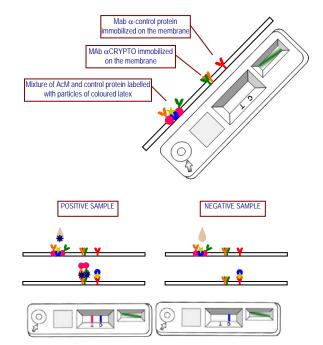
INGENASA

INgezim CRYPTO-CROM

R.10.CRY.K4



I Ngezim CRYPTO-CROM is a direct Immunochromatographic assay, based on a migration technique, which uses monoclonal antibodies (MAbs) specific to *Cryptosporidium parvum*.



TECHNICAL BASIS OF THE KIT

The device consists of a plastic casing with two windows:

- <u>Window for sample addition:</u> It contains a mixture of MAbs specific to *Cryptosporidium parvum* proteins and a Control Protein; all of them labelled with coloured particles of latex.
- <u>Window for results interpretation:</u> It contains a test line (T) with *Cryptosporidium* specific MAbs and a control line (C) with a MAb, specific to the control protein.

APPLICATION

Qualitative detection of antigen of *Cryptosporidium parvum*, in biological samples (faeces) from different animals (horses, rabbit, hen, sheep, goat, swine, bull, cattle and dogs).

INTERPRETATION OF THE RESULTS

Positive sample: Red/pink line in the Test zone and blue line in the Control zone.

Negative sample: only a blue line in the Control zone. **Not valid assay:** No blue line in the Control zone

VALIDATION

1. Sensitivity and specificity in relation to microscopy.

69 samples of faeces from different animals were analyzed. The test has showed high sensitivity and specificity in the study using positive and negative samples, both in relation to ELISA (>99.0%. r-Biopharm ELISA) and to microscopy (>99%).

2. Use with different species.

The assay was checked with 23 samples of faeces from different animals (horse, rabbit, hen, sheep, goat, bull, cattle and dog).

3. Analytical specificity.

The assay doesn't show cross-reactions with other parasites/virus/bacteria which could be present in faeces, like *Giardia lamblia, Rotavirus, Adenovirus, Astrovirus, H. pylory, E. coli, C. jejuni, B. hominis, I. bütschlii, C. mesnili,* tenia, *E. nana.*

COMPOSITION OF THE KIT

- Diagnostic devices individually wrapped
- Plastic pipettes for the dispensation of samples in the device.
- Vial with chromatographic buffer.



PRODUCT MANUFACTURED BY INGENASA REGISTTERED 1113 RD



SHELF LIFE: 24 months
Stored: 4°C-25°C

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