USP <797>

COMPLIANCE TESTING PRODUCTS

HARDY DIAGNOSTICS

A Culture of Service™

The 2023 revisions to USP <797> will require significant changes in the training and evaluations of all staff members in your facility. The purpose of this update is to ensure all people involved in compounding sterile preparations have the knowledge and expertise to safely and effectively maintain the quality of the environment, perform their job duties, and keep patients safe.

Our 2023 updated USP <797> catalog will help provide guidance and compliancy solutions for your facility.

You're not just a number. You're not a figure on a graph in a quarterly report. At Hardy Diagnostics, you're a partner. From laboratories that utilize our tests to diagnose illness, to our employee owners who ensure that every lot meets your rigorous expectations, Hardy Diagnostics is about a group of people coming together to better the world, one test at a time.

Hardy Diagnostics is a 100% employee-owned company that is licensed by the FDA as a medical device manufacturer, and its quality management system is ISO 13485 certified. Hardy Diagnostics has been helping people live healthier lives since 1980.

Our microbiology products are used all over the world to diagnose and prevent disease.

HARDY DIAGNOSTICS
A Culture of Service™

Contact Us

ADDRESS

1430 West McCoy Lane
Santa Maria, CA 93455

PHONE

800.266.2222

EMAIL

Sales@HardyDiagnostics.com

WEBSITE

HardyDiagnostics.com

usp <797> UPDATE – Denotes areas in USP <797> that have changed

Compliance has never been 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>.

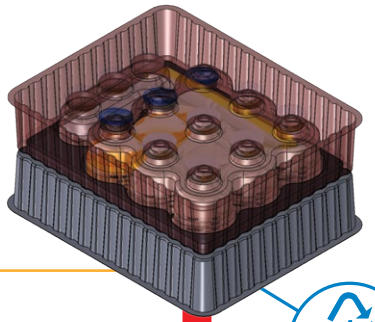
- Kits are designed to help you comply with USP <797> guidelines
- Quality culture media tested for performance, pH and sterility
- Hardy Diagnostics is ISO13485 Certified
- Kits supply what is needed to test the proficiency and aseptic technique of technicians or pharmacists in a self-contained ready-to-use format
- Kits are available for Low, Medium and High Complexity procedures
- **Á la carte components enhance kits or allow for customized tests based on your compounding processes**
- Results log sheet is included in each kit
- Expert technical support is available from our staff of microbiologists, call 800.266.2222 ext. 5658

Media Fill Test Kits

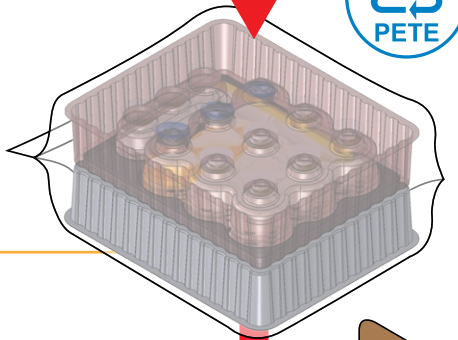
Aseptic Technique Validation

Choose from **five pre-assembled kits** for ease-of-use OR create your own with our **á la carte** line of **HardyVAL™** media products and containers.

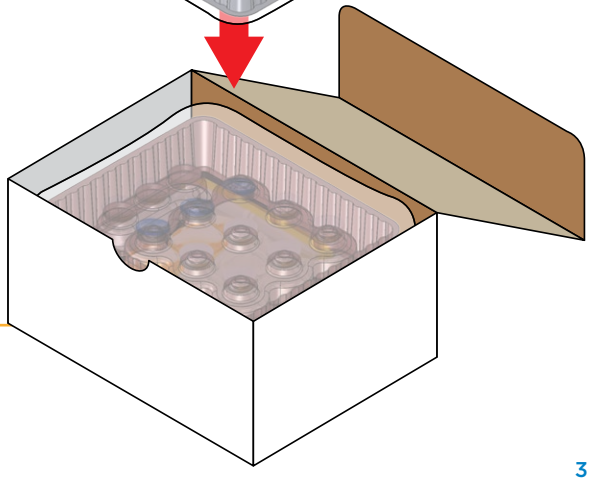
NEW fully recyclable thermoform packaging



Clean barrier zip-bag



Sturdy protective box



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

According to updated USP <797>:

"When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean–casein digest media (TSB)."

Who should be evaluated and how often?

According to updated USP <797>:

"For personnel compounding Category 1 and Category 2 CSPs, the aseptic manipulation competency must occur initially and at least every 6 months thereafter. For personnel compounding Category 3 CSPs, the aseptic manipulation competency must occur initially and at least every 3 months thereafter. Personnel who have direct oversight of compounding personnel must complete an aseptic manipulation competency evaluation annually. The evaluation should correspond to the type of activities of the personnel they oversee but does not require the same quantities. Personnel who have direct oversight of compounding personnel must not compound unless they successfully complete the aseptic manipulation competency evaluation that simulates the most difficult and challenging aseptic compounding procedures encountered by the person at the same intervals required for compounding personnel.

HardyVAL™ MTK

Multiple Technician Verification Kit

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

KIT CONTAINS:

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

5 tests per kit **HVMTK**

HardyVAL™ Low Complexity Kit

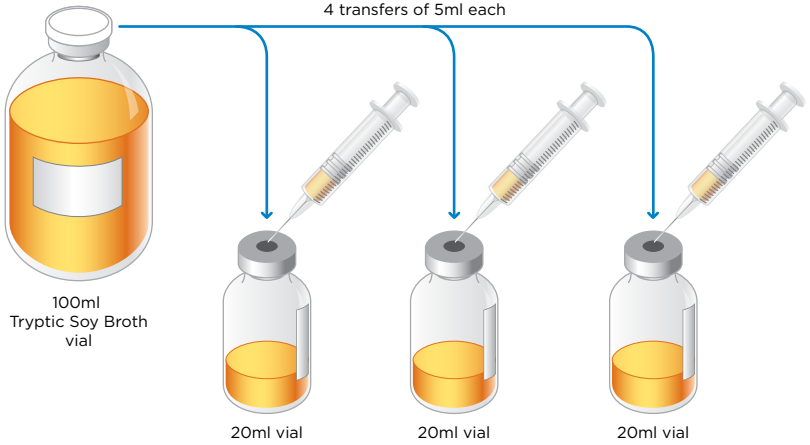
The Low Complexity Kit by Hardy Diagnostics is recommended for simulating manipulations involving vials and transfers, and for verifying aseptic technique. Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. The product is quality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

KIT CONTAINS:

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

Each **HVL1**

Procedure



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

Whirl-Pak® is a registered trademark of Filtration Group.

HardyVAL™ Medium Complexity Kit (Basic)

Recommended for simulating compounding manipulations involving vials and transfers, and for verifying aseptic transfer techniques of multiple solutions.

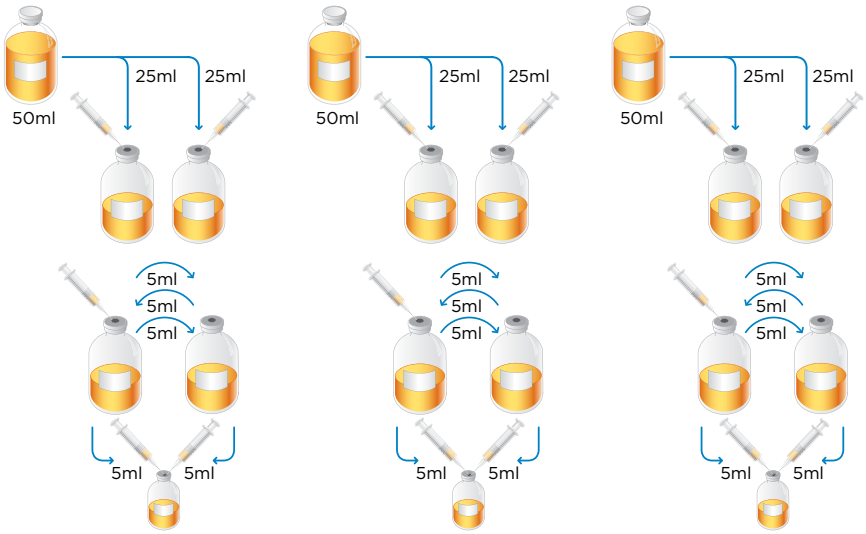
Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. The product is quality control tested for growth promotion, pH, and sterility.

KIT CONTAINS:

- 3 x 50ml Serum Vials 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

Each **HVM2**

Procedure



**Syringe(s), needle(s), and adhesive seals not included.*
Whirl-Pak® is a registered trademark of Filtration Group.

HardyVAL™ Medium Complexity Kit (Comprehensive)

Recommended for simulating compounding manipulations involving the preparation of IV Bags, and for verifying aseptic technique.

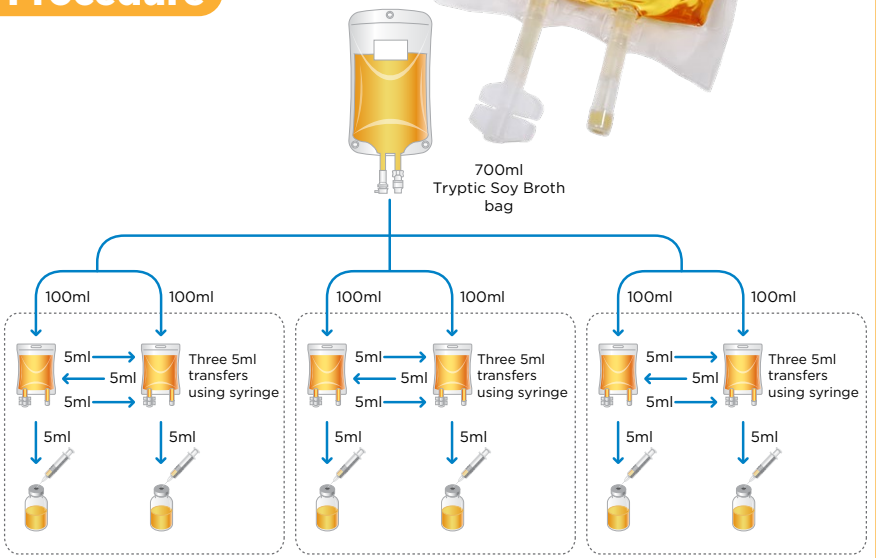
Kit performs one complete aseptic technique verification challenge test for one technician. Includes test results log sheet. The product is quality control tested for growth promotion, pH, and sterility.

KIT CONTAINS:

- 1 x 700ml Tryptic Soy Broth in 1,000ml 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

Each **HVM1**

Procedure



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

Whirl-Pak® is a registered trademark of Filtration Group.

HardyVAL™ High Complexity Kit

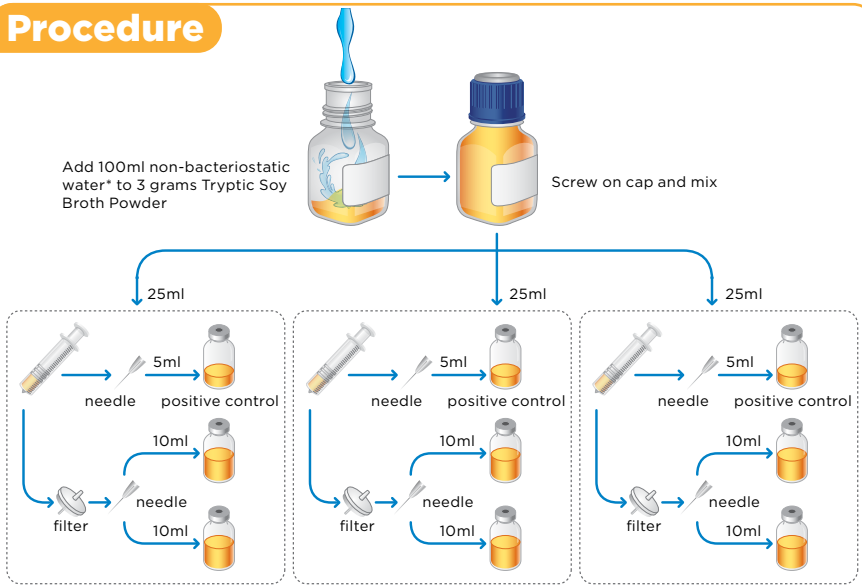
The High Complexity Level Kit by Hardy Diagnostics is recommended for simulating compounding manipulations, and for verifying aseptic techniques of non-sterile to sterile solutions. Kit performs one complete aseptic technique verification challenge test for one technician OR pharmacist. Includes test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

KIT CONTAINS:

- 1 x Bottle with 3gm TSB Powder
- 9 x 20ml Empty Sterile Vials
- 1 x Write-on Whirl-Pak Bag
- 1 x Results Log Sheet

Each **HVH1**

Procedure



**Syringe(s), needle(s), and adhesive seals not included.*
Whirl-Pak® is a registered trademark of Filtration Group.

HAZ DETECT™ Hazardous Drug Manipulation Technique for USP <800>

Training Kit

Assists in training for drug handling competency and verification. Can be used to simulate spills and subsequent clean-up protocol processes.

Design a training method to reflect your highest risk-associated process.

After performing the determined manipulation with the HAZ DETECT components, a UV light shined on the working surface will reveal any spills and the need for technician retraining.

KIT CONTAINS:

- 5 x 50ml Fluorescein powder vials
- 5 x 3ml reconstituted fluorescein septum tubes

Each **HVHAZ**

"The OSHA HCS and USP chapter <800> require employee training for the tasks that will be performed as part of the (hazardous drug compounding) safety program."

ASHP Guidelines on Handling Hazardous Drugs

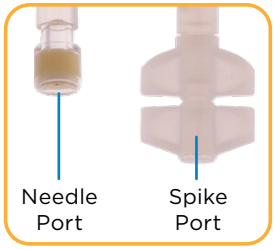
Needles, syringes, mini bag (see HVB10), and UV Lamp (see UVL56) not included.

UV Lamp, Hand Held, 6 Watt, 365nm Long Wave

A powerful 6 watt bulb for easier, more reliable detection than weaker models. Can be used for ALA, MUG, and fluorescent pigment detection in microbiology. Intensity is 1350 uW/cm2 of 365nm at 3 inches.

Each **UVL56**

Tryptic Soy Broth Media Bags



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

- 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
- Media Bags Cat. no. U100 are packaged in double 2mil zippered bags

AVAILABLE IN:

Media Bag TSB
100ml fill, 10pk **U100**

Media Bag TSB
700ml fill, 10pk **HVB5**

HardyVAL™ a la carte

Products to best simulate your most challenging media fill and compounding processes

Tryptic Soy Broth, USP

20ml vial, with needle-port septum, 15ml fill,
10/pk **U382**

Media Bag

Terminally sterilized, empty, 100ml media bag. For laboratory use only.
10/pk **HVB10**

HardyVAL™ a la carte

Tryptic Soy Broth, USP, Ampoules

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

20/pk **R35**

Media is tinted red to assist in media transfer visualization

Tryptic Soy Broth (Powder), USP

For high complexity compounding simulations.
3gm of non-sterile TSB powder,

10/pk **U130**

Serum Vials

Empty vial, 20ml capacity, terminally autoclaved,

10/pk **SV20**

Empty vial, 100ml capacity, terminally autoclaved,

10/pk **SV100**

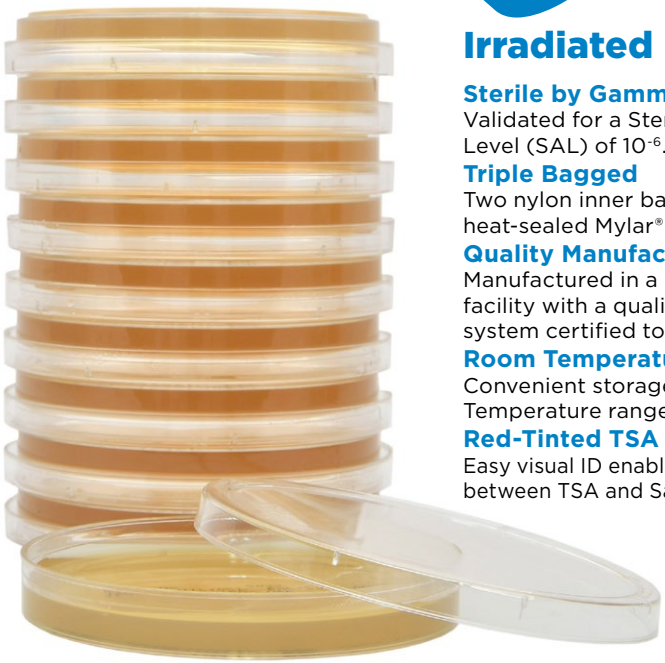
Tryptic Soy Broth, USP

100ml bottle with needle-port septum, 100ml fill,

10/pk **U101**

Environmental Monitoring Media

Irradiated, triple bagged media ensures safe and sterile transfer by removing one bag per pass-through material/air lock.



Irradiated Plates

Sterile by Gamma Irradiation
Validated for a Sterility Assurance Level (SAL) of 10^{-6}.

Triple Bagged
Two nylon inner bags with an outer heat-sealed Mylar® bag.

Quality Manufacturing
Manufactured in a licensed cGMP facility with a quality management system certified to ISO 13485.

Room Temperature
Convenient storage and ready-to-use. Temperature range 15-30 °C

Red-Tinted TSA dish option
Easy visual ID enables easy differentiation between TSA and SabDex.

Tryptic Soy Agar (TSA), USP
General growth medium for the isolation and cultivation of microorganisms. SterEM™, 15x100mm plate, triple bagged

10/pk **W570**

Tryptic Soy Agar (TSA), USP, Deep Fill
General growth medium for the isolation and cultivation of microorganisms. SterEM™, 15x100mm plate, triple bagged, 34ml fil,

10/pk **W540**

Red Tinted plate, triple bagged, 34ml fill

10/pk **W540R**

SabDex Agar, USP
For the detection and enumeration of yeasts and fungi. SterEM™, 15x100mm plate, triple bagged

10/pk **W565**

SabDex Agar with Lecithin and Tween® 80, USP, Deep Fill
For the detection and enumeration of yeasts and fungi. SterEM™, 15x100mm plate, triple bagged, 34ml fill

10/pk **W595**

R2A Agar, USP
For enumeration of heterotrophic bacteria in water, especially potable water. SterEM™, 15x100mm plate, triple bagged

10/pk **W530**

Gloved Fingertip Sampling

USP <797> STATES:
"Before being allowed to independently compound, all compounders must successfully complete gloved fingertip and thumb sampling on both hands... no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedures. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling on both hands at least every 12 months thereafter."

Tryptic Soy Agar with Lecithin and Tween® 80, USP

General growth medium for the isolation and cultivation of microorganisms. **Recommended for gloved fingertip sampling.**
SterEM™, 15x100mm plate, triple bagged

10/pk	**W520**

Prepared Media Accessories

60 contact plate holder,
Cat. no. DURA60C

Hardy Diagnostics
DuraRack™

Petri Plate Holder

Simply the most durable Petri plate storage rack you will every buy.

- Durable, coated steel wire rack
- Autoclavable
- Easy loading and unloading
- Sturdy welded design

60 Petri plate holder, **each**	**DURA60**
84 Petri plate holder, **each**	**DURA84**
60 contact plate holder, **ea.**	**DURA60C**

Cleanroom Bag

Sterile bags ideal for safely containing and transporting Petri dishes, Contact plates, swabs, or other objects, outside of the cleanroom.

5/pk	**BAS381BX**
750 Bags/Case	**BAS381**

Surface Sampling

USP <797> STATES:

usp <797> UPDATE

"...surface sampling should be performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected."

"For entities compounding Category 1 and Category 2 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be conducted at least monthly."

"For entities compounding any Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established for Category 2 CSP's and at least weekly..."

LOK TIGHT™ Contact Plates

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

For the cultivation and enumeration of microorganisms. 15x65mm contact plate,

10/pk **P34**

SabDex (Sabouraud Dextrose) Agar

For the cultivation of fungi. 15x65mm plate,

10/pk **P36**

MEA (Malt Extract Agar) with Lecithin and Tween® 80

For the cultivation and enumeration of fungi. 15x65mm contact plate,

10/pk **P93**

GAMMA IRRADIATED CONTACT PLATES

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

For the cultivation and enumeration of microorganisms. Recommended for surface sampling. Irradiated, triple bagged, 15x65mm,

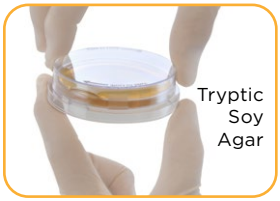
10/pk **P520**

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

For the cultivation of fungi. Irradiated, triple bagged, 15x65mm,

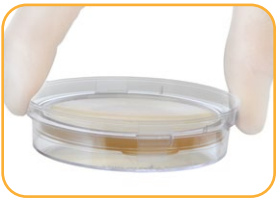
10/pk **P595**

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



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.

EnviroTrans™
ENVIRONMENTAL SWAB RINSE KIT

Pre-moistened, Ready-to-Use

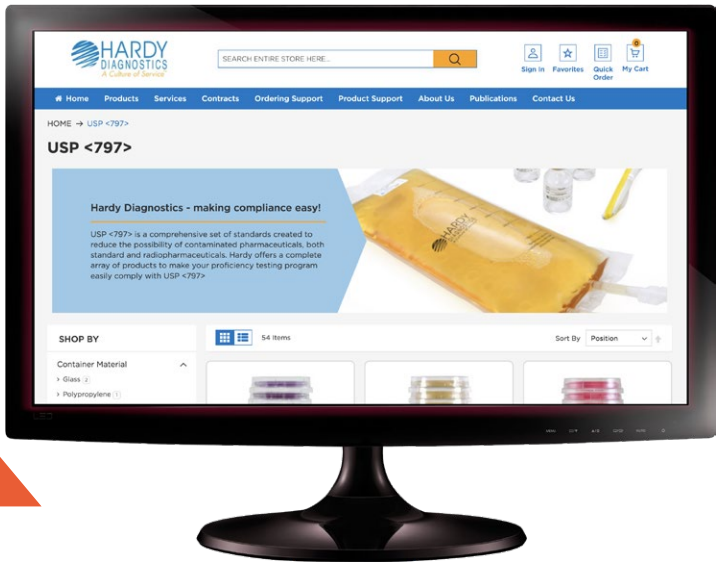
Neutralizing Saline

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**

Scan the QR code below

to access the entire Hardy USP <797> product suite



usp
<797>

Active Impact Air Sampling

USP <797> STATES:

"Volumetric active air sampling of all classified areas using an impaction air sampler must be conducted in each classified area..."

"For entities compounding Category 1 and Category 2 CSPs, this must be completed at least every 6 months. For entities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs."

usp <797> UPDATE

TRIO.BAS™
BIOLOGICAL AIR SAMPLER

The most complete line of active impact air samplers to ensure USP <797> compliance

MONO

DUO

AIRBIO DUO

For over 45-years, **TRIO.BAS™** has boasted a rich legacy of manufacturing expertise, being the pioneers that created the worlds ***first*** portable air sampler. These instruments are lightweight, ergonomic, offer data integrity with Bluetooth connectivity, and use standard media. Choose a format to best suit your environmental monitoring needs. See our website and online **TRIO.BAS™** catalog for all available models.

Looking to sample multiple location at the same time in your controlled environments?

We have the solutions for you.

TRIO.BAS™ MULTIFLEX 1+2

USP <797>, <1115>, <1116> guidelines include viable impact air sampling for viable particles as a part of an effective environmental monitoring program. The TRIO.BAS™ family of active microbial air samplers meets USP compliance standards.

The MULTIFLEX 1+2

- Ideal for use in Isolators/RABS
- Suited for facilities required to comply with quality standards and GMP, e.g: pharmaceutical, biotechnology and other critical cleanroom environments
- Offers versatility and unique sampling options
- Ideal for situations where there are a large number of sample points and sampling locations, with large staff rotations
- Fabricated in AISI 316 rated stainless steel

	Cat. no.
MULTIFLEX 1+2, 100 liters/min., contact plate	**BAS474K**
MULTIFLEX 1+2, 100 liters/min., Petri plate	**BAS475K**
MULTIFLEX 1+2, 200 liters/min., contact plate	**BAS476K**
MULTIFLEX 1+2, 200 liters/min., Petri plate	**BAS477K**

HARDY DIAGNOSTICS

A Culture of Service™

MORE THAN 40 Years of Bringing You A Culture of Service

100% Employee Owned

ESTABLISHED **1980**

MADE IN **USA**

Hardy Diagnostics donates 1% of net profits to charity.

bsi ISO 13485 Medical Devices Quality Management

FM 572526

Hardy Diagnostics has a Quality Management System that is certified to ISO 13485 and is a FDA licensed medical device manufacturer.

Headquarters

1430 West McCoy Lane
Santa Maria, CA 93455
800.266.2222
Sales@HardyDiagnostics.com
HardyDiagnostics.com

Distribution Centers

Santa Maria, California
Olympia, Washington
Salt Lake City, Utah
Phoenix, Arizona
Dallas, Texas
Des Moines, Iowa
Springboro, Ohio
Lake City, Florida
Albany, New York
Raleigh, North Carolina

GSA® Contract Holder
Contract # 47QSWA22D0077