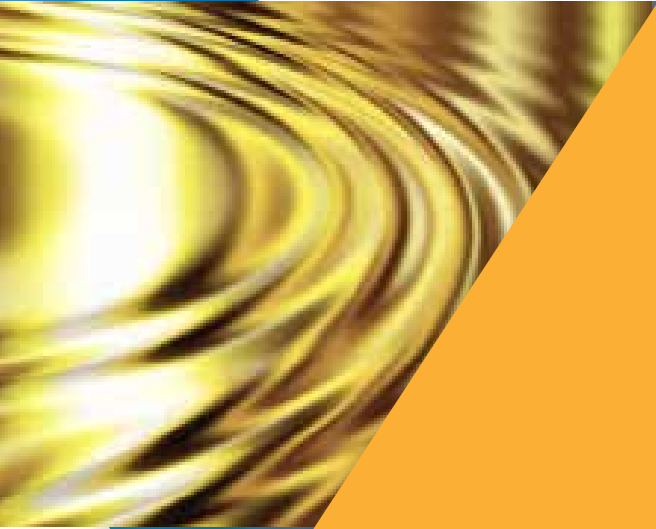




CLEANROOM

C O N N E C T I O N



USP
<797>
COMPLIANCE



USP

<797> COMPLIANCE

HardyVAL™
MEDIA FILL TEST KITS

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The Quality Management System at the Hardy Diagnostics manufacturing facility is certified to ISO 13485.

ISO 13485
FM 572526

Copyright © 2017 Hardy Diagnostics

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?**

USP <797> states, in part:

"When performing these testing procedures, use the most difficult and challenging compounding procedures and processing conditions encountered by the person during a work shift (e.g., the most manipulations, most complex flow of materials, longest time to compound), replacing all the components used in the CSP's with microbial growth medium."

NEW!



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

HVMTK

Hardy **VAL**™ MTK

MULTIPLE TECHNICIAN VERIFICATION KIT

Cat. no. HVMTK



LOW-COMPLEXITY

MEDIA FILL TEST KIT

Cat. no. HVL1



100ml Sterile
Tryptic Soy Broth Vial

4 transfers of 5ml each into each vial



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

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

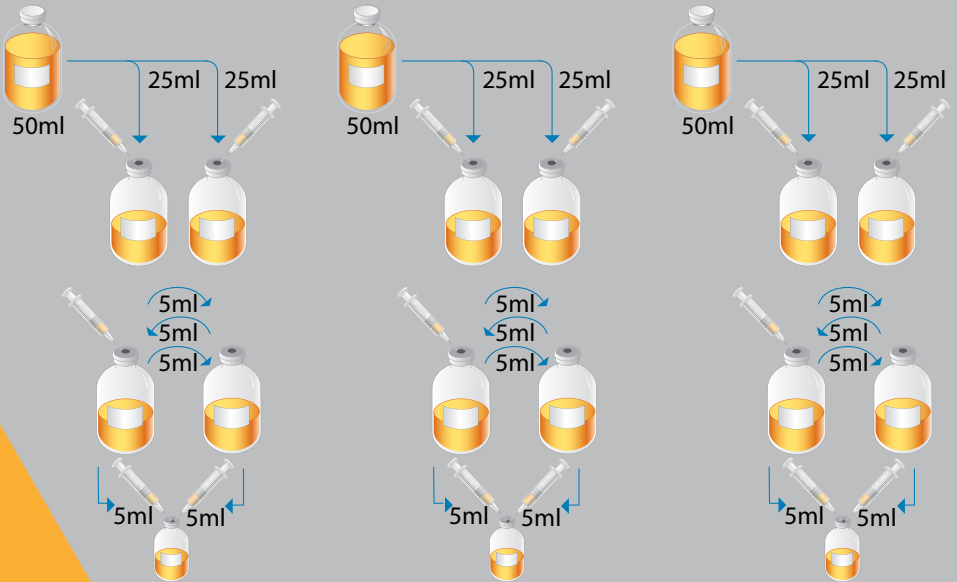
*Syringe(s), needle(s), and adhesive seals not included.

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

MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT BASIC

Cat. no. HVM2



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.

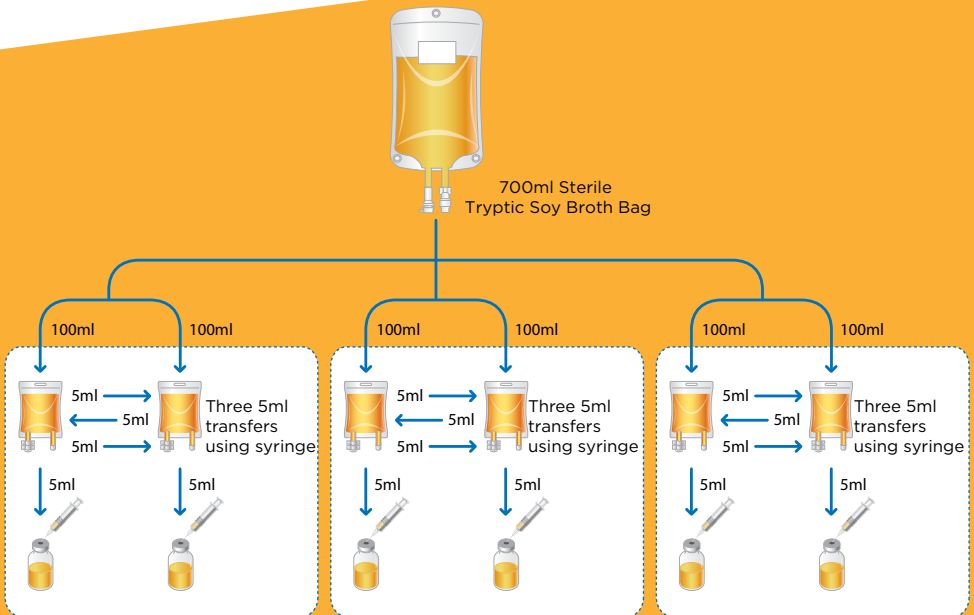
MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT - COMPREHENSIVE

Cat. no. HVM1

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



*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

HIGH-COMPLEXITY

MEDIA FILL TEST KIT

Cat. no. HVH1

HardyVAL™



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

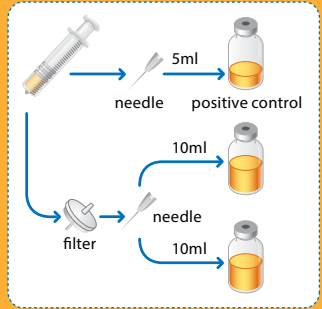
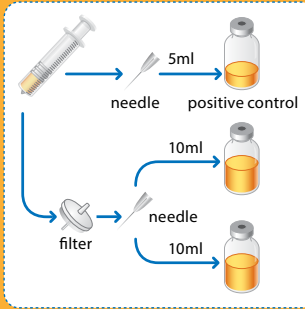
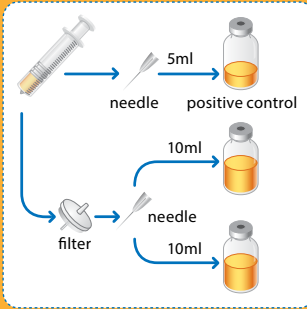


Screw on cap and mix

25ml

25ml

25ml



*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 **U100**

Media Bag TSB
700ml fill, 5pk **HVB5**



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. U100 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

R35



SCORE MARK

MEDIA IS TINTED
RED TO ASSIST
IN MEDIA
TRANSFER
VISUALIZATION

Media Bag

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

HVB10



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

Tryptic Soy Broth (Powder), USP

For High Complexity Compounding Simulations.
3gm of non-sterile TSB powder,
10/pk

U130



Tryptic Soy Broth, USP

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

U101



Tryptic Soy Broth

Tryptic Soy Broth, 15ml, USP
10/pk

U382



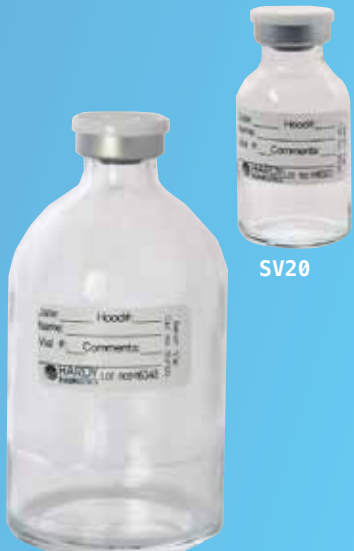
Serum Vial

Empty vial, 20ml capacity,
SAL 10⁻⁶,
10/pk

SV20

Empty vial, 100ml capacity,
SAL 10⁻⁶,
10/pk

SV100



SV20

SV100

AIR IMPACT SAMPLING USP <797>

USP <797> states, in part: "Impaction shall be the preferred method of volumetric air sampling."



TRIO.BAS
BIOLOGICAL AIR SAMPLER



MONO



DUO



TRIO

The **TRIO BAS**™ family of air samplers has a 35 year history and come from the engineers of the first portable air sampler. The instruments are lightweight, ergonomic, have data integrity with Bluetooth capability and use standard media. Choose a format to best fit your environmental monitoring needs. See our website and online **TRIO BAS**™ catalog for all available models.





PREPARED MEDIA

FOR AIR SAMPLING

PETRI PLATE

Malt Extract Agar

For the cultivation and enumeration of yeasts and molds. 15x100mm plate, 10/pk

W28

TSA (Tryptic Soy Agar), SterEM™, USP

General growth medium for the detection and enumeration of microorganisms. Irradiated, 15x100mm plate, 34ml fill, triple bagged, 10/pk

W3670

TSA (Tryptic Soy Agar), USP

General growth medium for the detection and enumeration of microorganisms. 15x100mm plate, 26ml fill, 10/pk

W64

SabDex (Sabouraud Dextrose) Agar, USP

For the cultivation of fungi. Irradiated. 15x100mm plate, 26ml fill, triple bagged, 10/pk

W1770

SabDex (Sabouraud Dextrose) Agar

For the cultivation of fungi. 15x100mm plate, 26ml fill 10/pk

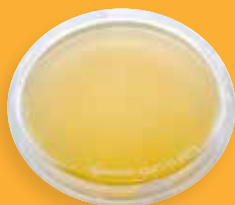
W70

Coming
Soon

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.
15x60mm contact plate,

10/pk

P34

SabDex (Sabouraud Dextrose) Agar

For the cultivation and enumeration of fungi.
15x60mm plate,

10/pk

P36

MEA (Malt Extract Agar) with Lecithin and Tween

For the cultivation and enumeration of fungi.
15x60mm contact plate,

10/pk

P93

IRRADIATED CONTACT PLATES

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

For the cultivation and enumeration of microorganisms.
Irradiated, triple bagged,
15x60mm,

10/pk

P740

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

For the cultivation of fungi.
Irradiated, triple bagged,
15x60mm,

10/pk

P750



1. Twist and remove lid.



2. Gently press plate to surface without twisting or sliding.



3. Twist clockwise until frosted bands line up and lock lids into place.



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 **SRK55**



FlexEM™ Media Paddles COME IN 2 FORMATS Tryptic Soy Agar (TSA) or Malt Extract Agar (MEA)

Tryptic Soy Agar (TSA) Media Paddles

Support the growth of a wide range of organisms. TSA Media-Paddles are often used for environmental and cleanroom monitoring for bacterial and fungal contamination.

Malt Extract Agar (MEA) Media Paddles

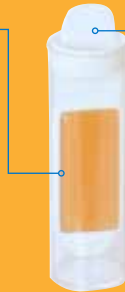
Specific for fungal growth, a general purpose agar that reduces bacterial growth.

Tryptic Soy Agar (TSA), FlexEM™ Media Paddles
10/pk **TSA10**

Malt Extract Agar (MEA), FlexEM™ Media Paddles
10/pk **MEA10**

Features and Benefits

- ▶ Flexible hinged paddle that can be angled up to 90+ degrees in each direction
- ▶ Quality tested for performance, pH and sterility
- ▶ Recessed handle built into the slide
- ▶ Dual sided - same agar on both sides of the paddle
- ▶ Identifier on the side - allows agar identification



Coming
Soon

FINGERTIP SAMPLING

Personnel monitoring (gloved fingertips) is required to be done at initial competency evaluation and no fewer than three times before being allowed to compound sterile preparations.



Gently press glove tips to plate surface.



FlexEM™ Media Paddle, Cat. no. **TSA10** can also be used for fingertip sampling.

STERILITY TESTING OF YOUR FINISHED COMPOUNDED DRUG

Sterisart® UNIVERSAL PUMP STERILITY TESTING SYSTEM

FEATURES AND BENEFITS

- ▶ Gold standard for sterility testing of drugs
- ▶ Closed system - decrease the chance of technician contamination
- ▶ Rugged and maintenance-free
- ▶ Compact and ergonomic construction
- ▶ Pump available with special software (menu-driven prompts for operator guidance; all process sequences can be logged; bar code recognition)
- ▶ Convenient foot switch activator

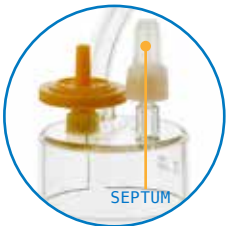
Sterisart® Universal Pump | Each 16420



DISPOSABLE SAMPLE CANISTERS AND ADAPTERS FOR USE WITH STERISART® UNIVERSAL PUMP

FEATURES AND BENEFITS

- ▶ For sterility testing in isolators and clean benches
- ▶ Individually sterile
- ▶ Double-packaged
- ▶ Gamma irradiated
- ▶ Stainless steel needles



Sterisart® Canisters available with or without a needle port septum for sub-culturing



Culture Media for Sterility Testing per USP <71>

- ▶ Tryptic Soy Broth (TSB), USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U46**
- ▶ Fluid Thioglycollate, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U84**
- ▶ Fluid A, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U109**
- ▶ Fluid D, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U110**



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.

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 U46

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 U38

Fluid Thioglycollate Broth Medium with Indicator, USP
For the cultivation of anaerobic microorganisms.

100ml glass bottle with needle port septum, 100ml fill,
20/pk U84

20ml glass bottle with needle port septum, 20ml fill,
50/pk U68

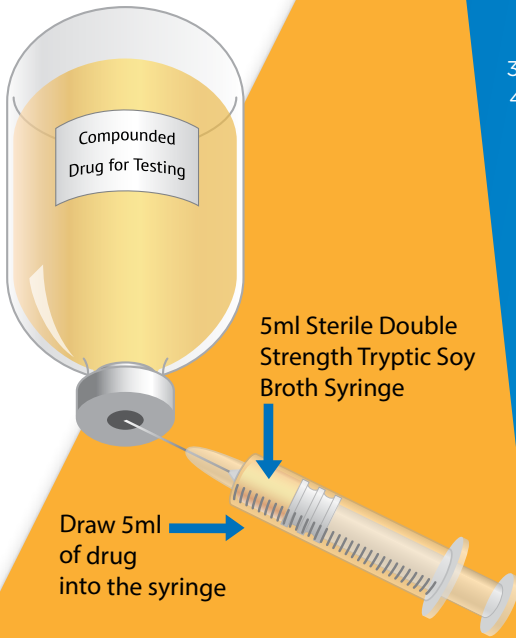
Culture Media is quality control tested for growth promotion, pH and sterility

Go to HardyDiagnostics.com for a complete listing of bottle and jar media. Custom containers and fill volumes are available upon request.

HardyVAL™

RANDOM TESTING

Cat. no. HVRI



Procedure Summary

1. Attach sterile needle to 5ml of sterile double strength Tryptic Soy Broth syringe.
2. Draw 5ml of compounded preparation into the Double Strength Tryptic Soy Broth Syringe.
3. Incubate syringe
4. Examine for turbidity at the end of 14 days.
5. Does not fulfill requirements for USP <71> Sterility Testing.

Kit Contents

- ▶ 5 x 5ml Double Strength Tryptic Soy Broth Syringes
- ▶ 5 x Write-on Whirl-Pak® Bags
- ▶ 1 x Results Log Sheet



Use on expired or returned drugs to check sterility (for quality assurance purposes only).

GROWTH PROMOTION TESTING USP <71>

QC MICROORGANISMS
FOR GROWTH
PROMOTION TESTING OF
YOUR CULTURE MEDIA



EZ-Accu Shot™ Select includes USP compendial QC microorganism strains for Growth Promotion Testing in one convenient package. EZ-Accu Shot™ Select lyophilized QC microorganism preparations are designed to deliver 10-100 CFU per 0.1 ml of hydrated suspension as recommended by the USP/JP/Ph. Eur. With little to no preparation time required and up to eight hours of stability, EZ-Accu Shot™ Select adds efficiency and flexibility to QC laboratories' busy schedules. Each 1.2 ml vial of hydrated suspension offers 10 inocula.

EZ-Accu Shot™ Select Licensed, traceable strains:

- ▶ *Bacillus subtilis* ssp. *spizizenii* ATCC ® 6633™*
- ▶ *Candida albicans* ATCC ® 10231™*
- ▶ *Pseudomonas aeruginosa* ATCC ® 9027™*
- ▶ *Staphylococcus aureus* ssp. *aureus* ATCC ® 6538™ *

EZ-Accu Shot™ Select Kit includes:

- ▶ 1 vial of each microorganism
(1 Lyophilized pellet per vial)
- ▶ 5 vials of hydrating fluid (1.2 mL in each vial)
- ▶ 5 peel-off labels, one for each strain

Kit

8172

***In addition to product Cat. no. 8172, shown above, this organism is also required for full compliance to USP <71>:**

Clostridium sporogenes, ATCC® 19404

- ▶ 5 vials with 1 pellet per vial,
- ▶ 5 vials of hydrating fluid
- ▶ Used for USP <62> and USP <71>
- ▶ ATCC Licensed Derivative®

▶ **Cat. no. 0317A**

Headquarters

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www.HardyDiagnostics.com

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Olympia, Washington
Salt Lake City, Utah
Phoenix, Arizona
Dallas, Texas
Springboro, Ohio
Lake City, Florida
Albany, New York
Raleigh, North Carolina

EQUIPMENT

INCUBATOR (LOW COST, SMALL FOOT PRINT)

This compact incubator fits easily on most counter tops. Incubator holds a constant temperature to plus or minus one degree. It is made of powder coated steel and has an acrylic, see-through door.

- ▶ Comes with two adjustable shelves
- ▶ Capable of temperatures up to 60 °C
- ▶ Capacity: 0.8 cubic feet
- ▶ Chamber's Inside dimensions: 13" W x 14" H x 16.25" D.

Each **132000**



THERMOMETER, EXACT-TEMP, REFRIGERATOR

Thermometer probe stays inside, digital display stays outside. No need to open the door!

- ▶ Temperature probe remains in plastic bottle with insulating liquid. Thermometer is traceable to National Institute of Standards and Technology (NIST) with certificate.
- ▶ Min/Max alarm settings with nine foot sensor cable.
- ▶ Choose between Celsius and Fahrenheit ranging from -50°C to 70°C (-58 °F to 158°F).
- ▶ Accurate up to $\pm 0.6^{\circ}\text{C}$ for precise measurements, Resolution: 0.1°C.
- ▶ Display size is 1.75 x .75 inches for easy viewing, powered by one AAA battery (included).

Each **R80301**



