LYSOSTAPHIN TEST KIT

INTENDED USE
Remel Lysostaphin Test Kit is recommended for use in qualitative procedures to differentiate between Staphylococcus spp. and Micrococcus spp.

SUMMARY AND EXPLANATION
In 1964, Schindler and Schuhardt isolated lysostaphin, an extracellular enzyme, from Staphylococcus staphylolyticus.1 Lysostaphin was found to lyse the cell wall of other species of Staphylococcus but not Micrococcus spp. Klesius and Schuhardt further demonstrated the use of lysostaphin in the isolation of polymerized DNA.2 Schleifer and Kloos used an agar overlay technique to demonstrate lysostaphin activity and differentiate Staphylococcus spp. from Micrococcus spp.3 In further testing, Geary and Stevens evaluated a rapid lysostaphin test which reliably differentiated staphylococci (sensitive) from micrococi (resistant) in 2 hours.4

PRINCIPLE
Lysostaphin is an endopeptidase which cleaves the interpeptidic pentaglycin bridges in the cell wall of staphylococcal peptidoglycan. The sensitivity of various strains of staphylococci is dependent on the contents of the interpeptidic bridge. Staphylococcus saphrophilicus, Staphylococcus haemolyticus, and Staphylococcus hominis have been found to be less susceptible than Staphylococcus aureus to lysostaphin due to the serine contained in their interpeptide bridge. These cross bridges are found in all staphylococci but not in micrococi.

REAGENTS (CLASSICAL FORMULA)*
Sodium Chloride USP (CAS 7647-14-7)..........................................................8.5 g
Sodium Phosphate Dibasic (CAS 7558-79-4)..............................................1.096 g
Sodium Phosphate Monobasic (CAS 7558-80-7)..........................0.315 g
Lysostaphin (CAS 9011-93-2)..........................................................0.050 g
Glacial Acetic Acid Buffer (CAS 64-19-7).........................................100.0 ml
Demineralized Water (CAS 7732-18-5)............................................1000.0 ml

*Adjusted as required to meet performance standards.

PRECAUTIONS
This product is for In Vitro diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

STORAGE
Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

PRODUCT DETERIORATION
This product should not be used if (1) the color has changed, (2) the expiration date has passed, or (3) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT
Specimens should be collected and handled following recommended guidelines.5,6

MATERIALS SUPPLIED
(1) Lysostaphin Solution and (2) Phosphate Buffer.

MATERIALS REQUIRED BUT NOT SUPPLIED

PROCEDURE
Reconstitute Lysostaphin Solution by adding the entire contents of the Phosphate Buffer vial to the Lysostaphin Solution vial. Mix together well. Store Lysostaphin Solution at 2-8°C for up to 30 days after preparation.

1. Prepare a suspension of the test isolate from a pure, 18-24 hour culture in 0.2 ml of sterile saline. Positive and negative control organisms should be set up concurrently.
2. Add 0.2 ml of Lysostaphin Solution to each test and control organism suspension.
3. Incubate the tubes aerobically at 35-37°C for 2 hours. Do not disturb suspensions before 2 hours.
4. Observe for clearing of the solution.

INTERPRETATION
Positive test - Solution clears, no turbidity remains
Negative test - Solution remains turbid, does not clear

QUALITY CONTROL
All lot numbers of Lysostaphin Test Kit have been tested using the following quality control organisms and have been found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL         INCUBATION         RESULTS
Staphylococcus aureus ATCC® 25923 Aerobic, 2 h @ 35-37°C Positive
Staphylococcus epidermidis ATCC® 12228 Aerobic, 2 h @ 35-37°C Positive
Micrococcus luteus ATCC® 4698 Aerobic, 2 h @ 35-37°C Negative

BIBLIOGRAPHY

PACKAGING
REF R21130, Lysostaphin Test Kit.................................................. 25 Tests/Kit

Symbol Legend

REF Catalog Number
IVD In Vitro Diagnostic Medical Device
LAB For Laboratory Use
IFU Consult Instructions for Use (IFU)
Temperature Limitation (Storage Temp.)
LOT Batch Code (Lot Number)
-pad Use By (Expiration Date)

ATCC® is a registered trademark of American Type Culture Collection. CAS (Chemical Abstracts Service Registry No.)