ROTA-VIRUS LATEX TEST KIT

Catalogue number	Product Description
ROV/012	Test Kit100

INTENDED USE
The Plasmatec Latex Test kit is for the detection of antigen in faeces by slide agglutination.

WARNINGS AND PRECAUTIONS
For *in vitro* diagnostic use only
For professional use only

Health and Safety warnings:
All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method.
Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.
Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.
Do not pipette by mouth.
The Reagents contain less than 0.1% sodium azide as a preservative. Avoid ingestion and contact with skin or mucus membrane.

Analytical precautions:
Do not modify the test procedure.
Do not dilute or modify the reagents in any way.
Allow all reagents and samples to reach room temperature (18 to 30ºC) before use.
Do not interchange reagents from different kit batches.

COMPOSITION
Kit contents:
- ??Latex reagent sufficient for 100 tests (Yellow label).
- ??Latex control reagent. (Blue label)
  The latex reagents should be well shaken to ensure homogeneity.
- ??Positive bovine rota-virus control, inactivated. (Red label)
- ??5x Conc. Extraction Buffer pH 7.2 (Green label). To 10 ml of extraction buffer, dilute with 40 mls of de-ionised water. This will give enough extraction buffer for 25 sample preparations.
- ??Pipette/ Stirrers/ agglutination slides.
- ??Pack insert.

STORAGE AND SHELF LIFE
Store reagents, upright at 2-8ºC. DO NOT FREEZE THE LATEX REAGENT
Do not use reagents after the stated expiry date.
Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.
Pipettes
Centrifuge

SPECIMEN AND SAMPLE PREPARATION
If the specimen is not to be tested immediately it may be stored overnight at 2-8°C or at -20°C or below for longer periods. Prepare an approximate 10% suspension of the faecal sample by adding 0.1ml/0.1g to 1.0ml of extraction buffer in a screw capped tube. Mix well. Stand at room temperature for 1-2 minutes. Proceed with test protocol as detailed below.

PROCEDURE
Principle:
Rota-virus has been shown to be a principle causative agent of gastro-enteritis. Patients may harbour up to 10^8 virus particles per gram of faeces. During the winter months rota-viral disease may occur in epidemic proportions, especially in neonates. The Plasmatec test reagent is composed of latex particles sensitised against a pool of different Rotavirus isolates, both human and animal, allowing detection of antigen by slide agglutination.

Method:
QUALITATIVE METHOD
1. Allow each component to reach room temperature.
2. To 10 ml of extraction buffer, dilute with 40 mls of de-ionised water. This will give enough extraction buffer for 25 sample preparations.
3. To a 2 ml aliquot of extraction buffer add 0.2 gms of faecal specimen.
4. Mix well on a vortex mixer, until solids are evenly dispersed.
5. Stand at room temperature for 10 mins.
6. Centrifuge test sample for 10 minutes at about 800g.
7. Place one drop of the supernatant from the faecal sample onto the circle of test slide.
8. Repeat step 7 using circle 2 of the test slide.
9. Add one drop of the **control** latex reagent next to the drop of faecal sample on circle 1.
10. Add one drop of the **test** latex reagent next to the drop of faecal sample circle 2.
11. Using the other end of the disposable pipette (broad end), spread the control latex reagent over the entire area of the test circle.
12. Repeat step 11 using the test latex on circle 2.
13. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes. The positive control is ready to use and should not be diluted. Normal laboratory precautions should be maintained whilst handling patients samples.

RESULTS
A **Positive** result is indicated by the visible agglutination of the test latex particles. This will normally occur within a few seconds of mixing , depending on the strength of the extract.
A **Negative** result is indicated by a milky appearance without any visible aggregation of the latex particles. However faint traces of granularity may be detected in negative patterns, depending on the visual acuity of the operator.

INTERPRETATION OF RESULTS

Strong agglutination with test latex **first** indicates a positive result. Only strong agglutination is significant, weak and granular reactions with control latex should be ignored.

If test remains indeterminate repeat on a fresh specimen diluting the supernatant 1:2 in pH 7.2 buffer prior to testing.

LIMITATIONS OF THE METHOD

Evaluate results in conjunction with full clinical data, as a positive test result does not preclude the possibility of other microbial infections. Plasmatec Rotavirus is an acute phase test. Samples collected after the acute phase may contain antigen concentrations below the threshold of the test.

REFERENCES

1. Haikala, O.J. et al (1983). Rapid detection of Rotavirus in stool by latex agglutination: Comparison with radioimmunassay and electron microscopy and clinical evaluation of the test. J.Med. Virol. 11, 91-97.
2. Sanders, R.C. et al (1986). Routine detection of human Rotavirus by latex agglutination: Comparison with enzyme linked immunosorbent assay, electron microscopy and polyacrylamide gel electrophoresis. J. Virol. Methods 13, 285-290.

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