

Standard Operating Procedure
Title: Control of Microbiology Test Methods

Department	Micro Laboratory		Document no	MICLAB 125	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER

Micro Laboratory Manager

2.0 PURPOSE

This document details the writing, control, and distribution of Microbiological Test Methods (MTM) for use in the GMP Microbiology Lab.

3.0 SCOPE

This procedure applies to Microbiological Test Methods that are controlled from beginning to end by the Microbiology Lab Manager.

4.0 RESPONSIBILITY \ BUSINESS RULES

Logging, Document Code Allocation, Template Provision, Word Document Administration, Distribution, Index Maintenance and Filing are the responsibility of the Lab Manager.

Word Document Preparation, Approval Signature Attainment is the responsibility of the Initiator.

5.0 PROCEDURE

5.1 Microbiological Test Method Template

5.1.1 Location

The template should be a Read Only file stored in the shared area of the network computers. Changes to the template are made and saved by the Lab Manager or delegates.

5.1.2 Set Security attributes on template

5.1.2.1 Set Security attributes under "Tools" to "Password required to modify" checking the "Read Only" box. Lab Manager should assign appropriate Password.

5.1.3 General Template Layout

5.1.3.1 Scope and Application: Details the test range the method covers.

5.1.3.2 Reagents and Materials Required: List the major or unique materials needed to carry out the test. This does not need to include standard microbiological items such as pipettes or loops unless specific details are required that cannot be detailed in the General Test Method section.

5.1.3.3 General Test Method: This details the actual test procedure from start to finish including any confirmatory testing that may take place.

5.1.3.4 Referenced Documents: List any documents directly referenced in the procedure.

5.1.3.5 Summary of Changes: Details changes of the current version from the preceded version.

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5.5 Distribution and Withdrawal

5.5.1 Distribution of new version

- 5.5.1.1 Print PDF version of document from the Distribution folder. Password is required to open the document for printing.
- 5.5.1.2 Signs and dates bottom of first page as having distributed copy to Laboratory: Only Lab Manager or delegates can distribute documents.
- 5.5.1.3 Places new version into a protective sleeve within the MTM procedure folder maintained within the lab.
- 5.5.1.4 Verifies current version is indicated as such in the MTM register.

5.5.2 Withdrawal of previous version

- 5.5.2.1 Removes previous version from the MTM procedure folder.
- 5.5.2.2 Using a red pen places a line across the first page and writes the comment "Superseded", initials and dates comment.
- 5.5.2.3 Verifies register indicates that version is listed as superseded per **section 5.1.5.**
- 5.5.2.4 Places superseded version into the Superseded MTM folder within the Microbiology Laboratory File Cabinet.

6.0 DEFINITIONS / ACRONYMS

None

7.0 REFERENCES

None

8.0 SUMMARY OF CHANGES

Version #	Revision History
MICLAB-125	New