

# Validation of stated shelf life in microbiology lab

## Abstract

### Purpose

To have a documented approved procedure that describes how to perform validation for stated shelf lives for prepared sterile media, poured agar Plates, prepared filtered disinfectant, sterile glassware used in microbiology lab.

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**Abbreviations:** NB, nutrient broth; TSB, tryptic soy broth; TSA, trypticase soy agar

## Scope

Different types of media in microbiology lab.

## Responsibilities

- Microbiology analysts or designee: Preparing the document, performing the tests as written in the procedure and recording the raw data.
- Microbiology supervisor or designee: Checks the results and collect the data.
- Quality manager or designee: approval and system compliance.

## Procedures

### For prepared sterilized media

#### For solid media:

- Maximum shelf life for sterilized solid media stored in refrigerator at 2-8°C is one month.
- Test the prepared media every 2 weeks during the month of storage for sterility by pouring 100ml of the media after being melted and cooled to 45°C aseptically in sterile plates.
- Incubate for 5 days at 32.5 °C±2.5 °C then examine for any growth after 2 days(for bacteria) and after 5days(for fungi).
- If the plates show no growth so proceed for testing the media for its performance by inoculation of the media tested with suitable organism(10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5°C±2.5°C and not more than 5days for fungi at 22.5°C±2.5°C and calculate for the recovery %.
- The test must be done for three consecutive times.
- the media passes the tests so you can store the sterilized media in refrigerator at 2-8°C for one month.

#### For liquid media:

- Maximum shelf life for sterilized liquid media stored in refrigerator at 8°C±2°C is one month.

- Test the prepared media every 2 weeks of storage for sterility by incubation of 100ml of the media for 14 days at 32.5°C±2.5°C then examine for any growth. N.B for TSB media incubate for 14 days at 22.5°C±2.5°C then examine for any growth.
- If the media shows no growth so proceed for testing the media for its performance by inoculation of the media tested with suitable organism (10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5°C±2.5°C and not more than 5days for fungi at 22.5°C±2.5°C and examine for growth.
- The test must be done for three consecutive times.
- If the media passes the tests so you can store the sterilized media in refrigerator at 2-8°C for one month.

### For poured agar plates

- Maximum shelf life for poured agar plates stored wrapped in refrigerator at 8°C±2°C is 7days.
- Test the poured agar plates after 3 and 7 days of storage for its sterility by incubation for 48hrs at 32.5°C±2.5°C then examine for any growth.
- If the plates show no growth so proceed for testing the media for its performance by inoculation of the media tested with suitable organism (10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5°C±2.5°C and not more than 5days for fungi at 22.5°C±2.5°C and calculate for the recovery %.
- The test must be done for three consecutive times.
- If the agar plates pass the tests so you can store them wrapped in refrigerator at 2-8°C for 7 days.

### For prepared filtered disinfectant

- Maximum shelf life for prepared filtered disinfectant stored at room temperature is one week.
- Test the prepared filtered disinfectant after 3 days and 7 days of storage for sterility .
- Test the prepared filtered disinfectant after 3 days and 7 days of storage for its efficacy .
- The test must be done for three consecutive times.

- e) If the prepared filtered disinfectant passes the tests so you can store it at room temperature for one week.

### For sterilized glassware

#### For sterile petri dishes:

- a) Maximum shelf life for sterile Petri dishes stored wrapped in its special containers is 14 days.
- b) Test the sterile Petri dishes after 7 and 14 days of storage for its sterility by pouring 15ml of TSA that has been melted and cooled to 45°C in 5 Petri dishes.
- c) Incubate for 48hrs at 32.5°C±2.5°C then examine for any growth.
- d) If the Petri dishes show no growth in so proceed for testing the media for its performance by inoculation of the media tested with suitable organism (10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5 °C±2.5 °C and not more than 5days for fungi at 22.5°C±2.5°C and calculate for the recovery %.
- e) The test must be done for three consecutive times.
- f) If the Petri dishes pass the tests so you can store them wrapped in its special containers for 14 days.

#### For sterile bottles:

- a) Maximum shelf life for sterile bottles stored in its special place is 14 days.
- b) Test the sterile bottles after 7 and 14 days of storage for its sterility by transferring aseptically 100ml of sterile TSB and incubate for incubate for 14 days at 22.5°C±2.5°C then examine for any growth.

- c) If the media show no growth so proceed for testing the media for its performance by inoculation of the media tested with suitable organism(10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5°C±2.5°C and not more than 5days for fungi at 22.5°C±2.5°C and examine for growth.

- d) The test must be done for three consecutive times.

- e) If the bottles pass the tests so you can store the sterilized bottles in its special place for 14 days.

#### For sterile pipettes:

- a) Maximum shelf life for sterile pipettes stored wrapped in its special place is 14 days.
- b) Test the sterile pipettes after 7and 14 days of storage for its sterility by withdrawing sterile TSB from its bottle aseptically and return it back using the tested pipette and incubate for 14 days at 22.5°C±2.5°C then examine for any growth.
- c) If the media show no growth so proceed for testing the media for its performance by inoculation of the media tested with suitable organism(10-100cfu/ml) then incubate for not more than 3 days for bacteria at 32.5°C±2.5°C and not more than 5days for fungi at 22.5°C±2.5°C and examine for growth.
- d) The test must be done for three consecutive times.

If the pipettes pass the tests so you can use the sterilized pipettes stored in its special place is for 14days.