SSI DIAGNOSTICA

Instructions for use

BACTERIAL STRAINS

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For *in vitro* diagnostic use

Intended use

The bacterial strains are intended to be used for research or as negative/positive controls for serotyping of antigens. For use by clinical laboratories by their established procedures. The analytical and clinical performance has not been established by manufacturer.

Description

The bacterial strains are supplied in either agar or as freeze-dried strains.

Strains in agar

E. coli and *Salmonella* strains are delivered in extract agar in either a sealed glass tube or in a cryogenic vial.

Streptococcal strains are delivered in Stuart transport medium.

Each strain has been grown on a non-selective agar plate overnight and the serotype verified with SSI Diagnostica specific antisera.

Freeze-dried strains

Pneumococcus and *Streptococcus* strains are freeze dried in Tod Hewitt broth or Brain Heart Infusion broth.

Each strain has been grown on a 5-10% blood agar plate overnight and the serotype verified with SSI Diagnostica specific antisera.

SSI Diagnostica bacterial strains are for use by laboratory professionals and/or healthcare professionals only.

Principle

Strains in agar

The bacterial strains have been QC tested as negative/positive controls for serotyping. The strains can be subcultured directly from the transport medium.

Freeze-dried strains

The strains are grown in serum broth overnight, and the serotype is verified by SSI Diagnostica specific antisera.

1 mL of the broth is afterwards dispensed in an ampoule and freeze-dried. The strains have been QC tested as negative/positive controls for serotyping.

Precautions

- Once an ampoule has been opened the freeze-dried bacteria cannot be stored but must be used immediately.
- Stuart transport medium - the strain should be subcultured or transferred to a storage medium immediately upon receipt.

Materials provided

Bacterial strains from SSI Diagnostica are supplied as 1 mL white powder in 5 mL ampoules or as extract agar in 2 mL vials.

Materials required but not provided

- Biological safety cabinet
- Gloves
- Inoculation needle or loop

Additional materials for *E. coli* and *Salmonella* on agar

- Non-selective agar plate (eg. beef extract agar)
- Incubator (35-37 °C)

Additional materials for *Streptococcus* on agar

- 5-10% blood agar plates
- Agar plate (selective)
- Storage medium
- 5% CO_2 incubator 35-37 °C (CO_2 is recommended but a normal incubator can be used)

Additional materials for freeze-dried strains:

- Todd Hewitt broth or Brain Heart Infusion broth
- 5-10% blood agar plate
- 70% Ethanol
- Gauze
- Sharp file
- Sterile pipette
- Biological safety cabinet
- 5% CO_2 incubator 35-37 °C (CO_2 is recommended but a normal incubator can be used)

Storage and stability
The product is to be stored in accordance with the established procedures of clinical laboratories. No storage information is provided

Sample collection and storage
Not relevant

Quality control
Quality control must be performed in accordance with established procedures by clinical laboratories.

Procedure
All strains and subsequent cultures must be regarded as potentially pathogenic and must be handled by persons trained in microbiological techniques. The working facilities should be classified according to the biosafety level 2. All ampoules should be wiped with ethanol solution before opening.

Work in a biological safety cabinet and wear gloves.

All waste should be handled and discarded as infected material.

Strains in agar

1. Let the container reach room temperature.

2. Remove the lid from the container.

3. Transfer aseptic bacterial material to a non-selective agar plate and a selective agar plate, by leading an inoculation needle/loop into the extract agar. For Stuart Transport medium use the inoculation pen from the tube.

4. Incubate the agar plates for 18-24 hours at 35-37 °C.

5. Inspect the agar plates for pure growth and serotype the isolate.

6. From the pure agar plate culture spread bacterial material on a new non-selective agar plate.

7. Incubate the agar plate for 18-24 hours at 35-37 °C.

8. Subsequent subcultures can be made from this agar plate.

Freeze-dried strains

1. Scratch using a sharp file on the narrow part of the ampoule approximately 0.5 cm from the top of the ampoule.

2. Wet a piece of gauze with 70% ethanol and disinfect the ampoule.

3. Wrap the gauze around the ampoule and break the glass at the scratched area. Be careful as this might leave sharp glass edges.

4. Discard the top of the ampoule as biological waste.

5. Add aseptically 1 mL Todd Hewitt or Brain Heart Infusion broth using a sterile pipette to the freeze-dried material in the ampoule and mix well.

6. Transfer the entire bacterial suspension to 7 mL preheated (35-37 °C) Todd Hewitt or Brain Heart Infusion broth.

7. Incubate the broth overnight at 35-37 °C in a 5% CO_2 incubator.

8. Next day transfer one drop of the bacterial suspension to a 5-10% blood agar plate and spread.

9. Incubate the agar plate for 18-24 hours at 35-37 °C in a 5% CO_2 incubator.

10. Next day inspect the blood agar plate for pure growth and serotype the isolate.

11. Subsequent subcultures can be made from the blood agar plate.

Interpretation of results

Not relevant

Disposal

All waste should be handled and discarded as infected material.

Limitations

Not relevant

Performance

Not relevant

Reproducibility
Not defined

Incident reporting
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Quality certificate
SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485. Certificate of analysis can be downloaded from our website: ssidiagnostica.com

IVD

REF

For the list of products and composition, see our website:
- https://ssidiagnostica.com/international/solutions/bacterial-strains/

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