PULSE SCIENTIFIC INC.

Unit 18, 5100 South Service Road
Burlington, Ont. Canada L7L 6A5
Tel: (905) 333-8188
Fax: (905) 333-0500
Toll Free: 1-800-363-7907

ROTAVIRUS LATEX TEST

INTENDED USE

The Pulse Rotavirus Latex Test (RVTEST) is a rapid qualitative latex agglutination slide test intended to be used for the detection of Rotavirus in faecal samples.

SUMMARY & PRINCIPLES

Rotavirus is a primary cause of acute gastroenteritis and diarrhea especially in children. This may result in dehydration and electrolyte imbalance. Its discovery in 1973 and its association with infantile gastroenteritis represented a very important advance in the study of gastroenteritis not caused by acute bacterial infection. A variety of techniques has been developed since to diagnose Rotavirus. Until recently, diagnosis of rotavirus has been confirmed mainly by electron microscopy. Latex agglutination and enzyme immunoassay have become available which are more convenient alternatives.

The RVTEST utilizes latex particles that coated with rabbit antibodies raised against a pool of different Rotavirus isolates, both human and animal. This kit also includes a latex control which consists of latex particles coated with normal rabbit globulin to detect non-specific reactions.

MATERIALS SUPPLIED

LATEX: suspension of latex particles coated with rabbit anti-rotavirus globulin in buffer with 0.1% sodium azide.

LATEX Control: Suspension of latex particles coated with normal rabbit globulin in buffer with 0.1% sodium azide.

Positive Control: Faecal extract containing 0.1% sodium azide as preservative. Extraction Buffer, stirrers and disposable test slides.

Additional Items Required:

Screw capped tubes, centrifuge, micro pipettes and timer.

STORAGE & STABILITY

When not in use, store reagents and controls at 2-8 degree Celsius. DO NOT FREEZE. Do not use after expiry date.

PRECAUTIONS

All clinical samples should be considered potentially hazardous and be handled in the same manner as an infectious agent. The preservative sodium azide may react with metal plumbing to form explosive metal azides. In disposal, flush with a large volume of water to prevent metal azide build up.

SPECIMEN COLLECTION

If the specimen is not to be tested immediately it may be stored overnight at 2-8 degree Celsius or at –20 degree Celsius or below for longer periods.
Prepare an approximate 10% suspension of the faecal sample by adding 0.1 ml/0.1 g of sample to 1.0 ml Extraction Buffer in a screw capped tube. Mix well. Stand at room temperature for 1-2 minutes. Proceed with the test procedures as follows.

PROCEDURE

Allow test reagents to reach room temperature.

1. Centrifuge specimen (prepared as above) at 1000g for 10 minutes.
2. Transfer one drop of supernatant onto each of two wells on a test slide.
3. Gently shake the LATEX Reagent to disperse and suspend the latex particles in the buffer solution, then, using the dropper provided, add one drop of suspension to the first circle (Test Circle).
4. Gently shake the LATEX Control Reagent to disperse and suspend the latex particles in the buffer solution, then using the dropper provided, add one drop of suspension to the second circle (Control Circle).
5. Mix the contents of each circle using a separate disposable stirrer ensuring coverage of the test circle with the mixture.
6. Gently and evenly, rock and rotate the test slide for 2 minutes. If using a rotator, set at 60-80 r.p.m.
7. At the end of 2 minutes, observe for the presence or absence of agglutination under strong light source and report results.

RESULTS

Positive: Agglutination in the Test Circle; no agglutination in the Control Circle.

Negative: No change in the latex suspension in either Test or Control Circles.

Non-specific: Agglutination in Control Circles. Samples exhibiting this reaction pattern are unsuitable for testing by latex agglutination methods.

QUALITY CONTROL

For reading comparison purpose, the use and the inclusion of positive control is recommended every time a set of clinical specimens are to be tested.

LIMITATIONS

Evaluation results only in conjunction with full clinical data as a positive RVTEST does not necessary preclude the possibility of additional microbial infection.
RVTEST is an acute phase test. Faecal samples collected after the acute phase may contain antigen concentrations below the threshold of reagent sensitivity.

REFERENCES

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