Evaluation of a novel ELISA for Schistosomiasis Serology.

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Introduction

Diagnosis of schistomosiasis, especially during the invasive phase when few or no eggs are excreted, is performed by detection of specific antibodies in travelers returning from endemic areas, with an history of bath in water. The serology is also used for screening of travel companions of confirmed cases, control programs in endemic areas and post therapeutic controls.

Bordier Affinity Products SA has developed an enzyme immunoassay for the diagnosis of human schisotosomiasis. We evaluated this new test with samples from patients with parasitologically proven or suspected shistosomiasis and we studied cross reactions with various other parasitic diseases.

Material and methods

Sera :

- 122 samples from healthy blood donors (Switzerland)
- 50 samples cryoconserved at -20°C, from patients followed in wards of Tropical Médicine, confirmed as positive for schistosomiasis by microscopic observation of *Schistosoma mansoni (Sm)* eggs in stools (15) or *Schistosoma haemotobium (Sh)* eggs in urine (22), or by a positive specific western-blot (LDBio) within a clinical and epidemiological compatible context (13).
- 128 samples cryoconserved at -20°C, from patients with other parasitic diseases: amoebiasis, leishmaniasis, malaria, toxoplasmosis, cysticercosis, hydatidosis, filariasis, strongyloidiasis, toxocariasis, trichinellosis and fasciolasis.

Studied reagents :

The kit provide the material needed to perform 96 enzyme-linked immunosorbent assays (ELISA) on microtitration plates sensitized with a mixture of adult and egg *Schistosoma mansoni* antigens. The presence of IgG antibody in serum is detected with a protein A-alkaline phosphatase conjugate. Sensitized wells are provided as breaktable strips. A negative control, a weak positive serum (cut off) and a positive control are also provided. A result is considered as positive when the absorbance of the analyzed sample is higher than the absorbance of the weak positive control.

Western blot :

Samples were tested with *Schistosoma* western-blot IgG, LDBio Diagnostics. A positive result is defined by the presence of 3 specific bands minimum[1].

Results

Specificity on blood donors:

On samples from healthy donors, the specificity is 99 %.

Specificity on patients with other parasitoses:

The results are shown in the table below. The specificity is 93%.

Parasitic diseases	Number of tested samples	Number of positives results
Amoebiasis	8	0
Leishmaniasis	11	3[1]
Malaria	19	0
Toxoplasmosis	20	1[1]
Cysticercosis	3	0
Hydatidosis	27	1[1]
Filariasis	20	3[1]
Strongyloidiasis	4	0
Toxocariasis	5	0
Trichinellosis	8	1[1]
Fasciolasis	3	0
Total	128	9 (7%)

1: Negative on *Schistosoma* WB,

Sensitivity:

With the 50 schistosomiasis patients, we observe a positive result with 47 samples, giving a sensitivity of 94%.

In details, positive results are obtained with 21/22 samples from patients with *Sh*, 13/15 samples from patients with *Sm* and 13/13 samples from patients with western-blot specific antibodies.

The positive predictive value is 81% and the negative predictive value is 90%.

Conclusions

Specificity on blood donors	**99 %**
Specificity on patients with other parasitoses	**93 %**
Sensitivity on patients with schistosomiasis	**94 %**

The *Schistosoma mansoni* ELISA kit evaluated is a good tool for the serological diagnosis of schistosomiasis.

Discussion

- With a specificity of 99 % and a sensitivity of 94 %, the cut off titer of the weak positive control discriminates optimally between sera of documented cases of shistosomiasis and normal human sera.
- The crossreactivities observed in this evaluation were reported in previous studies[2]. The clinical and epidemiological context and the results of the other serologies or parasitological examinations will strongly suggest if a positive serology is specific or is due to inter-species crossreactivities.
- Specificity and sensitivity of this reagent are satisfactory for the diagnosis of schistosomiasis. The good sensitivity could be due to the presence of soluble egg antigen mixed with adult worm antigen in the test[3].
- The immunoassay has to be combine with parasitological stool and urine exminations to make the specific diagnosis of the schistosomiasis.

References

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