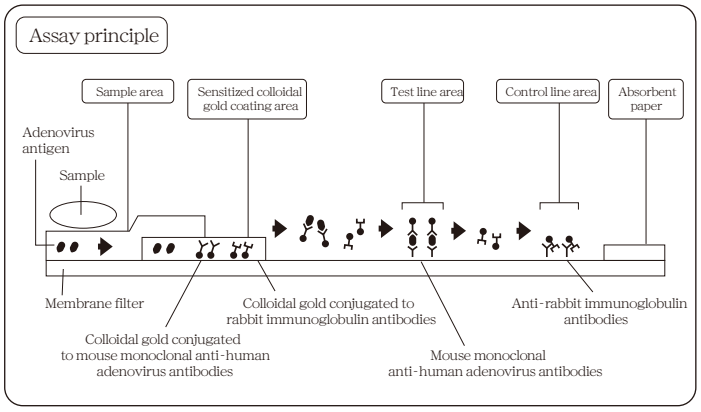
Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Adenovirus kit

Quick Chaser® Adeno



[General Precautions]

1) For in vitro diagnostic use only.
2) Confirmation of diagnosis should be made properly by physician in conjunction with the assessment of clinical symptom or results of other tests.
3) Adenovirus is a highly contagious. Therefore, please make an effort for the prevention of in-hospital infections.
4) The procedures which are not described in package insert, are not guaranteed.

[Contents]

1) Test plate - 10 tests
   - Mouse monoclonal anti-human adenovirus antibodies
   - Colloidal gold conjugated to mouse monoclonal anti-human adenovirus antibodies
2) Extraction reagent solution vial - 10 vials
   Extraction reagent solution is buffer containing detergent.
3) Swab (for pharyngeal swab specimen) - 10 pieces
4) Rack (for extraction reagent solution vial) - 1 piece
5) Filter (for extraction reagent solution vial) - 10 pieces
6) Blue cap (for temporal storage of Extraction reagent solution vial) - 10 pieces
7) Name label for extraction reagent solution vial - 1 sheet

[Intended use]

For detection of adenovirus antigen in pharyngeal mucosa epithelial cell(Aid in the diagnosis of infection by adenovirus).

[Principle of the test]

Quick Chaser® Adeno is the in-vitro reagent for detection of Adenovirus based on Immunochromatographic Assay.

Colloidal gold conjugated to mouse monoclonal anti-human adenovirus antibodies and colloidal gold conjugated to rabbit immunoglobulin antibodies for control line are coated in sensitized colloidal gold coating area in test strip. And mouse monoclonal anti-human adenovirus antibodies are immobilized in test line area and anti- rabbit immunoglobulin antibodies for control line are immobilized in control line area.

According to immunochromatographic principle, when samples are added to the sample area, in the presence of adenovirus, they migrate to the area between sample area and test line area, where reacting with colloidal gold conjugated to mouse monoclonal anti-human adenovirus antibodies and moreover, react with mouse monoclonal anti-human adenovirus antibodies and they are caught in test line area, where they are visible purple-red line and indicate the presence of adenovirus.

Simultaneously, purple-red line is also visible for catching colloidal gold conjugated to rabbit immunoglobulin antibodies on control line, regardless of presence of adenovirus.

[Procedural precautions]

1) Collected specimen should be prepared as sample in accordance with after-mentioned "Preparation of sample in Test procedure" and tested as soon as possible.
2) Add fixed volume (3 drops) of sample to the center of sample area from tip of filter about 10 mm away from the sample area so as to make droplets. In case of adding other than fixed volume, an accurate reaction may not be performed.
3) Bring test plate and extraction reagent solution to 15 ～ 30℃.
4) Interferring substances and medications.
   Following substances and blood were evaluated in Quick Chaser Adeno (Throat) at the concentration listed and were found not to affect test performance.

   Cold medicine ① (Concentration of Acetaminophen : 10mg/mL)
   Cold medicine ② (Concentration of Ibuprofen : 5mg/mL)
   Gargle ①, containing Chlorhexidine gluconic acid (0.25%)
   Gargle ②, containing Tincture of Myrrh (0.5%)
   Gargle ③, containing Povidoneiodine (0.42%)
   Intraoral antiphlogistics containing Sodium Azulene Sulfonate (10%)
   Throat candy ①, containing Dipotassium Glycyrrhizinate (20mg/mL)
   Throat candy ②, containing Nandina Fruit Extract (Dry) (20mg/mL)
   Throat candy ③, containing Cetylpyridinium chloride (20mg/mL)
   Acetyl salicyrate (10mg/mL)
   Diphenhydramine hydrochloride (5mg/mL)
   Dextromethorphan (5mg/mL)
   Oxymetazoline hydrochloride (2%)
   Phenylphrine hydrochloride (4%)
   Inhalation ① containing Salbutamol sulphate (50%)
   Inhalation ② containing Bromhexine hydrochloride (50%)
   Nasal drop ① containing Sodium cromoglicate, Chlorpheniramine monomaleate, Naphozoline hydrochloride (50%)
   Nasal drop ② containing Ketotifen fumarate (10%)
   Blood (2%)

5) Cross Reactivity
   Cross Reactivity were not observed with following virus and bacteria.
   - Virus
     Influenza A virus, Influenza B virus, Respiratory syncytial virus, Echovirus type 3, Echovirus type 9, Echovirus type 11, Echovirus type 14, Echovirus type 18, Echovirus type 30, Enterovirus type 71, Coxsackie A virus type 16, Coxsackie B virus type 1, Coxsackie B type 2, Coxsackie B virus type 4, Coxsackie B virus type 5, Herpes simplex virus type 1, Parainfluenza virus type 1, Parainfluenza virus type 2, Parainfluenza virus type 3, Poliovirus type 1, Polyovirus type 2, Poliovirus type 3, Mumps virus.

・Bacteria

Acinetobacter baumannii、*Bordetella pertussis*、*Branhamella catarrhalis*、*Candida albicans*、*Candida glabrata*、*Cardiobacterium hominis*、*Eikenella corrodens*、*Enterococcus faecalis*、*Enterococcus gallinarum*、*Escherichia coli*、*Group C streptococcus*、*Group G streptococcus*、*Haemophilus aphrophilus*、*Haemophilus influenzae*、*Haemophilus paraphrophilus*、*Klebsiella pneumoniae*、*Neisseria gonorrhoeae*、*Peptococcus asaccharolyticus*、*Peptostreptococcus anaerobius*、*Proteus mirabilis*、*Proteus vulgaris*、*Pseudomonas aeruginosa*、*Serratia marcescens*、*Staphylococcus aureus*、*Staphylococcus epidermidis*、*Streptococcus agalactiae (group B)*、*Streptococcus mutans*、*Streptococcus pneumoniae*、*Streptococcus pyogenes (group A)*、*Veillonella parvula*

[Test procedure]

●Specimen collection

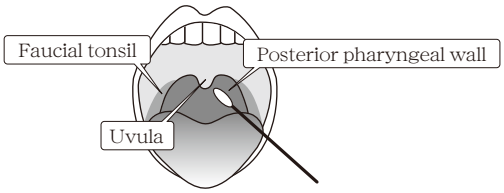
1) Preparation of specimen collection

①Swab (for pharyngeal swab specimen): Use swab of plastic axis included in kit.

②Extraction reagent solution : Use it without preparation.

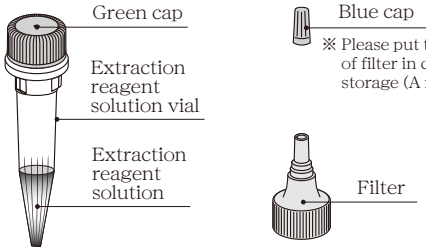
2) Specimen collection

Insert swab from oral cavity into pharynx. Collect mucosa epidermis with rubbing inframed parts of posterior pharyngeal wall or faucial tonsil several times.



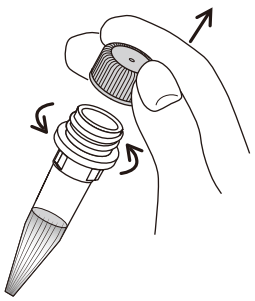
Collect inframed parts of mucosa epidermis

● Details of Extraction reagent solution vial

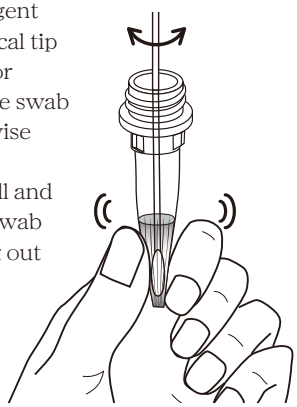


● Preparation of sample

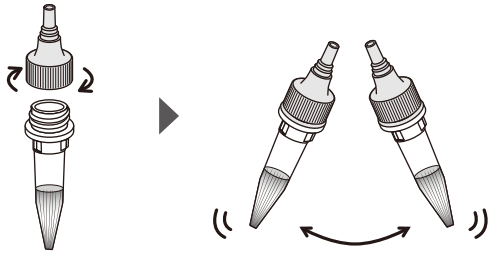
①Loosen green cap with turning it counterclockwise.



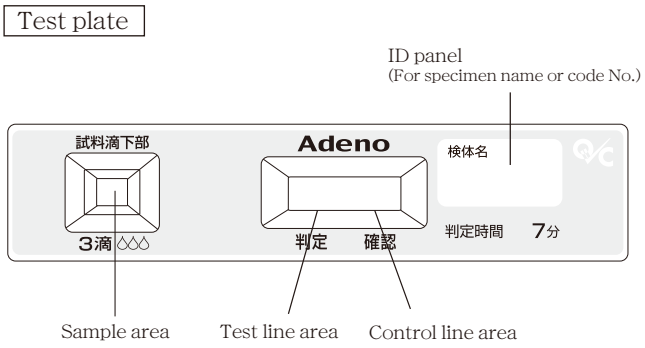
②Insert the spherical tip with specimen into extraction reagent solution vial and press spherical tip from the outside of the vial for extracting specimen. Turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and the bottom of the vial. Take swab out of the vial with squeezing out liquid from the spherical tip.



③Install filter (Pink color)and shake the vial lightly to mix specimen thoroughly. The sample is ready for use.



● Details of test plate



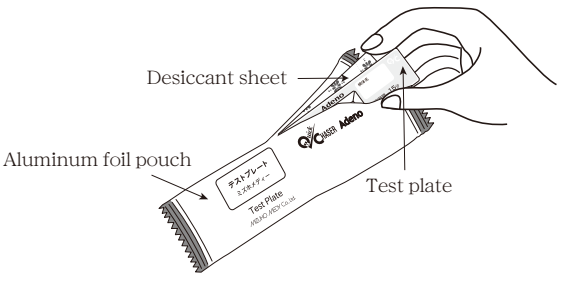
● Test procedure

1) Preparation of reagent

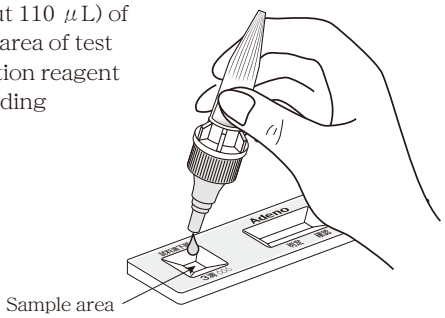
Test plate : No prior preparation required.

2) Test procedure

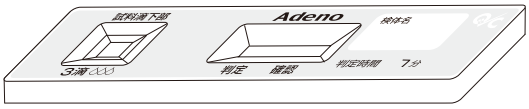
① Remove test plate from aluminum foil pouch. Discard desiccant sheet included in aluminum foil pouch.



② Add 3 drops (about 110 μL) of sample to sample area of test plate from extraction reagent solution vial including prepared sample.



③ Leave to react at 15℃～30℃.
Interpret test result visually by lines in test line area and control line area after 7 minutes.



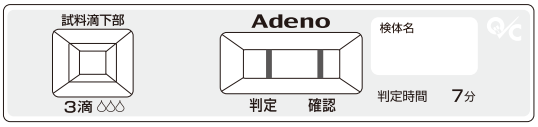
[Interpretation]

Interpretation by the existence of red-purple lines in Test line area.

《Positive》

Both test line and control line appear.

Positive



《Negative》

Only control line appears.

Negative

《Retest》

Both test line and control line do not appear or no control line appears for Adenovirus. Sample volume may not be enough. Recheck test procedure and retest with new test plate. If the same result come out in the retest again, confirm it with other method.

Retest

Retest

● **Interpretational precautions**

1) Interpretation is made at 7 minutes after dropping sample. Streak line might appear temporarily. Be careful not to interpret the temporal streak line as test line.
After interpretation time, colloidal gold can appear like line due to drying of test plate with time. Therefore interpret test results at the predetermined time.

2) This product is used as an aid in the diagnosis for infection of adenovirus. In case that adenovirus antigens in specimen are below the detection limit of the test or specimen collection is not enough, test result could be interpreted as negative, even though patients are infected by adenovirus. Moreover, special factors in specimen could cause non-specific reaction and negative specimen could be interpreted as positive. The definitive diagnosis should be made comprehensively in conjunction with the assessment of clinical progress and other test result.

[Performance characteristics]

1) Performance

①Sensitivity

・When In-house positive control A※1) was tested, a positive result was obtained.

②Accuracy

・When In-house positive control B※2) was tested, a positive result was obtained.
・When In-house negative control※3) was tested, a negative result was obtained.

③Reproducibility

・When In-house positive control B were tested, three times simultaneously, positive results were obtained in all cases.
・When In-house negative controls were tested three times simultaneously, negative results were obtained in all cases.

※1) Adenovirus purified antigen (in Adenovirus culture solution), diluted and adjusted with PBS, including 0.5% BSA to be equivalent to 1×10^7 $TCID_{50}$ / ml, is dilulted two hundred times to be used by In-house negative control.

※2) Adenovirus purified antigen (in Adenovirus culture solution), diluted and adjusted with PBS, including 0.5% BSA to be equivalent to 1×10^7 $TCID_{50}$ / ml, is dilulted one hundred times to be used by In-house negative control.

※3) Extraction reagent solution

$TCID_{50}$: Virus dilution fluid of 10^n of sample is inoculated on VeroE 6 cell (Cell line derived from monkey kidney tissue) and the virus dilution magnification by which the cytopathic effect (CPE) of 50% appears is called $TCID_{50}$. The calculation method is Barhrens-Karber method.

④Detectability (Detection limit)

・Detectability of following Adenovirus serotype were tested by making serial dilution. The results were as follows :

Serotype Type 1	1×10^4 $TCID_{50}$／mL
Serotype Type 2	1×10^5 $TCID_{50}$／mL
Serotype Type 3	1×10^4 $TCID_{50}$／mL
Serotype Type 4	2×10^4 $TCID_{50}$／mL
Serotype Type 5	2×10^5 $TCID_{50}$／mL
Serotype Type 6	2×10^4 $TCID_{50}$／mL
Serotype Type 7	4×10^4 $TCID_{50}$／mL
Serotype Type 8	1×10^3 $TCID_{50}$／mL
Serotype Type 11	3×10^5 $TCID_{50}$／mL
Serotype Type 19	1×10^3 $TCID_{50}$／mL
Serotype Type 31	1×10^3 $TCID_{50}$／mL
Serotype Type 37	1×10^1 $TCID_{50}$／mL
Serotype Type 53	3×10^1 $TCID_{50}$／mL
Serotype Type 54	2×10^0 $TCID_{50}$／mL

⑤Serotype and Reactivity

・It has been confirmed that following serotype of Adenovirus are detected by Quick Chaser Adeno (Throat).
Type 1 , 2 , 3 , 4 , 5 , 6 , 7 , 8 , 11 , 19 , 31 , 37 , 53 , 54 .

2) Correlation

Comparison with existing immunochromatographic product

Quick Chaser® Adeno

Other product (1)	Positive	Negative	Total
Positive	50	0	50
Negative	0	55	55
Total	50	55	105

Positive agreement rate : 100%(50/50)
Negative agreement rate : 100%(55/55)
Total agreement rate : 100%(105/105)

Quick Chaser® Adeno

Other product (2)	Positive	Negative	Total
Positive	47	0	47
Negative	3※	55	58
Total	50	55	105

Positive agreement rate : 100%(47/47)
Negative agreement rate : 94.8%(55/58)
Total agreement rate : 97.1%(102/105)

※ Above three specimen that became disagreed were confirmed to be positive by virus separation culture method and by above other product (1).

3) Calibration reference material (Standard material)

Adeno virus culture fluid (in-house standard)

[Precautions for use and handling]

1) Precautions for handling (Prevention of danger)

①Infectious materials such as HIV, HBV and HCV etc. could be included in sample (specimen). Be careful of handling sample (specimen) as potentially infectious materials.

②Be careful not to touch sample (specimen) or extraction reagent solution to skin or not to get into eyes directly in wearing glasses, disposable gloves or mask etc. at the time of use.

③Do not use swab to collect specimen, if it is already put into extraction reagent solution.

④If sample (specimen) and / or extraction reagent solution are got into eyes or mouth, flush with a plenty of water as emergency treatment and see a doctor, if necessary.

⑤Do not use blue cap included in kit for transportation or preservation because it does not have seal strength.

⑥Perform the collection of specimen under the guidance of the qualified person.

⑦Raw material of membrane which is used for test plate, is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.

⑧Wipe off with sodium hypochlorite solution in case of getting splattered with sample (specimen).

2) Precautions for use

①Do not freeze this product. Store this product in accordance with description of Instructions For Use. Do not use frozen reagents because they could show false result by change of quality.

②Do not use this product beyond expiration date.

③Do not store extraction reagent solution vial with falling sideways or inverting.

④Use the test plate immediately after opening aluminum foil pouch. If test plate is left in a room for a long time, it could not react by exposure to moisture.

⑤Do not touch sample area, test line area and control line area by hands directly.

⑥Do not perform test in the place such as under air conditioner where the dry wind directly blows the surface of test plate, to prevent uneven migration.

⑦Do not use the reagent and the accessories etc. of this product except the purpose of this testing.

⑧Test plate, swab and extraction reagent solution vial (Filter and caps are included) are intended for single use only.

⑨Use only swab included in this kit.

⑩Do not touch spherical tip of swab by hands before use.

⑪Use swab immediately after opening the package.

⑫If break and/or hole are found on the pouch of swab, do not use it.

⑬If swab is stained or broken or bent, do not use it.

⑭Do not bend the rod of swab before collecting specimen.

⑮Be careful not to break the rod of swab by pushing too hard at the time of specimen collection.

⑯Be careful not to splatter the sample at the time of taking the swab out of vial after preparing sample.

⑰In case that collection volume of specimen is excessive or the viscosity of the specimen is high, membrane filter could be clogged and the sample of appropriate quantity may not be dropped. In such case, collect specimen again and retest it with new test plate.

3) Precautions for waste disposal

①Treat liquid waste and used utensils by any one of following methods because sample (specimen) could contain infectious material such as HIV, HBV, and HCV etc.

a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or more.

b) Immerse in 2 % glutaraldehyde solution for 1 hour or more.

c) Autoclave at 121° C for 20 minutes or more.

②Regarding disposal of reagents and utensils etc. , dispose of them as medical waste, industrial waste or infectious waste inaccordance with your waste disposal laws and regulations.

[STORAGE・EXPIRY]

・Storage :1～30℃

・Expiry : 24 months

Technical information
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