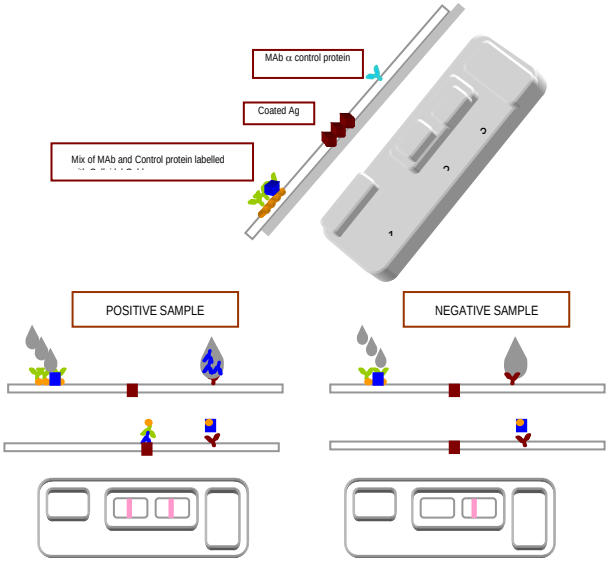
INGENASA

INgezim LEISHMA-CROM (Ab)

R.15.LSH.K41

INgezim LEISHMA-CROM is based on an indirect immunocromatography assay technique, which uses a monoclonal antibody (MAb) specific of canine IgG, and an inactivated antigen of *L. infantum*.



TECHNICAL BASIS OF THE KIT

The device consists of a plastic casing with three windows:

- Window1: Where the Monoclonal Antibody specific of canine IgG and the Control Protein are conjugated to colloidal gold particles.
- Window2: Where the inactivated antigen of *L. infantum* is adsorbed.
- Window 3: Where the MAb specific to the control protein is attached to indicate the validation of the assay.

APPLICATION

Detection of antibodies specific of Leishmania in canine sera or plasma samples.

INTERPRETATION OF THE RESULTS

Positive sample: Red/pink lines in the Test and Control zones. **Negative sample:** Only a red/pink line in the Control zone. **Not valid assay:** No line in the Control zone

VALIDATION

Correlation with ELISA

Study 1.
43 canine field sera (20 positive, 18 negative, 5 doubtful) previously classified by INgezim Leishmania, were analyzed. Considering doubtful ones as positive, the results indicated **95%** correlation between assays.

		ELISA (INGEZIM LEISHMANIA)		
		POSITIVE	NEGATIVE	TOTAL
INGEZIM LSHCROM	POSITIVE	23	0	23
	NEGATIVE	2	18	20
	TOTAL	25	18	43

Study 2.
86 canine field sera (45 positive, 41 negative) previously classified by INgezim Leishmania, were analyzed. The results indicated **96.5%** correlation between assays.

		ELISA (INGEZIM LEISHMANIA)		
		POSITIVE	NEGATIVE	TOTAL
INGEZIM LSHCROM	POSITIVE	42	0	42
	NEGATIVE	3	41	44
	TOTAL	45	41	86

COMPOSITION OF THE KIT

- Diagnostic devices individually wrapped
- Diluent tubes, to prepare the dilution of the sera samples
- Dropper bottle dilution buffer
- Disposable tips

PRODUCT MANUFACTURED BY INGENASA
REGISTERED 1110 RD

IT-73840
IT-73780
ISO 14001:2015 9191.INGE
ISO 9001:2015 9175.ING2

SHELF LIFE: 24 months
Stored: 4ºC-25ºC

Ed. 020217

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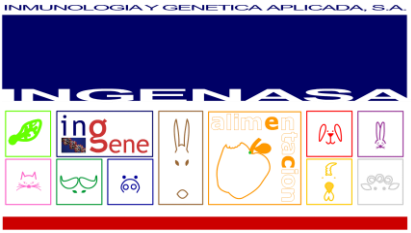


INGEZIM LEISHMACROM (Anticuerpo)

Prod Ref: 15.LSH.K41

Ensayo inmunocromatográfico para la detección de anticuerpos frente a Leishmania en sueros de perro.

Immunocromatographic assay for the detection of specific antibodies to Leishmania in dog sera samples.

Última revisión / Last revision: 27-10-08
Registrado por el MAPA nº 1110 RD

COMPOSICION DEL KIT
KIT COMPOSITION

Reactivo Reagent	**PRESENTACION KIT**		PRESENTATION OF THE KIT	
	12 Test	50 Test	12 Test	50 Test
Dispositivos inmunocromatograficos Diagnostic devices individually wrapped	12	50	12	50
Tubos diluyente de muestra para realizar la dilución de los sueros Diluent tubes, for preparing the dilution of the sera samples	12	50	12	50
Goteros de diluyente de cromatografia Chromatographic buffer dropper bottle	1	4	1	4
Tips desechables Disposable tips	24	100	24	100
Micropipeta volumen fijo 10 µl Micropipette of 10 µl	1	1	1	1

I. TECHNICAL BASIS

The technical basis of Ingezim Leishmacrom is an indirect immunochromatography, where we are going to detect the presence of specific antibodies to Leishmania.

II. . STORAGE:

All the reagents must be kept between 4 and 25 ºC.

¡IMPORTANT! DO NOT FREEZE

III. PRECAUTIONS:

1. Read carefully the instructions of use.
2. **Kept the reagents at room temperature before their use.**
3. Do not mix reagents or instruction from different kits.
4. Avoid any contamination of the reagents.
5. Do not use the kits after the expiry date.
6. There should be no eating, drinking or smoking where specimens or kit reagents are being handled.
7. Do not pipette by month.

IV. TEST PROCEDURE:

1. Preparation of the sample:

The sera sample needs to be at 1/50 dilution, so take 10 µl of the sera sample and put it into a diluent tube.

Shake for getting a right mixture.

2. **Sample addition:**

Dispense 10 µl of the sample dilution previously made in the lower section of the window "3" NOTE: Open the aluminium bag just in the moment to make the assay.

PRECAUTION: *The pipette never must touch the nitro-cellulose membrane.*

Chromatographic Buffer addition:

1 minute later add the chromatographic buffer solution (5 drops) in the window "1".

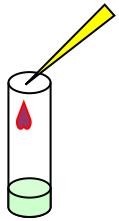
3. Read the results:

Read the results after 10 minutes.

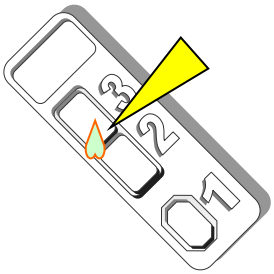
- In order to be sure that the chromatography has run properly, a pink line must appear at any case in the window nº 3 (control line window)
- If on the window nº 2 (test window), appears a pink line the sample assayed must be reported as ***POSITIVE*** to Leishmania antibodies. It doesn't matter the intensity on the colour, a presence of line in this window means presence of antibody in the sample
- If there is no line in the window "2" (result window) and there is a pink coloured line in the window "3" (control window) the sample must be reported as ***NEGATIVE*** to Leishmania antibodies.
- *NO VALID TEST:* If there is no line into the window "3" the assay can't be considered valid.

No result must be considered before 20 minutes. Any line arising after this period of time must be not considered.

1. - Preparation of the sample:

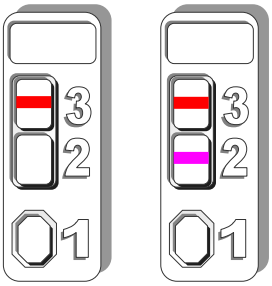


2. - Add 10 µl of the sample dilution **on the lower part of window "3".**



3. – After 1 minute add 5 drops of the buffer solution in the window "1".

4. – Wait ***10 minutes*** for reading results



NEGATIVE POSITIVE

Developed and manufactured in Spain by:

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