[Company]

**Quality Manual**

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# Overview

This Quality Manual has been developed as an easy and accessible means for managers and staff to reference the policies of the [Company] in an attempt to promote continual improvement, quality, quality control, and excellence in service. As always we strive for a safe work environment, to minimise inappropriate procedures, and provide the best possible service to our clients. These policies and procedures in our quality management system are the means by which we effectively monitor, control and adapt our policies and procedures to achieve this.

These policies and procedures are available to all staff.

All staff must make themselves acquainted with and understand and implement the policies and procedures of [Company].

A copy of this manual will be given to all staff as part of the induction programme on commencement of employment. Each new staff member will be given ample time to review all such written and given opportunity for clarification on any points not understood.

All staff must have a commitment to our Quality Policy.

# Quality Policy

[Company] has set the following quality objectives to enable the achievement of the organisation’s vision and mission.

*[For example:*

* *To ensure a high quality of laboratory performance.*
* *To operate an effective quality management system, measured through results of internal monitoring, audits and external proficiency testing.*
* *To improve experimental technique and documentation*

The vision and mission of [Company] is to [*Insert details of the company vision and mission statements]*

This will be achieved by the following actions.

*[Insert purpose of the organisation quality management system to support the Vision and Mission.]*

Further, [Company] has a commitment to good professional practice through compliance with the NPAAC standards and RCPA requirements and other professional bodies’ guidelines.

[Company] has established a management system to enable achievement of these objectives. The management system is described in this Quality Manual and supporting documents. Personnel involved in all aspects of the organisation must be familiar with and adhere to the policies and procedures outlined in this manual and the supporting procedures and protocols.

We are committed to the philosophy of continuous improvement.

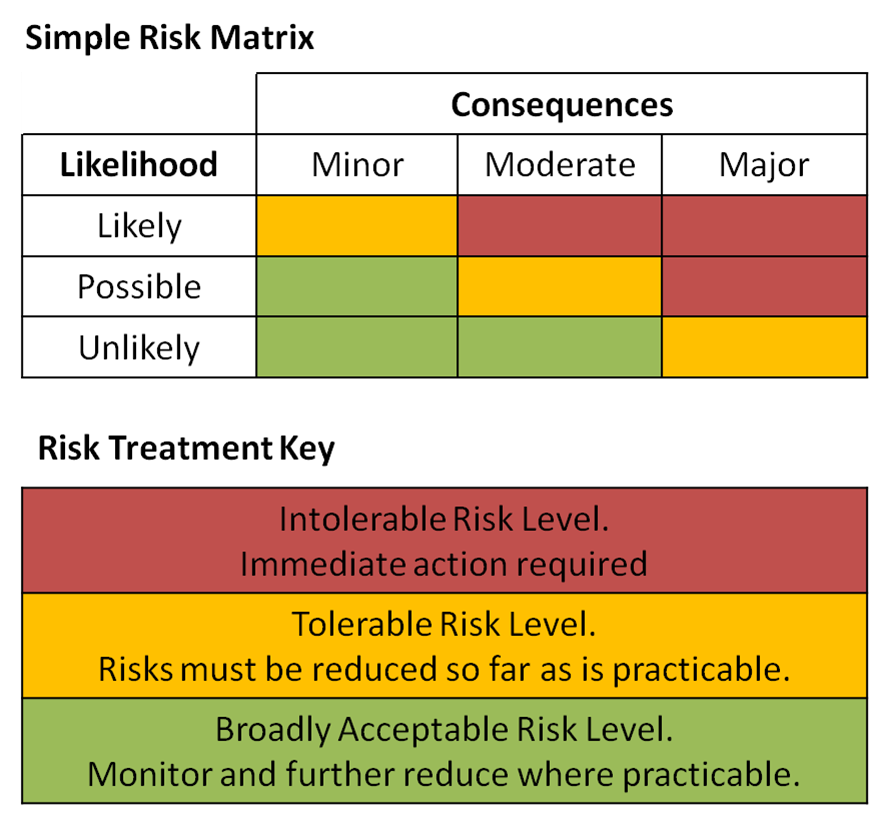
We aim to minimise the actual and potential for errors occurring in our work and to improve the overall efficiency and effectiveness of our processes. This will be practically achieved through means such as, ensuring that our people are appropriately trained and supported, implementation of an internal audit program and regular review of the processes in place within the organisation. These objectives will be reviewed annually for their continuing suitability and at the time of the formal management review. Measurement of achievement of these objectives shall be through numbers of customer complaints and corrective action, measurement of preventive action, and analysis of client survey results.

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# Risk Management

When new procedures and processes are introduced into the laboratory, [Company] undertakes a risk assessment to ensure that any serious risks are effectively mitigated.

Risk within a process or procedure is identified by the scientist responsible for development or implementation of the procedure or process, in collaboration with the *[Insert title of manager of the laboratory, eg Laboratory Manager]*. Once a risk has been identified, it is analysed with respect to the likelihood of occurrence and the consequence of the event occurring, as set out in Figure 1.



*Figure 1*: Risk analysis table

The level of risk is evaluated as shown in the Risk Treatment Key above and appropriate action is established and implemented to mitigate the identified risk. For example, the likelihood of the risk of a staff member suffering a needle stick injury when drawing sample from a vial may be possible, while the consequences of this event could be major, depending upon the material contained in the vial. This would place the activity at an intolerable risk level and require that action is taken to mitigate this risk.

The risk analysis must be documented in a Risk Analysis form. The outcome of this work is usually evidenced through the inclusion of safety notes in laboratory procedures.

# Document and information control

## Structure of the quality management system

The management system comprises of the Vision and Mission Statements, the Quality Manual, supported by procedures and records, as shown in Figure 2 below.

*Figure 2*: Documentation Structure

## Scope

All internal and external documents pertinent to the operations of [Company] need to be adequately controlled to ensure that the most current edition is used by staff and is accessed by clients, where appropriate.

## Document control procedures

### Responsibility

The *[Insert title of person responsible for document control, eg Quality Manager]* is responsible for preparing the Document Master List and has overall responsibility for ensuring this Document and Information Control procedure is followed. The *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* decides to whom the documents will be distributed. The *[Insert title of person responsible for document control, eg Quality Manager]* is also responsible for maintaining current and historical copies of superseded documents.

The authority for the approval of each document will be identified on the Document Master List.

### Introduction

Controlled documents and information will be listed on the Document Master List. This list will be prepared and maintained by the *[Insert title of person responsible for document control, eg Quality Manager]*.

Controlled documents will include but are not limited to:

* Quality Manual;
* Standard Operating Procedures (SOPs);
* Forms

In the case of documents issued by [Company], each controlled document will have a unique code determining its type and identification number within its group.

The codes will be:

* MAN for the Quality Manual
* SOP for supporting SOPs
* FRM for forms

The document’s identification will appear in the document header, while the person approving the document and the issue date will be shown in the footer of each page of a document, as demonstrated by the footer of this page.

### Document Approval and Issue

The development of documents under the quality management system can be done by any employee whose job is related to any subject included in the document and data or as a corrective or preventive action to satisfy the requirements of changing standards or internal audits. However, these must be reviewed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* in the first instance. Proposals for development of new documents must be completed using the Document Change Request Form and sent to the *[Insert title of person responsible for document control, eg Quality Manager]* for logging into the Document Tracking spreadsheet.

Once documents have been approved for use, an indication of the completion of this process will be provided in the footer of each page by the inclusion of the name of the person who has approved the document. The Document Change Request Form will also include the signature of the person approving the document, authorising the new or amended document. The *[Insert title of person responsible for document control, eg Quality Manager]* will update the Document Master List with details of the new document.

Hard copies of external documents are controlled by means of annotation of approval for use by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* and the date on which this approval was made.

### Document and Data Distribution

All documents issued by [Company] will be maintained in electronic format only and will be accessible via [Company]’s intranet in accordance with the employee’s access rights for documents.

### Document and Data Revision

Revision of documents and data will be initiated on the Document Change Request form. A change to a document and data may be requested by any employee whose job is related to any subject included in the document and data or as a corrective or preventive action to satisfy the requirements of changing standards or internal audits. For the evaluation of this request, the approval of the position allocated for the review of the document is required on the Document Change Request Form.

All change request forms will be kept by the *[Insert title of person responsible for document control, eg Quality Manager]*. Document changes will be tracked in the Document Tracking spreadsheet.

The person with responsibility for approving the change completes the Document Change Request form, including a signature to indicate the completion of the review process. The completed form is then returned to the *[Insert title of person responsible for document control, eg Quality Manager]*.

Upon approval of any revision to an existing document or data, or the issue of a new document or data, the *[Insert title of person responsible for document control, eg Quality Manager]* will update the Document Master List. The revised document will also include the name of the person authorising the change.

Staff are advised of the issue of new or amended documents via an email from the *[Insert title of person responsible for document control, eg Quality Manager]*. Staff shall indicate by return email that they have read new or amended documents. The *[Insert title of person responsible for document control, eg Quality Manager]* retains these emails as evidence that this has been undertaken.

Historical copies of superseded documents and data will be maintained by the *[Insert title of person responsible for document control, eg Quality Manager]*. For documents and data issued by [Company], superseded versions of documents and data will be transferred to an Archives server. In the case of standards and other external hard-copy documents, these will be scanned in or an electronic copy created, as appropriate, and marked as superseded or links to the document will be posted.

### Document review

Periodically, documents are reviewed to ensure their continued suitability and compliance with applicable requirements. The revision periods of documents under the quality management system are given in the Document Master List.

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# Control of records

A Master List of records is maintained by the *[Insert title of person responsible for document control, eg Quality Manager]*. This list contains details of identification, collection, indexing, access, storage, maintenance and disposal of records.

## Medical Records Policy

For the purposes of this policy the term Medical records refers to any documents, instrument records, paper reports, request forms or other relevant documents generated in the course of a patient’s dealings with [Company].

**Record retention**

[Company] retains medical records in both paper and electronic forms. Details of the retention period for medical records are included in the Master List of Records. Legal requirements in relation to record retention affect the minimum period for which these records are to be retained.

The electronic management information system record is maintained. To ensure adequate protection against local computer malfunction , *[Insert details of any back-up procedures, who is responsible for this and if any records are maintained in off site facilities]*.

## Medical records and patient identification protocols

Each patient has his or her current demographic data obtained via the Referral form. This data is entered into the management information system that automatically allocates a unique medical record number to each new patient, as well as a unique accession number for each examination performed. The referral form is archived in accordance with the policies discussed above.

Confirmation of patient identity on samples is conducted by verification of the patient’s name, address, age/date of birth and other relevant unique identification data associated with medical/clinical history.

All modifications and additions to the management information record are tagged to unique, password protected operator identity to provide an audit trail of changes to records.

# Human Resource Management

## Human Resource Policies and Procedures

Policies and procedures relating to the following issues have been developed.

* Staff ethics policy
* Operational integrity and undue influence on staff/ Code of Conduct
* Confidentiality
* Performance Management
* Leave entitlements and management
* Job descriptions

## Organisation structure

The organisation structure is outlined below:

[Insert organisation chart]

*Figure 3: Organisation chart*

## Job descriptions

Job descriptions for each position outlined in Figure 3 have been developed and form a part of the forms available. These are signed by staff and the signed job descriptions are filed in staff personnel records.

Technical and quality management for the organisation is provided by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*. The *[Insert title of person responsible for quality management, eg Quality Manager]* is responsible for the operational implementation of the quality management system.

## Training and competence of staff

### Staff Induction

All new staff undertake an Induction Program suitable to their position within [Company]. Induction training is provided by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* and the staff member’s immediate supervisor. The Induction Checklist is signed following the completion of the induction training.

### Ongoing training

[Company] requires that all staff undertake ongoing training as directed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager].*

Records of training are maintained in the Staff Training Log.

Staff receiving in-house training are firstly instructed in or observed performing the task outlined. Following the successful completion of the task, the staff member is determined and recorded as having attained a level of competence as outlined below:

The effectiveness of the training program is reviewed at the management review.

### Education Policy

On-going education is mutually advantageous to both employer and employee. It is a continuing investment in the growth and development of the business and should be an integral part of medium and long term business plans. Provision of such a policy demonstrates to staff and prospective employees of [Company]’s commitment to achieving best practice and highly skilled staff. It goes towards staff motivation and morale.

Application is to be made by the staff member, in writing with appropriate documentation supporting the application, via the supervisor or at the supervisor’s request when the business requires it. Supervisor approval is to be forwarded to the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* for final and prompt approval.

A debrief of the seminar in writing should be presented by the staff member to their supervisor.

# Purchasing of services and supplies

When new items that affect the quality of testing are to be purchased, the procedures outlined below are to be followed. Approved Suppliers are to be used wherever possible.

## Capital Expenditure items

1. A business case for capital expenditure is prepared. Consideration is given to issues that have arisen with the provision of similar services and supplies. For equipment purchases, references from other users may be sought, reference to OH&S considerations must also be included in the business case, as must input from the staff to use the piece of equipment.
2. The business case is considered by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*.
3. Once approval has been given by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*, the item may be purchased using an Order form.
4. The Order form is forwarded to the supplier.
5. On receipt of the items, staff check the Order form to verify that the goods received are as ordered. The invoice and delivery docket are forwarded to the Accounts section for payment of the invoice.

## Non-Capital Expenditure items

1. Non-capital expenditure items may be purchased by *[Insert title of person/s who may do this, eg Scientist]*. Purchase of these items is by means of completion of an Order form. The Order form is forwarded to the supplier.
2. On receipt of the items, staff check the order form to verify that the goods received are as ordered. The invoice and delivery docket are signed and forwarded to the Accounts department for payment of the invoice.

## Approved Suppliers

Suppliers of goods and services are selected in accordance with pre-defined criteria. These criteria are developed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* and *[Insert title of person responsible for quality management, eg Quality Manager].* Details of suppliers who meet the criteria are maintained in the Approved Suppliers system.

On an annual basis, the *[Insert title of person responsible for quality management, eg Quality Manager]* evaluates the performance of suppliers. A record is made and the outcome of this evaluation is reported in the management review.

# Service to clients

[Company] is willing to cooperate with all clients in clarifying requests and in monitoring the organisation’s performance in relation to the work performed, provided that this does not mitigate confidentiality requirements. Client requests to visit the organisation need to be made through the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*.

Any negative feedback or suggestions for improvement received from clients are examined under the continuous improvement processes described in Sections 9 and 10 of this Quality Manual.

## Tender and Contract Review

Upon notification of a tender, the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* reviews the documentation associated with this to determine whether the laboratory has the resources with respect to capabilities and staff resources to meet the tender requirements, Consideration will be given to the use of sub-contracted laboratories in the event that the laboratory is unable to meet all of the testing requirements. On that basis, the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* prepares a tender and submits this through the tender process.

If a contract is awarded to the laboratory, the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* reviews the content of the contract to ensure that the laboratory has the required resources with respect to capabilities and staff resources to meet the contract requirements. Should there be a discrepancy between any previous tender associated with the contract and the contract itself, the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* contacts the client to negotiate this and a record is made of this discussion. Once the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* is satisfied with the contract requirements, this is signed and returned to the client.

If the client requests variations to the contract, these are to be reviewed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* and a record made of this review.

## Review of requests for testing

Testing may result from contracts or ongoing associations with clients. Where such requests are unexpected or for those unaccompanied by samples, requests for testing are reviewed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager].* A record of this review is made by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* on the request form. If samples have been expected and arrive with the request for testing, these requests are handled as outlined in SOP 16 Sample Management.

## Client Satisfaction Surveys

Client satisfaction surveys shall be initiated periodically by the *[Insert title of person responsible for quality management, eg Quality Manager]* to elicit feedback from clients regarding the level of service of [Company]. The results of this survey shall be analysed by the *[Insert title of person responsible for quality management, eg Quality Manager]* with the outcome reported to the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*.

# Complaints and feedback

In the event that a grievance or complaint is lodged about either the organisation, the following procedures must be followed. Any positive feedback should also be shared with the relevant staff member to re-enforce positive behaviours and recognise exemplary performance. All feedback will be recorded.

This policy applies to clients and staff attending [Company] facilities.

[Company] will receive complaints from any source and views such as an opportunity to improve the quality of the services provided. To this end, complaints are regarded as serious and treated with the respect that they deserve.

## Positive Feedback & Complaints: General Information

All complaint handling and positive feedback received is to be directed to the *[Insert title of person responsible for quality management, eg Quality Manager]* who shall be responsible for responding to such feedback and investigating the root causes of all complaints.

## Handling of Complaints

In the event that a client makes a complaint to any staff member of [Company], it should be that staff member’s responsibility to take as much information as possible from the client in order to investigate the complaint. The complaint is to be reported to the *[Insert title of person responsible for quality management, eg Quality Manager]*.

Staff will inform the complainant that the matter will be investigated no matter how minor and an apology should be issued at the time of complaint.

Staff will explain to the complainant that to investigate thoroughly as much information as can be given will be taken and passed on to the appropriate individual for action.

Should the complainant be unhappy to provide details to the staff member at this point of contact, or should they wish to speak to the *[Insert title of person responsible for quality management, eg Quality Manager],* this should be facilitated as soon as is practical.

Complaint documentation will commence from the initial contact point and the person who initially discusses the matter with the complainant shall commence an Opportunity for Improvement form and attach any interview material. The steps set out in section 10 of this Quality Manual will be followed in this regard.

It is the duty of the relevant senior staff member to investigate and report findings and the incident to the *[Insert title of person responsible for quality management, eg Quality Manager]*. An investigation should yield sufficient information to issue an explanation of the facts or an apology with an undertaking to adjust processes to avoid further issues of similar nature.

[Company] undertakes to openly disclose information with respect to errors which may or may not be the source of a complaint. Following investigation of an incident or complaint, the complainant will receive a written response to their complaint outlining the causes and corrective actions taken in relation to the complaint. This will be the responsibility of the *[Insert title of person responsible for quality management, eg Quality Manager]*.and must be done in a timely fashion such as to assure the complainant of the seriousness of our commitment.

Should the complainant still feel dissatisfied with the results of the earlier parts of the process, they should be informed that they have the right to complain to the relevant authority, namely the Health Services Complaint Tribunal. Details and advice on which authority to contact should be supplied to the complainant.

## Positive Feedback

Any gifts or positive feedback given in written or verbal form should be documented and the person providing this feedback should be thanked for their support of our organisation and for letting us know that we meet their expectations.

Individual commendations shall be passed on via the *[Insert title of person responsible for quality management, eg Quality Manager]*.

Positive feedback is as vital to receive as a complaint as both are important markers of performance and as such can inform management with respect to policy decisions and the general direction of the organisation. All compliments and positive feedback received are to be reported at the management review meetings. This way the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* can be made aware of both the positive and negative feedback received.

# Continuous Quality Improvement

As outlined in the Quality Policy, [Company] is committed to the philosophy of continuous improvement.

A number of tools comprise the management system to facilitate continuous improvement efforts. These include management review, internal audits, customer surveys, the Opportunity for Improvement system, participation in external quality assurance programs, where available and analysis of quality control data.

## Responsibility

The *[Insert title of person responsible for quality management, eg Quality Manager]* is responsible for ensuring that this procedure is followed. Relevant staff are responsible for undertaking delegated parts of this procedure.

## Procedure

In the event that any aspect of [Company]’s activities does not meet the requirements of the management system, the following process shall occur.

1. The responsibilities and authorities for management of non-conformances will be designated by the *[Insert title of person responsible for quality management, eg Quality Manager]*.
2. An evaluation of the significance of the non-conformance will be made by the staff member responsible for managing this process.
3. If necessary, work may be halted until the investigations are completed and appropriate corrective action taken.
4. If the non-conformance is deemed to be significant, appropriate corrective action needs to be taken. This may involve recall of any reports already issued. The procedures for implementing corrective action will be followed in this event.
5. Authorisation for the resumption of work shall be given by the staff member assigned to managing the non-conformance.

The following steps must be taken in addressing any identified opportunities for improvement. This process is to be used for both corrective and preventive action purposes.

1. The problem or potential problem needs to be clearly recorded on an Opportunity for Improvement Form. This information can be completed by any staff member.
2. Once a problem or potential problem has been identified, the *[Insert title of person responsible for quality management, eg Quality Manager]* allocates investigation of this to the appropriate staff member. Allocation for investigation is recorded on the Opportunity for Improvement form and in the Improvement spreadsheet.
3. The root cause of the (potential) problem needs to be identified. This may not always be a simple task and some thought may need to be taken before the root cause is identified. Root cause analysis techniques are useful in this regard. This information is also recorded on the Opportunity for Improvement form.
4. A number of solutions to the problem may present themselves. All potential solutions should be recorded and the action most likely to eliminate the problem selected. The action to be taken and the timeframe for implementation are to be recorded on the Opportunity for Improvement form. The *[Insert title of person responsible for quality management, eg Quality Manager]* ensures that this information is recorded in the Improvement spreadsheet.
5. The effectiveness of the action taken must be monitored. The means by which this is to be achieved is to be recorded on the Opportunity for Improvement form. The *[Insert title of person responsible for quality management, eg Quality Manager]* has responsibility for ensuring that the effectiveness of the action taken has been verified and for subsequent closure of the Opportunity for Improvement.
6. The *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* should be notified in each instance via monthly reports. Copies of the Opportunity for Improvement forms with the outcomes and recommendations completed will also be provided for review.

# Internal audits

Internal audits are a valuable quality assurance tool used as an integral part of [Company]’s continuous improvement efforts.

## Responsibility

Management of the Internal Audit system is the responsibility of the *[Insert title of person responsible for quality management, eg Quality Manager].* Trained auditors are responsible for conducting audits as directed by the *[Insert title of person responsible for quality management, eg Quality Manager]*.

## Audit schedule and allocation of auditors

Internal audits shall be conducted by trained auditors in accordance with the Internal Audit Schedule. This schedule is administered by the *[Insert title of person responsible for quality management, eg Quality Manager]*. The composition of the audit team will be at the discretion of the *[Insert title of person responsible for quality management, eg Quality Manager]*.

## Audit records

Full records of internal audits shall be maintained using the Internal Audit form. At the conclusion of the audit, an Audit Report will be prepared by the auditor, outlining any deficiencies or areas for improvement.

When audit findings indicate departures from documented procedures or planned activities, corrective action shall be taken in accordance with the procedures outlined in section 10 of this Quality Manual.

Audits may also identify opportunities for improvement. These will be identified in the Audit Report and implementation will be considered immediately following the audit by the *[Insert title of person responsible for quality management, eg Quality Manager]* and *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*. Implementation of the selected opportunities for improvement will be managed via the improvement process outlined in section 10 of this Quality Manual.

## Review of audits

The outcomes of internal audits are reported to the *[Insert title of person responsible for quality management, eg Quality Manager]* and discussed at management review meetings.

# Management reviews

Management reviews will be undertaken at least annually by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* in consultation with the *[Insert title of person responsible for quality management, eg Quality Manager]*. This management review considers the continued suitability of the quality management system. The review will take account of:

* The suitability of policies and procedures
* The outcomes of both internal audits and assessments conducted by external bodies
* Safety matters
* Complaints received and positive client feedback
* Corrective and preventive actions
* Results of external quality assurance activities,
* Changes in the volume and type of work performed
* Recommendations for improvement
* Personnel issues

Records of these reviews will be maintained by way of minutes. Actions arising from the reviews shall be recorded and implemented via the improvement system outlined in section 10 of this Quality Manual.

# Testing Protocols

The testing protocols of [Company] are described in a series of SOPs. Staff are directed to these SOPs, as relevant to their job description.

# Equipment and consumables

Equipment is registered in the Equipment Register maintained by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*.

Equipment calibration and maintenance procedures are described in the relevant SOPs supplemented by information in related equipment instruction manuals. General procedures relating to the commissioning of equipment and calibration and maintenance system are described below.

## Equipment Commissioning

New equipment will be subject to appropriate testing during the commissioning phase to ensure that it meets the needs of the laboratory and any specifications for testing. The *[Insert title of person responsible for equipment management in the laboratory, eg Laboratory Manager]* will oversee this process and may delegate this to appropriate staff.

Records of commissioning of new equipment will be maintained. These records include the results of any testing of operational parameters of the equipment and software testing, as appropriate. Records of validation of any software performed either by the manufacturer or internally will also be maintained. These records will be filed in files dedicated to individual items of equipment. The date on which the equipment was approved for use will be recorded in the Equipment Inventory.

## Equipment calibration and servicing

The equipment calibration and servicing reminder system is managed through *[Insert details of how this is done, eg through MS Outlook or a planner]*. The *[Insert title of person responsible for equipment management in the laboratory, eg Laboratory Manager]* is responsible for managing this system and ensuring that equipment calibrations and services occur as scheduled.

Procedures for calibration of equipment are documented either in the test methods or in separate SOPs for this purpose, as appropriate. These procedures describe how equipment calibration records are to be maintained for each calibration activity.

# Facilities

The facilities at [Company] are required to meet regulatory requirements, such as *[Insert details of any regulatory requirements, eg Department of Health]*.

## Housekeeping

All staff should practice good housekeeping.

*[For example:*

* *General waste is placed in lined bins at various places around the premises where the cleaners take it to the exterior rubbish bins for removal.*
* *Yellow bins for collection contaminated waste are located in the laboratories, which are emptied into the large Clinical Waste bin provided by a Clinical Waste Collection and Disposal Company*
* *Rubbish bins are not to be over filled and are to be emptied when full.*
* *Walkways are to be clean and free of obstruction.*
* *Any dirt or dust or soiled property should be immediately cleaned by the staff member who notices it or where practical a note left for the cleaners.]*

# Patient management

## Review of requests for testing

Requests for testing are reviewed by the appropriate staff members responsible for sample receipt to ensure that these are complete. If staff have queries in relation to the nature of the request, these should be directed to the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*. If there are concerns regarding the appropriateness of the testing that has been requested, these concerns should be discussed with the referrer and agreement reached as to the testing to be performed. The request form will be annotated to this effect.

## Consent for testing by patients

Consent for performance of testing is obtained by referrers prior to sample collection. A record of having obtained informed consent is made on the request form.

It is the responsibility of the clinician collecting the sample and requesting the testing to ensure that the patient is fully aware of the actions and likely consequences and risks associated in conducting the testing.

## Sample receipt

Samples are received in the laboratory in the sample reception area. Staff are notified of the receipt of samples by the person delivering the samples.

Staff check the request for testing and confirm that the laboratory has received the correct samples. This involves a check of the patient name and date of birth against the request form and that the correct type of sample has been received to enable testing to be completed. If there are any problems at this stage, the client is contacted to resolve these discrepancies. Samples are then assigned a unique identifier that is used to identify the sample throughout the testing process. Samples are labelled with the unique identifier.

## Sample distribution

Samples are distributed within the laboratory to ensure that testing is completed within the required time frame. This may involve storage of samples in fridges and freezers to ensure the integrity of the samples are not compromised until such times as testing can be completed. The relevant laboratory staff are advised of the distribution of samples into the laboratory.

## Sample testing

Samples are tested using the relevant SOPs. The assigned laboratory identifier is used to identify samples during this process. Once testing has been completed, samples are stored as described as follows.

*[Insert details of how samples should be stored, location of storage and duration of storage]*

## Sample destruction

*[Insert details of sample destruction, eg discard into a secure waste bin, autoclaving, etc.]*

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# Reporting

## Report process

Reports are prepared by Scientists and are reviewed by the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]*. The *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* reviews the report for accuracy, clarity and conformance with any specific method or client requirements. The results of internal quality control activities associated with the reported results are also reviewed at that time. Once the *[Insert title of person responsible for overall management of the laboratory, eg Laboratory Manager]* is satisfied with the content and format of the report, it is signed and sent to the client as *[Insert report format as either hard copy, electronic or both types]* by *[Insert details of whether reports are sent via post, email or other means of communication]*.

## Report content

Reports are to include the following information.

1. A clear, unambiguous identification of the tests that are reported
2. Identification of the laboratory issuing the report
3. Patient/ sample identification
4. Client name and contact details
5. Date of sample collection
6. Time of sample collection, where relevant
7. Test method or measurement procedure
8. Results reported in SI units, units traceable to SI units, or other applicable units
9. Biological reference intervals, clinical decision values, or diagrams of clinical decision values, where applicable
10. Interpretation of results, where appropriate
11. Other comments such as cautionary or explanatory notes
12. Identification of the person reviewing the results and authorising report release
13. Date of the report
14. Pagination of the report, eg page 1 of 5.

Where the quality of the sample received is unsuitable for testing or could have compromised the result, this will be indicated in the report.

When test results fall within established “alert” or “critical” intervals, the client is to be notified of this immediately and a record of this notification is to be made, eg, date, time of notification, staff member and person to whom the notification was communicated. Any difficulties encountered in notifying the client of such results are also to be recorded.

## Interim reports

Where an interim report that has been issued, the final report is to clearly indicate it is a replacement of the interim report and include reference to the date or other unique identifier of the interim report.

## Amended reports

Where an original report that has already been issued requires revision, the replacement report must clearly indicate that it is a revised report and include reference to the date or other unique identifier of the original report.

## Verbal communication of results

If results are communicated verbally with the client, a record of this is to be made. This record must include the date, time of notification, staff member communicating verbal results and to whom the results were communicated. All verbal communication of results is to be followed by a written report.