

QUALITY MANUAL

This document together with specified procedures and manuals represents the Quality Management System of the **Willink Laboratory /Royal Manchester Children's Hospital**. It has been compiled to meet the requirements of the Clinical Pathology Accreditation UK Ltd (CPA) system and appropriate national and international standards. All procedures specified herein are **mandatory** for **all staff** within the *Willink Laboratory*

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1. GENERAL INFORMATION

1.1 INTRODUCTION TO THE QUALITY MANUAL (A6)

SCOPE OF THE QUALITY MANUAL

This Quality Manual describes the Quality Management System of the Willink Laboratory. Throughout the text there are references to CPA (UK) Ltd Standards and to management procedures, written to fulfil these standards. These are written in the form (Letter Number) e.g. (A6) for this manual, corresponding to the appropriate section in the CPA (UK) Ltd Standards For The Medical Laboratory.

This Quality Manual (A6) fulfils two functions. It describes the Quality Management System for the benefit of the laboratory's own management and staff, and it provides information for users and for inspection / accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of management, laboratory and quality procedures and forms. The sections of the Quality Manual are arranged so that they equate with the CPA Trust Ltd Standards (see table below). Under the title of each standard there is a brief description of the way in which the Willink Laboratory seeks to comply with the particular standard and references are given to appropriate procedures.

The sections of the standards should be seen to relate to each other in the following manner Section A describes the organisation of a laboratory and its quality management system which uses resources (Sections B, C and D) to undertake pre examination, examination and post examination processes (Sections E, F and G). The quality management system and the examination processes are continually evaluated and quality assured (Section H). The results feed back to maintain and, where required, improve the quality management process and to ensure that the needs and requirements of users are met.

STRUCTURE OF THE QUALITY MANUAL

The Quality Manual is structured as a series of interrelated chapters.

Sections in the Quality Manual	Section of CPA Standards
2 & 3	A Organization and quality management system
4	B Personnel
5	C Premises and environment
6	D Equipment, materials and reagents
7	E Pre examination process
8	F Examination process
9	G Post-examination process
10	H Quality assurance and evaluation

The aim of this Manual is to ensure that all staff adheres to the Quality Policy of the Laboratory **at all times**.

PROCEDURES, POLICIES AND MANUALS

More detailed procedures pertaining to the implementation of the quality policy in different areas of the Laboratory can be found in the following manuals:

- (a) **Management Procedure Manual:** which contains the procedures related to the laboratory operations involving several areas of activity. For example; Management Procedures for Obtaining Samples; Purchasing Materials; Stock Control; Health and Safety Manual; Laboratory User's Handbook etc.
- (b) **Analytical Manuals:** which comprises of the Standard Operating Procedures related to each test analysed within the Laboratory. For Example; White Cell β -glucosidase activity; Determination of Galactose-1-Phosphate concentrations in Red Blood Cells.
- (c) **IVD Manuals:** which comprises of the IVD Manuals for operating, maintaining, calibrating and controlling instruments within the Laboratory. For Example; IVD Manual Perkin Elmer LS 30 Luminescence Spectrophotometer.

1.2 DEFINITIONS AND ABBREVIATIONS

TERMS AND DEFINITIONS

All terms and definitions referred to in this manual are listed in the Management Procedure: Terms and Definitions.

1.3 LEGAL IDENTITY (A1)

The legal identity of the laboratory is defined in the Management Procedure: Legal Identity (A1).

1.4 CLINICAL ADVISORY SERVICES (E1, E6, F1, F2, G5, H4)

The laboratory provides a clinical advisory service to all referring clinicians. Advice on the suitability of tests and sample requirements is given by telephone, fax and email. The laboratory provides clinical and scientific advice to clinicians from the UK and around the world.

Clinical advisory services provided by the laboratory are described in the Management Procedures: Clinical Advisory Service; Turnaround Times, External Contractors and in the Laboratory User's Handbook.

1.5 RESEARCH AND DEVELOPMENT (A2, B3)

The laboratory takes part regularly in research projects to develop or evaluate new methods and methodologies. The laboratory gives support to clinical research within the unit, the Trust and internationally. The laboratory gives analytical and consulting support to clinical trials in the field of inborn errors of metabolism (primarily lysosomal storage disorders).

Details of the research and development policy of the laboratory is to be found in the Management Procedures: Research and Development and Medicinal Product Trials. (A2, B3)

A Research and Development annual report is prepared and updated by the Laboratory Head.

1.6 TEACHING (B3, B9)

The laboratory takes part in the teaching of students, technologists and trainees where applicable and strives to educate scientists and clinicians about the diagnosis of inborn errors of metabolism.

The laboratory policies for teaching and education are described in the Management Procedure: Teaching. (B3, B9)

1.7 EXTERNAL CONTRACTORS (E6)

The laboratory sends sample away for tests which are not performed in house. Only known experienced external contractors with a national or international reputation and proven expertise in the field demonstrated by peer reviewed publications are used.

The laboratory policy on the use of external contractors is defined in the Management Procedure: External Contractors.

2. QUALITY POLICY AND STRATEGY (A)

2.1 QUALITY POLICY OF THE PARENT ORGANISATION (A3)

The Willink Laboratory has its own Quality System which adheres to the guidelines of the Parent Organisation. As part of the Central Manchester and Manchester Children's Hospitals University NHS Trust, the Head of Laboratory periodically informs the Trust Quality Manager about any changes to the Willink Laboratories Quality System.

TRUST POLICIES AND PROCEDURES

The parent organisation policies and procedures are kept in the Trust Policies and Procedures files located in the Quality System Library. These are listed in the Trust Policies and Procedures Index at the front of the file. They can also be found on the Trust Intranet Site.

2.2 QUALITY POLICY AND STRATEGY OF THE LABORATORY (A3, A4, A5)

The quality policy and strategy of the Willink Laboratory is defined in the Quality Manual and the Management Procedures: Quality Policy and Strategy; Document Control, External Audit, Internal Audit, Internal and External Complaints, Quality Audit Program; Quality Control and Assurance and the Management Forms: Quality Policy; User Satisfaction Questionnaire, Audit Schedule, Audit Training, EQA Management, Horizontal Audit, Vertical Audit, Witness Audit, User Complaints, User Satisfaction, Nonconformities And Staff Suggestions.

2.3 DOCUMENT CONTROL (A3, A4, A6, A8, A9, C4, D)

The laboratory enforces strict document control for all procedures, manuals, COSHH assessments and forms. This is enforced by monthly audit arranged by the Quality Manager.

The production and control of documents within the laboratory is defined in the Management Procedures: Catalogue and Indexing of Museum Records, Document Control and Documentation.

2.4 CONFIDENTIALITY (C5, D2, E2, G3)

Information about patients is treated confidentially and measures to ensure this are defined in the Management Procedures: Confidentiality and Safety; Electronic Transmission of Results.

2.5 MANAGING IMPROPER INFLUENCE (A1)

The Laboratory and Trust have policies in place to prevent acceptance of inducements or favours designed to improperly influence members of the Laboratory Staff in the purchase of materials or otherwise unfairly favour any outside party.

Measures taken to protect against improper influence (corruption) are defined in the CMMC Trust Form: Ensuring Honesty and Integrity in the NHS to be found in the Quality Library and in the Management Procedure: Managing Improper Influence.

2.6 ANNUAL MANAGEMENT REVUE (A11)

The senior management of the Laboratory are responsible for conducting a review of the Quality System annually. This is arranged by the Quality Manager. The procedures are defined in the Management Procedures: Annual Management Revue and Documentation.

3 ORGANISATION AND MANAGEMENT (A)

3.1 EXTERNAL RELATIONSHIPS (A1)

THE PARENTAL ORGANISATION

There is a description of the position of the laboratory within the parent organisation. A flow diagram illustrating external relationships is contained in the Management Procedure: External Relationships.

EXTERNAL LIAISON OUTSIDE THE PARENTAL ORGANISATION

The laboratory Senior Scientists endeavor to promote good relations with users by liaison by telephone, e-mail and an annual user satisfaction questionnaire (Management Form: User Satisfaction Questionnaire). The immediate aims of such liaisons are to avoid samples being submitted unnecessarily, to encourage prompt submission of service requests for pertinent tests and promote optimal response times. Turnaround times are continually monitored. These processes are defined in the Management Procedures: Consultation and Efficacy; Clinical Advisory Services; Electronic Transmission of Results; Internal and External Complaints; Repertoire; Turnaround Times.

3.2 INTERNAL ORGANISATION STRUCTURE (A1, A7, B9, C5)

There is a description of the organisation and structure of the laboratory illustrated by diagrams in the Management Procedures: Management Structure of the Laboratory and Organisational Structure of the Unit.

There is a list of all functions and their tasks, responsibilities and competencies described in the Management Procedure: Laboratory Management.

A flow chart of the internal organisation is prominently displayed throughout the Laboratory. (Management Form: Organisational Structure of the Unit).

3.3 BUDGET MANAGEMENT (B2, C1, D1, D3)

The laboratory budget is controlled in cooperation with the Trust finance management.

The Laboratory policy of budget management is defined in the Management Procedure: Budget Control.

3.4 HEAD OF LABORATORY (B1)

The Head of the laboratory is a Clinical Biochemist who is recognised at a national level, registered with the Health Professions Council and is responsible for management and scientific direction.

The responsibilities and qualifications of the Head of Laboratory are detailed in the Management Procedure: Head of Laboratory.

3.5 PROFESSIONAL STAFF (B2, B8)

The laboratory staff include appropriate numbers of recognised laboratory specialists registered at national level. The staff have defined individual responsibilities for consultation, choice of methodology and quality of analyses as described in their individual job descriptions. There is a Quality Manager responsible for maintenance of the quality system and manual, reporting directly to the Head of Laboratory and senior management of the Unit. There is a Safety Officer. There are appropriate members of staff with the required training to ensure a satisfactory operation of service. Monthly Management and Laboratory Meetings are held to discuss organisation of services. All staff are involved in Laboratory Meetings and attendance is **mandatory**. Minutes are kept and audited. Both types of meeting must be held each month and this is monitored by means of a monthly check list (see Management Procedure: Monitoring Check Lists).

The structure and grades of professional staff in the Laboratory are defined in the Management Procedure: Professional Staff.

4 PERSONNEL (B)

4.1 JOB DESCRIPTION, DUTIES AND RESPONSIBILITIES (B2, B5)

There are job descriptions for different grades of staff and these are consistent with the management diagram.

All staff are issued with up to date copies of their job description. The duties and responsibilities of all staff are specified in their job descriptions. Copies of job descriptions are kept in Personal Portfolios.

Job descriptions are now prepared using the Trust template which is available on the intranet. This takes into account all the requirements of Agenda for Change and Knowledge and Skills Framework.

JOB DESCRIPTION (B5)

Information on the preparation of job descriptions for technical staff within the Willink Laboratory can be found in the Management Procedure: Preparation of Job Descriptions (B5).

The Quality Manager has the task of checking format and style when different people are writing job descriptions.

REFERENCE NUMBER

The reference number of a job description is a reference to the job and not the person employed in the job.

The Reference Number is issued by the Trust Human Resources Department.

4.2 SERVICE, LEAVE, RECRUITMENT AND SICKNESS (B3, B4, B6)

There is an adequate system of time scheduling of work hours, of leave planning and sickness substitution.

The laboratory management have an organisational plan, personnel policies and job descriptions that define qualifications and duties for all personnel. The Laboratory works within the Trust guidelines to define working hours and an absenteeism plan, including holidays, study leave, time off in lieu, part time working and sick leave. The Laboratory recruits staff according to the current Trust Human Resources Policy.

Procedures for these activities are defined in the Management Procedure: Service (B3, B4, B6)

4.3 STAFF ORIENTATION AND INDUCTION (B4)

New staff are given a comprehensive induction program both by the Trust and the laboratory. The latter is described in the Management Procedure: Laboratory Induction Program

4.4 STAFF APPRAISAL SYSTEM (B7)

Personal records are kept to ensure that there is evidence that each member of staff is regularly appraised, with clear statements of objectives as defined by their Knowledge and Skills post outline. This takes the form of an Annual Joint Review. The objective of this is to annually record an assessment of an employee's performance, potential and development needs. The appraisal is an opportunity to take an overall view of work content, loads and volume, to look back on what has been achieved during the reporting period and agree objectives for the future.

Details of the Joint Annual Review procedures are defined in the Management Procedure: Staff Appraisal System and utilise the appropriate Trust Forms. (B7).

The aims of the Joint annual Review are to discuss all aspects of the job away from pressures of daily work loads; to clarify how to contribute to the objectives and aims of the organisation; to identify job strengths and weaknesses; to clarify what is expected in the job, involving the holder in planning their work and their future and to recognise new ideas and tackle problem areas. It is an absolute responsibility of laboratory management to provide resources for staff to attend courses and international meetings in the field of their work. This is to ensure that they can continue their professional development and maintain their status as scientists registered with the Health Professions Council.

The Joint Annual Review has now been superseded by National Knowledge and Skills Framework.

5. PREMISES AND ENVIRONMENT (C)

5.1 LABORATORY SPACE (C1)

Laboratory space is subject to continual assessment and reallocation is performed as dictated by the needs of the service and its users.

Details of the laboratory space and areas of the Laboratory are contained in the Management Procedures: Laboratory Space and Main Areas of the Laboratory.

5.2 OFFICE SPACE (C1)

Details of available office space are described in the Management Procedure: Office Space.

5.3 FACILITIES FOR PERSONNEL (C2)

There are adequate facilities for staff relaxation. There is sufficient locker space and sanitary accommodation. Staff facilities are described in the Management Procedure: Staff Facilities.

5.4 FACILITIES FOR PATIENTS (C3)

Facilities for patients are provided within the clinical area of the Unit. There is no access for patients to the Laboratory.

5.5 SAFETY FACILITIES (C5)

The Laboratory seeks to ensure that there is a safe and secure working environment. Procedures are defined in the Management Procedures: Organisation and Management of Health and Safety, Security and Visitors to the Laboratory.

There are sufficient emergency exit facilities and fire protection facilities. There is safe storage for high-risk reagents. The Management Procedure: Infection Control gives details of precautions to protection against hazards from biological materials and the Manuals: Health and Safety Manual, Preparation, Use and Disposal of Cyanide, Chemical Waste Disposal.

Details of Health and Safety Procedures and Policies are present in the Health and Safety Manual. Health and Safety checklists for safety monitoring and forms for audit are described in this Manual.

The Health and Safety Manual is located in the Quality Library and in principal areas of the Laboratory. It is mandatory for all staff to read this manual and abide by its contents.

5.6 STORAGE FACILITIES (A10, C1, C4)

There are adequate and secure and regularly monitored refrigerators and freezers. For the storage of critical samples these are connected to an alarm system. There are adequate storage facilities for glassware, supplies, reagents, specimens and other materials.

Storage facilities are described in the Management Procedure: Storage Facilities.

5.7 PROVISION FOR THE WORKING ENVIRONMENT (C1, C4)

There is adequate provision for temperature control, power supply, and lighting (with back up facilities in case of power failure), ventilation, water and gases.

Information about this is detailed in the Management Procedure: Provision for the Working Environment

6. EQUIPMENT, MATERIALS AND REAGENTS (D)

6.1 PURCHASING AND ADMINISTRATION OF EQUIPMENT (D1)

There is a list of the major equipment in the Accreditation Database (Table: Equipment Inventory). This includes: identification, date received, manufacturer, costs and service arrangements.

Summary of documentation associated with each item of equipment is present in the relevant IVD Manual and includes IVD servicing and Adverse Incident forms.

Procedures for purchasing and administration of equipment are defined in the Management Procedure: Purchasing and Administration of Equipment, Procurement and Management of IVDs and Suppliers.

6.2 CALIBRATION (D3)

There are calibration procedures for basic equipment such as pipettes, balances and centrifuges.

There are procedures for calibration of major equipment laid down in IVD Manuals. Where practical, calibration materials should be used. The traceability of the calibration material should be stated.

The Management Procedure: Calibration describes the procedures to be followed for calibration of equipment. These are followed in conjunction with General Standard Operating Procedures for calibration of pipettes, temperature control appliances and balances.

6.3 INSTRUCTIONS FOR USE AND MAINTENANCE (D1)

There are IVD Manuals describing the use and operation of major instruments including periodic maintenance.

There are logbooks for all major equipment in which maintenance and trouble shooting are recorded.

The Management Procedures: IVD Manuals and IVD Log Books describe how these documents should be written and updated.

6.4 COMPUTER FACILITIES (D2)

Computer hardware and software are provided by the Trust and governed by the Trust I.T. department. Computer facilities within the Laboratory are defined in the Management Procedure: Computer Facilities. The computer hardware is detailed on the Accreditation Database: Table Computer Equipment.

6.5 ADMINISTRATION OF MATERIALS AND REAGENTS (D3)

Laboratory procedures for administration of materials and reagents are defined in the Management Procedures: Administration of Materials and Reagents, Inventory Control, Purchasing and Storage of Hazardous Materials, Suppliers and Storage Facilities. Full COSHH assessments are available for all chemicals and reagents used in the Laboratory. The preparation of these is described in the Management Procedure: Preparation of COSHH

Assessments. The manual: Chemical Waste Disposal, governs disposal of all waste products from the Laboratory.

6.6 SAFETY AND ENVIRONMENT (A10, C5, D1)

All matters concerning safety and the environment are defined in the Health and Safety Manual and in the Management Procedures: Control of Clinical Material, Dealing Safely with Spillages, Disposal of Specimens and Waste Material, Infection Control, Purchasing and Storage of Hazardous Materials, Risk Assessment, Safe Disposal of Leaking or Broken Samples, Safety and the Environment and Storage Facilities.

7. PRE EXAMINATION PROCESS (E)

7.1 USER INFORMATION (E1)

The user information system is the Laboratory User's Handbook.

The Handbook gives details of all tests undertaken in the Laboratory along with reference ranges and turnaround times. Details of sample requirements are also provided along with guidance as to the suitability of tests. Contact names are included for clinical advice and guidance. The Laboratory User's Handbook is also available on the internet at www.mangen.co.uk.

7.2 CONSULTATION AND EFFICACY (E1, E6, F1, F2, G5)

Consultation concerning efficacy of tests, repeat frequency and required type of specimen is available at all times. There are regular meetings of professional staff with clinical staff regarding use of the laboratory and for the purposes of consultation on scientific matters. The professional staff participate in clinical rounds enabling consultation on efficacy in individual cases as well as in general.

The Laboratory User's Handbook provides contact details for consultation.

Details of the consultation services of the Laboratory are contained in the Management Procedures: Consultation and Efficacy, Clinical Advisory Services and External Contractors.

7.3 REPERTOIRE (E1)

Information about the Laboratory's repertoire, reference values and specifications is contained in the Management Procedures: Repertoire, Methodologies and in the Laboratory User's Handbook.

7.4 REQUEST PROCEDURES (E2)

There are procedures for urgent and routine requests. These are defined in the Management Procedures: Request Procedures and Prioritising Samples for Analysis.

7.5 INFORMATION AND PREPARATION OF PATIENTS (E1)

There is information for patients and parents about special diets or other preparatory measures provided by clinical or nursing staff in the downstairs clinical area. There is no access to the laboratory for patients. The Laboratory does not provide information directly to patients. Information provided is detailed in the Management Procedure: Information and Preparation of Patients.

7.6 SPECIMEN COLLECTION (E3, E5)

Details of the procedures to be followed for the collection and identification of samples are defined in the Management Procedure: Specimen Collection.

7.7 SPECIMEN TRANSPORT AND HANDLING (E3, E4, E5)

The Laboratory's policy on specimen transport follows the Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens. WHO/EMC/97.3 1997 and is also detailed in the Management Procedure: Sample Reception. This includes criteria for rejection of samples and referral of samples to Reference Laboratories. Such referrals are detailed in the Management Procedure: External Contractors. Guidelines for adequate transport of samples are also to be found in the Laboratory User's handbook.

The procedure for prioritising samples received is defined in the Management Procedure: Prioritising Samples for Analysis.

7.8 EXPERIMENTAL TESTING (F1)

Policies and procedures for experimental testing are defined in the Management Procedure Experimental Testing. Testing will be performed according to strict protocols

7.9 MEDICINAL PRODUCT TRIALS (A2)

The Laboratory participates in medicinal product trials particularly in the field of lysosomal storage disorders. Procedures for medicinal product trials are defined in the Management Procedure: Medicinal Products Trials.

7.10 CONFIDENTIALITY AND SAFETY (D2, E2, G2, G3, C5)

Measures taken to ensure confidentiality and safety within the Laboratory are described in the Management Procedure: Confidentiality and in the Health and Safety Manual.

8. EXAMINATION PROCESS (F)

8.1 VALIDATION (F1)

Validation requirements of new analytical procedures are defined in the Management Procedure: Validation

8.2 CALIBRATION AND TRACEABILITY OF METHODS (F2, F3)

Calibration frequency and calibration methods are stated in the standard operating procedures. Laboratory procedures are defined in the Management Procedure: Calibration and Traceability of Methods.

8.3 STANDARD OPERATING PROCEDURES (F2)

Standard Operating procedures for all analyses are available in written and electronic form. Laminated working procedures are available at the bench. A list of the desired content is present in the Management Procedure: Standard Operating Procedures.

8.4 QUALITY CONTROL AND ASSURANCE (F3, H5)

Laboratory procedures concerning quality control and assessment are defined in the Management Procedures: Internal Audit, External Audit, Quality Control and Assurance and Quality Audit Program

8.5 AUTHORISATION (F2)

To ensure that results are authorised by suitably qualified staff before release from the Laboratory the Management Procedure: Authorisation is followed

8.6 ARCHIVING (A9)

Details of the methods of archiving results and procedures are given in the Management Procedures: Archiving Reports, Control of Clinical Material and Record Retention.

8.7 DISPOSAL OF SPECIMENS AND WASTE MATERIAL (C5)

Patient materials should be considered and treated as potentially infectious. Specimens, needles and blood-contaminated disposables are disposed of in special containers and treated as infectious waste. The Laboratory procedures on disposal of such items are defined in the Management Procedures: Dealing Safely with Spillages, Disposal of Specimens and Waste Material, Infection Control, Safe Disposal of Leaking or Broken Samples and the Health and Safety Manual.

9. POST EXAMINATION PROCESS (G)

9.1 REPORTING PROCEDURES (G1, G2, G3)

The Laboratory procedure for reporting results is defined in the Management Procedures: Reporting Procedures and Electronic Transmission of Results, Reporting Critical Values.

9.2 AMENDMENT PROCEDURES (G4)

Should it become necessary to change any reported results the Management Procedure: Amendment Procedures should be followed.

9.3 TURNAROUND TIME (E1, H4)

Information about turnaround times is documented in the Laboratory User's Handbook and the Management Procedure: Turnaround Times.

9.4 REFERENCE VALUES (E1, G2)

Information about reference values is located in the Laboratory User's Handbook and the Management Procedure: Reference Values. Where applicable, reference values are included in the report.

9.5 INTERPRETATION AND CONSULTATION (E1, G5)

Consultation on results and advice on further investigations is available at all times.

Laboratory procedures for interpretation and consultation on results and analyses are defined in the Management Procedures: Interpretation and Consultation and Reporting Critical Values.

9.6 ARCHIVING (A9)

Details of the methods of archiving results and procedures are given in the Management Procedures: Archiving Reports and Record Retention.

9.7 CONFIDENTIALITY (D2, E2, G2, G3)

Measures taken to ensure confidentiality within the Laboratory are described in the Management Procedure: Confidentiality and Safety.

10. EVALUATION OF THE QUALITY SYSTEM (H)

10.1 INTERNAL AUDIT (H3, H4, H6)

There is a system of planned internal audits defined in the Management Procedures: Creating an Audit Schedule, Internal Audit and Quality Audit Program. .

10.2 INTERNAL AND EXTERNAL COMPLAINTS (H2, H6)

Systems for reporting and recording internal and external complaints are defined in the Management Procedures: Handling Nonconformities and Internal and External Complaints

10.3 EXTERNAL AUDIT (A3, H5)

The Laboratory procedures concerning external audit are defined in the Management Procedure: External Audit.

Application for Accreditation to the C.P.A.(U.K.) is a priority and major component of external audit.

10.4 EVALUATION AND CONTINUAL IMPROVEMENT (A3, A5, H1, H5, H6)

The management of evaluation and continual improvement is the prime responsibility of the Quality Manager along with other personnel within the Laboratory. The procedures followed are defined in the Management Procedures: Management of Evaluation and Continual Improvement and Quality Control and Assurance.

Appendix 1

WILLINK LABORATORY QUALITY POLICY

The Quality Policy of the *Willink Biochemical Genetics Unit* is given below

The Willink Laboratory is committed to providing a high quality service and considering the requirements of its users

To meet the needs of users, the Willink Laboratory will:

- Operate a quality management system to integrate the organisation, procedures, processes and resources.
- Set quality objectives and plans.
- Ensure all personnel are familiar with this policy
- Commit to the health, safety and welfare of all staff.
- Ensure visitors are treated with respect and consideration given to their safety.
- Uphold professional values and commit to good professional practice.
- Comply with Environmental legislation.

The Laboratory will comply with standards set by the CPA Trust Ltd accreditation system and commit to:

- Staff recruitment, training, development and retention at all levels to provide an effective service to users.
- The proper procurement of equipment and other resources.
- The collection, transport and handling of all specimens in such a way as to ensure correct performance of examinations.
- The use of examination procedures that will be the highest quality for all tests performed.
- Report results of examinations in such a way as to be timely, accurate, confidential and clinically useful.
- Recommend appropriate use of tests.
- Develop new treatments by participating in clinical trials.
- Undertake a reference laboratory role on national and international level.
- Provide information on treatment and research.

- Integrate research and service activities.

Assessment of user satisfaction together with internal audit and external quality assessment will be used to implement continuing quality improvement.

The Laboratory Head has overall responsibility for implementing the quality policy in the laboratory.

The Quality Manager has overall responsibility for the control of quality and shall advise on and monitor all aspects of quality within the laboratory.

Appendix 2

SENIOR MANAGEMENT STRUCTURE OF THE LABORATORY

