Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Group A Streptococcal antigen kit

Quick Chaser Dip Strep A

[General precautions]

1) This product is for in-vitro diagnostic use only. Do not use for other purpose.
2) Diagnosis should be made properly in conjunction with the assessment of clinical symptom and other test results.
3) The procedures that are not described in instruction for use are not guaranteed.

[Contents]

1) Test strip -10 tests
   Rabbit polyclonal anti-Group A streptococcus
   Colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcus
2) Extraction reagent A (2.0mol/L Sodium Nitrite) - 10mL×1
3) Extraction reagent B (0.2mol/L Acetic Acid) - 10mL×1
4) Swab (For pharyngeal swab specimen) -10 pieces
5) Tube - 10 pieces
6) Tube rack - 1 piece

[Intended use]

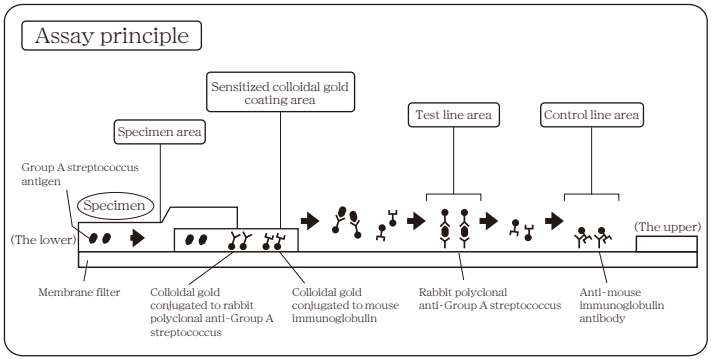
For detection of Group A Streptococcus antigen in pharyngeal mucosa epithelial cell
(To aid in the diagnosis of Group A Streptococcal infection)

[Principle of the test]

Quick Chaser Dip Strep A is the in-vitro diagnostic reagent for detection of Group A Streptococcus antigen based on Immunochromatographic Assay

Colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcus and colloidal gold conjugated to mouse immunoglobulin for control line are coated in sensitized colloidal gold coating area in test strip. Rabbit polyclonal anti-Group A Streptococcus is immobilized in the area of the test line and anti-mouse immunoglobulin antibody is immobilized in the area of control line.

According to immunochromatographic principle, in the presence of Group A streptococcus antigen in specimen, they migrate to the area between Specimen area and Test line area, where reacting with colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcus, and moreover, they react with rabbit polyclonal anti-Group A Streptococcus and are caught in the Test line area, where visible purple-red line indicates the presence of Group A Streptococcus. Simultaneously, purple-red line is also visible for catching colloidal gold conjugated to mouse immunoglobulin on control line, regardless of presence of Group A Streptococcus antigen.



[Procedural precautions]

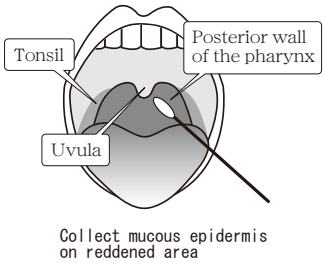
1) Do not use the collected specimen from other places than Pharynx area
2) If a large amount of mucus (saliva, nasal secretion etc.) are included in specimen, it could give bad influence to reaction and cause wrong test result. Therefore, be careful not to touch tongue,the inside surface of cheek and teeth for avoiding the collection of a large amount of mucus.
3) Collected specimen should be prepared in accordance with proper method and should be tested as soon as possible.If the swab specimen cannot be tested immediately, keep the swab specimen in a clean and dry closed container and prepare the speciment within 4 hours at room temperature or 48 hours at 2℃～8℃ for performing the test.
4) Keep volume of extraction reagent A and extraction reagent B (3 drops each). Proper result might not be obtained in case that the given amount is not kept.
5) Bring test strip and extraction reagent A and extraction reagent B to 15～30℃ prior to use.
6) Interfering substances and medications
   Following substances and blood were found not to affect test performance at the concentration listed.
   - Cold medicine ① (Concentration of Acetaminophen: 5mg/ml)
   - Cold medicine ② (Concentration of Ibuprofen: 5mg/ml)
   - Gargle ①, containing Chlorhexidine gluconic acid (0.25%)
   - Gargle ②, containing Myrrh Tincture (0.5%)
   - Gargle ③, containing Povidoneiodine (3.25%)
   - Oral antiphlogistic containing water-soluble azulene (10%)
   - Cough drop ①, containing Dipotassium Glycyrrhizinate (20 mg/ml)
   - Cough drop ②, containing Dry Nandin Fruit Extract (10 mg/ml)
   - Cough drop ③, containing Cetylpyridinium chloride (20 mg/ml)
   - Acetylsalicylic acid (20 mg/ml)
   - Diphenhydramine hydrochloride (5 mg/ml)
   - Dextromethorphane (10 mg/ml)
   - Whole blood (1%)
7) Cross Reactivity
   - Bacteria
     No cross reactivity was observed with *Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Psedomonas aeruginosa, Candida albicans, Enterococcus faecalis, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus mutans* and *Streptococcus sp.* Group B,C,F,G
     ※No cross reactivity was observed with *Staphylococcus aureus* (1.0×10^7 CFU /mL or lower)
   - Influenza A virus
     No cross reactivity was observed with A/PR/8/34(H1N1) and A/Victoria/3/75(H3N2)
   - Influenza B virus
     No cross reactivity was observed with B/lee/40 and B/Mass/3/66
   - Adeno virus
     No cross reactivity was observed with Adenovirus type 1, 2, 3, 4, 5 and 6
   - RSV
     No cross reactivity was observed with A2, long, B1wild, 9320 and CH18537

[Test procedure]

● Specimen collection and preparation

1) Preparation of specimen collection
Use swab provided in this kit.

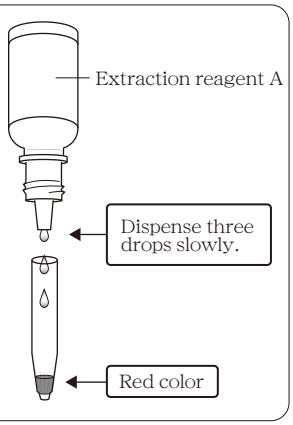
2) Specimen collection
Insert swab from oral cavity into pharynx. Collect mucous epidermis by rubbing several times reddened area of a posterior wall of the pharynx or tonsil.



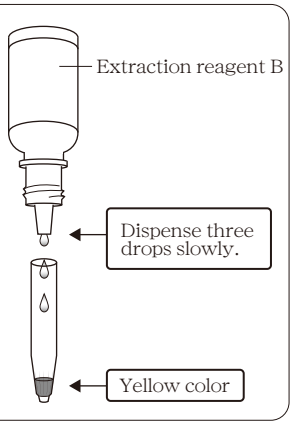
● Preparation of reagent

Bring test strip and extraction reagent A and extraction reagent B to 15～30℃ prior to use.

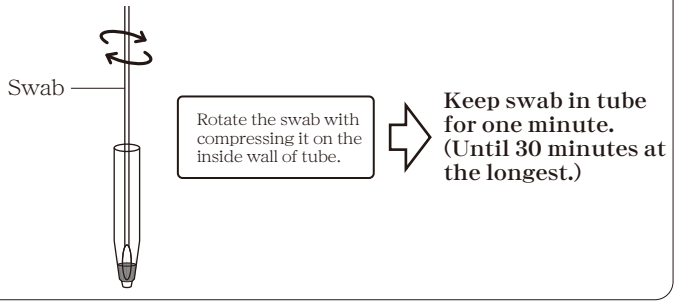
① Add 3 drops of extraction reagent A into tube with holding the bottle vertically. Extraction reagent A takes on red.



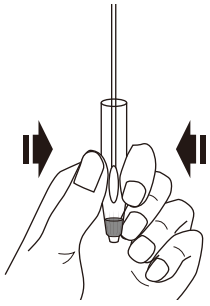
② Add 3 drops of extraction reagent B into the tube with holding the bottle vertically. The mixture solution turns yellow.The yellow mixture solution is used as extraction reagent solution.



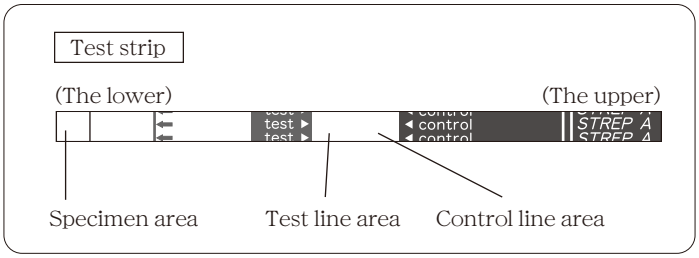
③ Immediately add the patient swab specimen to the tube. Rotate the swab with compressing spherical tip to the bottom of the tube to thoroughly extract specimen. Keep swab in tube for one minute.
Note) Do not keep the swab in tube for more than 30 minutes.



④ Take swab out of the tube while squeezing liquid from spherical tip by pressing the tip from the outside of the tube with fingers.

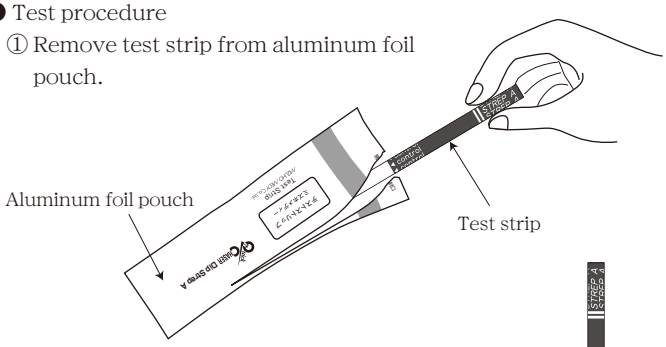


● Details of test strip

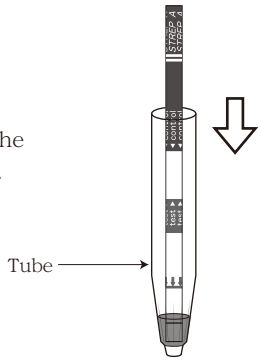


● Test procedure

① Remove test strip from aluminum foil pouch.



② Place the test strip into the tube with the arrows of the test strip pointing down.



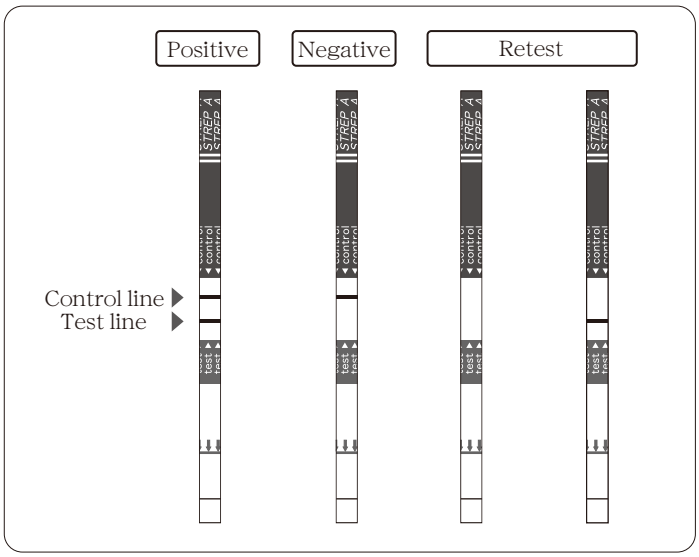
③ Interpret test visually by lines in test line area and control line area after 5 minutes. Streak line of the colloidal gold might be observed during migration of colloidal gold before 10 minutes. Do not interpret the temporal streak line as appearance of test line.
※Test result can be interpreted without taking test strip out of tube because it is made of transparent materials.

[Interpretation]

Interpret result by the existence of red-purple lines in Test line area and Control line area.

● Note for interpretation

Do not interpret the test result beyond 10 minutes after dipping into specimen. Exact test result cannot be read in case of interpretation after 10 minutes.



《Positive》
Both test line and control line appear.
《Negative》
Only control line appears.
《Retest》
Both test line and control line do not appear or no control line appears. Inappropriate test procedure such as short specimen volume might be thought about. Recheck test procedure and retest with new rest strip. If the same result comes out again, confirm it with other method.

[Performance characteristics]

1) Sensitivity
・When in-house positive controls(※1) are tested, positive results are obtained.

2) Accuracy
・When in-house positive controls are tested, positive results are obtained.
・When in-house negative controls(※2) are tested, negative results are obtained.

3) Reproducibility
・When in-house positive controls are tested three times simultaneously, positive results are obtained in all cases
・When in-house negative controls are tested three times simultaneously, negative results are obtained in all cases.

※1 Reference Group A Streptococcal antigen solution diluted by extraction reagent A and B to 5.0×10^5 CFU/ml.
※2 Buffer diluted by extraction reagent A and B

4) Detection limit
1.0×10^5 CFU/ml

5) Correlation
Comparison with existing immunochromatographic test product approved in Japan

Quick Chaser Dip Strep A

Other product 1

	Pos.	Neg.	Total
Pos.	53	4※1	57
Neg.	0	53	53
Total	53	57	110

Negative agreement rate: 93.0%
Positive agreement rate: 100%
Total agreement rate: 96.4%

Quick Chaser Dip Strep A

Other product 2

	Pos.	Neg.	Total
Pos.	57	0	57
Neg.	3※2	50	53
Total	60	50	110

Negative agreement rate: 100%
Positive agreement rate: 95.0%
Total agreement rate: 97.3%

※1: 4 discrepant specimen showed positive by other product 2.
※2: 3 discrepant specimen showed negative by other product 1.

6) Calibration standard : ATCC19615

[Precautions for use and handling]

1) Precaution for handling (Prevention of danger)
① Be careful of handling specimen as potentially viral or bacterial infectious material. Wear disposable gloves for avoiding potential infection at the time of testing.
② Be careful not to touch specimen or extraction reagent solution directly to skin or eyes.
③ Do not use swab, if it is already put into extraction reagent solution, to collect specimen.
④ If specimen and/or extraction reagent solution are accidentally got into eyes or mouth, flush with plenty of water as emergency treatment, and see a doctor if necessary.
⑤ 2.0 mol/L Sodium nitrite is contained in Extraction reagent A and 0.2 mol/L Acetic acid is contained in Extraction reagent B so they are accidentally got into eyes or mouth, flush with plenty of water as emergency treatment, and see a doctor if necessary.
⑥ Do specimen collection under guidance of technically qualified person.
⑦ Raw material of membrane used for test strip is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.
⑧ Wipe scattered specimen off by alcohol for disinfection.

2) Precaution for use
① Do not use beyond expiration date.
② Do not freeze. Store in accordance with description of instruction for use. Do not use frozen reagents because they could show incorrect test result.
③ Immediately use test strip after opening of foil pouch. If it is left in air for long time after the opening, it could be non-reactive due to getting moistened.
④ Do not touch Specimen area, Test line area and Control line area by hands directly.
⑤ Do not perform test in the place such as under air conditioner where the dry wind blows the test strip into uneven migration.
⑥ Use only swab included in the kit.
⑦ Use swab immediately after opening package.
⑧ If break and/or hole are found on the package of swab, do not use it.
⑨ If swab is stained, broken or bent, do not use it.
⑩ Do not bend the rod of swab before collecting specimen.
⑪ Do not touch spherical tip before use.
⑫ Be careful not to break the rod of swab by pushing too hard at the time of collecting specimen.
⑬ Be careful not to splatter the specimen at the time of taking the swab out of vial after preparing specimen.
⑭ Do not mix each kit composition from different lot numbers.
⑮ Be careful not to interchange bottle caps with extract reagents because it could make extract reagents mix together

3) Precaution for waste disposal
① Regarding disposal of reagents and utensils, dispose of them in accordance with local law and regulation.

[Storage・Expiry]

・Storage: 1 ～ 30℃
・Expiry: 24 months (As indicated on package)

[Reference]

1)Lancefield,R.C. : J.Exp.Med.,57;571-591, 1933

Technical information
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“Quick Chaser” is a registered trademark of Mizuho Medy Co., Ltd.

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