



RAPID LATEX KIT DIRECTIONS FOR USE

Rotavirus Latex Test Kit: For Detection Of Rotavirus In Faeces.

SUMMARY

Rotavirus 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 rotaviral disease may occur in epidemic proportions, especially in neonates.

PRINCIPLE

When used by recommended techniques, reagent will agglutinate (clump) in presence of Rotavirus antigens. No agglutination usually indicates the absence of Rotavirus antigens (see **Limitations**).

KIT DESCRIPTION

Lorne Rotavirus Kit is for the detection of rotavirus in faeces. The latex reagent is composed of antibody-sensitised latex particles. All the latex reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. Reagent will remain stable for up to 7 days when subjected to temperatures not exceeding 30°C.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents contain less than 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
5. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the Positive and Latex Control reagents be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Allow all the reagents to reach 18-25°C prior to testing.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of the kit and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
6. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENTS SUPPLIED

- Rotavirus Latex Test Reagent (Yellow label).
- Rotavirus Latex Control Reagent (Blue label).
- Rotavirus Positive Bovine Control (Red label).
- 5x Concentrated Extraction Buffer pH 7.2.
- Disposable specimen droppers.
- Disposable agglutination slides.
- Mixing sticks.

MATERIALS AND EQUIPMENT NOT SUPPLIED

- Small glass or plastic tubes.
- Vortex mixer.
- Centrifuge.

DILUTION OF EXTRACTION BUFFER

To 10 ml of Concentrated Extraction Buffer add 40 ml of deionised water. This will give enough extraction buffer for 25 specimens.

RECOMMENDED QUALITATIVE TECHNIQUE

1. To 2 ml of Extraction Buffer add 0.2 g of faecal specimen.
2. Mix well on a vortex mixer, until solids are evenly dispersed and then stand at 18-25°C for 10 minutes.
3. Centrifuge the test specimen for 10 minutes at 800 rcf.
4. Place one drop of specimen supernatant onto a circle on the agglutination slide.
5. Repeat step 4 using circle 2 of the agglutination slide.
6. Add one drop of the **control latex reagent** next to the drop of faecal specimen on circle 1.
7. Add one drop of **latex test reagent** next to the drop of faecal specimen on circle 2.
8. Using mixing stick provided spread the **specimen** and **control latex reagent** over the entire area of the test circle.
9. Repeat step 8 using the latex test reagent on circle 2.
10. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes.

INTERPRETATION OF RESULTS

1. **Positive:** Visible strong agglutination of latex particles constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of Rotavirus antigens.
2. **Negative:** No visible agglutination of latex particles constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of Rotavirus antigens.
3. **Equivocal:** If agglutination occurs with both reagents then repeat with a fresh specimen diluting supernatant 1:2 in diluted extraction buffer.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 2-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne Rotavirus Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.








AVAILABLE KIT SIZES

Kit Size	Catalogue Number
50 Tests Per Kit	035050
100 Tests Per Kit	035100

For the availability of other sizes, please contact:

Lorne Laboratories Limited
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Danehill
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TABLE OF SYMBOLS

	Batch Number		<i>In-vitro</i> Diagnostic
	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		