

Q.I. MEDICAL, INC.

EnviroTest™ Training

EnviroTest™

- Used for monitoring the microbiological quality of controlled environments and compounding personnel



EnviroTest™ is available in two media formulations

ET1000

Trypticase Soy Agar (TSA) for general microbial contamination



- The TSA of the ET1000 is supplemented with lecithin and polysorbate 80 to inactivate residual disinfecting agents on surfaces – allows best microbial recovery
- Also known as Microbial Content Test Agar, this medium is shown to be as nutritive as TSA

EnviroTest™ is available in two media formulations

ET3000

- Malt Extract Agar (MEA) for targeting yeast, mold, and fungal contamination
- Includes antibiotics to reduce bacterial overgrowth of fungal colonies



Comprehensive kit for testing

- **Contents of each box:**
 - 10 Double sided agar paddles
 - 10 Gummed labels
 - 1 Directions for use
 - 1 Test results log
- **Certificate of analysis:**
 - available for download at www.qimedical.com

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Quality Control Certificate

Catalog #: ET1000

Description: EnviroTest™ TSA (trypticase soy agar) Media Paddles

Lot #: 1518076

Expiration: 28FEB14

The Agar Media in this lot was formulated, manufactured, and tested in accordance with USP General Chapter <797>. Representative samples of this lot were tested and the results are listed below. Validated sterile the if tube is not damaged or opened.

Procedure: Standardized aliquots of the listed cultures were inoculated onto selected samples for growth promotion performance testing. Aggressive growth must occur within 48 hours. Samples were visually examined and tested for physical characteristics.

USP Test Organisms	Results
<i>Bacillus subtilis</i> (ATCC # 6633)	Positive Growth
<i>Aspergillus niger</i> (ATCC # 16404)	Positive Growth
<i>Candida albicans</i> (ATCC # 10231)	Positive Growth

Additional Test Organisms	Results
<i>Escherichia Coli</i> 1	Positive Growth
<i>Klebs. Pneumoniae</i> 1	Positive Growth
<i>Prot. Mirabilis</i> ATCC 7002	Positive Growth
<i>Prot. Mirabilis</i> 1	Positive Growth
<i>Ent. Faecalis</i> 1	Positive Growth
<i>Staph. Aureus</i> 162	Positive Growth
<i>Pseud. Aeruginosa</i> 1	Positive Growth

Physical Characteristics

Sterility: No growth at specified time and temperature

Media: Trypticase soy agar, filtered during filling, contains Lecithin & Polysorbate 80

Appearance: Clear

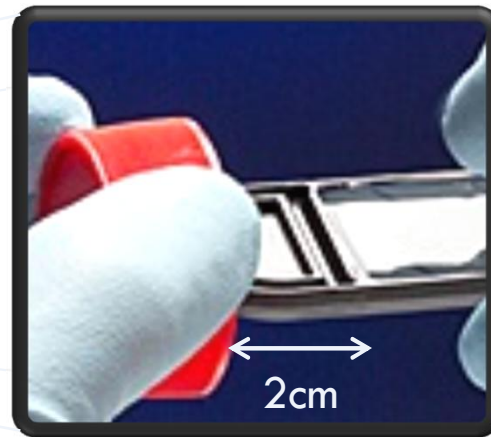
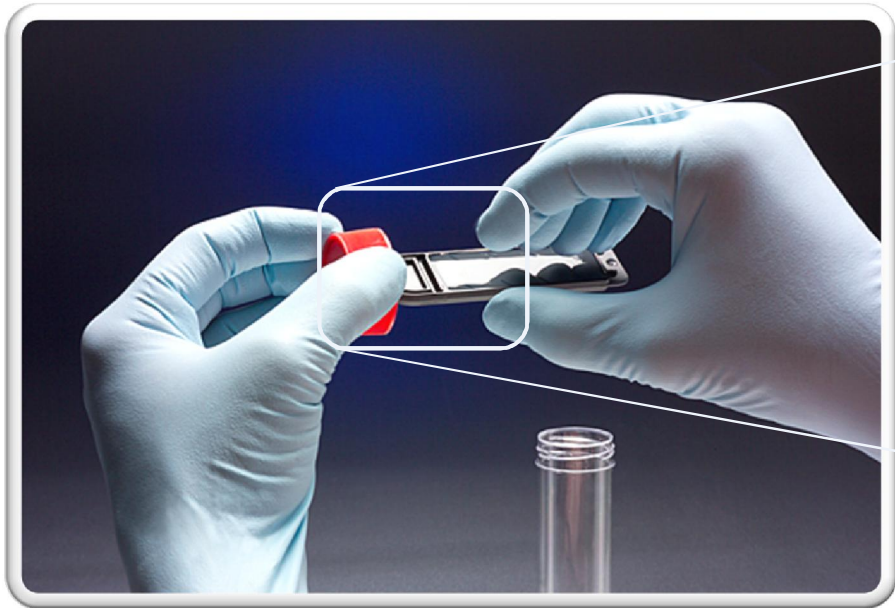
pH: 6.8 - 7.4

FDA Device Establishment Registration # 2950467 DOC221 G 11/11

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Key features of the EnviroTest™

- 2cm separation between agar and fingertips, helps prevent accidental contamination



- Built in hinge to aid in reaching difficult surfaces



Proper testing is critical for sterile compounding



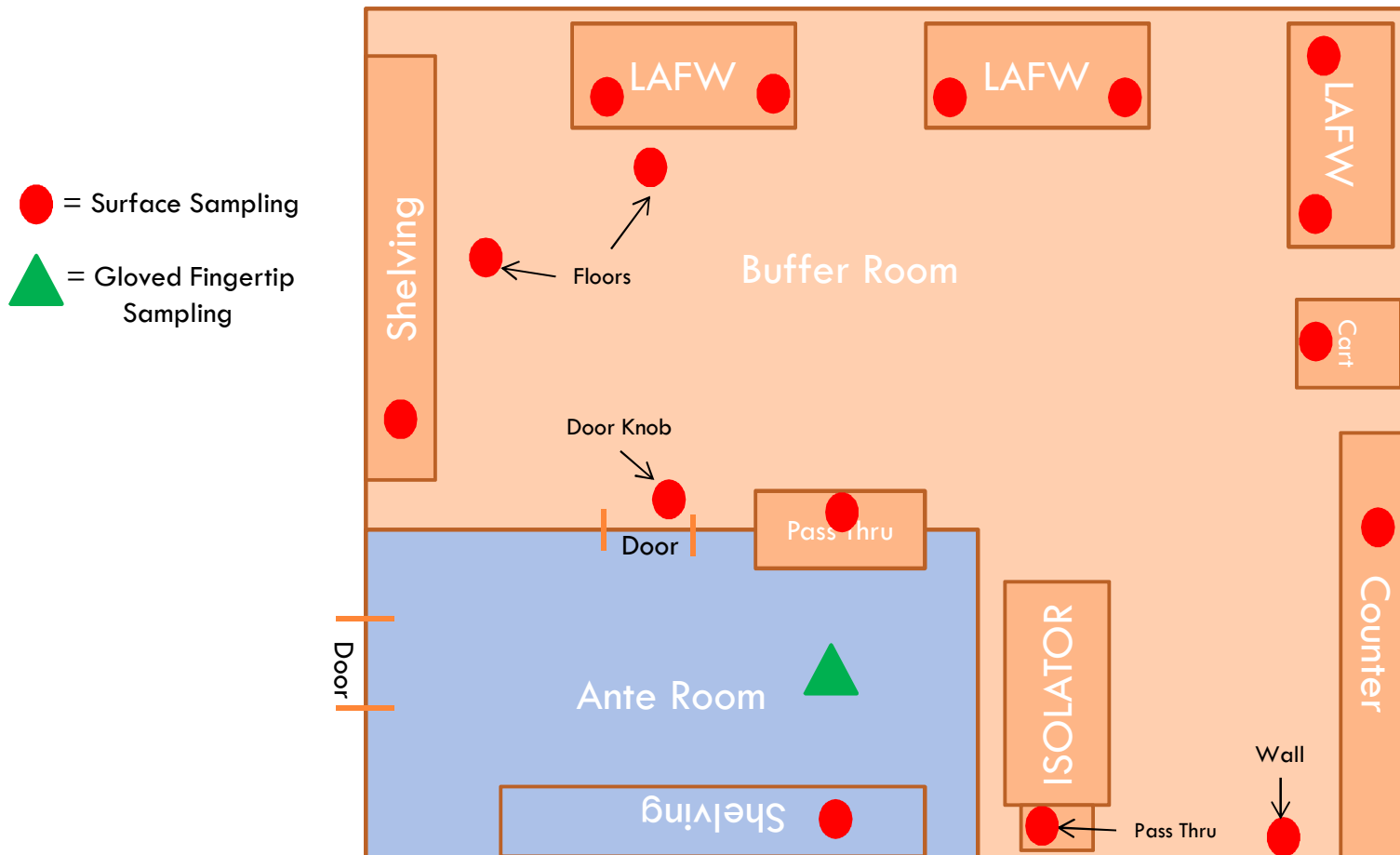
- Follow guidelines set forth in USP chapter <797>
- USP chapter <1116> also a good reference in establishing protocols
- Outsourcing facilities should review CGMPs for specific testing requirements

Key factors in a sampling plan

- Testing gloved fingertips and thumb prints of both hands immediately after gowning/garbing
- Test key surface areas of compounding environment
(Hoods, Pass thrus, Carts, Shelving)
- Test surfaces of key components
(Handles, buttons, key pads)
- Frequency of testing see USP <797> for minimum requirements

Developing a written sampling plan

- Must include sterile gloved fingertips and ALL ISO classified areas
- Clean surfaces after testing with 70% IPA and non-shedding wipe



*Diagram is meant to illustrate an example sampling plan. Each facility will vary in terms of layout

EnviroTest™ is ideal for meeting sampling requirements



High traffic entrance button

Pass Thru surface



EnviroTest™ can access hard to reach areas better



Front and backside pass thru handle that is curved could easily harbor bacteria



EnviroTest™ can access hard to reach areas better

Pass Thru handle on barrier isolator



Commonly used plates cannot access the same areas



Plates are also awkward to handle in these areas

Hinge makes testing high traffic areas easy

Isolator button



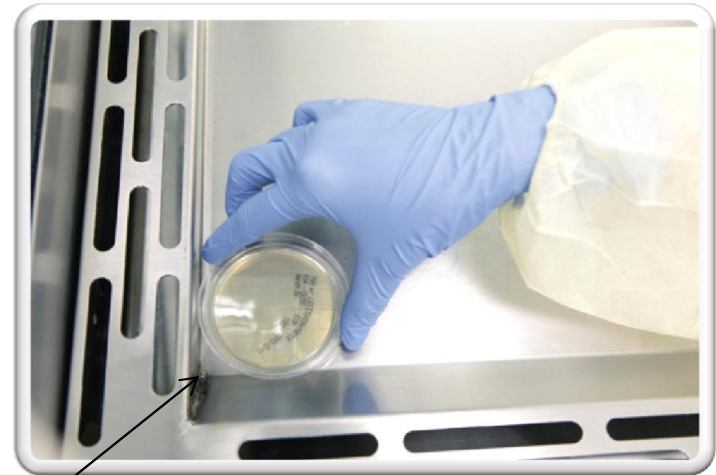
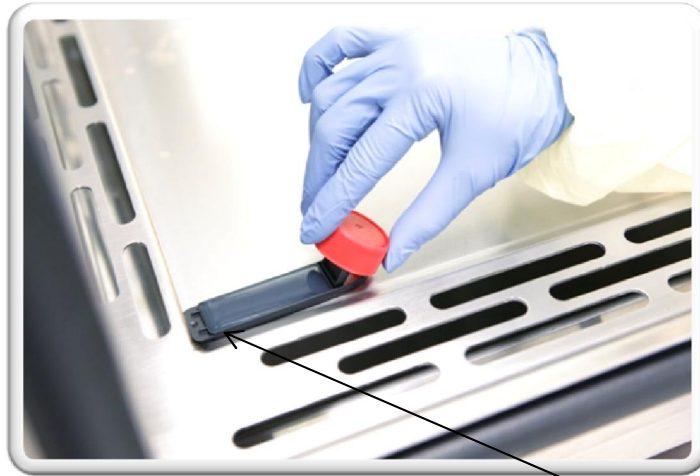
Floor area



Key pad panel



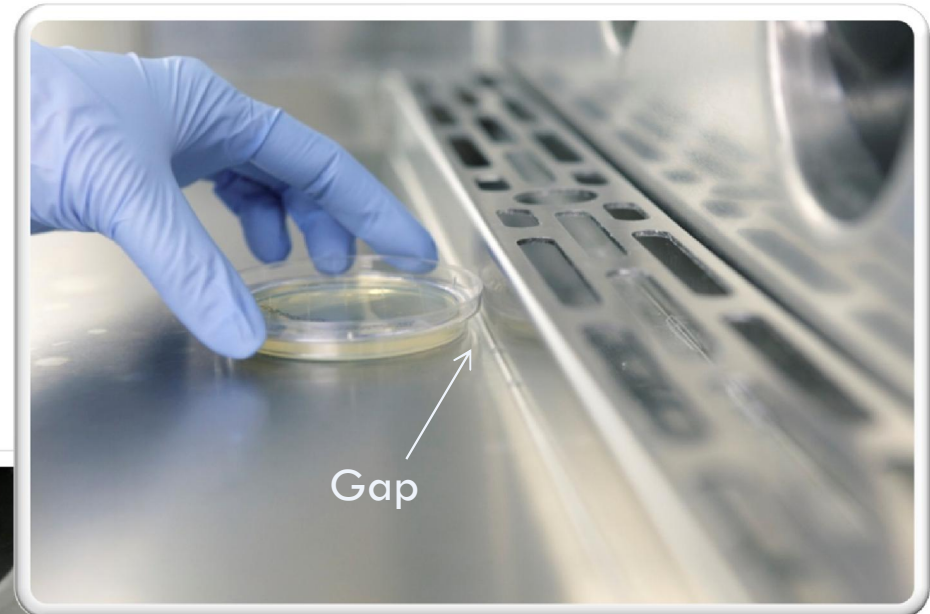
EnviroTest™ is superior in testing corners of hoods



Air circulation within hoods often deposits particles in the edges and corners of the hood where a circular plate cannot reach

Edges are another issue for plates

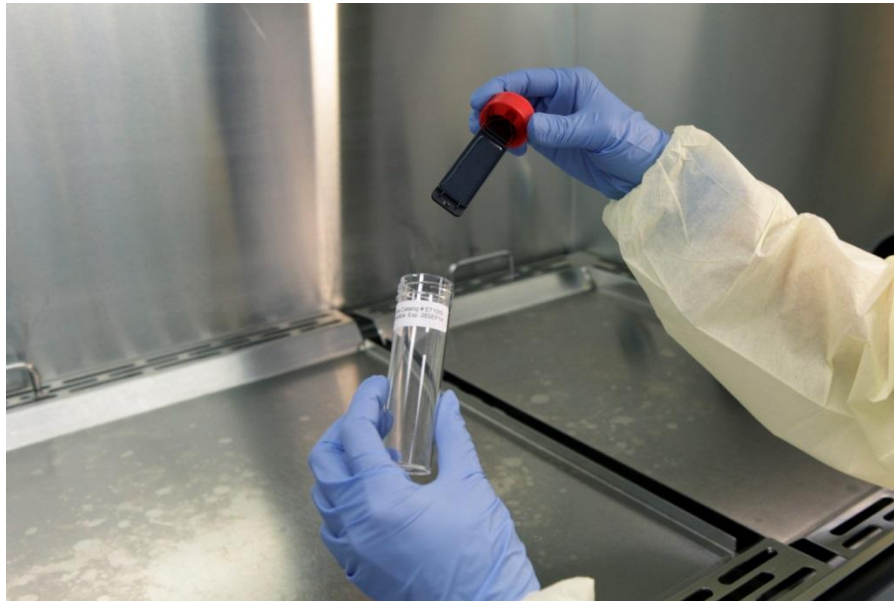
Recessed surface of a plate makes it impossible to access raised edges



Place paddle in tube and incubate

USP <797>: Temperature and duration vary depending on agar used

- ET1000: 30-35°C for 48-72 hours (2-3 days)
- ET3000: 26-30°C for 120-168 hours (5-7 days)



Disposal

- Discard in a manner consistent with State & Federal regulations as this may vary



Special Thank You



- Q.I. Medical would like to thank Mercy San Juan Hospital Pharmacy Department for the use of their time and facility during this process

Reference Links



- www.usp.org
- www.qimedical.com