IFU

Instructions for Use

HARDYVAL™ MTK (MULTIPLE TECHNICIAN VERIFICATION KIT)

Cat. no. HVMTK	HardyVal™ MTK (Multiple Technician Verification Kit)	1 kit
Each kit contains:		
TSB (Tryptic Soy Broth) Red, Ampoule, 3mL		5ea
TSB (Tryptic Soy Broth), USP, 20ml serum vial with needle-port septum, 15mL		5ea
TSB (Tryptic Soy Broth), USP, Bag, 100mL		5ea
Whirl-Pak® Bag		1ea

INTENDED USE

Hardy Diagnostics HardyVal™ MTK (Multiple Technician Verification Kit) is recommended for verification of personal aseptic technique for low and medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for up to five technicians.

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

SUMMARY

High risk manipulations, such as those performed during the manufacture of compounded sterile preparations or used in aseptic transfers performed in environmentally controlled or cleanroom applications, require specified training and routine verification of aseptic skills. Aseptic technique verification is used to verify that personnel have the necessary skills to compound sterile preparations. HardyVal™ MTK (Multiple Technician Verification Kit) is designed for use in performing aseptic technique training or in the routine verification and recertification of aseptic technique.

HardyVal™ MTK contains Tryptic Soy Broth formulated in accordance with the U.S. Pharmacopoeia standard formula for Soybean Casein Digest Broth. Tryptic Soy Broth is widely used for the cultivation of microorganisms from environmental sources; supporting the growth of the majority of bacteria and fungi. 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 microorganisms. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is incorporated as an energy source. The dipotassium phosphate is included in the formulation as a buffer to maintain pH. In addition, the TSB Red, Ampoule component contains an inert red dye to aid in the visual verification of aseptic transfer.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	17.0g
Sodium Chloride	5.0g
Papaic Digest of Soybean Meal	3.0g
Dextrose	2.5g
Dipotassium Phosphate	2.5g

In addition, Tryptic Soy Broth (TSB) Red, Ampoule contains an inert red dye.

Final pH 7.3 +/- 0.2 at 25ºC.

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

Formulated in accordance with USP <62>.[1]

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-25ºC 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. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

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. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

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

PROCEDURE

NOTE: An assessment should be performed to determine if additional supplies or equipment are needed to validate the process when performing complex manipulations or in the verification of aseptic technique. Technicians should be recertified at regular intervals as dictated by laboratory need or determined by the complexity or risk level performed.[1]

Method of Use: Perform procedures in accordance with USP <797>.[1] The steps below outline the basic manipulation when using this product. Modify the procedure below to simulate the most challenging aseptic manipulations

performed at the facility or by the technician. Use appropriate gowning techniques and sanitize or disinfect surfaces and the outside of containers--including ampoules, septa, and bag ports--prior to use. Perform all manipulations inside a laminar airflow clean bench or similar environmentally controlled area using a validated process.

1. Select 20 sterile 18G x 1" needles (or smaller size, as appropriate) and one sterile 3, 5, or 6cc disposable syringe.

2. Aseptically attach a sterile needle to the sterile syringe.

3. Carefully break the top of the ampoule (Cat. no. TSBA) using an ampoule breaker. Draw up the entire volume of the ampoule contents using the syringe.

4. Inject the entire volume of ampoule media into the TSB serum vial (Cat. no. TSB15V) and mix the vial to evenly distribute the contents.

5. Withdraw 1.0mL of media from the TSB serum vial (Cat. no. TSB15V) and aseptically inject this into the port on the TSB Bag (Cat. no. TSB100B).

6. Aseptically change the needle after this exchange to increase the complexity of the manipulations using the "worst case scenario" approach. Use the same syringe throughout the test.

7. Repeat the procedure (in step #5), changing the needle after each transfer from the TSB serum vial (Cat. no. TSB15V) to the TSB Bag (Cat. no. TSB100B), using the remaining needles, as needed. The final transfer should empty the contents of the TSB serum vial (Cat. no. TSB15V) and there will be approximately 118mL in the TSB Bag (Cat. no. TSB100B).

8. Immediately inspect the TSB Bag (Cat. no. TSB100B) for visible particulates, corings, or fibers and note these, if present. The presence of these particles should not be recorded as microbial growth at the end of the test.

9. Label the TSB Bag (Cat. no. TSB100B) and place it in the Whirl-Pak® bag for transport to the incubator. Incubate at 20-25°C or 30-35°C for a total of 14 days in compliance with USP <797>.[(1)]

10. Examine the media daily for turbidity (cloudiness) or the formation of a precipitate or visible signs of growth at the top of the broth. If turbidity, growth or precipitation is observed during the incubation period, this is a positive test and indicative of a failure in aseptic technique. If the media remains clear through the incubation period, this is indicative of a negative test and verification of acceptable aseptic skills.

11. At the end of 14 days, record results and discard the test, as needed.

INTERPRETATION OF RESULTS

Visible growth or turbidity observed on or before 14 days of incubation is a positive test for the presence of microorganisms. If positive, the test has failed and indicates a non-sterile technique was used.

No visible growth or turbidity observed in 14 days indicates a negative result and the technique used during the test was aseptic.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Rare, fastidious microorganisms may not grow on general non-selective media formulations.

Failure to perform gowning procedures or to adequately sanitize or disinfect surfaces or the outside of containers--including ampoules, septa, and bag ports--prior to use may result in growth during the incubation window or a failed test.

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

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as sterile 18G x 1" needles, sterile disposable syringes, ampoule breaker, sterile gauze pads, other culture media, incinerators, incubators, etc., as well as sanitizers and disinfectants are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538	J	24-72hrs	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	24-72hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24-72hrs	30-35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	3-5 days	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	5 days	20-25°C	Aerobic	Growth

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

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 certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

The HardyVal™ MTK (Multiple Technician Verification Kit) contains the following components:

Tryptic Soy Broth (TSB) Red, Ampoule, 3mL should appear clear and red in color.

Tryptic Soy Broth (TSB), USP, 20ml serum vial with needle-port septum, 15mL should appear clear and light amber in color.

TSB, USP Bag, 100mL should appear clear and light amber in color.

***Components inside the kit may have different lot numbers and expiration dates. The expiration date of the

completed kit is based on the component with the shortest shelf life. Quality Control testing was performed on the kit lot components, as stated above.

REFERENCES

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

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RESULTS LOG

Name: _____ Date Test Performed: _____

Signature: _____ Kit lot#: _____ Kit Expiration Date: _____

Date	Sample#	Initials	Hood/ Bench#	Sample/ Process Tested	TSB Bag Lot#	Inoc. Temp[1]	Results		
							Negative	Positive	Organism ID
							Initials/ Date	Initials/ Date	

1. Recommended incubation period is 14 days and incubation temperature is 20-25ºC and/or 30-35ºC per USP <797>

HARDY DIAGNOSTICS

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Ordering Information

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

HDQA 2207H [D]