TRYPTIC SOY AGAR (TSA) WITH LECITHIN AND TWEEN®, USP

Cat. no. W2530	Tryptic Soy Agar (TSA) with Lecithin and Tween®, Irradiated, USP, 15x100mm Plate, 26ml, Double Bagged*	10 plates/bag
Cat. no. G41	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP, 15x100mm Plate, 20ml	10 plates/bag
Cat. no. P34	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP, 15x60mm Contact Plate, 15ml	10 plates/bag
Cat. no. P740	Tryptic Soy Agar (TSA) with Lecithin and Tween®, Irradiated, USP, 15x60mm Contact Plate, TapTight™, 15ml, Triple Bagged*	10 plates/bag
Cat. no. P740R	Tryptic Soy Agar (TSA) with Lecithin and Tween®, Irradiated, USP, 15x60mm Red Contact Plate, 15ml, Triple Bagged*	10 plates/bag

* An additional sterile sample bag is included for packaging after the sample is collected.

INTENDED USE

Hardy Diagnostics Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP is recommended for use as a general growth medium for establishing microbiological trends, alerts and action levels in biologically controlled environments.

The medium is based on Soybean-Casein Digest Agar and is formulated according to the United States Pharmacopoeia (USP) <62> and meets the required USP performance specifications.[1]

SUMMARY

Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP is prepared according to the U.S. Pharmacopoeia standard formula for Soybean-Casein Digest Agar and contains digests of soybean meal and casein, which provide amino acids and other nitrogenous compounds to promote growth. Sodium chloride is added to help cells maintain osmotic equilibrium. Dextrose is added as an energy source. Agar is the solidifying agent. Lecithin and Tween® 80 are added to neutralize the antimicrobial effects of disinfectants or cleaning solutions used on environmental surfaces.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	15.0gm
Peptic Digest of Soybean Meal	5.0gm
Sodium Chloride	5.0gm
Tween® 80	5.0gm
Lecithin	0.7gm
Agar	15.0gm

Final pH 7.3 +/- 0.2 at 25 degrees C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store Cat. no. G41, W2530 and P34 at 2-8 degrees C. away from direct light. Store Cat. no. P740 and P740R at 15-30 degrees C. Media should not be used if there are any signs of deterioration (shrinking, cracking, or 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 applies to the product in its intact packaging when stored as directed.

This product has the following shelf life from the date of manufacture:

90 Days:	G41	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP
	P34	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP
120 Days:	W2530	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP
180 Days:	P740	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP
	P740R	Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP

Refer to the keyword "Storage", in the Hardy Diagnostics' software program HUGO™, for more information on storing culture media.

PRECAUTIONS

This product is for laboratory use only and 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". The "Guideline for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the keyword "Precautions", in the Hardy Diagnostics' software program HUGO™, for more information regarding general precautions when using culture media.

Refer to the keyword "MSDS", in the Hardy Diagnostics' software program HUGO™, for more information on handling potentially hazardous material.

PROCEDURE

Before Use: It is possible that variation in temperature and pressure during shipping and storage may cause condensation on the innermost bag surrounding the product. If condensation of the packaging or plates does occur, remove the plates from the innermost bag in a sterile environment and allow them to dry for 10-15 minutes immediately before use.

The medium should be warmed to room temperature and the surface should be dry prior to use. To reduce the potential for cross-contamination, it is strongly suggested that appropriate gowning and glove procedures, designated aseptic processing areas, appropriate sporicidal disinfectants, and environmental monitoring procedures be strictly followed to reduce the likelihood of accidental contamination.[(1)]

Method of Use: For environmental monitoring procedures, consult USP <1116> *Microbiological Evaluation of Clean Rooms and Other Controlled Environments*.[(1)] Incubate media using appropriate atmospheric, temperature, and duration conditions as outlined by the test method.[(1)] Count the number of colonies and report as the number of colony forming units (CFU).

Sedimentation Plate Method: Place the plate on a clean piece of paper and expose the agar by removing the lid. Do not invert the lid while removed to avoid exposure to falling sediment. Expose the agar for 15 minutes or longer, depending upon established procedures, and replace the lid. Incubate according to laboratory protocol.

Impact Air Sampling Method: Use the plate size specified for the impact air sampling unit. Remove the sampler head and place the plate, lid up, into the slot. Aseptically remove the lid and expose the agar; do not invert the lid while removed to avoid exposure to falling sediment. Place the sampler head back on the unit and turn the unit on; sample a specific volume of air according to laboratory procedure. After sampling, remove the sampler head, aseptically return the lid of the plate and remove the plate from the sampling unit; incubate per laboratory protocol.

Contact Plate Method: Select surface to sample and remove the lid of the plate; do not invert the lid while removed to avoid exposure to falling sediment. Sample the surface by firmly pressing the agar against the test area, using the thumb and second finger to hold the plate, while using the index finger to press the plate firmly and evenly against the base. The same amount of pressure should be used for each sample. Do not twist or move the plate laterally, as this spreads contaminants across the agar surface. A rolling motion may be used when slightly curved surfaces are sampled. Areas to be assayed may be divided into grids or sections, and samples taken from specific areas within these divisions. Incubate per laboratory protocol.

INTERPRETATION OF RESULTS

Consult the appropriate reference for information regarding further testing and identification of microbial cultures.[1]

Because of the inherent variability of environmental sampling methods, it is more useful to trend contamination recovery results rather than focus on the number of colonies recovered from a single sample. Action should be required when the contamination recovery rate trends above the recommended action levels for a significant time.

If action levels have been identified, a thorough investigation into the adequacy of personnel work practices, operational procedures, cleaning procedures and solutions, and air filtration efficiency within the processing area must be made. Once changes have been made, monitoring procedures must be repeated to determine if the changes made were effective. Documentation of all monitoring results, remedial action and follow-up monitoring must be maintained. Consult listed reference for more detailed information concerning plate count methods.[1]

LIMITATIONS

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

Accurate counting may be difficult with molds or spreading colonies.

Sampling challenges may occur with irregular, porous, rough or textured media surfaces.

Contact plate media are not recommended for sampling crevices or irregular surfaces.

Rare fastidious organisms may not grow on Tryptic Soy Agar with Lecithin and Tween®.

Refer to the keyword "Limitations", in the Hardy Diagnostics' software program HUGO™, for more information regarding general limitations on culture media.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, and 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	
Staphylococcus aureus ATCC® 6538	J	≤ 3 days	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	≤ 3 days	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	≤ 3 days	30-35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	≤ 5 days	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	≤ 5 days	20-25°C	Aerobic	Growth
Escherichia coli ATCC® 8739**	J	≤ 3 days	30-35°C	Aerobic	Growth
Salmonella enterica ATCC® 14028**	J	≤ 3 days	30-35°C	Aerobic	Growth

Lots of TSA with Lecithin and Tween® irradiated media are held for seven days to confirm the media meets the validated sterility assurance level (SAL) of 10^{-5} for Cat. no. W2530 and 10^{-6} for P740 and P740R.

* Tested in accordance with USP <61> and <62>.[(1)]

** Organisms not tested on Cat. no. P34.

USER QUALITY CONTROL

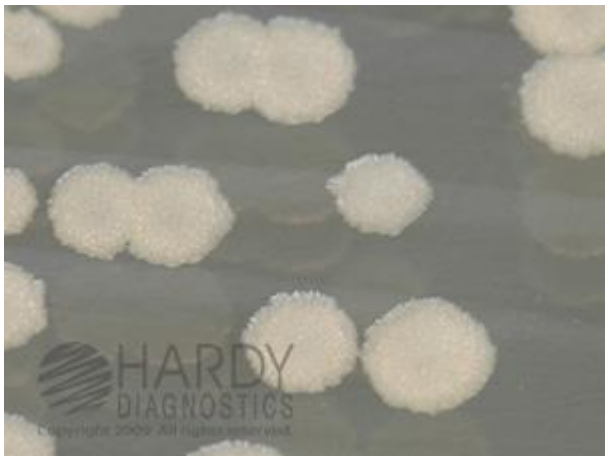
Check for signs of contamination and deterioration. Users of commercially prepared media may be required to perform quality control testing with at least one known organism to demonstrate growth or a positive reaction; and at least one organism to demonstrate inhibition or a negative reaction (where applicable). Refer to the following keywords, in the Hardy Diagnostics' software program HUGO™, for more information on QC: "Introduction to QC", "QC of Finished

Product", and "The CLSI (NCCLS) Standard and Recommendations for User QC of Media". Also see listed references for more information.[1]

Physical Appearance

Tryptic Soy Agar (TSA) with Lecithin and Tween®, USP should appear clear to slightly hazy and light amber in color.

Candida albicans (ATCC® 10231) colonies growing on TSA with Lecithin and Tween® (Cat. no. G41). Incubated aerobically for 24 hours at 35 deg. C.



Bacillus subtilis (ATCC® 6633) colonies growing on TSA with Lecithin and Tween®(Cat. no. G41). Incubated aerobically for 24 hours at 35 deg. C.

Uninoculated plate of TSA with Lecithin and Tween® (Cat. no. G41).

REFERENCES

1. *United States Pharmacopoeia 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.