

PRODUCT INSERT
LyfoCults® Plus Quant



INTENDED USE

LyfoCults® Plus Quant are ready-to-use vials containing stabilized, lyophilized, viable microorganisms in an easy to use format at an assayed CFU level of <100 per two drops from the device or 0.1 ml of the prepared suspension. These organism preparations meet the US Pharmacopoeia recommendations for use in growth promotion studies and other applications for validation of performance of culture media in industrial settings.

SUMMARY AND EXPLANATION

Drying of organisms for maintenance and preservation has improved over the recent years. Original methods were time consuming and labor intensive. Later developments simplified the process, making it a cost effective alternative to organism maintenance.¹⁻³ LyfoCults® Plus Quant are a modification of the standard lyophilization formulation to produce an easy to use, cost effective and reliable organism suspension.

PRINCIPLE

Ingredients used in preparing the suspensions preserve and protect the microorganisms for use when needed. Following the recommended rehydration procedure, they are immediately ready to use to provide a growth promotion challenge of <100 CFU's per two drops or 0.1 ml of the prepared suspension.

REAGENTS*

LyfoCults® Plus Quant - Active Ingredients:

Assayed microorganism population		
Albumin	Ascorbic Acid	Dextrose
Glycerol	Mannitol	Gelatin
Skim Milk	Tryptic Soy Broth	Trehalose
Rehydration Ampoule: 1.3 ml, 0.45% Saline		

*Adjusted as required to meet performance standards.

PRECAUTIONS

LyfoCults® Plus Quant are for use as described in US Pharmacopoeia guidelines. They are for use in adequately equipped microbiology laboratories and by properly trained individuals who are familiar with laboratory procedures necessary for working with infectious materials.

LyfoCults® Plus Quant contain viable organisms and are potentially infectious. All organism containers and subsequent cultures should be handled according to appropriate CDC/NIH Biosafety Level guidelines and disposed of according to OSHA and local biohazard disposal regulations.⁴

STORAGE

LyfoCults® Plus Quant should be stored in their original unopened containers at 2-8°C until used or until expiration. When stored properly, organisms will retain viability until the expiration date. **bioMerieux does not recommend freezing or reusing LyfoCults® Plus Quant after they are initially rehydrated and does not warrant the product if reuse occurs or used after the expiration date.**

PRODUCT DETERIORATION

Each LyfoCults® Plus Quant should contain a milky-beige pellicle at the bottom of the container. This product should not be used if there are any signs of deterioration such as premature rehydration, color change, or damage to the container or outer package.

MATERIALS REQUIRED BUT NOT SUPPLIED

The LyfoCults® Plus Quant requires standard microbiological supplies such as loops or spreading devices. Plating media and other equipment are not provided.

PROCEDURE (See illustrations)

1. Allow the device to come to room temperature in the pouch. Remove label from the pouch and place on culture media. Tear open foil pouch at notch and remove LyfoCults® Plus Quant device.
2. Remove the protective wrap using the red tear strip.
3. Carefully unscrew applicator from vial to vent, and activate ampoule by squeezing button firmly.
4. With the applicator at a slight angle to the vial, carefully and slowly squeeze the ampoule, dispensing all of the hydration fluid into the vial.
5. Re-insert applicator into vial and gently mix from side-to-side. **DO NOT INVERT.** Immediately prior to use, vortex the vial for 5-10 seconds to achieve a homogeneous suspension. Aspiration can be used as an alternate method. To mix by aspiration, loosen the ampoule device and holding the vial at a slight angle, aspirate and expel the suspension repeatedly until the suspension appears homogeneous. The suspension must be used within 30 minutes after rehydration.
6. Holding the ampoule device vertically, place 2 drops of resulting suspension on culture media. (Alternatively, a calibrated pipette may be used to dispense 0.1 ml to the media.)

TROUBLE SHOOTING GUIDE

All LyfoCults® Plus Quant lot preparations are quality control tested prior to release to ensure product specifications are met. When reconstituted according to the Product Insert, final suspensions will yield concentrations of <100 CFU per 2 drops or 0.1 ml. Should the product yield results outside of this range, the following should be considered as possible causes.

PROBLEM	POSSIBLE CAUSE	RECOMMENDATIONS
NO RECOVERY	1) Use of inappropriate or selective media	Not all media will support the growth of all microorganisms. Please check the manufacturer's insert for appropriate organism use. Selective media may inhibit recovery of the organism partially or completely (even if appropriate for that organism).
	2) Incorrect incubation time, temperature or atmosphere	Verify that all incubators are at appropriate temperatures, and that incubation time, temperature and atmosphere are correct for the organism being cultured.
	3) Improper storage of organism devices	LyfoCults® Plus Quant should be stored in their original containers at 2-8° C. Desiccant packages must not be removed. Equilibration to room temperature must be done before opening. If this step is not done, condensation may collect in the vial and combined with oxygen can produce free radicals which may result in reduction in recovery of the lyophilized organisms.
	4) Used beyond 30 min after rehydration	The Product Insert states that the suspension must be used within 30 min. of rehydration. Use beyond this period may result in erroneous results.
HIGH RECOVERY	1) Insufficient Mixing	Suspension should appear homogeneous with no visible clumps.
	2) Addition of more than 2 drops or greater than 0.1 ml of solution	LyfoCults® Plus Quant are designed to deliver <100 CFU per 2 drops or 0.1 ml. Assure that the device is held vertically when dispensing drops or that pipettes are calibrated to deliver 0.1 ml.
	3) Used beyond 30 min after rehydration	The instructions for use in the Product Insert states that suspension must be used within 30 min of rehydration. Use beyond this period may result in erroneous results.

Should recovery fall outside the expected range or for additional technical support, please contact bioMerieux Technical Support at 800.634.7656 or e-mail csi.stl@biomerieux.com for assistance.

PROCEDURE (continued)

7. Spread the suspension over the media and incubate in appropriate atmosphere.

8. Discard used LyfoCults® Plus Quant in an appropriate biohazard receptacle. Appropriate quality control for growth promotion and other testing should be performed as described by the US Pharmacopoeia or as defined in other recommended guidelines or internal laboratory procedures.

QUALITY CONTROL

Each lot number has been tested and approved using standard microbiological techniques and procedures. When using this product for growth promotion testing, follow USP Guidelines. If the rehydrated culture fails to yield the expected results, either in quantity or growth characteristics that are typical for the specific reference microorganism strain, then the product should not be used.

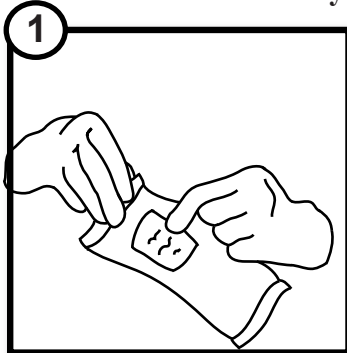
LIMITATIONS

These organisms are not intended or warranted for use on inhibitory or selective media and may not perform as expected.

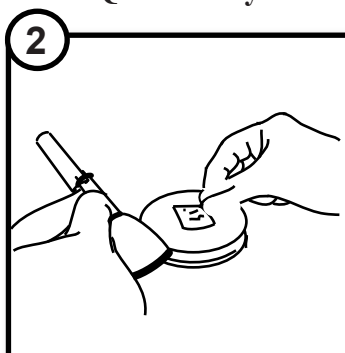
REFERENCES

1. Stamp, Lord, *J. Gen. Microbiology*, 1947, 1:251-265.
2. Annear, D.I., *Austral. J. Exp. Biol*, 1958, 36:211-222.
3. Obara, Y. S., et al, *J. Clin Microbiology*, 1981, 14:61-66.
4. Richmond, J.Y. and R. W. McKinney; CDC/NIH Manual, Biosafety in Microbiological and Biomedical Laboratories 4th Edition, U. S. Dept. of Health and Human Services, Washington, D.C., 1999.

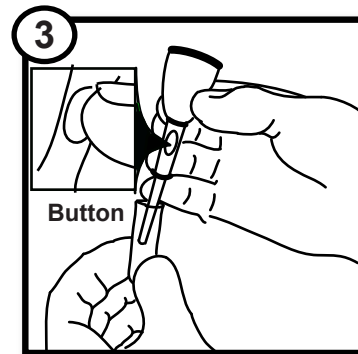
LyfoCults® Plus Quant Rehydration Instructions



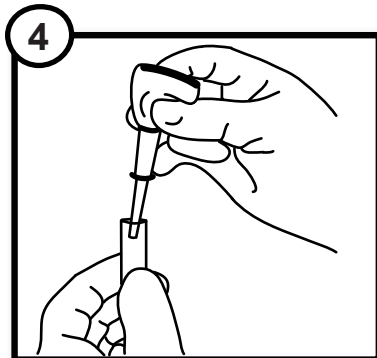
Allow device to come to room temp. Open foil pouch at notch. Remove label and LyfoCults® Plus Quant device.



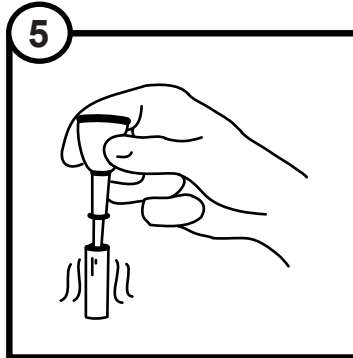
Place label on culture media. Remove the protective wrap from device using the red tear strip.



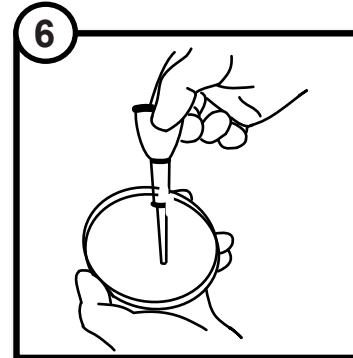
Activate ampoule by squeezing button firmly.



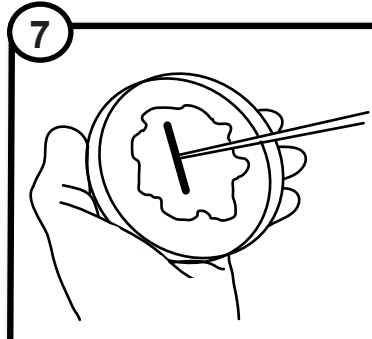
With the applicator at a slight angle to vial, squeeze ampoule dispensing all of hydration fluid into vial.



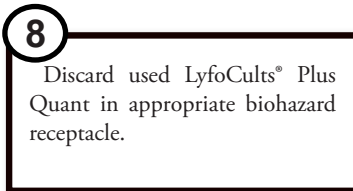
Re-insert applicator into vial, gently mix from side-to-side. **DO NOT INVERT.** Immediately prior to use, vortex the vial for 5-10 seconds to achieve a homogeneous suspension. Aspiration can be used as an alternate method. To mix by aspiration, loosen the ampoule device, hold vial at a slight angle, aspirate and expel the suspension repeatedly until the suspension appears homogeneous.



Using the applicator as a transfer pipette, hold vertical and place 2 drops of suspension on culture media. Alternately, use a calibrated pipette to dispense 0.1 ml. Use within 30 min of rehydration.



Spread the suspension over the media and incubate in appropriate atmosphere.



Discard used LyfoCults® Plus Quant in appropriate biohazard receptacle.

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