



## TECHNICAL DATA SHEET

**DESCRIPTION** TSA AIRCHECK® P – PENASE IRR 3 X WRAP VHP, 90MM PLATES

**SGL PRODUCT CODE** 5403

Tryptone Soya Agar (TSA) Aircheck® P, also known as casein soya bean digest agar, is a medium primarily designed to recover a wide range of micro-organisms as described in the European Pharmacopoeia (EP) 2.6.12 and United States Pharmacopeia (USP) <61>. The medium contains Penase, a  $\beta$  lactamase designed to inactivate penicillin and allow microbial growth. The 90mm diameter plates are triple wrapped and irradiated to ensure sterility and intended for use in cleanroom environments.

### FORMULATION

Typical product composition\*:

COMPONENT	WEIGHT / VOLUME
Pancreatic digest of casein	15.0 g
Papaic digest of soya bean	5.0 g
Sodium chloride	5.0 g
Agar	15.0 g
Penase	250 IU
Purified water	1000 ml

\*Product may be adjusted and/or supplemented to meet performance criteria

### QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Clear, pale straw coloured gel
pH at 20-25°C	7.3 $\pm$ 0.3

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for at least 5 days	No growth detected
Incubation at 30-35°C for at least 5 days	No growth detected



<b>GROWTH PROMOTION / INHIBITION TESTS</b>	<b>SPECIFICATION CRITERIA</b>
<i>Staphylococcus aureus</i> ATCC 6538 NMT 100 CFU inoculum	50-200% CFU recovery compared to control at 30-35°C incubation after not more than 3 days
<i>Pseudomonas aeruginosa</i> ATCC 9027 NMT 100 CFU inoculum	50-200% CFU recovery compared to control at 30-35°C incubation after not more than 3 days
<i>Bacillus subtilis</i> ATCC 6633 NMT 100 CFU inoculum	50-200% CFU recovery compared to control at 30-35°C incubation after not more than 3 days
<i>Candida albicans</i> ATCC 10231 NMT 100 CFU inoculum	50-200% CFU recovery compared to control at 30-35°C incubation after not more than 5 days
<i>Aspergillus brasiliensis</i> ATCC 16404 NMT 100 CFU inoculum	50-200% CFU recovery compared to control at 30-35°C incubation after not more than 5 days

NMT = Not more than

NLT = Not less than

CFU = Colony forming units

<b>PENASE ACTIVITY TEST</b>	<b>SPECIFICATION CRITERIA</b>
Neutralisation of Penicillin 250µmol/L	Neutralisation of Penicillin detected

Additional specification testing may be performed as requested by the customer.

Manufactured in compliance with ISO 9001 (Ref No FM37824).