West of Scotland Specialist Virology Centre

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| Any further amendments will require this document to be updated to the next version. This new version will incorporate all the above listed amendments plus any change requests raised in Q-pulse.Amendment history is available in Q-pulse |

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# Introduction

The West of Scotland Specialist Virology Centre is UKAS accredited to **ISO 15189:2012** - Reference number 9319

The full scope of accredited tests offered is available on the UKAS website <http://www.ukas.com>

Any tests reported by the laboratory which are NOT on this scope are clearly identified as such on the report; see also 5.8 reporting of results.

The laboratory has a quality management system in place to direct and control the laboratory with regard to quality. This system has established a quality policy and quality objectives and is designed to achieve those objectives. This is done through a process of quality planning which is the part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil quality objectives.

The Quality Management system ensures that:

* Laboratory management establishes written quality objectives, which are consistent with the quality policy and are regularly reviewed.
* This quality manual is reviewed regularly, updated as required and any changes communicated to all personnel concerned.
* There is a quality manager who has responsibility for the implementation and maintenance of the quality management system.
* There is a process of document control.
* The control of process and quality records is according to current legislation, regulations and guidelines.
* The control of clinical material is according to current legislation, regulations and guidelines.
* Laboratory management conducts an annual review of the laboratory’s quality management system and all its services.

This Quality Manual is cross-referenced to the procedures and forms used by the WoSSVC.

The layout of this Quality Manual follows that of the ISO 15189:2012 Standard for Medical Laboratories and is reviewed at the Annual Management Review.

In order to achieve an effective quality management system, there is a structure of documentation which covers all process undertaken by the laboratory

# General information

##

## The West of Scotland Specialist Virology Centre (WoSSVC)

The West of Scotland Specialist Virology Centre is part of the Department of Laboratory Medicine within NHS Greater Glasgow and Clyde Health Board.

Contact details:-

West of Scotland Specialist Virology Centre

##### Level 5, New Lister Building.

Glasgow Royal Infirmary,

10 – 16 Alexandra Parade,

Glasgow, G31 2ER.

###

### Tel: +44 (0)141 201 8722

Fax: +44 (0)141 201 8723

Email: west.ssvc@nhs.net

Information on the services provided and contact telephone numbers are available through the NHS Greater Glasgow and Clyde website:-

 <http://www.nhsggc.org.uk/virology>

 Core working hours are:

 08:45- 17.00 Monday - Friday
09:00 – 13.00 Saturday

At all other times the “on call” virologist can be contacted *via* the hospital switchboard (0141 211 4000).

Advice on all aspects of clinical virology is available 24 hours a day, 7 days a week.

 The West of Scotland Specialist Virology Centre at Glasgow Royal Infirmary:-

* Provides routine diagnostic services to patients with viral illnesses in the West of Scotland, and specialist testing facilities for patients outside this area.
* Provides a wide range of molecular diagnostic tests using automated extraction procedures, a full serology service and specialist virus detection systems.
* Provides sequencing for genotypic resistance markers, viral typing and molecular epidemiology.
* Is the national surveillance laboratory for viral respiratory infections for Scotland.
* Is a Health Protection Scotland (HPS) specialist testing laboratory for blood borne viruses.
1. **Introduction to the Quality Manual.**

This Quality Manual describes the Quality Management System (QMS) of the WoSSVC.

This manual fulfils two functions.

* It describes the QMS for the benefit of the laboratory’s own management and staff.
* It provides information for users and for inspection/accreditation bodies.

This Quality Manual may be regarded as the index volume to the WoSSVC management, laboratory, clinical and quality procedures. Subsequent sections of this Quality Manual are arranged so that they equate with sections of ISO 15189:2012. There is a brief description of the way in which the WoSSVC seeks to comply with the particular section of the standard and references are given to appropriate procedures.

The quality management system and the examination processes are continually evaluated and quality assured. 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.

The quality manual is reviewed on a yearly basis and knowledge of the quality manual is ensured by Q-Pulse e-mail document acknowledgement

4.0 Management requirements

#

# 4.1 Organisation and management responsibility

**4.1.1.1 General**

The organisation and management of the WoSSVC is detailed in this manual. The laboratory accepts its responsibility to meet the requirements of ISO15189:2012 when carrying out work at its permanent facility at the New Lister Building, Glasgow Royal Infirmary.

4.1.1.2 Legal entity

The West of Scotland Specialist Virology Centre is part of the acute services division of NHS Greater Glasgow and Clyde (GG and C).

The centre provides a comprehensive and efficient diagnostic, clinical advisory and educational service of the highest quality to the Division hospitals, other hospitals and Primary Care services within and beyond the Greater Glasgow area. In addition to our routine repertoire we are part of The Scottish National Blood Borne Virus Specialist Testing Service which provides specialist testing for blood borne viruses for Scotland. We are also responsible for testing respiratory specimens for national surveillance purposes.

The North Glasgow Hospital Division of GG and C Health Board is the organisation legally responsible. The Laboratory is encompassed under the Directorate of Clinical Microbiology, which offers diagnostic services and clinical liaison including infection control to Greater Glasgow and Clyde and other Health Boards

ED-228 Clinical negligence and other risk indemnity

ED-229 CNORIS – Confirmation of Cover 2016/17

## Relationship to the Host Organisation

The Microbiology Management Team (MMT) NHS Greater Glasgow and Clyde consists of:

Head of Service, General Manager, Assistant General Manager, WoSSVC Head of Department and Technical services manager, a Lead Clinician from microbiology laboratories in the north sector, the south sector, the Argyll and Clyde sector and Microbiology Technical Services Manager.

Microbiology, together with 5 other laboratory disciplines, is part of the Department of Laboratory Medicine. The Diagnostics Directorate is formed from Laboratory Medicine and Diagnostic Imaging.

##

#### **NHSGGC Management Team**

Board Chief Executive – Jane Grant

#### **Acute Division**

Chief Operating Officer (acting) Johnathan Best

#### **Diagnostics Directorate**

Director – Aileen MacLennan

Associate Medical Director – Dr Rachael Green

#### Diagnostic Imaging

HoS

Biochemistry

HoS

Genetics

HoS

Pathology

HoS

Haematology

HoS

Immunology

#### **Head of Service**

Microbiology

**Prof. Brian Jones**

#### **Department of Laboratory Medicine**

General Manager – Isobel Neil

Clinical Director – Dr. Ann Cruickshank

Assistant General Manager – Bernadette Findlay

**West of Scotland Specialist Virology Centre**

Head of Department – **Dr. Rory Gunson**

4.1.1.3 Ethical conduct

NHSGG and C Standing Financial Instructions and Fraud Policy [external documents ED-13 andED-14 in Q-Pulse] ensure that work quality is not affected by external pressure, that users’ confidential information is protected and that the department cannot undertake activity that would diminish confidence in its impartiality or operational integrity.

Any potential conflicts of interest must be declared

See Trust policies:

Register of Interests Policy

<http://www.staffnet.ggc.scot.nhs.uk/Applications/GAD/Pages/Summary.aspx>

Information Governance policy

<http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Documents/NHS%20GGC%20Clinical%20Governance%20Policy%20June%202016.pdf>

Conduct of individual staff is governed by their Contract of Employment, Professional bodies (General Medical Council, HCPC), Staff Code of Conduct, Standing Financial Instructions, Caldicott report and the Data Protection Act. Staff are made aware of this information at induction and on an ongoing basis as part of the Ethics, equality and diversity Competency MAN-F-337

All staff attends Statutory Mandatory Training provided by GG and C every three years

Users’ confidential information is also governed by our procedure MAN-SOP-024 ‘Management of data and information’ and by NHSGG and C I.T. Policy. For report confidentiality, see MAN-SOP-001 and MAN-Q-033 (the telephoned report).

4.1.1.4 Laboratory director

The West of Scotland Specialist Virology Centreis under the professional direction of

Head of Department Dr. Rory Gunson Consultant Clinical Scientist MSc, PhD, FRCpath

Competence is demonstrated in the following ways:

* Participation in Continuing Professional Development (CPD).
* Membership of the Royal College of Pathologists
* Appointment as a consultant by an Advisory Appointments Committee
* Evidence of continuing practice in the specialty
* Recorded attendance at regular departmental meetings to review service issues and to set quality objectives

The responsibilities of the Head of Department include a range of functions relevant to the services offered by the WoSSVC.

Some functions are delegated to members of the Management Group however the Head of Department maintains the ultimate responsibility for the operation of the laboratory.

All non-clinical organisational and administrative duties relevant to the services provided are delegated to Stephen Hughes, the Technical Services Manager

Duties and responsibilities of Head of Department include but are not limited to:

AGM – Assistant General MANAGER

TSM – Technical services Manager

SL – Site Lead

Budget planning and financial management – delegated to AGM + TSM

Effective liaison with patient population and the healthcare community

Effective liaison with accrediting bodies and SLE providers – in agreement with AGM

Ensure laboratory is staffed appropriately to provide a service which meets the needs and requirements of users – in conjunction with TSM

Ensure the implementation of the quality policy – delegated to Quality Manger

Ensure a safe laboratory environment – in conjunction with all staff

Serve as a contributing member of the medical staff for NHSGG and C

Ensure appropriate clinical advice is provided with respect to the choice of examinations, use of the service and interpretation of results

Select and monitor laboratory suppliers – delegated to TSM + SL

Select referral laboratories and monitor the quality of their service – in conjunction with Quality Manager

Provide PDP for staff and opportunities to participate in relevant activities out with the laboratory – in conjunction with TSM

Define, implement and monitor standards of performance and quality improvement of the WoSSVC service – in conjunction with Quality Manager

Monitor all work performed in the laboratory to determine that the information generated is clinically relevant.

Address any complaint, request or suggestion from users or staff – in conjunction with TSM + QM.

Develop a Contingency plan for emergency situations (resilience) – in conjunction with TSM + SL. There is a plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable. See MAN-SOP-023 Risk Management (Business continuity) for details.

Plan and direct research and development

4.1.2.1 Management commitment

Management have shown commitment to the development and implementation of the QMS and to continually improving its effectiveness by:-

* Ensuring laboratory personnel are aware of the importance of meeting the needs and requirements of users as well as regulatory requirements by having these as standing agenda items at management meetings, staff meetings and by using CPD accredited quizzes.
* Establishing a quality policy see MAN-Q-002 an original copy signed by the director is displayed at the specimen reception desk. The Quality Policy is reviewed for suitability and effectiveness at Annual Management review meetings.
* Establishing quality objectives and plans. See MAN-F-216 for the current version. Quality Objectives and Plans are also a standing agenda item at the monthly Compliance meetings. Management ensures the setting of Plans and Objectives by following the Quality Procedure MAN-Q-065.
* Responsibilities, authorities and inter-relationships of all personnel are defined under section 4.1.2.5
* Communication processes are described under section 4.1.2.6.
* Appointment of a Quality manager shared on a 50:50 basis with the Scottish Microbiology Reference Laboratories (Glasgow).
* There is an annual management review of the year conducted at the beginning of the following calendar year. MAN-Q-067 defines the conduct of the annual management review.
* Competency assessment is a key component of our training programme. It is assessed and reviewed according to criteria set down in MAN-SOP-032.
* Management ensure adequate resources are available by careful selection, induction and training of appropriately qualified staff.
* Accommodation is a recently completed state-of-the-art laboratory in the New Lister Building
* Examination processes are verified and validated before use. Processes are continuously monitored by using IQC and EQA checks.
* Equipment and consumables are procured and maintained using the Abbott Managed Service Contract.
* Pre-examination information for users is contained in the departments website:

 <http://www.nhsggc.org.uk/virology>

4.1.2.2 Needs of users

There is daily interaction with service users via phone calls and e-mails

The needs of the users are kept under constant review, and are a standing agenda item at management meetings. The procedure is defined in ‘Needs and requirements of users’ MAN-Q-068.

They are monitored in a variety of ways including the distribution of the User Satisfaction Survey (most recent April 2016), meetings with specific key users and by individual contact between the Head of department, TSM, Site Lead, Medical Consultants and others who use the service.

Outcomes from these interactions are translated into requirements, which form the focus of objective setting and planning within in the Quality Management System. Assessment of user satisfaction and complaints is conducted on a regular basis and consideration of the findings discussed between the Head of department, TSM, Site Lead, Quality Manager and Medical Consultants. They also form part of the Annual Management Review.

Needs and requirements of users is a commitment in our Quality Policy MAN-Q-002.

Information for users, including turnaround times, is contained in the user manual accessible *via* the department’s NHS Greater Glasgow and Clyde website:- <http://www.nhsggc.org.uk/virology>

There is a permanent user feedback field on this website for any comments/suggestions users may have.

Medical, senior scientific and BMS staff are in daily contact with users to provide support and advice.

Frequent meetings are also held with consultants of various clinical specialities *e.g*. ITU units, Transplant units (renal, bone marrow and cardiac), infectious disease and respiratory units. Consultant staff or their deputies attend weekly ward rounds.

# 4.1.2.3 Quality Policy

The Quality Policy of the West of Scotland Specialist Virology Centre is published as a separate controlled document (MAN-Q-002) which is displayed at the laboratory entrance. The purpose of the quality policy is to set down, for the information of staff and users, the course of action and measures that the WoSSVC has taken in order to provide a service of the highest quality.

**4.1.2.4 Quality objectives and planning**

The Laboratory Management Group defines the quality objectives of the laboratory and is responsible for ensuring that plans are made to meet these objectives. The management review, which is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising objectives and plans and the functioning of the quality management system. See MAN-Q-065 (setting plans and objectives) and MAN-F-216 (Quality plans and objectives).

4.1.2.5 Responsibility, authority and interrelationships

## Organisation and Responsibilities within the West of Scotland Specialist Virology Centre

Management Group

Assistant General Manager Bernadette Findlay

Admin and Clerical

BMS

Specialist BMS

Consultant

Clinical Scientist

Dr. Rory Gunson

Head of Department

Technical Services Manager

Stephen Hughes

Quality Manager

Jane McOwan

Consultant Dr.Eleri Wilson-Davies

BMS Site Lead

Ann Hawthorn

Data Analyst

Specialist Registrar

Consultant

HCSW

Support

Research Scientist

Clinical Scientist

Senior Specialist BMS7.

AandC Band 5

Office manager

Microbiology

AandC Band 4

Band 3

Virology

AandC Band 4

Band 3

Band 2

1

Ref Labs

AandC Band 4

The Laboratory has five teams. Overall clinical responsibility for these teams lies with Medical and Scientific Consultants

1. **Molecular**
2. **Serology**
3. **Specialist testing**
4. **Office**
5. **Laboratory Support**

The Consultants’ and Technical Services Manager’s time is allocated as required.

Clinical Scientist

Specialist Registrar

Clinical Reporting

**Molecular Team**

Consultant Head of Department

Technical Services Manager

Senior Specialist BMS (Site Lead)

Senior Specialist BMS (TM)

Specialist BMS

HCSW

**Serology Team**

Technical Services Manager

Consultant Clinical Virologist (BBV)

Senior specialist BMS

(Site Lead)

HCSW

Senior Specialist BMS (TM)

Specialist BMS

Clinical Scientist

Specialist Registrar

Clinical Reporting

**Specialist Testing Team**

Consultant Head of Department

Consultant Clinical Scientist

Technical Services Manager

Clinical Scientist

Senior specialist BMS (TM)

Research Scientist

HCSW

Laboratory Support Team

Office Team

Technical Services Manager

Technical Services Manager

Quality Manager

Senior Specialist BMS (Site lead)

Senior Specialist BMS

(Site lead)

Data Analyst

A and C Band 5 Office Manager

Specialist BMS

A and C Band 3

A and C Band 2

A and C Band 4

HCSW

Head of Department

The Head of Department is a competent individual with responsibility for, and authority over the whole laboratory. The Head of Department is the individual who ensures, on behalf of the laboratory, that all aspects of the laboratory including management organisation and quality, personnel, premises and environment, equipment, information systems, materials and pre- and post- examination processes function correctly.

This is achieved in co-ordination with the Technical Services Manager, Site Lead, Quality Manager, Technical Managers, Biomedical Scientists and Clinical Support Workers.

Technical Services Manager

The Technical Services Manager is the individual who has overall responsibility, for the management of all aspects of the laboratory including, quality, personnel, premises and environment, equipment, information systems and materials and that examinations both pre and post function correctly. This is achieved in coordination with the Head of Department, Site Lead, Quality Manager, Technical Managers, Biomedical Scientists and Clinical Support Workers.

Site Lead

The Site lead is the individual who ensures, on behalf of the laboratory, that the management of all aspects of the laboratory including, quality, personnel, premises and environment, equipment, information systems and materials and examinations both pre and post function correctly. This is achieved in coordination with the Head of Department, Technical Services Manager, Quality Manager, Technical Managers, Biomedical Scientists and Clinical Support Workers.

Quality Manager

The quality manager is the individual who ensures, on behalf of the laboratory management, that the quality management systems function correctly. This is achieved in co-ordination with the Head of Department, Technical Services Manager, Site Lead, Technical Managers, Biomedical Scientists and Clinical Support Workers.

The following personnel have designated roles within the WoSSVC:-

|  |  |  |
| --- | --- | --- |
| **Staff member** | **Post** | **Deputy** |
| Dr. Rory Gunson | 1. Head of department2.Head of molecular diagnostics in microbiology. 3.Director of the West of Scotland BBV lab,4. Training Co-ordinator  (Clinical scientist staff). | 1.Dr. E. Wilson-Davies2.Dr Samantha Shepherd/Dr Amanda Bradley-Stewart3.Dr Amanda Bradley-Stewart4. Dr Samantha Shepherd |
| Dr. Eleri Wilson-Davis | Training Co-ordinator(Medical staff). | To be appointed (vacant consultant post) |
|  Alison Devanney | Training Co-ordinator (BMS and HCSW staff). | Elaine Murray |
| Stephen Hughes | 1. Technical Services Manager.2. Safety Officer.3. Training Officer (BMS and HCSW staff). | Ann Hawthorn – Site Lead |
| Jane McOwan | Quality Manager. | Sally Taylor |
| Graeme Gillespie | 1. I.T. Support.2. Staff Side Representative. | 1.Eileen Campbell |
| Anthony Bimpson | Health and Safety Co-ordinator. | Jane McOwan |

4.1.2.6 Communication

## The communication and committee structure of internal and external communications is shown below. The committee structures within Level 5 of the New Lister Building has been reviewed with the intention of simplifying and streamlining activity in areas common to both departments i.e. West of Scotland Specialist Virology Centre, Scottish Microbiology Reference Laboratories, Glasgow.

## Microbiology Management Team – Greater Glasgow and Clyde

Every 4-6 weeks.

Feedback from this meeting is given by Technical services manager/Quality Manager to senior staff at Senior Scientist’s meeting

Attended by

Clinical Director,

General Manager,

Assistant General Manager,

Head of Microbiology Services,

Lead Microbiologists,

Head of Department WoSSVC,

Consultant staff WoSSVC,

Technical Services Managers

Integrated System Managers.

Meetings are held in “partnership” with staff side representatives.

 **WoSSVC / SMRL Compliance / Operational Team Meeting**

Every 4-6 week

Minutes can be accessed via 1.Virology /SVC meetings

Attended by:

Technical Services Manager

Site Leads

Quality Manager

Training Officers

IT managers

Health and Safety Officer (TSM)

Chaired by the Technical Services Manager

Compliance reports are reviewed and any issues discussed and actioned - reports include Review of Quality Objectives and Plans Needs and Requirements of Users, Non-conformances/Datix/Complaints, Health and Safety including CL3, IQC and EQA results and IT Data Quality.

This report covers any issues arising from the quality management system and also all areas of the laboratories pre- examination, examination and post examination processes.

Operational issues relating to WoSSVC and SMiRL are also discussed and actioned

**Senior Scientist’s meeting**

Every 4-6 weeks

Minutes can be accessed via 1.Virology/SVC meetings

Attended by:

Consultant staff

Technical Services Manager

Site lead

Quality Manager

Technical Managers

Office manager

Chaired by the Technical Services Manager, and is attended by the site lead, team leaders (BMS, Clinical Scientist and clerical staff) and the Quality Manager. All operational issues are discussed.

#### The Quality Manager presents a compliance report which includes trending of non-conformances and turnaround times for tests. The audits for the coming month will be discussed and scheduled with the appropriate team leaders.

#### Team leaders present a section report – this includes measure of uncertainty with trending of IQC/QC results, EQA results and Audit findings discussed.

Any issues arising from these reports are actioned.

This meeting deals with any issues arising from the quality management system and also all areas of the laboratories pre-examination, examination and post examination processes.

#### Where appropriate, information from the Management Group will be discussed by the Technical Services Manager, and any issues raised here can be discussed at the relevant meeting, *e.g*. Clinical Group.

#### Information from this meeting is cascaded to individual team members at regular informal meetings within each section.

**All Staff Meeting – Friday morning update meeting**

Weekly:

 Notes from the meeting are e-mailed to all staff members and can be accessed via 1.virology /SVC meetings

Full staff meetingsare held weekly and notes are taken. These meetings are chaired by the Technical Services Manager or Site Lead, and act as a channel for informing staff of proposed changes, or other relevant information that may affect management structure or laboratory procedures. It is also an opportunity for staff side and all staff to raise issues or complaints relevant to the efficient running of the laboratory. On the first Thursday of each month the TSM holds a joint meeting with all WoSSVC and Scottish Microbiology Reference Laboratory staff.

Any staff suggestions raised through documents placed in the staff suggestion box are recorded in Q-pulse and discussed at this meeting. Outcomes are also recorded in q-pulse

**Health and Safety Committee**

Four times a year.

Minutes can be accessed via common/SVC meetings

The Laboratory representatives are:-

Technical Services Manager

Site Leads

Quality Manager

Health and Safety Co-ordinator

The Health and Safety Committeemeets quarterly and is chaired by the TSM. A representative from each grade of staff of the laboratory attends. The meeting is minuted. Staff may ask a committee member to raise a concern at the next meeting. All safety issues are considered, including accidents (and near misses) and audits of the premises. Issues raised are passed to the relevant Technical Services Manager for action, or discussed at the Microbiological Operational Management Group, as appropriate.

Fire training is provided as yearly on-line “LearnPro” tutorials and Trust wide Statutory and mandatory training every three years – this includes moving and handling, Health and Safety and infection control.

**The Virology Management Group** . Held monthly when possible. Action tracker is recorded. The group meets to allow discussion of ongoing or urgent matters relating to service delivery. Items discussed include staffing (including training), operational issues (*e.g*. fabric of the building), quality and development/ongoing projects.

Issues raised at the monthly Microbiology Operational Management Meeting are reported back to this group.

**The Clinical Group** meets once per week and is un-minuted. It is chaired by a Senior Registrar and is attended by all staff involved with clinical reporting, the Technical Services Manager and any visiting trainee medical / scientific staff. All clinical issues are discussed. A short, daily meeting occurs when ongoing clinical issues are discussed with relevant reporting staff, and consultant staff are present to give advice.

Ongoing training and development plus quality and accreditation issues are discussed at both the Clinical Group and the Senior Scientists Meeting.

**IT meeting.** Held monthly when possible. Action tracker are recorded. It is chaired by the Technical Services Manager and is attended by Site Lead, Quality Manager, Laboratory IT Manager and deputy. An update is given by the IT manager including discussion of any IT issues within the department e.g. LIMS, Analyser interfaces etc. These are logged on the IT tracker database.. Progress of these issues are followed up.

**Molecular Development Group***.* This is held as needed and is chaired by the Consultant Clinical Scientist in charge of molecular development. Clinical Scientist and BMS staff involved in the development of molecular assays, together with the BMS in charge of that section, attend this meeting. The Technical Services Manager and other interested staff are encouraged to attend. The primary remit of this group is to assess new molecular tests, either “in-house” or commercial, for possible implementation in the laboratory as part of the continual improvement procedure.

Its main roles are:

* Discussion of protocols for retrospective and prospective testing using molecular assays
* To discuss the results of the above and make recommendations to the Virology Management Group for implementation of either a new or modified assay. These assays may either be previously published or developed by WoSSVC staff. If more than a month remains before this meeting, the assay can be authorised, in the interim, by the Management Group.

Once an assay has been implemented and is part of the routine service the ongoing quality assurance of that assay will be discussed at the Senior Scientists’ meeting. Issues not able to be resolved by this group will be referred to the Molecular Development Group for investigation.

Self taken meetings are also held by **Band 6 BMS** and **Health Care Support Workers**. No member of staff outwith the particular staff group is present at these meetings which will be held monthly where possible

Issues are fed back to TSM and Quality Manager who address them with site leads.

 Feedback is given to staff.

Additional communication methods

Information within the laboratory is also cascaded to staff through the use of e-mailed memos. The contents of these memos are discussed at the Friday catch up meetings with all staff.

NHS Greater Glasgow and Clyde send out regular ‘Core Briefs’ and Monthly News Letters to all staff by e-mail– this is a keeps staff up to date with developments within the Health Board

 To view Staff Communications online, visit: [www.nhsggc.org.uk/staffcommunications](http://www.nhsggc.org.uk/staffcommunications)

Follow NHSGGC on Twitter: [**@nhsggc**](https://twitter.com/NHSGGC)

There are also NHS GG and C, General Notification e-mails sent as and when necessary by the board which alert the relevant staff to various issues for example ‘downtime’ in the Datix reporting system for maintenance

4.1.2.7 Quality Manager

The Quality Managers post is shared on a 50:50 basis with the Scottish Microbiology Reference Laboratories. The Quality Manager reports directly to the Technical Services Manager and also the Assistant General Manager of Diagnostics.

The Quality Manager has delegated responsibility for establishing, implementing and maintaining a quality management system and reporting to management on its performance and needs for improvement.

They provide support and advice to senior staff on quality management matters at service and directorate level and monitor the requirements of the Department’s users and ensure that they are reflected within defined quality performance measures.

**4.2 Quality management system.**

**4.2.1 General requirements and Overview of system**

Laboratory management demonstrates its commitment to fulfilling the needs and requirements of its users by clearly defining the way in which the laboratory is organised and managed.

The laboratory has established and implemented a robust quality management system as documented in this Quality Manual and associated procedures.

Evidence that we have established a quality management system includes:-

* Our Quality Manual, Quality Policy, the appointment of a quality manager and the implementation of a quality management system.
* The QMS processes and application, criteria and methods, availability of resources and its monitoring for improvement action are set down in documents held in Q-Pulse.

The key ones are:-

* MAN-Q-001‘Quality Manual.’
* MAN-Q-002 ‘Quality Policy’.
* MAN-F-216 ‘Quality Objectives and Plans.’
* MAN-Q-003 ‘Document control and review.’
* MAN-Q-067 ‘Annual Management review.’

The effectiveness of the WoSSVC Quality Management System and the processes within it are monitored through planned and scheduled internal audit processes, against agreed criteria, by personnel trained in internal audit. See MAN-Q-073.

4.2.2 Document requirements

4.2.2.1 General

The laboratories Management Team defines the quality objectives of the laboratory and is responsible for ensuring plans are made to meet these objectives. The management review which is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and the functioning of the quality management system.

All policies and procedures are available via Q-Pulse.

4.2.2.2 Quality Manual

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This Quality Manual (MAN-Q-001) is underpinned by the department laboratory and management procedures. It is the responsibility of the Quality Manager to ensure the implementation and monitoring of the quality management system, and it is the responsibility of Laboratory Management to ensure that the correct resources are in place to allow implementation and continuation of the quality management system.

**4.3 Document control.**

Document control is an essential component of the Quality Management System.

All documents (internally generated and from external sources) required for the Quality Management System will be subject to the Laboratory’s document control procedures.

The laboratory utilises the Q-Pulse Quality Management Software to assist in an effective document control system. All documents within the quality management system for use in the WoSSVC must be stored/managed on Q-Pulse allowing full traceability**.**

All documentation is properly controlled. SOPs, forms, work instructions and external documents have a unique identifying code, review date, version number, pagination and name of authoriser (owner), which correctly identifies the type, number and version of the document.

Documents cannot be amended on Q-Pulse without the required privilege level and all the controlled documents are printed with coloured headers and footers. Only active documents are at workstations with obsolete or inactive documents removed and stored indefinitely electronically only. Refer to MAN-Q-003

**4.4 Service agreements**

**4.4.1 Establishment of service agreements**

**4.4.2 Review of service agreements**

Formal Service Level Agreements are in place between the WoSSVC and Health Protection Scotland (HPS) for the provision of specialist Blood-Borne Virus work and community acquired respiratory virus surveillance work.

At present these contracts require the laboratory to submit 6 monthly reports for both the testing and financial status of the work involved. Regular meetings occur between the Head of department /Consultant Clinical Scientist and HPS to discuss the specialist testing service and to review testing protocols/new developments *etc*. No specimens are sent to third parties. For details see MAN-SOP-034.

**4.5 Examination by referral laboratories.**

4.5.1 Selecting and evaluating referral laboratories and consultants

We aim to carefully select which referral centres we use, for the benefit of our users. The WoSSVC makes every effort to use other Laboratory services that meet CPA/ISO 15189:2012 standards. This will ensure that the quality of our service is not compromised by the actions of a third party. See MAN-SOP-028.

**4.5.2 Provision of examination results.**

We aim to provide accurate results for our users by ensuring that our procedures state that we, as the referring laboratory, are responsible for ensuring the results from the referral laboratory are delivered to the person making the request.

See MAN-SOP-001 Reporting results

**4.6 External services and supplies**

We aim to continually improve the quality of our service by carefully selecting suppliers, and by regularly reviewing their performance.

The majority of services and supplies are procured *via* Abbott Managed Service Contract.

Consideration is taken of:

* Quality of service
* Professionalism
* Costs
* Contractual obligation
* Recent performance
* Availability of stock
* Time to delivery

See MAN-SOP-009 Management of materials and reagents and MAN-SOP-025 Evaluation, selection and review of suppliers for further details.

A list of selected and approved suppliers is stored in Q-pulse

**4.7 Advisory services.**

We aim to maintain close contact with our users in order to ensure that the service meets their needs and requirements.

Communication with users is kept under constant review. In practice, this is achieved by user-satisfaction questionnaires, meetings with specific key users and by individual contact between the Head of department, TSM, Medical Consultants and others who use the service. Staff ensure that users are aware how to obtain advice about choice of examinations, clinical cases, interpretation of results, how to make best use of the service and how to ensure specimens meet our acceptance criteria.

See MAN-Q-068 for more detail.

The Laboratory User Guide is published as part of our website.

<http://www.nhsggc.org.uk/about-us/professional-support-sites/microbiology/west-of-scotland-specialist-virology-centre/>

This gives guidance on how to use the service and available examinations including sample types and any additional requirements or limitations.

Medical or clinically qualified staff are available at all times for clinical advice and interpretation of results

Contact details for medical staff and the laboratory management team for additional technical or logistical advice are listed on the website.

There is also a general Virology queries ‘NHS mail’ email to which users can direct enquiries and requests for advice. Enquiries and feedback can also be submitted via the WoSSVC website.

**4.8 Resolution of complaints.**

We aim to continually improve the quality of our service by building confidence in our users that complaints will be thoroughly investigated and corrective action taken. All complaints will be logged within the CAPA module in Q-Pulse.

The process is:-

* To take all complaints seriously.
* To deal with the client in a courteous manner.
* To try to resolve the issue immediately at a local level.
* To inform the client about the progress of the complaint.
* To make corrective action as soon as possible.
* To investigate root cause analysis to prevent recurrence

See MAN-Q-014 Complaints procedure

There is also a documented procedure for laboratory staff to follow when raising a complaint. See MAN-SOP-012 Information for staff

**4.9 Identification and control of non-conformities**

There are many possible sources where non-conformance may be identified within the laboratory including:

* Internal audit
* External audit
* QC failure
* Instrument failure
* Calibration failure
* Complaint
* Product/reagent recall or failure

These are all managed in the same way e.g. identify the non-conformance, report the non-conformance using Q-Pulse, investigate to find the root cause, put into place corrective action to prevent the incident occurring again and review to check that any corrective action has been successful.

We aim to ensure that nonconformities are effectively managed in order to build confidence in our users and to continually improve our service.

Non-conformity reports from all areas of the Quality management system including the pre-examination, examination and post-examination processes are documented and appropriately managed so as to minimise risks to service users.

These are submitted to the quality manager as they arise, and cumulative data forms part of the monthly compliance report and annual management review.

The identification and control of non-conformances is described in MAN-Q-032 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

**4.10 Corrective action.**

A corrective action deals with a nonconformity that has occurred. Actions taken can be both immediate (remedial) and long term to prevent the incident occurring again.

Removing the root cause of a problem is the true corrective action as it prevents the issue happening again

We investigate and, where possible, remove the root cause of all nonconformities.

See MAN-Q-032 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

All non-conformances raised are investigated and corrective action implemented by the designated person in discussion with the Quality manager/Site manager. This corrective action is recorded in the CAPA record in Q-Pulse along with any evidence of implementation available.

The Quality manager reviews all non conformances and presents a report at monthly meetings including the number of NCs recorded, number in progress, number closed and number overdue. From this the % performance is calculated and reported.

If the NC has been raised from an audit – a re-audit is scheduled to establish if the corrective action has been effective.

**4.11 Preventive action**

A preventive action is a change implemented to address a weakness in the system that has the potential to allow non-conformity to occur.

It is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints

Audits can highlight areas that require preventative action e.g. a potential for transcription error is witnessed and an extra check is included into the procedure. There are however many other areas apart from review of operational procedures that could instigate preventative action including trend analysis of QC data and EQA results

Preventative action is to avoid creating non-conformities but it also often includes improvements in efficiency.

Within the lab preventative action includes:

* Equipment service and calibration – this ensures the equipment e.g. pipettes perform as expected reducing potential non-conformities
* Validation/verification - gives evidence that the process is operating within established parameters effectively, giving consistent results meeting predetermined specifications established to fulfil the requirements of the laboratory
* Reporting of QC performance to the senior scientist monthly meeting
* Analysis of any EQA IQA failure for root cause
* Pre-acceptance of kits before use
* Change control of e.g. any changes in IT
* Recording daily temperatures of fridges / incubators (for drift trending)

Preventative action is agreed between the Technical manager, Site Manager and Quality Manager. Any preventative action implemented is recorded in the CAPA module of Q-Pulse. Were appropriate a re-audit or review of data must be carried out to establish if the preventative action has been effective.

See MAN-Q-032 Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).

**4.12 Continual improvement**

We aim to ensure that the service provided by the WoSSVC meets the changing needs and requirements of our users by having evaluation and improvement processes in place which include:

* Assessment of user satisfaction MAN-Q-068.
* Regular discussion with users of the service to discuss service needs.
* Participation in clinical meetings.
* Internal audit of examination processes MAN-Q-066.
* Internal audit of the quality management system.
* External quality assessment MAN-F-336
* A process for continuous quality improvement MAN-Q-069.
* Q-Pulse - Non-conformance (CAPA) and Root Cause Analysis (RCA).MAN-Q-032
* Quality indicators MAN-Q-086

The results of these evaluation and improvement processes are available to staff and users as required. Analysis, recording and interpretation of the data forms part of the annual review.

Quality objectives and plans – MAN-F-216 are set at the beginning of each year after completion of the Annual Management Review. They are regularly reviewed by the laboratory management team and the document updated quarterly. This document is communicated to staff via Q-Pulse document acknowledgement sign off.

Error logs, assessment reports and complaints are presented by the Quality Manager to monthly senior scientific staff meetings as well as to the Annual Management Review. Outstanding non-conformances are investigated by the Quality Manager with timescales set for corrective action.

Performance in EQA schemes are analysed by the Technical Manager of the appropriate section and then summarised at the meetings. Corrective action is taken as appropriate.

The Quality Manager will monitor that both remedial and corrective actions have been taken and recorded.

User surveys, complaints and training are discussed at the Senior Scientists’ meetings and information is disseminated to the staff during full staff meetings

Staff suggestions are encouraged by using an initiative and suggestion form MAN-F-290 which can be returned anonymously if preferred by using the Suggestion Box - these are recorded in Q-Pulse

Suggestions can also be raised directly in Q-Pulse by any staff member.

Staff feedback/concerns are voiced at the full staff meetings.

**4.13 Control of records.**

We aim to adhere to the rules governing record control, in order to ensure accuracy and availability of all aspects of our service. The process is defined in MAN-Q-003 Document control and review Records and specimens are stored in accordance with RCPath and IBMS guidelines (see ED-9 in Q-Pulse). Quality records are available in Q-Pulse or from the quality manager. Process records are stored at workstations or are archived.

Disposal of these records is in accordance with the NHSGG and C policy on confidential waste.

**4.14 Evaluation and audits.**

### **4.14.1 General**

We aim to continuously interrogate our service by a system of audits, in order to detect weaknesses before they cause an error. There is planned and scheduled internal audit of the pre-examination, examination and post-examination processes against agreed criteria, by personnel trained in internal audit. See MAN-Q-73 These audits ensure conformity to the Quality Management System and contribute to improving its effectiveness.

All processes are validated or verified before introduction into the laboratory to ensure their performance meets the needs and requirements of our users.

Results of these are discussed at the annual management review

### **4.12.2 Periodic review of requests, and suitability of procedures and sample requirements**

The laboratory test repertoire is monitored by medical staff who review requests made for referral tests, coding protocols are reviewed annually. Amendments to the lab repertoire is discussed in management meetings and reviewed during the annual management review. There is guidance in the User Guide published on the website regarding sample requirements with regard to collection, storage and transport which is reviewed at least annually.

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**4.14.3 Assessment of user feedback**

User surveys have had limited success in the past due to poor response. It is thought a limited distribution of a survey every two years to our main users including Sandyford Central Clinic, other laboratories who send us samples and Organ Transplant Donor Team would be more informative.

There is a permanent feedback link on the website for any comments or suggestions users may have, also a generic laboratory e-mail they can use to contact us.

Medical, Scientific and BMS staff are in daily contact with users to provide support and advice therefore will receive feedback.

 Any feedback is recorded in Q-pulse as a ‘feedback notice’ FBN document stream

Consultant staff attends clinical meetings at a number of departments, for example the Princess Royal Maternity Hospital and Bone Marrow unit.

Informal meetings with users are undertaken by virology staff in person during visits, or by telephone and e-mail interactions. Any issues arising from telephone calls or e-mails will be passed to the quality manager to deal with

User complaints are dealt with according to the Clinical Adverse Patient Incident Reporting Policy, and the WoSSVC Complaints procedure.

User feedback and review is a standing item at the monthly Compliance Meeting.

**4.14.4 Staff suggestions**

The identification of improvements is a pro-active process and forms part of the continual improvement process in the laboratory. Staff are encouraged to identify possible improvements to the quality system or to test procedures. Suggestions can be made at any time but are most likely to be made during internal quality audits. Suggestions can also be raised anonymously using MAN-F-290 Initiative and suggestion form and placing it in the suggestion box. Staff suggestions for quality improvements can be raised and recorded using the CAPA module on Q-Pulse.

Staff suggestions and feedback is a standing agenda item at the 5th Floor all staff meeting to encourage staff to participate and to feedback on any suggestions made.

**4.14.5 Internal audit**

We aim to continuously interrogate our service by a system of audits, in order to detect weaknesses before they cause an error – See MAN-Q-083 Examination audit schedule

This is a planned scheduled internal audit program using a set of predetermined criteria, undertaken by members of staff trained in internal audit. Any non conformities are identified and a time frame given for their correction. The audit findings (non-conformances identified and corrective action taken) are presented by the Quality Manager at the senior scientist meeting and any trends identified discussed at the Annual Management Review.

 The records of internal audit include:

* The activities, areas or items audited.
* Any nonconformities or deficiencies found.
* Recommendations and time scale for corrective and preventive actions.
* The results of internal audit are regularly evaluated and decisions taken are documented, monitored, reviewed and acted upon.
* Audit findings are communicated to appropriate personnel.

Audits are also carried out on pre and post examination processes and the QMS

**4.14.6 Risk Management**

We aim to establish business continuity in order to fulfil our responsibilities under the overall objective of providing a safe environment for patients, staff and visitors as well as to comply with relevant legislative requirements

This requires contingency planning by management and is detailed in MAN-SOP-023 Risk Management (Business continuity)

### **4.14.7 Quality indicators**

Quality indicators are established by the management team prior to implementation. The objectives, methodology and duration of measurement are detailed in MAN-Q-086

**4.14.8 Review by external organisations**

External reviewers can include UKAS and Health and Safety Executive.

Any non conformities raised externally are followed up immediately or by required timeframe and reported back to the relevant organisation.

Reports are stored in Q-Pulse, any information gathered as part of external assessment contributes to continual quality improvement within the laboratory.

4.15 Management review

We aim to regularly review our quality management system, in order to ensure its continued suitability, adequacy and effectiveness in support of patient care.

4.15.2 Review input

The Laboratory management team conduct an annual review which considers the following items of information see MAN-Q-067:

* the periodic review of requests and suitability of procedures and sample requirements
* assessment of user feedback
* staff suggestions
* internal audits – including any improvement findings
* risk management
* use of quality indicators
* reviews by external organisations
* results of participation in inter-laboratory comparison programmes
* monitoring and resolution of complaints
* performance of suppliers
* identification and control of non-conformities
* Results of continual improvement including current status of CA/PA
* follow up actions from previous management reviews
* changes in the volume and scope of work, personnel and premises that could affect the
* quality management system
* Recommendations for improvement, including technical requirements.

These are all reviewed to identify any issues/trends developing which could highlight developing problems with process

4.15.4 Review output

A record of the meeting is compiled by the Quality manager – Q-Pulse MAN-Q-001 This report is communicated to all staff. Q-Pulse acknowledgement is implemented.

The meeting is a review of Quality Management System, policy and objectives.

The objectives set at the beginning of the year during the AMR of the previous year are reviewed again for progress/completion.

Discussions take place between management including possible improvements to the service the laboratory delivers to users, any improvements that could be made in the Quality management system and its processes and also how to facilitate these improvements.

These outputs form quality objectives for the forthcoming year and are documented in MAN-F-216 in Q-Pulse and communicated to staff .These are also held within the Compliance meeting ‘action tracker’ where they are reviewed monthly with any further goals added as they arise.

The AMR includes root cause, trending of non conforming work e.g. IQC,EQA results etc to identify any patterns that may indicate there is a problem with a process and improvement opportunities.

**5.0 Technical requirements**

* 1. **Personnel.**
		1. **General**

See MAN-SOP-012 Information for staff

* + 1. **Personnel qualifications**

A record of each staff member’s qualifications, training and copies of HCPC Registration certificates (if appropriate) are kept in the site managers’ office.

5.1.3 Job descriptions

To allow each member of staff to know their duties, responsibilities and rights they are given written job descriptions.

Job descriptions include:

* Job title
* The location within the organisation
* Accountability
* Main purpose of the job
* Main duties and responsibilities
* Staff annual joint review

All staff have a contract of employment, which is in compliance with current legislation and provides clear terms and conditions of service.

Job descriptions are available as controlled documents via the Q-Pulse document control software.

5.1.4 Personnel introduction to the organisational environment

GG and C Health Board has a comprehensive staff orientation and induction programme. An induction pack is issued on or before a new employee's starting date and local induction training is carried out on the first day of work.

This local induction training covers such areas as:

* Department/Division information
* Working environment
* Terms and conditions of employment
* Patient confidentiality and data protection
* Health and Safety
* Job description including an organisational chart
* Salaries and wages
* Staff facilities
* Equality and Diversity
* Records of staff orientation and induction are kept in individuals personal files.

5.1.5 Training

Trainee BMS staff participate in courses at Glasgow Caledonian University according to the requirements set by the IBMS for eligibility for HCPC registration. Trainee BMS staff are required to complete the IBMS Competency Portfolio to enable them to become registered. Registrant BMS staff are then required to complete the IBMS Specialist Portfolio. They are also actively encouraged to participate in MSc courses. All trainee scientists and medical staff will follow the appropriate training manual and maintain the log book. All trainees will be reviewed on a regular basis on completion of each training section and in the annual review.

Professional development of all staff is encouraged. A professional development system is available *via* the Institute of Biomedical Science, and BMS staff are encouraged to participate in this scheme. It is mandatory for all HCPC registered staff to demonstrate continued professional development. The Royal College of Pathologists has a CPD scheme for all College members in career grade posts (consultant and non-consultant); non-medical and Clinical Scientists grades C and B are eligible to register.

Rotation through the laboratory for less qualified staff is an essential element of training for HCPC registration purposes. Qualified staff may also be expected to rotate as required for the efficient running of the laboratory.

 5.1.6 Competence assessments

There are competence records held for all processes in the department and individual records are kept for all staff members.

 5.1.7 Review of Staff performance

 Staff annual joint review is carried out in accordance with health board policy.

All staff participates in an annual joint review (e-KSF PDP) which includes consideration of:

* e-KSF outline for the job role.
* The quality objectives and plans of the laboratory.
* The current job content.
* Documentation of training needs and agreed personal objectives with the appraiser.
* Evidence that management has recognised the agreed development needs of individual staff members.

All staff performing e-KSF PDPs have been trained and records of all staff PDPs are kept.

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#### **5.1.8 Continuing education and professional development (CPD)**

It should be noted that all of the WoSSVC groups/committees have a training element and should be attended by trainees where possible.

All staff are encouraged to participate in "Continuing Professional Development" (CPD), which is now mandatory for continuing registration with HCPC.

Opportunities for further education and training are available in relation to the requirements of the service and individual personal development.

The Department provides resources for such education that includes:

* Access to library and information services.
* Suitable accommodation for private study.
* Opportunity to attend meetings, seminars and conferences.
* Financial support.

Records of training and education are kept by each member of staff.

**5.1.9** **Personnel records**

The Human Resources Department of the Diagnostic Directorate of the Acute Division of NHS Greater Glasgow and Clyde holds the complete staff record. The Occupational Health Department holds vaccination records and the Pay Department holds records of payments.

In addition, confidential staff records are kept including:

* Personal details.
* Employment details.
* Job description.
* Terms and conditions of employment.
* A record of staff induction and orientation.
* A record of attendance at fire lectures.
* A record of attendance at manual handling courses.
* A record of education and training.
* Relevant educational and professional qualifications.
* Certificate of registration with the Health and Care Professions Council (HCPC).
* Absence record.
* Accident record.
* Record of annual joint review.
* Occupational health record.
* A record of disciplinary action.

All of the above paperwork is held with the site manager

**5.2 Accommodation and environmental conditions.**

A laboratory requires sufficient space to ensure that work is performed safely and efficiently. We aim to ensure that the WoSSVC provides a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises are a state-of-the-art building which meets all current regulations for medical laboratory accommodation.

The premises have space for:

* Specimen reception
* The functioning and use of all equipment.
* Separation of incompatible activities (*e.g*. Office and laboratory).
* Storage facilities.

Access to the premises is by swipe card entry *via* locked doors.

**5.2.1 General**

We aim to ensure there is a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises are a state-of-the-art building which meets all current regulations for medical laboratory accommodation.

The premises have space for:

* Specimen reception.
* The functioning and use of all equipment.
* Separation of incompatible activities (e.g. Office and laboratory).
* Storage facilities.

Access to the premises is by swipe card entry via locked doors.

**5.2.2 Laboratory and office facilities**

These are well separated / demarcated.

**5.2.3 Storage facilities**

Paper-light systems operate with regards to reports and storage of paper records. Scanning options are available. Consumables and reagent storage is appropriate with large functional areas (cold and ambient).

**5.2.4 Staff facilities**

Common room refectory, with cooking, eating and drinking facility provided. Toilets, including disabled, shower facilities are plentiful and substantial.

**5.2.5 Patient sample collection facilities**

(N/A)

**5.2.6 Facility maintenance and environmental conditions**

Recently refurbished building with new temperature and air management systems in place. Quarterly workplace inspections are carried out and reported to facilities.

Laboratory management’s safety responsibilities are defined in the Health and Safety Manual and in the Division's H and S Policy.

A hard copy of this manual is kept in the Site Managers office.

**5.3 Laboratory equipment, reagents and consumables.**

We aim to ensure that sufficient and appropriate equipment is available so that service quality is at the highest level. A commitment to this effect is included in the quality manual and in document MAN-SOP-009. This includes rules for equipment procurement.

See the equipment inventory and laboratory equipment records for further details.

5.3.1 Management of equipment

There is a procedure for procurement and management of equipment MAN-SOP-010

The procedure contains:-

* Assessment and Justification of Need
* Selection
* Evaluation of Suppliers
* Purchasing arrangements

##  Establishment and Maintenance of an Equipment Inventory File

## Equipment Maintenance, Service and Repair

An Inventory of equipment is maintained in Q-Pulse, which includes:

* Manufacturer’s name.
* Serial number.
* Date of purchase or acquisition.
* Maintenance contract.

The Estates department performs electrical safety testing (PAT) on a regular basis.

A decontamination certificate is issued before an engineer is allowed to work on the appropriate item of equipment EQP-F-068

Equipment purchase and maintenance is arranged by ABBOTT Ltd *via* a Managed Service Contract

Requirement for new equipment is highlighted to the Management Group *via* the Laboratory Manager’s Group.

#### A business case is put forward to the Directorate for all new equipment, including upgrading of existing equipment. Selection of appropriate equipment is based on laboratory requirements and cost. Quotations/tenders are obtained from suppliers/manufacturers. A safety assessment is carried out for the positioning of the equipment in the laboratory, and any special requirements noted.

For all items over £5000, completion of a Capital Equipment Request Form is required.

For all items under £5000, (including IT equipment), the appropriate forms are submitted to the Directorate for approval. A centrally held budget is available for equipment within this category.

Training is directed by the supplier/manufacturer of the equipment, and where appropriate both off-site and on-site training are given.

Maintenance agreements and scheduled service visits are arranged with the Technical Services Manager.

Service and breakdown reports and corrective action taken are filed in Q-Pulse.

User, maintenance and decontamination procedures are described in equipment SOPs (EOPs). Disposal of redundant/ broken equipment is arranged through the relevant company or GRI Estates department, and the equipment removed from the asset register.

**5.3.1.2 Equipment acceptance testing**

All new and replacement equipment is assessed before being put into use. This includes:

* Health and safety implications
* Throughput
* Trial by comparison with current methods by testing both methods in tandem.
* Management review of costs, supply, equipment, staffing and service issues.
* Production of business plan and specification

#### **Equipment instructions for use**

Sufficient and appropriate equipment is provided to meet the needs and requirements of the users. This is regularly maintained and all staff are instructed in its correct use. Training and competency records for all examinations processes, including the use of the relevant equipment are maintained.

Instructions for use are in individual SOPs where applicable and manufacturer’s manuals are available either electronically or as hard copies.

#### **Equipment calibration and metrological traceability**

Appropriate calibration of equipment is detailed in relevant SOP/EOPs. Calibration may also be performed by the manufacturer as part of periodic service and preventive maintenance. Records of calibration, where provided, are stored on Q-Pulse.

The following UKAS documents provide further information on metrological traceability and the calibration of lab equipment to ensue conformity with **ISO 15189:2012**:

* TPS 41: UKAS Policy on Metrological Traceability ED-222
* LAB 14: In-house Calibration and Use of Weighing Machines ED-183
* LAB 15: Traceability: Volumetric Apparatus ED-184

For further information see LAB 5 Reporting Calibration Results ED-182 and LAB 11: Traceability of Temperature Measurement ED-110

#### **Equipment maintenance and repair**

Day to day maintenance of all equipment is carried out and recorded according to manufacturers’ instructions.

The Manufacturers or service contractors perform service checks and repair of all equipment. The laboratory management holds all purchase and service contracts. Engineer’s reports are held electronically within the Asset record.

All equipment undergoes regular PAT Electrical safety checks, carried out by the Estates Department and is marked accordingly.

#### **Equipment adverse incident reporting**

Adverse incidents and accidents involving equipment are reported through the GG and C IntraNet DATIX system where appropriate actions and follow up are recorded.

Equipment faults are logged within the Q-Pulse asset record where details of notification to manufacturers, repairs and engineers’ visits are recorded. Other general issues with equipment suppliers are recorded as Supplier non-conformances in Q-Pulse.

#### **Equipment records**

An inventory of all laboratory equipment is held in Q-Pulse. This is reviewed annually and includes Serial Number, Asset Number and date of purchase.

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### **5.3.2 Reagents and consumables**

#### **5.3.2.1 General**

Reagents, consumables, calibrators and quality control materials are purchased from appropriate suppliers and manufacturers in adequate quantities to ensure continued provision of service.

A procedure MAN-SOP-009 is established for the management of reagents and materials:

* Selection, purchasing and ordering.
* Assessment of suppliers.
* Receipt and verification of identity and condition.
* Issue and inventory management.
* Safe disposal.

The SOP for reviewing suppliers is MAN-SOP-025.

Materials in use are correctly identified with date of receipt, lot numbers and expiry.

All purchasing of reagents and consumables material is in line with the Health Boards Standing Financial Instructions ED-13.

Purchasing of all materials is through approved suppliers. Materials are selected following evaluation of their suitability by the laboratory. Orders are placed electronically onto the supplies PECOS system and, dependant on the value, are authorised by appropriate staff. Orders up to £5000 can be authorised by the Technical Services Manager and deputy up to £2,500 and orders are e-mailed to suppliers via the PECOS system.

Reagents within the Abbott Managed Service Contract are ordered directly from Abbott by authorised personnel *via* an electronic link:- the Abbott Reagent Management Software (RMS). E-mail confirmation is received by the Technical Services Manager.

All other materials, either “stock” (*i.e.* NHS supplied), or non-stock items are ordered electronically through the PECOS system by generating a unique order number, identified as a WoSSVC order.

Materials are received in the laboratory at specimen reception. Deliveries are logged and given a unique number. This number is also logged onto the delivery note. Goods are checked for damage and to ensure that details are correct. Any discrepancies are brought to the attention of the appropriate Technical Manager, and the supplier contacted. All materials are then dated, and stored appropriately in accordance to the manufacturer’s instructions, and recorded on stock control forms. When materials are in use they are removed from the stock control forms, and are dated. Lot numbers are recorded on worksheets, as described in the corresponding SOPs.

The SOPs also contain COSHH references and describe the appropriate handling precautions and safe disposal of all materials. Materials in use are correctly identified with the date of receipt, lot numbers, first use and expiry date.

#### **Reagents and consumables — Reception and storage**

Reagents and consumables are delivered directly to the department and are signed for by laboratory staff. This is recorded in LS-F-036 - Receipt of goods delivered.

Reagents are checked on arrival for damage or missing reagents and stored according to manufacturer’s instructions.

**5.3.2.3 Reagents and consumables — Acceptance testing**

Acceptance testing of kits and reagents is performed prior to use in examinations to verify performance. This is carried out and recorded according to individual Work Instructions

* + - 1. **Reagents and consumables — Inventory management**

Stock control is through Abbott Reagent Management System (RMS) or stock logs in each section of the laboratories where specific records are kept for kits not on the Managed Service Contract. All reagents are handled as detailed in individual standing operating procedures

#### **Reagents and consumables — Instructions for use**

Instructions for use of kits and reagents are outlined in bench SOPs specific to the test in question. See laboratory procedures on Q-Pulse.

#### **Reagents and consumables — Adverse incident reporting**

See also section **5.3.1.6**.

Adverse incidents and accidents involving reagents are reported through the GG and C IntraNet DATIX system where appropriate actions and follow up are recorded.

Technical issues with reagents or suppliers are logged non-conformances in Q-Pulse.

**5.3.2.7 Reagents and consumables — Records**

Records are kept of all reagents used in the performance of examinations including date of receipt, lot numbers, expiry date and results of acceptance testing. See individual process SOP/EOPs

**5.4 Pre-examination processes.**

We aim to ensure that our users are fully aware of our service in order that they can make the best use of it. The information including how to contact us, how to correctly send specimens for analysis, and how to obtain clinical advice is available in the user manuals displayed on the web site see [www.nhsggc.org.uk/virology](http://www.nhsggc.org.uk/virology).

Information for users and patients

The information for users includes:

* Contact details of key staff
* Location of the laboratory
* Opening hours
* Instructions for specimen transport
* Availability of clinical advice and interpretation
* The repertoire of tests offered, specimen type required and turnaround time
* Key factors which are known to affect the validity of results

**Request form**

The request forms are designed to include:

* Sufficient information to allow unique identification of the patient
* The source of the request
* The requesting individual
* The date and time of specimen collection
* Specimen type and where appropriate the anatomical site of origin
* The investigation required
* Relevant clinical information
* Location to which report should be sent (including copy report)
* The unique laboratory accession number

The date and time of receipt at the laboratory is recorded using either a date/time electronic stamp or in the LIMS if PID done upon and at computer entry (PID).

The department encourages proper completion of the request form.

Specimen collection and handling

* Checking the completion of the request form and confirming the identity of the patient
* Checking that the specimen container is correctly labelled
* Ensuring that the specimen is correctly collected
* Minimising the risk of interchange of samples and sub samples
* Ensuring that environmental and storage conditions are fulfilled
* Ensuring the safe disposal of all materials used in specimen collection
* Ensuring that high risk specimens are identified and processed correctly
* Ensuring that all spillages and breakages are dealt with correctly
* Minimising the risk to ensure the safety of the specimen collector carrier, the general public and the receiving laboratory

**Specimen transportation**

* The GG and C Specimen Transport Policy fulfils this standard.
* Measures to ensure the safety of the courier the general public and the receiving laboratory
* Measures to ensure the confidentiality of patients' samples whilst in transit
* Measures to minimise delay in delivery
* Disinfection protocol following spillage
* Model rules on the type of outer container used to transport specimens.
* This policy is also subject to audit

**Specimen reception**

The Specimen Reception procedure LS-SOP-009 includes instructions on:

* Accurate matching of request form and specimen
* Recording date of receipt
* Assigning a unique laboratory accession number
* Handling urgent samples
* Spillage protocol
* Staff safety
* The procedure has instructions for the rejection of specimens that includes:
* The criteria for rejection of specimens.
* The recording of rejected samples.
* Notification of the user concerning rejected specimens.

Referral to other laboratories

* Very few items are referred to other laboratories.
* Maintaining a record of all samples referred.
* Recording of dispatch dates.
* Monitoring the return of reports from referral laboratories.
* Turnaround time of results from referral laboratories

**5.5 Examination processes.**

We aim to use procedures that are selected to meet the needs and requirements of the users, in order to make them confident that our test repertoire is designed for the maximum benefit of their patients.

Selection and validation of examination procedures

Prior to introduction, all examination procedures are validated for their intended use and the methods used and results obtained are recorded.

When examination procedures are changed so that results or their interpretation may be significantly different, the changes are explained to users prior to the introduction of the new procedure.

Examination procedures

The standard operating procedures (SOPs) for the conduct of all examinations are prepared according to the Document Preparation and Control procedure MAN-Q-003

Procedures for the conduct of all examinations include the following:

* The purpose and scope of the examination.
* Responsibility.
* Definitions.
* Documentation (e.g. cross reference to).
* Safety considerations.
* Procedure (including limitations and QC).
* References.
* Appendices (where necessary).

Procedural SOPs are available as hard copy in the relevant laboratory in addition to the master copy held electronically in Q-Pulse.

Refer to MAN-SOP-027 for details on evaluation, validation and verification procedures. Refer to MAN-Q-070 for determination of uncertainty of measurement.

**5.6 Ensuring quality of examination results**

Ongoing evaluation and improvement processes are essential to ensure that the service provided by the laboratory meets the needs and requirements of its users. The quality of results is maintained by a system of internal quality control (IQC) and external quality assessment (EQA)

**IQC**

We aim to use a wide range of procedures in order to detect errors and prevent release of erroneous results. The WoSSVC has a comprehensive range of procedures for internal quality control (IQC) of all examinations, which verify that the intended quality is achieved. These include:

* Records of date, source and storage of IQC material.
* A process for validation of IQC material prior to use.
* Appropriate statistical methods
* Acceptance criteria for results with IQC material (*e.g*. Assay control parameters).
* Evaluation of IQC results with corrective/preventive actions taken and recorded.

For serological assays, third party quality control material is used to control and validate test runs. Quality Control material is stored according to manufactures descriptions and used within expiry dates. Records of batch numbers and results are recorded. See MAN-WI-189

Internal quality control is reviewed regularly and prior to validation of results. Serological Assay SOPs describe the procedures for quality control including details of acceptance criteria, corrective action and documentation.

In house molecular assays are monitored by firstly testing 20 times any new batch of controls, setting +3/-3 SDs from the mean, and then comparing the positive control Ct value of each run against these values.

MID-SOP-120 describes the Westgard rules for control of molecular tests.

The Identification and Control of Nonconformities MAN-Q-032 outlines the procedures to be taken where there is a quality control failure identified, requiring a cessation of an examination and subsequent issuing of reports.

Results of IQA and EQA are monitored via monthly quality reports to identify trends.

**EQA**

This includes participation in inter laboratory comparisons and commercial proficiency testing programs where available e.g. NEQAS/QCMD. These are an important tool for demonstrating the technical competence of the laboratory. They are monitored for trends in performance which may signal an issue with the procedure and allow preventative action to be taken.

 All results are recorded and any deviation from the expected result must be fully investigated and recorded as a non-conformance with the appropriate corrective and preventative action carried out. MAN-SOP-038 details the schemes in place including a plan for the level and frequency of participation of schemes, acceptance criteria and procedure for investigating anomalous results. This is reviewed on an annual basis at the Annual Management Review or as necessary in response to changes in methodology, equipment scope etc.

**5.7 Post-examination processes**

Review of results

We aim to ensure that authorised personnel review the results of our examinations in order to ensure that patient safety is not compromised.

Storage, retention and disposal of clinical samples

We aim to comply with all regulations concerning this aspect of our service, in order to ensure that samples which must be stored are correctly handled, and samples which are marked for disposal are dealt with in accordance with the relevant legislation.

Storage, retention and disposal of clinical samples is described in ED-9. See also WoSSVC storage policy MAN-WI-137.

**5.8 Reporting of results**

The report

We aim to produce reports which are clear and unambiguous and which contain sufficient information to enable our users to interpret the results for accurate treatment of their patients.

In accordance with UKAS LAB1 - Reference to Accreditation for Laboratories, URN BIS 16/25 - The National Accreditation Logo and Symbols: Conditions for use by UKAS and UKAS accredited organisations and the laboratories signed UKAS Agreement of Accreditation, the West of Scotland Specialist Virology Centre clearly identifies all non-accredited tests on our reports for the information of our users.

 Comment codes - ‘Test not included in UKAS Accreditation (9319) Scope’ is automatically linked by the laboratory Telepath computer system to defined non accredited tests in accordance with the published scope.

The comment is printed on each report beside the related result.

Reports include the following information:

* Accreditation status of test reported if not on scope
* The laboratory name and contact phone number.
* The name, date of birth and CHI number of the patient.
* The requesting individual and the source to which reports are returned.
* The specimen type and date of collection.
* Date of report.
* Examination result and reason if not carried out.
* Interpretive comments as appropriate.
* Highlighting of abnormal results.

The telephoned report

The GG and C Telephone Policy MAN-Q-033 details procedure for issuing results by phone and includes:

* The circumstances in which reports may be given.
* The individuals who may issue results.
* The individuals who may receive results.
* A method of mutual identification of the patient between reporter and receiver.
* Confirmation of correct transmission.
* The mechanism for recording the event.
* Maintaining confidentiality.
* The process for sending a follow up report.

The amended report

The procedure MAN-SOP-001- Reporting Results - includes instructions for issuing an amended report, this includes:

* The criteria for issuing amended reports.
* Authorisation level of staff able to amend reports.
* The identification of amended reports to the user.
* A process of recording the issue of an amended report.
* The reason for issuing an amended report.
* Instigation of corrective and/or preventive action, if required.
* A process for archiving amended results.

**5.9 Release of results**

We have procedures in place to ensure that the results of our tests are accurate and are reviewed by authorised staff before release if required , in order to prevent any patient being endangered. Refer to MAN-SOP-001- Reporting Results

**5.10 Laboratory information management**

We aim to ensure that our data storage ensures accurate records are maintained in a form that is only accessible to authorised staff and users, in order to protect patient confidentiality.

The laboratory information system is TelePath, supported by other IT equipment for specialised tasks and it is accessed by CSW, Biomedical Scientist, Clinical Scientist, and Medical and Administrative staff. They are supported by the IT Department of NHSGG and C.

I.T. security is governed by the Data Protection Act, NHSGG and C I.T. Policy, and local SOP. Data and information are available to provide a service that meets the needs and requirements of users.

Laboratory IT Management ensures the following:

* Security.
* Access is password protected,
* Confidentiality and data protection.
* Back-up systems.
* Storage, archive and retrieval.
* Safe disposal.

References

**ISO 15189:2012**

**UKAS Lab 1,3,11,13,31**

**UKAS TP 63**

**UKAS TPS 47, 57**

**ILAC 9**

**EA18**

**URN BIS 16/25**