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Comparative analysis of two serological techniques for *Strongyloides stercoralis* antibody detection

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Background: *Strongyloides stercoralis* diagnosis is based on parasitological techniques and serological tests. The main limitations of serological tests are their low specificity and the difficulties to evaluate their performance since there is not an established *gold-standard*. New and theoretically more specific serological tests based on recombinant antigens have been recently developed. The aim of our study was comparing two commercial serological tests for *S.stercoralis* diagnosis.

Material/methods: A retrospective laboratory-based study was conducted in Hospital 12 de Octubre. Sera from patients with a requested *S.stercoralis* serology were tested in parallel with two commercial microwell enzyme-immunoanalysis assays using two different antigens: Crude larval suspension (SciMedx®, SciMedx Corporation, Denville, NJ, USA) and recombinant antigens (NovaTec®, NovaTec Immunodiagnostica GmbH, Germany)

Interpretation of the results was: Positive [absorbance reading ≥ 0.2 OD units (SciMedx) or absorbance $\times 10/\text{Cut-off} > 11$ (Novatec)], equivocal [absorbance reading $\times 10/\text{Cut-off}$ between 9 and 11 (Novatec)] and negative [absorbance reading < 0.2 OD units (SciMedx) or absorbance reading $\times 10/\text{Cut-off} > 11$ (Novatec)]

Results were classified as:

Concordant: positive result or negative result with both tests.

Major discordance: positive result with one technique and negative result with the other.

Minor discordance: positive or negative result with SciMedx and equivocal with NovaTec.

A primary *gold-standard* reference method was defined as demonstration of *S.stercoralis* larvae in stool either by direct visualization, agar-plate culture (APC) or RT-PCR.

Noting that some of the patients did not have requested parasitological tests and the small number of positive stool samples, a composite *gold-standard* was defined. Patients were classified as:

Infected: A positive fecal test (direct visualization, APC and/or RT-PCR in stool) or a positive result in at least one of the serological tests plus an epidemiological risk factor (endemic country of origin or travel to endemic areas)

Not infected: Negative or not performed fecal tests and negative serological results with both techniques or a positive result with one or both serological tests without epidemiological risk factors.

Kappa index was calculated. Follow-up samples were excluded to calculate sensitivity, specificity and predictive values (PPV, NPV). Equivocal results were considered negative. Confidence interval was 95%.

Results: 250 samples with a requested serology for *S.stercoralis* were tested (15/250 were follow-up and 235/250 diagnostic samples). 190(76.0%) were concordant: 76(30.4%) positive and 114(45.6%) negative. 52(20.8%) were major discordances and 8(3.2%) minor discordances. Kappa index was 0.58 (0.44-0.65)

	SciMedx (Primary <i>gold-standard</i>)	SciMedx (Composite <i>gold-standard</i>)	NovaTec (Primary <i>gold-standard</i>)	NovaTec (Composite <i>gold-standard</i>)
Sensitivity	100.0%(80.8-99.6%)	96.2%(90.1-98.8%)	76.2%(52.4-90.9%)	63.2%(53.2-72.2%)
Specificity	55.6%(40.1-70.0%)	82.9%(75.1-88.8%)	84.4%(69.9-93.0%)	93.0%(86.8-96.5%)
PPV	51.2%(35.4-66.8%)	82.3%(74.1-88.3%)	69.6%(46.9-85.9%)	88.2%(78.2-94.1%)
NPV	100.0%(83.4-99.6%)	96.4%(90,5-98.8%)	88.3%(74.1-95.6%)	75.5%(67.9-81.8%)

Conclusions: Recombinant antigen test is more specific than crude antigen suspension test, but its low sensitivity may limit its use in *S.stercoralis* screening. Results with both techniques were moderate concordant. New diagnostic tests are needed for the indirect diagnosis of *S.stercoralis*.