ISO 17025 – Microbiological Testing

Testing of *Bacteria species* in food

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.

300656 – Laboratory Quality Management

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Appendix:

1 INTRODUCTION

Testgroup Pty Ltd is a relatively young company, as it was founded in 1992 by a group of aspiring microbiologists. The company was formed with the plan to develop reputable testing methods of *Bacteria species* in food that can be used across the industry. Dependable testing methods are vital in the food industry, as they can deliver accurate, consistent results regarding food microbiology.

Microorganisms in food products have the ability to cause detrimental effects to individuals' health, in particular *Bacteria species.*

In accordance with NATA, Testgroup Pty Ltd have constructed this laboratory quality manual to demonstrate all procedures used for testing of *Bacteria species*, as well as the relevant documentation. This manual follows the criteria set by ISO 17025.

Testgroup Pty Ltd first published this document in 2012 in order to satisfy the needs of NATA as well as the customer.

2 SCOPE

Testgroup Pty Ltd continuously strive to maintain its effective quality system, ensuring all operations are conducted with the highest quality, enabling accurate and precise results in all work we bear. This Quality Manual before you pronounces and defines the quality management program implemented at Testgroup Pty Ltd.

The aim of this Quality Manual is to:

- Define quality systems
- Acquire commitment from management regarding quality
- Provide a framework for continuous quality to be performed
- Meet all guidelines and requirements laid by governing bodies such as NATA

The laboratory conducts all measurements under conditions which, and by using techniques that, are conducive to a high degree of reliability and follows generally recognized good laboratory practices.

2.1 TERMS AND DEFINITIONS

Audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Calibration: Comparison and adjustment to a standard of known accuracy.

Certified Reference Culture (CRC): Microbiological; a reference culture certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body; e.g., cultures used to verify test systems, validate methods, perform quality control of test media, etc. must be traceable to a type culture collection. Synonymous with Standard Reference Materials (SRM).

Check Samples: Sets of samples tested by laboratories to determine if their processes are in control. A test sample with known properties of microorganisms examined on a routine basis to evaluate laboratory performance.

Client: An entity (e.g., customer, agency, company, person, etc.) that receives a test result done according to specified requirements.

Conformance: Compliance with specified requirements.

Control: To exercise authority over and regulate.

Controlled Document: A policy or procedure related to the documented quality system that is subjected to controls to ensure that the same version of the document and any revisions are held by or available to all personnel to whom the document is applicable.

Corrective Action Measures taken to rectify conditions adverse to quality and to eliminate recurrence.

Culture: An isolated microorganism grown on laboratory medium.

Documentation: Recorded information.

Food Testing Laboratory: Laboratory that performs tests on finished food product, ingredients, in-process samples and associated environmental samples for microorganisms.

In-process Samples: Samples in the laboratory that are in the process of being tested (not to be confused with in-process product samples from a manufacturing standpoint).

Inspection: Activities such as measuring, testing and examining one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.

Internal Audit: A formal review of the performance of a quality system conducted by laboratory personnel from outside of the laboratory or department under review.

Method: A document that provides detailed "how to" instructions to accomplish a task.

Monitor: A substance, device or system for observing, recording or detecting the operation, condition or performance of a microbiological test procedure.

Nonconformity: The non-fulfilment of a specified requirement.

Proficiency Test Samples: Test materials (split samples) with microorganisms (antibiotics and toxins) that are tested periodically by a number of locations to determine the proficiency of recovery, using statistical analysis where appropriate.

Quality: Conformance to specified requirements.

Quality Assurance: All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Quality Control: The operational techniques and activities that are used to fulfil requirements for quality.

Quality System: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Raw Material: A material used in food processing whose properties may impact the quality of the final result.

Reference Culture (RC): A culture with cultural characteristics sufficiently well established to be used to calibrate/verify test systems and test media and validate methods.

Replicate tests*:* Samples of RMs or CRMs which are tested by the same analyst in duplicate or by two different analysts. In each case, the results are compared for precision.

Report: Final presentation of results sent to a customer.

Sample: Any material brought into the laboratory for analysis.

Self-Audit: A review of the performance of the quality system within a limited area conducted by the personnel with responsibility for the area.

Split Samples: Unknown test samples of adequate homogeneity, sub-sampled and sent to laboratories for proficiency testing.

Standard Operating Procedure: A document that specifies or describes how an activity is to be performed. It may include methods to be used and a sequence of operations.

Traceability: The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (e.g., all media, reagents and kits must be traceable to a result and to

the appropriate Certified Reference Material, Certified Reference Culture, Reference Culture or Reference Material.)

***Validated method*:** A method whose performance characteristics (selectivity and specificity, range, linearity, sensitivity, ruggedness, accuracy and precision and quantitation and detection limits) meet the specifications related to its intended use.

Verification: Confirmation by examination and provisions of evidence that specified requirements have been met.

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4 MANAGEMENT REQUIREMENTS

4.1 ORGANISATION

The team at Testgroup Pty Ltd are each held responsible for the obligation to meeting the quality standards set by the International Standards Organisation regarding test results, data and documentation. Together, the Laboratory Manager along with the Documentation Manager, Laboratory Operations Managers and Quality Assurance Manager, are responsible for upholding safe laboratory practices and procedures, within the guidelines of ISO 17025:2005.

It is the Laboratory Manager's role to supervise all tasks and activities carried out under the company name. Furthermore, these tasks and activities are monitored by the Laboratory Manager to ensure they meet the company's policies and procedures.

Additionally, it is the Laboratory Manager's responsibility to delegate their roles and responsibilities and appoint an Acting Laboratory Manager, whilst in absence.

4.1.1 ENTITY

Testgroup Pty Ltd is a third party independent laboratory that can be held legally responsible.

4.1.2 RESPONSIBILITIES & REQUIREMENTS

It is the responsibility of Testgroup Pty Ltd to operate, through testing and calibration activities, in accordance with the requirements of the National Association of Testing Authorities (NATA) and the ISO 17025:2005. The actions of Testgroup Pty Ltd also need to be carried out where needs of the customer, as well as NATA are satisfied.

4.1.3 MANAGEMENT SYSTEM

Management will undertake all work in the laboratories provided at Testgroup Pty Ltd. located in Richmond, NSW. External sites are not used, unless an emergency occurs where the work cannot be carried out safely or adequately.

4.1.4 CONFLICT OF INTEREST

When a conflict arises within the organisation regarding any activity, it is the responsibility of the Laboratory Manager and Document Manager to identify these potential conflicts of

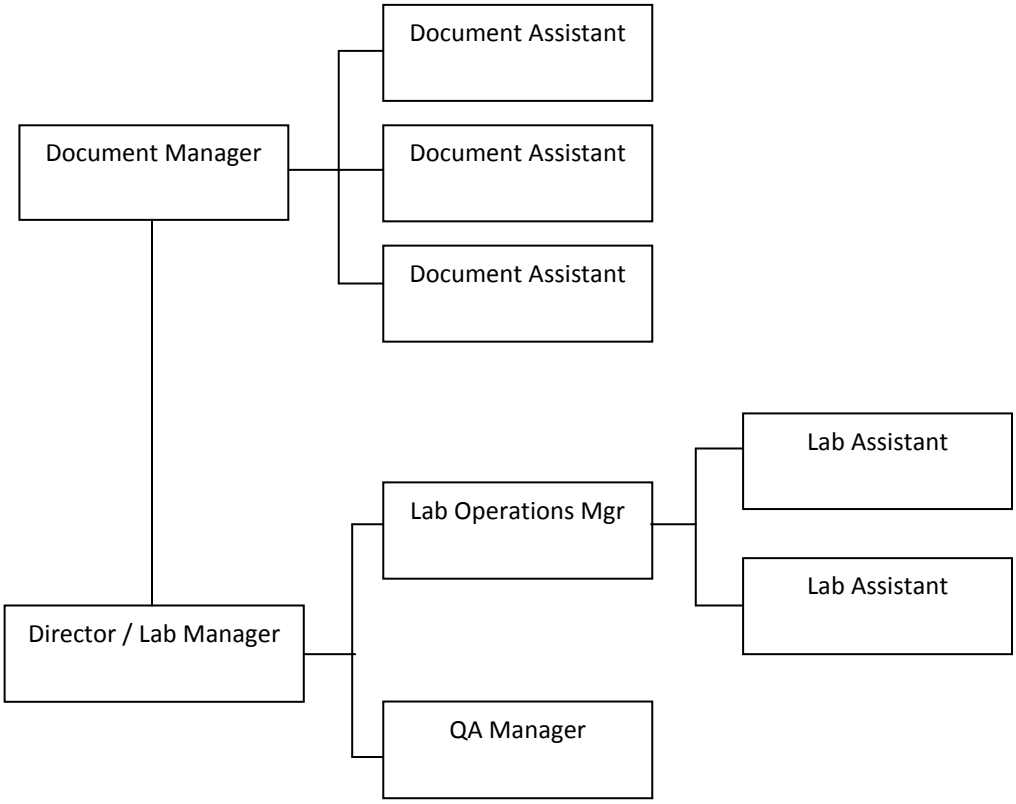
interest. Each manager only identifies potential conflicts, if they are associated with their working activities.

Once the conflict of interest has been identified by the respective manager, the other will provide support to them when needed. This support involves finding a solution to the initial problem, and acting to prevent the conflict of interest from rising again.

The two managers are both appointed as identifiers, as one can step in if the other is biased towards an issue. This will ensure unbiased decisions and results. If both managers cannot make unbiased judgments, a mediator is then appointed to do so.

These appointments and resulting actions are made to achieve reliable and unbiased results, ensuring all guidelines are met, therefore ensuring all clients and governing bodies are satisfied.

FIG. 4.1.5. STAFF & MANAGEMENT STRUCTURE



4.1.5.1 MANAGERIAL & TECHNICAL PERSONNEL

It is made aware to the Testgroup team that managerial personnel have the authority to make decisions affecting operations, activities and the relevant staff involved. Testgroup provides all appropriate resources needed for management and technical staff to carry out their activities and tasks. If resources pertaining a high value are needed, it is requested that this be put in writing with relevant quotes and reasoning behind the need. It is asked that this request be placed with management well in advance. This ensures duties are carried out with a high degree of quality and accuracy, whilst meeting all required guidelines.

4.1.5.2 UNDUE PRESSURE

As with other people-focused workplaces, arrangements have been made to ensure there are limited pressures placed on staff that may adversely affect the quality of their work. Arrangements include a support hotline, the availability of advanced payments, and an open-door policy to all staff.

4.1.5.3 CUSTOMER CONFIDENTIALITY

Customer confidentiality is maintained throughout Testgroup due to the active strict policies and procedures in place. All clients are requested to view and sign confidentiality agreements upon test sample submission.

All staff at Testgroup Pty Ltd upon employment is requested to sign confidentiality agreements that comply with the company's strict privacy policy. This ensures the staff are aware of the customer confidentiality policy and outlines that only relevant staff have access to electronic data and hard-copy results, which are stored in private files.

4.1.5.4 OPERATIONAL INTEGRITY

It is the responsibility of each manager to supervise all activities carried out under Testgroup, and implement or make alternate procedures, if they can visualise a potential threat that will affect the integrity of the operations at Testgroup. This ability to react quickly and make responsible decisions is taken from their extensive management experience. This ensures all work carried out at Testgroup is produced with high quality, unbiased results that are at an elevated standard of operational integrity and ethics.

4.1.5.5 ORGANISATIONAL CHART

Refer to Figure 4.1.5

4.1.5.6 RESPONSIBILITY & AUTHORITY

Each and every staff member working in the laboratory or controlling laboratory documents have the potential to affect the quality of tests and calibrations. The Document Manager has authority over each of the Document Assistants, whilst the Laboratory Manager oversees the QA Manager, as well as the Laboratory Operations Manager who then oversees the Laboratory Assistants. In the absence of the Document manager, the Laboratory Manager has authority to undertake any such documental change as required. Each respective team are required to communicate regularly and effectively, to ensure a safe and reliable working environment. It is the duty of the Quality Assurance Officer to oversee and ensure that all Standard Operating Procedures (SOP) are being followed and maintained. The Laboratory and Document Managers must be in constant communication to ensure all information in the laboratory is reflected in the Quality Manual. As each person has an effect on the quality of results, they are each responsible for carrying out work whilst following all policies and procedures, to produce results of a high standard.

4.1.5.7 LABORATORY SUPERVISION

As stated previously, it is the Laboratory Manager's responsibility to ensure the laboratory is constantly supervised. This can be performed by the Laboratory Manager themselves, or by an Acting Laboratory Manager, appointed by the Laboratory Manager when in absence. This ensures all staff are provided with constant support, enabling them to produce results of a high standard.

4.1.5.8 TECHNICAL MANAGEMENT

The Lab Manager/Director of Testgroup Pty Ltd has overall responsibility for technical operations and resources. The Document Manager is in regular contact with the Director, having a daily progress meeting at the beginning of each working day. Both managers then provide this information to their staff, ensuring all teams are up-to date with current procedures and policies, as well as clients and projects. Either are authorised to act independently in the absence of the other.

4.1.5.9 QUALITY MANAGER

The Quality Assurance Manager is responsible for implementing and maintaining the quality management system. This responsibility includes document control relating to quality, calibrations and holding regular quality updates. The Quality Assurance Manager has direct contact with senior management, allowing them to have better access to them, ensuring the notification of any quality-related matter to be instant.

4.1.5.10 MANAGERIAL DEPUTIES

The Document Manager reports to the Laboratory Manager. This ensures there is appropriate coverage for both teams, and that duties are spread equally amongst management staff.

4.1.5.11 IMPORTANCE OF ROLES

All staff are aware that they have an impact on the quality of test results, therefore know the importance of their roles and responsibilities at Testgroup. Staff are physically shown what their work leads to, demonstrating that their work does in fact affect all results achieved.

Staff are made aware of their importance on their first days of employment through position descriptions and initial inductions. This is also refreshed in their minds when performance reviews are conducted bi-annually.

4.1.6 COMMUNICATION

It is required that communication takes place regularly in order to ascertain an effective workplace. An effective communication process is established at Testgroup and involves weekly meetings that include client, project, policy, procedural updates and any non conformity. The information correlated in these meetings is then passed down the management line.

There are also emails, notices, announcements, presentations and verbal agreements that all contribute to the effectiveness of the communication system.

4.2 MANAGEMENT SYSTEM

4.2.1 POLICY

A management system will be not only designed, but implemented and maintained in a way that it is relevant to the activities of Testgroup. The management system is designed to fulfil the needs of the customer, NATA and ISO 17025:2005.

The system will entail procedures and policies that are recorded and kept up to date, ensuring the undertaking of quality laboratory work.

All documentation is made available to the management team and is then further made available to the relevant and appropriate staff. This ensures all staff are aware of the relevant information needed to carry out their work.

Management communicate all policies and procedures to staff at Testgroup Pty Ltd and ensure that they are understood and implemented.

A copy of Testgroup's policies and procedures are supplied to staff on the commencement of their employment, as well as made available in the staff room.

4.2.2 QUALITY POLICY STATEMENT

The quality policy statement of Testgroup Pty Ltd is: "All required tests and calibrations will be undertaken with the utmost degree of quality whilst following stated procedures, in order to fulfil customers' needs. Testgroup is committed to working in accordance with ISO 17025:2005 and will endeavour to continually improve the effectiveness of the management system". This statement is visible on all contracts and communication made with suppliers, customers and governing bodies, ensuring all parties are aware of the commitment Testgroup makes to their tasks and activities.

Management at Testgroup Pty Ltd are committed to good professional practice and quality of its service by strictly following all SOP and methods, as well as its documentation policies. In doing so, this will ensure customers are able to produce quality products, knowing they are safe. These procedures have been designed to produce results of the highest accuracy, precision and reliability.

The Laboratory's Standard of Service entails meeting and exceeding the requirements of customers and governing bodies, whilst producing results of high quality with a great degree of accuracy and precision. This statement ensures the customer that they are receiving accurate data from our highly skilled and experienced laboratory staff.

The purpose of the management system is to ensure the laboratory produces are accurate, precise and supply consistent results, in turn, satisfying the needs of the customer. Management also ensure the laboratory is in compliance with the guidelines set by NATA and ISO 17025:2005 by making certain all resources are made available to staff to allow them to work in a manner, producing quality work.

Ensuring quality throughout the workplace also requires that all staff are familiar with quality documentation. This is made possible by delegating portions of the Quality Manual to each person from both the document and laboratory teams. As Policy and Procedural documents are provided to them on employment, they are still made available in the staff room for viewing and consulting. This ensures all personnel are aware of the reasons behind the way of work upheld at Testgroup Pty Ltd, and allows them to produce work in a quality manner.

Management at Testgroup are forever committed to complying with ISO 17025:2005 as well as NATA requirements. This is achieved by keeping in regular contact with NATA to access support, advice and guidance on procedures and policies, as well as familiarisation with the ISO Standard. This ensures clients and governing bodies are satisfied.

4.2.3 MANAGEMENT COMMITMENT

The management team at Testgroup are committed to working effectively together to ensure a quality management system. This is achieved through regular communication, entailing reviews, improvements and updates.

Management is committed to reviewing the quality policy statement objectives, and continually improving the quality system.

4.2.4 CUSTOMER REQUIREMENTS

Top management reinforces to the organization that not only is it important to meet the needs of the customer, but also meeting statutory and regulatory requirements.

In order to do so, these requirements are communicated throughout the laboratory in forms of announcements, poster materials, electronic messages, as well as monthly organisational meetings, where management convey the significance of working in accordance with ISO 17025:2005.

4.2.5 QUALITY MANUAL

The quality manual comprises of and references all technical and management procedures used within the organization, such as the Standard Operating Procedures. These are included in the document in the Appendix, ensuring all required procedures and relevant documentation is accessible through the quality manual.

The quality manual clearly defines the policies and objectives upheld by personnel at Testgroup Pty Ltd, and encourage staff to follow all guidelines and recommendations. This is a documentation tool for all activities and tasks undertaken at the laboratories at Testgroup Pty Ltd. The quality procedures are authorised by the Laboratory manager and the Document Manager.

4.2.6 ROLES AND RESPONSIBILITIES

4.2.6.1 TECHNICAL MANAGEMENT

The technical management team at Testgroup Pty Ltd refer to the Laboratory and Document Manager. The role of the Lab Manager is to oversee the entire operations of the Laboratory and be the first point of contact for NATA. The role of the Laboratory Manager is to ensure all tasks undertaken in the laboratories are safe and pose no risk to personnel or clients, as well as producing results that will satisfy the customers' needs. The Laboratory Operations Manager is the first point of contact for customers. The role of the Document Manager is to delegate tasks to the Document Assistants and oversee and approve all amendments, revisions and re-issues. It is the responsibility of the Document Manager to be up-to date with ISO 17025:2005 and revise current documentation to meet all requirements. The Laboratory Manager must also be trained in the ISO as they are physically and directly involved in its operations.

4.2.6.2 QUALITY MANAGER

The role of the Quality Assurance Manager is to ensure all documentation coincides with the operations of the laboratory, and that each follows the requirements set by NATA and ISO 17025:2005.

4.2.7 MAINTENANCE OF MANAGEMENT SYSTEM

As changes are made to improve the effectiveness of the management system, each modification is recorded. Modifications may include updating management contact information, new procedures implemented that have been developed and customer contracts. Regularly recording any updates ensures the system is reliable and maintained to the highest quality, ensuring the integrity of the management system is maintained.

4.3 DOCUMENT CONTROL

4.3.1 GENERAL

All procedures regarding documentation are well-established and maintained. These procedures outline the processes for managing quality documents such as the SOP, as well as client confidentiality agreements, recording of results and the Quality Manual. The Document Manager is responsible for implementing and maintaining these procedures.

4.3.2 DOCUMENT APPROVAL AND ISSUE

4.3.2.1 DOCUMENT APPROVAL

The Document Manager is responsible for reviewing and approving the documentation, prior to release to staff. The documentation is also made available to the Laboratory Manager and Director, although the Document Manager has full control.

The Document Manager states the level of access that each staff member has to each document. This ensures the strict confidentiality procedures are upheld at Testgroup Pty Ltd.

It is also the responsibility of the Document Manager to implement and maintain a master list (Form 4.3.2.1), which identifies the revision status and distribution of documents. This ensures all staff are aware of the most recent versions, and unbiased decisions can be made upon this.

4.3.2.2 OBSOLETE DOCUMENTS

Once documents become invalid, they are then labelled with this term and removed to an archive location. Documentation stored includes that needed for legal, or knowledge preservation purposes. An obsolete document form (Form 4.3.2.2) is maintained by the Document Manager and is kept on location at Testgroup Pty Ltd, allowing the manager to view what documents have been archived.

4.3.2.3 DOCUMENT IDENTIFICATION

Once a document has been received or created, it is given a documentation code that is unique, making it easier to recognise and access any document. The Document Manager applies this code, and records it in the Document Identification Form (Form 4.3.2.3a).

Other identification tools on documents include original date of review and issue, revision dates, re-issue dates, number of variations made and an approval signature. An example of this can be seen in Figure 4.3.2.3b.

4.3.3 DOCUMENT CHANGES

4.3.3.1 REVIEWING DOCUMENT

Document reviews are conducted annually, by the Document Manager, in conjunction with the Laboratory Manager. This ensures that there is input from both parties, giving an unbiased result. Reviews can also take place at any time, from the request of a client or governing body.

4.3.3.2 DOCUMENT ALTERATIONS

When an alteration has occurred within a document, a copy of the preceding document must be made obsolete and kept on the obsolete documents form (Form 4.3.2.2) and stored. These alterations are carried out whilst following all document policies and procedures, and are made under the supervision of the Document Control Manager.

The document must be renamed, with the altered date, allowing the staff using documents to become aware of the updated version.

4.3.3.3 HANDWRITTEN AMENDMENTS

Handwritten amendments on documents at Testgroup Pty Ltd are not permitted under any circumstances.

4.3.3.4 ELECTRONIC DOCUMENTS

As amendments are made electronically, under the supervision of the Document Manager, they must be recorded on the Alteration Record Form (Form 4.3.3.4). This ensures all changes are identified and understood.

Figure 4.3.2.3b Identification Tools Example

4.4 REVIEW OF REQUEST AND TENDERS

4.4.1 REVIEW

Review of requests, tenders and contracts are performed bi-annually or at the request of the client, and are essential in maintaining a quality management system. All requirements stated by the customer are understood and accepted or rejected before the commencement of work with that customer. The majority of requests are accepted, and only rejected when they exceed the laboratory's capabilities and resources. If this is so, Testgroup Pty Ltd endeavours to further assist the customer by providing them with other contacts that can assist them in ways Testgroup Pty Ltd cannot.

4.4.2 RECORDS OF REVIEW

Records of reviews are maintained by Testgroup Pty Ltd to ensure all information is captured and can be referred to at a later date. This is maintained in Form 4.4.2a. Discussions as well as any significant changes throughout the contract are also recorded in Form 4.4.2b.

4.4.3 SUBCONTRACTING LABORATORIES

Testgroup Pty Ltd does not participate in subcontracting clients' work to other laboratories, however contacts for outside of Testgroup Pty Ltd are provided, for further work where Testgroup cannot produce.

4.4.4 NOTIFICATION OF CUSTOMER

If there is any deviation made by Testgroup Pty Ltd to the contract, the customer must be notified immediately. Likewise, if a customer requests a deviation from the contract, it must be brought to the attention of the Laboratory Manager at Testgroup Pty Ltd to see if it can be accounted for.

4.4.5 CHANGES TO CONTRACTS

If a contract needs to be amended after work has commenced, the same contract review process (refer to 4.4.1) is applied. All affected personnel need to be notified of the change, and the issues needs to be recorded and identified.

4.5 SUBCONTRACTING OF TEST AND CALIBRATIONS

4.5.1 EMPLOYMENT OF SUBCONTRACTORS

Testgroup Pty Ltd carries out all clients laboratory work by its own staff and within its own premises. However, in the rare case that Testgroup Pty Ltd might require the use of a 3rd party organisation, on a temporary basis (due to perhaps increased workloads or need of additional expertise), only accredited sources will be used.

Before employment of any subcontractor, a copy of certification or records are required to prove that the laboratory is either NATA accredited or complies with ISO 17025:2005. This scope of accreditation is handed over from the 3rd party organisation to our Document Manager and is stored on hand at the Testgroup Pty Ltd laboratory.

4.5.2 CUSTOMER NOTIFACTION AND APPROVAL

In the rare event that subcontracting occurs, all customers affected will be advised that a 3rd party is involved, and the arrangement will be detailed in writing. Before the commencement of the subcontractor employment, an approval will need to be received from the customer agreeing to the input by subcontractors on the proposed assignment.

4.5.3 CHAIN OF RESPONSIBILITY

Testgroup Pty Ltd takes full responsibility for the work of any subcontractor hired by them. In the case of a subcontractor specified for use by either the customer or a regulatory authority, full responsibility is revoked.

4.5.4 REGISTER OF APPROVED SUBCONTRACTORS

For every subcontractor that Testgroup employs, a register will be kept detailing which tests/calibrations are performed by them. When applicable, evidence that is compliant to ISO 17025:2005 will be met. Otherwise all suppliers and manufacturers of equipment shall provide documentation and guarantees (Form 4.5.4).

4.6 PURCHASING SERVICES AND SUPPLIES

4.6.1 PURCHASING POLICIES AND PROCEDURES

Any supplies that Testgroup Pty Ltd purchases which may affect the quality of any test/calibration performed, shall have a procedure which will be followed for the purchasing, receipt and storage of these supplies. Procedures will also be in place for services relevant to the tests/calibrations.

Supplies are only selected and purchased with the approval of the Laboratory Manager and received and stored by the Laboratory Assistants. If received supplies do not meet specifications or standards, this must be reported to the Laboratory Manager as soon as possible, and recorded. The supplier will then be notified by the Laboratory Manager and the issue will be resolved. Refer to Appendix 9 and 10.

4.6.2 INSPECTION AND/OR VERIFICATION OF MATERIALS

Any materials and supplies that have been purchased by Testgroup Pty Ltd for use in testing/calibration are first inspected before use (if not already verified) to ensure that they comply with the specified requirements of the test. This is performed by the Laboratory Assistants. The documentation records of verification from suppliers or records detailing the measures taken to check the compliance of these materials will be kept and maintained (Refer to Form 4.6.2). The Document manager oversees all corresponding documentation and ensures the validity of the materials received.

The medium needs to be assessed for typical morphological and colony size to complete the performance evaluation of the medium. This will ensure any contamination throughout the process will be identified. For batch control of medium growth should be assessed quantitatively, semi-quantitatively and qualitatively. Plates will be compared to previous batches of the same medium and a viable plate count for test and reference medium are compared.

Sampling Plan for PEMBA Agar.

Batch size	Sample No.		1st Sample		2nd Sample	
	1st Sample	2nd Sample	Accept	Reject	Accept	Reject
101-150	5	5	0	2	1	2
151-280	8	8	0	2	1	2
281-500	13	13	0	2	1	2

Double Sampling Plan (>100 units), According to AS1199.1-2003.

4.6.3 DOCUMENTATION OF PURCHASED SUPPLIES

All evidence of purchased supplies which affect the quality of the laboratory output will include a description of the supply/service ordered. Such descriptions may include;

- Type, class or grade
- Precise identification number or reference
- Specifications
- Date
- Other relevant technical data

These purchasing documents will be reviewed and approved before release.

4.6.4 SUPPLIER EVALUATION

For every supplier of materials relating to testing and/or calibration, an evaluation will be carried out to ensure they are a credible source. The evaluation will cover;

- The supplier's workplace environment and surroundings
- The materials and supplies
- The training and competency of employees

- The policies and procedures implemented and whether they follow the appropriate industry standards

This evaluation will be carried out yearly to ensure that the supplied materials are of highest quality. These evaluations will be recorded, ultimately creating a document of all approved suppliers.

4.7 SERVICE TO THE CUSTOMER

4.7.1 COOPERATION

For each client assignment, a Testgroup Pty Ltd staff member will be appointed the liaison who will have responsibility of upholding communication with the client. This liaison will ensure that the client is informed at all stages throughout the assignment and will be available to clarify any of the client's questions or concerns. Should the client wish to monitor the progress at Testgroup Pty Ltd premises, the liaison will organise clearance, which includes signing a confidentiality agreement and an agreement to abide by the laboratory's OHS regulations.

4.7.2 FEEDBACK

To ensure that Testgroup Pty Ltd is providing a consistent service, and to improve on services, feedback in the forms of positive and negative from customers is sought after. After each assignment or service, customers are sent a satisfaction survey (Form 4.7.2) which is then reviewed by Testgroup Pty Ltd staff member who will take necessary action. Any negative feedback will be recorded, analysed and discussed to rectify the issue. Once this has taken place, the customer will be notified of the corrective action as a result of their feedback.

4.8 COMPLAINTS

4.8.1 CLIENT COMPLAINTS

In the case that a client is not satisfied with the services provided and a complaint is made, a procedure is set in place that aims to rectify the issue. Testgroup Pty Ltd complaints team will first record the complaint with the date it was made, the corresponding company and contact, and the details of the nature of the complaint (Form 4.8.1). It will then be forwarded to the associated department who with the manager, will meet to analyse the problem and discuss possible ideas for rectification.

Meeting minutes will also be recorded and the corrective action chosen will be set in place (Refer to section 4.11). The associated client will be informed of the corrective action carried out, and after completion, a follow up customer feedback form will be sent to ensure that the issue has been resolved and the client is satisfied.

4.8.2 OTHER COMPLAINTS

In the case that a complaint is sent to Testgroup Pty Ltd from another party other than a client, such as a supplier or subcontractor, a similar procedure is followed as stated in 4.8.1. Testgroup Pty Ltd complaints team will first record the complaint details (Form 4.8.1) and will notify the department associated with the complaint made. From there it will be analysed, discussed and the appropriate course of action will follow.

This will be made known to the party involved and all correspondence will be kept and recorded. To review the corrective action and to ensure the other party is satisfied with the actions made, the Testgroup Pty Ltd complaints team will send a follow up feedback form (Form 4.8.2).

4.9 CONTROL OF NONCONFORMING TESTING AND/OR CALIBRATION WORK

4.9.1 NONCONFORMITY POLICIES AND PROCEDURES

Any non-conformance encountered within the testing process, such as issues concerning instrument calibration, customer complaints, audits, quality control, or management reviews, must follow the policies and procedures as outline in the following sections of 4.9.

4.9.1.1 RESPONSIBILITIES

It is the responsibility of any staff member to raise a non conformance should one be brought to their attention. In the case that a non-conformance arises, the laboratory manager will be given the responsibility of dealing with the issue. This includes the responsibility for all correspondence, delegation of tasks, evaluations and taking necessary further action such as ceasing work and withholding test reports and calibration certificates as necessary.

4.9.1.2 EVALUATION

The laboratory manager will firstly evaluate the significance of the non conforming work. Depending on the non-conformance, this may be carried out by visual inspection, further testing, discussions, research, or calibration of equipment. A record will be kept outlining the method of evaluation and its outcome (Form 4.9.1)

4.9.1.3 CORRECTION

Based on the significance of the issue evaluated as in 4.9.1.2, the appropriate action will be decided upon and applied as soon as possible. The method chosen will be recorded in Form 4.9.

4.9.1.4 CUSTOMER NOTIFICATION

Where necessary the laboratory manager will notify the affected customer as soon as the issue is evaluated. The customer will be informed of any corrective actions that take place and shall be notified of any new decisions or developments during the process. In the case that a recall is necessary, the same steps apply and the customer will be notified and reassured that the issue is being amended.

4.9.1.5 CONTINUATION OF WORK

Once the steps in 4.9.1 have been completed, the laboratory manager will authorise the continuation of work when he/she feels it is safe/correct to do so.

4.9.2 POSSIBILITY OF REOCCURRENCE

If the evaluation in section 4.9.1.2 concludes that there is a chance that the non-conformance could reoccur, or if any doubt exists after correction has taken place, then the corrective action procedures outlined in section 4.11 will be followed promptly.

4.10 IMPROVEMENT

Testgroup Pty Ltd strives to continually improve its management system in order to maintain a quality service to all clients. To do so, this laboratory quality manual is reviewed and edited bi-annually, as well as when there is an occurrence of a non-conformance, change of management or suppliers or addition/change in equipment or procedures. As an addition to continuous review, Testgroup Pty Ltd improves its laboratory management system by frequent audits, analysis of data and implementation of corrective and preventative actions.

4.11 CORRECTIVE ACTION

4.11.1 GENERAL

In the case where non-conforming work or failure to follow policies, procedures or technical operations occurs, Testgroup have a set procedure in place which is to be followed by all staff. The hierarchy if such event was to occur, places the laboratory manager with the responsibility to implement corrective actions as they see fit. If necessary, the laboratory manager will assign a team to assist in the areas of cause analysis and the recommendation, implementation and monitoring of action (Refer to sections 4.11.2- 4.11.4).

4.11.2 CAUSE ANALYSIS

The assigned team will carry out an investigation on every aspect of the problem in attempt to reveal the cause of the problem. Depending on the nature of the problem, the investigation will aim to cover all internal and external inputs such as supplier materials, samples, staff skills and training, equipment calibration, methods, procedures, and specifications. This analysis will then be discussed with both the Document and Laboratory Managers, where further corrective actions will be selected and implemented.

4.11.3 SELECTION AND IMPLEMENTATION OF CORRECTIVE ACTIONS

Once section 4.11.2 has been applied and the potential root cause is identified, the appropriate methods of action will be discussed, selected and then implemented. The magnitude of the issue will be taken into account and thus, a mode of action of an equal degree will be applied. All corrective actions will be authorised by the Laboratory Manager in conjunction with the Document Manager, and will be recorded, along with any future changes seen necessary due to the investigation.

4.11.4 MONITORING OF CORRECTIVE ACTIONS

To ensure that they are effective, Testgroup Pty Ltd will monitor the results of the corrective actions put into place. Monitoring may include visual inspections, further testing and analysing results. Each of these observations and results will be recorded in the Laboratory Manager's general laboratory notebook.

Until it has been proven that these actions are achieving the desired result, work cannot be resumed. All details of the corrective action procedure will be recorded (Form 4.11.4), and work will resume once the laboratory manager has given instructions to do so.

4.11.5 ADDITIONAL AUDITS

Where there is any doubt on the effectiveness of either the applied corrective actions, or the adherence to Testgroup Pty Ltd policies or ISO 17025:2005, an internal audit can be carried out at the discretion of the Laboratory Manager. Refer to section 4.14.

4.12 PREVENTIVE ACTION

At Testgroup Pty Ltd we aim to take the necessary preventative actions to improve on our service and to reduce the number of unexpected outcomes. The need for improvement and preventative measures is identified in various ways including;

- Internal and external audits
- Control charts
- OHS and other general meetings
- Employee input
- Analysis of results
- Client feedback

If the above sources reveal that there is a need for improvement (a potential non-conformance), the appropriate plan of action will be decided upon. Implementation will occur as soon as possible and will be closely monitored thereafter. Where possible, controls will be used to measure the degree of effectiveness. The preventative actions implemented will be recorded on form 4.11.4.

4.13 CONTROL OF RECORDS

4.13.1 GENERAL

4.13.1.1 PROCEDURES

Procedures have been established and will be maintained by Testgroup Pty Ltd that covers all aspects for control of quality and technical records. These procedures include identification, collection, indexing, access, filing, storage, maintenance, disposal and back-up.

Identification procedures are established to ensure all documents and records are easily identified and attained. Here, unique codes are implemented to classify certain documents from others.

Data and record collection at Testgroup Pty Ltd is a significant process and needs to be performed according to policies and procedures. For all handwritten notes and documentation, each employee is required to maintain a Laboratory Notebook that must be dated, signed off and include all notes taken whilst in the laboratory. These notebooks are kept at Testgroup Pty Ltd and solely belong to the laboratories. Data is then transferred to a computer system to ensure it will not deteriorate or become affected by moisture or heat over time.

Access to documents and records requires a certain access level to be placed upon each staff member. This access is monitored by the Document Manager. Minimising access to documents by the entire team prevents breaches of confidentiality agreements.

Filing is performed in the office attached to the laboratory, as well as a storage unit. Valid and active documents are stored in alphabetical order of their unique code in the office, whilst invalid obsolete documentation is stored off-site. A procedure is already in place for filing obsolete documentation and is recorded on Form 4.3.2.2.

Maintenance of these record systems is performed bi-annually to ensure documentation is being completed and stored effectively. Maintenance includes an internal audit to ensure all documentation is present, as well as clean-ups where active documents are made obsolete, and obsolete documents are disposed of once past the expiration date.

As documents need to be held by the laboratory for a period for legal purposes, they must also be disposed of in a confidential matter. Testgroup Pty Ltd uses a Secured Paper Disposal Unit that disposes of documents in a secure manner. It is the responsibility of the Document team to handle this disposal.

4.13.1.2 RECORD INTEGRITY

All data is recorded in Laboratory notebooks and is dated, signed and includes all notes taken. This data also needs to be legible, ensuring all parties are able to read and understand material. This is then transferred to a computer system where the medium will not deteriorate over time. The integrity of records is maintained as they are updated and well documented, including every detail.

4.13.1.3 SAFETY OF HARDCOPY DATA

All hardcopy data, including Laboratory Notebooks are kept in confidence, and as previously mentioned; belong solely to Testgroup Pty Ltd. They are kept at the premises to ensure there is no unsolicited copying occurring. Once data becomes obsolete, it is transferred to the storage unit where it is kept under lock and key. It is the Document Manager's responsibility to keep record of where documents are kept at all times, using the appropriate forms. Documents are kept for a minimum of 7 years, allowing access to previous research papers, client information and test results accessible for a long period of time.

4.13.1.4 SAFETY OF ELECTRONIC DATA

All electronic data on the computer system at Testgroup Pty Ltd is only accessible from computers and laptops belonging to Testgroup Pty Ltd. Personnel require a specific login to access this information. All data is backed up daily by documentation staff to ensure the safety of all files.

The Internet is not permitted for recreational, personal and leisure use. Only secured websites are available to be accessed by Testgroup personnel at the laboratories. This ensures zero hacking activity, allowing the integrity of our documents to be maintained.

4.13.2 TECHNICAL RECORDS

4.13.2.1 RETAINING TECHNICAL RECORDS

Testgroup Pty Ltd ensures that all records are retained, including original observations, derived data, calibrations records, test reports, staff training records, as well as sufficient information to establish an audit trail. This is the responsibility of the Laboratory staff to record all data, then communicate it to the Document team in order to transfer to the computer system. It is also the responsibility of the Document team to keep and maintain records regarding staff, and the identities of staff responsible for sampling, testing and calibrations, as well as checking results. Each of these records are required to be legible, to allow for effective reproducibility of tests and results.

4.13.2.2 RECORDING

At Testgroup Pty Ltd, all observations, data and calculations are recorded at the time they are made. This is to ensure no loss of information and to uphold the integrity of work performed in the laboratories.

Each recording is identifiable to its specific task as each page is labelled with the project the work belongs to. It is also dated and signed off.

4.13.2.3 CORRECTIONS TO RECORDS

Testgroup Pty Ltd requires that in any circumstance where a correction is made, the original record should not be obscured.

4.13.2.3.1 HARCOPY RECORDS

Any corrections made to hardcopy records, such as laboratory notebooks need to have a single line made through the incorrect figure or statement, then initialled by the staff member who is making the change. The correct figure or statement is then hand-written next to the crossed out statement, and signed and dated. The incorrect statement or figure still must be legible, for back tracking of documentation.

4.13.2.3.2 ELECTRONIC RECORDS

Corrections on electronic records are not permitted at Testgroup Pty Ltd. However, if change needs to occur, the records must be revised and updated with a new date. This prevents any loss of data.

4.14 INTERNAL AUDITS

4.14.1 REQUIREMENTS

Testgroup Pty Ltd believes continuous improvement in the quality management system can be achieved through conducting internal audits. These are conducted periodically and in accordance with a scheduled time. The aim of internal audits is to ensure work undertaken at Testgroup Pty Ltd follows all procedures and guidelines, and is in accordance with the requirements of the management system, NATA and ISO 17025:2005.

The Quality Assurance Officer is responsible for planning, organising and carrying out these audits, unless they partake in any of the activity being audited, whereby a trained and qualified independent person will conduct the audit. In general, the audits are planned two weeks in advance to ensure all planned work can still be carried out in a timely manner.

Each section of the laboratory is to be audited every two months, therefore within a year; the entire laboratory will have undergone auditing.

Refer to Appendix 14, 15 and 16 for an outline of the audit procedure and audit checklist template.

4.14.2 CORRECTIVE ACTION AND NOTIFICATION OF CUSTOMER

Once an internal audit has been conducted and it has been discovered that procedures are not being followed, operations are not being conducted in accordance with NATA and ISO 17025:2005, or validity of results have been questioned, corrective action is undertaken to decipher how the issue occurred and how it can be prevented from occurring again.

If this occurs, all staff as well as customers are formally notified in writing. This is achieved by form 4.11.4.

4.14.3 RECORDS

A record of the corrective actions, audit findings, conclusions, next steps and area audited must be retained. This is the responsibility of the Quality Assurance Officer, as well as the Document Manager.

4.14.4 FOLLOW UP AUDITS

Further follow-up audits must be conducted at Testgroup Pty Ltd. These audits must indicate whether corrective actions have been implemented, and comment on the effectiveness of them.

4.15 MANAGEMENT REVIEWS

4.15.1 OBJECTIVES

At Testgroup Pty Ltd, management reviews are conducted annually. These focus on quality management and all testing activities performed in all laboratories as it ensures an effective working environment that is able to produce reliable results, in turn satisfying the needs of the customer and relevant governing bodies.

Reviews are conducted with a minimum of two weeks' notice, allowing laboratory staff to ensure projects and testing activities will not be affected. This also allows time for necessary improvements or changes to be made to the management system.

The review will be applied to all areas of the quality management system, including:

- Relevance of policies and procedures
- All management reports
- Results from recent internal audits
- Corrective and preventive actions
- Results of proficiency tests within the laboratory
- Assessments conducted by governing bodies
- Customer relations, including complaints and feedback
- Changes in the volume and type of work
- Recommendations for improvement
- Other relevant information

Once results of management reviews have been collated, they are then presented to the Testgroup team in their annual Business Evaluation Meeting. This action allows all personnel at Testgroup Pty Ltd to become familiar with the quality management system and the ways it can be improved.

4.15.2 ACTIONS AND RECORDS

All findings and actions must be completed within a certain timeframe to ensure continual improvement within the management system. Each action needed is placed into a numbered category (1, 2, 3 or 4). A number 1 action means these needs to be applied as soon as possible. A number 2 action generally requires a little time to be implemented, and needs to be completed within two weeks of the review, whilst a number 3 action needs to be resolved within 4 weeks of the review. A number 4 category is used to label the actions that have no specific time limit.

5 TECHNICAL REQUIREMENTS

5.1 GENERAL

Testgroup Pty Ltd employs highly trained staff to ensure that all tests and calibrations being carried out are correct and reliable by determining all factors.

This section provides detailed knowledge on how the laboratory takes into account contributions from the following factors:

- Human factors (refer to section 5.2)
- Accommodation and environmental conditions (refer to section 5.3)
- Test and calibration methods and method validation (refer to section 5.4)
- Equipment (refer to section 5.5)
- Measurement traceability (refer to section 5.6)
- Sampling (refer to section 5.7)
- The handling of test and calibration items (refer to section 5.8)
- Assuring the quality of test and calibration results (refer to section 5.9)
- Procedures for reporting results (refer to section 5.10)

5.2 PERSONNEL

5.2.1 PERSONNEL COMPETENCE

The laboratory management at Testgroup Pty Ltd ensure all staff that operates equipment, perform tests and calibrations, evaluate results, sign test reports and calibration certificates are highly competent, and are well trained in their skills and abilities to perform required tasks.

All personnel are qualified in appropriate education, training, experience and demonstrated skills. The competence of all staff members is maintained by staff completing in-house training programs set by senior analysts. Staff are deemed competent when the trainee performs side by side testing with an operator and they successfully retain 80% of culture from a spiked sample. This documentation can be found on Form 5.2.1 (Training template).

Results from training are documented along with any other personnel education, experience and skills they may acquire.

Staff who release test results are approved on the basis of their ability and must be able to demonstrate their capability of evaluating the validity of the test results. This is demonstrated through academic qualifications and practical experience. The employees are required to have a degree in subjects relevant to the testing concerned, and a minimum of 2 years practical experience.

All staff that have been approved to release test results and the information which the approval was based on is documented and maintained.

5.2.2 SKILL, EDUCATION AND LEARNING GOALS

Testgroup Pty Ltd formulates goals for all laboratory personnel focusing on their skills, education and training. These goals are focused on both the short and long term development of staff.

The training of personnel is provided as by Testgroup's policy and procedures based on both the present and anticipated tasks. These are planned so that all tasks are relevant to the special training modules.

Testgroup Pty Ltd offers up to date training courses in food microbiology with particular focus and emphasis on laboratory-based practical aspects. Aspects which are covered in training include:

- The operations and practices of laboratory equipment
- Conventional methods for microbiological examination
- Confirmation tests and how they work
- An introduction to 'alternative' microbiological methods

The effectiveness of such training is evaluated and documented in performance evaluations, management reviews and proficiency testing. All documents pertaining to this are withheld by the Document Manager.

5.2.3 EMPLOYEES CONTRACT AND PERSONNEL

Testgroup Pty Ltd engages full time employees as well as external contractors in extreme cases. In the case of external contractor being employed, Testgroup Pty Ltd will ensure that they are both supervised and able to perform the task as well as ensuring that they work within our management system.

5.2.4 JOB DESCRIPTIONS

Testgroup Pty Ltd maintains extensive documentation of current job descriptions for all positions, including managerial, technical and support personnel, involving tests and calibrations. Job descriptions are established based on responsibilities, expertise, experience and qualifications required. These descriptions are constantly available upon request from the Document Manager, and upon employment employees are given a copy outlining the full details of what is expected of their employment.

5.2.5 MANGEMENT AUTHORIZATION

Testgroup Pty Ltd authorizes specific employees to:

- Undertake sampling, testing and calibration
- Issue test report and calibration certificates

- Give opinions and interpretations
- Operate particular types of equipment

Records are kept in regards to authorization, competence, qualifications, training, skills and experience of all employees. These records are dated and readily available.

5.3 ACCOMODATION AND ENVIRONMENTAL CONDITIONS

5.3.1 FACILITIES AND ENVIRONMENTAL CONDITIONS

All facilities at Testgroup Pty Ltd are kept in such a state as to facilitate correct performance of the tests and calibrations to elicit valid and reliable results. These include, but are not limited to energy sources, lighting and environmental conditions. Additionally, when such tests, sampling and calibrations are undertaken at external sites particular care is taken. Factors that can affect the validity and reliability of results are documented.

5.3.2 MONITORING

Testgroup Pty Ltd controls, monitors and records environmental conditions deemed to affect the quality of results of the various testing procedures conducted within the laboratory. These conditions include, but are not limited to:

- Biological sterility
- Dust
- Humidity
- Electrical supply

- Temperature
- Air flow

Employees are trained in the affects that different environmental conditions may have on tests results and are instructed to cease testing when environmental conditions may influence results.

The environment in the labs at Testgroup Pty Ltd is also monitored quarterly to check for contamination issues in the form of air settle plates. These can be located near doors, at air grills and in the corners of rooms. There is an acceptance criterion which is deemed as an uncontaminated and safe environment in a four hour period of <1 to 50.

5.3.3 CROSS-CONTAMINATION

Areas in which incompatible activities are being performed are separated effectively.

Measures will be taken to avoid cross contamination including:

- the storage of samples in specified areas
- the independent storage of standard and references samples
- ensuring separate work areas are allocated for the preparation of media
- using biological containment hoods
- restrict highly contaminated samples to separate areas
- restrict operations to selected areas when high levels of pathogens may be encountered

5.3.4 ACCESS

Testgroup Pty Ltd has in place rules which govern security and access to specific areas of the laboratory. These are areas which may affect the quality of results of tests and calibrations.

Mechanisms include:

- having visitors sign in upon arrival to reception
- issuing identification badges to all visitors with details confirming identity
- being escorted around by a senior member of Testgroup Pty Ltd
- security guards in place around the laboratory

5.3.5 HOUSEKEEPING

Testgroup Pty Ltd ensures that all laboratory facilities are maintained in a state to prevent contamination of sample and hence inaccurate test results. In order to achieve this laboratories are kept in a clean and orderly state.

5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

5.4.1 GENERAL

At Testgroup Pty Ltd, all employees are appropriately trained in the methods and procedures used. These include sampling, handling, transport, storage and preparation.

Instructions regarding the operation of laboratory equipment as well as the preparation of items for testing, absence of which could lead to inaccurate results, are available in the SOP which can be found in Appendix 12. All such instructions, standards and manuals are kept up to date and are readily available to employees. All changes to these methods should be documented.

5.4.2 SELECTION OF METHODS

All methods used by Testgroup Pty Ltd are both appropriate for the needs of the customer and for the needs of the test or calibration undertaken. Methods, such as those published in the latest editions of international, Australian regional or national standards will be prioritised.

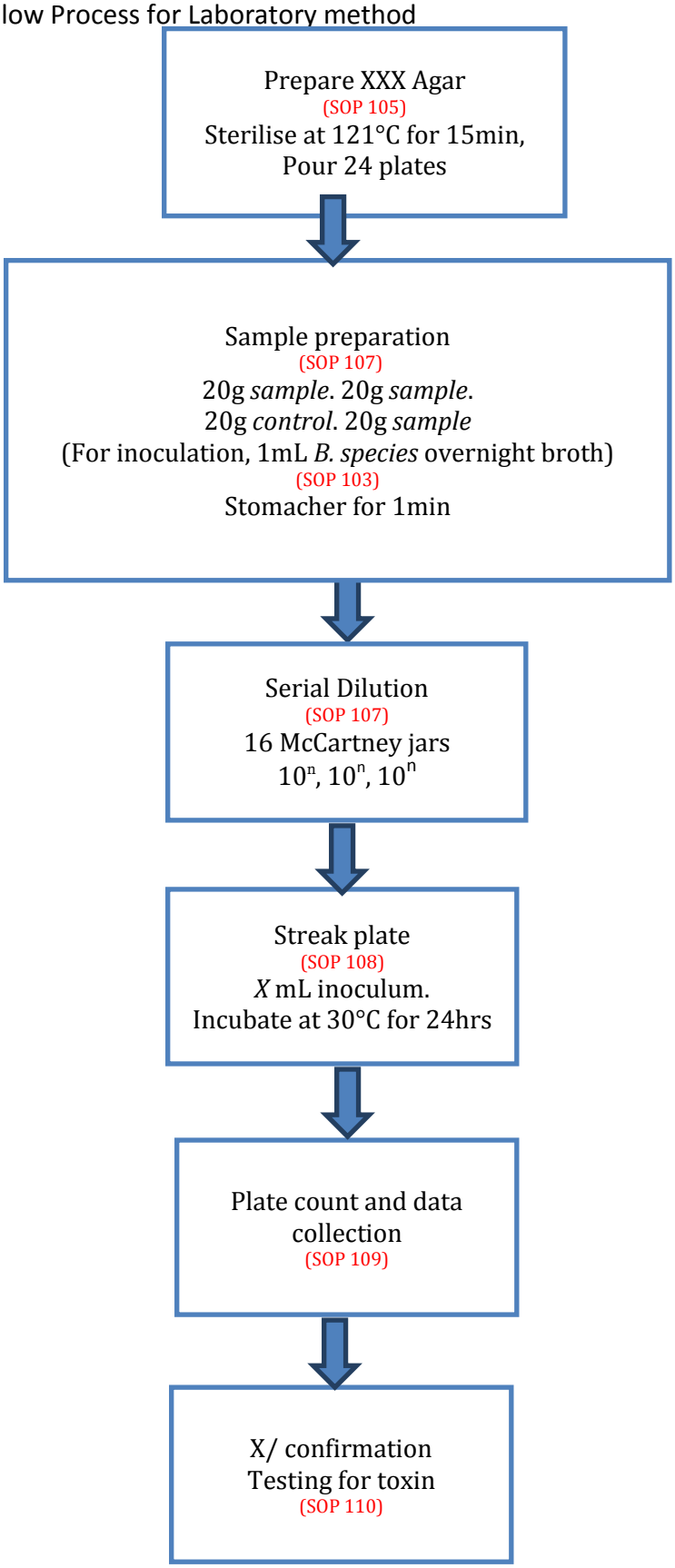
Testgroup will select an appropriate method and the customer informed about the method chosen.

Testgroup Pty Ltd uses standard methods that are appropriate for testing the validity of the PEMBA method in testing food for *Bacteria species*. Refer to Figure 5.4.2 for the flow process chart.

When choosing the appropriate method, Testgroup Pty Ltd verifies the method by setting up positive and negative samples for the target determinations. It must be demonstrated that the proposed method can be applied and interpreted competently.

These procedures used for the verification of standard methods are documented and records of any verification made are retained.

Figure 5.4.2 Flow Process for Laboratory method



5.4.3 LABORATORY DEVELOPED METHODS

Testgroup Pty Ltd develops its own test and calibration methods for use in our laboratories. This is a planned activity with employees being assigned to the task and given adequate resources. In order to achieve this, communication between employees is crucial as well as the updating of plans as developments move forward. For test methods refer to SOP (see appendix 12).

5.4.5 VALIDATION OF METHODS

5.4.5.1 DEFINITION

Validation as by the International standard AS ISO/IEC 17025 is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 METHODS REQUIRING VALIDATION

All methods, either standard or non-standard that are used outside of their intended scope, amplification and modification of a standard method are validated by Testgroup Pty Ltd; this will ensure the method will elicit an accurate result. The results of the extensive validation will be recorded and a decision made as to whether the method is fit for use.

Note 1. Procedures for sampling, handling and transportation are included in validation.

Note 2. Other techniques are included for the determination of the performance of a method.

5.4.5.3 PROCESS

When using validated methods, the accuracy and range of attainable results must be appropriate to the customers' needs. For example the uncertainty of results, detection limit, linearity and selectivity must be appropriate to the customer's needs.

5.4.6 UNCERTAINTY OF MEASUREMENT

5.4.6.1 ESTIMATION OF UNCERTAINTY

For all calibrations performed at the Testgroup laboratory, certain procedures are employed to estimate the uncertainty of measurement.

5.4.6.2 PROCEDURES FOR ESTIMATING UNCERTAINTY

The nature of some calibrations performed at Testgroup Pty Ltd does not allow rigorous and statistically valid calculations of uncertainty to be obtained. In such cases Testgroup Pty Ltd attempts to make estimation. Based on previous experience and validation data as well as performance knowledge of the method, estimation can be made. The preciseness of the estimation of uncertainty needed depends on:

- the requirements of the test method and customer
- narrow limits on which decisions on conformity are based

A procedure for measurement uncertainty must be documented as the test results are quantitative in nature.

The procedure which is used at Testgroup Pty Ltd uses reproducibility replicates to estimate uncertainty for the same type of sample matrix analysed.

This technique uses replicates of the sample be made under all different conditions which may occur in the laboratory capturing various sources of uncertainty that can affect routine customer.

5.4.6.3 UNCERTAINTY COMPONENTS

Testgroup Pty Ltd takes into account all uncertainty components when estimating the uncertainty of a measurement.

Uncertainty components include references standards and reference materials, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated and the operator.

5.4.7 CONTROL OF DATA

5.4.7.1 CALCULATIONS AND DATA TRANSFERS

Testgroup Pty Ltd ensures that all calculations and data transfers undergo appropriate checking procedures.

5.4.7.2 DATA MAINTENANCE

At Testgroup Pty Ltd computer and automated software are often used in the acquisition, processing, recording, reporting and storage of test or calibration data. In order for this to be an efficient process Testgroup Pty Ltd ensures that:

- the equipment is validated for use
- data protection methods are implemented protecting the integrity and confidentiality of the data
- computers and such equipment are properly maintained and are maintained in good operating condition.

5.5 EQUIPMENT

5.5.1 LABORATORY EQUIPMENT

To ensure the reliability and validity of testing conducted at Testgroup Pty Ltd, all laboratories are fitted with equipment that is needed for correct performance of sampling, testing and calibrating and the analysis of data. Testgroup Pty Ltd owns all equipment used, however in the case where the laboratory needs equipment which is not permanently kept on the premise, outsourcing is used and Testgroup Pty Ltd ensures all requirements of the International standard AS ISO/IEC 17025 are met.

5.5.2 EQUIPMENT CAPABILITY

All equipment and software used at Testgroup Pty Ltd is proficient in achieving the accuracy required. This is achieved by regular maintenance compiling with the testing load undertaken in the laboratory.

Calibration programmes have been set by Testgroup Pty Ltd to establish the correct values and quantities needed for testing instruments. This is implemented where the values and quantities have a significant effect on the results.

Calibration occurs prior to the use of the equipment and prior to the servicing of equipment as per the international standard, ensuring it meets the specifications and requirements which are given by the laboratory; also making sure it complies with the relevant standard specifications.

5.5.3 AUTHORIZED PERSONNEL

Testgroup Pty Ltd employs authorized personnel to operate all equipment (section 4.1.5 outlines specific details on the roles of the employees). All manuals (manufacturer's manuals inclusive) are readily available to all personnel and provide to up to date instruction in the uses of equipment.

5.5.4 IDENTIFICATION OF EQUIPMENT

For equipment used in testing and calibration please refer to Appendix 9.

5.5.5 EQUIPMENT RECORDS

Testgroup Pty Ltd ensures all equipment (refer to appendix 9) is kept in their electronic database. The following information exists for each piece of equipment:

- the identity of equipment
- manufacturers name and information unique to the manufacturer such as serial number
- identifying compliancy of equipment with specification
- where the item is located
- any instruction from manufacturer
- information on calibration certificates, adjustments, acceptance criteria and the date of next calibration
- maintenance plans
- any damage, malfunction, modification or repair to the item

5.5.6 EQUIPMENT MANAGEMENT

To ensure proper functioning and to prevent contamination or deterioration of equipment, Testgroup Pty Ltd have identified procedures for safe handling, transport, storage, use and planned maintenance which comply with the International standard AS ISO/IEC 17025.

An example on the use of the pipette can be found in Appendix 17.

5.5.7 DEFECTIVE EQUIPMENT

Equipment which has been mishandled, overused, gives unusual results or has been shown to be defective is immediately taken out of action by staff. The equipment is isolated with the item marked “out of service” until the item is repaired and calibration tests confirm correct performance. Previous tests are examined by laboratory staff to inspect the effect the defected item of equipment caused conforming to section 4.9 of this manual.

5.5.8 CALIBRATING STATUS

All equipment used in Testgroup’s laboratory which requires calibration is to be clearly labelled with the calibration status. The label must include the date of last calibration and the date of next calibration. Calibration is done every 6 months or as the item requires it. All information on calibration is also kept on the company’s databases.

5.5.9 EQUIPMENT LEAVING THE LABORATORY

If any of the equipment should leave the laboratory for any reason then upon its arrival the item staff check the function and status of that item ensuring it is in a satisfactory condition before being able to use it again.

5.5.10 CALIBRATION CONFORMATION

To ensure quality control, immediate calibration conformation checks are performed on equipment.

5.5.11 CALIBRATION CORRECTION FACTORS

Testgroup Pty Ltd has procedure in place notifying all staff and updating all documentation on the status of equipment should correction factors arise regarding calibrations.

5.5.12 SAFEGUARDING EQUIPMENT

Testgroup Pty Ltd offers controlled laboratory access to ensure the safety of test and calibration equipment and to safeguard any unauthorized changes which would invalidate the test or calibration.

5.6 MEASUREMENT TRACEABILITY

5.6.1 GENERAL

Testgroup Pty Ltd has programs and procedures outlined to calibrate and verify all aspects which could potentially affect the validity of the test result of quality control. In the case of food microbiology all media will be tested against international standards. Media is a critical point of accuracy and validation and to maintain accreditation. Cultures will also be checked against reference material (Appendix 13).

5.6.2 SPECIFIC REQUIREMENTS

5.6.2.1 CALIBRATION

All equipment used as a part of analysis will be calibrated and checked against reference material where applicable and must follow international standards. All aspects of calibration must be comparable to the international system of units. For example in the case of in-house digital thermometers will be calibrated against reference certified thermometers.

5.6.2.1.1 *USE OF REFERENCE CULTURE AND CERTIFIED REFERENCE CULTURES AS REFERENCE STANDARDS*

If international standards are not available for some equipment / materials and method types, separate procedures are available concerning that area. This includes proficiency testing, use of reference cultures, certified reference cultures (refer to Appendix 13) and agreements between laboratory and the client.

As a part of a controlled laboratory the traceability system covers all aspects from fulfilling necessary requirements of national, international standards and units of measurement.

Reference material must be selected based on country of laboratory and depending on type of standard being followed.

5.6.2.2 TESTING

5.6.2.2.1 UNCERTAINTY

All tests conducted in Testgroup Pty Ltd laboratories must be reported in a way that indicates the uncertainty related to the result. Therefore, the accurate calibration of equipment decreases the variations in uncertainty and results are more reliable and close to the true value.

Note1. Calibration variations must be noted and recorded and considered when statistical analysis is being conducted.

5.6.2.2.2 ENSURING TRACEABILITY

Dependant on sample type and measurement type the same traceability systems will be followed.

All Reference material will be:

- Traceable
- maintained for biochemical integrity
- maintained for physiological integrity

The use of reference cultures (RC) and certified reference cultures (CRC) will not be transferred more than 5 times from original source. Additional purchasing new cultures will be done to ensure integrity of the culture in maintained. Cultures can be frozen and kept in storage, maintained in stab cultures where glycerol is present, in accordance with international standards.

All raw material suppliers must comply with ISO 17025.

5.6.3 REFERENCE STANDARDS AND REFERENCE MATERIALS

5.6.3.1 REFERENCE STANDARDS

Testgroup Pty Ltd follows traceability procedures to ensure calibration of reference standards are maintained and recorded. Reference standards such as reference thermometers and weights will be used to maintain calibrations, this will verify results accurately.

5.6.3.2 REFERENCE CULTURE

Through the use of appropriate forms of measurement (such as certified reference materials); culture reference materials will be traced by internal and external systems**.** Results will be checked by any technical and economical means available. There will be quality control checks for each batch of media produced, both liquid and solid media.

5.6.3.4 TRANSPORT AND STORAGE

Conditions from the client to the test laboratory must be that the characteristics of the food samples are maintained. This action must be prompt and the package integrity is intact to protect against breakages. Correct information of the sample must also be obtained upon receipt or pick up, such as sample labels.

Following ISO 6887 for recommendations of storage temperatures depend on the sample type.

Discussions and agreements must be done prior to work commencing to ensure all parties understand the specifications of the service.

In some cases the client will conduct an internal incubation to increase the numbers of the microorganisms to be detected. Generally, this is undertaken for pre operational testing and sanitising testing. Regular record keeping will be conducted concerning environmental storage and the monitoring of temperatures. Samples will not be accepted if the temperature is above 5°C ±1°C; a checklist provided to the transport worker will be issued to ensure regular temperature checks have taken place every 2 hours, or electronic data provided, dated and signed off each temperature check (refer to Appendix 4).

5.7 SAMPLING

5.7.1 SAMPLING PLAN AND PROCEDURES

All samples provided by the client will be treated in accordance to the procedures outlined in the standards.

5.7.2 CLIENT VARIATION

Client information regarding sample quality and purpose will be profiled and analysed. All information regarding the samples will be gathered (refer to Appendix 5).

5.7.3 LABORATORY RECORDINGS

All aspects of the initial information gathering will be recorded and signed off by the microbiologist conducting the data. This will assist and enable the analyst to calibrate and test the food sample as a part of the SOP. Information regarding the sample will include environmental conditions, who gathered the sample, sampling procedure used, use of pictures, and any other description of the sample procedure used.

5.8 HANDLING OF TESTS AND CALIBRATION ITEMS

5.8.1 HANDLING PROCEDURES

All aspects from sampling, storage, handling, protection, receipt, disposal of any items, will be detailed in Appendix 4-6, to ensure the customer, laboratory technician and all those involved are protected as well as preserving the sample. Information concerning common defects and potential cross contamination will also be outlined. Visual checks upon receival will provide evidence of quality control (refer to Appendix 101).

5.8.2 IDENTIFICATION

All samples incoming and outgoing from the laboratory at all times will be labelled with correct information and cross checked throughout the time of the sample at the laboratory. The Laboratory at Testgroup Pty Ltd will be set up in a way to reduce the likeliness of contamination; storage conditions will also be controlled.

Through the use of a checking system and bar-coding samples, identification system will ensure customer receives correct information and methods used will be accurate.

5.8.3 CONFORMANCE/NON CONFORMANCE

Reproducibility is a key determinant of a quality controlled laboratory. Upon receival from the client, visual inspections, temperature checks and sample integrity will be evaluated. Testgroup Pty Ltd has the right to refuse a sample if the sample is deemed unfit for food testing. Further discussion will take place with the client to evaluate the situation. This could result in a decision for another sample to be taken or more technical training undertaken concerning sampling from the processing line.

5.8.4 HANDLING, STORAGE AND PREPARATION

Information will be gathered concerning the customers routine samples. Client and staff will also be trained on how to obtain a sample that will gain the best results, and when required samples may be obtained aseptically. Client will also obtain records of workers signing off on their training.

Following AS 5013.11.4-2006 of Food Microbiology, SOP and reference materials, all procedures and methods will be available on M drive of all computers and as a hard copy in archives within the quality assurance office.

All methods will be updated on a 6 monthly basis or where required, and recorded in the master list.

Sample must be received in the same sample container provided by Testgroup Pty Ltd, of which is free from external influences. Containers must not be filled more than ¾ full, this is to ensure that spillage of the sample is avoided.

Sample exposure must only occur for the time needed for the subsample to be taken.

Note 1. Technical training concerning the sampling procedure is important in the results of the test. Specifications will be provided to the client concerning ways to avoid cross contamination, best way to sample, best times to sample and storage environments. List of "do's and don'ts" will be supplied.

Test samples will be handled according to the characteristics of the sample. The use of controlled refrigeration environments from customer to the laboratory will be in place. Monitoring systems will also be in place to ensure temperatures are maintained, monitored and recorded for record keeping.

Agreements with the customer regarding the handling instructions will be discussed and followed. The customer will also have suitable equipment to maintain the characteristics of the test sample on site in the lag time between sampling and pick up; this ensures results are close to the true value. Where needed, for example a raw material testing, samples will be gathered aseptically. The customer will also maintain, monitor and control these environments as a part of their quality management system.

Responsibility of the integrity of the sample will be placed on the party who at that stage obtains the sample. Once samples are picked up, the laboratory holds responsibility for any deterioration loss or damage to the sample.

Note 1. Any samples that are in the possession of the client needs special considerations, of which must be taken. This is to guarantee the sample will not be affected in any way. Training and SOP must be followed. The waiting period between sampling and pick up is a vital aspect for the integrity of the sample. Customers must be equipped with suitable equipment that allows for careful controlling and monitoring.

Note 2. For each sample with varied methods the laboratory must provide SOP to be followed, from the client through to transport worker to the laboratory. Sampling procedures and information regarding the storage and transport of samples will be provided. A summary of quality control points will be established to identify areas that influence the sample integrity or calibration results.

Note 3. All aspects from sampling to the laboratory must be carefully controlled and records kept as a part of the quality management system. This is useful for replication and if needed corrective actions.

5.9 ASSURING THE QUALITY TEST AND CALIBRATION RESULTS

5.9.1 QUALITY CONTROL PROCEDURE

5.9.1.1 INTERMEDIATE CHECKS

Quality checks throughout testing methods of sample will be conducted to verify and increase confidence in final result. Through the use of presumptive and confirmatory testing to ensure no contamination has occurred or quality of the raw materials is apparent.

All information regarding the critical control points of the laboratory will be gathered and statistically analysed to ensure all aspects are kept within specification and control. This is achieved by the use of verified and validated methods of certified reference materials, software programs and standards followed.

All analytical calculations will be checked by the quality assurance manager and signed off as a part of the quality control procedures.

Upper limits and lower limits will be calculated to provide specifications within a range that maintains the quality control system. Variations deviating from the control system will be recorded and appropriate corrective action will be taken to bring the system back into line.

Analytical and monitoring programs used will be updated and reviewed to ensure employees are using the computer software program correctly. Reference material will be internationally certified and retesting calibration will be compared with external references of which that are certified.

Results obtained will be correlated to identify any deviation from the true value to ensure quality procedures are effective. Control plates will be used for each batch of medium produced, which will demonstrated both positive and negative controls systems. The level of inoculum must be shown to be between 10 – 100 cells, replicating a low contamination level and the limit of detection use.

Assurance of procedures will be conducted on a daily basis concerning CRC's, which maintains the confidence in the current quality system, any non-conformance will be recorded and appropriate corrective action taken.

All employees will receive ongoing training and records of competency and how this was achieved (refer 5.2.1).

5.9.2 CORRECTIVE ACTIONS

Data results that have been analysed will be recorded and appropriate corrective action will be taken to ensure results obtained are correct and close to the true value as possible. All corrective actions will be followed up and checked.

5.10 REPORTING RESULTS

5.10.1 COMMUNICATING ANALYSIS

Results obtained from analysed samples will be recorded in an accurate, clear layout with legible handwriting (if necessary). Results will be unbiased and follow specific criteria for test result or calibration methods.

All results obtained will be communicated back to the customer as test reports or calibration certificates. All information communicated will hold required information for the customer to interpret, knowledge of the methods used for the analyses undertaken in the laboratory will also be clearly outlined.

Note 1. Information regarding the test methods and results will be communicated in either a test report or calibration certificate.

Note 2. Communication will be through both channels of electronic and hard copy. Electronic version will be transferred via PDF to ensure no possibility of tampering can occur. Reports will follow international standards.

5.10.2 TEST REPORTS

All microbiological methods will have individual methods for analysis, policies and procedures. An example given can be in the identification of serological types or biotypes of an organism, such as *Bacteria species.*

As this service is externally obtained environmental factors can influence the integrity of the sample or calibration test. On a case by case basis an assessment will be conducted and procedures developed to ensure interpretations and analyses are correct and monitored. All variations will still follow AS ISO/ IEC 17025.

Test reports and calibration certificates will consist of

- Title, name and address of the laboratory, also the location and information regarding the laboratory site where the tests took place, only if it is different to the address of the headquarters of the company.
- Traceability number unique to that test report, this is be on each page of the document.
- Name and address of the customer.

- Identification method used or a description of the method date received, and the date the test commenced
- Information regarding reference material of sampling plan and procedures.
- Units of measurement recorded.
- States the name, management positions and signature of person authorising the report and verifying the test report or calibration certificate
- Statement concerning the results.

Note 1. Test report and calibration certificates will consist of page numbers and total numbers of page.

Note 2. A statement concerning copy right approval of replication, to ensure information is not reproduced.

5.10.3 TEST REPORTS

5.10.3.1 ADDITIONAL INFORMATION

Including necessary sections from part 5.10.2, test reports and calibration certificates will also provide information regarding all aspects of variations from specifications. Deviations, additions and or exclusions from the agreed test methods are included. Also included is any information regarding environmental conditions, materials used and a change in the raw material suppliers.

Additionally, information regarding any compliance or noncompliance issues regarding agreed specifications is included.

Calculation of uncertainty measurement will also be recorded and any information regarding upper or lower limits depending on the sample or calibration method.

A statement concerning technical opinions and interpretation of the test report or calibration certificate if applicable will be supplied. Information regarding improvements, professional technical information which will assist the client in obtaining good samples and results are included.

Any information regarding as important will also be added to the final results, these results are informative and detailed concerning the sample.

5.10.3.2 FURTHER ADDITIONAL REQUIREMENTS

Included to sections 5.10.2 and 5.10.3.1, additional information regarding traceability will also be apparent. Including dates of sampling, photographs, diagrams, reference materials used in the test undertaken.

5.10.5 OPINIONS AND INTERPRETATION

Any additional information regarding the test report must be documented, also by whom and dates inclusive. Any opinions must be verified by upper management for a second and third opinion to ensure these evaluations are correct unbiased and informative.

Note 1. All opinions and interpretations must follow standards and not be confused with inspection and product certifications.

Note 2. Opinions can include areas for test improvement, how to use results, whether or not the test was compliant not compliant.

Note 3. Opinions and interpretation can also take the path of verbal communication where these conversations must be recorded or written down.

5.10.7 ELECTRONIC TRANSMISSION OF RESULTS

Test reports can be obtained via telephone, telex, facsimile or other means and follows international standards of communication.

5.10.8 FORMAT OF REPORTS AND CERTIFICATES

Information contained in test reports must be free of jargon, microbiological technical language and must be easily understood and useful.

Layout should follow easy flow of information that follow general formatting of other laboratories. All headings are to be standardised.

5.10.9 AMENDMENTS TO TEST REPORTS

Test reports will follow a data transfer system. This is where the previous report of certificate will be the reference material as an extended document. Stating ‘Supplement to Test Report’, also containing the unique identification number. This will enable helpful archiving of information, and if needed in times of auditing identifying root cause of a problem or proof of the sample traceability.

DOCUMENT CONTROL FORMS

Form 4.3.2.1 Master List

17/11/2009 21/12/2009 21/12/2009

Document Name:	Revision Number:	Revision Date:	Revised by:	Access Level:

#2 J. O'Neill

Form 4.3.2.2 Obsolete Documents

17/11/2009 21/12/2009 21/12/2009

Document **Name:**	**Last Revision Date:**	**Obsolete Date:**	**Approved by:**	**Location of Storage:**

#2 *J. Neill*

Form 4.3.2.3a Document code list

17/11/2009 21/12/2009 21/12/2009

Code	**Document**
QM	Quality Manual
COA	Confidentiality Agreement
CON	Client Contract
EQL	Equipment List
MAL	Materials List
SOP	Standards of Operating Procedures

#2 *J. O'Neill*

Form 4.3.3.4 Alteration record form

17/11/2009 21/12/2009 21/12/2009

Document Name:	Description of Amendment:	Date Amended:	Initial:	Approved by:
4.1.5.3	Added staff confidentiality	8.11.12	S.M	J.O'Neill
4.1.5.9	Changed all ref to QA Manager	8.11.12	S.M	J.O'Neill
4.1.5.11	Added in inductions and performance review	8.11.12	S.M	J.O'Neill
4.1.6	Changed from daily to weekly	8.11.12	S.M	J.O'Neill
4.2.5	Added management procedures	8.11.12	S.M	J.O'Neill
4.2.6.2	Changed to QA Manager	8.11.12	S.M	J.O'Neill
4.3.2.3a	Added SOP to list	16.11.12	S.M	J.O'Neill
4.3.3.1	Changed from quarterly to annually	8.11.12	S.M	J.O'Neill
4.5.1	Certification of records added	16.11.12	S.M	J.O'Neill
4.5.4	Added suppliers and manufacturers documentation shall be supplied	16.11.12	S.M	J.O'Neill
4.6.2	Included media quality check on PEMBA	16.11.12	S.M	J.O'Neill
4.8.1	Updated record of complaints form	16.11.12	S.M	J.O'Neill
4.9.1.1	Added any staff member can raise non conformance	16.11.12	S.M	J.O'Neill
4.11.4	Added preventative methods to form	16.11.12	S.M	J.O'Neill
4.11.5	Added internal audit to be carried ut	16.11.12	S.M	J.O'Neill
4.12	Added reference to form 4.11.4 for preventative actions	16.11.12	S.M	J.O'Neill
4.12.1.2	Added needs to be legible	8.11.12	S.M	J.O'Neill
4.13.2.1	Added staff training records	8.11.12	S.M	J.O'Neill
4.13.2.3.1	Added signed and dated	8.11.12	S.M	J.O'Neill
4.14.1	Added audit details	8.11.12	S.M	J.O'Neill
4.14.2	Added refer to table 4.11.4	8.11.12	S.M	J.O'Neill
4.15.1	Added changes in volume and type of work	8.11.12	S.M	J.O'Neill
4.15.2	Added category 4	8.11.12	S.M	J.O'Neill

5.2.1	Added in house training and testing with spiked sample, qualifications required and staff to release test results	16.11.12	S.M	J.O'Neill
5.3.2	Omitted, updated and revised test conditions undertaken	16.11.12	S.M	J.O'Neill
5.4.2	Added information on methods, changed flow process to sterilise	16.11.12	S.M	J.O'Neill
5.4.4	Removed section	16.11.12	S.M	J.O'Neill
5.4.6.2	Added procedure for measurement of uncertainty	16.11.12	S.M	J.O'Neill
5.5.6	Added refer to Appendix	16.11.12	S.M	J.O'Neill
5.6.1	Removed calibration	8.11.12	S.M	J.O'Neill
5.6.2.1	Added where applicable	8.11.12	S.M	J.O'Neill
5.6.3.2	Changed heading to Reference Material	8.11.12	S.M	J.O'Neill
5.6.3.3	Removed section and combined with 5.3.3.2 and 5.6.3.4	8.11.12	S.M	J.O'Neill
5.7	Amended description	8.11.12	S.M	J.O'Neill
5.8.1	Added refer to Appendix 101	8.11.12	S.M	J.O'Neill
5.8.4	Amended description and merged some of 5.7 into section	8.11.12	S.M	J.O'Neill
5.9.1	Added Section No., referred to Section 5.2.1, included information on control limits from NATA	8.11.12	S.M	J.O'Neill
5.10	Removed calibration reporting	16.11.12	S.M	J.O'Neill
Appendix	Added tolerance levels	16.11.12	S.M	J.O'Neill
Appendix	Updated Appendix 6 form	16.11.12	S.M	J.O'Neill
Appendix	Altered equipment and supplier list	16.11.12	S.M	J.O'Neill
Appendix	Added Appendix 17 Test method Audit	16.11.12	S.M	J.O'Neill
Manual	Removed all forms and added to separate file	16.11.12	S.M	J.O'Neill

#2 *J. ONeill*

Form 4.4.2a Record of Contract Reviews

17/11/2009 21/12/2009 21/12/2009

Contract Review			
Client:			
Contract Number:		Contract Date:	
Amendment Description:			
Effective Date:			
Approved by:			
Client Signature:		Testgroup Signature:	
Date:		Date:	

#2 *J. O'Neill*

Form 4.4.2b Discussion Notice

17/11/2009 21/12/2009 21/12/2009

Memo			
Topic:		Date:	Time:
Discussed with:			
Discussed:			
Next Steps:			
Signature		Time ended:	

#2 *J. O'Neill*

Form 4.5.4 Subcontractor register

17/11/2009 21/12/2009 21/12/2009

Company **Name**	**Company Contact**	**Test/Calibration**	**Accreditation Supporting Documents attached**	**Last Reviewed**

#2 *J. ONeill*

Form 4.6.2 Record of Inspection/Verification of Supplies

17/11/2009 21/12/2009 21/12/2009

Date	Supply/Material	Batch/Lot Number	Supplier verification received? (Y/N)	Inspection Completed? (Y/N)	Fit for Use? (Y/N)	Sign

#2 J. Neill

Form 4.7.2 Customer Feedback Survey

17/11/2009 21/12/2009 21/12/2009

Thank you for choosing Testgroup Pty Ltd. We value the opinion of our clients and to ensure that our services are meeting all expectations, we kindly ask that you assist us by taking a few minutes to fill in the following survey.

Company Name _____ Company Liaison _____

Contact Details _____ Date _____

Mark X in the box which represents your answer

	Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	Testgroup Pty Ltd provided a reliable service which met our needs and expectations					
2	Testgroup Pty Ltd clarified all queries and questions which arose before, during and/or after the service					
3	Communication was sufficient throughout the time working with Testgroup Pty Ltd					
4	We trust the results we received and they will be of value to us					
5	We would recommend Testgroup Pty Ltd to others					
6	We will be using Testgroup Pty Ltd again in the future					

Comments:

_____

_____

_____

_____

#2 *J. ONeill*

Form 4.8.1 Record of Complaints

17/11/2009 21/12/2009 21/12/2009

Complaint Reference #	Date	Client Involved	Details of Complaint	Complaint sent & reviewed by appropriate team?	Date Complaint Actioned	Client notified of action? Y/N	Sign

**Attach all correspondence

#2 *J. O'Neill*

Form 4.8.2 Follow Up Customer Feedback Survey

17/11/2009 21/12/2009 21/12/2009

We were sorry to hear that our services did not originally meet your expectations. Testgroup Pty Ltd aims to provide a high quality service to all clients and will endeavour to correct the situation should a client feel this was not the case.

We kindly ask that you take a short few minutes to complete the following survey to ensure that our subsequent actions have met your needs.

Company Name _____

Company Liaison _____

Contact Details _____

Date _____

Mark X in the box which represents your answer

	Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	Testgroup Pty Ltd contacted us within a reasonable time frame after our complaint was made					
2	Testgroup Pty Ltd were genuinely concerned with our complaint and listened attentively					
3	Testgroup Pty Ltd communicated well throughout the process					
4	Testgroup Pty Ltd offered solutions, suggestions and alternatives where possible					
5	We are satisfied with the end result					
6	We will be using Testgroup Pty Ltd again in the future					

Comments:

_____

_____

_____

_____

_____

#2 *J. O'Neill*

Form 4.9.1 Nonconformities Record

17/11/2009 21/12/2009 21/12/2009

NCR Reference # _____

Date:	Time:	Area:
Assignment Reference #:	Client:	Staff member involved:
Description of non-conformance (include background information):		
Immediate action that was taken:		
Signature:	Date:	

Laboratory Manager

Date:	Recipient:
Evaluation (Method & Conclusion):	
Corrective action required? (Y/N)	Corrective action form raised? (Y/N) Reference #:
Customer notification required? (Y/N)	Person responsible to take action:
Method of resolution:	
NCR closed? Y/N)	
Date of closure:	

Signature_____ Name_____
Date_____

#2 *J. ONeill*

Form 4.11.4 Record of Corrective Actions

17/11/2009 21/12/2009 21/12/2009

Reference Number_____
Date & Time _____
Laboratory Manager_____
Corrective Action Team Members _____
Non-conformance/Issue Description

_____
_____
_____
_____

Cause Analysis

_____
_____
_____

Corrective Action Description

_____
_____

Preventive Actions

_____
_____

Monitoring Procedure and Results

_____
_____
_____
_____

Follow Up Required?	Closure Date	Related Documents Reference Number(s)	Laboratory Manager Signature

#2 *J. ONeill*

Form 5.2.1 Training Template

17/11/2009 21/12/2009 21/12/2009

Trainee	**Trainer**	**Method used**	**Competency met (Y/N)**	**Additional comments**	**Date completed**	**Sign**

#2 *J. O'Neill*

APPENDIX

1 LABORATORY RISK ASSESSMENT

Service: Food Microbiology		**Reference:** 1A
Activity: Laboratory Analysis of *Bacteria species* in food	**Site:** Testgroup Pty Ltd, College Dr, Richmond, NSW	
People at Risk: All employees involved in Laboratory work	**Additional Information:** All employees shall own a copy of the Risk Analysis and be aware of the risks involved in undertaking tasks within a laboratory environment	
Contact Persons: Sonya Muhlsimmer, Jacinta O'Neill **Job Title:** Laboratory Manager / Document Manager		**Review Date:** Dec 2013

Legal Obligation: The NSW OHS Act 2000 and OHS Regulation 2001 requires identification of all foreseeable hazards in the workplace, assessment of the risks that these hazards pose to health and safety and the elimination or control of these risks.

Declaration: I understand that this Laboratory Risk Assessment is a true record of the Risk Assessment undertaken. I agree to monitor the effectiveness of control measures and review this Risk Assessment is in line with the requirements of the OHS Regulation 2001

Signature: **Date:**

2 RISK EVALUATION

Are Standard Operating Procedures (SOP) / Audit checklist available for any of the identified risks? Yes / No
Please refer to Appendix 12, 14 & 15.

Hazard	Risk	Initial Rating (L, M, H,)	Risk Control Measures	Final Rating (L, M, H,)	Trained in Control Measures
Physical	**Slipping on the floor**	**H**	**Take care moving around the lab**	**L**	**Y**
Physical	**Burns from Autoclave**	**H**	**Wear PPE**	**M**	**Y**
Physical	**Burns from Bunsen burner**	**H**	**Take care with open flame**	**M**	**Y**
Electrical	**Dysfunctional Autoclave / Water bath**	**L**	**Tagged and tested equipment**	**L**	**Y**
Biological	**Contamination of pathogenic bacteria**	**H**	**Wear PPE**	**M**	**Y**
Chemical	**Irritant chemicals**	**H**	**Wear PPE**	**M**	**Y**

L, Low priority, M, Medium priority, H, High priority
PPE, Personal Protective Equipment.

3 HAZARD & INCIDENT REPORT FORM

SECTION A: Details of person involved (Please tick the appropriate box if applicable):

- ☐ Person involved in incident
- ☐ Person reporting hazard or damage

  Surname:

  Given names:

  ID number:

  M/F:
- ☐ Staff
- ☐ Contractor
- ☐ Visitor
- ☐ Student
- ☐ Others:

SECTION B: Incident details or Nature of hazard or damage:

Date of incident/hazard/damage:

Time (am/pm):

Date when first noticed or diagnosed:

Location of incident/hazard/damage:

Description of incident/hazard/damage:

SECTION C: Injury or illness details

Describe the injuries or illness including part(s) and side(s) of the body:

Name and contact details of witness or first person at the scene:

Treatment details:

Signature of injured person:

Date:

Signature of witness:

Date:

SECTION D: Corrective actions and investigation

Cause of incident/hazard/damage:

Corrective/Preventative action recommended/taken:

Supervisor name, employee number and contact details:

Supervisor signature and date:

Safety Officer Name, employee number and contact details:

Safety Officer Signature and date:

SECTION E: Follow-up

Quality Officer or Safety Officer:

Recommendations in Section D have been executed:

- ☐ Yes
- ☐ No
- ☐ In progress

4 RECIEVAL OF TEST SAMPLE

Conducted by…… Date.....

Product code- Type of sample	Date of receival	Temperature of receival	Temperature recording (yes Y/no N)	Accepted	Visual inspection	Allocated Job No.	Signed off

5 INTERNAL INVENTORY

Conducted by…… Date…….

Purchase order no.	Product code-description	Test performed	Date archived	Date test performed	Overall findings	Attach photo evidence	Hard copy location

6 DESPATCH OF TEST SAMPLE, CUSTODY AFTER TESTING

Conducted by…… Date…….

Job No. e.g. RICH 1234	Product code- Type of sample e.g. Raw material, end of life, surface testing, shelf life study.	Test performed / date	Email verification / received and copy attached	Test verification	Upper limit	Outside limit	Corrective actions	Autoclaved / disposed of (Y/N, date)

7 CLIENT VARIATION FORM

Conducted by…… Date……

Client reference number	Job no.	Test sample	Variation to sample procedure	Authorised by

MICROTEX PTY LTD
1 Richmond Rd, Richmond 2222 • 0244455587 example@microtex.com.au

MICROREPORT
REPORT 1

Address of client
ATT: QA MANAGER: name
Date:
Date received:
Date tested:

Page 1 of
REQ NO.

Sample type:
Method No.

Sample Type	Test Type	Count/ results
Raw material	e.g. PEMBA	e.g. <10.000cfu/g

NATA
WORLD RECOGNISED ACCREDITATION

Signature
Insert name
Laboratory Manager

Signature
Insert name
Laboratory Manager

- Limit of detection of conventional plate count methods=10 cfu unless otherwise stated test report only relating to specific item being tested which implies no comparison of guarantee of any other item.
- Methods used unique to in-house operations, standards available upon request.
- Detection limit only applicable to test method
- Test report may not be reproduced unless written approval form CEO
- Testgroup Laboratories

9 SUPPLIES & INVENTORY CHECKLIST

Consumables	Item No.	Supplier
Petri plates	PET1	Thomas Scientific
Weigh boats (small and large)	WB10 / WB100	Thomas Scientific
Spatula	SP100	Thomas Scientific
Pipette tips		Eppendorf
-0.2 - 10	Epptips-10	Eppendorf
-10 – 100	Epptips-100	Eppendorf
100 - 1000	Epptips-1000	Eppendorf
Inoculation loop	Inloop	Thomas Scientific
Glass hockey stick	GLS325	Thomas Scientific
Pure culture of *B. species*	ATCC 14579 (non emetic) NC 7401 (emetic)	Microbiologics
Crystal violet 250mL	CV250	Lab Chem
Concentrated iodine 250mL	CI250	Lab Chem
Iodinated alcohol 250mL	IA250	Lab Chem
Safranine 250mL	SAF250	Lab Chem
Oil immersion 250mL	OI250	Lab Chem
Peptone 500g	P7365A	Neogen
Sodium Chloride 500g	NaCl500	Neogen
Agar technical agar 500g	L13 Oxoid	Oxoid
Egg yolk emulsion 250mL	SR0047	Oxoid
Bacteria species Agar Base 500g	CM0617 Oxoid	Oxoid
Bacteria species Selective Agar 500g	BC0127 Oxoid	Oxoid
Polymyxin B supplement 20g	SR0099E	Oxoid
Brilliant – *Bacteria species* agar 500g	Oxoid	Oxoid
Brain heart infusion 500g	CM0225 Oxoid	Sigma-Aldrich
Nutrient agar 500g	NUA500	Sigma-Aldrich

Elisa Kit	BCET - RPLA	Oxoid
Cavacide 2Ltr	CAV2000	Thermo Fischer
Ethanol 1Ltr	Eth1L	Lab Chem
pH buffer (pH 4, 7, 9) 1Ltr	Phb4, Phb7, Phb10	Lab Chem
Probe solution (KCl) 1Ltr	KCl1L	Lab Chem
Avaguard 3M Hand wash 2Ltr	AV3M	Thermo Fisher
Miscellaneous	**Item No.**	**Supplier**
Nitek gloves (S,M,&L)	NitGS / NitGM / NitGL	Livingstone
Pipette	PP100	Thomas Scientific
Micropipette		Eppendorf
-0.2 - 10	Epp research-10	Eppendorf
-10 – 100	Epp research-100	Eppendorf
100 - 1000	Epp research-1000	Eppendorf
Latex gloves (S,M &L)	LaGS / LaGM / LaGL	Livingstone
Funnel	Fun1	Thomas Scientific
Tongs	TG50	Thomas Scientific
Test tube 18mm OD x 150mm	TT150	Thomas Scientific
Test tube rack	TTR30	Thomas Scientific
Glass slide	GS1000	Thomas Scientific
Cover plate	CP1000	Thomas Scientific
Roll towel	ROL50	Thomas Scientific
Microwipes	KIMWIPE	Thomas Scientific
Parafilm	PAF68	Thomas Scientific
Schott pyrex bottles 500mL, 1Ltr	SCP500, SCP1000	Thomas Scientific
Stomacher bags	STBG50	Thomas Scientific
Autoclave bags	AUB250	Thomas Scientific
Graduated cylinder	GC100	Thomas Scientific
McCartney bottles	MCCB1000	Thomas Scientific
Lighter / matches	RHM500	Thomas Scientific
Reagent bottles 250mL	RB250	Thomas Scientific
Dilution bottles	DB200	Thomas Scientific
Washing detergent 5Ltr	DW5L	Thermo Fisher

Food samples cooked / raw	Uncle Bens cooked food, Basmati food	Supermarket

Equipment used	Brand / Model No.	Calibration / log book	Inspection & tagged
Precision balance	Mettler Toledo PB3002-L	Y	Y
Water bath	Labec	Y	Y
Water distiller	Labec	N	Y
Stomacher	Seward Stomacher	N	Y
Laminar flow cabinet	Thermo laminar	N	Y
Ice machine	Scotsman AF80	N	N
Freezer -80°C	Thermo ultra low	Y	Y
Bunsen burner	Thermo	N	Y
Incubator	Thermo FBH1	Y	Y
Cool room	Thermo	Y	Y
Microscope	Thermo	N	Y
pH meter	Thermo	Y	Y
Autoclave	Thermo sterimatic	N	Y
Elisa Plate Reader	Thermo Multiskan	Y	Y

- The Laboratory Manual is located on the top shelf of the glass door cabinet in the Laboratory.
- All MSDS are located in the glass door cabinet near the Laboratory Manual, next to the chemical cabinet.
- The Risk assessment can be sourced in Appendix 1 of the Laboratory Manual.
- All labels for chemicals and reagents have been copied and printed and are available in the folder next to the MSDS.

10 CONTACT REGISTER FOR SUPPLIES, SERVICING AND REPAIRS

Tools / equipment	Name of supplier	Phone No.
Required tools / Miscellaneous	Thomas Scientific	02 9665 3654
	Eppendorf	02 9633 8547
	Livingstone	02 9785 4215
Reagents / cultures	Microbioogies	02 9365 4569
	Lab Chem	02 9741 5222
	Neogen	02 9288 4122
	Oxoid	02 9635 8741
	Sigma – Aldrich	02 9852 7741
	Thermo Fisher	02 9665 2225

Equipment calibration, servicing and repairs	Brand / Model No.	Service provider	Phone No.
Precision balance	Mettler Toledo PB3002-L	Fisher scientific	02 9899 1234
Water bath	Labec	Fisher scientific	
Water distiller	Labec	Fisher scientific	
Microscope	Thermo	Fisher scientific	
pH meter	Thermo	Fisher scientific	
Autoclave	Thermo sterimatic	Fisher scientific	
Bunsen burner	Thermo	Fisher scientific	
Stomacher	Seward Stomacher	Fisher scientific	
Laminar flow cabinet	Thermo laminar	Fisher scientific	
Ice machine	Scotsman AF80	Express coolroom repair	02 9996 8554
Freezer -80°C	Thermo ultra low	Express coolroom repair	

Cool room	Thermo	Express coolroom repair	
Incubator	Thermo FBH1	Incubator specialists	02 9798 9211

- Spare safety equipment (Safety glasses and Laboratory coat) is stored in the store room; this is not to leave the Laboratory.
- Calibration log books must be compiled regularly on all equipment required as per stated on the previous page.
- Ensure equipment is safe to use before commencement of any activity.
- Ensure when ordering of supplies or requesting repair or general maintenance on equipment, obtain a reference number from the relevant establishment to ensure the request can be traced.

11 EQUIPMENT CALIBRATION LOG BOOK

Precision balance calibration scales log book – Month / Year **Mettler Toledo PB3002 - L**					
Date	**0.02g**	**0.5g**	**2g**	**Conducted by**	**Comments**

Note: Perform daily calibrations.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

Please refer to Supplies Inventory and Checklist for repair, parts and calibration services.

Water bath temperature log book – Month / Year
Labec water bath

Date	Set temperature °C Test 1	Set temperature °C Test 2	Temperature reached °C	Conducted by	Comments

Note: Perform weekly calibrations. Please refer to Supplies Inventory and Checklist for repair, parts and maintenance.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

If the equipment fails to reach desired temperature, report the fault immediately to the Laboratory Manager.

Cool room / freezer temperature log book - Month / Year				
Date	**Temperature °C Cool Room Thermo**	**Temperature °C Freezer Thermo Ultra low**	**Conducted by**	**Comments**

Note: Perform daily recordings. Please refer to Supplies Inventory and Checklist for repair, parts and maintenance.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

If the equipment fails to reach desired temperature, report the fault immediately to the Lab Manager.

Incubator temperature log book - Month / Year Thermo FBH1					
Date	**Model**	**Set temperature**	**Temperature reached**	**Conducted by**	**Comments**

Note: Perform daily recordings. Please refer to Supplies Inventory and Checklist for repair, parts and maintenance.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

If the equipment fails to reach desired temperature, report the fault immediately to the Lab Manager.

Elisa Plate Reader log book - Month / Year
Thermo Multiskan Spectrum

Date	Nominal Absorbance 0,25 /0,5 / 1,0 /1,5 /2,5	Absorbance at nm 405, 450, 490, 650	Conducted by	Comments

Note: weekly calibrations. Please refer to Supplies Inventory and Checklist for repair, parts, calibrations, solutions and buffers.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

Use calibration standard 666.013.

pH meter calibration log book – Month / Year Thermo Orion 266S pH meter						
Date	**Model**	**pH4**	**pH 7**	**pH 9**	**Conducted by**	**Comments**

Note: Perform weekly calibrations. Please refer to Supplies Inventory and Checklist for repair, parts, calibrations, solutions and buffers.

Only use the equipment if it has been tested and tagged by a qualified technician. If there is no tag present, do not use.

If the equipment is not in use, mark under comments as NIU.

12. STANDARD OF OPERATION PROCEDURES

Quality Assurance

Purpose of the work: For ensuring the reliability of data, a Total Quality Management program exists. Also to ensure the practice is in line and complies with ISO / IEC 17025.

Risk assessment: Physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure: 1. Sample selection – to be carried out for a specific purpose.

2. Sample handling – the laboratory has a documentation procedure in place for handling samples after receival. The sample has been given a specific sample No. and all data is collected relating to the sample.

3. Sample disposal – The sample is retained and disposed of to ensure no cross contamination or a hazardous risk may occur. All sample disposals are documented.

4. Environmental – The environment contain within the laboratory do not adversely affect the results. A 'no way back' flow process shall exist.

5. Equipment – All equipment must be in a good working order and all calibrations, maintenance and repairs are documented.

6. Reagents – All reagents and solutions are used by the preparation and method as outlined according the instructions provided by the manufacturer.

7. Staff – The staff must be trained in accordance to the method undertaken and are aware and engage in a safe work method abiding to the risks outlined in the Risk Assessment.

8. Reference materials – Are necessary for accurate comparison of the bacterial micro organism. The staff are trained in microbiological analysis for identifying certain strains.

9. Internal / external quality control – A quality control Laboratory Manual is in place and the Laboratory is proficient in obtaining results.

10. Accreditation – The Laboratory is NATA accredited and procedures are in conjunction with ISO / IEC 17025.

Standard of Operation Procedures

SOP No: 101 TEST SAMPLE RECEIPT

Compiled by: Sonya Muhlsimmer

Sample No:

Sample description (macroscopic identification):

Comments:

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure the sample has been efficiently transported to the laboratory within adequate time; it has been kept at a suitable temperature, is in a leak free sterile container and is clearly labelled with relevant details.

2. Record information on the receival of test sample form (Appendix 4) assigning the sample and job with a specified number.

3. Store the sample immediately at 4°C ± 2°C or analyse the sample immediately in accordance by the client request. If the test sample cannot be analysed within 4 days after collection, freeze the sample at 20°C ± 2°C until examined. Thaw at room temperature then proceed with the test method required.

4. Once the testing is complete compile Internal Inventory (Appendix 5), Dispatch of Test Sample (Appendix 6), Client variation form (Appendix 7) and Micro-report (Appendix 8).

Retain and dispose of the sample in a safe manner and in accordance to SOP No.113, documenting procedures.

Standard of Operation Procedures

SOP No: 102 ASEPTIC TECHNIQUE

Compiled by: Desmond Yang

Purpose of Work: A routine procedure to prevent microbial contamination of the self, environment and the sample.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Sterilise the inoculating loop

   Pass inoculating loop at an angle through a gas burner flame until the whole length of the wire turns orange from the heat. Let the loop cool for a few seconds in avoiding to kill the inoculum.

2. Remove the inoculum.

2a. To remove the inoculum from a broth culture :

- Hold culture tube in one hand, and hold the sterilised inoculating loop in your other hand like holding a pencil.
- Remove the pure culture tube cap by using the little finger of your loop hand. Do not lay the cap down to prevent contamination.
- Briefly flame the lip of the culture tube to create a convection current that forces air out of the tube, and prevents airborne contaminants to enter the tube.
- Holding the culture tube in an angle, insert inoculating loop to remove a loopful of inoculum.
- Then flame the lip of the culture tube.
- Replace the cap.

2b. Removing the inoculum from a plate culture :

- Lift the culture plate lid slightly and insert the loop into the agar away from any growth, in order to cool the loop.
- Scrape off a small amount of the organisms and then close the lid.

3. Transfer the inoculum to the sterile medium.

3a. Transferring the inoculum into a broth tube:

- Pick up the sterile broth tube; remove the cap by using the little finger of your loop hand. Do not put the cap down.
- Briefly flame the lip of the broth tube.
- Place a loopful of inoculum into broth, and withdraw the loop. Do not place the loop down!
- Flame the lip of the tube again.
- Replace the cap.
- Resterilise the loop by passing it in the flame until it turns orange.

3b. Transferring the inoculum into a Petri plate:

- Lift the edge of the lid just adequate to insert the loop.
- Streak the loop across the agar medium surface by using the pattern shown. Hold the loop horizontally while streaking.
- Remove the loop and then close the lid.
- Resterilise the inoculating loop.

SOP No: 103 OVERNIGHT CULTURES

Compiled by: Desmond Yang

Purpose of Work: For the resuscitation or return to viability from environmental stress of the microorganism. To ensure the sufficient growth of the bacterial culture for examination.

Risk Assessment: Biological and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Sterilize the counter and light Bunsen burner to create a germ-free work space.

2. Add 25 mLs of desired broth aseptically to a labelled sterile flask.

3. Dip a sterile loop into a liquid bacterial culture.

4. Dip the loop into the sterile broth, and inoculating it.

5. Label flask as described above.

6. Place the flask into a shaking (100-150 rpm) water bath at 37 °C ± 2°C for 16 - 24 hours.

SOP No: 104 BRAIN HEART INFUSION BROTH

Compiled by: Desmond Yang

Purpose of Work: For the cultivation of fastidious, pathogenic microorganisms in the examination of foods. This culture is used as an overnight broth.

Risk Assessment: Biological and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Suspend 37.0g in 1 litre of distilled water.

2. Heat if necessary to dissolve the medium completely.

3. Dispense into bottles or tubes as desired. Sterilize by autoclaving at 15Ibs (121^0C) for 15 minutes.

4. Cool to 45-50^0C ± 2°C.

5. Aseptically dispense 9mLs into sterile 20ml universal tubes.

6. Perform sterility testing.

7. Label the side of each tube with date of preparation and batch number.

8. Store the culture medium at 2-8^0C ± 2°C sealed in plastic bags to reduce chances of contamination.

9. Test Samples of the finished product for performance, using stable, typical control cultures.

Standard of Operation Procedures

SOP No: 105 PREPARATION OF POLYMYXIN PYRUVATE EGG YOLK MANNITOL BROMOTHYMOL BLUE AGAR (PEMBA)

Compiled by: Dave De Fretes

Purpose of Work: To isolate and enumerate *Bacteria species* in foods. To selectively detect a small number of *Bacteria species* cells and spores in the presence of large numbers of other food contaminants.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory safety glasses, coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure protective gear is worn (Laboratory safety glasses, coat and latex gloves).

2. Clean work bench with cavacide disinfectant and paper towel.

3. Collect equipment(s) required.

- Pressure cooker/Autoclave (if available) Water bath at 50°C.
- Pyrex bottles with lids.
- Micro scale.
- Micro pipette.
- Petri dishes.

4. Pre-sterilise Pyrex bottles prior to use.

5. Suspend 20.5g of dehydrated agar powder in 475mL of distilled water in Pyrex bottles to dissolve completely in the preheated water bath.

6. Place the bottles in the pressure cooker until it reaches 15lbs for 15 minutes or autoclaving at 121°C for 15 minutes.

7. Release the pressure if using pressure cooker.

8. Cool the bottles to 50°C ± 2°C.

9. Aseptically add one vial of reconstituted Polymyxin B Supplement (SR0099) to the cooled agar mix.

10. Add25mL of sterile Egg Yolk Emulsion (SR0047).

11. Mix well by applying minimum speed motion to prevent bubbles from developing.

12. Pour mixture to sterile Petri dishes.

13. Shake gently to level the mixture.

14. Leave to set before use.

Standard of Operation Procedures

SOP No: 106 PREPARATION OF PEPTONE WATER

Compiled by: Dave De Fretes

Purpose of Work: A non-selective medium used as a basal medium for biochemical tests and to prevent the cultivation of non-fastidious organisms.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory safety glasses, coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure protective gear is worn (Laboratory safety glasses, coat and latex gloves).

2. Clean work bench with cavacide disinfectant and paper towel.

3. Collect equipment(s) required.

- Pressure cooker/Autoclave (if available).
- 1x 1000mL Pyrex beaker.
- 2x 500mL Pyrex bottles with lids.
- Micro scale.
- Water bath at 70°C.

4. Pre-sterilise Pyrex bottles prior to use.

5. Dissolve 1g of Peptone and 1000mL of distilled water in the Pyrex beaker using the preheated water bath.

6. Distribute the dissolved solution into two 500mL Pyrex bottles.

7. Place the bottles in the pressure cooker until it reaches 15lbs for 15 minutes or autoclaving at 121°C for 15 minutes.

8. Release the pressure if using pressure cooker.

9. Cool the solutions before use.

Standard of Operation Procedures

SOP No: 107 SAMPLE PREPARATION AND SERIAL DILUTIONS

Compiled by: Dave De Fretes

Purpose of Work: To prepare the samples for serial dilutions. Dilutions are prepared to reduce the concentration of cells in a sample as the microbial load is too high to count directly on the sample.

Risk Assessment: Biological and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory safety glasses, coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure protective gear is worn (Laboratory safety glasses, coat and latex gloves).

2. Clean work bench with cavacide disinfectant and paper towel.

3. Collect equipment(s)/sample(s) required.

- Stomacher.
- 4x Stomacher bags.
- 16x 9mL Peptone water dilution blank in plastic jars.
- Peptone water.
- 2x 20g raw food.
- 2x 20g cooked food.
- *Bacteria species* pure culture in an overnight Brain heart Infusion broth (BHI).
- Micropipette.

4. Label stomacher bags; *Cooked control* (CC)*, Cooked Inoculated* (CI)*, Raw control* (RC), *Raw Inoculated* (RI).

Label blank dilutions in of 10^{-1}, 10^{-2}, 10^{-3} and 10^{-4} with each treatment.

5. In a stomacher bag, put 20g of food with 50mL of Peptone water (1mL of *Bacteria species* pure culture in overnight BHI for the inoculated sample) and using the stomacher apply the motion for one minute.

6. Using micropipette take 1mL from the treated bag into blank dilution 10^{-1}.

7. Using 10^{-1} dilution, take 1mL with micropipette into 10^{-2} blank dilution.

8. Take 1mL from 10^{-2} dilution using micropipette into 10^{-3} blank dilution.

9. Using micropipette take 1mL from 10^{-3} dilution into 10^{-4} blank dilution.

10. Repeat steps 5 - 9 with the different sample treatments.

Standard of Operation Procedures

SOP No: 108 STREAKING PEMBA AGAR PLATES WITH INOCULUM

Compiled by: Dave De Fretes

Purpose of Work: To isolate and enumerate *Bacteria species* by streaking the inoculum using hockey stick method.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory safety glasses, coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure protective gear is worn (Laboratory safety glasses, coat and latex gloves).

2. Clean work bench with cavacide disinfectant and paper towel.

3. Collect equipment(s)/sample(s) required.

- 24x PEMBA agar plates.
- Serial dilutions of treatments at 10^{-2}, 10^{-3} and 10^{-4}.
- 20-200µL micropipette.
- Glass hockey stick.
- Ethanol 95%.
- Bunsen burner.
- Lighter (Laboratory certified).

4. Label the bottom of the PEMBA plate with the required information.

5. Light on the Bunsen burner and out on yellow flame during preparation of the plates and serial dilutions.

6. Lay out 2 plates with lid closed.

7. Open the lid with one hand and apply 100µL of 10^{-2} dilution to the PEMBA agar plates and immediately close the lid back.

8. Switch the yellow flame to blue flame.

9. Place the ethanol bottle away from the burner.

10. Dip the hockey stick in the ethanol and burn it until the ethanol evaporated.

11. Air cool the stick close to the flame.

12. With one hand open the lid and using the hockey stick on the other hand, spread the dilution evenly over the entire surface of the plate.

13. Close back the lid.

14. Perform steps 6 – 13 for 10^{-3}, 10^{-4} dilutions.

15. Repeat steps 6 – 14 for each treatment.

16. Incubate inoculated plates at 30° ± 2°C for 24 hours.

Standard of Operation Procedures

SOP No: 109 PLATE COUNT, GRAM STAIN AND DATA COLLECTION

Compiled by: Sonya Muhlsimmer

Sample No:

Purpose of the work: A plate count macroscopically identifies cultures and is also used to enumerate the culture growth. This assumes that each cell in the population can divide and continue forming other colonies. A gram stain is a confirmatory test to microscopically identify the bacterial culture. Further confirmatory tests may be required.

Risk assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. With the culture containing Petri dish count the number of colonies on each plate. Choose the plate which has the dilution that gives approximately 25 – 250.

2. Record the count on the Plate Colony count graph.

3. Calculate the number of colony forming units (CFU).

$$\text{Average No. Of colonies from all plates} \times \frac{1}{\text{Dilution factor}} \times \frac{1}{\text{Volume plated}} = \text{CFU / mL or gm}$$

4. Record the CFU count on the Plate CFU / ml or gram graph.

5. If necessary perform a gram stain.

6. Set light microscope to Kohler illumination.

7. Prepare a heat fixed smear by heating slide through a Bunsen burner flame and aseptically placing a small loop of inoculum onto the slide and let air dry.

8. Heat fix the slide under the Bunsen burner flame.

9. Stain with Crystal Violet for 1 to 1 ½ mins.

10. Wash under running tap water.

11. Then stain the slide with concentrated iodine for approximately 1 to 1 ½ mins.

12. Decolourise with iodinated alcohol until the liquid running off the slide is clear but not for any longer than 10 secs.

13. Wash the slide under running tap water.

14. Stain the slide with Safranine for approximately 1 to 1 ½ mins.

15. Wash under running tap water and blot the slide dry carefully with paper towel and pass the slide through the Bunsen burner flame.

16. Examine the slide under a microscope which has been set for the Kohler Illumination setting. An oil immersion can be used.

17. Record your results. A drawing is acceptable on the results report.

Purple / gram positive
Pink / gram negative

18. Confirmatory test (Reverse Passive Latex Agglutination) / Elisa test (SOP No. 110).

19. Dispose of the sample in a safe manner following SOP 113.

Gram stain performed: Yes / no

Results of gram stain:

Differential strain comparison using tests outlined in Appendix 13: Yes / No

Enterotoxin confirmatory test required: Yes / No

Which test is to be undertaken.

Reverse Passive Latex Agglutination: Yes / No

Elisa (SOP 110): Yes / No

Visually read plates:

The intensity of the colour is indicative of the concentration of the target antigen.

Positive Control: #3 - #5 (colour card)

Negative Control: #1 (colour card)

Sample Results:

Results:

Plate Colony count – number of colonies detected				
Sample No.				
Dilution	**Sample**			

Plate CFU / ml or gm– calculated from plate count colony				
Sample No.				
Dilution	**Sample**			

CFU calculated as:

No. Of colonies x 1 x 1

Dilution factor Volume plated

Standard of Operation Procedures

SOP No: 110 ELISA CONFIRMATORY TEST FOR EMETIC TOXIN

Compiled by: Raisa Matillano & Sanjana Rahman

Purpose of Work: For the detection of Bacteria spp in food, food related and environmental samples. The results can be obtained within 42 hours and can detect 1 - 5 cfu / 25 gram of sample following enrichment. Elisa is a toxin detection method to differentiate between diarrhoeal and non-diarrhoeal strains of *B. species.*

Risk Assessment: Biological and physical hazard. Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Make sure all reagents are at 20-25^{0}C ± 2°C
2. Arrange three (3) wells as triplicates of enrichment sample, one (1) for Positive Control (PC) and one (1) for Negative Control (NC) firmly into the well holder
3. Pre-soak wells by filling each well with Wash Solution. Soak for 10 minutes at 20-25^{0}C ± 2°C
4. Empty the wells into absorbent paper towels
5. Transfer 200µl of each enrichment sample into 3 wells, 200µl of the PC and 200µl of the NC into separate wells.
6. Cover wells with adhesive cover to prevent evaporation and incubate for 2 hours at 36±2^{0}C
7. To wash, completely empty the wells into absorbent paper towels.
8. Completely fill the wells with Wash Solution, taking care not to trap air bubbles in the bottom of the wells. Wash wells thoroughly a total of 4 times.
9. Add 200µl of Conjugate dilution into each empty well.
10. Cover wells with adhesive cover to prevent evaporation and incubate for 1 hour at 20-25^{0}C ± 2°C
11. Wash the wells as stated in procedures 7 and 8 above, a total of 5 times
12. Add 200µl of Substrate to each empty well and incubate for 30 minutes at 20-25^{0}C ± 2°C, avoiding temperature fluctuation
13. Gently tap the well holder to distribute the colour uniformly before recording results.

- PC should be at least as dark as Colour Card 2 template #4
- If PC fails to reach minimum colour after 45 minutes of final incubation, the assay is invalid and test results cannot be used.
- NC must not be darker that Colour Card 2 template #2 for the assay to be valid

RESULTS

Visually read results.

The intensity of colour is indicative of the concentration of the target antigen.

Positive Control: #3 to #5 (colour card). As the control varies in colour intensity, the acceptable limit is when the colour matches a limit of at least #3 and above.
Negative Control: #1 (colour card)

Sample Record Sheet

Operator..... Date.....

Run No.....

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Standard of Operation Procedures

SOP No: 111 INOCULATION OF AN AGAR PLATE WITH A PURE CULTURE

Compiled by: Sonya Muhlsimmer

Purpose of Work: To multiply, identify and enumerate *Bacteria species* for routine surveillance and to ensure culture continues to survive for reference identification plate.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. Ensure protective gear is worn (Laboratory coat and latex gloves).

2. Clean work bench with cavacide disinfectant and paper towel.

3. Collect equipment needed
-Ethanol
-Bunsen burner
- Inoculation loop
-Pure culture in overnight broth (SOP 103)
-Agar plate (Brain Heart Agar / Nutrient agar)
- Broth (Brain heart or nutrient)

4. Prepare the Bunsen burner in a suitable position on the bench and light it. Obtain the overnight broth and using aseptic techniques place the flamed inoculation loop into the broth. With the inoculated loop, make a smear onto the edge of the agar and streak a quarter of the plate.

5. Close the plate and flame the loop. Allow the loop to cool and starting from the edge of the last streak, but not to let the lines cross over more than once, streak another quarter of the plate.

6. Repeat step 5 two more times, until the whole plate has been streaked. Incubate at 30°C ± 2°C for 24 hours.

Disposed of in a safe manner in accordance with SOP 113: Yes / No

Standard of Operation Procedures

SOP No: 112 ROUTINE SURVEILLANCE FOR BACILLUS CEREUS IN FOOD USING PEMBA AGAR

Compiled by: Sonya Muhlsimmer

Purpose of work: A standard operation to ensure methods, material and results obtained are validated and verified in which comply with standards. The use of pure reference materials for the identification of *Bacteria species* is necessary to give information on the cultural characteristics of the strain.

Risk Assessment: Biological, chemical and physical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

All plates are to be in triplicate and prepared following SOP 105, 107 & 108 (PEMBA preparation, serial dilution and plate streaking). If the quantity of food to be examined is large, take a sample of approximately 50g each from different parts of the sample.

All diagnostic / selective plating media for *B. species* are surface inoculated with 0.1mL of inoculum spread evenly onto the surface of each plate with a hockey stick.

CFU calculated as: (for one plate)

$$\text{No. Of colonies} \times \frac{1}{\text{Dilution factor}} \times \frac{1}{\text{Volume plated}} = \text{CFU / mL or gm}$$

Enumeration of *B. species*:

Prepared from a pure culture (SOP 103) of *B. species* and suspended in Brain Heart Broth overnight.

Incubation temperature: 30°C± 2°C

Incubation time: 24 hours

Overnight broth culture of *B. species* (approx 10^9 cfu / ml)

Plate count of *B. species*:

Observe for colonies surrounded by a precipitated zone. This is an indication that lecithinase is produced. If the plate samples are not clear, incubate plates for an additional 24 hours. Select plates containing approximately 25 – 250 colonies.

Results:

Plate Colony count – number of colonies detected				
Raw food			**Cooked food**	
Dilution	**Control**	**Inoculated**	**Control**	**Inoculated**
10^{-2}				
10^{-3}				
10^{-4}				

Plate CFU / ml or gm– calculated from plate count colony				
Raw food			**Cooked food**	
Dilution	**Control**	**Inoculated**	**Control**	**Inoculated**
10^{-2}				
10^{-3}				
10^{-4}				

Transferred to Nutrient agar slants: Yes / No

Gram stain performed: Yes / no

Results of gram stain:

Endotoxin confirmatory test required: Yes / No

Which test is to be undertaken.

Reverse Passive Latex Agglutination: Yes / No

Elisa (SOP 110): Yes / No

Visually read results.

The intensity of colour is indicative of the concentration of the target antigen.

Positive Control: #3 to #5 (colour card). As the control varies in colour intensity, the acceptable limit is when the colour matches a limit of at least #3 and above.
Negative Control: #1 (colour card)

Sample Results:

Diagnostics:

Interpretation:

Bacteria cereus shows crenated, colonies about 5mm in diameter, turquoise blue in colour, surrounded by a distinct opaque zone of egg yolk precipitation of the same colour of the colonies.

Acceptable limit for routine foods:
No. Of strains tested: 10
Recovery in $\log_{10}$ cfu / ml: 7.3 ± 0.2

Does the sample comply with the limits according to Appendix 13: Yes / No

Comments:

Disposed of the sample in a safe manner in accordance to SOP 113: Yes / no

Standard of Operation Procedures

SOP No: 113 DISCARDING OF BIOLOGICAL HAZARD WASTE

Compiled by: Sonya Muhlsimmer

Purpose of the work: For the safe transport and disposal of biological and chemical hazardous waste from the premise of Testgroup Pty Ltd, and to ensure no contamination of these hazards occurs to the external or internal environment.

Risk assessment: Biological, Physical and Chemical hazard. Refer to Risk Assessment (Appendix 1). Laboratory coat and latex gloves must be worn when undertaking any duties in the Laboratory.

Procedure:

1. It is the responsibility of all laboratory personnel to ensure that the appropriate waste is placed in a specific container, autoclave bin or bag.

- Autoclave bags are permitted Petri dishes and paper.

- Autoclave bins are permitted glassware, pipettes, micropipette tips, sharp objects and slides.

3. Record each run of the autoclave for traceability purposes. The clip board log book is located directly on the wall beside the autoclave. This documentation must be performed as it is a requirement for NATA accreditation and ISO / IEC 17025.

4. Sterilize all rubbish in the autoclave for 121°C for 90 minutes.

5. Remove the bag from the autoclave and dispose of in the hopper at the rear of the building for the removal by waste management.

5. Clean the autoclave out with hot water.

13 CHARACTERISTICS OF *Bacteria species*, MICROBIAL QUALITY OF COOKED FOOD, FOOD-BORNE INCIDENCE AND REFERENCE STRAIN

Basic and differential characteristics of selected Bacteria species

Morphologic group 1	Gram reaction	Motility	Catalase production	Citrate utilisation	Anaerobic growth	V.P Reaction	Growth at 50 °C	Growth in 7% NaCl	Nitrate Reduction	Egg Yolk reaction	Known pathogenic / characteristic
B species	+	+	+	+	+	+	-	+	+	+	Enterotoxin
B species subsp mycoides	+	-	+	+	+	+	-	+	+		
B anthracis	+	-	+	V	+	+	-	+	+	+	Pathogenic to human and animals
B thuringiensis	+	+	+	+	+	+	-	+	+	+	Endotoxin crystals
B licheniformis	+	+	+	+	+	+	+	+	+		
B subtilise	+	+	+	+	-	+	V	+	+		
B firmus	+	V	+	-	-	-	-	+	+		
B coagulans	+	+	+	v	+	+	+	-	v		

Note: V.P, Vogas-Proskauer. +, positive. -, negative. V, variable.

Microbiological quality of cooked food

Test	Microbiological quality (CFU per gram)			
	Satisfactory	**Marginal**	**Unsatisfactory**	**Potentially Hazardous**
Indicators				
Escherichia coli	<3	3-100	>100	*
Pathogens				
Bacteria species	<102	102 - 103		≥104

Note: *Pathogenic strains of E. coli should be absent

Uncooked food is a shelf stable food; there should be no *Bacteria species* present unless inoculated.

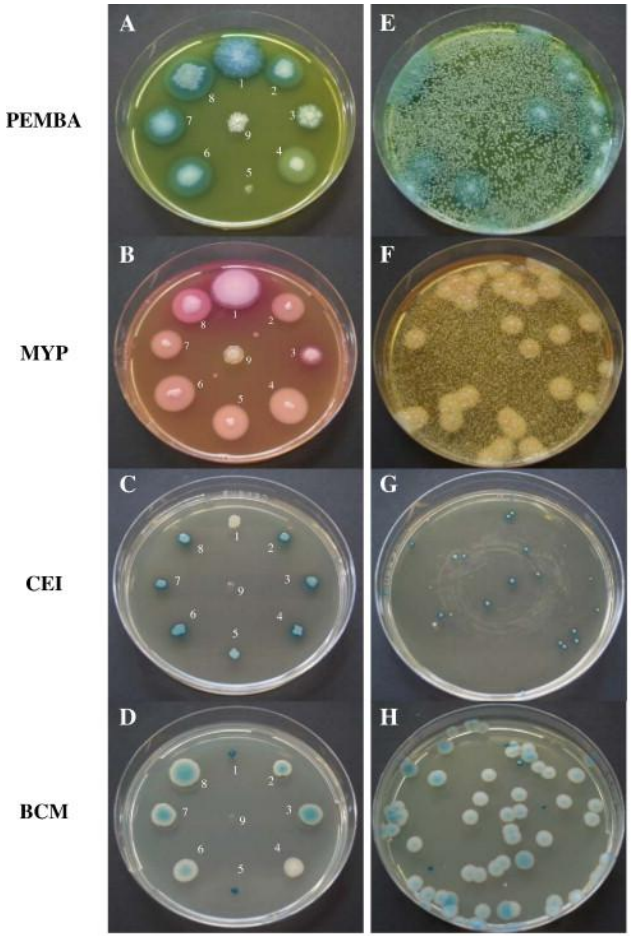
Incidence of *Bacteria species* in food borne disease outbreaks.

Surveillance testing.

Type of food	**% Positive**	**Range (cfu g^{-1} or mL $^{-1}$)**
Food and Food products		
Raw food	40 – 100	$10^2 – 10^3$
Boiled food	10 – 93	10^1 - 10^7
Fried food	12 – 86	10^1 - 10^5
Food dishes	3 - 40	10^1 - 10^5

Note: Food items are frequently involved in food-borne disease outbreaks. 'Ready to eat' products can be seen to exceed 1 x 104 organisms $g^{1.}$ for *Bacteria species.*

Reference strains for *Bacteria species* are necessary for accurate comparison of the bacterial microorganism.



(Fricker et al, 2008)

Reference strains used:

1. NVH 0391-98 (reference strain)

2. NC7401 (isolate from emetic outbreak)

3. RIVM BC 67 (human faeces)

4. RIVM BC90 (human faeces)

5. WSBC 10204

6. WSBC 10882 (isolate from emetic toxin)

7. F4810 / 72 (reference strain from emetic toxin)

8. ATCC 14579 (B. cereus)

9. B. licheniformis (Negative control, food isolate)

Pemba: Polymyxin Pyruvate Egg yolk Mannitol Bromothymol Blue Agar

MYP: Mannitol-Egg yolk-Polymyxine-Agar

Name	***Bacteria cereus***
Authors:	Frankland and Frankland 1887
Status:	species (AL)
Reference:	Int. J. Syst. Bacteriol. 30:256 (AL) [Literature]
Type strain:	ATCC 14579, CCM 2010, DSM 31, NCIB 9373, NCTC 2599
Synonym(s):	*Bacteria medusa*
more information:	LPSN (J.P. Euzéby)

14 MICROTEX AUDITS

Audit Requirements

Audits are carried out biannually in Testgroup Laboratories as part of consistent quality control. Testgroup employs both independent external auditors and Testgroup's own Quality Assurance Officer as internal auditor. Testgroup aims to protect its employees and visitors, ensure safety within the workplace and enforce procedures that conform to the Australian Standards (ISO / IEC 17025) and NATA.

Internal Audits

Internal audits are conducted six months after an external audit or when non-conforming results are acquired. The internal audits are prepared and carried out by Testgroup's Quality Assurance Officer. Internal audits aim to identify non-conforming procedures or results; ensure appropriate and regular documentation of personnel, procedures and corrective actions, and recognizing the need to improve the safety management system.

External Audits

External Audits are executed by NATA once a year to verify Testgroup's compliance with Australian Standards ISO / IEC 17025, implementation of safety management system and company policies. External audits serve as validation of internal audit results and may help improve internal audit checks and Testgroup policies and processing procedures.

Amendment

In the event of an audit's identification of the need for corrective action for a hazard or non-conforming procedure, the object or procedure in question shall be immediately put on hold and assessed until the issue is rectified. A new Standard Operation Procedure will be procured in place of the non-conforming procedure and all stakeholders will be notified.

Audit Documentation and Record

The audit documentation must be copied, recorded and filed immediately after the audit. Audit records must be kept in file for at least six years in case of a recall and for quality assurance purposes. The audit record must include:

- Audit Checklist
- Auditor's name
- Auditor's employer or company
- Date of audit
- Signature of auditor
- Area and equipment being audited
- Complete results of audit including Incident Report Form (if applicable)
- Any recommendation for improvement of management and policies
- Any recommendation for corrective actions (if applicable)

Follow-up Audits

If the most recent audit identified non-conformity in policy, management or procedures within Testgroup, a follow-up audit may be implemented after the corrective action has been enforced. Documentation of the previous audit must be available for use during the follow-up audit for quality assurance.

Non- conformance

In the event of non-conforming data are obtained from expected results during processing or testing, it is Testgroup procedure to carry out the same methodology again with duplicates to ensure that non-conforming data are true results and not normal fluctuations or variations. If data obtained still vary, the testing or processing shall be halted and any stakeholder affected shall be notified. Corrective action must be employed until the issue is rectified. An internal audit of the process may be implemented for quality assurance.

15 INTERNAL AUDIT: MICROBIOLOGY LABORATORY CHECKLIST

Inspection team members:

Supervisor:

Inspection date:

Laboratory / Location number:

Instructions:

- Mark boxes with tick (✓) as items are observed or with a cross (X) if absent. Write 'NA' if item is not applicable. Any item marked with a cross requires a corrective action.
- Any corrective action which cannot be resolved must be recorded into the Hazards and Incident Report Form at the completion of the inspection to appraise the risk and determine appropriate controls, actions and timeframes.
- If the corrective action is immediately accomplished, please write 'COMPLETED' under the Reference Number column.
- If a maintenance number has been identified please record the apparatus number in the Reference Number column.

QUESTION	✓	X	NA	CORRECTIVE ACTION	REFERENCE NUMBER
Layout					
Area clean and well kept					
Floor area free of obstructions					
Floor coverings in good quality					
Floor surface is not slippery					
Separate section or cabinet for personnel's personal belongings					
Work Environment					
Hazard and safety notifications clearly visible on entrance					
Emergency instructions clearly visible in case of fire					
First Aid signs are clearly noticeable					
Lighting functioning and sufficient					
Temperature is comfortable and appropriate					

Area is free of odours					
Noise level is acceptable and appropriately controlled					
Ventilation is sufficient					
Special Ventilations are covered and operational					
Manual Tasks					
Items frequently used are within easy reach between knee and shoulders					
Heavy items are stored at waist height					
Handling equipment accessible for heavy items and loads					
Manual lifting instructions are clearly visible					
Personal Protective Equipment					
PPE correctly stored					
Appropriate PPE easily accessible					
PPE maintained and restocked					
PPE requirement signs are clearly visible					
Emergency					
Exits are clear and free of obstruction					
Exit signs and instructions clearly visible					
Spill kits or equipment available					
Fire fighting equipment accessible with instructions					
Fire fighting equipment correctly labelled and maintained every 6 months					
Safety shower easily accessible with instructions					
Eye wash station easily accessible with instructions					
Chemical Aspects					
Containers correctly labelled					
Chemicals correctly stored in suitable containers					
Chemicals stored according to compatibility					
Flammables and corrosive chemicals stored in					

appropriate storage cabinets					
Chemicals stored appropriately					
Laboratory and Equipment					
Work stations clean and tidy					
Laboratory and equipment maintained and in good state					
Laboratory cannot be accessed when left unattended					
Emergency stops are working					
Log book maintained for use					
Warning and instruction labels on equipment present					
Welding screens or ventilation screens in good state and maintained regularly					
Electrical equipment maintained, tested, tagged and in date					
Power points and sources in good condition					
Power boards used (not double adaptors)					
Gas lines in good condition, checked and maintained regularly (free of leaks, wear and tear)					
Chairs maintained and fit under work stations					
Windows sealed and maintained					
Compressed gases					
Cylinder contents are labelled correctly					
Cylinders are secure					
Cylinders stored appropriately					
Comments: **Recommendations for corrective action or management:**					

16 INTERNAL AUDIT: TEST METHOD CHECKLIST

Inspection team members:

Supervisor:

Inspection date:

Laboratory / Location number:

Instructions:

- Mark boxes with tick (✓) as items are observed or with a cross (X) if absent. Write 'NA' if item is not applicable. Any item marked with a cross requires a corrective action.
- Any corrective action which cannot be resolved must be recorded into the Hazards and Incident Report Form at the completion of the inspection to appraise the risk and determine appropriate controls, actions and timeframes.
- If the corrective action is immediately accomplished, please write 'COMPLETED' under the Reference Number column.
- If a maintenance number has been identified please record the apparatus number in the Reference Number column.

QUESTION	✓	X	NA	CORRECTIVE ACTION	REFERENCE NUMBER
Raw material					
Follow manufacturers instruction, use and expiry date					
Regular turnover of stock (FIFO)					
Recheck seal, date of opening, visual assessment of contents					
Lot acceptance of Dehydrated Culture Media					
Enumeration media: Quantitative recovery of test media					
Selective media: Semi quantitative recovery of test microbe					

Non selective: Semi quantitative / qualitative recovery of test microbe					
Finished Product					
Physical: Inspection of physical imperfections					
Chemical: Final pH of medium to be measured					
Sterility; Sampling incubation and inspection of units from each batch produced					
Sample Plan					
Large batch >100 units according to AS 1199.1-2003					
Small batch <100 units according to ISO/TS 11133.2					
Final volume of media within specifications: dispenser to discharge margin to allow for loss					
Cultures					
Control strain recommended is used					
Culture activated and tested for purity					
Culture identification verified: Master culture					
Stock culture prepared and frozen					
Working culture segregated from master and stock culture					
Master culture stored at -70°C					
Stock culture stored at -20°C					
Test Procedure Methodology					
Isolated colonies suspended in small volume of					

culture medium and incubated					
Nutritive capacity of medium delivers in a loop $10^3 – 10^4$, 25-250 CFU/plate					
Inhibitory capacity of medium inoculated with 10 times more than nutritive test, and delivers $10^4 – 10^5$, 250 – 25000 CFU/plate					
Nutritive capacity of liquid medium delivers 10^2 CFU per unit of test medium					
Broth sub cultured to check correct inoculum					
Streak Plate method					
5 Zone streak plate method is followed, loop to be flamed between sections					
Incubation Conditions					
Incubation of test media in a range of zones: 5°C, 25°C, 30°C, 37°C, 44°C, 55°C for the normal period					
Parameters Measured					
Reference medium is to be used for results interpretation					
Growth Recovery of Control Microorganisms					
For batch control of culture medium, growth is assessed quantitatively, semi quantitatively and qualitatively as according to Culture Media SIG					
Interpretation of Results					
Acceptance and rejection criteria on Lab media specifications					
User Quality Assurance Practices					

Certificates retained for 3 years					
Labels record: Date received, product, batch No., expiry date, date manufactured, condition upon delivery, size of delivery					
Reviewing of the Media Quality Control Control Certificates					
Review of Q.C certificates: correct microbes have been tested by correct protocol, growth extent recorded, colony colour recorded					
Remedial Action for Deficiencies Observed					
Manufacturer notified: Product affected, batch No., expiry date, date received by user					
Comments: **Recommendations for corrective action or management:**					

17 PIPETTE PROCEDURES

Procedure on using a pipette:

1. Change the amount of micro litres to be pipetted by using the dial located on the top of the pipette.

2. Making sure the correct size tip is available, press the end of the pipette firmly into the new tip.

3. Whilst placing your thumb on the trigger, draw up the pre-selected amount of liquid into the pipette tip.

4. Press the trigger to release the liquid from the pipette.

5. Discard of the pipette tip making sure a new tip is used every time the pipette is used.

RESULTS OF ROUTINE SURVEILLANCE

DURING AUGUST – NOVEMBER 2012

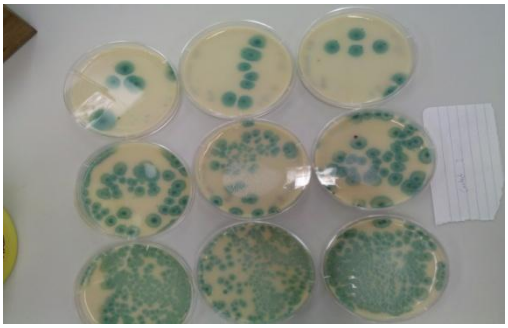
Results: Week 5 (31.8.12)

Test: Brilliant Agar chromogenic media

Plate Colony count – number of colonies detected								
Sample No. Cooked food -					**Raw food**			
Dilution	**Sample 1 Control**		**Sample 1 inoculated**		**Sample 2 Control**		**Sample 2 Inoculated**	
10^{-2}	0	10	TNTC	22	0	18	TNTC	116
	0	21	TNTC	37	0	10	TNTC	105
	0	28	TNTC	38	1	12	TNTC	126
10^{-3}	0	19	52	8	0	1	TNTC	125
	0	28	71	3	0	7	TNTC	117
	1	36	53	9	0	37	TNTC	122
10^{-4}	0	21	6	10	1	0	41	12
	0	17	7	10	0	2	46	18
	0	13	7	22	0	36	65	11
Plate CFU / ml or gm– calculated from plate count colony								
Sample No. Cooked food					**Raw food**			
Dilution	**Sample 1 Control**		**Sample 1 inoculated**		**Sample 2 Control**		**Sample 2 Inoculated**	
10^{-2}	0	$1x10^4$	TNTC	$2.2x10^4$	0	$1.8x10^4$	TNTC	$1.2x10^5$
	0	$2.1x10^4$	TNTC	$3.7 x10^4$	0	$1x10^4$	TNTC	$1.1x10^5$
	0	$2.8x10^4$	TNTC	$3.8 x10^4$	$1x10^4$	$1.2x10^4$	TNTC	$1.3x10^5$
10^{-3}	0	$1.9x10^5$	$5.2x10^5$	$8 x10^4$	0	$1x10^4$	TNTC	$1.3x10^6$
	0	$2.8x10^5$	$7.1x10^5$	$3 x10^4$	0	$7x10^4$	TNTC	$1.2x10^6$
	0	$3.6x10^5$	$5.3x10^5$	$9 x10^4$	0	$3.7x10^5$	TNTC	$1.2x10^6$
10^{-4}	0	$2.1x10^6$	$6x10^5$	$1x10^6$	$1x10^5$	0	$4.1x10^6$	$1.2x10^6$
	0	$1.7x10^6$	$7x10^5$	$1x10^6$	0	$2x10^5$	$4.6x10^6$	$1.8x10^6$
	0	$1.3x10^6$	$7x10^5$	$2.2x10^6$	0	$3.6x10^6$	$6.5x10^6$	$1.1x10^6$

Comments: Wrong agar supplied (was UTI chromogenic, not *B. species chromogenic*)

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$



Week 6 – (7.9.12) Issue with Agar supply. No plates available.

Week 7 – (14.9.12) Made more agar, also premade agar plates supplied.

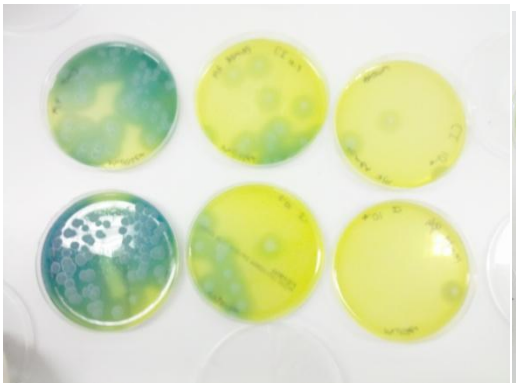
Results: Week 8 (21.9.12)

Test: PEMBA Agar

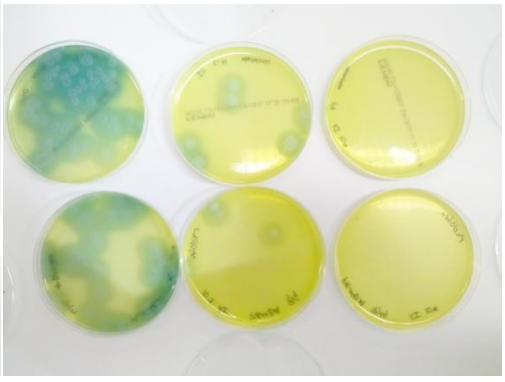
Plate Colony count and CFU / ml or gm of colonies detected								
Sample No. Cooked food					**Raw food**			
Dilution	**Control**	**CFU**	**Inoculated**	**CFU**	**Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	0	0	41	$4.1x10^4$	0	0	TNTC	TNTC
	0	0	45	$4.5x10^4$	0	0	TNTC	TNTC
	0	0	25	$2.5x10^4$	0	0	TNTC	TNTC
10^{-3}	0	0	9	$9x10^4$	0	0	131	$1.3X10^6$
	0	0	2	$2x10^4$	0	0	142	$1.4X10^6$
	0	0	6	$6x10^4$	0	0	111	$1.1X10^6$
10^{-4}	0	0	0	0	0	0	6	$6X10^5$
	0	0	0	0	0	0	11	$1.1X10^6$
	D	0	0	0	0	0	10	$1X10^6$

Comments: Contamination, control exhibited growth of other microorganism.

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$



Cooked inoculated



Raw inoculated

Week 9 – (28.9.12) Mid semester break.

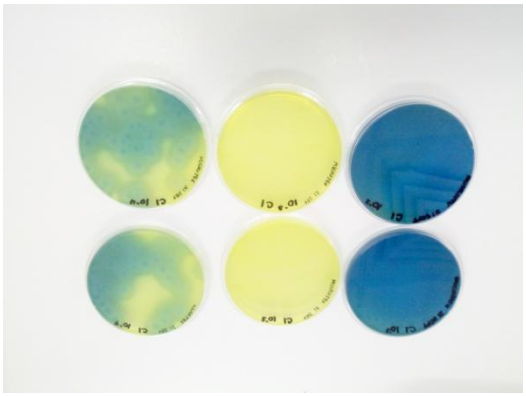
Results: Week 10 (5.10.12)

Test: PEMBA Agar

Plate Colony count and CFU / ml or gm of colonies detected								
Sample No. **Cooked food**					**Raw food**			
Dilution	**Sample 1 Control**	**CFU**	**Inoculated**	**CFU**	**Sample 2 Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	0	0	TNTC	TNTC	0	0	136	$1.4x10^5$
	0	0	TNTC	TNTC	0	0	109	$1.1x10^5$
10^{-3}	0	0	45	$4.5x10^6$	0	0	23	$2.3x10^5$
	0	0	54	$5.4x10^6$	0	0	37	$37x10^5$
10^{-4}	0	0	0		0	0	4	$4x10^5$
	0	0	0		0	0	3	$3x10^5$

Comments:

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$



Cooked inoculated

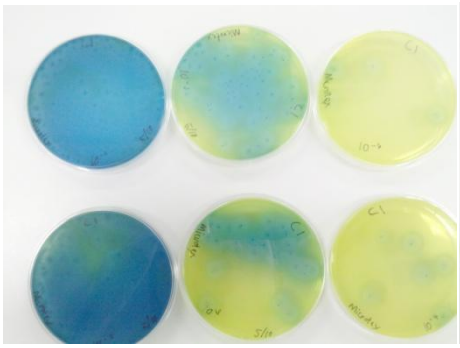
Results: Week 11 (12.10.12)

Test: PEMBA Agar

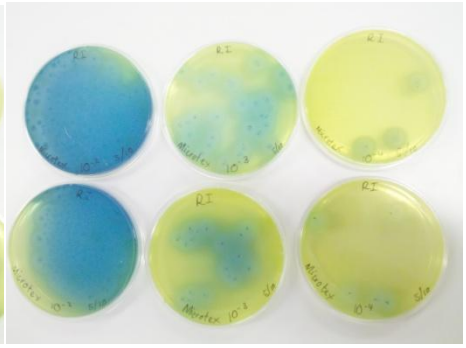
Plate Colony count and CFU / ml or gm of colonies detected								
Sample No.								
Cooked food					**Raw food**			
Dilution	**Sample 1 Control**	**CFU**	**Inoculated**	**CFU**	**Sample 2 Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	0	0	TNTC	TNTC	0	0	TNTC	TNTC
10^{-3}	0	0	85	$8.5x10^5$	0	0	49	$4.9x10^5$
10^{-4}	0	0	10	$1.0x10^6$	0	0	8	$8x10^5$

Comments:

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$



Cooked inoculated



Raw inoculated

Results: Week 12 (19.10.12)

Test: PEMBA Agar

Plate Colony count and CFU / ml or gm of colonies detected								
Sample No. **Cooked food**					**Raw food**			
Dilution	**Sample 1 Control**	**CFU**	**Inoculated**	**CFU**	**Sample 2 Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	0	0	2	$2x10^3$	0	0	1	$1x10^3$
	0	0	6	$6x10^3$	0	0	1	$1x10^3$
10^{-3}	0	0	0	0	0	0	1	$1x10^4$
	0	0	1	$1x10^4$	0	0	1	$1x10^4$
10^{-4}	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0

Comments: Possible errors; overnight culture may not have been used, fresh culture chosen instead. Error in inoculation or serial dilution.

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$

No photo available

Results: Week 13 (26.10.12)

Test: PEMBA Agar

Plate Colony count and CFU / ml or gm of colonies detected								
Sample No.								
Cooked food					**Raw food**			
Dilution	**Sample 1 Control**	**CFU**	**Inoculated**	**CFU**	**Sample 2 Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	0	0	3	$3x10^3$	0	0	0	0
	0	0	4	$4x10^3$	0	0	1	$1x10^3$
10^{-3}	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
10^{-4}	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0

Comments: Possible errors; overnight culture may not have been used, fresh culture chosen instead. Error in inoculation or serial dilution.

$$\text{CFU ml / g} = \text{No. Of colonies} \times \frac{1}{\text{Dilution factor}} \times \frac{1}{\text{Volume plated}}$$

No photo available

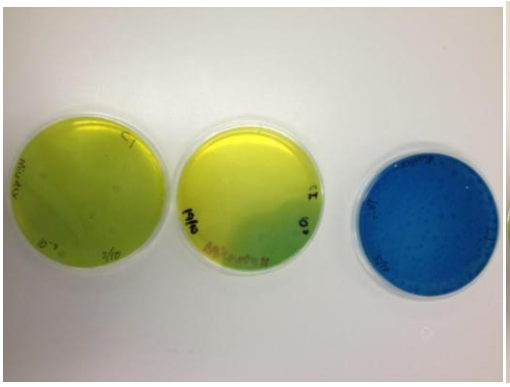
Results: Week 14 (2.11.12)

Test: PEMBA Agar

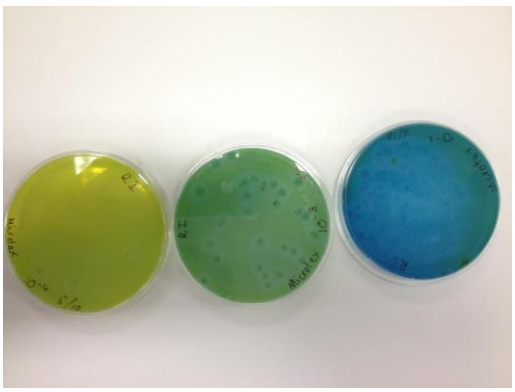
Plate Colony count and CFU / ml or gm of colonies detected								
Sample No.								
Cooked food					**Raw food**			
Dilution	**Sample 1 Control**	**CFU**	**Inoculated**	**CFU**	**Sample 2 Control**	**CFU**	**Inoculated**	**CFU**
10^{-2}	TNTC	TNTC			0	0	TNTC	TNTC
10^{-3}	13	$1.3x10^5$			0	0	32	$3.2x10^5$
10^{-4}	6	$6.0x10^5$			0	0	3	$3.0x10^5$

Comments:

CFU ml / g = No. Of colonies x $\frac{1}{\text{Dilution factor}}$ x $\frac{1}{\text{Volume plated}}$



Cooked inoculated



Raw inoculated

ELISA

RESULTS

Visually read results.

The intensity of colour is indicative of the concentration of the target antigen.

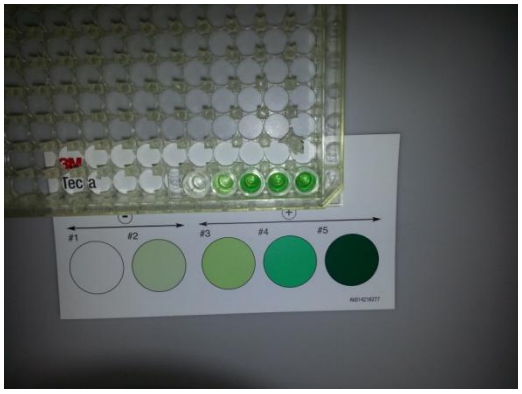
Positive Control: #3 to #5 (colour card). As the control varies in colour intensity, the acceptable limit is when the colour matches a limit of at least #3 and above.
Negative Control: #1 (colour card)

Sample Record Sheet

Operator.....Raisa Matillano.....

Date	**Well 1**	**Well 2**	**Well 3**	**Well 4** **+**	**Well 5** **-**	**Results**
12.10.12	1	1	1	1	1	No results
19.10.12	>4	>4	>4	3	1	Positive for B. species. (Pix 1)
1.11.12	>4	>4	>4	3	1	Positive for B. species. (Pix 2)

Well 4; + positive control. Well 5; - negative control. Only 3 well used.

1. 

2.