Acute Care PHARMACEUTICALS
A hospeco BRANDS GROUP COMPANY

GFT & AESEPTIC TESTING

Garbing & Hand Hygiene Competency	Aseptic Manipulation Competency
• Visual Observation • Garbing • Gloved fingertip and thumb (GFT) sampling	• Visual observation • Gloved fingertip and thumb (GFT) sampling • Surface sample of direct compounding area

GFT SAMPLING PROCEDURES

Plates for testing:

P34- Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP is recommended for use as a general growth medium for establishing microbiological trends, alerts, and action levels in biologically controlled environments. Single bag. P34 is a standard contact plate, also commonly referred to as Rodac ™, for surface monitoring featuring the Lok-Tight™ lid that securely fastens to the base. Ideal for environmental monitoring in a clean room setting.

W570- Irradiated Tryptic Soy Agar (TSA), USP is recommended for use as a general growth medium for the detection and enumeration of microorganisms. W570 is a standard size (15X100mm) passive settling plate for air monitoring of bacteria or fungi. Ideal for environmental monitoring in a clean room or clean bench setting. The plates are triple bagged and sterilized by irradiation to promote a higher sterility assurance level.

For this stage of testing

- What:
  - Sample gloved fingertip/thumbs on each hand using sampling media containing microbial growth agar.
- When:
  - Part of garbing and hand hygiene competency
    Part of garbing and hand hygiene and garbing for initial
    After media fill for ongoing
- Why:
  - Demonstrate proper technique
    Donning sterile gloves without contamination (initial)
    Maintaining gloves after compounding/media fill (ongoing)

***Technique: Roll fingertip pads and thumb pads over the agar surface**

GFT & AESEPTIC TESTING

Gloved fingertip and thumb sampling action levels

GFT Sampling	Action Levels (total number of CFU on both hands)
After garbing (initial)	>0
After media-fill testing (ongoing)	>3

Documentation of the GFT must include:

- Name of the person evaluated
- Evaluation date/time
- Media and components used, including manufacturer, expiration
- date and lot number
- Starting temperature for each interval of incubation, dates of incubation
- Results and the identification of the observer
- Name of the person who reads and documents the results

MEDIA FILL PROCEDURES

Low Complexity

HVL1- The Low Complexity Kit by Hardy Diagnostics is recommended for simulating manipulations involving vials and transfers, and for verifying aseptic technique. Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. The product is quality control tested for growth promotion, pH, and sterility.

Medium Complexity

HVM1- Hardy Diagnostics Medium Complexity Level Kit-Comprehensive is recommended for simulating pharmacy compounding manipulations involving the preparation of IV Bags and verifying aseptic technique. Ideal for pharmacy proficiency testing for compounding sterile preparations according to USP <797>. Kit performs one complete aseptic technique verification challenge test for one pharmacy technician. Includes test results log sheet. The product is quality control tested for growth promotion, pH, and sterility.

GFT & AESEPTIC TESTING

HVM2- The Medium Complexity Level Kit- Basic by Hardy Diagnostics is recommended for simulating compounding manipulations involving vials and transfers and verifying aseptic transfer techniques of multiple solutions. Ideal for pharmacy aseptic technique proficiency testing of compounded sterile preparatuibs to comply with USP <797>. Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. The product is quality control tested for growth promotion, pH, and sterility.

High Complexity

HVH1- The High Complexity Level Kit by Hardy Diagnostics is recommended for simulating compounding manipulations, and for verifying aseptic techniques of non-sterile to sterile solutions. Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. Product is quality control tested for growth promotion and pH.

Multiple Technician Verification

HVMTK- Hardy Diagnostics HardyVal™ MTK (Multiple Technician Verification Kit) is recommended for simulating compounding manipulations involving vials, ampoules, and bags for verifying aseptic technique within a sterile compounding pharmacy facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for up to five technicians. Product is quality control tested for growth promotion, pH, and sterility in a cGMP and ISO certified facility.

- What:
  - A compounding test that simulates the most difficult and challenging aseptic compouning procedures encountered using soybean-casein digest media
- When:
  - Part of aseptic manipulation competency
- Why:

QUESTIONS?
GIVE US A CALL

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GFT & AESEPTIC TESTING

- Demonstrates proper technique for maintaining CSP sterility during most challenging conditions

The simulation must capture elements that could potentially affect the sterility of the CSP, including but not limited to:

- Factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment)
- Number of aseptic manipulations or transfers
- Number,type, and complexity of manipulations
- Number of personnel in the buffer room or SCA

Media Fill Testing Procedures:
The growth-promoting ability of culture media must be certified by the manufacturer (See Certificate of Analysis). Each COA will be sent by your Acute Care account manager.

SURFACE SAMPLING

P34- Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP is recommended for use as a general growth medium for establishing microbiological trends, alerts, and action levels in biologically controlled environments. Single bag. P34 is a standard contact plate, also commonly referred to as Rodac ™, for surface monitoring featuring the Lok-Tight™ lid that securely fastens to the base. Ideal for environmental monitoring in a clean room setting.

- Surface sampling of the direct compounding area must occur as part of the aseptic manipulation competency
- Sampling media(e.g., plates, paddles) containing microbial growth media must be used f or sampling flat surfaces
- A failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency
- Incubate the sampling media device at a temperature of 30°–35°C for no less than 48 hours then at 20°–25°C for no less than 5 additional days
- Record the number of discrete colony forming units (CFUs) on each media device