Medical Device

Asan Easy Test® Noro

ASAN

※Caution: Please read the precautions and test procedure in this manual before using.

◎LOT number and Expiry date

Refer to external indication (packaging box) LOT number and expiry date.

◎Package Unit

For the number of test kits per package, refer to the labeling on the box.

Package unit	25 Test / Kit
Test Device	25 EA
Extraction Buffer	1.0ml×25EA
Dropper filter tip	25EA
Sample collection swab	25EA

◎Purpose of Use

Asan Easy Test Noro is an in-vitro diagnostic medical device that diagnoses Noro diseases by qualitatively testing antigens of Noro in human feces specimens by immunochromatographic assay (ICA).

◎How to use

(1) Test Explanation

Using the sample collection swab included in the kit, a fecal sample from a patient suspected of having norovirus infection is collected by pricking 5 to 6 different places in the feces, and placed in a buffer solution for sample dilution to extract the viral antigen. Attach the filter cap to the extracted buffer tube and drop the extract into the sample drip port. In the presence of a viral antigen, an antibody with specificity for anti-norovirus GI type and GII type is conjugated to gold particles, causing a primary immune response to form a norovirus antigen-antibody-gold particle complex, which It develops by capillary action. This complex causes a secondary immune reaction with the anti-norovirus antibody immobilized on the test line, and a red band appears on the test line. Depending on the presence or absence of color bands, positive and negative are judged. If there is no norovirus antigen in the sample, no lines appear on the test line, only the control line. The final result is visually checked and judged.

(2) Specimen collection and storage

1) Liquid stool specimen
Using the sample collection swab, collect the swabs so that they are sufficiently covered (about 1.0mL), and then dilute them in a tube for sample extraction containing the extraction solution.

2) Solid or soft stool specimen
Using the sample collection swab, prick 5 or 6 different points of the fecal residue sample to collect samples, and collect enough samples to sufficiently cover the swabs.

3) Storage of collected specimens
If possible, it is recommended to use the specimen in a fresh state immediately after collection. If it is not possible to test immediately after collection, the collected feces should be tested within 3 days when refrigerated (2~8℃), and if stored longer than that, stored frozen (below -20℃). When stored frozen (below -20℃), it is stable for up to 6 months.

(3) Preparation before testing

Before the test, place the test device product, sample extraction buffer, and sample at room temperature for about 30 minutes, and let the temperature equal the room temperature. The most suitable temperature condition for the test is room temperature (15~25℃), which is the daily living temperature. If the reagent is stored at room temperature, it can be used immediately after opening.

(4) Test procedures

1) Put the patient's fecal residual sample (0.1g) into a tube containing the extraction buffer (1.0mL) and rub it against the tube wall, turning it at least 8 to 10 times to ensure sufficient extraction.
2) After extraction, the swab is taken out while turning it along the wall of the buffer tube. During this process, squeeze out the extract solution on the swabs.
3) Used swabs are classified as infectious waste and disposed of safely.
4) Remove the device from the aluminum pouch and place it on a flat surface. After combining the sample extraction buffer tube with the dropper filter tip to the sample well of the test device, 4-5 drops (120-150 μl) are added to react.
5) If the control line appears red after 15 minutes, read the result.
6) As the reaction time increases, the degree of color development of the control line and the test line can become stronger. Therefore, it is possible to obtain more accurate results by always making the determination at a certain time after the start of the reaction.

(5) Results

For this product, the red band of the test line appears or does not appear depending on the presence or absence of the norovirus antigen in the sample.

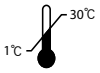
1) **Negative :** There is only red line on the Control line (C) and no red line on the test line (T). It can be determined to Negative.

2) **Positive :** There are red line on the Control line (C) and Test Line (T). It can be determined to Postivie.

3) **Invalid or Re-test :** Because there would be quality problem, It needs to be re-test with new device if there are no red line on the both Control Line (C) and Test Line (T) or there is only red line on the Test Line (T). It needs re-test with new device.

◎How to store

Unopened 1~30℃ storage, 24 months after manufacturing date.



◎Precautions for use

1. This reagent is for in vitro diagnostic use only.
2. This reagent is disposable and cannot be reused.
3. This reagent must be placed in a sealed aluminum pouch until use.
4. When handling this reagent, be careful not to let your hands or other foreign objects directly touch the test line area.
5. This reagent is very sensitive to moisture, so pay attention to performance degradation due to moisture. In particular, if the container is opened when the temperature of the test device is lower than room temperature, the moisture content of the device will increase due to dew condensation, so be careful.
6. When handling specimens, use disposable surgical gloves and be careful as there may be infections caused by unknown microorganisms or viruses. Also, wash your hands thoroughly after handling.
7. Do not use the product if the aluminum pouch is damaged or the sealing is not good before using the reagent, or the product has expired.
8. The solid waste used in the experiment is sterilized by autoclaved at 121 for 1 hour or more.
9. The sample dilution buffer in this reagent contains sodium azide and TX-100 as an extractant. If any part of this solution gets into your eyes, mouth, or comes in contact with your skin, rinse thoroughly with running water and seek medical attention if necessary.
10. This product cannot completely rule out the possibility of false-positive and false-negative results due to various factors. Therefore, the final diagnosis should not be made based on the results of this product alone, and the final diagnosis should be made by a specialist based on other test methods and clinical findings. diagnosis should be made.

◎Exchanges and Returns

This product has undergone strict quality control. If the expiration date of the product has passed when purchased or if it has been deteriorated, damaged, or contaminated, it will be exchanged.

ASAN
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