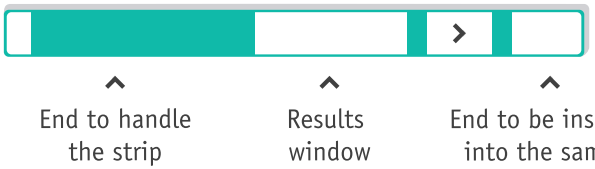
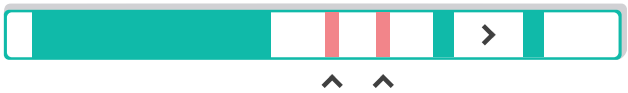
which a second coloured horizontal line is formed (control line). This control line is formed with all samples, regardless of whether they have rotavirus or not, as a demonstration that the reagents have functioned correctly.





Center for Genetic Engineering and Biotechnology
Distinctive company of Cuban biotechnology which develops, produces, markets and exports innovative products, for key areas of the biomedical, veterinary, agricultural, aquaculture and industrial sectors, for one health. It has a portfolio of research and development (R&D) projects and products, protected by patents. Its more than 30 products marketed in more than 35 countries, include first and only drugs of its kind, to treat diseases that do not have other effective therapeutic solutions. Several of its medicines are inserted into national programs to offer comprehensive health care. We work with social responsibility and in harmony with the environment.

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HeberFast Line® Rotavirus

TEST FOR RAPID DETECTION OF ROTAVIRUS IN STOOL

SIMPLE, FAST AND RELIABLE METHOD

HeberFast Line® Rotavirus

Test for rapid detection of rotavirus in stool

SIMPLE, FAST AND RELIABLE METHOD

• **HEBERFAST LINE® ROTAVIRUS** IS A SIMPLE, FAST AND RELIABLE METHOD.

• **HEBERFAST LINE® ROTAVIRUS** IS A QUALITATIVE IMMUNOCHROMATOGRAPHIC REACTIVE STRIP, WITH HIGH SENSITIVITY AND SPECIFICITY TO DETECT GROUP A ROTAVIRUS OR ITS ANTIGENS IN FECAL SAMPLES.

• **HEBERFAST LINE® ROTAVIRUS** OFFERS THE RESULT IN ONLY 10 TO 15 MINUTES.

PRESENTATION

• Case containing 24 test strips, individually packaged in aluminum bags together with a desiccant sachet and a bottle with 25 mL of extraction solution. Each kit contains 25 cotton applicators for the collection and dilution of stool samples, and instructions for use.
• Case containing 50 test strips, packaged in 10 aluminum bags, each containing 5 test strips and a desiccant sachet. Each kit contains 2 vials each containing 25 mL of extraction solution; a nylon zippered bag to store unused strips immediately after opening the aluminum bag; 50 cotton applicators for collection and dilution of stool samples; and instructions for use.

ADDITIONAL MATERIALS REQUIRED

• 1.5 mL reaction tubes: one tube for each test.
• Rack for reaction tubes
• Pipette to dispense 1 mL
• Gloves

STORAGE CONDITIONS

The reagents and components of the **HeberFast Line® Rotavirus** test is stable until the expiration date printed on the label, if maintained at a temperature of 2 to 8 °C. Do not freeze.

The extraction solution is stable until the original expiration date, after the bottle containing it has been opened, if kept at 2 to 8 °C in its original, tightly closed container.

Strips not used immediately after opening the sealed aluminum bag should be stored at 2 to 8 °C in the nylon zippered bag supplied with the desiccant sachet for a maximum of 7 days. After this time, unused strips should be discarded.

INDICATION

HeberFast Line® Rotavirus test is recommended for the detection of group A rotavirus or its antigens in stool samples.

FUNCTIONING OF THE TEST

HeberFast Line® Rotavirus test is based on the use of two specific monoclonal antibodies against the VP6 protein, which is the majority of the rotavirus group A capsid. VP6 is the most commonly used antigen in commercially available immunoassays.

By inserting the end of the test strip into the stool sample diluted with the extraction solution, this dilution begins to move through the results window; the viral antigens react with the colloidal gold-labeled monoclonal antibody, and an antigen-antibody complex form. This immunocomplex migrates by capillarity to the test strip result window, and reacts with a second anti-VP6 monoclonal antibody attached to the nitrocellulose membrane, and a first horizontal coloured line is formed (positive line).

In the absence of viral antigens in the sample, this positive line does not form.

The excess conjugate not trapped in the positive line continues to move and is captured in the solid phase in