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 serological results was performed according to manufacturer's instructions:

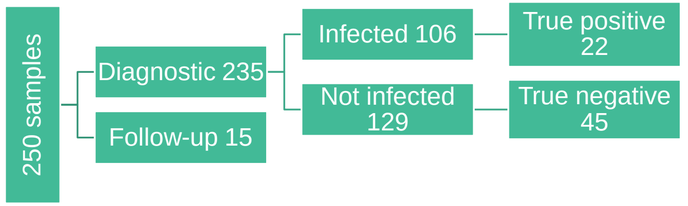
- Positive [absorbance reading ≥0.2 OD units (SciMedx) or absorbance x10/Cut-off>11 (Novatec)]
- Equivocal [absorbance reading x10/Cut-off between 9 and 11 (Novatec)]
- Negative [absorbance reading <0.2 OD units (SciMedx) or absorbance reading x 10/Cut-off>11 (Novatec)]

Table 1: *Gold-standard* definition

Primary *Gold-standard*		Composite *Gold-standard*	
True positive	Positive DV/APC and/or PCR in stool samples	**Infected**	Positive DV/APC and/or PCR
			or
			≥1 positive serological technique PLUS a risk factor
True negative	Negative DV/APC and/or PCR (in at least one sample) without risk factors	**Not infected**	Negative or not performed DV/APC/PCR PLUS 2 negative serological techniques with or without risk factors*
			or
			Negative or not performed DV/APC/PCR PLUS ≥1 positive serological technique without risk factors*

*Endemic country of origin and/or travels to endemic areas

Figure 1: Distribution of samples



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.

Kappa index for concordance was calculated.

In order to calculate sensitivity, specificity, positive and negative predictive values (PPV, NPV) follow-up samples were excluded and equivocal results with Novatec were considered negative. Confidence interval was 95%.

Primary *gold-standard* reference method was defined as demonstration of *S.stercoralis* larvae in stool either by direct visualization (DV) after formol-ether concentration procedure, agar-plate culture (APC) or 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 also defined including epidemiological data. Endemic country of origin or travel to endemic areas were considered epidemiological risk factors (Table 1).

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). Sample distribution is shown in figure 1. Sensitivity, specificity PPV and NPV results are shown in Table 2.

Table 2: Performance of serological tests

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

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