



This lot of product meets the accepted performance criteria recommended in the USP and in compliance with ISO 11138-1.

PRODUCT NAME: Quality Control Suspension

FOR USE IN MONITORING: Growth Capabilities

ORGANISM: *Staphylococcus aureus*, ATCC® 6538

LOT	010121		2021-01-01		2021-04-01
REF	USA-01	POPULATION:		≤100 Colony Forming Units/0.1 mL	
Number of Passages: 5		VOLUME:		10 mL each vial	

Instructions for Use

1. Manually shake or vortex Vial of Suspension.
2. Remove cap, insert pipette or insert syringe through cap septum and withdraw 0.1 mL of Suspension.
3. Deposit Suspension in Fluid Thioglycollate or Soybean Casein Digest tube of broth.
4. Repeat process in steps 1 – 3 until the target number of tubes is achieved.
5. For a Positive Control, deposit 0.1 mL of Suspension in a previously accepted lot of media.
6. An un-inoculated tube of media can serve as a Negative Control.
7. Incubate tubes at 30-35°C for 2 – 3 days.
8. Evaluate tubes for growth as evidenced by turbidity and/or formation of cream sediment in the tube.
9. Interpretation of Results:
 Growth of the organism in the inoculated tubes = Pass, media is capable of supporting growth
 Growth in Positive Control = Pass
 No Growth in the Negative Control = Pass

Storage and Shelf Life			
	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
Shelf-life	3 Months from the date of manufacture.		
	Do not use damaged vials of Spore Suspension. Do not use after expiration date. Spore Suspensions contain live cultures and should be handled with care.		

Dispose: Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

QUALITY ASSURANCE APPROVAL

June 16, 2021
DATE