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CENTRO NAZIONALE DI REFERENZA PER L'ECHINOCOCCOSI
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VALIDATION OF A METHOD FOR THE DIAGNOSIS OF *E. GRANULOSUS* AND *E. MULTILOCULARIS* IN HUMANS BY MEANS OF A COMMERCIAL ELISA

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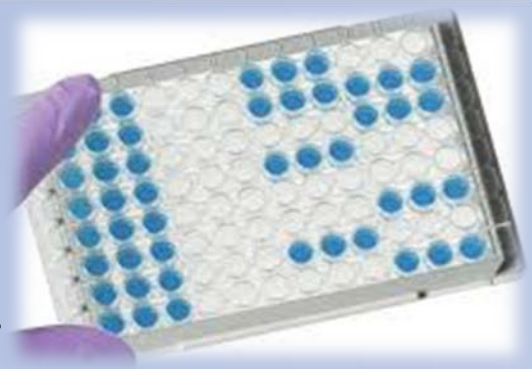
Evaluation of several parameters determined to assess the suitability for the validation of a diagnostic method for the detection of IgG antibodies anti *E. granulosus* and *E. multilocularis* useful for a screening of human sera. Suitability of the parameters estimated carry to accreditation of the method.

Trials were performed according with the OIE guidelines and the quality management system of IZSs based on ACCREDIA (Italian Accreditation Body) procedure (Regulation UNI CEI EN ISO/IEC 17025).

MATERIALS AND METHODS



For this purpose we employed the commercial ELISA kit "*Echinococcus IgG*" (*DRG, Germany*).

A total of 180 serum samples were tested:
80 belonged to people infected with *E. granulosus* (n=70) or *E. multilocularis* (n=10), 80 to *Echinococcus* free healthy donors and 20 to people infected with *Trichinella britovi, Opistorchis felineus, Tenia solium*, *Filarioidea*. (Neg samples from our Lab – EC Pos from Bio-Bank – sera pos to other parasites were provided by ISS - thank to Adriano Casulli and Maria Angeles Morales Gomez (EURLP).

Diagnostic sensitivity (**DSe**), specificity (**DSp**), positive (**PPV**) and negative predictive values (**PNV**) were determined by a 2x2 contingency table by testing a statistical representative number of sera.

Moreover, analytical specificity (**Asp**) was assessed testing 30 sera divided in 5 groups, each of these infected by other parasites, analysed besides to *E. granulosus* and a negative control group.

The **repeatability** and **accuracy**, were evaluated by 3 operators that tested in triplicate a blind set of 20 samples, the agreement was calculated by Cohen-K, as well as, the **reproducibility,** evaluated by using 2 different sets of instruments, by 2 operators the analysed of a blind set of 27 samples.

RESULTS

DIAGNOSTIC SPECIFICITY AND SENSITIVITY (DSp – DSe)

		Clinical signs			
		Presence of cysts	Absence of cysts	Total	
					PPV
Test Results	Pos	80 (VP)	10 (FP)	90 (VP+FP)	88.9 VP/(VP+FP)
					PNV
	Neg	0 (FN)	90 (VN)	90 (FN+VN)	100 VN/(VN+FN)
	Total	80 (VP+FN)	100 (FP+VN)	180 (VP+FP+FN+VN)	
		DSe 100 VP/(VP+FN)	DSp 90 VN/(VN+FP)		

ANALYTICAL SPECIFICITY (Asp)

PARASITE SPECIES	ELISA RESULTS	
	positive	negative
Echinococcus granulosus	5/5	0/5
Trichinella britovi	1/5	4/5
Opistorchis felineus	2/5	3/5
Filariasi	5/5	0/5
Tenia soliuum	2/5	3/5

ANALYTICAL SPECIFICITY (Asp)

		Clinical signs			
		Presence of cysts	Absence of cysts	Total	
					PPV
Test Results	Pos	5 (VP)	10 (FP)	15 (VP+FP)	33,3 VP/(VP+FP)
					PNV
	Neg	0 (FN)	15 (VN)	15 (FN+VN)	100 VN/(VN+FN)
	Total	5 (VP+FN)	25 (FP+VN)	30 (VP+FP+FN+VN)	
		ASe 100 VP/(VP+FN)	ASp 60 VN/(VN+FP)		

- **Repeatability** and **Accuracy** (operator performance)
- **Reproducibility** (different instruments)

excellent (k=1.00) agreement of the results

CONCLUSIONS

According to the results of the parameters evaluated for validation, the ELISA method "*Echinococcus IgG*" showed a good performance, demonstrating that it is suitable for the accreditation .