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SUBJECT **Rotagen evaluation**



Please find attached the summary of an evaluation performed with Rotagen, a latex agglutination test for rotavirus antigen detection, in comparison to a commercially available immunochromatographic device.

The study was conducted in the Microbiology Laboratory of the paediatric hospital, "Hospital Sant Joan de Déu" in Barcelona.

A total of 121 stool samples from paediatric patients with gastrointestinal pathologies were studied.

The concordance of both methods was very high.

EVALUATION OF THE BIOKIT ROTAGEN TEST KIT FOR DETECTING THE ROTAVIRUS ANTIGEN IN STOOL

OBJECTIVE

To determine the correct functioning of the Rotagen test kit by the commercial firm Biokit in relation to that of the rotavirus antigen detection method routinely used in the laboratory where the study was conducted.

MATERIAL AND METHODS

SAMPLES

A study was conducted on a total of 121 stool samples of paediatric patients with gastrointestinal pathologies (64 girls and 57 boys), ranging in age from 11 days to 17 years. This took place between June 2003 and February 2004.

The breakdown of samples by age was:

- 17 patients under 1 month of age.
- 87 patients between 1 month and 2 years of age.
- 17 patients over 2 years of age.

Table 1 shows the breakdown of samples studied by month and Table 2, the breakdown of samples by age.

REAGENTS

The material used to conduct the study was:

- Immunochromatography method on strip based on colloidal gold, routinely used in the laboratory.
- Rotagen by Biokit. Latex agglutination method on slide.

Both reagents are designed to detect the rotavirus antigen in stool. Both the performance and interpretation of the assays were carried out by meticulously following the manufacturer's instructions.

RESULTS

The results obtained are summarised below and listed in the tables:

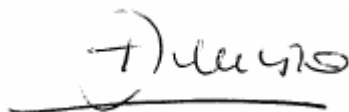
- 40 positive samples using both methods
Of the 40 positive samples, 9 corresponded to infants of 20 to 30 days old, 30 to patients of 1 month to 2 years of age, and 1 to a boy of 10 years of age.
Not a single positive result was detected during the first 4 months of the study (June, July, August and September 2003).

- 79 negative samples using both methods
In 6 of the 79 patients with negative results for rotavirus, a bacterial pathogen was isolated in a stool culture obtained from the same sample. Of these 6, the following were determined: 4 Salmonella enteritidis, 1 Campylobacter coli and 1 Pseudomona aeruginosa (pure culture).

- 2 discrepant samples
The two discrepant samples corresponded to 1) a one-month-old infant girl admitted in December for bronchiolitis with a normal stool culture which resulted positive using Rota-Strip and non-specified using Rotagen, since it also bound with the control reagent; and 2) a 20-day-old infant boy whose determination was performed during the month of February, and which resulted positive using Rota-Strip and non-evaluable using Rotagen since it bound with the negative control.
The two discrepant samples were not repeated.

CONCLUSIONS

The concordance of results between both methods was very high. Thus, the Biokit Rotagen technique is considered to be perfectly valid for use in determining the presence of rotavirus in stool.



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Table 1: Distribution per month

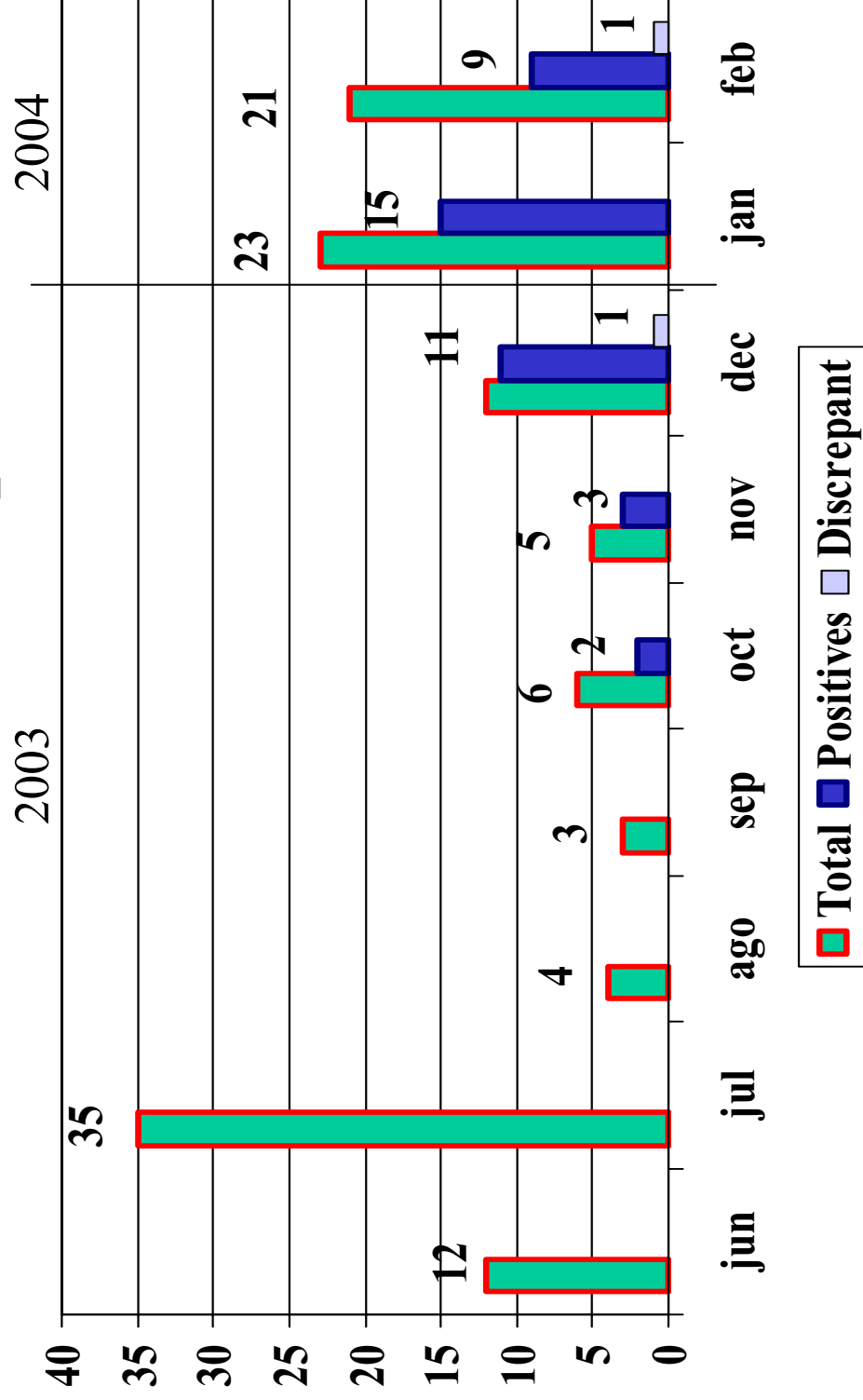


Table 2. Distribution per ages

