

# Preliminary evaluation of a new Schistosoma Immunochromatographic Test

Silvia S. Longoni<sup>1</sup>, Chiara Piubelli<sup>1</sup>, Francesca Perandin<sup>1</sup>, Eleonora Rizzi<sup>1</sup>, Nadia Luchetta<sup>1</sup>,  
Monica Degani<sup>1</sup>, Stefano Tais<sup>1</sup>, Antonio Mori<sup>1,2</sup>, Zeno Bisoffi<sup>1,2</sup>

<sup>1</sup>Department of Infectious-Tropical Diseases and Microbiology, IRCCS Sacro Cuore Don Calabria Hospital, Negrar, Verona, Italy.

<sup>2</sup>Department of Diagnostics and Public Health, University of Verona, Verona, Italy.

[silvia.longoni@sacrocuore.it](mailto:silvia.longoni@sacrocuore.it)

## INTRODUCTION

- >90% of schistosomiasis infections occur in sub-Saharan Africa. Migration and environmental changes contribute to the spread of infectious diseases worldwide.
- Most of *Schistosoma* infections remain clinically silent for a long time and hence not routinely screened in at risk populations.
- Commercially available ICT is based on pink-latex matrix and can be used only with serum or plasma. The new ICT, based on black-latex matrix, can overcome the limitation of possible colour interferences of the Pink-latex matrix with blood.
- A rapid ICT test to be used on whole blood would be an easy and cheap tool that could be implemented also in the field.
- We evaluate the performance of the new Black-ICT for the detection of *Schistosoma* sp. infection on archived serum samples.

## MATERIALS AND METHODS

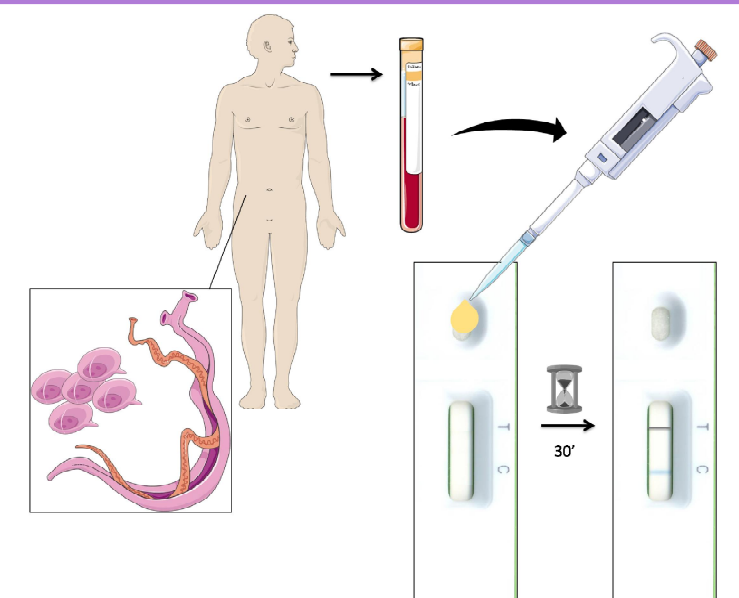
**REFERENCE TEST:** Commercially available "Pink-ICT" (SCHISTOSOMA ICT IgG-IgM, LDBIO Diagnostics)

**NEW TEST:** New "Black-ICT" (SCHISTOSOMA ICT IgG-IgM, LDBIO Diagnostics)

**POPULATIONS:** 100 serum samples: 50 from *Schistosoma* infected and 50 uninfected patients. Positivity = direct detection of *Schistosoma* sp. eggs in stools/urine and/or at least 2 concordant positive out of 4 different immunological tests.

**EXECUTION:** Two blinded operators interpreted the test

**INNOVATION:** Development of an in-house reference colorimetric signal scale to evaluate the signal intensity of the new "Black-ICT"



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### Diagnostic performance of the new ICT test

	Se %	Sp %	PPV	NPV	
Pink-ICT*	96 (91-99)	83 (77-87)	78%	97%	
Black-ICT	Op_1	100 (92.9-100)	15.2 (6.34-28.9)	56.2.%	100%
	Op_2	98 (89.4-99.9)	87.8 (75.2-95.4)	89.1.%	97.7%

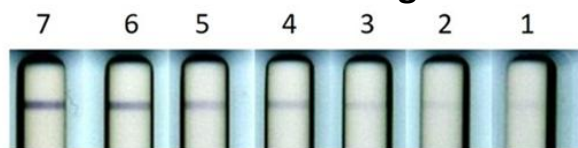
Se = sensitivity; Sp = specificity; ( ) confidence interval; PPV = positive predictive value; NPV = negative predictive value. \* "Schistosoma ICT IgG-IgM" (LDBIO Diagnostics), (Beltrame et al., 2017).

### Agreement between the two operators

	Op1-Op2
Agreement	63%
Kappa Index	0.17
p value	0.001

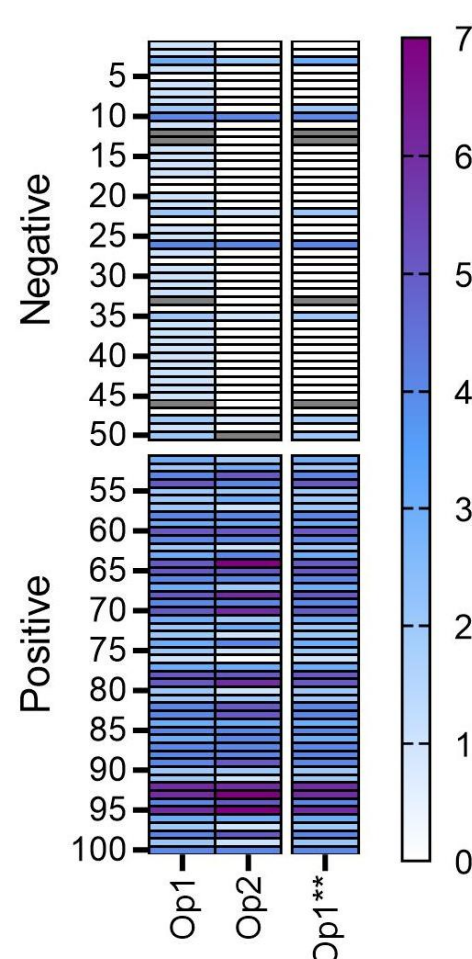
The Black-ICT presented a weak background signal in several samples, which could mislead the operator.

### Reference colorimetric signal scale



1 = faint positive signal and 7 = maximum intensity, being 0 a negative result

### Black-ICT results



Grey squares mean equivocal results

Considering the colorimetric scale, we observed that several false positives, scored as faint bands or equivocal by operator 1, were scored as negative by operator 2.

Op\_1: Operator 1; Op1\*\*: Values obtained applying a cut-off. Op\_2: Operator 2.

### Diagnostic performance of the new ICT test

	Se %	Sp %	PPV	NPV	
Pink-ICT*	96 (91-99)	83 (77-87)	78%	97%	
Black-ICT	Op_1**	98 (89.4-99.9)	82.6 (68.6-92.2)	86%	97.4%
	Op_2	98 (89.4-99.9)	87.8 (75.2-95.4)	89.1.%	97.7%

Se = sensitivity; Sp = specificity; ( ) confidence interval; PPV = positive predictive value; NPV = negative predictive value. \* "Schistosoma ICT IgG-IgM" (LDBIO Diagnostics), (Beltrame et al., 2017).

### Agreement between the two operators

	Op1**-Op2
Agreement	94%
Kappa Index	0.88
p value	<0.0001

Applying a cut-off threshold at bands scored as faint (score =1) for operator 1, it results in an increase in the specificity. Indeed, the performance of the new tests resulted similar to those of Pink-ICT.

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A control sample to exclude the background signals or a colorimetric guide to read and interpret the results, for the new Black-ICT is needed.

## FUTURE STEPS

A further prospective study (including the above suggestion) should be indeed planned for the performance evaluation of the Black-ICT on whole blood from finger prick.

### FURTHER READING

Beltrame et al. 2017, <https://doi.org/10.1371/journal.pntd.0005593>  
Buonfrate et al. 2018, <http://dx.doi.org/10.1136/bmjopen-2017-019228>