# AG- ADENOVIRUS Ag RAPID TEST KIT

## INSTRUCTION FOR USE

AstraGene – Adenovirus Ag Rapid Test kit is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigen in eye conjunctive swab, throat swab and nasopharyngeal swab as an aid in the diagnosis of adenovirus infections.

## PRINCIPLE

AstraGene – Adenovirus Ag Rapid Test kit is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in eye conjunctive swab, throat swab and nasopharyngeal swab. In this test, antibody specific to the adenovirus is separately coated on the test line region of the test cassette. During testing, the extracted specimen reacts with the antibody to adenovirus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to adenovirus on the membrane and generate a colored line in the test line region. The presence of this colored 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 region if the test has performed properly.

## PACKAGE CONTENTS

| Description | 10 tests | 1 test |
|---|---|---|
| Test Cassettes with desiccant | 10 | 1 |
| Extraction tube with cap | 10 | 1 |
| Extraction Buffer | 1×4.0mL | 1×0.40mL |
| Sterile swabs | 10 | 1 |
| IFU | 1 | 1 |

| Catalogue Number | 10 tests | 1 test |
|---|---|---|
| Cassette Model | AG/RTK/ADVAg/24/01 | AG/RTK/ADVAg/24/02 |

## MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Disposable Gloves

## STORAGE &STABILITY

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

## SPECIMEN COLLECTION & PREPARATION

- It is applicable to the diagnosis of the Adenovirus antigen from the samples of eye conjunctive swab, throat swab and nasopharyngeal swab with the Adenovirus pneumoniae Antigen Rapid Test.
- Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.
- Eye conjunctive swab sample: Use the sterilized swab supplied in this kit to gently wipe the eye conjunctive several times to collect the eye secretions.
- Throat swab sample: Insert the sterilized swab into the throat and swab surrounds mandible tonsil and posterior hypo pharyngeal for several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.
- Nasopharyngeal swab sample: 1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
  2. Swab over the surface of the posterior nasopharynx 5-10 times.

## PROCEDURE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1.Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

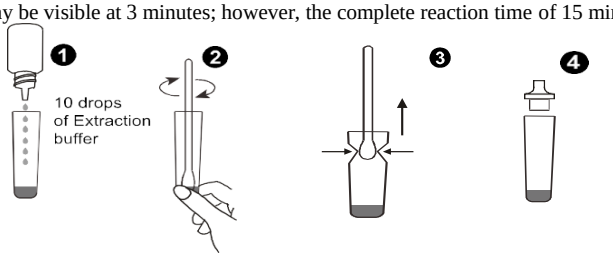
2.Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 400 µL) to the Extraction Tube. See illustration 1.

3.Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.

4.Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.

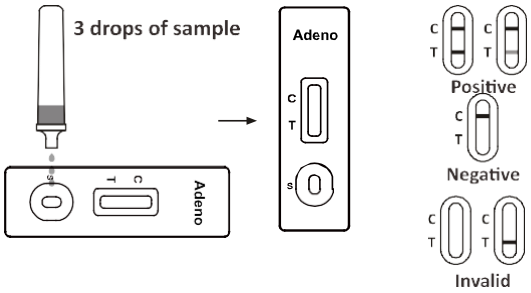
5.Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4

6.Add three drops of the solution (approx.120 µL) to the sample well and then start the timer. Read results at 15 minutes and disregard after 20 minutes. A positive result may be visible at 3 minutes; however, the complete reaction time of 15 minutes is required to confirm a negative result.



# AG- ADENOVIRUS Ag RAPID TEST KIT

## RESULT INTERPRETATIONS




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

**Positive :** A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for HBV 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:

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. laboratory.

## LIMITATION OF THE PROCEDURE

- AstraGene – Adenovirus Ag Rapid Test kit is for in vitro diagnostic use only. The test should be used for the detection of adenovirus antigen in eye conjunctive swab, throat swab and nasopharyngeal swab specimens only. Neither the quantitative value nor the rate of increase in adenovirus antigen concentration can be determined by this qualitative test.
- This kit will only indicate the presence of adenovirus in the specimen and should not be used as the sole criteria for the diagnosis of adenovirus.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of adenovirus infection.
- This is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with adenovirus.
- Performance of the test has not been established for monitoring antiviral treatment of adenovirus.
- AstraGene – Adenovirus Ag Rapid Test kit detects both viable and non- viable adenovirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis evaluated.

## SENSITIVITY & SPECIFICITY

The relative sensitivity of the AstraGene – Adenovirus Ag Rapid Test kit is 98.6%, and the relative specificity is 98.1%, and the relative accuracy is 98.2%.

## 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 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  ISO  GMP

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