelines from relevant professional and registration bodies. Records of education and training (including CPD and Competences) are maintained. The training programme, as appropriate, includes the following:

- assigned work processes and procedures
- the quality management system
- applicable computer system(s)
- health and safety, including the prevention or containment of the effects of adverse incidents
- the ethics and confidentiality of information.

Competency to perform assigned tasks is assessed following training and regularly thereafter. Staff records include competency assessments (ISO 15189 2012:5.1.6).

The following resources are available to all staff:

- Access to reference material and information services
- Access to a quiet area and facilities for Internet connection and IT applications.
- Opportunities for attendance at meetings and conferences.
- Financial support if training has been approved.
- Access to support in meeting training needs via a departmental Training Officer.

See Pathology Training Policy [PO-U-GEN-Training Policy].

All personnel undergoing training always work under supervision and would never be allowed to release results without them being authorised by a qualified member of staff.

The effectiveness of the training programme is reviewed both by the Pathology Training Committee and by individual departments as part of the competency process as well as during the management review process.

5.1.6 Competence assessment

Pathology has a policy [PO-U-GEN-Competence assessment policy pathology] which details the process and the criteria used across pathology to ensure that, following appropriate training, staff performing specific managerial or technical tasks are fully competent in what they are doing at all times. The process for reassessment and retraining where necessary is also detailed within this document. As the range of competences required across pathology is far reaching it is impossible to identify all of the competency documents here but these can be accessed in the individual departments as required.

5.1.7 Reviews of staff performance

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All staff participate in an annual personal development review [LP-U-GEN-Personal Development review process] that includes consideration of:

- The stated quality objectives and plans of the laboratory (ISO 15189 2012:4.1.2.4).
- The current job description and content.
- Personal objectives of the individual.
- Agreed training and development needs.
- Continuing Professional Development (CPD).

Human Resources provide appropriate training for reviewers and reviewees.

5.1.8 Continuing education and professional development

Continuing education and professional development is dealt with in a variety of ways. Lunchtime meetings or seminars are held by individual disciplines with an open invite to all staff if the subject matter is appropriate. Various educational meetings are held within the trust to which all staff are again invited. Senior staff are constantly reviewing the effectiveness of these meetings and looking for innovative ways to provide this training in a format which is acceptable to both the staff member and the smooth running of the department.
Individually the IBMS offer regular CPD opportunities which many staff partake in.
When re-registering with HCPC each registered member must sign a declaration that they are actively partaking in CPD and if requested produce their portfolio for independent scrutiny.

5.1.9 Personnel records

Confidential personnel records are kept securely by department managers. (ISO 15189 2012:5.1.9) These records are readily available to relevant personnel and as a minimum include:

a) educational and professional qualifications:

b) copy of certification or license, when applicable:

c) previous work experience:

d) job descriptions:

e) introduction of new staff to the laboratory environment: induction paperwork

f) training in current job tasks:

g) competency assessments:

h) records of continuing education and achievements:

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i) reviews of staff performance:

j) reports of accidents and exposure to occupational hazards:

k) immunisation status, when relevant to assigned duties.

NOTE: The records listed above may not be stored in the laboratory but if not then they remain accessible as needed.

5.2 Accommodation and environmental conditions

5.2.1 General

Laboratory facilities on both sites are in purpose built facilities which are designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients, and visitors. As processes and ways of working have changed over the years laboratory management have evaluated the sufficiency and adequacy of the space allocated for the performance of the work carried out and made what changes can be reasonably done to make the most efficient and safe use of the space and facilities available.

Health and safety: The following policies ensure the health, safety, and welfare of all personnel: -

- Trust Health & Safety Policies, available on the intranet. [Health and Safety Policy WAHT-CG-125]
- A Pathology Health& Safety Policy [HS-U-GEN-Path Health &Safety policy]
- A Pathology COSHH Policy [HS-U-GEN-COSHHPol&Procedures]
- Local departmental SOPs including risk assessments

Laboratory containment facilities conform to the requirements of the Advisory Committee on Dangerous Pathogens (ACDP) Guidelines.

All staff are informed of their responsibilities relating to Health & Safety through appropriate training, notices and labelling.

All adverse incidents or near misses resulting or potentially resulting in harm to patients, staff or visitors and the associated actions arising are reported using DATIX as well as being recorded in i-passport as a non-conformance. Serious incidents are recorded on the Pathology Risk Register in DATIX and discussed at the PEMC and Pathology Quality and Accreditation meetings. Datix incidents are monitored by the Trust Clinical Risk Department.

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Chemical waste for all of Pathology is disposed of via Cellular Pathology. This is collected from their stores by Genta Medical Ltd, who are registered with the environment agency for waste collection/disposal.

5.2.2 Laboratory and office facilities

The laboratory and associated office facilities on both sites provide an environment suitable for the tasks to be undertaken with the following conditions being met:

a) Access to laboratory premises is restricted to authorised personnel
b) Once in the department access to any IT system containing medical or personal information is controlled by individual passwords with different and appropriate levels of access to different grades of staff. Patient samples and other associated data are always treated confidentially and retained for the length of time and temperature appropriate to the item(s) in question.
c) The facilities provided including energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions are appropriate to allow for correct performance of examinations.
d) Communication systems e.g. telephones, electronic links etc. meet the needs and requirements of users.
e) Safety facilities and devices including alarm systems for cold rooms, eyewash stations and emergency showers are provided and their function regularly verified.

5.2.3 Storage facilities

Storage space is provided in the way of store rooms, fridges, cold room, freezers, etc. to ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect the quality of examination results. Where necessary the temperature in these areas is monitored.

Clinical material is stored according to policy [PO-U-GEN-CtrlClinMat]. Materials used in examination processes are normally stored separately. If both samples and materials used in examination procedures must be stored together then the samples are always stored below the materials in order to avoid cross contamination.

Hazardous substances are managed in accordance with the COSHH policy [HS-U-GEN-COSHHPol&Procedures].

5.2.4 Staff facilities

The following facilities are provided for staff:

- Sufficient toilets within access of the laboratories on each site.
- Rest areas are available with limited catering facilities. There is also a restaurant where hot food and drinks are available. Drinking water is always available.

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- Secure storage for personal effects is provided. Suitably sited hangers are available within each department for laboratory coats
- Swipe-card or keypad access to all laboratory areas, with security staff or alarm systems where appropriate for lone workers. (ISO 15189 2012:5.2.4)
- A seminar room is available within the pathology area on the Worcester site for staff activities such as meetings and interviews. Quiet study is best done in the hospital library to which all staff have access although there are also areas within the pathology footprint on both sites where this can be done on an ad hoc basis.

5.2.5 Patient sample collection facilities

In Worcestershire Royal Hospital Pathology Department these include: -

- A waiting/reception area for clinic patients, with access for disabled patients.
- Consulting rooms for clinics and patient examination where relevant.
- Toilet facilities for patients

There are notices advising patients and visitors of health and safety precautions.

Other facilities for patients come under the Out Patient Directorate, Surgical or Medicine Divisions.

Patient facilities are not required within the Pathology Departments of the Alexandra Hospital. (ISO 15189 2012:5.2.5)

5.2.6 Facility maintenance and environmental conditions

The WRH site facilities are managed by our PFI partners, Engie, Siemens and ISS with regular input from laboratory managers when issues are identified. The trust estates department manages the Redditch site again with regular input from laboratory managers when issues are identified. Both sites are kept maintained in a functional and reliable condition. Work areas are kept clean and well maintained.

Where the environmental conditions may influence the quality of results of examinations and or the health of staff then attention is given to monitoring, controlling, and recording these as required with relevant policies being itemised in the associated documents list at the end of this document.

Within departments adequate space has been allocated for the use of all equipment and separation of incompatible activities. Procedures are in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.

Where it is needed the laboratory provides a quiet and uninterrupted work environment.

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5.3 Laboratory equipment, reagents, and consumables

5.3.1 Equipment

5.3.1.1 General

Management of equipment: Laboratory Management ensures that equipment is sufficient and appropriate to provide the service. Procurement and management of equipment is in accordance with Trust Standing Financial Instructions, the Trust Medical Devices Policy: [Medical Devices policy including Education and Training: WAHT-CG-022] and Pathology Procurement and Management of Equipment Procedure [MR-U-GEN-ProcMgtEquip] and takes account of energy usage and disposal requirements.

The laboratory selects and approves suppliers using relevant criteria based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's and end user's requirements. This is done in collaboration with the procurement department who ensure that purchasing information describes the requirements for the product or service to be purchased.

A list of selected and current approved suppliers of equipment, reagents and consumables can be obtained from i-passport on demand at any time which includes evidence that the performance of suppliers is monitored to ensure that purchased services or items consistently meet the stated criteria. [MR-U-GEN-External Services and supplies] (ISO15189:2012:4.6)

The inventory of equipment supplied through the PFI is held by Siemens (on the WRH site) although Laboratory Managers can obtain a complete list of all equipment in their department(s), irrespective of funding source, from i-passport on demand at any time.

All assets on the PFI schedule have an expected lifetime determined on installation but should there be a requirement to replace earlier or later than this, for example, due to technological change, then this can be negotiated between the PFI, finance and the pathology management. The Trust assets are replaced as required to ensure the quality of examination results normally by production of a business case.

5.3.1.2 Equipment acceptance testing

Equipment once obtained is subject to validation and verification as per the pathology wide policy: [PO-U-GEN-Validation and Verification Policy]. Information about the equipment including its unique identifiers is entered onto i-passport where the verification data is also stored. Further re-verification is then carried out when changes are made, repairs or any other interventions are carried out or if other concerns are raised and this data is added to the entry in i-passport.

This process would apply equally to equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.

5.3.1.3 Equipment instructions for use

Anyone using equipment unsupervised would have been trained in its use and have a completed competence form for it.

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Current instructions for use would normally be in the form of an SOP on i-passport and any relevant manuals would be indexed as external documents again on i-passport and listed as either links or attachments on the relevant i-passport file for that particular piece of equipment.

Most equipment used in the laboratory is fixed so transport and storage is not normally an issue.

5.3.1.4 Equipment calibration and metrological traceability

Because of the diverse nature of the equipment used across the various areas of pathology the documented procedure for the calibration of equipment that directly or indirectly affects examination results would be specific to that particular type of assay or analyser hence the recording of the information required by this standard would all be itemised within the individual SOPs, i.e.

a) considering conditions of use and the manufacturer's instructions;

b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;

c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

d) recording the calibration status and date of recalibration;

e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;

f) safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability will always be to a reference material or reference procedure of the highest metrological order available.

5.3.1.5 Equipment maintenance and repair

Because of the diverse nature of the equipment used across the various areas of pathology the documented procedure for the programme of preventive maintenance would be specific to that analyser and as such would form part of the SOP.
Procedure: [MR-U-GEN-ProcMgtEquip] details how the preventive maintenance contracts would be set up as well as the procedures to be carried out in the event of defective equipment, decontamination and post repair performance verification.

The safe handling and disposal of chemical and biological materials is also detailed in the individual SOPs and would only be carried out by authorized persons

5.3.1.6 Equipment adverse incident reporting

Procedure: [MR-U-GEN-ProcMgtEquip] details how equipment adverse incident reporting would be carried out.

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5.3.1.7 Equipment records

Equipment Records are maintained on i-passport for each item of equipment that contributes to the performance of examinations and as a minimum includes:

a) identity of the equipment;

b) manufacturer's name, model and serial number or other unique identification;

c) contact information for the supplier or the manufacturer;

d) date of receiving and date of entering into service;

e) location;

f) condition when received (e.g. new, used or reconditioned);

g) manufacturer's instructions;

h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;

i) maintenance carried out and the schedule for preventive maintenance;

j) equipment performance records that confirm the equipment's on-going acceptability for use;

k) damage to, or malfunction, modification, or repair of the equipment.

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These records are maintained, updated as appropriate and are readily available for the lifespan of the equipment as specified in the laboratory's Control of Records procedure [PO-U-GEN-ControlProcessQualRec] although the records would in fact be available for as long as the QMS system was operational.

5.3.2 Reagents and consumables

5.3.2.1 General

The management of reagents, calibration and quality control material is in accordance with the pathology wide Management of Materials Policy [PO-U-GEN-ManagementMaterials] and specific departmental procedures which are linked in i-passport to this policy.
This includes both the process for selecting an appropriate supplier and the acceptance criteria once goods have been received. Before putting any goods into use they would be subject to appropriate verification as per departmental procedures.

5.3.2.2 Reagents and consumables — Reception and storage

Deliveries of goods to the laboratory normally occur through the loading bays at either WRH or the Alexandra Hospital. While there are no specific storage facilities in either of these areas the goods are delivered to the department as soon as possible. Audits are carried out to confirm this and any issues arising from these would be dealt with by both the loading bay and the laboratory management.

Once received in the laboratory received reagents and consumables are stored according to manufacturer's specifications.

5.3.2.3 Reagents and consumables — Acceptance testing

Due to the diverse nature of the various reagents and consumables used across the various areas of pathology the process for acceptance testing of both reagents and consumables is specific to each discipline and ensures in all cases that each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before use in examinations. The same applies to consumables that can affect the quality of examinations. As detailed above these documents can be found on i-passport and are linked to the Management of Materials Policy [PO-U-GEN-ManagementMaterials]

5.3.2.4 Reagents and consumables — Inventory management

Within the acceptance testing processes detailed above each discipline within pathology has specific procedures for inventory control of reagents and consumables which ensures that uninspected and unacceptable reagents and consumables are segregated from those that have been accepted for use.

5.3.2.5 Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers are retained as per the Document Control policy: [MO-U-GEN-Document Control] and are readily available.

5.3.2.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents would always be recorded as non-conformances on i-passport and fully investigated. If it was found that the incident can be attributed directly to specific reagents or consumables then this would be reported to the manufacturer and appropriate authorities, as required.

5.3.2.7 Reagents and consumables — Records

Records are maintained as required to comply with ISO 15189 for each reagent and consumable that contributes to the performance of examinations as part of the individual discipline's stock control and acceptance testing policies.

There are now very few reagents prepared or completed in-house but where this is the case the records include, in addition to the basic information required, reference to the person or persons undertaking their preparation and the date of preparation.

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5.4 Pre-examination processes

5.4.1 General

Pathology discusses with users of the service the way requests are communicated to the laboratory, either through the User Interaction groups or other less formal routes.

Requests and results reporting are now almost exclusively done using the Sunquest ICE system. Where there are technical or practical difficulties in achieving this Worcestershire Acute Hospitals NHS Trust supplies various departmental specific pathology request forms for both hospital and GP use.

There is a pathology wide policy which is used on all sites for the patient sample and request form identification criteria [PO-U-GEN-ReqCriteria] as well as a policy for the acceptance and rejection of specimens [PO-U-GEN-PolSpecAcceptance]. (ISO 15189 2012:5.4.3)

There is detailed information on the pathology website http://www.worcsacute.nhs.uk/pathology for each individual test indicating any particular requirements for pre-examination activities in order to ensure the validity of the results of examinations.

5.4.2 Information for patients and users

Information for users and patients is available on the Pathology Website: http://www.worcsacute.nhs.uk/pathology , is reviewed by the website group and is accessible from any internet enabled device.

Other information, such as patient information leaflets are prepared by departments as appropriate and contain an explanation of the procedure and patient preparation details.

Specimen collection and handling: The Pathology Website http://www.worcsacute.nhs.uk/pathology includes comprehensive information for users on specimen collection and handling including volume requirements. Laboratory staff also provide advice to users on request. (ISO 15189 2012:5.4.4)

Specimen transportation: A courier service is provided for specimen transportation between the hospitals, GP surgeries and the pathology departments. In the Bromsgrove and Redditch areas this is provided by Worcestershire Health and Care NHS Trust and elsewhere across the county, and between the various trust sites, by Worcestershire Acute Hospitals NHS Trust (ISO 15189 2012:5.4.5) .

Between 7pm and 7am Monday to Thursday and 7pm Friday to 7am Monday and all day on bank holidays we use a voluntary organisation called Severn Freewheelers to transport samples between sites and across the area. If this service is not available, for whatever reason, contracted private hire vehicles (Taxis) are used.

Specimens referred to other laboratories are transported in accordance with current legislation using Trust transport, Royal Mail, TNT, Hayes DX Network Services, PDP and private hire vehicles.

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There is a policy [PO-U-GEN-SpecTransport] for the transport of specimens to which appropriate departmental procedures are linked detailing specific instructions for packaging, labelling and despatch of specimen types which have specific requirements.

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5.4.3 Request form information

Wherever possible we encourage the use of ICE electronic requesting, or where this is not possible hard copy request forms, which ensures that at a minimum the following information is given:

a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;

b) name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;

c) type of primary sample and, where relevant, the anatomic site of origin;

d) examinations requested;

e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;

f) date and, where relevant, time of primary sample collection;

The date and time of sample receipt are recorded on the LIMS system when the request is booked in.

The format of this requesting system has evolved over the years following feedback from users particularly around the use of specific disease related testing profiles.

The pathology website documents the procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent.

If there is any doubt or concern about the clarity of the user's request this will be dealt with either by the Biomedical Scientist dealing with the issue of if necessary one of the clinical staff.

5.4.4 Primary sample collection and handling

5.4.4.1 General

The pathology website has details about the proper collection and handling of primary samples including any special requirements for specific tests. The website is freely available to all on any internet enabled device.

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these are recorded and included in all documents containing examination results and communicated to the appropriate personnel on the report.

Before carrying out any special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, a more detailed explanation is

given to the patient and where necessary written consent is obtained and the consent form retained.

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5.4.4.2 Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities are available test by test on the pathology website and include the following:

a) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);
b) type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
c) special timing of collection, where needed;
d) clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

Instruction on completion of electronic requests is included when trained in use of ICE and on-line guides are also available within ICE.

5.4.4.3 Instructions for collection activities

The instructions for collection activities are documented in procedures devised by the Out-Patients manager, who is responsible for phlebotomy with additional information being available on the pathology website and include the following:
a) determination of the identity of the patient from whom a primary sample is collected;
b) Verification that the patient meets pre-examination requirements (e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.);
c) instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;
d) in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions;
e) instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;
f) recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;
g) instructions for proper storage conditions before collected samples are delivered to the laboratory;
h) safe disposal of materials used in the collection.

5.4.5 Sample transportation

The laboratory's instructions for post-collection activities can be found on the pathology website [PO-U-GEN-SpecTransport] and include packaging of samples for transportation.

As part of the pre-analytical process a regular audit (RADT) is done of the journey time of the sample to confirm they have been transported:
a) within a time-frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;
b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;

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c) in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

In addition to this all the trust vans are fitted with tracker devices so data can be extracted as to when the samples were collected and delivered.

As this laboratory is not involved in primary sample collection and transportation we would always contact the sender immediately when, upon receipt of a sample, we discovered that the integrity was compromised or it could have jeopardized the safety of the carrier or the general public and inform them about what measures need to be taken to eliminate recurrence of the issue.

5.4.6 Sample reception

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At Worcestershire Royal Hospital there is a pathology sample receipt area where all pathology samples, from transport couriers or personal callers, i.e. Doctors, Nurses, Patients, etc. are handed over to reception staff. Staff and resources in this area are managed by the Blood Sciences Pre-Analytics manager who is also responsible for all aspects of the pre-analytical components of the work in Blood Sciences on both this and the Redditch site. Microbiology and Cellular Pathology samples are placed in their labelled receptacles and then handed over to staff from these disciplines that then perform any necessary pre-analytical work on these samples under the direction and guidance of the laboratory manager for their own discipline. Blood Sciences samples with their associated request forms are sorted from their outer transport bags and are transferred into receptacles for delivery to the appropriate departmental specimen reception area, for example: Haematology, Biochemistry and the Urine bench where the bags are opened and the appropriate checks done on the sample and form.

At Redditch, the samples are delivered either by hand to a table inside an access controlled area, but out with of the main secure laboratory area, where they are collected by Blood Science MLA staff or in the case of hospital patients by air tube directly into the main blood sciences specimen reception area where they are then appropriately dealt with. Samples for Microbiology arrive in separate marked bags and are picked up regularly by the transport staff and delivered to Worcestershire Royal Hospital along with Cellular Pathology samples and blood science samples requiring assays not offered on this site where they are dealt with as explained above.

At Kidderminster, the samples are transported in a safe and timely manner to Worcestershire Royal Hospital.

Additional information about this aspect of the work is detailed in the Pre-Analytical Department Information procedure: [LP-U-CHM-Pre-Analytical department information]

It is not until the samples arrive within the designated department specimen reception area that the samples are removed from the sample pouch in line with the individual departmental specimen reception procedures, identified in the associated documents list at the end of this document, that identify the processes for:

- Accurate matching of the request card and specimen including any subsequent sample aliquots with the unique identifying number
- Data entry of request form and specimen information onto the Laboratory Information System
- Recording of date and time of receipt of specimens.
- Handling urgent specimens
- Ensuring staff safety (e.g. H&S procedures)

A Pathology Policy [PO-U-GEN-PolSpecAcceptance] exists in combination with local procedures which are linked in i-passport to this policy for:

- Criteria for rejection of specimens
- Recording of rejected specimens.
- Notification of the user concerning rejected specimens.

As part of the regular management review process authorised personnel regularly review requests and samples and decide examinations to be performed and methods used. (ISO 15189 2012:5.4.6)

5.4.7 Pre-examination handling, preparation and storage

The laboratory is equipped with appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage. The process used is detailed in the pre-analytics SOP: [LP-U-CHEM-Pre-Analytical Department Information]

Laboratory procedures and the pathology website indicate time limits for requesting additional examinations or further examinations on the same primary sample.

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

Selection and verification of examination procedures is carried out according to the pathology wide policy [LP-U-GEN-Selection and Verification of Examination Procedures.]

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The identity of persons performing activities in examination processes can be determined by reference to past work rotas or by the various audit trails in use across the department.

5.5.1.2 Verification of examination procedures

All examination procedures are subject to validation and verification prior to introduction. Validated examination procedures used without modification are subjected to independent verification by the laboratory before being introduced into routine use. If the procedure was not a 'preferred procedure' used without modification then a full validation would have to be carried out before any verification could proceed.
The laboratory would obtain information from the manufacturer/method developer confirming the performance characteristics of the procedure and using the form: [LF-U-GEN-Verification of Examination procedures] would confirm and record through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met.
The performance claims for the examination procedure confirmed during this verification process would be those which were relevant to the intended use of the examination results.
Evaluation of procedures is performed using "in-house" or nationally recommended methods, i.e. ACB guidelines. The method, results and conclusions and any associated paperwork are recorded and stored in i-passport following review by staff with the appropriate authority.
When changes to examination procedures significantly affect the results or their interpretation, full information on these changes is provided to users through the user interaction groups and by letter prior to the introduction of the change alongside appropriate comments on the reports.

As part of the regular management review process examination procedures are reviewed to ensure they continue to meet the needs and requirements of users.

5.5.1.3 Validation of examination procedures

If an examination procedure was derived from any of the following sources:
a) non-standard methods;
b) laboratory designed or developed methods;
c) standard methods used outside their intended scope;
d) validated methods subsequently modified.

A full validation would be carried out and would be as extensive as is necessary in order to confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

The laboratory would then document the procedure used for the validation and record the results obtained on i-passport following review by staff with the appropriate authority. Once validated the examination procedure would be subjected to verification as detailed above. When changes are made to a validated examination procedure, the influence of such changes would be documented and, when appropriate, a new validation carried out.

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5.5.1.4 Measurement uncertainty of measured quantity values

All areas of the laboratory have determined measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory has defined performance requirements for the measurement uncertainty of each measurement procedure and regularly reviews estimates of

measurement uncertainty. This data is readily available and could be supplied to users who requested it.

5.5.2 Biological reference intervals or clinical decision values

The laboratory has defined the biological reference intervals or clinical decision values and documented the basis for the reference intervals or decision values on the website which is available to all users.
If a particular biological reference interval or decision value was no longer relevant for the population served, appropriate changes would be made and this information would be communicated to the users.
Whenever a change occurs to either an examination procedure or pre-examination procedure, the laboratory reviews the associated reference intervals and clinical decision values, as applicable and notifies users accordingly.

5.5.3 Documentation of examination procedures

The format of Standard Operating Procedures is in accordance with the Document Control Policy and Procedure [MO-U-GEN-Document Control]. All examination procedures are readily available on the electronic document control system (i-Passport) with controlled hard copies being available where required on the relevant benches

When changes to examination procedures significantly affect the results or their interpretation, full information on these changes is provided to users through the user interaction groups and by letter prior to the introduction of the change alongside appropriate comments on the reports.

5.6 Ensuring quality of examination results

5.6.1 General

There are departmental procedures which are itemised in the associated documents list at the end of this document for selection, use and interpretation of internal quality control (IQC), performed under controlled conditions, for all examinations to ensure the quality of laboratory examinations. These include:

- Implementation of appropriate pre-examination processes
- Provision of trained staff, appropriate premises and environmental conditions, equipment and materials information systems, and the use of documented procedures.
- Use of internal quality control

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- The determination of uncertainty
- Calibration of measuring systems

- Verifying the comparability of results
- Participating in external Proficiency Testing Schemes
- Records of date, source and storage requirements of IQC material
- The process of validation of IQC material prior to routine use
- Appropriate statistical procedures and acceptance criteria for results where applicable.
- All IQA results are regularly recorded, evaluated and any remedial or corrective actions recorded on the individual evaluation sheets.

The laboratory determines the uncertainty of results, where relevant and appropriate using methods appropriate to the nature of the results concerned, i.e. quantitative/qualitative.

The laboratory uses material for calibration of measuring systems and verification of trueness which has defined metrological traceability designed to ensure that results are traceable, where possible, to SI units or to a stated reference material.

Where examinations are performed using different procedures or equipment or at different sites the departments involved have mechanisms in place, itemised in the associated documents list at the end of this document, to ensure that results are comparable throughout clinically appropriate intervals. (ISO 15189 2012:5.6 and UKAS supplementary document (GEN-1 Assessment of CAB's by UKAS- Appendix C)

5.6.2 Quality control

5.6.2.1 General

The laboratory ensures that there are quality control procedures in place that verify the attainment of the intended quality of results.

5.6.2.2 Quality control materials

The laboratory always strives to use quality control materials that react to the examining system in a manner as close as possible to patient samples. Given the amount of substances added to most QC materials to achieve values around clinical decision levels this can sometimes be difficult to achieve.

Each area of the laboratory examines Quality control materials with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

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Wherever possible independent third-party control materials are used, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

5.6.2.3 Quality control data

Across pathology there are many ways in which the release of patient results in the event of quality control failure is avoided. In some cases, the release of patient results is blocked until all quality control results are acceptable and in others this is a manual process. In any case good laboratory practice dictates that patient samples are not analysed until there is clear indication that the method is under control.

When the quality control rules are violated after patient results have been released and there are indications that examination results are likely to contain clinically significant errors immediate action is taken to reject the results and to contact users if necessary to advise them. Relevant patient samples would then be re-examined after the error condition has been corrected and within-specification performance is verified. A process would then be put into place as per individual disciplines procedures to evaluate the results from patient samples that were examined after the last successful quality control event in order to identify at what point results became invalid. Once determined all results would be repeated from this point. At all stages of this process the Laboratory Director would be kept aware so that they could deal with any clinical issues arising from the problem.

Quality control data is reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded.

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5.6.3 Inter-laboratory comparisons

5.6.3.1 Participation

All departments participate in approved External Quality Assurance/Proficiency Testing (EQA/PT) Schemes appropriate to the examinations and interpretations provided, most of which are now ISO17043 compliant or working towards it. TPS47 is used to guide the selection and interpretation of the results.
Departments have documented procedures, itemised in the associated documents list at the end of this document, for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.
The inter-laboratory comparison programme(s) chosen by the laboratory, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures.

A record of results against agreed performance criteria in approved schemes is maintained by departments and performance is reviewed by competent staff and action plans devised where necessary to determine what corrective actions need to be implemented to come within the agreed performance criteria. Decisions taken are recorded, monitored, and acted upon in accordance with departmental procedure. Information on Proficiency Testing (PT) results are regularly communicated to staff within each department and discussed at PQAC.

5.6.3.2 Alternative approaches

Across pathology we would not attempt to accredit an assay unless there was a proven EQA Scheme available. If an assay was required whereby there was no proven EQA Scheme available then arrangements would be made to facilitate some sort of interim inter-laboratory comparison and the assay would have to be offered as an assay which was outside of the scope of the laboratories accreditation process until such times as a proven EQA scheme became available.

5.6.3.3 Analysis of inter-laboratory comparison samples

The laboratory integrates inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. Samples are examined by personnel who routinely examine patient samples using the same procedures as they use for patient samples.
The laboratory does not communicate with other participants in the inter-laboratory comparison programme about sample data until after the date for submission of the data and does not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

5.6.3.4 Evaluation of laboratory performance

The performance in inter-laboratory comparisons is reviewed and discussed with relevant staff.

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When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff participate in the implementation and recording of corrective action. The effectiveness of corrective action is monitored and any further necessary corrective actions implemented. The returned results are evaluated for trends that indicate potential nonconformities and preventive action is taken.

5.6.4 Comparability of examination results

There are defined means within individual departments, itemised in the associated documents list at the end of this document, for comparing procedures, equipment and methods used and establishing the comparability of results across platforms and across sites for patient samples throughout the clinically appropriate intervals.

The laboratory would notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.

The laboratory documents, records and, as appropriate, expeditiously acts upon results from the comparisons performed. Problems or deficiencies identified are acted upon and records of actions retained.

5.7 Post-examination processes

5.7.1 Review of results

Individual departments within the directorate have specific procedures, itemised in the associated documents list at the end of this document, to ensure that competent authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

When the procedure for reviewing results involves automatic selection and reporting, review criteria have been established, approved and documented.

5.7.2 Storage, retention and disposal of clinical samples

The laboratory has a documented procedure [PO-U-GEN-CtrlClinMat] along with linked departmental procedures, itemised in the associated documents list at the end of this document, for identification, collection, retention, indexing, access, storage, maintenance

and safe disposal of clinical samples which is based on the current edition of: *The retention and storage of pathological records and specimens – The Royal College of Pathologists and the Institute of Biomedical Science*

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Individual departments procedures also define the length of time clinical samples are to be retained with retention time being defined by the nature of the sample, the examination and any applicable requirements with processes being in place for those instances where legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) require the retention of certain samples for much longer periods than for other samples.

Safe disposal of samples is carried out in accordance with individual departments procedures in a way which is commensurate with the risk involved with the specific sample type.

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5.8 Reporting of results

5.8.1 General

There is a procedure that has been established in collaboration with users for reporting results [PO-U-GEN-ReportingResults] which includes:

- Printed reports
- Electronic transmission via the GP link and the ICE electronic reporting system
- Telephoned (verbal) and faxed reports
- Amended reports
- Clinical advice and interpretation

  The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.
- There is a pathology wide policy which gives guidance on transcription of results: Correctness of transcription of laboratory data, [PO-U-GEN-Correctness of transcription] and individual departments within pathology have details within individual SOPs to ensure the correctness of transcription of laboratory results.
- Reports include the information necessary for the interpretation of the examination results.
- The laboratory through the individual departments has processes in place for notifying the requester when an examination is delayed that could compromise patient care.

5.8.2 Report attributes

In order to effectively communicate laboratory results and meet the users' needs the laboratory ensures that on the report

- Comments are made on sample quality where this might compromise examination results:
- Comments are made regarding sample suitability with respect to acceptance/rejection criteria:
- Critical results, where applicable are highlighted:

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- Interpretive comments on results are added where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report.

5.8.3 Report content

The reports are designed to comply with the needs of the users and the requirements of the local medical records system. The reports include the following (where available):

- Laboratory name
- Unequivocal patient identification information on each page of the report.
- Requester name and address for delivery where supplied
- Type of specimen, date and time of collection where supplied
- Time and date of reporting
- Results, including reasons if no examination is performed
- Reference intervals where appropriate
- Interpretative comments where appropriate.
- Highlighting of abnormal results and/or inclusion of critical limits
- A comment if the test is not accredited to the ISO 15189 standard
- Status of report as appropriate.
- Page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.).
- Where possible identification of person(s) verifying and authorising the release of the report.

There is a Pathology referral to other laboratories policy [MR-U-GEN-Examination by Referral Labs and Consultants].

Reports issued following receipt of the results from referral laboratories or Consultants additionally include:

- Identification of the referral laboratory. Where a laboratory is identified by a code, the name and address of the referral laboratory is available on request
- All the results
- A comment if the test is not accredited to the ISO 15189 standard
- Appropriate interpretative comments received from the referral laboratory.

5.9 Release of results

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5.9.1 General

The procedure for reporting results [PO-U-GEN-ReportingResults] includes telephoning and faxing results. Specific departmental SOPs give more detail relevant to the type of information they need to transmit if necessary. These include:

- Circumstances for phoning reports.
- Staff authorised for giving or receiving reports.
- Methods for mutual identification, confirmation, and maintenance of confidentiality.
- Recording mechanisms.
- Requirements for sending a follow-up report.

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5.9.2 Automated selection and reporting of results

The laboratory implements a system for automated selection and reporting of some results from some departments and has established procedures to ensure that:

a) The criteria for automated selection and reporting are defined and approved by relevant and appropriately qualified staff within that department and are available and understood by the staff

b) The criteria mentioned above are used by the laboratory IT manager to set up rules within the various systems and are validated for proper functioning before use and verified after changes to the system that might affect their functioning:

c) The process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination is part of the data manager linked to the main analysers and ensures that data received by the host computer system already contains relevant information about these interferences. In many cases the results are automatically removed before getting to the LIMS if the interference level is such that the result could be adversely affected.

d) The process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria is part of the data manager linked to the main analysers and ensures that data received by the host computer system already contains relevant information about these warnings:

e) Results selected for automated reporting are identifiable on the auto-authorisation PC at the time of review before release and include date and time of selection:

f) Should the automated selection and reporting of results need to be suspended this could be rapidly achieved by the IT manager or his deputy changing the rules on the pathology computer system.

5.9.3 Revised reports

The procedure for reporting results [PO-U-GEN-ReportingResults] includes the process for amended reports and includes:

- The criteria and reason for issuing an amended report.
- The process of staff authorisation to amend reports.
- Identification to the user of amended reports.
- Recording of amendments made to reports as well as evidence of the original results via the computer audit trail.
- The instigation of corrective and preventive action, if required. (ISO 15189 2012:5.9.3)

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5.10 Laboratory information management

5.10.1 General

Management of data and information: Laboratory Management ensures the availability of data and information required to provide a service that meets the needs and requirement of users. The Laboratory Information Management System is WinPath and was procured from CliniSys in 2006.

There is an electronic document control system used for quality management (i-Passport) and this is administered by the Departmental Laboratory Managers and the Directorate Support Manager.

SGSS (formally CoSurv) is jointly managed by the Office of the Regional Epidemiologist and the Trust IT Department.

ComputaCentre maintains all hardware and networks Trust wide.

There is a procedure [MR-U-GEN-Data&InfoManagement] for the management of data and information.

Managers, the Trust Information Security Officer and the Caldecott Guardian are responsible for implementation of The Trust Information Governance Policy [WAHT-CG-579] to ensure compliance with current national legislation and regulations in relation to data protection. There is also a Pathology Policy [PR-U-GEN-TrustComputerUse] which supports the Trust

Information Governance Policy (ISO 15189 2012:5.10).

There are procedures [PO-U-GEN-ReportingResults] for ensuring that the reports are handled and transmitted confidentially according to Trust Information Governance Policy [WAHT-CG-579]**.** Access to the computer is password controlled, transmitted electronic data is encrypted and hard copies of reports are treated as confidential. (ISO 15189 2012:5.10.1)

5.10.2 Authorities and responsibilities

The authorities and responsibilities for the management of the information system are defined, [MR-U-GEN-Data&InfoManagement] including the maintenance and modification to the information system(s) that may affect patient care. There are various levels of access which are determined by laboratory managers and then set up on the system by the Pathology Computer Manager.

5.10.3 Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information was validated by the supplier and verified for functioning by the laboratory before introduction with any subsequent changes to the system being similarly authorized, documented and verified before implementation;

Documentation has been produced including that for day to day functioning of the system and is readily available to authorized users;

The system is password protected with an automatic timeout and mandatory password changes to protect it from unauthorized access;

The hardware is secured against tampering or loss;

The system is operated in an environment that complies with supplier specifications.

Regular maintenance is carried out on the system to ensure the integrity of the data and information and system failures are recorded along with the appropriate immediate and corrective actions.

The system complies with national or international requirements regarding data protection.

Systems are in place to verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.
The laboratory has documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. [PO-U-GEN-PathologyITBusinessContinuityPolicy]

Laboratory management maintains responsibility for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard for the parts of the information system(s) which are managed and maintained off-site or sub-contracted to an alternative provider.

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Associated Documents

http://www.worcsacute.nhs.uk/pathology	Pathology Website
http://www.worcsacute.nhs.uk/about-us/trust-board-whos-who/ - Trust Board	
AD-U-GEN-DirectorateOrgChart	Directorate Organisational Chart
AD-U-MIC-DepartOrgChart	Microbiology Organisational Chart
AD-U-CHM-Organisational chart chemistry	Biochemistry Organisational Chart
AD-U-HIS-Departmental Organisational Chart	Cell Path Organisational Chart
AD-U-GEN-Haematology and Blood Transfusion organisation chart	
	Haematology and Blood Transfusion organisational chart
MR-U-GEN-ExeMeetConst	Executive Management Committee
MR-U-GEN-PQACMeetConst	Pathology Quality & Accreditation Committee Terms of Reference
ED-U-GEN-Declaration of interests and acceptance of gifts and hospitality	
	Standards of Business Conduct- Declaration of interests and acceptance of gifts and hospitality
ED-U-GEN-Code of Conduct in respect of Confidentiality	
	Code of Conduct in respect of Confidentiality
ED-U-GEN-Trust Complaints Process flowchart	Trust Complaints Process flowchart
PO-U-GEN-Userfeedback	User Feedback
MR-U-GEN-Complaints	Complaints procedure
ED-U-GEN-Pneumatic tube policy	Pneumatic tube transfer service operational policy
MO-U-GEN-Document Control	Document Control Policy and Procedure
PR-U-GEN-PersonnelManagement	Personnel Management
PO-U-GEN-PathologyIndPolicy	Pathology Induction Policy
PO-U-GEN-Training Policy	Training Policy
LP-U-GEN-Personal Development review process	

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	Personal Development review process
PO-U-GEN-CtrlClinMat	Control of Clinical Materials
LP-U-HAE.TRA Control, Retention and Storage of Records and Clinical Materials	
	Control, Retention and Storage of Records and Clinical Materials
LP-U-MIC-CtrlCliMat	PROCEDURE FOR THE CONTROL OF CLINICAL MATERIAL
LP-U-CHM-Control of Clinical Material	Procedure for the Control of Clinical Material
LP-U-HIS-CtrlCliMat	PROCEDURE FOR THE CONTROL OF CLINICAL MATERIAL
PO-U-GEN-ControlProcessQualRec	Control of Process & Quality Records
LP-U-MIC-CtrlProcQualRec	CONTROL OF MICROBIOLOGY PROCESS & QUALITY RECORDS
MO-U-HIS-Control of Process and Quality Records	
	Control of Process and Quality Records
LP-CHM-ControlProcessRecords	Control of Process and Quality Records
LP-U-HAE.TRA Control, Retention and Storage of Records and Clinical Materials	
	Control, Retention and Storage of Records and Clinical Materials
MR-U-GEN-External Services and Supplies	External Services and supplies
MR-U-GEN-ProcMgtEquip	Procurement and Management of Equipment
Medical Devices policy including Education and Training: WAHT-CG-022	
	Trust Medical Devices policy
PO-U-GEN-ManagementMaterials	Management of Materials Policy
LP-U-CHM-8000 Automated Section Stock Control and Pre Acceptance	
	Automated Section Stock Control & Pre Acceptance
LP-W-CHM-SEMI-AUTOMATED SECTION STOCK CONTROL & PRE-ACCEPTANCE	
	Semi-automated Section Stock Control & Pre-acceptance
LP-U-MIC-StockControlandOrdering	Stock Control and Ordering
LP-U-HAE-STOCK CONTROL	Stock control Haematology

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LP-U-HIS-Acceptance testing and receipt of goods

Acceptance testing and receipt of goods

LP-U-MIC-ConsumableAcceptanceProcedure Consumable Acceptance procedure

LP-U-COAG-PROCEDURE FOR RECEIPT AND PRE-ACCEPTANCE TESTING IN COAGULATION

Procedure for Receipt and Pre Acceptance Testing in Coagulation

LP-U-HAE-Reagent acceptance and verification haematology

Reagent acceptance and verification haematology

LP-U-TRA-Reagent pre acceptance testing Reagent pre acceptance testing

LF-W-HAE-Receipt and pre-acceptance testing for TOSOH G8 reagents

Receipt and pre-acceptance testing for TOSOH G8 reagents

LP-W-CHM-TOSOH G8 Stock acceptance TOSOH G8 Stock delivery and Pre-Acceptance

LP-U-GEN-Selection and Verification of Examination Procedures Procedure for selection and Verification of Examination Procedures

LF-U-GEN-Verification of Examination procedures

Verification of Examination procedures form

PO-U-GEN-Validation and Verification Policy Validation and Verification Policy

MR-U-GEN-Process Risk management Process Risk management

MR-U-GEN-Examination by referral labs and consultants

Examination by referral labs and consultants

ED –U-HAE.TRA ExternalSuppliers & Referral Laboratory Reviews

MR-U-GEN-SLA Procedure for Establishment & Review of Agreements to Provide Services to External Users

MR-U-GEN-Service Agreement Internal Procedure for Establishment & Review of Agreements to Provide Services to Internal Users

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PO-U-GEN-PolSpecAcceptance	Policy for acceptance and rejection of specimens
LP-U-CHM-Pre-Analytical department information	
	Pre-Analytical department information
LP-U-CHEM-Rejected samples	Rejected sample policy
LP-U-MIC-VirolSpecRecep	PROCEDURE FOR RECEIVING SPECIMENS IN VIROLOGY
LP-U-HIS-Cut up-receipt of Histology specimens	
	Cut up-receipt of Histology specimens
LP-A-HAE.TRA-Specimen Reception	Specimen Reception, Staffing Levels and Workflow
LP-U-MIC-SpecRecep	SPECIMEN RECEPTION PROCEDURES
LP-W-BSC : Front Reception Procedures	Front Reception Procedures
PO-U-GEN-ReqCriteria	Requesting Criteria
PO-U-GEN-SpecTransport	Specimen Transport Policy
PO-U-GEN-Correctness of transcription	Procedure for the Correctness of transcription of laboratory data
PO-U-GEN-Continuous Quality Improvement	Continuous Quality improvement Policy
LP-U-TRA-Recall procedure	Recalling blood components/products
PO-U-GEN-ReportingResults	Policy for reporting results
PR-U-GEN-Non-conformance procedure	Non-conformance procedure
PR-U-GEN-Recording of Non-Conformances on i-passport	
	Recording of Non-Conformances on i-passport
PO-U-GEN-Audit policy and procedure	Audit policy and procedure
LP-U-HAE.TRA Audit Procedure for Haematology & Blood Transfusion	Departmental Audit Procedure
LF-U-GEN-Staff Suggestion for Improvement Form	
	Staff Suggestion for Improvement Form
ED-U-GEN-The retention and storage of pathological records and specimens (5th edition, 2015)	

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	Retention and storage of pathological records and specimens
HS-U-GEN-COSHHPol&Procedures	Control of Substances Hazardous to Health
HS-U-GEN-Path Health &Safety policy	Pathology Health and Safety Policy
Health and Safety Policy WAHT-CG-125	Trust Health and Safety Policy
PO-U-GEN-Competence assessment policy pathology	
	Competence assessment policy pathology
PR-U-GEN-TrustComputerUse	Trust Computer Use Policy
MR-U-GEN-Data&InfoManagement	Data & Information Management
PO-U-GEN-PathologyITBusinessContinuityPolicy	
	Pathology IT Business Continuity
Trust Information Governance Policy [WAHT-CG-579]	
	Trust Information Governance Policy
TPS47 UKAS policy on participation in proficiency testing	
GEN-1 Assessment of CAB's by UKAS	

The following documents exist within individual departments as mentioned in the main text of this document.

Selection, use and interpretation of internal quality control (IQC)

	LP-U-CHM-IQC validation procedure
	LP-U-HIS-Internal Quality Control In Histopathology and Cytology
	LP-U-COAG-COUNTYWIDE IQC PROCEDURE IN BLOOD COAGULATION
	LP-U-HAE-Countywide IQC procedure
	LP_U_MIC_IQCProc
	LP-U-TRA-Procedure for using the automated blood group analyser

Interlaboratory comparisons	LP-U-CHEM-EQA-CONTENTS

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LP-U-MIC-EQA: EQA PROCEDURE

LP-U-HAE-EQAprocessing

MP-U-HIS-External Quality Assurance and Reports from external bodies

LP-U-TRA-Proficiency Testing in Blood Transfusion

Where examinations are performed using different procedures or equipment or at different sites the departments involved have mechanisms in place to ensure that results are comparable throughout clinically appropriate intervals

LP-U-CHM-QC-SAMPLE COMPARISON
LP-U-HAE-HAEMComparisons: Comparisons countywide Haematology
LD-U-TRA-Blood transfusion inter-analyser comparison
LP-U-MIC-EquipmentComparison

Procedures to ensure that competent authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

LP-U-CHM-Clinical Validation

LP-U-HAE-Authorisation of FBC results

LP-U-HIS-HistoRptAuth (WRH)

LP-U-HIS-Reporting Procedure of NG Specimens

LP-U-HIS-Reporting of synovial fluids

LP-U-MIC-Winpath reporting

Safe disposal of samples is carried out in accordance with either the individual departments procedures or the pathology wide one in a way which is commensurate with the risk involved with the specific sample type.

LP-U-GEN-Waste disposal
LP-U-CHM-waste disposal in the automated section
DP-U-HIS-Disposal of Laboratory waste
LP-U-MIC-WasteDisposal

Environmental testing is done according to: LP-U-HIS-FormaldehydeMon:

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LP-U-HIS-Weekly Airflow AFOS Monitoring

LP-U-HIS-Xylene monitoring

LP-U-HIS-Temperature Log

LP_U_MIC_TempMonitoring
LP-U-MIC-AnemometerOperationMaintenanceProc
LP_U_MIC_SterileFluidsEnvMonitoring

Departments have the following processes in place for notifying the requester when an examination is delayed that could compromise patient care.

AD-U-CHM-AS-Quick Reference Manual: Winpath

LP-U-HAE-Contingency Planning HaematologyDepartmental Induction procedures:
LP-U-CHM-Lab Induction

LF-U-HIS-Cellular Pathology Induction

LF-U-MIC-Departmental Induction Orientation

LF-U-MIC-MicrobiologyLaboratoryInduction

LP-U-HAE.TRA Haematology Departmental Induction Programme for New EmployeesTR-U-MIC-Medical Microbiology Consultant Induction

LP-U-CHM-Pre-Analytical Departmental Induction

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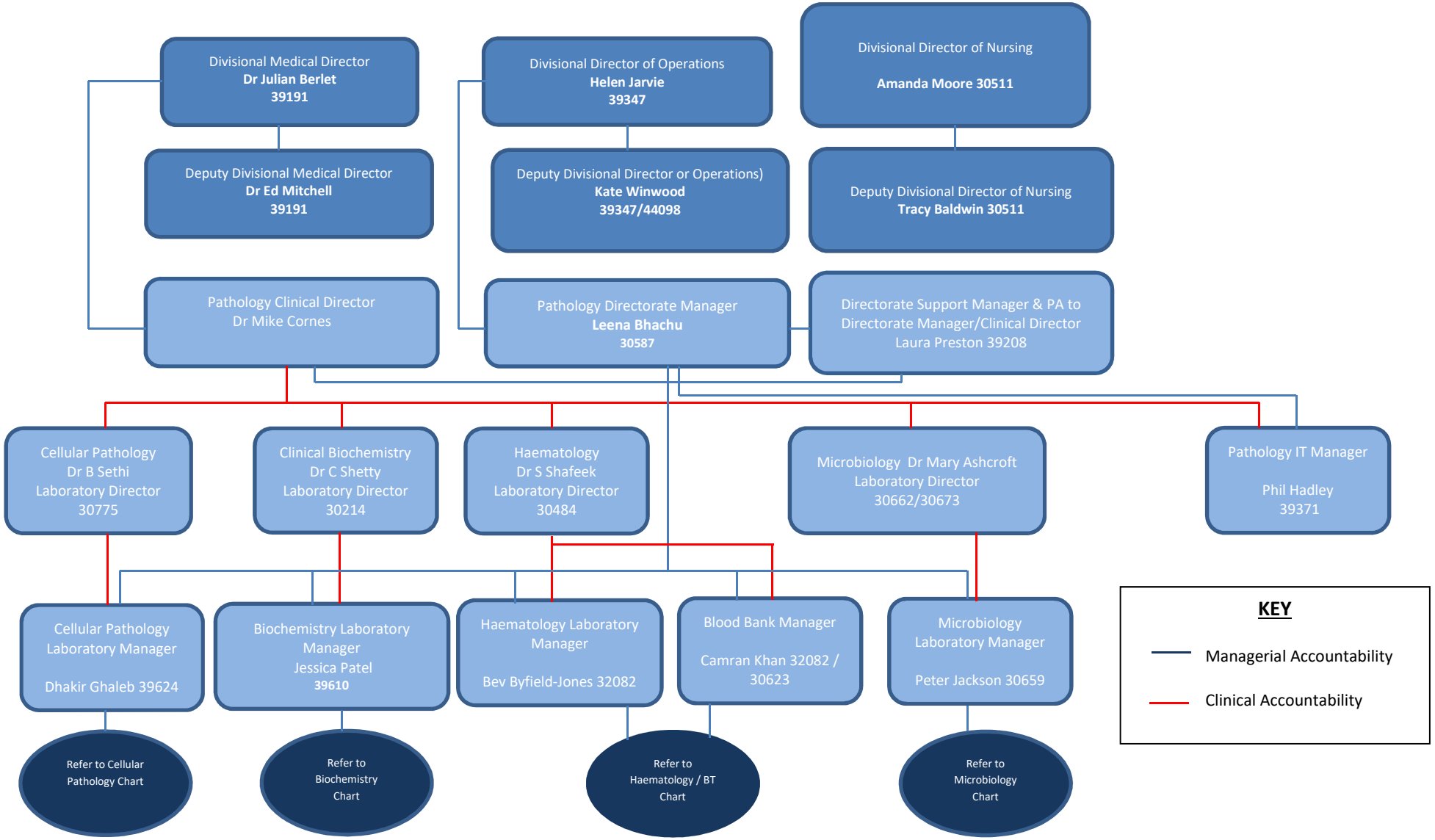
Pathology Organisational Chart



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	Key post-holders in Pathology Directorate, Worcestershire Acute Hospitals Trust.					
POSTS	**POSTHOLDERS BY DEPARTMENT**					
	Biochemistry	**Pre-Analytics**	**Haematology**	**Blood Transfusion**	**Cellular Pathology**	**Microbiology**
Divisional Medical Director	Dr Julian Berlet					
Divisional Director of Operations	Tracey Pearson					
Clinical Director of Pathology	Dr Mike Cornes					
Directorate Manager	Harlovleen Bhachu					
Lab Director	Dr C Shetty		Dr Shafeek		Dr B Sethi	Dr Mary Ashcroft
Deputy Lab Director	Dr M Cornes		Dr S Hebballi			Dr Emma Yates
Budget Holder	Dr Shetty		Dr Shafeek		Dr B Sethi	Dr Ashcroft
Laboratory Manager	Jessica Patel		Bev Byfield-Jones	Camran Khan	Dhakir Ghaleb	Peter Jackson
Budget Manager	Jessica Patel		Bev Byfield-Jones	Camran Khan	Dhakir Ghaleb	Peter Jackson
Deputy Laboratory Manager (site)	Hannah Spavin	Vacancy	Anthea Norwood (WRH) Louise Hepburn (AHR)	Emily Murphy/ Emma Loxley(WRH) Paul Weaver (AHR)	Sue Lovelock	Ruksarna Hussein-Jackson
Quality Manager	Jessica Patel		Bev Byfield-Jones		Alicia Philo	Stephanie Jankee
Quality Lead	Natasha Payne		Hamida Ara	Emily Murphy	Sue Lovelock	John Evans Jane Mulpeter
Health and Safety Officer	Jessica Patel		Bev Byfield Jones		Sue Lovelock	Peter Jackson
Training officer	Hannah Spavin		Anthea Norwood	Emma Loxley	Karen Williams	John Stanley
Deputy Training Officer(s)	n/a		Katie Downing		n/a	Emily Beattie
POCT manager	Emma Illingworth		n/a	n/a	n/a	n/a
POCT deputy (site)	Karen Mason-Towers (AHR)	n/a	n/a	n/a	n/a	n/a