



HardyVAL™

MEDIA FILL TEST KITS

USP
<797>
COMPLIANCE



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USP

<797> COMPLIANCE

HardyVAL™
MEDIA FILL TEST KITS

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Compliance was never so easy!

Verify The Efficacy Of Your Aseptic Technique

Hardy Diagnostics offers all the products you need to easily assess the risk of microbial contamination of your CSPs (Compounded Sterile Preparations) according to USP Chapter <797>.

- ✓ Quality culture media tested for performance, pH and sterility
- ✓ Kits are designed to help you follow USP <797> guidelines
- ✓ Kits supply what is needed to test the proficiency and aseptic technique of technicians or pharmacists in a self-contained ready-to-use format
- ✓ Kits are available for low, medium, and high complexity procedures
- ✓ Results log sheet is included in each kit
- ✓ À la carte components enhance kits or allow for customized tests based on your compounding processes
- ✓ Expert technical support is available from our staff of microbiologists, call 800.266.2222 ext. 5755
- ✓ Surface Sampling
- ✓ Air Sampling
- ✓ Sterility Tests



HardyVAL™

MEDIA FILL TEST KITS

ASEPTIC TECHNIQUE VALIDATION

5 Choose from five pre-assembled kits for ease-of-use
KITS OR create your own aseptic technique challenge
with our **à la carte line** of HardyVAL™ media and containers.

How do I determine which kit or products are right for me?

According to USP <797>:

"All compounding personnel must perform media-fill testing to assess their sterile technique and related practices initially and every 6 months after. When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person, replacing all the components used in the CSPs with soybean-casein digest media."



Recommended for verification of personal aseptic technique for low and medium complexity levels within a sterile compounding facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for **up to five technicians**. Culture media is quality control tested for growth promotion, pH, and sterility.

Each kit contains:

- ▶ Tryptic Soy Broth (TSB), USP, Media Bags, 100ml, 5/kit
- ▶ Tryptic Soy Broth (TSB), USP, 20ml serum vial with needle-port septum, 15ml fill, 5/kit
- ▶ Tryptic Soy Broth (TSB), 3 ml Ampoules, (non-toxic red dye is added to the TSB to easily visualize the sample being transferred), 5/kit

5 tests per kit

76121-434

HardyVAL™ MTK

MULTIPLE TECHNICIAN VERIFICATION KIT

LOW-COMPLEXITY

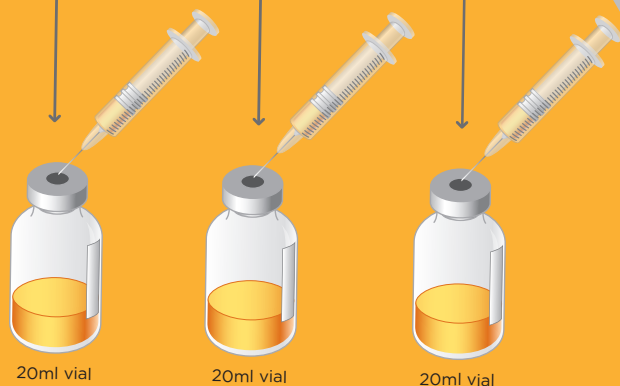
MEDIA FILL TEST KIT

VWR Cat. no. 89408-156



100ml Sterile
Tryptic Soy Broth Vial

4 transfers of 5ml each



20ml vial

20ml vial

20ml vial

Kit Contents

- ▶ 1 x 100ml Sterile Tryptic Soy Broth Vial
- ▶ 3 x 20ml Empty Sterile Vials
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet

*Syringe(s), needle(s), and adhesive seals not included.

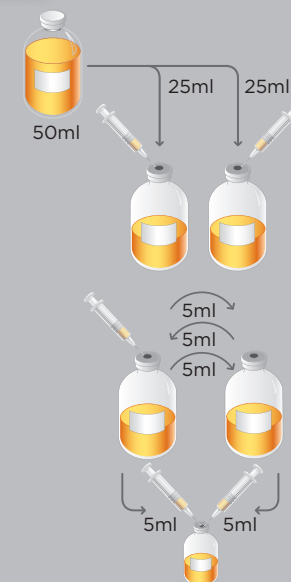
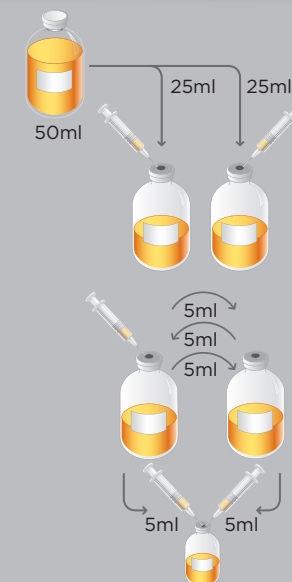
Whirl-Pak® is a registered trademark of Nasco Industries, Inc.

Culture Media is quality control tested
for growth promotion, pH and sterility

MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT BASIC

VWR Cat. no. 89408-158



Kit Contents

- ▶ 3 x 50ml Serum Vials Sterile Tryptic Soy Broth
- ▶ 6 x 50ml Serum Vials (empty), sterile
- ▶ 3 x 20ml Serum Vials (empty), sterile
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet

*Syringe(s), needle(s), and adhesive seals not included.

Whirl-Pak® is a registered trademark of Nasco Industries, Inc.

MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT - COMPREHENSIVE

VWR Cat. no. 89408-160

Kit Contents

- ▶ 1 x 700ml Sterile Tryptic Soy Broth Bag
- ▶ 6 x 100ml Empty Sterile Bags
- ▶ 6 x 20ml Empty Sterile Vials
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet



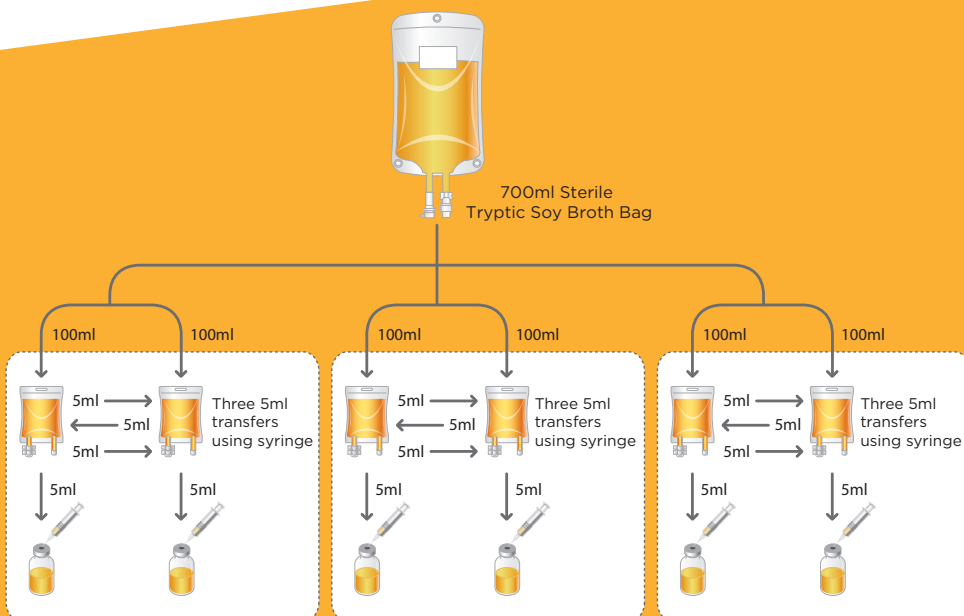
HIGH-COMPLEXITY

MEDIA FILL TEST KIT

VWR Cat. no. 89408-154



HardyVAL™



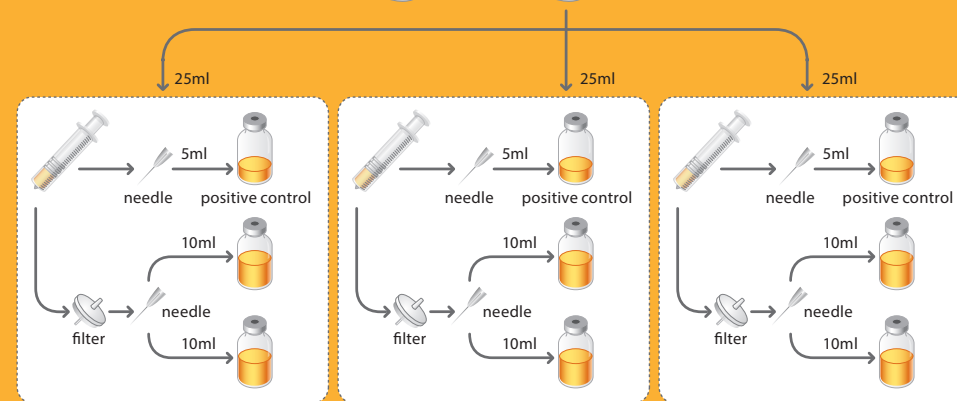
*Syringe(s), needle(s), adhesive seals, non-bacteriostatic water, and filters not included.
Whirl-Pak® is a registered trademark of Nasco Industries, Inc.

Culture Media is quality control tested
for growth promotion, pH and sterility

Add 100ml non-bacteriostatic water*
to 3 grams Tryptic Soy Broth Powder



Screw on cap and mix



*Syringe(s), needle(s), adhesive seals, non-bacteriostatic water, and filters not included.
Whirl-Pak® is a registered trademark of Nasco Industries, Inc.

Kit Contents

- ▶ 1 x 3gm Tryptic Soy Broth Powder (non-sterile)
- ▶ 9 x 20ml Empty Sterile Vials
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet



Available in:

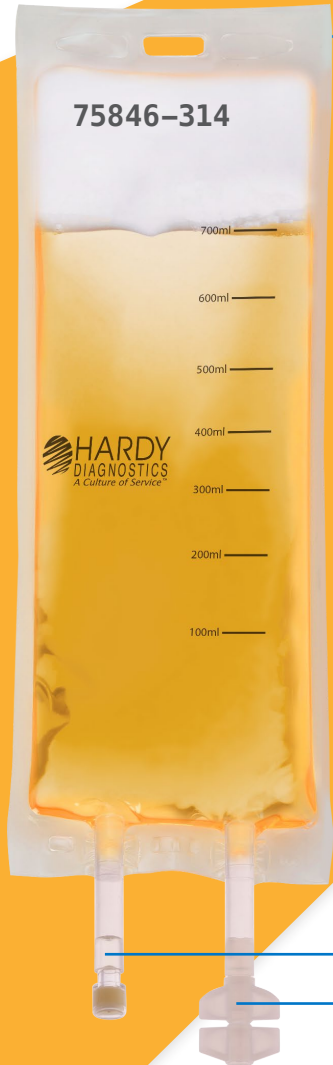
Media Bag TSB
100ml fill, 10pk **75814-002**

Media Bag TSB
700ml fill, 5pk **75846-314**

75814-002

Hang Notch

Needle Port
Spike Port



Needle Port
Spike Port



75846-314

TRYPTIC SOY BROTH MEDIA BAGS

Ideal for verifying aseptic technique of pharmacists, nurses, or pharmaceutical manufacturing technicians.

- ▶ Two ports: needle-port and spike-port
- ▶ Terminally autoclaved for high sterility assurance
- ▶ Quality tested to USP <71> Standards
- ▶ Tryptic Soy Broth (TSB) is manufactured in an ISO 13485 Facility
- ▶ Growth promotion testing performed on each lot of media
- ▶ Hang Notch on the top of the Media Bag™ allows the technician to hang the bag
- ▶ Media Bags Cat. no. 75814-002 are packaged in double 2ml zippered bags

Culture Media is quality control tested for growth promotion, pH and sterility

DESIGN CUSTOM
MEDIA FILL MANIPULATIONS
to best simulate your most
CHALLENGING COMPOUNDING PROCESSES

with our

à la carte

LINE OF MEDIA

Tryptic Soy Broth

Ampoules

3ml glass ampoules of media designed to complement personal aseptic technique proficiency tests as described in USP procedures.

20/pk **76018-782**



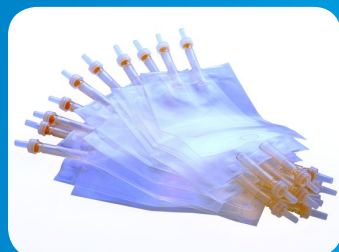
SCORE MARK

MEDIA IS TINTED RED TO ASSIST IN MEDIA TRANSFER VISUALIZATION

Media Bag

Terminally sterilized, empty, 100ml media bag, 10/pk

76018-772



Tryptic Soy Broth (Powder), USP

For High Complexity Compounding Simulations.

3gm of non-sterile TSB powder, 10/pk

76121-432



Tryptic Soy Broth, USP

100ml bottle with needle-port septum, 100ml fill, 10/pk

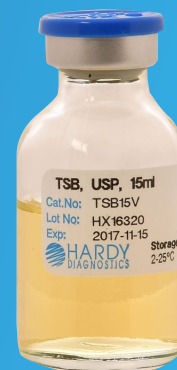
76018-776



Tryptic Soy Broth

Tryptic Soy Broth, 15ml, USP 10/pk

76018-774



Empty vial, 100ml capacity, terminally autoclaved, 10/pk

76018-780



76018-780

Serum Vial

Empty vial, 20ml capacity, terminally autoclaved, 10/pk

76018-778



76018-778

Aspirating head with quick bayonet fixing system for easy manipulation

Aspirating chambers designed for standard agar plates: contact or mono Petri dishes

Easy to clean surface with antimicrobial coating and IP65 dust and waterproof certification

Programmable time, volume, place, and person options

No plugs or external connections



MONO

Ideal for cleanroom use



Each kit includes:

- TRIO.BAS MONO air sampler
- Induction battery charger and cable
- Aspirating head
- Cover head
- ROBUSTUS carrying case
- Calibration certificate
- IQ, OQ, PQ fillable document

Features:

- No plugs or external connections
- Delayed interval sampling and remote start capabilities

	VWR Cat. No.
MONO Kit, 100 liters/min., contact plate	76076-704
MONO Kit, 100 liters/min., Petri plate	76169-642
MONO Kit, 200 liters/min., contact plate	76076-706
MONO Kit, 200 liters/min., Petri plate	76169-644



TRIO.BAS
BIOLOGICAL AIR SAMPLER



DUO

Achieve faster sampling times and better statistical results with the DUO!

Ideal for cleanroom use



Each kit includes:

- TRIO.BAS DUO air sampler
- Induction battery charger and cable
- Aspirating heads
- Cover heads
- ROBUSTUS carrying case
- Calibration certificate
- IQ, OQ, PQ fillable document

Features:

- No plugs or external connections
- Two aspirating heads for sampling on separate plates to determine bacterial and yeast/mold counts
- Programmable for simultaneous or interval aspirating times

VWR Cat. No.

DUO Kit, 100 liters/min., contact plate	76076-710
DUO Kit, 100 liters/min., Petri plate	76169-646
DUO Kit, 200 liters/min., contact plate	76076-710
DUO Kit, 200 liters/min., Petri plate	76169-648

PREPARED MEDIA FOR AIR SAMPLING

PETRI PLATES

Tryptic Soy Agar (TSA)

General growth medium for the isolation and cultivation of microorganisms. SterEM, 15x100mm plate, triple bagged, 10/pk **76200-286**

Tryptic Soy Agar (TSA) Deep Fill

General growth medium for the isolation and cultivation of microorganisms. SterEM, 15x100mm plate, triple bagged, 34ml fill 10/pk **76200-294**

Tryptic Soy Agar (TSA) Deep Fill

General growth medium for the isolation and cultivation of microorganisms. SterEM, 15x100mm **Red Tinted** plate, triple bagged, 34ml fill 10/pk **76200-296**

Tryptic Soy Agar with Lecithin and Tween® 80

General growth medium for the isolation and cultivation of microorganisms. SterEM, 15x100mm plate, triple bagged 10/pk **76200-292**

SabDex Agar

For the detection and enumeration of yeasts and fungi. SterEM, 15x100mm plate, triple bagged 10/pk **76200-288**

SabDex Agar with Lecithin and Tween® 80

For the detection and enumeration of yeasts and fungi. SterEM, 15x100mm plate, triple bagged, 34ml fill 10/pk **76200-290**

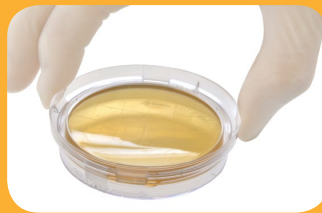
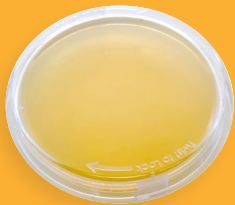


Culture Media is quality control tested for growth promotion, pH and sterility

SURFACE SAMPLING

Surface sampling shall be performed in all ISO classified areas on a periodic basis per USP <797>

LOK TIGHT™ Contact Plate



Friction lid design keeps lids in place. Locking feature assures lids stay secured.

TSA (Tryptic Soy Agar) with Lecithin and Tween® 80

For the cultivation and enumeration of microorganisms. 15x65mm contact plate, 10/pk **89408-026**

SabDex (Sabouraud Dextrose) Agar

For the cultivation of fungi. 15x65mm plate, 10/pk **89407-878**

MEA (Malt Extract Agar) with Lecithin and Tween

For the cultivation and enumeration of fungi. 15x65mm contact plate, 10/pk **89407-708**

IRRADIATED CONTACT PLATES

TSA (Tryptic Soy Agar) with Lecithin and Tween® 80, USP

For the cultivation and enumeration of microorganisms. Irradiated, triple bagged, 15x65mm, 10/pk **76200-280**

SabDex (Sabouraud Dextrose) Agar with Lecithin & Tween® 80, USP

For the cultivation of fungi. Irradiated, triple bagged, 15x65mm, 10/pk **76200-284**



PRE-MOISTENED, READY-TO-USE

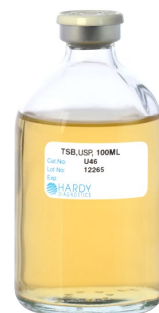
This ready-to-use swab and tube is pre-filled with 5mls of terminally sterilized neutralizing saline. Simply remove the cap, which is attached to the Dacron® swab. Collect your sample by swabbing the surface, recap, and send to the lab. The solution can then be inoculated onto a Tryptic Soy Agar petri plate (Cat. no. G60). This kit is excellent for detection or enumeration of microorganisms from environmental surfaces and hard to reach areas.

5ml, 20/box **89407-512**



STERILITY TESTING by Direct Inoculation of Pharmaceuticals using Hardy Diagnostics Media <USP 71>

USP recommended media for direct inoculation



Tryptic Soy Broth, USP

Recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of bacteria and fungi.

100ml glass bottle with needle port septum, 100ml fill, 20/pk **89408-048**

Tryptic Soy Broth, USP

Recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of bacteria and fungi.

20ml glass bottle with needle port septum, 20ml fill, 50/pk **89408-068**

Fluid Thioglycollate Broth Medium with Indicator, USP

For the cultivation of anaerobic microorganisms.

100ml glass bottle with needle port septum, 100ml fill, 20/pk **10158-356**

20ml glass bottle with needle port septum, 20ml fill, 50/pk **89407-584**

Drug solutions can be tested for sterility by direct inoculation into Tryptic Soy Broth (TSB) and Fluid Thioglycollate according to procedures found in <USP 71>. By incubating for 14 days, a lack of fungal, aerobic, and anaerobic bacterial contamination can be proven. Please consult <USP 71> (Table II) to verify proper inoculum size and media volume.

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