PHARMACY COMPOUNDING PERSONNEL GLOVED FINGERTIP SAMPLING AND MEDIA FILL TEST PROCEDURES

Summary of Changes

	NEW	Previous
BC Cancer	April 13, 2022 January 9, 2023- Fixed references and links to appendices.	

1. Introduction

1.1. Focus

The Personnel Sampling component of the Overall Quality Management Program for sterile compounding is designed to ensure that personnel work practices reflect relevant regulatory requirements and current pharmacy practice standards. Compounding staff must receive education related to principles of compounding and training on specific policies and procedures. Staff knowledge and performance must be verified through testing and competency evaluation. Data obtained through personnel sampling ensures objective evaluation and pragmatic changes that will ensure and improve performance and quality.

1.2. Health Organization Site Applicability

BC Cancer Regional Cancer Centre Pharmacies

1.3. Practice Level

Pharmacy compounding personnel must receive comprehensive education and training in the theoretical principles and practical skills of aseptic manipulations; proper conduct in controlled environments; and actions taken to achieve and maintain ISO Class 5 conditions in the direct compounding area.

Pharmacy compounding personnel must successfully complete the following psychomotor tests in this order before compounding sterile preparations for patients:

- Initial Gloved Fingertip Sampling in association with Hand Hygiene and garbing competency (3 distinct separate instances).
- Completion of a Media Fill Test followed by gloved fingertip sampling in the BSC.

Pharmacy Professional Practice Leaders

- Provide necessary equipment for sampling and testing
- Provide training on when and how to perform gloved fingertip sampling and media fill testing

Pharmacy Personnel

- Perform gloved fingertip sampling
- Perform media fill testing

1.4. Definitions

Absence of growth: As it relates to media, absence of growth means there is no visible sign of growth in or on an agar plate or in a media fill bag.

Anteroom: A room equipped with doors, with a system/procedures that allows only one door to be open at any given time, which allows passage or movement of people or things from one environment to another, while keeping the two environments isolated from one another.

Biological Safety Cabinet: A device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding and that is designed to minimize airborne contamination of hazardous products, to protect workers and the environment from exposure to hazardous drugs.

Cleaning: Removal of dirt, dust and other substances that may host microorganisms.

Clean Room: A room in which atmospheric properties are controlled. The room's functional parameters are kept at specified levels. The room is designed to minimize the introduction, generation and retention of particles. The clean room is an ISO Class 7 environment. For hazardous compounding, the clean room has negative pressure relative to adjacent areas.

Controlled Area: An area or space where the only activities taking place are those related to the compounding of sterile preparations. The controlled area is designed to minimize the introduction, generation and retention of particulate and microbial contamination.

Disinfectant: A disinfecting agent, typically of a chemical nature, that can destroy microorganisms or other pathogens, but not necessarily bacterial or fungal spores. Refers to substances applied to inanimate objects.

Gloved fingertip sampling (GFS): Method of assessing whether pharmacy compounding personnel are meeting the standards for aseptic technique. Using contact plates the assessor obtains prints of gloved thumb tip and fingertips from both hands. The agar plates are then incubated and the colony-forming units counted.

Hand Hygiene: All methods related to hand washing performed with soap and water, followed by a waterless alcohol-based hand rub with persistent activity.

High-Risk Compounding: Final product compounded using non-sterile ingredients or equipment before terminal sterilization; and/or non-sterile preparations containing water are stored for more than six hours before terminal sterilization; and/or improper garbing or gloving by compounding personnel.

Low-Risk Compounding: Final product compounded using up to three sterile units; and/or no more than two septum punctures at the injection site for each sterile unit; and/or simple aseptic transfer; and/or drug prepared for one patient (patient-specific dose).

Media fill test (MFT): Test used to qualify aseptic techniques of compounding personnel and their ability to produce preparations that are "sterile." For this test, a nutrient medium replaces the actual product during performance of the aseptic technique.

Medium-Risk Compounding: Final product compounding using four or more sterile units; and/or complex manipulations; and/or prolonged preparation time; and/or batch preparations (preparing more than one unit of the same composition during one compounding session)

Personal Protective Equipment: All garb and accessories, such as mask, gloves, gown, and safety goggles, that protect both the sterile preparation and the personnel. It enables compliance with the expected specification of a controlled environment and protects personnel from exposure to physical or chemical risks.

Presence of growth: As it relates to media, presence of growth means there is visible sign(s) of growth in or on an agar plate or in a media fill bag.

Session: A testing period during which a single assessor may collect samples from multiple staff but without leaving the controlled area.

Transfer Bin: Cleanable open-top container (plastic or metal) used for moving wiped items into or out of a controlled area.

1.5. Abbreviations and Acronyms

BSC: Biological Safety Cabinet

CFU: Colony Forming Unit

CSTD: Closed System Drug Transfer Device

DCA: Direct Compounding Area

FDA: Food and Drug Administration

G: Gauge

GFS: Gloved Fingertip Sampling

ISO: International Standards Organization

MFT: Media Fill Test

PPE: Personal Protective Equipment

PPL: Professional Practice Leader

sIPA: sterile Isopropyl Alcohol

TSA: Tryptic Soy Agar

TSB: Tryptic Soy Broth

1.6. Need to Know

Initial Gloved Fingertip Sampling (GFS) occurs during the initial employee orientation to parenteral compounding (or at program start for tenured staff). The purpose of initial gloved fingertip sampling is to verify that compounding personnel can don sterile gloves without contaminating them. It is performed in replicate to enhance the likelihood that inadequacies in staff ability to consistently and successfully perform this psychomotor skill will be identified.

Additionally, gloved fingertip sampling is performed in association with media fill testing to assess the ability of compounding personnel to keep gloves from becoming contaminated when performing aseptic technique processes.

Initial Media Fill Test (MFT) occurs during the initial employee orientation to parenteral compounding (or at program start for tenured staff). The purpose of the media fill test is to assess the compounding staff member's compliance with operating procedures and knowledge of aseptic technique processes. It is performed to enhance the likelihood that inadequacies in staff ability to successfully perform this psychomotor skill will be identified.

Personnel who do not achieve a result of "Compliant" on the GFS or MFT assessment need only to be retested for the assessment they were not compliant on.

On-Going Gloved Fingertip Sampling and Media Fill Test occurs at least annually for staff that perform low- and Medium-risk Compounding or semi-annually for staff that perform High-risk Compounding.

Table 1. Gloved fingertip Sampling & Media Fill Test Frequency	
Test Type	**Required Frequency**
Initial Gloved Fingertip	After hand hygiene / garbing competency, not less than 3 times before compounding for patients. Each assessment must be performed independently of each other, not at the same time. (e.g., first thing in the morning, after the first coffee break of the day, after lunch). Additionally, after performing the initial media fill test.
Initial Media Fill Test	Before working independently compounding for patients.
Annual or Semi-Annual Gloved Fingertip	After performing hand hygiene / garbing competency, once. After performing the media fill test, occurring at least annually (low- and medium-risk compounding) or semi-annually (high-risk compounding).
Annual or Semi-Annual Media Fill	Before performing gloved fingertip sampling, occurring at least annually (low- and medium-risk compounding) or semi-annually (high-risk compounding).

1.7. Equipment and Supplies

For Gloved Fingertip Sampling

- Agar contact media plates. Media must:
  - Be from a reputable company that has an ISO Certificate of Registration as an ISO 9001 or ISO 13485 facility;
  - Be terminally sterilized, double (or triple) bagged in appropriate Clean Room packaging;
  - Come with a Certificate of Analysis from the manufacturer that is examined and retained on paper or electronically;
  - Contain Tryptic Soy Agar (TSA) (also known as Soybean-Casein Digest Agar), with lecithin and polysorbate 80 to neutralize Cleaning agent residues that may be present in order to help eliminate the possibility of false negative results; and
  - (if coming from the United States), be from a supplier registered with the United States Food and Drug Administration (FDA).
- Tamper or other tape
- Sterile plastic bags
- Incubator

For Media Fill Test

- Media must:
  - Be from a reputable company that has an ISO Certificate of Registration as an ISO 9001 or ISO 13485 facility;
  - Be terminally sterilized, double (or triple) bagged in appropriate Clean Room packaging;
  - Come with a Certificate of Analysis from the manufacturer that is examined and retained on paper or electronically;
  - Contain tryptic soy agar or soybean-casein digest nutrient medium; and
  - (if coming from the United States), be from a supplier registered with the United States Food and Drug Administration (FDA).
- 1 x 100 mL TSB media bag
- 2 x 20 mL TSB media vials
- 1 x 5 mL syringe
- 1 x 20 mL syringe
- 2 x 18G needles
- 1 x winged infusion set
- 1 x chemotherapy vent
- 1 x chemotherapy dispensing pin
- 1 x CSTD bag spike
- 1 x CSTD vial spike
- 1 x CSTD syringe injector
- sIPA swabs
- 1 x sharps container
- 1 x waste container (e.g., zip lock bag)
- 1 x clear, unlabelled zip lock bag large enough for the TSB solution bag
- Incubator

2. Procedures

2.1. Steps and Rationale

Ordering, Receiving, Storing of Test Media

1. Order sufficient quantities for scheduled tests keeping in mind the usual expiry dates and storage capacity at your site.

2. Check expiry dates on all media as they are received. Check with the manufacturer as to whether plates can be used to sample on the expiration date or if the incubation period must be complete prior to the expiration date.
3. Leave plates in the inner and outer packages they come in.
4. Store media according to manufacturer's directions.
   - If refrigerated plates are used, they should be removed from the refrigerator approximately 1 hour before sampling is planned to allow them to come to room temperature.
   - If the media is subjected to temperatures outside the manufacturer's specified range, it must be evaluated before use and discarded if required.
5. Store plates flat, media side down, not on their sides.

Determining the Number of Agar Plates Required and the Location of Testing

Two different gloved fingertip testing procedures are required. One for testing compounding personnel after Hand Hygiene and garbing and another for post-media fill testing. The type of test determines the location and number of agar plates required. Table 2 provides an overview of this information.

Table 2. Gloved Fingertip Sampling overview & determining number of agar plates required

Personnel Type	Number of sets needed for GFS	Number of agar plates needed	When to collect the sample	Where to collect the sample	Frequency	Target for Compliance (Standard Met)
Initial GFS* *For new personnel*	4 sets	8	After hand hygiene and garbing[ᵗ].	In the anteroom.	One time, initially, performed on 3 separate occasions.	Zero CFUs from all 6 plates sampled.
			After the Media Fill Test[ᵗ].	Inside the BSC±.	One time after the Media Fill Test.	Not more than 3 CFUs total from both plates.
Annual or Semi-Annual GFS* *For current personnel*	2 sets	4	After hand hygiene and garbing[ᵗ].	In the anteroom.	Once every 6 or 12 months, depending on the contamination risk level.	Zero CFUs from both plates sampled post-hand hygiene and garbing.
			After the media fill test[ᵗ].	Inside the BSC±.		Not more than 3 CFUs total from both plates sampled.

* Need to also include plate(s) for negative controls, as needed. See section on Use of Media Controls.

[ᵗ] Remember that sampling *must precede* use of sIPA or any other cleaning/disinfecting agent on gloved hands.

± Remove the lid from the agar plate inside the direct compounding area of the biological safety cabinet.

Transferring Media into the Controlled Area

On the day of sampling, disinfect the supplies needed to complete the Media Fill Test (if applicable), the outer package containing the agar plates, and a Transfer Bin using a sporicidal agent. Using the bin, bring the media and supplies into the Controlled Area either through the Anteroom, the gowning room or via the pass-through. Enter the controlled area donning full Personal Protective Equipment and the remaining Clean Room garb per site-specific procedures.

On the clean side of the anteroom (GFS post-Hand Hygiene and garbing) or in the clean room (GFS post media fill test), disinfect gloves using sterile 70% isopropyl alcohol and carefully remove and dispose of the outer layer of packaging on the agar plates.

Labelling of Media

Agar Plates:

Each agar plate must be labelled in order to identify who it belongs to. Use a thin-tipped permanent marker to help improve ease of reading plates should there be microbial growth.

1. Label the agar plates with:

- Name or initials of the person being assessed
  - Or code to maintain confidentiality
- Date
- Test type
- Set number (as applicable)
- Hand
- E.g., MK-17Nov2020-GFS-I1-L ([employee code or initials]-Date-Gloved Fingertip Sample-Initial 1st set-Left hand)
  - Write on the base of the agar plate only, closer to the outer circumference to avoid obstructing the view of the agar when reading the plates:
    - If the lid becomes detached, the plate can still be properly identified.
    - The plates can be identified in the incubator, as they are incubated upside-down.
- Mark a star on the outer edge of the plate as per the diagram in the Fingertip Placement Guide (Figure 2) to identify where the thumbprint is placed.

***TSB Solution Bags*:**

Each TSB solution bag must be labelled in order to identify who it belongs to using a permanent marker.

1. Label the top corner of the finished TSB solution bag with:

- Name or initials of the personnel being assessed
  - Or code to maintain confidentiality
- Date
- Test type
- Set number (as applicable)
- E.g., MK-17Nov2020-MFT-I1 ([employee code or initials]-Date-Media Fill Test-Initial 1st assessment)
  - A re-assessment as a result of an unsuccessful attempt could be labelled as MK-01Dec2020-MFT-I2 (Initial 2nd assessment)

Steps for Gloved Fingertip Sampling Test Administration in the anteroom

IMPORTANT
GFS testing must be done ***before*** the application of sterile 70% isopropyl alcohol (sIPA). Disinfecting gloves with sterile alcohol immediately before sampling *leads to* ***false negatives***.

For the assessor:

1. Check that the growth media is not expired.
2. Bring the GFS plates into the Controlled Area per site-specific procedures.
3. On the dirty side of the Anteroom, remove the inner bag containing the plates from the outer packaging. Dispose of the outer packaging.
4. Disinfect the inner bag containing the GFS plates using sterile 70% isopropyl alcohol (sIPA) and place it onto the clean side of the anteroom (e.g., on a shelf or onto a cart designated for use on the clean side of the anteroom).
5. Don appropriate Personal Protective Equipment and Clean Room garb to work on the clean side of the anteroom including sterile gloves per site-specific procedures.
6. Clean and disinfect the surface where the GFS plates will be placed once removed from the inner bag using a germicidal Disinfectant detergent followed by sIPA.
7. Disinfect gloves using a new wipe moistened with sIPA and allow the alcohol to dry.
8. Carefully remove one plate from the bag, working it to the opening without placing hands inside the bag.

9. Visually inspect the growth media for signs of damage or contamination (do not use if compromised or contaminated). Contents should be clear, not cloudy, and without particles. Small air bubbles in the media are acceptable and will not affect the results.
10. Write relevant information on the bottom of the plate, designating it as the negative control. Note only one negative control plate per sleeve per Session is required. Sleeves may be used for multiple staff in a single session and also for more than one session. A new control plate must be set aside each new session, for every new sleeve used, and for every new lot number.
11. Carefully remove two more plates from the bag, working them to the opening without placing hands inside the bag. Only remove enough plates to test one staff member at a time. Roll the top of the bag closed immediately after removing the plates.
12. Visually inspect the plates for signs of damage or contamination.
13. Mark a small star on the other two plates to identify where the thumbprint will be placed.
14. Follow the star & Fingertip Placement Guide (Figure 2) to perform the assessment.
15. Disinfect gloves using a new wipe moistened with sIPA and allow the alcohol to dry.
16. Carefully remove the lid from one agar plate and present the media to the compounding personnel being assessed.
17. Once the sample has been taken, replace the lid onto the agar plate.
18. Place the plate onto the previously cleaned and disinfected surface.
19. Repeat the steps in numbers 15 to 18 to test the other hand.
20. After the samples have been taken, use tamper or other tape to tape the plates closed as shown in Figures 3 and 4.
21. Write relevant identification information on the bottom of each test plate using a permanent marker.
22. Save unused plates for storage and future use by rolling the top of the bag closed and placing into a new sterile plastic bag.
23. Place the control and test plates in a designated container (e.g., tray or bin) for carrying out of the Controlled Area. After leaving the controlled area, immediately place the samples into an incubator or package them for shipping.

For the compounding personnel being assessed:

1. In the Anteroom, don appropriate Personal Protective Equipment and remaining Clean Room garb per site-specific procedures.
2. Perform one GFS test on one hand at a time as each media plate is presented by the assessor. Start with the thumb. Ensure the thumbprint is next to the star as pictured in the Fingertip Placement Guide (Figure 2).
3. For the thumb and each finger, as contact is made, slightly roll from one side of the thumb/finger pad to the other. Move thumb/finger pads unidirectionally, not back and forth.
4. Complete each thumb/finger before moving onto the next finger.
5. Be gentle when touching the surface of an agar plate with a finger pad. Pushing too hard may crack the surface, which makes it difficult to read the results.
6. Use a different spot on the agar surface for each finger avoiding overlap where possible.
7. For the initial GFS: repeat on two different occasions (e.g., after a coffee break and after lunch) for a total of three tests (six plates). Initial GFS may be completed over multiple days if necessary.

Figure 1. Gloved Fingertip Sampling Test Administration

Steps for Gloved Fingertip Sampling following Media Fill Test inside the BSC

IMPORTANT
GFS testing must be done ***before*** the application of sterile 70% isopropyl alcohol (sIPA). Disinfecting gloves with sterile alcohol immediately before sampling *leads to* ***false negatives***.

For the assessor:

1. Check that the growth media is not expired.
2. Bring the GFS plates into the Controlled Area per site-specific procedures.
3. Outside the Clean Room, remove the inner bag containing the plates from the outer packaging. Dispose of the outer packaging.
4. Disinfect the inner bag containing the GFS plates using sterile 70% isopropyl alcohol (sIPA) and place the plates into the pass-through to the clean room or onto a cart on the clean side of the Anteroom.
5. Don appropriate Personal Protective Equipment and clean room garb to enter the clean room including sterile gloves per site-specific procedures.
6. Follow the steps outlined in Appendix 3.

For the compounding personnel being assessed:

1. Follow the steps outlined in Appendix 3.

Fingertip Placement Guide

Using a reference point (such as a star), helps identify which fingers are contaminated should there be microbial growth. See Figure 2 for example on how to place fingers onto the agar plates.

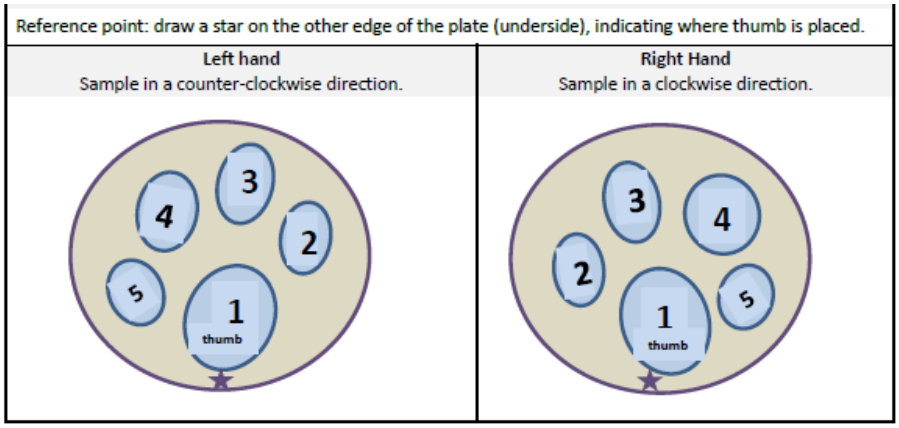


Figure 2. Fingertip Placement Guide

After the GFS Samples Have Been Taken

For the assessor:

1. After each pair of samples has been taken, use tamper or other tape to tape the plates closed as shown in Figures 3 and 4.
2. Save unused plates for storage and future use by rolling the top of the bag closed and placing into a new sterile plastic bag.
3. Place the control and test plates in a designated container (e.g., tray or bin) for carrying out of the Controlled Area. After leaving the controlled area, immediately place the samples into an incubator or package them for shipping.

For the compounding personnel being assessed:

- Gloves worn during a Media Fill Test or a Gloved Fingertip Sampling assessment must be disposed of and replaced prior to performing any other activities in the Controlled Area.
  - Immediately after completing the *initial* GFS assessment in the Anteroom, perform Hand Hygiene and don PPE appropriate for the next activity e.g., entering the Clean Room to compound; leaving the controlled area.
  - Immediately after completing the *annual* GFS and/or MFT assessment(s), prior to any further work in the clean room including compounding of patient medications, exit the clean room according to usual procedures. Perform hand hygiene and don PPE appropriate to the next activity e.g., entering the clean room to compound; leaving the controlled area.

Taping the Plate

Using tamper or other tape, secure the lid to the base as shown in Figures 3 and 4.

Figure 3. Taped Sample Plate Example (top view)

Figure 4. Taped Sample Plate Example (side view)

Steps for Media Fill Test (MFT)

For the assessor:

1. Visually inspect the growth media components for expiry date (do not use if expired) and signs of contamination (do not use if compromised or contaminated). Contents should be clear, not turbid, and without particles.
2. Once the supplies for the MFT have been introduced into the BSC, read the step-by-step instructions to the compounding personnel being assessed (see Appendix 2).
3. At the completion of the MFT assessment, BEFORE gloves have been wiped with any decontaminating or disinfecting agent, perform the GFS.
4. Once the TSB solution bag has been removed from the BSC, write the relevant identification information on the top corner of the solution bag using a permanent marker.
5. Place the TSB solution bag into a clear, unlabelled zip lock bag for removal from the Clean Room.
6. Place the TSB solution bag and control and test agar plates into a designated container (e.g., tray or bin) for carrying out of the Controlled Area. After leaving the controlled area, immediately place the samples into an incubator or package them for shipping.

For the compounding personnel being assessed:

1. Decontaminate and disinfect the work surface of the BSC.
2. Using sIPA, introduce the supplies listed in Appendix 1 into the BSC.
3. Follow the steps in Appendix 2 to complete the MFT.
4. Use aseptic technique throughout.
5. Before using any decontaminating or disinfecting solutions on gloves or the TSB solution bag, perform the GFS assessment.
6. After the gloved fingertip sample assessment has been completed, decontaminate gloves and the TSB solution bag per site procedures and pass the solution bag to the assessor.
7. Immediately after completing the assessments, prior to any further work in the Clean Room including compounding of patient medications, exit the clean room according to usual procedures for garb, PPE, and Hand Hygiene. Don PPE appropriate for the next activity.

Use of Media Controls

Media controls are used to verify that any growth that occurs during incubation of the used samples is due to the testing rather than prior contamination of the media by the manufacturer.

Positive controls

- Positive controls are not required to be done, but if desired may be done at each site's discretion.
- **Rationale:** the selected agar plates are from a qualified manufacturer that performs growth promotion testing on the growth medium showing that the medium is able to support growth of target organisms in the practice setting. This documentation is available from the manufacturer, often entitled Certificate for Quality or Certificate of Analysis (see Appendix 6 for example of a Certificate of Analysis for Media). This documentation is required for each batch of media received and used.

Negative controls

- A negative control is not needed for MFTs because each sterile unit is closed, designed to maintain the sterility of its contents until the time of manipulation. However, a new non-expired TSB solution bag is used for comparison at the time incubated samples are assessed for growth.
- A negative control verifies the plates used during administration of the test were not contaminated.
- Number of negative control plates to use:
  - One negative control plate per lot number per Session when unopened sleeves of plates are used. Reserve a negative control plate from each partial sleeve of plates used.
  - One negative control plate if multiple personnel are being assessed in the same BSC consecutively.
  - When a second person is being assessed beginning at a different time of Clean Room entry, or is using a different BSC, a separate negative control is used.
- The negative control plate is the first entry in the GFS log for the personnel (see Appendix 5).

- **Process:**
  1. Bring the negative control plate(s) into the same areas as the plates that will be used to assess compounding personnel. This means that the negative control plate(s) goes to and from any room or space as the plates used to obtain a sample by the compounding

personnel being assessed. Exception: control plates do not need to be brought into the BSC when performing the GFS.

2. Place the plates in the same area, right next to each other whether on a table in the Anteroom or in the Clean Room, so as to maintain a similar environment where possible.
3. Write on the bottom (agar side) of a control plate (e.g., NEG CTRL #001) to identify the negative control plate.
4. Record the negative control plate number first in the GFS log. Then record applicable compounding personnel's plates in the log below that negative control.
5. Repeat each time a new negative control plate is used; numbering the control plate sequentially and recording the plate number and compounding personnel's identification in the log.

Incubation of Agar Plates

1. Place the plates in the incubator at the earliest opportunity after sampling.
   - Note: It is acceptable to set the plates aside (in a bin in the Clean Room or inside a pass through) and bring to the incubator at the next natural break upon leaving the clean room.
2. Before placing the plates in the incubator, write "Inc." (for incubated) and the time the plate was placed into the incubator on the same side as the personnel codes.
3. Time begins when the plates are placed into the incubator, not the time when the plates were inoculated by the assessed staff.
4. Read the results within 48 to 72 hours after incubation.
5. Ensure the incubator temperature is maintained between 30°C and 35°C.

Placement of plates inside the incubator

- Plates must be incubated in an inverted position (that is agar side upwards) as per Figure 5 to prevent condensation falling onto the agar contaminating it or moving any formed colonies across the agar.

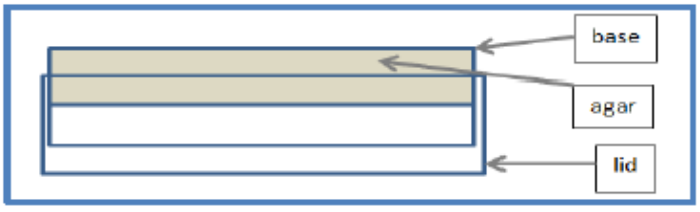


Figure 5. Placement of contact plates during incubation

Organization of incubation shelf

General notes

- Place items starting from the left side, then chronologically by time across to the right side.
- In this way, oldest plates are furthest left, and newest plates are furthest right. This improves organization and optimizes efficiency when reading results.
- When another row is needed, move the existing plates to become the front row (closest to the incubator door), and start a new row behind. Also place from the left side to the right side. Create more rows as needed this way.

For multiple contact plates

- Stack plates from the same set, of the same personnel, on top of each other. Also group the negative control plates together (if applicable).
- Avoid mixing stacks from different personnel, if space permits. This improves organization & optimizes efficiency when reading results.

Incubation of MFT TSB Solution bags

- Place solution bags into the incubator at the earliest opportunity after sampling.
- Ensure the incubator temperature is maintained between 30°C and 35°C.
- Be sure to record the start date of the incubation in the Log.
- Lay the bag flat in the incubator in a position that allows for air circulation around the bag.
- Record the days when the sample must be read counting from the day incubation begins.
  - day 7
  - day 14 (if Absence of Growth identified at day 7)
- If Presence of Growth is identified at day 7, it is not necessary to continue to incubate the solution bags.

Reading the Results

When to read agar plates

Note the day and time that the plates are to be read per the example in Table 3.

Table 3. When to read agar plates

Date of Test	Day of Test*	Time of incubation	Personnel Test Type	Personnel Code	When to read the agar plate(s) (Date)	When to read the agar plate(s) (Day of the week)	Time to read the agar plate(s)
17 Nov 2020	Tuesday	1300h	Negative Control # 001		19 Nov 2020	Thursday	~1130 to 1200h
17 Nov 2020	Tuesday	1300h	Initial	ABC-17Nov2020-GFS-I1-L	19 Nov 2020	Thursday	~1130 to 1200h
17 Nov 2020	Tuesday	1300h	Initial	ABC-17Nov2020-GFS-I1-R	19 Nov 2020	Thursday	~1130 to 1200h
18 Nov 2020	Wednesday	1400h	Negative Control # 002		20 Nov 2020	Friday	~1130 to 1200h
18 Nov 2020	Wednesday	1400h	Annual	SS-17Nov2020-GFS-A1-L	20 Nov 2020	Friday	~1130 to 1200h
18 Nov 2020	Wednesday	1400h	Annual	SS-17Nov2020-GFS-A1-R	20 Nov 2020	Friday	~1130 to 1200h
20 Nov 2020	Friday	1000h	Negative Control #003		23 Nov 2020	Monday	~0830 to 0900h
20 Nov 2020	Friday	1000h	Initial	DEF-17Nov2020-GFS-I1-L	23 Nov 2020	Monday	~0830 to 0900h
20 Nov 2020	Friday	1000h	Initial	DEF-17Nov2020-GFS-I1-R	23 Nov 2020	Monday	~0830 to 0900h

* Tip: Be mindful of statutory holidays when choosing a day to administer the GFS test. Consider feasibility of reading the plates in a timely manner.

Note in this example, the 'A' in the Personnel Code refers to 'Annual" testing.

Reading the agar plates- Process

1. Don a pair of non-sterile gloves
2. Remove from the incubator and read the negative control plate(s) first
    a. If the negative control plate(s) show Absence of Growth, then proceed to read the relevant sampling plates.
    b. If the negative control plate(s) show Presence of Growth, then the personnel plates used for sampling from that sleeve/Session of plates that show growth cannot be used to determine whether the standard has been met. The observed growth may not be due to personnel gloving or compounding technique. The GFS assessment for each of those compounding personnel must be administered again.
    c. If the negative control plate(s) show presence of growth, then the personnel plates used for sampling from that sleeve/session of plates that show Absence of Growth are considered to have met the standard. The GFS assessment for each of those compounding personnel does not need to be administered again until the next scheduled annual assessment.
3. Remove one compounding personnel's set of plates (2) at a time from the incubator.
4. Read the agar plate immediately after removing it from the incubator. Otherwise, condensation that develops as it begins to cool could make viewing and reading the plate more difficult.

5. Examine under good lighting, in a designated area, usually next to or close to the incubator. Use a clean, smooth opaque white and/or black background to make assessment easier. This is never to be done in a Controlled Area.
6. Keep the lid shut; never open it when counting the colony forming units (CFUs).

Reading the agar plates- for Colony Forming Units

- Visually inspect both sides of the plate (some colony forming units may be easier to see on one side of the plate versus the other side).
- Count all visible colony forming units (CFUs) appearing on the agar plate.
- Each circle or dot represents a discreet colony and is counted as 1 CFU.
- Any questionable Presence of Growth is reviewed by a second pharmacy staff member trained to read media results.
- Presence of growth found in any sample is verified by a second pharmacy staff member trained to read media results.

Figure 6 Presence of growth on a contact plate with 1 CFU

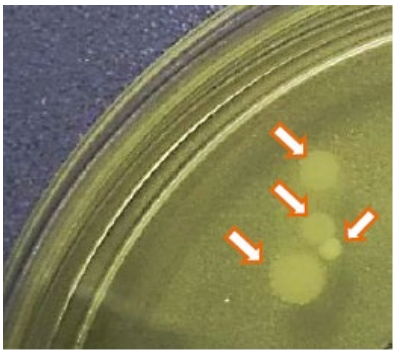


Figure 7. Presence of growth on a contact plate with multiple CFUs The section shown has 4 CFUs.

Colony Forming Units (CFUs) Verification

- If there is any question regarding the number of CFUs present on a plate, another count by an independent appropriately trained person may be performed (e.g., if a distinction between 3 or 4 overlapping CFUs would determine whether the standard is met or not met for current staff).

When to Read MFT TSB Solution Bags

- The date of reading should be determined at the time of incubation and noted on the MFT TSB Solution Bag Log (7 and 14 days).
- Preliminary readings are done at 7 days to aid in the scheduling of re-tests if growth is present at 7 days. If growth is present at 7 days, it is not necessary to continue to incubate the solution bag.

Table 4. When to read Media Fill Test Tryptic Soy Broth (TSB) Solution bags

Date of Test	Day of Test*	Personnel Test Type	Personnel Code	Date of interim reading	Date of reading
17 Dec 2020	Thursday	Initial	ABC-2020-DEC-17-MFT-I	23 Dec 2020	30 Dec 2020
17 Dec 2020	Thursday	Initial	DEF-2020-DEC-17-MFT-I	23 Dec 2020	30 Dec 2020
22 Dec 2020	Tuesday	Annual	GHI-2020-DEC-22-MFT-A	28 Dec 2020	4 Jan 2021
22 Dec 2020	Tuesday	Annual	JKL-2020-DEC-22-MFT-A	28 Dec 2020	4 Jan 2021

* Tip: Be mindful of statutory holidays when choosing a day to administer the MFT test. Consider feasibility of reading the plates in a timely manner.

Preparing to Read MFT TSB Solution bags

- This is never to be done in a Controlled Area.
  1. Don a pair of non-sterile gloves
  2. Use a new non-expired TSB solution bag for visual comparison, to help prevent false negative readings.
  3. Gently remove the test bag from the incubator without agitating the solution inside. Close the incubator door. Read immediately.

Reading MFT TSB Solution Bags

1. Examine each test bag under good lighting. Use a smooth, opaque, white and/or black background to make assessment easier.
2. Visually inspect the bag, looking for microbial growth, which may occur in various patterns. Examples include:
   - Turbidity (cloudiness) throughout, is the easiest to identify
   - Strings or clumps of turbidity, possibly near the top or bottom of the bag
   - Sediment or filaments
   - Pellicles (a layer at the surface)
3. Any questionable Presence of Growth is reviewed by a second pharmacy staff member trained to read media results.
4. Presence of growth found in any sample is verified by a second pharmacy staff member trained to read media results.

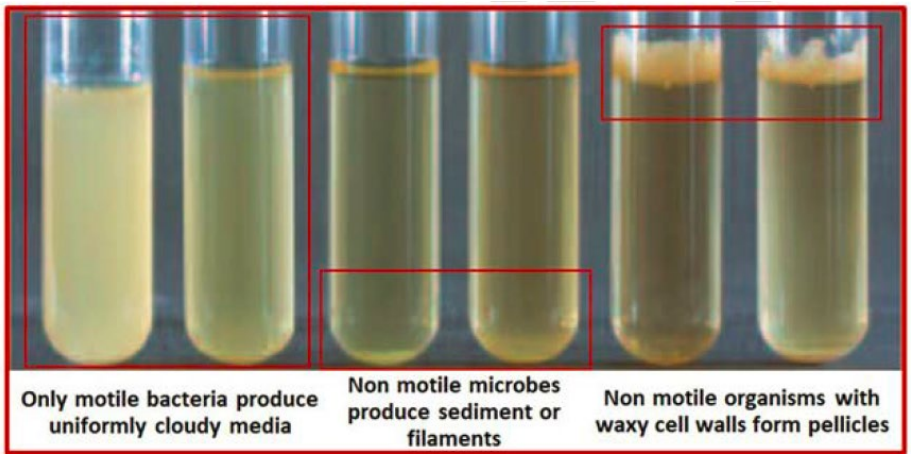


Figure 8. Different growth patterns in a media fill test with presence of growth

2.2. Documentation of Results

1. Record the results of reading the agar plates and MFT solution bags in the appropriate GFS/MFT log (see Appendix 4 and Appendix 5).
2. Complete all relevant columns of the log.
3. Ensure that any personnel competency assessment results are communicated in a timely fashion.

For Presence of Growth (Standard not met, Non-Compliance)

To document Presence of Growth, two pharmacy staff members trained to read media results must initial the GFS or MFT log after examining the agar plate or TSB solution bag.

For Absence of Growth (Standard met, Compliance)

To document the Absence of Growth, two pharmacy staff members trained to read media results must initial the GFS or MFT log after examining the agar plate or TSB solution bag.

Interpretation of Results & Communication

1. Determine if the GFS/MFT standard is met (Compliance), or unmet (Non-Compliance). Use Table 5 below as needed.
2. Document this in the GFS/MFT log.
3. If Presence of Growth is noted, notify the relevant supervisor promptly and arrange for re-training and re-testing. Complete the process for personnel tracking as per site process.

Table 5. Compliance Thresholds		
Personnel type	**Target**	**Interpretation**
Initial GFS post hand hygiene For **new** personnel	***Zero*** CFUs from all plates.	• Must have zero growth on all six plates to be considered compliant (standard met). • A number greater than zero is considered non-compliant (standard unmet). • Must redo all components of the initial GFS assessment if compounding personnel need to be re-tested
Annual GFS post hand hygiene All personnel	***Zero*** CFUs from both plates.	• Must have zero growth on both plates to be considered compliant (standard met). • A number greater than zero is considered non-compliant (standard unmet).
Initial and annual GFS post MFT All personnel	***Not more than*** 3 CFUs from all plates.	• Must have 3 CFUs or less, to be considered compliant (standard met). Some growth allowed. • A number greater than 3 is considered non-compliant (standard unmet).
MFT All personnel	***No growth***	• No sign of microbial growth in media fill test TSB solution bag after 14 days of incubation to be considered compliant (standard met). • Any sign of microbial growth in media fill test TSB solution bag is considered non-compliant (standard unmet).

Storage of Documents

Hardcopies or electronic copies of the GFS and MFT logs are to be retained in a confidential location that is only accessible by appropriate supervisors (or delegates).

Growth media must be certified by the manufacturer to be terminally sterilized and to meet growth promotion tests. This information is provided with each lot of growth media in a Certificate of Analysis (see Appendix 6). These certificates must be readily retrievable (paper or electronic files).

2.3. Transportation of Samples

Transportation of Samples for Incubation and/or Speciation

When Presence of Growth on agar plate(s) results in non-compliance for compounding personnel, microorganism(s) on each plate must be identified by a microbiology lab to the genus level. Corrective and preventive actions (e.g., garbing and Hand Hygiene) will be based on this information.

Identification of microorganisms in a MFT is not required but may be done at the discretion of the site Pharmacy PPL as part of a review and remediation plan.

Transportation to a lab for speciation

After incubation time is complete, plates with a Presence of Growth are kept at room temperature until shipped to a microbiology lab. Overnight delivery to the designated microbiology lab may be acceptable.

Most microbiology labs have an existing process for packing & shipping. Follow the process as outlined by the lab. If no particular process is specified, follow the recommendations in the following section.

Transportation to a centralized location or lab for incubation and/or growth identification

Sample plates and TSB solution bags being transported between sites should be packaged in an insulated shipping container. Samples should be protected from damage within the container by using filler material such as Styrofoam peanuts, bubble wrap, or packing paper. Taped plates (two pieces of tape are sufficient; no need to tape fully around the circumference) should be stacked together and placed into a sealable plastic bag, if not already placed in a plastic bag by staff performing the sampling. MFT TSB solution bags should also be placed into a sealable plastic bag.

Space around the agar plates and TSB solution bags should allow for packing material to fully surround them within the shipping container. Position stacked plates within the shipping container so that they are inverted. The shipping container should then be kept upright at all times – label appropriately. Ice packs should not be used as they increase the risk of condensation formation and media freezing. No temperature verification device is required. Temperature variation during transportation in an insulated container has been found to stay within acceptable limits for sample viability. Standard overnight shipping is recommended (do not ship on a Friday). Keep samples at room temperature while awaiting pickup (do not refrigerate).

Staff at the centralized location reading the plates will arrange for transport to a lab for speciation when applicable.

2.4. Disposal

Plate(s) with Presence of Growth that will be sent to a laboratory for speciation will be disposed of by the laboratory.

Once reading is complete, dispose of used growth media following the centre's policies and procedures on waste management segregation. Dispose of growth media in bins labelled as biomedical waste.

Agar plates and TSB solution bags should be disposed of only after all necessary documentation is complete and speciation is not required.

Do not un-tape or open agar plates, or access TSB solution bags following incubation. These are to be disposed of intact.

3. Related Documents and References

3.1. List of Tables

- Table 1. Gloved Fingertip Sampling & Media Fill Test Frequency
- Table 2. Gloved Fingertip Sampling overview & determining number of agar plates required
- Table 3. When to read agar plates
- Table 4. When to read Media Fill Test Tryptic Soy Broth (TSB) Solution bags
- Table 5. Compliance Thresholds

3.2. List of Figures

- Figure 1. Gloved Fingertip Sampling Test Administration
- Figure 2. Fingertip Placement Guide
- Figure 3. Taped Sample Plate Example (top view)
- Figure 4. Taped Sample Plate Example (side view)
- Figure 5. Placement of contact plates during incubation
- Figure 6. Presence of growth on a contact plate with 1 CFU
- Figure 7. Presence of growth on a contact plate with multiple CFUs. The section shown has 4 CFUs.
- Figure 8. Different growth patterns in a media fill test with presence of growth

3.3. Related Documents

- BC Cancer Pharmacy Practice Standards for Hazardous Drugs Manual
- Review and remediation plan for positive results
- Gloved Fingertip Sampling Log
- Media Fill Test Log

3.4. References

Controlled Environment Testing Association. (2021). CETA Application Guide CAG-011 Gloved Fingertip Testing for Sterile Compounding Personnel. Raleigh, NC.

Controlled Environment Testing Association. (2021). CETA Application Guide CAG-013 Media-Fill Testing for Sterile Compounding Personnel. Raleigh, NC.

CriticalPoint. (2018). Pearls of Knowledge, Choosing the Right Media. Totowa. NJ.

GroMed (QI Medical) Media Fill Test Procedure

LMPS Quality Team. (2018). Standard Operating Procedure & Reference Guide: Gloved Fingertip Sampling (GFS). Langley, BC.

LMPS Quality Team. (2020). Standard Operating Procedure & Reference Guide: Media Fill Test MFT). Langley, BC.

Media Fill Test Certificate of Analysis Example (see: https://peernetwork.criticalpoint.info/questions/how-to-tell-if-media-will-support-the-growth-of-organisms

National Association of Pharmacy Regulatory Authorities. (2016). NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. NAPRA: Ottawa, ON. Retrieved from Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised_b.pdf (napra.ca)

United States Pharmacopeia. (2021). <797> Pharmaceutical Compounding - Sterile Preparations. Rockville, MD: USP Convention. Retrieved from https://go.usp.org/Proposed_2021_Revisions_795_797

4. Appendices

Appendix 1- Gloved Fingertip Sampling and Media Fill Test Equipment List

Appendix 2- Media Fill Test Steps

Appendix 3- Gloved Fingertip Sampling Inside the Biological Safety Cabinet

Appendix 4- Media Fill Test Incubation Documentation Log

Appendix 5- Gloved Fingertip Sampling Incubation Documentation Log

Appendix 6- Example of Certification of Analysis for Media

Appendix 1: Gloved Fingertip Sampling and Media Fill Test Equipment List

Gloved Fingertip Sampling Equipment

- Tryptic Soy Agar (TSA) contact media plates, with lecithin and polysorbate 80
- Tamper or other tape
- Sterile plastic bags

Media Fill Test Equipment

- 2 x 20 mL tryptic soy broth vials
- 1 x 100 mL tryptic soy broth solution bag
- Incubator
- 1 x 5 mL syringe
- 1 x 20 mL syringe
- 2 x 18G needles
- 1 x winged infusion set
- 1 x chemotherapy vent
- 1 x chemotherapy dispensing pin
- 1 x CSTD bag spike
- 1 x CSTD vial spike
- 1 x CSTD syringe injector
- sIPA swabs
- 1 x sharps container
- 1 x clear, unlabelled zip lock bag large enough for the TSB solution bag

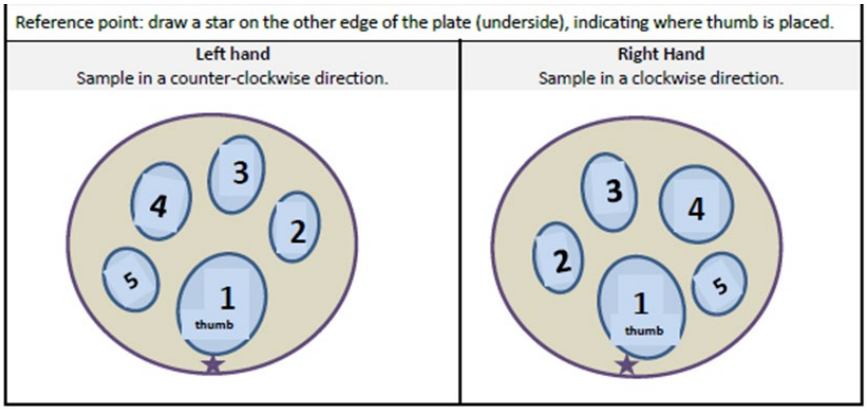
Appendix 2: Media Fill Test Steps

1. Use aseptic technique throughout.
2. Using the FIRST 20 mL TSB vial, a 5 mL syringe, an 18G needle, and a winged infusion set, withdraw 4 mL from the vial using negative pressure technique and inject into the injection port of the TSB solution bag through the winged infusion set.
3. Insert the chemotherapy vent into the same FIRST 20 mL TSB vial stopper. Using the same syringe and a new 18G needle, withdraw 4 mL from the vial and inject into the TSB solution bag using the same winged infusion set.
4. Remove the chemotherapy vent and insert in its place the chemotherapy dispensing pin. Using the same syringe, withdraw 4 mL from the vial and inject into the TSB solution bag using the same winged infusion set.
5. Remove the winged infusion set from the TSB solution bag port and dispose of the winged infusion set and syringe per site procedures.
6. Insert the CSTD bag spike into the TSB solution bag administration port.
7. Insert the CSTD vial spike into the SECOND 20 mL TSB vial stopper.
8. Attach the CSTD syringe injector to the 20 mL syringe and withdraw 10 mL from the SECOND 20 mL TSB vial.
9. Inject into the TSB solution bag through the CSTD bag spike.
10. Using the same syringe, withdraw another 10 mL from the SECOND 20 mL TSB vial and inject into the TSB solution bag.
11. Before using any decontaminating or disinfecting solutions on gloves or the TSB solution bag, perform the annual GFS assessment (if applicable).

Appendix 3: Gloved Fingertip Sampling Inside the Biological Safety Cabinet

For the assessor:

1. Inside the clean room, clean and disinfect the surface where the GFS plates will be placed once removed from the inner bag using a germicidal disinfectant detergent followed by sIPA.
2. Retrieve the bag of GFS plates from the pass-through or the cart and place onto the cleaned and disinfected surface.
3. Disinfect gloves using a new wipe moistened with sIPA and allow the alcohol to dry.
4. Carefully remove one plate from the bag, working it to the opening without placing hands inside the bag.
5. Visually inspect the growth media for signs of damage or contamination (do not use if compromised or contaminated). Contents should be clear, not cloudy, and without particles. Small air bubbles in the media are acceptable and will not affect the results.
6. Write relevant information on the bottom of the plate designating it as the negative control. Note only one negative control plate per sleeve per session is required. Sleeves may be used for multiple staff in a single session and also for more than one session. A new control plate must be set aside for each new session, for every new sleeve used, and for every new lot number.
7. Carefully remove two more plates from the bag, working them to the opening without placing hands inside the bag. Only remove enough plates to test one staff member at a time. Roll the top of the bag closed immediately after removing the plates.
8. Visually inspect the plates for signs of damage or contamination.
9. Mark a small star on the other two plates to identify where the thumbprint will be placed.
10. Follow the star & Fingertip Placement Guide below to perform the assessment.



11. Disinfect gloves using a new wipe moistened with sIPA and allow the alcohol to dry.

12. Immediately after compounding personnel has finished the Media Fill Test and before they have cleaned or disinfected their gloves, bring one test plate into the BSC.
13. Without putting down the plate or lid, or touching any surface inside the BSC, carefully remove the lid from that agar plate and present the media to the compounding personnel being assessed.
14. Once the sample has been taken, replace the lid onto the agar plate.
15. Remove the plate from the BSC and place it on the previously cleaned and disinfected surface.
16. Repeat the steps in numbers 11 to 15 to test the other hand.
17. After each pair of samples has been taken, use tamper or other tape to tape the plates closed as shown in Figures 3 and 4.
18. Write relevant identification information on the bottom of each test plate using a permanent marker.
19. Save unused plates for storage and future use by rolling the top of the bag closed and placing into a new sterile plastic bag.
20. Place the control and test plates in a designated container (e.g., tray or bin) for carrying out of the controlled area. After leaving the controlled area, immediately place the samples into an incubator or package them for shipping.

For the compounding personnel being assessed:

1. Immediately after completing the Media Fill Test, before cleaning or disinfecting gloves, perform GFS as follows.
2. Perform GFS test on one hand at a time as each media plate is presented by the assessor. Start with the thumb. Ensure the thumb print is next to the star as pictured in the Fingertip Placement Guide (Figure 2).
3. For the thumb and each finger, as contact is made, slightly roll from one side of the thumb/finger pad to the other. Move thumb/finger pads unidirectionally, not back and forth.
4. Complete each thumb/finger before moving onto the next finger.
5. Be gentle when touching the surface of an agar plate with a finger pad. Pushing too hard may crack the surface, which makes it difficult to read the results.
6. Use a different spot on the agar surface for each finger, avoiding overlap where possible.
7. Immediately after completing the GFS and/or MFT assessment(s), prior to any further work in the clean room including compounding of patient medications, exit the clean room according to usual procedures. Perform hand hygiene and don PPE appropriate to the next activity e.g., entering the clean room to compound; leaving the controlled area.

Appendix 4: Media Fill Test Incubation Documentation Log

Site:	
Name or ID Code of personnel being tested:	
Sampling Date & Time:	
Check one only: ☐ Annual ☐ Initial	Attempt #
Sampling Location: C-PEC #	
Assessor:	

Type of Media	**Manufacturer**	**Lot Number**	**Expiration Date**

	Media Fill Bag	
Code written on media fill bag		
Date & Time bag placed in incubator		
Initials of staff placing bag into incubator		
Date day 7 reading must occur		
Incubation at 30-35°C for 7 to 14 days		
Date & Time day 7 reading done		
Initials of assessor reading bag		
Presence of growth observed (Y/N)		**If YES skip to "Continue here" row below.**
		If NO, continue in next row.
Continue 14 days incubation at 30-35°C		
Date day 14 reading must occur (if no growth present at day 7)		
Date & Time day 14 reading done		
Initials of assessor reading the bag		
Presence of growth observed (Y/N)		
Continue here		
Initials of verifying assessor (reading and documentation)		
Standard Met (Y/N) Standard = no growth observed		
Supervisor informed of result (Y/N)		

Comments:

Appendix 5: Gloved Fingertip Sampling Incubation Documentation Log

Site:	
Name or ID Code of personnel being tested:	
Sampling Date & Time:	
Check one only: ☐ Annual ☐ Initial #1 ☐ Initial #2 ☐ Initial #3	Attempt #
Sampling Location: ☐ Anteroom ☐ C-PEC #	
Assessor:	

Type of Media	**Manufacturer**	**Lot Number**	**Expiration Date**

	GFS Left Hand	**GFS Right Hand**	**Control Plate**
Code written on plate			
Date & Time sample placed in incubator			
Initials of staff placing plate into incubator			
Date & Time window in which reading must occur			
Incubation at 30-35°C for 48-72 hours			
Date & Time reading done			
Initials of assessor reading plate(s)			
# of CFU present			
Initials of verifying assessor (reading and documentation)			
Standards: Initial GFS = 0 CFU Annual GFS ≤ 3 CFU	Total CFUs (both hands):		N/A
	Standard Met (Y/N):		
Supervisor informed of result (Y/N)			N/A
Plate sent for speciation (Y/N)			
Microorganism identified (if applicable)			

Comments:

Appendix 6: Example of Certificate of Analysis for Media

Steritest™ Media for Sterility Test
Soybean Casein Digest Medium (Trypcase Soy Broth or Tryptic Soy Broth)

Certificate of Quality

We certify that the product described within meets the following criteria.

Catalogue Number : STBMTSB12
Lot Number : F9KA82171
Expiry date : AUG-2020

Product Description

Soybean-Casein Digest Medium is intended for the detection of aerobic bacteria and fungi. This medium is used for sterility testing by membrane filtration or by direct inoculation. Performance and preparation of this medium comply with the European Pharmacopeia (EP), United States Pharmacopeia (USP) and Japanese Pharmacopeia (JP) for Soybean-Casein Digest Medium.
Soybean-Casein Digest Medium is also used as pre-enrichment broth for non sterile products as described in the European Pharmacopoeia (EP), the United States Pharmacopoeia (USP) and the Japanese Pharmacopeia (JP).
One box of product contains 12 bottles of 100ml of Medium, each bottles have a screw cap with a septum.

Composition per liter of purified water

Casein peptone	17.0 g
Soy peptone	3.0 g
Sodium chloride	5.0 g
Dibasic potassium phosphate	2.5 g
Monohydrated/Anhydrous dextrose	2.5 g/2.3 g

Formula can be adjusted and/or supplemented and sources of components are selected to meet the performance criteria required.

Precautions

- Do not inhale or ingest while handling the product.
- Decontaminate grey stoppers thoroughly prior to perforation in particular when performing sterility testing by membrane filtration.
- For direct inoculation or transfer of the liquid, before unscrewing the top in a controlled environment, decontaminate thoroughly the different components.

Storage Conditions

2 to 25°C (35 to 77°F) protected from light.

Good Manufacturing Practices

This product was manufactured in a Millipore SAS facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore SAS facility whose Quality Management System is approved by an accredited registering body to ISO 9001 Quality System Standard.

Pharmacopoeia references

European Pharmacopeia, 2.6.1 Sterility, 2.6.12 & 2.6.13. Microbial examination of non sterile products.
United States Pharmacopeia, <71> Sterility tests, <61> & <62> microbial examination of non sterile products.
Japanese Pharmacopeia, 4.06 Sterility test.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released according to the following specifications :

100 % visual control

Biological Tests

Sterility

Representative samples were incubated at 20-25°C and 30-35°C for 14 days.

Fertility / Growth Promotion

Fertility tests were conducted by direct inoculation. All samples provided good growth associated to a clearly visible turbidity of the medium.

Batch Record

The lot of bottles has a complete documentation which includes product description, test methods, test specifications and results.

Lot Analysis

This product was designed and manufactured to meet the following specifications.

Criteria	Specifications	Results
Appearance of the media	Light yellow clear liquid	Conform
pH	7.3 +/- 0.2	Conform
In process volume control	100 to 106 ml	Conform
Sterility Assurance Level	No contamination after 14 days at 20-25°C and 30-35°C	Conform
Growth promotion :		
Bacillus subtilis ATCC® 6633	Inoculum ≤ 100CFU Clear visible growth within 3 days at 20-25°C and 30-35°C	Conform
Candida albicans ATCC® 10231	Inoculum ≤ 100CFU Clear visible growth within 5 days at 20-25°C	Conform
Aspergillus brasiliensis (niger) ATCC® 16404	Inoculum ≤ 100CFU Clear visible growth within 5 days at 20-25°C	Conform
Staphylococcus aureus ATCC® 6538	Inoculum ≤ 100CFU Clear visible growth within 3 days at 30-35°C	Conform
Pseudomonas aeruginosa ATCC® 9027	Inoculum ≤ 100CFU Clear visible growth within 3 days at 30-35°C	Conform

According to the above results, the product complies with Millipore SAS's acceptance criteria and is released.

Christel Noehringer
BioMonitoring Quality Manager

000128887M REV.I

****Last page of document****

First Issued:	13-APR-2022		
Approving Body:	Provincial Pharmacy Professional Practice Council (P4C)		
Final Sign Off:	**Name**	**Title**	**Date Signed**
	Lynne Nakashima	BC Cancer Senior Director, Provincial Pharmacy	13-APR-2022
Developed By:	**Name**	**Dept.**	**HO**
	Michelle Koberinski	Oncology Certification Program, Provincial Pharmacy	
	James Conklin	Oncology Certification Program, Provincial Pharmacy	
Owner(s):	Michelle Koberinski	Oncology Certification Program, Provincial Pharmacy	
	James Conklin	Oncology Certification Program, Provincial Pharmacy	
Posted Date:	15-APR-2022		
Version:			
Revision:	**Name of Reviser**	**Description**	**Date**
			DD-MMM-YYYY