IFU

Instructions for Use

HardyVal™ CSP RANDOM TEST KIT

Cat. no. HVR1	Random Test Kit	5 tests/kit
	Each kit contains:	
	Tryptic Soy Broth, Double Strength (DS), 12ml Syringe, 5.2ml	5 syringes
	Whirl-Pak® Bag	5 bags
	Results Log Sheet	1 sheet

INTENDED USE

Hardy Diagnostics HardyVal™ Random Test Kit is recommended for use in quality assurance monitoring of Compounded Sterile Preparations (CSPs), as an indicator of gross microbial contamination of therapeutic solutions.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

The compounding pharmacy is responsible for the proper packaging, handling transport and storage of all Compounded Sterile Preparations (CSPs) prepared or dispensed from it whether the preparations are used within the facility or transported outside of the institution. Sterile products must be transported by a means to insure that they are protected from excesses of temperature and light and pharmacists must ascertain that the end-user knows how to properly store products. A formal patient or caregiver training program is mandated. As part of their Quality Assurance Program, all CSP providers must have formal procedures to monitor, evaluate, correct, and improve the activities and processes outlined in USP <Chapter 797>.[1] Return product evaluation testing can be to evaluate transportation, handling and storage conditions of an expired product. This product can be used to detect gross contamination of products. This method is not adequate for use in “Sterility Testing” procedures as described in USP <71>.[1]

Sterile syringes are filled with 5.2ml of sterile, double-strength (DS) Tryptic Soy Broth. When expired or unused sterile preparations are returned to the pharmacy, an aliquot of the preparation may be removed using a syringe containing TSB. The entire syringe is then incubated at 30-35 degrees C. for 14 days. After the incubation period, the syringe barrel is examined for growth and/or turbidity. If growth is observed, the product has been contaminated. Aseptic technique, procedures, transport, and storage conditions must be examined and remedial action identified and implemented.

Tryptic Soy Broth is widely used for the cultivation of microorganisms from environmental sources; supporting the growth of the majority of bacteria and fungi. Tryptic Soy Broth is also recommended for use in sterility testing for the detection of contamination with low incidence fungi and aerobic bacteria.[1]

Tryptic Soy Broth, also known as TSB or Soybean-Casein Digest Broth, conforms to the formula given by the U.S. Pharmacopeia.[1] This medium contains digests of soybean meal and casein, which provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of

organisms. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is incorporated as an energy source. The dipotassium phosphate is in the formulation serves as a buffer to maintain the proper pH.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	34.0gm
Sodium Chloride	10.0gm
Papaic Digest of Soybean Meal	6.0gm
Dextrose	5.0gm
Dipotassium Phosphate	5.0gm

Final pH 7.3 +/- 0.2 at 25°C.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25°C. away from direct light. Media should not be used if there are any signs of deterioration (discoloration), contamination, or if the expiration date has passed. Protect from light, excessive heat, moisture, and freezing.

The expiration date applies to the product in its intact packaging when stored as directed.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin

This product is for laboratory use only. Not for injection or ingestion. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified personnel. Sterilize all biohazard waste before disposal.

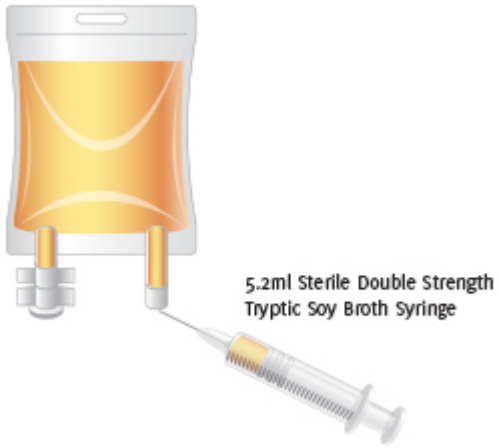
Rare fastidious organisms may not grow in Tryptic Soy Broth.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

1. Aseptically remove the cap at the end of the syringe containing double strength Tryptic Soy Broth and attach a sterile 18-gauge needle.
2. Withdraw a 5ml aliquot of the sterile preparation into the syringe barrel.
3. Remove the needle and re-cap the syringe using a sterile Luer-Lok® tip cap or equivalent. Carefully invert the syringe a few times to insure proper mixing of the aliquot and broth.
4. Place the syringe in a Whirl-Pak®, seal the bag and transport to the incubator.
5. Incubate the syringe at 30 to 35 degrees C. for up to 14 days and examine broth for turbidity and/or growth. If growth is observed the syringe may be discarded. Do not continue to incubate for the full 14 days.

6. Record results on the “Results Log Sheet”.
7. Discard of used materials as biomedical waste.



INTERPRETATION OF RESULTS

The presence of growth or turbidity found during the incubation period indicates gross contamination of the unit tested. Procedures used in the initial preparation and in transportation, storage and handling of the preparation must be re-evaluated. Once corrective action has been identified, it must be implemented and monitored for effectiveness. All corrective action and remediation must be documented.

No growth or absence of turbidity indicates that aseptic technique, procedures, handling, transportation and storage conditions were adequate to protect the compounded preparation from gross contamination.

LIMITATIONS

Rare fastidious organisms may not be capable of growth in Tryptic Soy Broth.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as needles, Luer-Lok® tip caps, thermometers, incinerators, incubators, etc., as well as serological and biochemical reagents are not provided.

QUALITY CONTROL

The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Bacillus subtilis ATCC® 6633	J	1-7 days	20-25ºC, 35ºC	Aerobic	Growth; turbidity
Candida albicans ATCC® 10231	J	1-7 days	20-25ºC	Aerobic	Growth; turbidity
Aspergillus brasiliensis ATCC® 16404	J	1-7 days	20-25ºC	Aerobic	Growth; turbidity

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy

Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

* Refer to the document "Inoculation Procedures for Media QC" for more information.

PHYSICAL APPEARANCE

Tryptic Soy Broth (TSB), Double Strength (DS) should appear clear, and medium amber in color.

REFERENCES

1. *United States Pharmacopeia and National Formulary (USP-NF).* Rockville, MD. United States Pharmacopeial Convention.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

LOG SHEET
RANDOM TESTING

CSP ID #	Date CSP Prepared	Date CSP Tested	Results (Growth/No Growth)	Interpretation (Satisfactory/Corrective Action Required)	Supervisor Signature

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