

## Instructions for Use

REF - PP2210

**Actinomyces Agar**

Pre-Poured Media

### 1. Intended Use

For *in vitro* diagnostic use only. PP2210 Actinomyces Agar is a selective medium for the isolation of *Actinomyces* spp. from clinical specimens.

### 2. Composition\*

<u>Ingredient</u>	<u>g/L</u>
Peptone mix	23.0
Vitamin K	0.001
Sodium chloride	5.0
Soluble pyrophosphate	0.25
Soluble starch	1.0
Sodium succinate	0.5
Agar	12.0
Sodium bicarbonate	0.4
Glucose	1.0
Sodium pyruvate	1.0
Metronidazole	0.006
L-cysteine HCl	0.5
Nalidixic acid	0.02
L-arginine	1.0
Haemin	0.01
Defibrinated horse blood	70.0ml

\*Adjusted/supplemented as needed to meet performance requirements

### 3. Summary and Explanation

*Actinomyces* species cause the chronic disease, actinomycosis. However, some *Actinomyces* species are opportunistic pathogens and are associated with other mixed anaerobic infections and in infections in severely compromised patients<sup>(1)</sup>. For *in vitro* growth *Actinomyces* spp. require an enriched medium, and growth is enhanced with added carbon dioxide. Anaerobic conditions are favoured but some species can be cultured aerobically or in air plus 5% CO<sub>2</sub>. Colonies may appear after 3-7 days of incubation, but detection may require 10-14 days incubation.

PP2210 is recommended as a selective isolation medium for *Actinomyces* species by UK Standards for Microbiology Investigations<sup>(2 3 4)</sup>.

### 4. Principle

Actinomyces agar is based on Fastidious Anaerobe Agar that has been enriched with 7% defibrinated horse blood and made selective by the addition of nalidixic acid to inhibit most aerobes (particularly Gram-negative bacilli) and metronidazole to suppress other anaerobes. The formulation of PP2210 is complex and includes detoxification agents (starch and sodium bicarbonate) and growth enhancing agents (L-cysteine, arginine, vitamin K, sodium succinate, glucose and pyrophosphate), as well as haemin. The peptone is the source of the required nitrogen, carbon and vitamins. Glucose also acts as a carbon source and sodium pyruvate as an energy source. Sodium chloride maintains the osmotic balance in the medium. Sodium pyrophosphate acts as a buffering agent.

### 5. Physical Characteristics

	Medium
Appearance and Colour	Dark red firm gel
pH	7.2 ± 0.2

### 6. Materials Provided

PP2210 Actinomyces Agar is supplied in packs of 10 x 90mm P090 Petri dishes (18-22ml fill) (product code: PP2210-P090); each plate is ink-jet printed with (abbreviated) product name, product code, lot number and expiry date.

### 7. Materials Needed but not Provided

Standard microbiological laboratory materials e.g., sterile loops or swabs, collection containers, incubators, and quality control organisms.

## 8. Specimens

PP2210 Actinomyces Agar is suitable for the testing of the following specimens:

- Clinical Specimens: Samples for the testing and isolation of anaerobic bacteria may include swabs from the infected areas, biopsy material, pus, bone, and blood.

Sampling and transport equipment must be used in accordance with the end user's suppliers' recommendations. Refer to appropriate standard method or local guidance on sample collection and subsequent processing.

## 9. Test Procedures and Interpretation of results

Allow the plates to come to room temperature.

Based on sample type and information provided, check to see if the specimen needs to be pre-enriched prior to inoculation to the prepared medium.

Inoculate plated media directly with the sample, or subculture onto plated media after incubation in enrichment broth where required.

### Clinical Specimens:

Inoculate specimen, or pre-enriched sample, directly onto the medium and streak across the agar surface using a sterile loop or automated plate streaker. Incubate anaerobically at  $37 \pm 1^\circ\text{C}$  for 5-10 days.

After incubation, examine agar for colonies. Perform further biochemical, serological, or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

## 10. Quality Control

Organism	Incubation	Result (Specificity)
<i>A. israelii</i> (NCTC 10236)	Anaerobically at $37 \pm 1^\circ\text{C}$ for 72-120 hours.	Growth: Pale yellow colonies
<i>E. coli</i> (NCTC 12241)	Anaerobically at $37 \pm 1^\circ\text{C}$ for 72-120 hours.	Inhibited
<i>C. perfringens</i> (NCTC 8237)	Anaerobically at $37 \pm 1^\circ\text{C}$ for 72-120 hours.	Inhibited

It is the responsibility of the user to perform Quality Control testing taking into consideration the intended use of the medium and in agreement with any local relevant guidelines (e.g., frequency, strains used, atmosphere, incubation temperature).

## 11. Performance

To fully verify PP2210 Actinomyces Agar performance, samples were tested to assess colony morphology and recovery level (where an acceptable range is  $\geq 50\%$  and  $\leq 120\%$ ) compared to a non-selective reference medium. Samples were inoculated with 30-150cfu for the target organisms and  $10^4$ - $10^5$  cfu for the non-target organisms then incubated at anaerobically at  $37 \pm 1^\circ\text{C}$  for 72-120 hours. All samples showed expected recovery and morphology of the required test organism: *Actinomyces israelii* (NCTC 10236), and no recovery of the non-target test organisms: *Escherichia coli* (NCTC 12241) and *Clostridium perfringens* (NCTC 8237). Therefore, it can be concluded that PP2210 Actinomyces Agar, meets performance criteria when used according to the instructions outlined above. Trend analysis data available upon request.

## 12. Limitations of the Media

- Due to natural variation, some strains may grow poorly on this medium.
- It is recommended that biochemical and/or serological tests be performed on colonies from pure culture for complete identification.

## 13. Precautions and Warnings

This product is considered non-hazardous under CLP regulations. Wear such PPE as recommended by laboratory COSHH assessment. During and after use, always handle all materials in a manner conforming to Good Laboratory Practices and consider that material under test should be regarded as a potential biohazard if mishandled.

Refer to E&O Poured Plate Material Safety Data Sheet.

## 14. Storage conditions and Shelf life

Store PP2210 in the original packaging between 2 and  $8^\circ\text{C}$  in the dark. Kept under these conditions it may be used up to date of expiry shown on product label.

Dispose of in accordance with local and national authority requirements. Do not use media if it is contaminated, discoloured, out of date, cracked or a precipitate is present. Additionally, do not use media if it has been stored inappropriately or the packaging has been damaged.

## 15. References

1. Bowden, G. (1996) *Actinomyces, Propionibacterium propionicus, and Streptomyces*. Medical Microbiology. 4th ed. Galveston (TX): University of Texas Medical Branch at Galveston.
2. Public Health England (2018) Investigation of pus and exudates. UK Standards for Microbiology Investigations. Bacteriology, B 14(6.2). London: Standards Unit, Microbiology Services.

3. Public Health England (2018) Investigation of tissues and biopsies from deep-seated sites and organs. UK Standards for Microbiology Investigations. Bacteriology, B 17(6.3). London: Standards Unit, Microbiology Services.
4. Public Health England (2024) Identification of Anaerobic Actinomyces species. UK Standards for Microbiology Investigations. Bacteriology – Identification, ID 15(3). London: Standards Unit, Microbiology Services’

**Version History\***

- 001 28/03/2023 - New document created
- 002 03/03/2026 - Added additional SMI references, updated colour and performance section to harmonise with QCR

\*Note: minor typographical, grammatical, and formatting changes are not included in the revision history.













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IFU/PP2210 REV. 002

**TABLE OF APPLICABLE SYMBOLS**

 REF Catalogue number	 LOT Batch code	 IVD In vitro Diagnostic Medical Device	 Manufacturer	 Use by
 Temperature limitation	 Contents sufficient for <n> tests	 Consult Instructions for Use	 Keep away from direct light	 Store in a dry place