

# AG- Bacteriology Control Strain (Lyophilized) - IFU

## INTENDED USE:

Lyophilization is a recommended method for long-term preservation of microorganisms.

Astragene's Bacteriology control strains are lyophilized cultures intended to be used for quality control of culture media.

The microorganisms are lyophilized in a suitable suspension buffer that acts as a lyo-protectant, preserving the integrity of the microbial cell wall during the freeze-drying process.

Astragene's lyophilized Microbial Control Strains are manufactured under ISO 13485 certification, GMP accreditation and represent a direct minimal-passage descendant of the original material ensuring a top-quality, and fully characterized strain. With Astragene's Control Strains you can rely on identification and strain characterization to establish identity, viability, and purity. The lyophilized strain could be utilized as a seed stock to minimize subculturing, antimicrobial resistance research, drug development, enteric disease research, and infectious disease research.

## PRODUCT DESCRIPTION:

Astragene's Bacteriology Control Strain (Lyophilized) is contained in a vacuum sealed 10ml vial capped with a rubber stopper and crimp sealed. Also, 1ml of reconstituting reagent is provided per sample. Each lyophilized microorganism preparation is less than or equal to two passages from the reference culture. Refer annexure 1 for list of ATCC strains equivalent to the World Data Centre for Microorganisms (WDCM).

## STORAGE & STABILITY:

Store the lyophilized AG- Bacteriology Control Strain at 2°C to 8°C in the original, sealed vial.

Stored as directed, the lyophilized microorganism preparation will retain viability until the expiration date stated on the device label, its specifications and performance within the stated limits.

AG- Bacteriology Control Strain should not be used if it was stored improperly, if there is evidence of excessive exposure to heat or if the product has passed its expiry.

## DIRECTIONS FOR USE:

- Remove AG- Bacteriology Control Strain vial from 2°C to 8°C storage and allow the unopened vial to reach the room temperature.
- Aseptically hydrate the entire lyophilized material using 500µl of reconstituting reagent in a biosafety cabinet.
- Take a sterile inoculating loop, immerse it into the hydrated culture and plate it onto an appropriate Agar/Slant (see Annexure 1)
- Inoculate the primary culture plate(s) by using a 10µl loop and streak to facilitate colony isolation.
- Using proper biohazard disposal, discard the remaining hydrated material.
- Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

## WARNING & PRECAUTIONS:

- For *In vitro* diagnostic use only.
- For professional use only.
- Directions should be read and followed carefully.
- It is not intended for any animal or human therapeutic use, any human or animal consumption
- Safety precautions should be taken in handling, processing and discarding all clinical specimens.
- Samples should be processed in the correct containment level conditions.
- Dispose of all material in accordance with local regulations.

### Annexure 1

Product Name	ATCC	NCTC	WCDM	Preferred media for strain isolation
<i>Aspergillus niger</i>	ATCC 16404	NCPF 2275	NA	Sabouraud Dextrose Agar
<i>B. cepacia</i>	ATCC 25416	NCTC 10743	NA	Burkholderia Cepacia Selective Agar
<i>Bacteroides ovatus</i>	ATCC 1296	NA	NA	CDC anaerobic blood agar
<i>B. subtilis</i>	ATCC 11778	NCTC 10320	NA	Tryptic Soy Agar
<i>Candida albicans</i>	ATCC 10231	NCPF 3179	NA	Sabouraud Dextrose Agar

<i>Candida albicans</i>	ATCC 14053	NA	00054	Sabouraud Dextrose Agar
<i>C. jejuni</i>	ATCC 33291	NCTC 13367	00005	Camphylobacter blood agar
<i>Clostridium perfringens</i>	ATCC 13124	NCTC 8237/6125	00007	Thioglycolate broth
<i>Clostridium septicum</i>	ATCC 12464	NCTC 547	NA	Sheep Blood agar
<i>Enterococcus casseliflavus</i>	ATCC 700327	NA	NA	Sheep blood Agar
<i>E coli</i>	ATCC 8739	NCTC 12923	00012	Mac conkey Agar
<i>Escherichia coli</i>	ATCC 25922	NCTC 12241	00013	Mac conkey Agar
<i>Eikenella corrodens</i>	ATCC 1152	NA	NA	Chocolate Agar
<i>Enterococcus faecalis</i>	ATCC 29212	NCTC 12697	00087	Mac conkey Agar
<i>Enterobacter hormaechei</i>	ATCC 700323	NCTC 13870	NA	Hektoen Enteric agar
<i>Hemophilus influenzae</i>	ATCC 10221	NCTC 13377	NA	Haemophilus Agar
<i>Issatchenkia orientalis</i>	ATCC 6258	NA	NA	Sabouraud Dextrose Agar
<i>Klebsiella pneumoniae</i>	ATCC 2814	NA	NA	Mac conkey Agar
<i>Klebsiella Pneumoniae ESBL</i>	ATCC 700603	NCTC 13870	NA	Mac conkey Agar
<i>L.anisa</i>	ATCC 35292	NCTC 11974	00106	Legionella selective media
<i>L.pneumophila</i>	ATCC 33152	NCTC 11192	00107	Legionella selective media
<i>MRSA</i>	ATCC 43300	NCTC 13373	00211	Chrome MRSA agar
<i>Neisseria gonorrhoeae</i>	ATCC 43069	NA	NA	GC/ Martin Lewis Agar
<i>Neisseria meningitidis</i>	ATCC 13090	NCTC 10026	NA	GC/ Martin Lewis Agar
<i>P.aeruginosa</i>	ATCC 9027	NCTC 12924	00026	Cetrimide agar
<i>Pseudomonas Aeruginosa</i>	ATCC 27853	12903	00025	Cetrimide agar
<i>Proteus mirabilis</i>	ATCC 12453	NA	NA	Xylose-lysine-deoxycholate
<i>Proteus vulgaris</i>	ATCC 8427	NA	NA	Xylose-lysine-deoxycholate
<i>Staphylococcus aureus</i>	ATCC 6538	10788	00193	Mueller Hinton Agar
<i>Staphylococcus Aureus</i>	ATCC-29213	12973	00131	Mac conkey Agar
<i>Stenotrophomonas Maltophilia</i>	ATCC 17666	NA	NA	Mac conkey Agar
<i>Streptococcus pneumoniae</i>	ATCC 6305	NA	NA	Sheep blood Agar
<i>Streptococcus Pneumoniae</i>	ATCC 49619	NCTC 12977	NA	Sheep blood Agar
<i>Streptococcus pyogenes</i>	ATCC 19615	NCTC 12696	NA	Sheep blood Agar
<i>Salmonella typhimurium</i>	ATCC 14028	NCTC 12023	00031	Salmonella Shigella Agar
<i>Shigella. Flexneri</i>	ATCC 12022	NCTC 12698	00126	Salmonella Shigella Agar
<i>V.parahemolyticus</i>	ATCC 17802	NCTC 10903	00037	Thiosulphate Citrate Bile salts Agar
<i>Staphylococcus Saprophyticus</i>	ATCC15305	NCTC 7292	15305	Mannitol salt agar
<i>Others as applicable</i>				

**SYMBOLS:**


Do not use if package is damaged



Manufacturer



Batch Code



CE mark of Conformity



Refer to the instructions



ISO



GMP


 AstraGene FZ LLC, Office No. 208 – 209, Dubai Science Park Building, Dubai, United Arab Emirates  
 +971-4-8781222, [contact@astragene.com](mailto:contact@astragene.com)