INDICAID™

RAPID STREP A ANTIGEN TEST

INSTRUCTIONS FOR USE

For *in vitro* diagnostic use.
For prescription use only.

INTENDED USE

The Rapid Strep A Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of Streptococcus pyogenes (Group A ß-hemolytic Streptococcus, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A Streptococcus bacterial infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.

SUMMARY

Streptococcus pyogenes is non-motile gram-positive coccus, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[1] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[2,3]

The Rapid Strep A Antigen Test is a rapid test to qualitatively detect the presence of Group A Streptococcal antigen in throat swab specimens, providing results within 5 minutes. The test utilizes specific and sensitive antibodies reactive to the Rapid Strep A Antigen and is specific to group A with no cross-reactivity from other groups of Streptococci.

PRINCIPLE

The Rapid Strep A Antigen Test is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, an antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIAL

Material Provided

- 25 Test Strips
- 25 Sterile swabs
- 25 Disposable extraction tubes
  - One tube for each test strip
- 1 Reagent A*
  - 10mL; 2M Sodium Nitrite
- 1 Reagent B*
  - 10mL; 0.2M Acetic Acid
- 1 Positive Control
  - 1mL: Non-viable Strep A; 0.05% Proclin300
- 1 Negative Control
  - 1mL: Non-viable Strep C; 0.05% Proclin300
- 1 Instructions for Use

** Reagent A and B are caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents contact the skin or eyes, flush with a large volume of water.*

Material Required But Not Provided

- Timer, clock, or watch for specimen collection and test procedure.

WARNINGS AND PRECAUTIONS

- This kit is for prescription, *in vitro* diagnostic use only.
- Do not use the test kit beyond the expiration date printed on the pouch.
- Do not use the test kit if the pouch is punctured or not well sealed.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.
- Discard after use. The test strip cannot be used more than once.
- The extraction tube and swab are single use items – do not use with multiple specimens.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Test strips must remain sealed in the pouch until just prior to use.
- Reagent A and B are caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents contact the skin or eyes, flush with a large volume of water.
- The positive and negative controls contain prodin300 as a preservative.
- All specimens should be treated as potentially infectious diseases. Protective gloves should be worn when handling the specimen. Wash hands thoroughly afterwards.
- Dispose of the used strip, swab and extraction tube in accordance with your laboratory guidelines and local, state, or federal regulations.

KIT STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C (39-86°F)). **DO NOT FREEZE** (below 0°C(32°F)). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use.

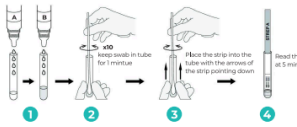
SPECIMEN COLLECTION AND PREPARATION

- Only use the reagents and sterile swabs provided in the kit.
- Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[4]
- Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 48 hours at room temperature [15-30°C (59-86°F)] or 72 hours at 2-8°C (36-46°F).
- If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Rapid Strep A Antigen Test.

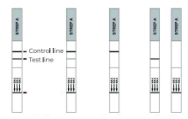
TEST PROCEDURE

IMPORTANT: Do not remove the test strip from the foil pouch until ready to perform the assay. Allow the test strip, reagents, throat swab specimen, and/or controls to reach room temperature [15-30°C (59-86°F)] prior to testing.

1. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is light red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube.
2. Immediately place the throat swab into the extraction tube. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then, press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
3. Remove the test strip from the foil pouch. Place the test strip into the tube with the arrows of the strip pointing down and then start the timer. Do not handle or move the strip until the test is complete and ready for reading.
4. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



INTERPRETATION OF RESULTS



Positive Result

Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative Result

One colored line appears in the control line region (C). No line appears in the test line region (T).

Invalid Result

Control line fails to appear.
NOTE: Insufficient specimen volume, incorrect operation procedure, or the use of expired tests are the most likely reasons for control band failure.

LIMITATIONS

- The Rapid Strep A Antigen Test is for in vitro diagnostic use only. The test should be used for the detection of Group A Streptococcal antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Group A Streptococcal antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of Group A Streptococcal antigen in the specimen from both viable and non-viable Group A Streptococcus bacterium.
- A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Group A Streptococcal antigen present in the throat swab is not adequate or is below the detectable level of the test.
- The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

QUALITY CONTROL

Built-in Procedural Control Features

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. If a color band is not visible in the control region (C), the test is invalid.

External Quality Control

In addition to your laboratory's standard quality control procedures, it is recommended that positive and negative external controls be tested at least once per kit lot number and by each new untrained operator. This will verify that the reagents and test strips are working properly, and the operator is able to correctly perform the test procedure.

Procedure for External Quality Control Testing

1. Add 4 full drops of Reagent A and 4 full drops of Reagent B into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least 10 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4. Continue with Step 3 in the **TEST PROCEDURE** Section. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact Technical Services or Customer Support.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection of the test is 7.2×10^5 CFU/mL. This was established by testing cultures of Streptococcus pyogenes with a known number of organisms, ATCC 19615. The organisms were serially diluted and spiked with clinical matrix and tested using the Rapid Strep A Antigen Test.

Clinical Sensitivity and Specificity

The Rapid Strep A Antigen Test was used to evaluate 368 throat swab specimens collected from patients presenting with pharyngitis from three physician offices. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Rapid Strep A AntigenTest vs. Culture

INDICAID™ Rapid Strep A Antigen Test Results	Culture Results	
	Positive	Negative
Positive	200	1
Negative	6	161
Total	206	162

Sensitivity: 97.1% (95% C.I. = 93.7 – 98.8%)
Specificity: 99.4% (95% C.I. = 96.2 – 100.0%)

Clinical Performance Stratified by Age

Age	Sensitivity	95% CI	Specificity	95% CI
0 - 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
>5 – 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
>21	100% (7/7)	59.6% - 100.0%	100% (21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0

Cross-Reactivity

To confirm the cross-reactivity of Rapid Strep A Antigen Test organisms likely to be found in the respiratory tract were tested and were all found to be negative when tested with the Rapid Strep A Antigen Test. The tested concentration of each microorganism is documented in the following table. No microbial interference was found for each microorganism at the listed concentration.

Microorganism	Concentration Tested
Arcanobacterium haemolyticum	2.6×10^6 CFU/mL
Bordetella pertussis	7.5×10^6 CFU/mL
Candida albicans	9.5×10^6 CFU/mL
Corynebacterium diphtheria	5.37×10^6 CFU/mL
Enterococcus faecalis	2.3×10^6 CFU/mL
Enterococcus faecium	4.4×10^6 CFU/mL
Enterovirus (VR-28 Human Coxsackievirus)	1.6×10^6 $TCID_{50}$/mL
Escherichia coli	1.1×10^6 CFU/mL
Fusobacterium necrophorum	7.3×10^6 CFU/mL
Haemophilus parahaemolyticus	1.3×10^6 CFU/mL
Haemophilus influenzae	4.5×10^6 CFU/mL
Haemophilus parainfluenzae	1.6×10^6 CFU/mL
Human metapneumovirus (HMPV-27 A2)	3.55×10^5 $TCID_{50}$/mL
Human coronavirus OC43	1.7×10^5 $TCID_{50}$/mL
Klebsiella pneumoniae	3.1×10^6 CFU/mL
Legionella pneumophila	1×10^6 bacteria/mL
Lactobacillus sp. (Lactobacillus casei)	6.5×10^6 CFU/mL
Mycobacterium tuberculosis	1×10^5 bacteria/mL
Moraxella lacunata	1.95×10^6 CFU/mL
Moraxella (Branhamella) catarrhalis	4.8×10^6 CFU/mL
Mycobacterium tuberculosis (avirulent strain)	2.3×10^6 CFU/mL
Neisseria gonorrhoeae	3.8×10^6 CFU/mL
Neisseria lactamica	1.19×10^6 CFU/mL
Neisseria meningitides	7.5×10^6 CFU/mL
Neisseria mucosa	3.25×10^6 CFU/mL
Neisseria sicca	8.5×10^6 CFU/mL
Neisseria subflava	3.27×10^6 CFU/mL
Staphylococcus epidermidis	2.1×10^6 CFU/mL
Staphylococcus marcescens	1.5×10^6 CFU/mL
Staphylococcus haemolyticus	1.58×10^6 CFU/mL
Streptococcus agalactiae (Group B)	7.9×10^5 CFU/mL
Streptococcus dysgalactiae (Group C)	1.43×10^6 CFU/mL
Streptococcus sp. (bovis II) Group D	5.6×10^6 CFU/mL
Streptococcus sp. Strain H60R (Group F)	1×10^6 CFU/mL
Streptococcus anginosus (Group G)	4.2×10^6 CFU/mL
Streptococcus pneumoniae	4.2×10^6 CFU/mL
Streptococcus salivarius	8.7×10^6 CFU/mL
Streptococcus mitis	5.9×10^6 CFU/mL
Streptococcus mutans	4.7×10^6 CFU/mL
Streptococcus oralis	6.4×10^6 CFU/mL
Streptococcus sanguis	1.5×10^6 CFU/mL
Yersinia enterocolitica	2.0×10^6 CFU/mL

Microorganism	Concentration Tested
Adenovirus Type I	3.09×10^5 $TCID_{50}$/mL
Adenovirus Type II	3.9×10^5 $TCID_{50}$/mL
Adenovirus 3	1.5×10^6 $TCID_{50}$/mL
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL
Cytomegalovirus	1.6×10^5 $TCID_{50}$/mL
Epstein Barr Virus	7.85×10^5 copies /mL
HSV Type 1 MacIntyre strain	1.6×10^6 $TCID_{50}$/mL
Human parainfluenza Type 1	1.6×10^5 $TCID_{50}$/mL
Human parainfluenza Type 2	1.6×10^5 $TCID_{50}$/mL
Human parainfluenza Type 3	1.6×10^5 $TCID_{50}$/mL
Human rhinovirus 26	5×10^6 $TCID_{50}$/mL
Measles Virus	8.9×10^5 $TCID_{50}$/mL
Proteus vulgaris	2.9×10^6 CFU/mL
Pseudomonas aeruginosa	5.1×10^6 CFU/mL
Serratia marcescens	2.1×10^6 CFU/mL
Staphylococcus aureus	3.2×10^6 CFU/mL
Mumps virus	1.38×10^7 $TCID_{50}$/mL
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL

Interference Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the upper respiratory tract, were evaluated with the Rapid Strep A Antigen Test at the concentrations listed below and were found not to affect test performance.

Interfering Substance	Concentration Tested
Endogenous	
Blood (human)	20% (vol/vol)
Mucin	1 mg/mL
OTC Mouthwashes	
Colgate Total Pro-Shield, Spearmint	20% (vol/vol)
Crest Pro Health Multi Protection Clean Mint	20% (vol/vol)
Crest Pro-Health Clean Mint	20% (vol/vol)
Listerine Antiseptic Cool Mint	20% (vol/vol)
OTC Lozenges	
Cepacol Extra Strength Sore Throat & Cough Drop Lozenges, Cherry	5 mg/mL
Halls Mentho-Lyptus Drops Cherry	5 mg/mL
Halls Cough Suppressant Cherry Triple Soothing Action	5 mg/mL
Sucrets Sore Throat Lozenges Cherry	5 mg/mL
Sucrets Sore Throat & Cough Lozenges, Honey Lemon	5 mg/mL
OTC Throat Sprays	
Cepacol Dual Relief	20%(vol/vol)
Chloraseptic Max	20%(vol/vol)
OTC Cough Syrups	
Basic Care Tussin DM, Cough Suppressant &	10%(vol/vol)
Expectorant	10%(vol/vol)
Children's Dimetapp Cold & Cough	10%(vol/vol)
Robitussin Nighttime Cough	10%(vol/vol)
Robitussin (Guaifenesin Syrup)	10%(vol/vol)
Tylenol Cough and Sore Throat	10%(vol/vol)

Active Ingredients	Concentration Tested
Acetaminophen (Tylenol)	5 mg/mL
Brompheniramine Maleate	5 mg/mL
Chlorpheniramine Maleate	5 mg/mL
Dextromethorphan HBr	5 mg/mL
Diphenhydramine HCl	5 mg/mL
Doxylamine Succinate	5 mg/mL
Guaifenesin (Guaiacol Glyceryl)	5 mg/mL
Ibuprofen (Advil)	5 mg/mL
Phenylephrine HCl	5 mg/mL

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4. **Shea, Y.R.** Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
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6. **Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA.** Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

SYMBOL GLOSSARY

Do not re-use
Consult instructions for use
Expiration date
Test per kit
Store between 4°C-30°C (39°F-86°F)
Keep dry
LOT Batch number
REF Catalog number
Keep away from sunlight
UDI Unique device identifier
IVD In vitro diagnostic medical device
Warning

ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number 1-877-625-1603 (9 a.m. to 5 p.m. CDT).

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