AG-Strep A Ag RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Strep A Ag rapid test kit is a rapid and convenient immunochromatographic assay for the qualitative detection of Group A *streptococcus* (Strep A) antigen from patient throat swab specimens. It is intended for professional use as an aid in the diagnosis of Strep A infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test

PRINCIPLE

AstraGene Strep A Ag rapid test kit is an antigen-capture immunochromatographic assay, which detects the presence of Strep A in throat swab samples. Monoclonal antibodies specifically against Strep A are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line of the nitrocellulose membrane. When adequate volumes of the test sample is added the antibody conjugate is rehydrated and the Strep A, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If Strep A are absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result. The detection limit of AstraGene Strep A Ag rapid test kit is approximately 105 Group A *Streptococci* organisms.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Sample Extraction Buffer A	1 No.	1 No.
Sample Extraction Buffer B	1 No.	1 No.
IFU	1 No.	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/SPAAg/24/01	AG/RTK/SPAAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Sample extraction tube.
- Sterile dacron-tipped swabs.
- Glove, clock or timer.

STORAGE &STABILITY

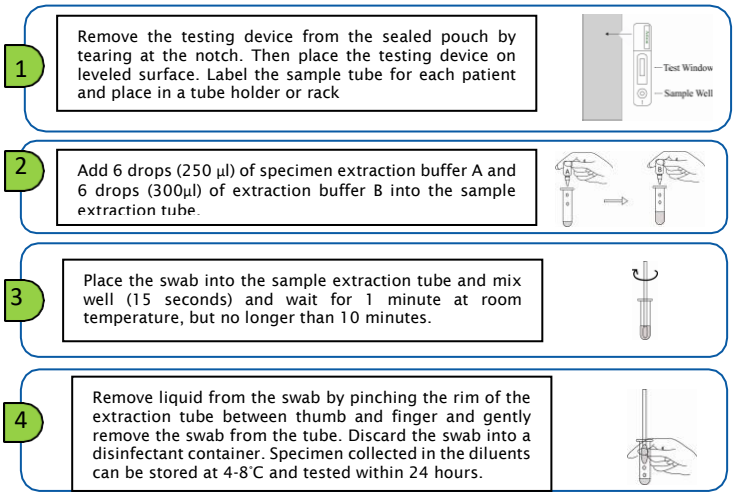
- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- Swab the posterior pharynx, tonsils and other inflamed areas (Note: avoid touching the tongue, cheeks and teeth with the swab).
- A specimen should be collected by standard throat swab collection methods. It is preferable to use Dacron-tipped sterile swab with plastic shafts. Swabs should be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped tube or bottle. Swabs which have been transported in liquid media such as modified Stuart's Transport Medium may be used in the test provided the liquid medium has a volume of 1 ml or less. Do not use semisolid transport media containing charcoal. Specimen swabs may be refrigerated (2-8 ^{0}C) for up to 5 days.
- If a culture is desired, lightly roll the swab tip onto a Group A selective blood agar plate before using the swab in the Strep A Rapid Test Device.

PROCEDURE

Bring all the test samples and controls to room temperature (15°-28°C) prior to testing.



AG-Strep A Ag RAPID TEST KIT

Add three full drops (130 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

Read the result in 10 minutes. Read results as shown under interpretation section
NOTE: Strong positive specimens may produce positive result in as little as 1 minute. Confirm negatives in 10-20 minutes before interpreting the result.

DO NOT INTERPRET RESULTS AFTER 10 MINUTES

RESULT INTERPRETATIONS

Negative
A colored band appears only at the control region (C), indicating a negative result for Strep A infections.

Positive
A clear control band (C) and a detectable test band (T) appear, indicating a positive result for Strep A infections.

Invalid
No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal control (colored line in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

LIMITATION OF THE PROCEDURE

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting Strep A infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only. Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch. Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests. Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations. Keep out of children's reach.

SYMBOLS

Do not use if package is damaged | Manufacturer | LOT Batch Code

CE mark of Conformity | Refer to the instructions | ISO 13485:2016 | GMP

AstraGene FZ LLC, Office No. 208 – 209, Dubai Science Park Building, Dubai, United Arab Emirates
+971-4-8781222, contact@astragene.com