Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Group A Streptococcal antigen kit

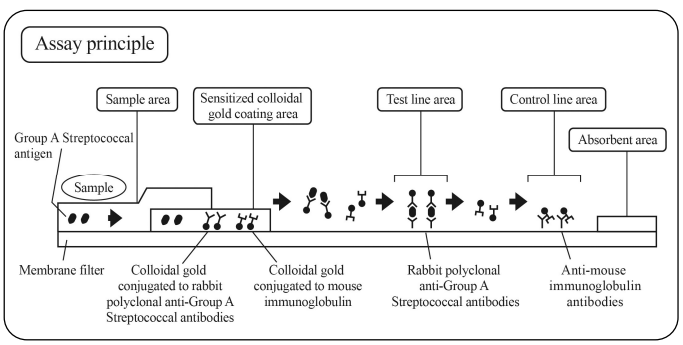
Quick Chaser Strep A

[Package]
70020: Quick Chaser Strep A - 10 tests/kit

[Contents]
1) Test plate - 10 tests
   • Rabbit polyclonal anti-Group A Streptococcal antibodies
   • Colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcal antibodies
2) Extraction reagent A (2.0mol/L Sodium Nitrite) - 5mL×1 bottle
3) Extraction reagent B (0.2mol/L Acetic Acid) - 5mL×1 bottle
4) Swab (For oropharyngeal swab specimen) -10 pieces
5) Extraction reagent solution vial - 10 vials
6) Filter (for extraction reagent solution vial) - 10 pieces

[Intended use]
For qualitative detection of Group A Streptococcal antigen in pharyngeal mucosa epithelial cell
(An aid in the diagnosis of Group A Streptococcal infection)

[Principle of the test]
"Quick Chaser Strep A" is the in vitro diagnostic reagent for qualitative detection of Group A Streptococcal antigen based on the immunochromatographic assay.
Colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcal antibodies and colloidal gold conjugated to mouse immunoglobulins for control line are coated in sensitized colloidal gold coating area on a membrane filter which is set in test plate. Also, rabbit polyclonal anti-Group A Streptococcal antibodies are immobilized in the test line area and anti-mouse immunoglobulin antibodies are immobilized in the control line area.
If Group A streptococcal antigens are present in the sample, according to the principle of immunochromatography, they react with colloidal gold conjugated to rabbit polyclonal anti-Group A Streptococcal antibodies as they migrate from the sample area. Moreover, they are captured in the test line area by reacting with rabbit polyclonal anti-Group A Streptococcal antibodies. As a result, a purple-red line with the colloidal gold appears in test line area.
At the same time, the colloidal gold conjugated to mouse immunoglobulins also migrate and will be captured by the anti-mouse immunoglobulin antibodies on the control line area, resulting in the appearance of a purple-red line in the control line area regardless of the presence or absence of Group A Streptococcal antigens.



[Warnings and Precautions]
1) For in vitro diagnostic use only.
2) Procedures not described in the Instructions for Use are not guaranteed.
3) This product can be interpreted both visually and with the dedicated device "Smart QC Reader". When interpreting with the dedicated device, use it according to the Instructions for Use and User Manual of the dedicated device.
4) Bring test plate and extraction reagent solution to 15 to 30℃ prior to testing.
5) Sample (specimen) may contain infectious materials such as HIV, HBV, and HCV, etc. Handle sample (specimen) with great care as there is a risk of infection during the test.
6) When using, wear protective equipment (glasses, disposable gloves, mask, etc.) and be careful not to let the sample (specimen) or extraction reagent solution directly adhere to the skin or get into your eyes.
7) Do not collect the specimen with a swab soaked in the extraction reagent solution.
8) If a sample (specimen) or extraction reagent solution accidentally gets into your eyes or mouth, take first-aid measures such as rinsing it thoroughly with water and seek medical attention if necessary.
9) Extraction reagent A contains 2.0 mol/L Sodium nitrite and Extraction reagent B contains 0.2 mol/L Acetic acid respectively, hence if they accidentally get into eyes or mouth, take first-aid measures such as rinsing it thoroughly with water, and seek medical attention if necessary.
10) Perform the specimen collection under the guidance of a qualified person.
11) The material of the membrane used for the test plate is nitrocellulose. Do not perform tests near a fire as nitrocellulose is extremely flammable.
12) If the sample (specimen) spatters, wipe it off with alcohol for disinfection, etc.
13) Do not freeze this product. Store it in accordance with the description of storage. Do not use frozen reagents as they may change the quality and may not give correct results.
14) Do not use this product beyond the expiration date.
15) Use the test plate immediately after opening the aluminum foil pouch. If the test plate is left in a room for a long time, it could not react by exposure to moisture.
16) Do not touch sample area, test line area, and control line area by hand directly.
17) Do not perform the test in a place such as under an air conditioner where the dry wind directly blows the test plate to prevent uneven migration.
18) Do not use the reagents, accessories, etc. of this product for any purpose other than this inspection.
19) Test plate, swab, and extraction reagent solution vial (including filter and caps) are intended for single use only.
20) Use swabs included in this product.
21) Do not touch the spherical tip of the swab before use.
22) Use swab immediately after opening the package.
23) Do not use a swab if a break and/or hole are found on the package.
24) Do not use a swab if stained, broken, or bent.
25) Do not bend or curve the rod of the swab before collecting the specimen.
26) Be careful not to break the rod of the swab or damage the collection site (mucosa) by applying too much force or pressing too hard when collecting specimen with a swab.
27) After preparing the sample, be careful not to spatter the sample when removing the swab.
28) If the amount of specimen collected is excessive or the specimen is highly viscous, the filter may become clogged, and adequate sample volume may not be dropped. In that case, collect a new specimen and perform the retest.
29) Do not mix reagent of different lots.
30) Be sure to use the correct bottle cap for each extraction reagent solution, as mixing up the caps may cause extraction reagents to mix together.
31) Handle liquid waste and used utensils by any of the following disinfection and sterilization methods as sample (specimen) may 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 longer
   b) Immerse in 2% glutaraldehyde solution for 1 hour or longer
   c) Autoclave at 121℃ for 20 minutes or longer
32) Regarding disposal of used reagents and utensils, dispose of them in accordance with the Local Regulation and Law of waste disposal.

[Storage and stability of the device]

Store kit at 1 to 30°C, out of direct sunlight or high humidity. Kit contents are stable until the expiration dates printed on the product box and packaging. Do not freeze.

[Preparation of specimen collection]

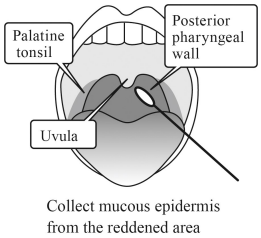
This product can be interpreted both visually and with a dedicated device. "Specimen collection" and "Sample preparation" are common to both visual and dedicated devices.

1) Swab (for oropharyngeal swab specimen): Use swab included in this kit.
2) Extraction reagent solution: Refer to “Reagent preparation”

[Specimen collection and handling]

Proper specimen collection and handling are critical to the performance of this kit.

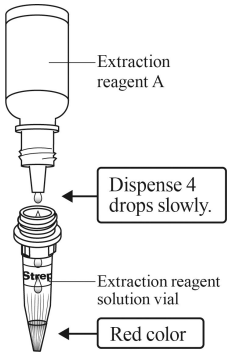
1. Oropharyngeal swab specimen:
Insert swab (for oropharyngeal swab specimen) from oral cavity into pharynx, and collect mucous epidermis by rubbing the reddened area of the posterior pharyngeal wall, uvula, or palatine tonsil several times by swab.



Specimens should be tested as soon as possible. However, if the test cannot be performed immediately, swab specimen can be stored in a clean and dry sealed container for up to 4 hours at room temperature or 48 hours at 2 to 8 ℃ before sample preparation and testing. Bring samples to room temperature before testing.

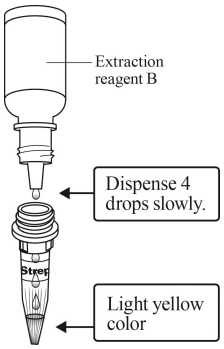
[Reagent preparation]

1. Add 4 drops of extraction reagent A into extraction reagent solution vial while holding the bottle vertically.
Extraction reagent A appears red.



2. Add 4 drops of extraction reagent B into the extraction reagent solution vial while holding the bottle vertically.
The mixture solution turns light-yellow.
The light-yellow mixture solution is used as extraction reagent solution.

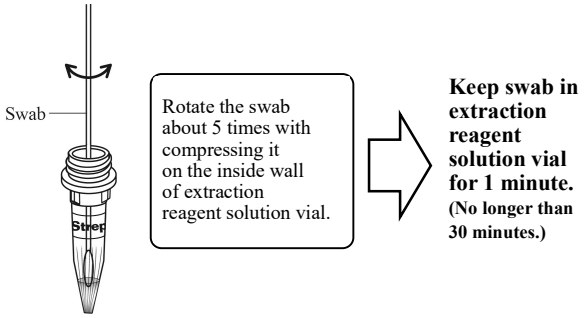
Note) Use the extraction reagent within 60 minutes.



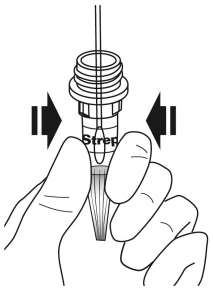
[Sample preparation and Test procedure]

• Sample preparation

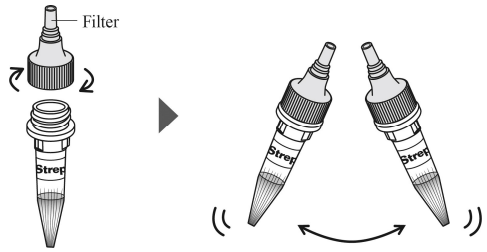
1. Dip the swab specimen into the tube. Turn the swab clockwise and counterclockwise about five times while pressing the spherical tip on the inside wall of the vial to extract specimen thoroughly. Leave the swab in extraction reagent solution vial for one minute.
Note) Do not leave the swab in extraction reagent solution vial for more than 30 minutes.



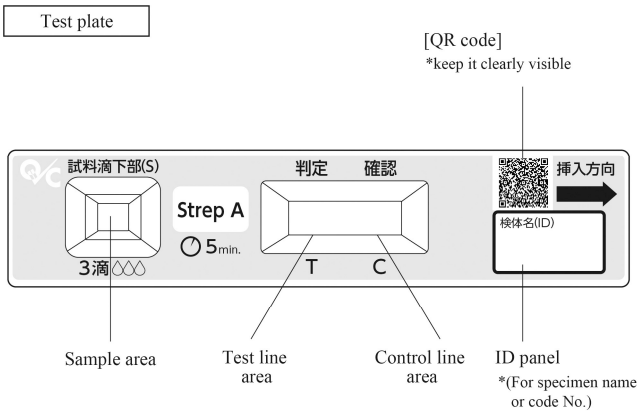
2. Lift the swab above the liquid surface, hold the spherical tip from outside the viral with fingers, squeeze as much liquid as possible, and then remove the swab. At this time, do not remove the swab while holding the spherical tip.



3. Install filter and shake the vial gently to mix specimen thoroughly. The sample is ready for use.



· Details of test plate



· Test procedure

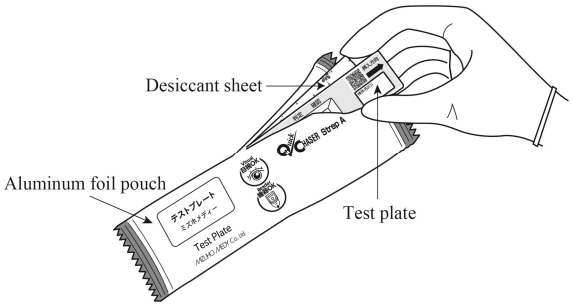
1) Preparation of reagent

Test plate: No prior preparation required.

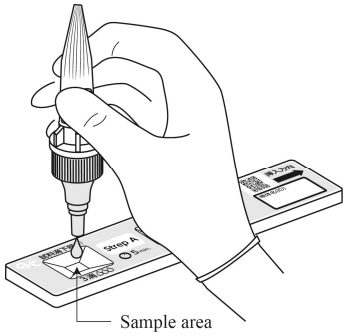
2) Test procedure

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

(Note) Please be careful not to stain the QR code when writing the sample name in the ID panel.



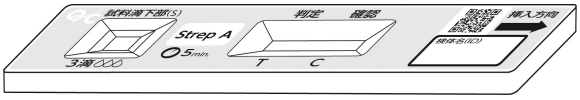
2. Add 3 drops (about 140μL) of sample to the sample area of the test plate from the extraction reagent solution vial containing the prepared sample. Hold the vial vertically so that the tip of the extraction filter does not come into contact with the sample area of the test plate.



<When interpreting visually>

3.-1 Leave to react at 15 to 30°C.

Interpret test results visually by reading lines in the test line area and control line area after 3 to 5 minutes.



<When interpreting with the dedicated device>

3.-2 A method of reading and interpreting the lines that appear in the test line area and control line area with the dedicated device.

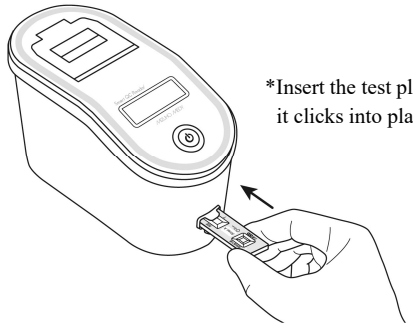
After checking the insertion direction of the test plate, measure according to the operation method of "Mode 1" or "Mode 2".

Note) · Do not attach labels etc. on the test plate.

· Be careful not to touch the sample area when inserting the test plate.

· Insert the test plate by keeping it horizontal to prevent the sample from spilling or splashing into the instrument.

· Insert the test plate all the way.



*Insert the test plate until it clicks into place.

1) Mode 1 [Read Now]

This mode interprets the test plate after the reaction time has elapsed.

1. Leave to react at 15 to 30°C.
2. After 5 minutes, insert the test plate into the test plate insertion slot of the dedicated device.
3. The lines appearing in the test line area and control line area are read inside the dedicated device.

2) Mode 2 [Walk Away]

This mode automatically interprets the test plate after dropping the sample inside the dedicated device.

1. Immediately after dropping the sample, insert the test plate into the test plate insertion slot of the dedicated device.
2. The measurement starts automatically, and the lines appearing in the test line area and control line area are read every minute after 3 minutes inside the dedicated device.

*When the environmental temperature is lower than 15°C, the temperature of the test plate is controlled to be 15 to 30°C. (function only in Mode 2)

[Interpretation]

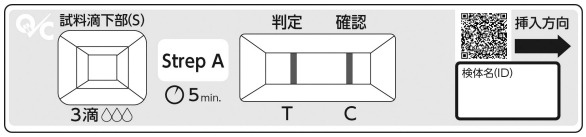
<When interpreting visually>

Interpretation by the existence of red-purple lines in the test line area and control line area.

<Positive>

Both test line and control line appear.

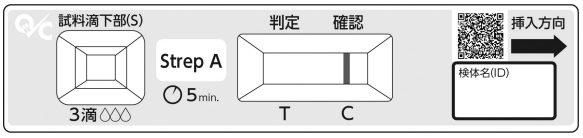
Positive



<Negative>

Only a control line appears.

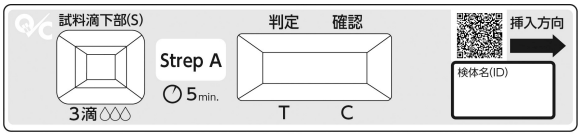
Negative



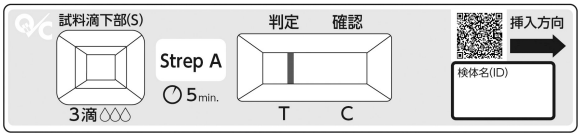
<Retest>

If both test line and control line do not appear or no control line appears, an operational error such as insufficient sample volume may be considered. Recheck test procedure and retest with the new test plate. If the same result comes out in the retest again, confirm it with other methods.

Retest



Retest



<When interpreting with the dedicated device>

Both Mode 1 [Read Now] and Mode 2 [Walk Away] are automatically interpreted according to the interpretation method of < When interpreting visually> based on the result of reading the lines with the dedicated device. Interpretation and display on the device screen are the same in Mode 1 [Read Now] and Mode 2 [Walk Away].

Interpretation	Display on the device screen
Positive	STREP A : ＋
Negative	STREP A : －
Retest	STREP A : ＊　#03

*Error code #03: Error when the control line is not detected.

*For error codes other than error code #03, refer to the User Manual of the dedicated device.

[Limitations]

1) Diagnosis of Group A Streptococcal infection should not be based solely on the test results of this product but should be comprehensively made in consideration of other test results and clinical symptoms.
2) Do not use specimen except for which collected from the pharynx area.
3) When collecting a sample, if specimen contains a large amount of mucus (saliva, nasal secretion etc.), it may affect reaction and cause an incorrect interpretation, therefore, keep swab from touching tongue, the inside surface of cheek and teeth in order to avoid the collection of a large amount of mucus.
4) Ensure to follow specified volume of extraction reagent A and extraction reagent B (4 drops each). When adding a sample, keep the tip of the filter by about 10mm from the center of the sample area so that a drop can be formed, and add the specified volume (3 drops). If the sample volume is not as specified, the reaction may not be accurate.
5) In the case of test line and control line appear at 3 to 5 minutes after dropping the sample, it can be interpreted as positive. Negative should be interpreted at 5 minutes after dropping the sample. The streak line might appear before 5 minutes temporarily due to the flow of colloidal gold. Do not interpret the temporal streak line as the appearance of the test line. After 5 minutes, colloidal gold can appear like a line due to the drying of the test plate with time. Therefore, please interpret test results within 5 minutes.
6) This product is used as an aid in the diagnosis for Group A Streptococcal infection. In case Group A Streptococcal antigen amount in the specimen is below the detection limit of the test or inadequate specimen collection, test result could be interpreted as negative, even though the patient is infected by Group A *Streptococcus*. In addition, a non-specific reaction may occur depending on the factors in the sample, and a negative specimen may be interpreted as positive. The final definitive diagnosis should be made comprehensively from clinical symptoms and other test results.
7) The results of the visual interpretation and the interpretation with the dedicated device may not match. In such a case, make a comprehensive judgment based on both results, clinical symptoms and other test results.
8) When interpreting with the dedicated device, if the control line area or test line area of the test plate is scratched or foreign matter (dust) is attached, it may be mistakenly detected as a line.
9) When using Mode 1 [Read Now] in the interpretation with the dedicated equipment, be sure to perform the measurement 5 minutes after the sample is dropped. If measured within 5 minutes, correct results may not be obtained.

[Performance characteristics]

1) Performance
   1. Sensitivity
      When in-house positive control [note 1)] was tested, a positive result was obtained.
   2. Accuracy
      • When in-house positive control was tested, a positive result was obtained.
      • When in-house negative control [note 2)] was tested, a negative result was obtained.
   3. Reproducibility
      • When in-house positive control was tested three times simultaneously, positive result was shown in all cases.
      • When in-house negative control was tested three times simultaneously, negative result was shown in all cases.

   Note 1) Reference Group A Streptococcal antigen solution diluted by extraction reagent A and B to be equivalent to 5.0×10^5 CFU/mL.
   Note 2) Buffer diluted by extraction reagent A and B

   4. Detection limit
      1.0×10^5CFU/mL

2) Correlations
   Comparison with existing approved products (immunochromatographic assay)

Quick Chaser Strep A

Other product (1)	Positive	Negative	Total
Positive	54	0	54
Negative	0	53	53
Total	54	53	107

Positive agreement rate : 100%(54/54)
Negative agreement rate : 100%(53/53)
Total agreement rate : 100%(107/107)

Quick Chaser Strep A

Other product (2)	Positive	Negative	Total
Positive	52	0	52
Negative	2*	53	55
Total	54	53	107

Positive agreement rate : 100%(52/52)
Negative agreement rate : 96.4%(53/55)
Total agreement rate : 98.1%(105/107)
* Both two discrepant cases were positive with the PCR method and with Other product (1).

3) Calibration reference material (Standard material)
   ATCC19615

4) Interfering substances and medications
   Following substances and blood did not interfere with the performance of this product at the concentration listed below.

   • Cold medicine 1 (Concentration of Acetaminophen: 5mg/mL)
   • Cold medicine 2 (Concentration of Ibuprofen: 5mg/mL)
   • Gargle 1 containing Chlorhexidine gluconate (0.25%)
   • Gargle 2 containing Myrrh Tincture (0.5%)
   • Gargle 3 containing Povidone iodine (1.63%)
   • Oral antiphlogistic containing water-soluble azulene (10%)
   • Cough drop 1 containing Dipotassium Glycyrrhizinate (20mg/mL)
   • Cough drop 2 containing Dry Nandin Fruit Extract (10mg/mL)
   • Cough drop 3 containing Cetylpyridinium chloride (20mg/mL)
   • Acetylsalicylic acid (20 mg/mL)
   • Diphenhydramine hydrochloride (5 mg/mL)
   • Dextromethorphan (10 mg/mL)
   • Blood (1%)

5) Cross reactivity

Cross reactivity was not observed with the following viruses and bacteria.

- Influenza A virus
  A/PR/8/34(H1N1) and A/Victoria/3/75(H3N2)
- Influenza B virus
  B/lee/40 and B/Mass/3/66
- Adeno virus
  Adenovirus type 1, 2, 3, 4, 5 and 6
- RS virus
  A2, Long, 9320 and CH18537
- Bacteria
  Escherichia coli, Hemophilus infuenzae, Klebsiella pneumoniae, Pseudomonas aeruginosa, Candida albicans, Enterococcus faecalis, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus mutants and Streptococcus sp. Group B, C, F, G
  * No cross reactivity was observed with *Staphylococcus aureus* (1.0×10^7 CFU /mL or lower)

[Shelf life]

24 months from the date of manufacture
(As indicated on the product box and packaging)

[Reference]

Lancefield,R.C.：J.Exp.Med.， 57， 571-595(1933)

Technical information
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