

Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Rotavirus kit · Adenovirus kit

Quick Chaser® Rota / Adeno

[General precautions]

- 1) For in vitro diagnostic use only.
- 2) The diagnosis of rotavirus infection and adenovirus infection should be comprehensively made not only by test results of this product, but also in conjunction with the assessment of clinical progress and results of other tests.
- 3) Procedures which are not described in instructions for use, are not guaranteed.

[Contents]

- 1) Test plate - 10 tests
 - Mouse monoclonal anti-human rotavirus antibodies
 - Mouse monoclonal anti-human adenovirus antibodies
 - Colloidal gold conjugated to mouse monoclonal anti-human rotavirus antibodies
 - Colloidal gold conjugated to mouse monoclonal anti-human norovirus antibodies
- 2) Extraction reagent solution vial - 10 vials
- 3) Swab - 10 pieces
- 4) Rack (for extraction reagent solution vial) - 1 piece
- 5) Filter (for extraction reagent solution vial) - 10 pieces
- 6) Blue cap (for temporary storage of extraction reagent solution vial) - 10 piece
- 7) Name label for extraction reagent solution vial - 1 sheet

[Intended use]

Detection of rotavirus antigen and adenovirus antigen in feces
(Aid in the diagnosis for infection of rotavirus and adenovirus)

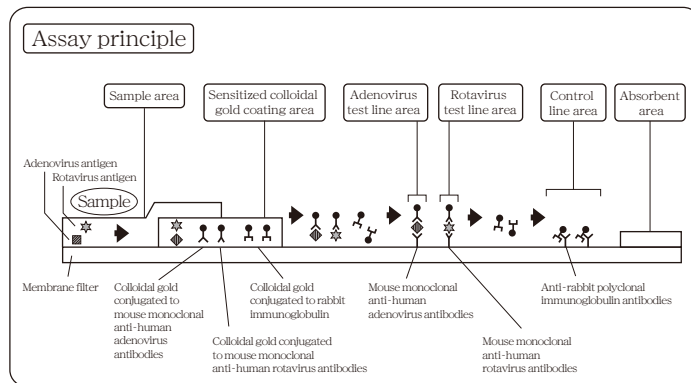
[Principle of the test]

「Quick Chaser® Rota/Adeno」 is the in vitro reagent for detection of rotavirus antigen and adenovirus antigen based on Immunochromatographic Assay.

Colloidal gold conjugated to mouse monoclonal anti-human rotavirus antibodies, colloidal gold conjugated to mouse monoclonal anti-human adenovirus antibodies and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in sensitized colloidal gold coating area in test plate. And mouse monoclonal anti-human rotavirus antibodies and mouse monoclonal anti-human adenovirus antibodies are immobilized in test line area. 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 rotavirus and/or adenovirus, they migrate to the area between sample area and test line area, where respectively reacting with colloidal gold conjugated to mouse monoclonal anti-human rotavirus antibodies and colloidal gold conjugated to mouse monoclonal anti-human adenovirus antibodies, react with mouse monoclonal anti-human rotavirus antibodies and mouse monoclonal anti-human adenovirus antibodies and they are caught in test line area.

As a result, purple-red line is visible. Moreover, purple-red line is also simultaneously visible for catching colloidal gold conjugated to rabbit immunoglobulin by anti-rabbit immunoglobulin antibodies in control line area, regardless of presence of Rotavirus and Adenovirus.



[Procedural precautions]

- 1) Do not use vomit and foods etc. as specimen except feces.
- 2) Use swab, included in this product at the time of specimen collection.
- 3) Collected specimen should be prepared as sample in accordance with after-mentioned "Preparation of sample in Test procedure" and should be tested as soon as possible. In case that test is not performed immediately or specimen need to be stored for a long time, store specimen at -20°C or less. Specimen should not be repeatedly frozen or thawed. Specimen should be brought to $15 \sim 30^{\circ}\text{C}$ before being used.
- 4) Avoid the storage of suspension in extraction reagent solution.
- 5) Add fixed volume (3 drops) to the center of sample area from tip of filter about 10mm 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.
- 6) Bring test plate and extraction reagent solution to $15 \sim 30^{\circ}\text{C}$ prior to testing.
- 7) In case that pieces of disposable diaper are mixed in specimen, it may be impossible to add sample. Do not use pieces of diaper with feces as specimen.
- 8) In case that suppositories (NAUZELIN® Suppository or DIAPP® SUPPOSITORIES etc.) containing macrogol (polyethelene glycol) as base are mixed, these suppositories could cause poor migration of extraction reagent solution or false positive. Avoid specimen collection after using these suppositories.
- 9) Interfering substances and medications
Following substances and blood did not interfere the performance of this product at the concentration listed below.

Hemoglobin	0.5g/dL
Intralipid® fluid solution 10%	1% as final concentration of fat content (It is assumed that fat is contained in feces.)
Glycerin enema	5% as final concentration of glycerin
Polycarbophil calcium (Gelling antifatulent)	1%
Blood	2%

10) Cross reactivity

Cross reactivity with following virus and bacteria were not observed.

• Virus	
Polio virus type 1	$6.3 \times 10^5 \text{CCID}_{50}^{\text{Note 1}} / 50 \text{mL}$
Polio virus type 2	$6.3 \times 10^4 \text{CCID}_{50} / \text{mL}$
Polio virus type 3	$2.0 \times 10^5 \text{CCID}_{50} / \text{mL}$
Note 1) CCID_{50} : 50% cell culture infectious dose	
• Bacteria	
<i>Bacillus cereus</i>	$1.0 \times 10^3 \text{CFU}^{\text{Note 2}} / \text{mL}$
<i>Campylobacter coli</i>	$1.0 \times 10^5 \text{CFU} / \text{mL}$
<i>Campylobacter jejuni</i>	$1.0 \times 10^3 \text{CFU} / \text{mL}$
<i>Citrobacter freundii</i>	$1.0 \times 10^3 \text{CFU} / \text{mL}$
<i>Clostridium difficile</i>	$1.0 \times 10^3 \text{CFU} / \text{mL}$
<i>Clostridium perfringens</i>	$1.0 \times 10^5 \text{CFU} / \text{mL}$
<i>Enterococcus faecalis</i>	$1.0 \times 10^8 \text{CFU} / \text{mL}$
<i>Escherichia coli</i> O6	$1.0 \times 10^3 \text{CFU} / \text{mL}$

<i>Escherichia coli</i> O78	1.0×10 ⁵ CFU/mL
<i>Escherichia coli</i> O114	1.0×10 ³ CFU/mL
<i>Klebsiella pneumoniae</i>	1.8×10 ⁷ CFU/mL
<i>Listeria monocytogenes</i>	1.0×10 ³ CFU/mL
<i>Proteus mirabilis</i>	1.0×10 ³ CFU/mL
<i>Pseudomonas aeruginosa</i>	1.0×10 ⁷ CFU/mL
<i>Salmonella</i> Enteritidis	1.0×10 ³ CFU/mL
<i>Salmonella</i> Typhimurium	1.0×10 ³ CFU/mL
<i>Shigella flexneri</i>	1.0×10 ³ CFU/mL
<i>Shigella sonnei</i>	1.0×10 ³ CFU/mL
<i>Staphylococcus aureus</i>	6.0×10 ⁷ CFU/mL
<i>Vibrio cholerae</i>	1.0×10 ³ CFU/mL
<i>Vibrio parahaemolyticus</i>	1.0×10 ³ CFU/mL

Note 2) CFU : colony forming unit

11) Information related to cross reactivity with norovirus

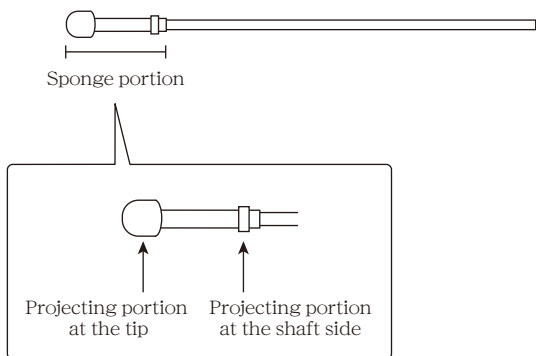
As a result of having tested 5 norovirus Genogroup I -positive specimens, 75 Genogroup II -positive specimens by this product, all of them showed rotavirus negative and adenovirus negative.

[Test procedure]

●Specimen collection

1) Preparation of specimen collection

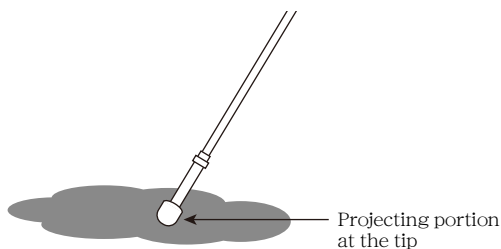
- ① Extraction reagent solution : No prior preparation required.
- ② Swab : Use swab included in this test kit.



2) Specimen collection

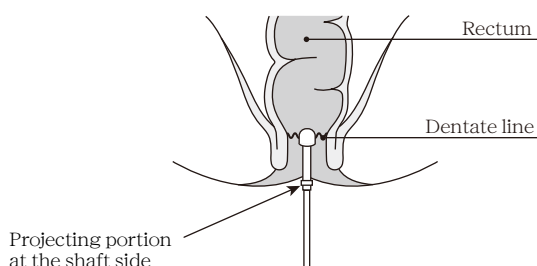
① Naturally evacuated feces • enema feces

- Collect specimen by swab included in this test kit.
- Impregnate at least entire projecting portion at the tip sufficiently in case of watery feces. Watery feces can also be collected by impregnating entire sponge portion.
 - Collect the feces so as to cover the whole from the half of projecting portion at the tip loosely in case of solid feces.



② Rectal feces:

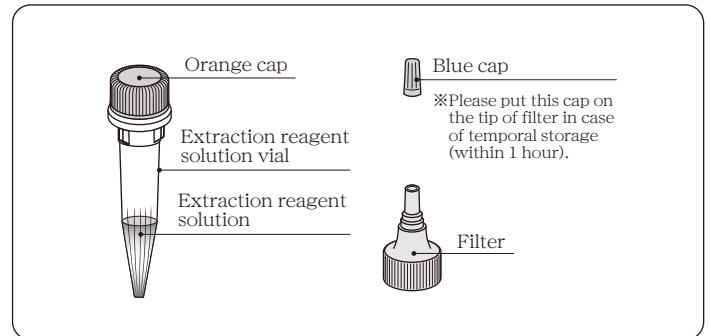
Taking particular attention not to injure patients when collecting rectal feces, insert swab turning softly so that entire sponge portion is hidden in anus of patient (to the position of projecting portion at the shaft side) and collect feces.



3) Adequate specimen volume

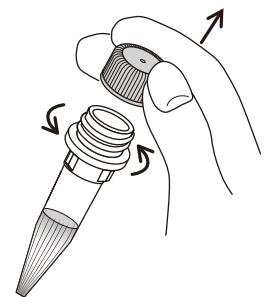
Watery feces (75~150 μL)			Solid feces (50~100mg)			
Insufficient volume	Adequate volume	Adequate volume	Insufficient volume	Adequate volume	Adequate volume	Excessive volume
X 			X 			X

●Details of Extraction reagent solution vial

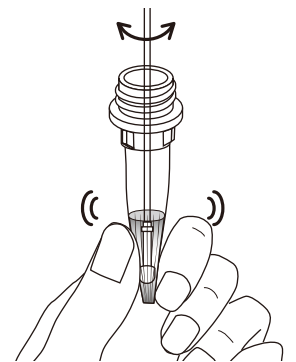


●Preparation of sample

- ① Loosen pink cap with turning it counterclockwise.

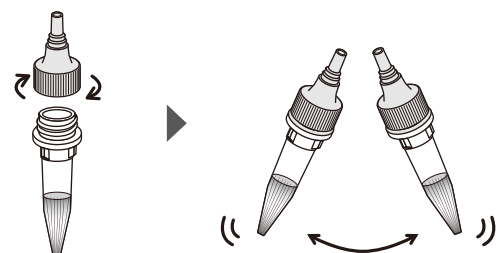


- ② Insert the sponge portion with specimen, into the bottom of extraction reagent solution vial and press the sponge portion from the outside of the vial for extracting specimen and turn the swab clockwise and counterclockwise about five times and rub the sponge portion on the inside wall and bottom of the vial. Take swab out of the vial with squeezing out liquid from the sponge portion, pressing the sponge portion.

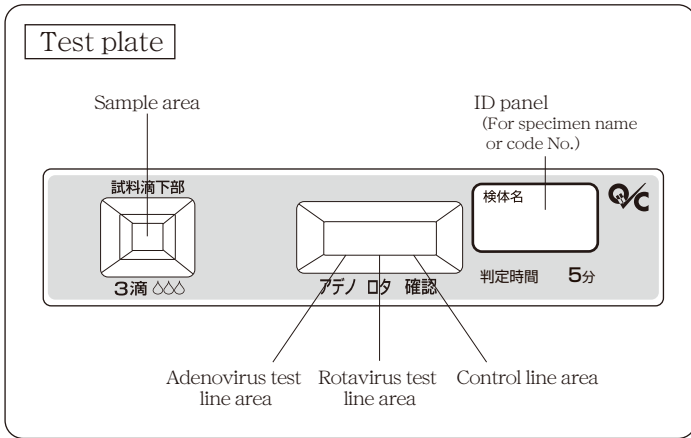


Note) Do not use the fecal suspension which were left for 1 hour or more after suspending.

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



●Details of test plate



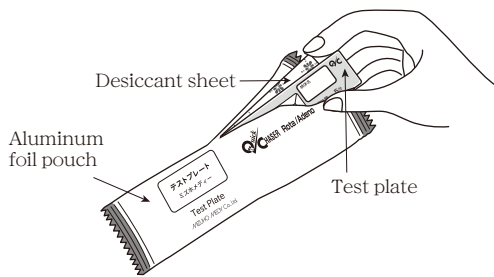
●Test procedure

1) Preparation of reagent

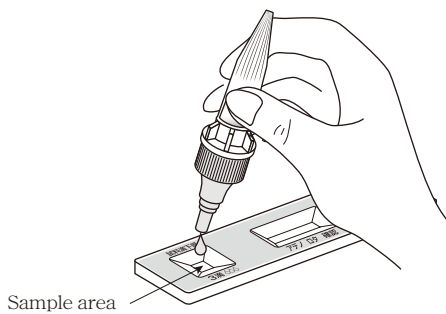
Test plate: No prior preparation required.

2) Test procedure

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

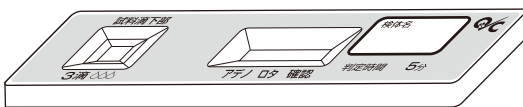


- ② Add 3 drops (about 110 μL) of sample vertically to the sample area of test plate from extraction reagent solution vial including prepared sample with avoiding contact of tip of extraction filter with sample area.



- ③ Leave to react at 15°C ~ 30°C.

Interpret test results visually by lines in test line area and control line area after 5 minutes.



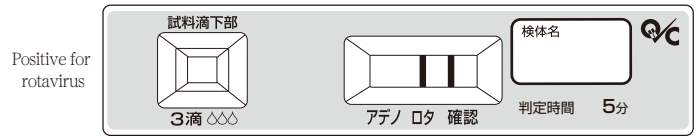
[Interpretation]

Interpret by existence of red-purple lines in rotavirus test line area, adenovirus test line area and control line area.

《Positive》

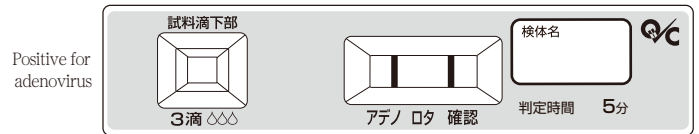
[Positive for rotavirus]

Both rotavirus test line and control line appear.



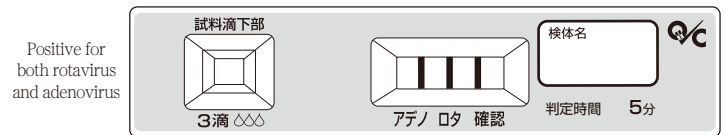
[Positive for adenovirus]

Both adenovirus test line and control line appear.



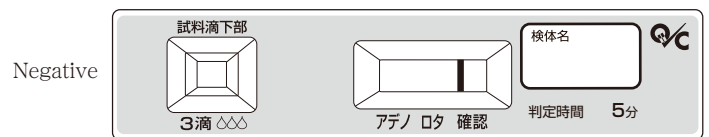
[Positive for both rotavirus and adenovirus]

Both test lines for rotavirus and adenovirus and control line appear.



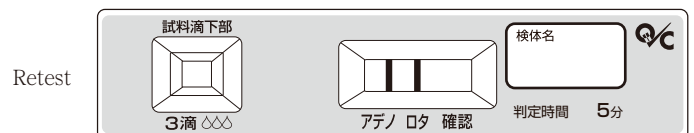
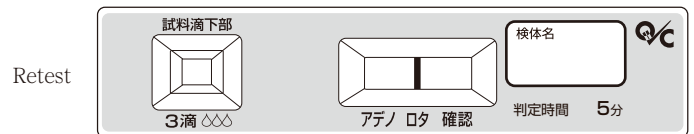
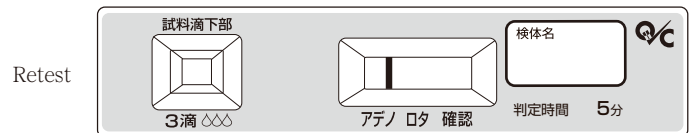
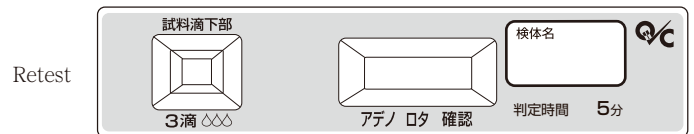
《Negative》

Only control line appear.



《Retest》

If both test lines and control line do not appear or no control line appear, operational mistakes such as the lack of sample are thought. Recheck test procedure and retest with new test plate. If the same result comes out in the retest again, confirm it with other method.



● Interpretational precautions

- The interpretation should be done at 5 minutes after adding sample. Do not interpret after 10 minutes. Please note that streak line may appear temporarily due to a flow of colloidal gold, but this is not real test line. Colloidal gold can appear like line due to drying of the test plate with time after interpretation time. Therefore, interpret test results at predetermined time.
- This product is used as an aid in the diagnosis for infection of rotavirus and adenovirus. In case that rotavirus antigen and adenovirus antigen 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 rotavirus or 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 results of other tests.
- When oral inoculation of rotavirus vaccine is made, rotavirus derived from vaccine is excreted in feces for a few days, and it may become rotavirus-positive.

[Performance characteristics]

1) Performance

① Sensitivity

- When in-house rotavirus positive control ^{Note 1)} is tested, rotavirus positive result is obtained.
- When in-house adenovirus positive control ^{Note 2)} is tested, adenovirus positive result is obtained.

② Accuracy

- When in-house rotavirus positive control is tested, rotavirus positive result is obtained.
- When in-house adenovirus positive control is tested, adenovirus positive result is obtained.
- When negative control ^{Note 3)} is tested, a negative result is obtained.

③ Reproducibility

- When in-house rotavirus positive controls are tested three times simultaneously, rotavirus positive results were obtained in all cases.
- When in-house adenovirus positive controls are tested three times simultaneously, adenovirus positive results are obtained in all cases.
- When in-house negative controls are tested, negative results are obtained in all cases.

Note 1) Rotavirus purified antigen diluted by extraction reagent solution to become the 1.0×10^6 copies/mL.

Note 2) Adenovirus purified antigen diluted by extraction reagent solution to become the 4.0×10^8 copies/mL.

Note 3) Extraction reagent solution

④ Detection limit

2.5×10^5 copies/mL (Rotavirus antigen)

5.0×10^7 copies/mL (Adenovirus antigen)

⑤ Serotype and reactivity

It is confirmed that this product reacts with Adenovirus type 1, type 2, type 3, type 4, type 5, type 6, type 7, type 8, type 11, type 19, type 31, type 37, type 40, type 41, type 53 and type 54, and rotavirus type G1, type G2, type G3, type G4 and type G9.

2) Correlation

Comparison with existing approval product
(immunochromatographic assay)

<Rotavirus>

		Quick Chaser Rota/Adeno		
		Positive	Negative	Total
Other product (1)	Positive	58	2 ^{*2}	60
	Negative	2 ^{*1}	118	120
	Total	60	120	180

Positive agreement rate : 96.7% (58/60)
 Negative agreement rate : 98.3% (118/120)
 Total agreement rate : 97.8% (176/180)

- ※1 Regarding two samples which were interpreted as negative by other product (1), but positive by Quick Chaser Rota/Adeno, they were interpreted as positive by RT-PCR.
- ※2 Regarding two samples which were interpreted as positive by other product (1), but negative by Quick Chaser Rota/Adeno, they were interpreted as negative by RT-PCR.

		Quick Chaser Rota/Adeno		
		Positive	Negative	Total
Other product (2)	Positive	59	1 ^{*4}	60
	Negative	1 ^{*3}	119	120
	Total	60	120	180

Positive agreement rate : 98.3% (59/60)
 Negative agreement rate : 99.2% (119/120)
 Total agreement rate : 98.9% (178/180)

- ※3 Regarding one sample which was interpreted as negative by other product (2), but positive by Quick Chaser Rota/Adeno, it was interpreted as positive by RT-PCR.
- ※4 Regarding one sample which was interpreted as positive by other product (2), but negative by Quick Chaser Rota/Adeno, it was interpreted as negative by RT-PCR.

<Adenovirus>

		Quick Chaser Rota/Adeno		
		Positive	Negative	Total
Other product (1)	Positive	56	6 ^{*2}	62
	Negative	4 ^{*1}	114	118
	Total	60	120	180

Positive agreement rate : 90.3% (56/62)
 Negative agreement rate : 99.2% (114/118)
 Total agreement rate : 94.4% (170/180)

- ※1 Regarding four samples which were interpreted as negative by other product (1), but positive by Quick Chaser Rota/Adeno, they were interpreted as positive by PCR.
- ※2 Regarding six samples which were interpreted as positive by other product (1), but negative by Quick Chaser Rota/Adeno, they were interpreted as negative by PCR.

		Quick Chaser Rota/Adeno		
		Positive	Negative	Total
Other product (2)	Positive	55	0	55
	Negative	5 ^{*3}	120	125
	Total	60	120	180

Positive agreement rate : 100% (55/55)
 Negative agreement rate : 96.0% (120/125)
 Total agreement rate : 97.2% (175/180)

- ※3 Regarding five samples which were interpreted as negative by other product (2), but positive by Quick Chaser Rota/Adeno, they were interpreted as positive by PCR.

3) Calibration reference material (Standard material)

Rotavirus antigen solution (in-house standard)

Adenovirus antigen solution (in-house standard)

[Precautions for use or handling]

1) Precautions for handling (hazard prevention)

- Other infectious materials could be included besides rotavirus and adenovirus in sample (specimen). Be careful of handling sample (specimen) as potentially infection materials.
- Be careful not to touch sample (specimen) or extraction reagent solution directly to skin or not to get into eyes in wearing glasses, disposable gloves, mask at the time of use.
- Do not use swab to collect specimen, if it is already put into extraction reagent solution.
- If 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.
- Do not use blue cap which belongs to kit for transportation or preservation because it does not have seal strength.
- Perform the collection of feces from rectum under the guidance of the qualified person.
- Raw material of membrane which is used for test plate, is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.
- Wipe off with sodium hypochlorite solution (effective chlorine concentration: 1,000ppm or more) etc. in case of getting splattered with sample (specimen).
- Do not insert swab into eyes, a mouth (throat) or nose etc.
- Take extra care of handling specimen and utensils contacted by specimen because there are risks of secondary infections.

2) Precautions for use

- ① Do not freeze this product. Store this product in accordance with description of instruction for use. Do not use frozen reagents because they could show false result by change of quality.
- ② Do not use this product beyond expiration date.
- ③ Do not store extraction reagent solution vial with falling sideways and an inverting.
- ④ Use extraction reagent solution included in this kit or Quick Chaser® Noro. Do not use any extraction reagent solution in other kits.
- ⑤ Use the test plate immediately after opening aluminum foil pouch. If test plate is left to for a long time, it could not react by exposure to moisture.
- ⑥ Do not touch sample area, test line area and control line area by hands directly.
- ⑦ Do not perform test in the place such as under air conditioner where the dry wind directly blows the surface of the test plate, to prevent uneven migration.
- ⑧ Regarding reagent and accessories etc. included in this product, do not use them for any purposes other than purpose of this test.
- ⑨ Test plate, swab and extraction reagent solution vial (Filter pink cap and blue cap are included) are intended for single use only.
- ⑩ Use swab included in this product.
- ⑪ Do not place swab in place of sunlight such as near window for a long time. Sunlight may cause discoloration etc. of sponge portion.
- ⑫ Do not touch portion of sponge of swab by hands before use.
- ⑬ Use swab immediately after opening the pouch.
- ⑭ If break and/or hole are found on the pouch of swab, do not use it.
- ⑮ If swab is stained, broken or bent, do not use it.
- ⑯ Do not bend and curve the rod of swab before collecting feces from rectum.
- ⑰ Be careful not to break the rod of swab and injure region to be collected (mucous membrane) by excessive force or pushing too hard at the time of collecting feces from rectum.
- ⑱ Be careful not to splatter the sample at the time of taking the swab out of vial after preparing sample.
- ⑲ In case that collection volume of specimen is excessive or much solid are included in feces, membrane filter could be clogged. Restart from collection of feces using new extraction reagent solution and filter without filtering forcedly.

3) Precautions for waste disposal

- ① Treat liquid waste and used utensils by any one of following methods because sample (specimen) could contain other infectious materials besides norovirus.
 - a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1000ppm) 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.
- ② Regarding disposal of reagents and utensils etc. , dispose of them in accordance with your waste disposal laws and regulations.

[Storage • Expiry]

- Storage : Room temperature (1 ~30°C)
- Expiry : 24 months (As indicated on package)

Technical information
Telephone **+81-942-85-3845**

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

Manufacturer: **Mizuho Medy Co.,Ltd.**

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