

# Strep-A-Chek™

Reagent Strips  
Cat. No.: 13-051-00

## Intended Use

**Strep-A-Chek™ Reagent Strips** are a component of the **Strep-A-Chek™ Kit** (Cat. No: 13-050-00) and are to be used with **EY-20™ Reagent Tubes**. They are intended for use in the detection of pyrrolidonyl arylamidase (PYR) from beta-hemolytic colonies grown on blood agar plates, as an aid in the presumptive identification of Group A *Streptococcus*.

## Description

**Strep-A-Chek™ Reagent Strips** are paper strips impregnated with a chromogenic substrate for the detection of pyrrolidonyl arylamidase (PYR), an enzyme reported to be present in Group A beta-hemolytic *Streptococcus*. The PYR enzyme has been shown to be accurate in differentiating Group A streptococci and enterococci from other *Streptococcus* species. **Strep-A-Chek™** kit when used in conjunction with other tests such as CAMP, hippurate, and bile-esculin, may be used for the presumptive identification of beta-hemolytic streptococci or enterococci from any source.

## Chemical Principle

Hydrolysis of the chromogenic substrate impregnated on the **Strep-A-Chek™ Reagent Strip** by pyrrolidonyl arylamidase (PYR) releases a free beta-naphthylamine derivative. This complexes with a diazo dye, Fast Garnet, the color developer present in **EY-20™ Reagent Tubes**, to produce a PINK/RED color, which is indicative of a positive result.

## Materials Supplied

100 **Strep-A-Chek™ Reagent Strips** impregnated with 0.1% L- Pyroglutamyl-β-naphthylamide.

## Materials Needed but not Supplied

Inoculation loop or applicator stick      Pipette or dropper      Distilled or Deionized water

**EY-20™ Reagent Tubes** (Cat. No.: 13-020-50)

## Recommended Quality Control Organisms and Expected Results

Good laboratory practices include the use of control specimens to ensure proper kit performance. Positive and negative organisms should be tested according to the laboratory's established Quality Control program.

ORGANISM (not supplied)	ATCC#	EXPECTED RESULTS
<i>Streptococcus pyogenes</i>	19615	PINK/RED color change
Group C streptococci	12449	No color change

## Precautions

**Strep-A-Chek™ Reagent Strips** are intended for *IN VITRO* DIAGNOSTIC USE ONLY and should be used by properly trained, qualified laboratory personnel. Normal precautions should be taken against dangers of microbial hazards. Sterilization of all materials used during testing is recommended.

## Storage

Store **Strep-A-Chek™ Reagent Strips** desiccated and in the original box at 2-8°C. This product should not be used past the expiration date. Allow **Strep-A-Chek™ Reagent Strips** to come to room temperature (20°-28°C) before using.

## Specimen Collection

- A GRAM STAIN and CATALASE TEST **MUST** be performed on the specimen before using **Strep-A-Chek™**. Group A *Streptococcus* are gram positive and catalase negative.
- Only beta-hemolytic colonies should be selected from blood agar plates.  
**NOTE:** Group A streptococci colonies are surrounded by a well-defined zone of complete hemolysis, usually two to four times the diameter of the colony. However, the appearance of the colonies may vary greatly depending on the medium used.

## Procedure

- Allow the **Strep-A-Chek™ Reagent Strips** to come to room temperature (20°-28°C) before using.
- Reconstitute the contents of the **EY-20™ Reagent Tube** (not provided) by adding 1.0 ml of distilled or deionized water to the tube and agitating. 1 ml of **EY-20™** solution is sufficient for more than 5 tests.  
**Note:** Store reconstituted **EY-20™ Reagent** at room temperature (20°-28°C) protected from light. Use within 8 hours of reconstitution.
- Remove **Reagent Strip** from its container. Remove at least 5 well isolated beta-hemolytic streptococci colonies from the blood agar plate using a wooden applicator stick or inoculation loop.
- Inoculate **Reagent strip** by rubbing colonies onto filter paper area of strip.
- Add 1 drop of **EY-20™** solution to the inoculated area. Incubate at room temperature (20°-28°C) for up to 10 minutes.
- View for color formation. Formation of a PINK/RED color in the test area indicates the detection of pyrrolidonyl arylamidase (PYR), a POSITIVE result for the presumptive identification of Group A *Streptococcus*. A NEGATIVE result should be recorded if there is no color change after 10 minutes.

## Interpretation of Results

OBSERVATION	INTERPRETATION	RESULT
PINK/RED color change	Pyrrolidonyl arylamidase (PYR) detected	Presumptive identification of Group A <i>Streptococcus</i>
No color change	Pyrrolidonyl arylamidase (PYR) NOT detected	NEGATIVE

## Limitations of Test

It must be emphasized that only pure cultures with characteristics listed in SPECIMEN COLLECTION should be tested with the **Strep-A-Chek™** system. Some Leuconostoc and Streptococcus strains may appear coccobacillary, even rod shaped, and are often confused with members of the genus Lactobacillus. These strains may also be gram positive and catalase negative. The source of the specimen and clinical symptoms are important. Further biochemical and serological testing is necessary for definitive identification.

## Performance Characteristics

In a clinical trial by Yajko, *et al.* comparing **Strep-A-Chek™** with bacitracin disk susceptibility test for accuracy in the presumptive identification of *Streptococcus pyogenes* (Group A *Streptococcus*) from a primary blood agar plate the sensitivity and specificity was 100%. **Strep-A-Chek™** was evaluated using a total of 320 clinical isolates of beta-hemolytic streptococci (See table). These included 169 group A, 42 group B, 38 Group C, 21 group F, 39 group G and 11 beta-hemolytic streptococci which did not agglutinate with antisera to groups A,B,C,D,F, or G with the Streptex Latex agglutination test.

### Comparison of Bacitracin with Strep-A-Chek™

	No. TESTED	NO. BACITRACIN SENSITIVE	(%)	NO. PYR POSITIVE	(%)
<i>S. Pyogenes</i>	167	167	(100)	167	100
GROUP B	42	0	(0)	0	(0)
GROUP C	38	16	(42)	0	(0)
GROUP F	21	0	(0)	0	(0)
GROUP G	39	7	(18)	0	(0)
NON-GROUPABLE	11	0	(0)	0	(0)
<i>S. MILLERI</i> (GROUP A)	2	0	(0)	0	(0)
	320	190	(59)	167	52

False positive rate for Bacitracin = 15%

In another clinical trial by Daly, *et al.* comparing **Strep-A-Chek™** with Streptex and Litmus milk reduction for identification of Streptococci the sensitivity and specificity was also 100%. A total of 311 isolates were evaluated and included 176 group A, 43 group B, 8 group C, 9 group F and 9 group G. 100% of 52 group D enterococci and 100% of 14 group D non-enterococci were identified by **Strep-A-Chek™**.

## Bibliography

- Bosley, G.S., R.R. Facklam & D. Grossman, 1983. Rapid Identification of Enterococci. J. Clin. Microbiol. 18:1275-1277.
- Daly, J.A., and J.L. Rufener, 1985. Comparison of Strep-A-Chek™, Streptex and Litmus Milk Reduction for Identification of Streptococci. Abstracts of the 1985 Annual Meeting of the American Society for Microbiology.
- Facklam, R.R., L.G. Thacker, B. Fox & L. Eriquez, 1982. Presumptive Identification of Streptococci by a New System. J. Clin. Microbiol. 15:987-990.
- Facklam, R.R., J.F. Padula, L.G. Thacker, E.C. Wortham, & B.J. Sconyers. 1974. Presumptive Identification of Group A, B, and D Streptococci. Appl. Microbiol. 27:107.
- Facklam, R.R. Isolation and Identification of Streptococci. 1. Collection, Transport and Determination of Hemolysis. CDC Laboratory Manual U.S.D.H.E.W. CDC, Atlanta.
- Lawrence, J., D.M. Yajko, & W.K. Hadley, 1984. Comparison of Strep-A-Chek™ with Bacitracin for the Presumptive Identification of *Streptococcus pyogenes* (Group A Strep). Abstracts of the 1984 Annual Meeting of Interscience Conference on Antimicrobial Agents and Chemotherapy.
- Lenette, E.H., A. Ballows (ed), 1991. Manual of Clinical Microbiology, 5th ed. American Society for Microbiology, Washington D.C.
- Yajko, David M., J. Lawrence, P. Nassos, J. Young, & W.K. Hadley, 1986. Clinical Trial Comparing Bacitracin with Strep-A-Chek™ for Accuracy and Turnaround Time in the Presumptive Identification of *Streptococcus pyogenes*. J. Clin. Microbiol. 24:431-434.

**EY LABORATORIES, INC.**  
107 North Amphlett Blvd.  
San Mateo, CA 94401

Tel: 650-342-3296  
Fax: 650-342-2648  
Orders: 1-800-821-0044  
(Outside CA only)  
Rev. 3 (3/06)