remel

12.5% GELATIN REAGENT

INTENDED USE
Remel 12.5% Gelatin Reagent is recommended for use in qualitative procedures to detect gelatinase activity of microorganisms.

SUMMARY AND EXPLANATION
Gelatin liquefaction is used to aid in identification of aerobic and anaerobic bacteria of clinical significance.[1] Lombard et al. developed an agar medium for determining gelatinase production by anaerobes.[2] Originally described by Frazier, Gelatin Reagent (12.5%) was used by Centers for Disease Control and Prevention (CDC) to detect gelatinase activity of anaerobes in their Presumpto plate system.[3,4]

PRINCIPLE
Gelatinase activity is detected using an appropriate agar medium inoculated with the test isolate and incubated for an appropriate length of time. After incubation, 12.5% Gelatin Reagent is added to the surface of the agar plate. When gelatinase is produced by the test isolate, the gelatin in the agar is hydrolyzed and a clear zone appears around the bacterial growth. If the test isolate does not produce gelatinase, the gelatin in the agar is precipitated and the medium becomes cloudy.

REAGENTS (CLASSICAL FORMULA)*

Mercuric Chloride (CAS 7487-94-7)	125.0 g
Hydrochloric Acid (CAS 7647-01-0)	168.0 ml
Demineralized Water (CAS 7732-18-5)	832.0 ml

*Adjusted as required to meet performance standards.

PRECAUTIONS
DANGER! POISON, may be harmful or fatal if swallowed. **CORROSIVE**, may cause burns or irritation to skin, eyes, or respiratory tract. Avoid breathing vapor and eye/skin contact.

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. Read and follow directions carefully. Refer to Material Safety Data Sheet for additional information on reagent chemicals.

STORAGE
This product is ready for use, no further preparation is necessary. Store product in its original container at room temperature until used and protect from light.

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, TRANSPORT
Specimens should be collected and handled following recommended guidelines.[5]

MATERIALS REQUIRED BUT NOT SUPPLIED
(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Anaerobic CDC #3 Quad (REF R03401), (7) Thioglycollate Broth or Lombard-Dowell Broth, (8) McFarland Equivalence Standard #1 (REF R20411), (9) Sterile pipettes.

PROCEDURE
Anaerobic CDC #3 Quad:
1. Prepare inoculum from a pure culture of the test isolate in Thioglycollate Broth or Lombard-Dowell Broth equivalent to the density of a #1 McFarland Standard or equivalent.
2. Inoculate Quadrant 1 (gelatin quadrant) of Anaerobic CDC #3 Quad using a sterile swab dipped in the broth culture. Remove excess fluid by pressing swab against the wall of the tube and make a single streak across the middle of the quadrant.
3. Incubate anaerobically for 48-72 hours at 35-37°C.
4. After incubation, add several drops of 12.5% Gelatin Reagent to Quadrant 1. Allow reagent to penetrate agar medium 10-20 minutes before interpreting results. A positive reaction is indicated by a clear zone around the growth.

INTERPRETATION
Positive Test - Clear zone around area of growth within 20 minutes
Negative Test - No zone around area of growth within 20 minutes

QUALITY CONTROL
All lot numbers of 12.5% Gelatin Reagent 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
Clostridium sporogenes ATCC® 3584	Ambient, 48-72 h @ 35-37°C	Positive
Bacteroides ovatus ATCC® 8483	Ambient, 48-72 h @ 35-37°C	Negative

BIBLIOGRAPHY

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3. Frazier, W.C. 1926. J. Infect. Dis. 39:302-309.
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PACKAGING

REF R21226, 12.5% Gelatin Reagent..... 25 ml/Btl

Symbol Legend

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

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

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