

1. IDENTIFICATION OF THE IVD REAGENT

- Catalase Reagent
- Catalog #: 300195

2. INTENDED USE

Catalase reagent is used for the detection of microorganisms that possess the catalase enzyme.

3. SUMMARY AND EXPLANATION

Most aerobic and facultatively anaerobic bacteria possess the catalase enzyme except for *Streptococcus spp.* The catalase test is most often used to differentiate *streptococci* from *staphylococci*. Usually, organisms which lack the cytochrome system also lack the catalase enzyme and, therefore, are unable to break down hydrogen peroxide. It can also be used to separate gram positive bacilli from mycobacteria.

3.1. PRINCIPLE

Microorganisms that possess the catalase enzyme can break down hydrogen peroxide into oxygen and water, thus producing gas bubbles.

3.2. COMPOSITION

Hydrogen Peroxide (3%)

This formulation is typical. Production lots may be adjusted if necessary to offset variations in raw materials to meet performance criteria.

3.3. PRODUCT DESCRIPTION

Catalase Reagent droppers are ready for use. The solution is colorless, clear, and free of precipitate or foreign matter.

4. WARNINGS AND PRECAUTIONS

This reagent is for IN VITRO DIAGNOSTIC USE only. Precautions should be taken against the dangers of microbiological hazards. After use, all materials should be placed into an appropriate container for biohazardous material disposal. Refer to the SDS for more detailed information. Avoid contact with eyes or skin as some reagents and stains are harmful. Wear protective goggles and gloves. Wash hands thoroughly after handling. The product is not intended for human, animal, or pet consumption.

5. SPECIMEN COLLECTION

Obtain and process specimens according to the techniques and procedures established by laboratory policy.

6. MATERIALS REQUIRED BUT NOT PROVIDED

Sterile containers or sterile swabs, inoculating loops, needles or applicator sticks, glass slides, plated or tubed media, Bunsen burner or incinerator, and quality control organisms.

7. INSTRUCTIONS FOR USE

1. Remove the cap from the dropper bottle.
2. Invert and slightly squeeze the bottle to dispense one drop of reagent to an isolated colony.
 - a. Slide Test Method: Using an inoculating needle or applicator stick, pick a well-isolated colony and transfer it to a glass slide.
 - b. Agar Method: Add a drop to the surface of an 18-24 h agar plate/tube that does not contain blood.
3. Examine immediately and observe the reaction for the production of gas bubbles.

8. STORAGE AND EXPIRATION

Store at 15 to 30°C. Catalase reagent is light sensitive. Protect from light. Do not use this reagent if the expiration date has passed or if it fails to meet specifications for performance.

9. USER QUALITY CONTROL

Activity of the Catalase Reagent may be checked using stock cultures of *Staphylococcus aureus* and *Streptococcus pyogenes* and following procedures outlined above. Quality Control requirements must be performed in accordance with accreditation requirements and laboratory Quality Control standards. It is recommended that the user refers to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

10. EXPECTED RESULTS

A positive test is indicated by immediate gas bubble production and sustained effervescence. A negative test produces no gas or bubbles.

Microorganism(s)	Result(s)
<i>Streptococcus pyogenes</i> (ATCC 19615)	Negative
<i>Staphylococcus aureus</i> (ATCC 25923)	Positive




















11. LIMITATIONS

Catalase reagent may be used as an aid in the identification of microorganisms. Additional biochemical testing using pure cultures is recommended for complete identification.

Culture media containing blood are unacceptable for this test due to the presence of catalase in erythrocytes. When picking colonies from plated blood media, avoid carryover if performing a slide test.

Dirty glassware can cause false-positive results. Use properly cleaned slides. Inoculating needles or loops containing iron may produce false-positive results. Avoid contact of the catalase reagent with iron-containing needles and loops.

Lactobacillus species may produce pseudocatalase reactions that can be prevented by adding 1% glucose to the growth medium. Anaerobic cultures grown on a blood-free medium must be exposed to the air for a minimum of 30 minutes before testing.

KEY					
	Manufacturer		Keep Dry		Positive control
	Date of manufacture		Intended Use		Negative control
	Catalog Number		In vitro diagnostic		Biological risk
	Lot Number/Batch Code		Do not re-use		Caution
	Temp. Limit/Storage Temp.		Consult instructions for use		Contains sufficient for <n> tests
 	Expiration/Use-by-Date		Authorized Representative in the European community		Total number of products in a package

12. PRODUCT WARRANTY

This product is covered under warranty to meet the specifications and performance printed in product inserts, instructions, and supporting literature. The warranty, expressed or implied, is limited when:

- the procedures employed in the laboratory are contrary to printed directions and instructions.
- the products are employed for applications other than the intended use cited.

13. REFERENCES

1. P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.). Manual of Clinical Microbiology, 6th ed. American Society for Microbiology, Washington, D.C.

14. ACKNOWLEDGEMENTS

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