

Communication piece: Commercially available diagnostic tests

(N.B. This document will continuously be updated as further information becomes available)

Schistosomiasis affects over 200 million people worldwide¹, and more than 700 million people in endemic areas are at risk of infection², being one of the most prevalent of the Neglected Tropical Diseases (NTDs). It also accounts for an estimated 1.9 million disability-adjusted life years (DALYs) annually². Several million people all over the world suffer from severe morbidity as a consequence of schistosomiasis³.

In 2012, World Health Assembly Resolution 65.21 called on countries to intensify control and initiate elimination campaigns where feasible. In the same year, the WHO defined control of morbidity as <5% prevalence of heavy intensity infection in school-aged children, and elimination as a public health problem as <1% prevalence of heavy intensity infection in school-aged children.

National NTD programmes and collaborating partners need to track progress towards reaching the WHO NTD Roadmap goals. Each country has a strategic or masterplan with specific objectives and actions to reach the control and elimination goals and to measure achievements through specific coverage and infection indicators.

Both infection prevalence and intensity are key indicators used by countries to monitor and evaluate interventions and to track progress towards control or elimination of the disease. Countries require sensitive diagnostic tools that are affordable and can be used in low-resource settings. It is therefore vital to gather information about currently available diagnostic tests. First, in order to know which tools are available and in which context they can be used, so that national programmes can have the right diagnostic tool for achieving their targets. Secondly, to identify the diagnostic gaps and requirements for schistosomiasis programmes moving from disease control to elimination as a public health problem, and for schistosomiasis surveillance post-transmission interruption. Finally, there is a need for further standardization of diagnostics tests and their output, in order to increase transparency of collected data and improve comparability of surveys or the outcome of different intervention programs.

The Global Schistosomiasis Alliance (GSA)* [Diagnostic Work Stream](#) has gathered information on commercially available diagnostic tests for schistosomiasis in order to make this information accessible to Ministries of Health, policy makers, schistosomiasis researchers and other stakeholders. The focus is on schistosome endemic regions, but the outcome is also likely to facilitate decisions about how to improve the diagnostic workflow for imported schistosomiasis cases in non-endemic settings. The best diagnostic tool will depend on different factors, such as the setting where it is going to be used, the species of *Schistosoma* to be detected, and the goal or strategy of the programme. Higher sensitivity and specificity will be needed when moving towards elimination goals, or when diagnosing returning travellers in non-endemic areas,

¹ WHO Schistosomiasis and soil-transmitted helminthiases: number of people treated in 2018. Wkly Epidemiol Rec. 2019; 50: 601–612.s

² Abajobir et al. Global, regional, and national disability-adjusted life-years (DALYs) for 333 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390: 1260–1344.

³ WHO Key Facts on Schistosomiasis: <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis>

typically showing low intensity infections. However, when the aim is to reach morbidity control, the focus would probably be on ease-of-use and low cost to be used as a Point-Of-Care / Point-Of-Need test. In this case, an ideal diagnostic test would follow the WHO ASSURED criteria (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users)⁴.

The following tables (table 1a, 1b and 1c) list currently commercially available diagnostics. Not all are recommended by WHO nor GSA^a. The diagnostic methods that are currently recommended by WHO are the microscopy methods – Kato-Katz (KK) on faecal samples for the diagnosis of intestinal schistosomiasis, and Urine Filtration (UF) for urogenital schistosomiasis⁵. These methods, although specific, lack sensitivity. In addition, in *S. mansoni* transmission areas, WHO also recommends the Point-of-Care test based on circulating cathodic antigen (POC-CCA) detection⁶. While schistosome circulating antigens reflect the presence of viable worms (current infection), specific antibodies cannot distinguish past and/or present infections. Consequently, antibody detection tests are not suitable for identifying current infections.

The GSA Diagnostic Work Stream hopes to update this list as new diagnostics become available. Please contact [the GSA office](#) for comments, updates or additional information.

*Global Schistosomiasis Alliance

The [Global Schistosomiasis Alliance \(GSA\)](#) is a coalition whose objective is to bring together the different actors needed to advance in the control and elimination of schistosomiasis. It is constituted as a diverse but representative partnership of endemic countries, academic and research institutions, international development agencies and foundations, international organizations, non-governmental development organizations, private sector companies and advocacy and resource mobilizations partners.

^a The table below is not a list of recommended tests or a list of tests to be used by stakeholders, this is only an information piece collating what is currently commercially available. Manufacturers should be contacted to find out intended and appropriate use as well as details on methodology, logistics, cost and safety. As diagnostic test properties are dependent on locally performed procedures and endemicity characteristics, it is important to follow diagnostic protocols as indicated by the provider and also to perform proper test verification in your own settings. Where appropriate, participation in an external quality assessment scheme is recommended.

This information was collected by consulting a number of stakeholders and reaching out to manufacturers for more information. Where information is missing this is because this was not easily available and/or the manufactures did not respond to requests for more information. The GSA and its members and partners take no responsibility for any incorrect information or inadequate or negative outcome from the use of these diagnostics tests.

⁴ Mabey et al. Diagnostics for the developing world. Nature Reviews Microbiology 2004; 2: 231–240.

⁵ Bench aids for the diagnosis of intestinal parasites, second edition. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO

⁶ Bärenbold O, Garba A, Colley DG, Fleming FM, Haggag AA, Ramzy RMR, et al. (2018) Translating preventive chemotherapy prevalence thresholds for *Schistosoma mansoni* from the Kato-Katz technique into the point-of-care circulating cathodic antigen diagnostic test. PLoS Negl Trop Dis 12(12): e0006941. <https://doi.org/10.1371/journal.pntd.0006941>

Table 1a: Commercially available diagnostic tests for schistosomiasis diagnosis – Microscopy & Microhaematuria

Type	Product	Species (not stated by manufacturer)	Sample type	Type of diagnostic	Company	Estimated Cost (refers to material only, may vary based on quantity and inflation) \$ = USD £ = GBP € = Euro (prices do not include taxes)	Manufacturers intended use (taken directly from the manufacturers website where available).	Product and manufacturer information
Microscopy ***	Sterlitech Kato-Katz kit	Intestinal species*^	Stool	Eggs	Sterlitech	\$130.91 (kit for 500 tests) ** Contents of Kit: - Applicator Sticks (500 pieces) - Nylon Screen, 100 mesh (500 pieces) - Template, calibrated to 41.7mg (500 pieces) - Hydrophilic Cellophane (500 pieces)	People infected with STH or intestinal Schistosomiasis pass the eggs of the worms through their feces. By examining a stool sample under a microscope, it is possible to count the number and the type of eggs that are present. (WHO, 2008) [From Sterlitech Kato-Katz website]	Sterlitech corporation, 22027 70th Avenue S, Kent, WA 98032-1911 USA. Sterlitech Kato-Katz website
	HELM TESTE Kato-Katz kit	Intestinal species*^	Stool	Eggs	BIO-MANGUINHOS	(2)	This is a qualitative-quantitative test based on the Kato-Katz method technology. The parasitological examination allows to reveal helminth eggs present in stool samples such as: <i>Ascaris</i> , <i>Schistosoma</i> , hookworms, <i>Trichuris</i> , <i>Taenia</i> and less frequently those of <i>Enterobius</i> and <i>Strongyloides</i> . The kit identifies the prevalence of disease as schistosomiasis, allowing the Ministry of Health to expand the surveillance and monitoring of parasitic diseases, and to work on their prevention. [From Bio-Manguinhos-Fundação Oswaldo Cruz website Translated from Portuguese by https://www.deepl.com]	Fundação Oswaldo Cruz/ Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos; Avenida Brasil 4365 -Manguinhos- CEP: 21040-900, Rio de Janeiro, Brazil. Bio-Manguinhos-Fundação Oswaldo Cruz website.
	Fill-FLOTAC	Intestinal species*^	Stool	Eggs	University of Naples Federico II	1 Fill-FLOTAC €10 12 Fill-FLOTAC €100 Flotac website	Refer to: https://www.parassitologia.unina.it/flotac/flotac/suggested-for/	Unità di Parassitologia e Malattie Parassitarie, Università degli Studi di

							Contents can be reused (https://www.parassitologia.unina.it/wp-content/uploads/2015/07/Manual_HUMAN.pdf).	Napoli Federico II. Naples, Italy FLOTAC website .
Mini-FLOTAC	Intestinal species*^	Stool	Eggs	University of Naples Federico II	1 Mini-FLOTAC €15 5 Mini-FLOTAC €65 10 Mini-FLOTAC €120 Mini-Flotac website		Refer to: https://www.parassitologia.unina.it/flotac/flotac/suggested-for/ Contents can be reused (https://www.parassitologia.unina.it/wp-content/uploads/2015/07/Manual_HUMAN.pdf).	Unità di Parassitologia e Malattie Parassitarie, Università degli Studi di Napoli Federico II. Naples, Italy. Mini-FLOTAC website .
Sterlitech Schistosome Test Kit	<i>Urogenital species* ></i>	Urine	Eggs	Sterlitech	\$507.47 (kit for 500 tests) Content of kit: - 500 polycarbonate screen membrane filters (13 mm diameter, 13 / 20 µm pore size) - 5 plastic Swinnex filter holders (13 mm) - 2 syringes (10 cc) - Forceps & Plastic case		<i>The Schistosome Test Kit is a portable, all-in-one-tool for immediate determination of schistosome eggs in urine. Testing for schistosome eggs is extremely important as hundreds of millions of people are infected with the parasitic disease known as Schistosomiasis.</i>	Sterlitech corporation, 22027 70th Avenue S, Kent, WA 98032-1911 USA. Sterlitech Schistosome Test website
Millipore urine filtration kit	<i>Urogenital species* ></i>	Urine	Eggs	Merck Millipore	£64.30 for Swinnex Filter holder (box of 10 holders) £151.00 for Isopore Membrane filter (box of 100 filters)	(2)		Millipore Merck KGaA, Darmstadt, Germany Swinnex Filter holder - Swinnex website Isopore Membrane filter - Isopore website
SEFAR NITEX filters	<i>Urogenital species* ></i>	Urine	Eggs	SEFAR	(2) filters only. Price varies on the number ordered.	(2)		Sefar Ltd. Bury Business Centre, Kay Street, Bury Lancashire BL9 6BU England, UK

								https://www.sefar.com Contact:filtration@sefar.com
Micro-haematuria	Hemastix	<i>Urogenital species* ></i>	Urine	Micro-haematuria	Siemens Healthcare Diagnostics	\$0.50 (\$25.00 for a pack of 50)	<i>The strips are for professional, in vitro diagnostic use only. Hemastix® urinalysis test strips are ready to use upon removal from the bottle and may be read visually or read instrumentally using the CLINITEK Status®+ Urine Analyzer. [From Hemastix Siemens Healthcare.]</i>	Siemens Healthcare Diagnostics GmbH, Eschborn, Germany. In Partnership with Pharmaforte Singapore Pte. Ltd Hemastix Siemens Healthcare.
	Multiplex Urine Strips (1)	<i>Urogenital species* ></i>	Urine	Micro haematuria	Multiple companies ⁺	Contact supplier (1) *	[There are many types and forms of urine analysis test strips. Different types will allow not only the POC detection of blood in urine (haematuria) but also other biomarkers such as sugar, proteins, leukocytes etc. in a multiplex format. Some suppliers are detailed but alternatives maybe available.]	F. Hoffmann-La Roche Ltd, Corporate Communications, Grenzacherstrasse 124, CH-4070 Basel, Switzerland. La Roche website. Medisave supplier website

(1) A large range of reagents strips that detect blood (Heme, Hb) in urine are available from multiple companies.

(2) Cost/info not known

* non species specific

**contact supplier for more information and bulk buying savings

*** individual items (e.g. cellophane, sieves) of microscopy-based kits can often be purchased in-country. The GSA office can put you in contact with experts if specific advise is needed

>*S. haematobium* and *S. haematobium* group hybrids

^*S. mansoni*, *S. intercalatum*, *S. guineensis*, *S. japonicum*, *S. mekongi*

Table 1b: Commercially available diagnostic tests for schistosomiasis diagnosis – Antibody

Type	Product	Species	Sample type	Type of diagnostic	Company	Estimated Cost (refers to material only, may vary based on quantity and inflation) \$ = USD £ = GBP € = Euro (prices do not include VAT)	Manufacturers intended use (taken directly from manufacturers website where available)	Product and manufacturer information
Antibody	Bilharziosis F UMOUZE® IHA (indirect hemagglutination assay)	(1)	Serum	IgG + IgM? (1)	Fumouze Laboratories (now acquired by Biosynex)	(1)	(2)	BIOSYNEX SA, 22 Boulevard Sébastien Brant 67400 Illkirch-Graffenstaden, France. Biosynex flyer link.
	ELIH.A.	<i>S. mansoni</i> , <i>S. haematobium</i> , <i>S. intercalatum</i> *	Serum	IgG and IgM	ELITech Group	£78 (kit 120 tests)	<i>ELITech developed the ELI.H.A Schistosoma, an indirect haemagglutination assay, for the quantitative determination of anti-Schistosoma mansoni, anti-Schistosoma haematobium and anti-Schistosoma intercalatum antibodies in the serum. [From ELITech website]</i>	ELITech Group, 13-15 bis rue Jean Jaurès, 92800 Puteaux, France. ELITech website.
	SCHISTO-96	<i>S. mansoni</i> , <i>S. haematobium</i> *	Serum	Antibodies (not specified)	SCIMEDX	\$325 (96 tests)	<i>Intended for the qualitative determination of serum antibodies in humans, primarily IgG, to Schistosoma spp. using the ELISA technique. [From Scimedx website]</i>	Scimedx Corporation 2017, 53 Richboynton Road, Dover, NJ 07801, USA. Scimedx website.
	<i>S. mansoni</i> IgG (ELISA)	<i>S. mansoni</i>	Serum	IgG	IBL International	£166 (12 tests)	<i>The Schistosoma mansoni IgG ELISA is intended for the qualitative determination of IgG class antibodies against Schistosoma mansoni in human serum or plasma (citrate, heparin).</i>	Tecan Group Ltd. Seestrasse 103 8708 Männedorf, Switzerland.

							<i>[From IBL - IgG website.]</i>	IBL - IgG website.
S. mansoni IgM (ELISA)	<i>S. mansoni</i>	Serum	IgM	IBL International	£166 (12 tests)	(2)		Tecan Group Ltd. Seestrasse 103 8708 Männedorf, Switzerland. Contact manufacturer for more info: ibl@tecan.com
SCHISTO II WB IgG	<i>S. mansoni, S. haematobium*</i>	Serum	IgG in Western Blot	LDBIO Diagnostics	(1)		<i>SCHISTO II Western Blot (WB) IgG is a qualitative IgG serological diagnostic immunoblot test for schistosomiasis (or bilharzia) offered as a confirmatory test for a positive or equivocal result obtained by conventional screening tests. [From LDBIO IgG Western Blot website translated from French by https://www.deepl.com]</i>	LDBIO Diagnostics, Lyon, France. LDBIO IgG Western Blot website.
SCHISTOSOMA ICT IgG-IgM	All*	Serum	IgG/IgM in lat flow (latex)	LDBIO Diagnostics	(1)		<i>SCHISTOSOMA ICT IgG-IgM is a qualitative unitary rapid test using the immuno-chromatographic technique that allows the simultaneous detection of anti-Schistosoma IgG and IgM in human serum. [From LDBIO IgG/IgM website translated from French by https://www.deepl.com]</i>	LDBIO Diagnostics, Lyon, France. LDBIO IgG/IgM website.
Indirect haemagglutination assay (IHA)	<i>S. japonicum</i>	Serum	IgG	Yueyang Xunchao Biotechnology Co., LTD.	\$0.5 per test	(2)		Yueyang Xunchao Biotechnology Co., LTD.
				Anhui Anji Medical Technology Co., LTD.	\$0.5 per test	(2)		Anhui Anji Medical Technology Co., LTD.
Dot immunogold		Serum	IgG	Yueyang Xunchao	\$1 per test	(2)		Yueyang Xunchao Biotechnology Co., LTD.

filtration assay (DIGFA)	<i>S. japonicum</i>			Biotechnology Co., LTD.			
				Sichuan Maike Biotechnology Co., LTD.	\$1 per test	(2)	Sichuan Maike Biotechnology Co., LTD.
				Shanghai Jikong Biotechnology Co., LTD.	\$1 per test	(2)	Shanghai Jikong Biotechnology Co., LTD.
Dipstick dye immuno assay kit (DDIA)	<i>S. japonicum</i>	Serum	IgG	Wuxi Saide Technology Development Co.,LTD.	\$1 per test	(2)	Wuxi Saide Technology Development Co., LTD.
Magnetic particle antibody immunoassay (MPAIA)	<i>S. japonicum</i>	Serum	IgG	Beijing Beiaikang Biological technology Co., LTD.	(2)	(2)	Beijing Beiaikang Biological technology Co., LTD.
Enzyme-linked immunosorbent assay (ELISA)	<i>S. japonicum</i>	Serum	IgG	Shenzhen Huakang Biomedical Engineering Co., LTD.	\$80 (96 tests)	(2)	Shenzhen Huakang Biomedical Engineering Co., LTD.
				Guangzhou Darui Biological technology Co., LTD.	(2)	(2)	Guangzhou Darui Biological technology Co., LTD.
SEA anti-Schistosoma ELISA	<i>S. mansoni</i>	Serum	IgG	Euroimmun	(2)	(2)	Euroimmun, Germany – Sao Paulo, Brazil Euroimmun SCH website Email: infection-pm@euroimmun.de

	SWAP anti-Schistosoma ELISA	<i>S. mansoni</i>	Serum	IgM	Euroimmun	(2)	(2)	Euroimmun, Germany – Sao Paulo, Brazil Email: infection-pm@euroimmun.de
	Schistosoma mansoni IgG	<i>S. mansoni</i>	Serum or plasma	IgG	NovaTec Immundiagnostica	(1)	<i>The Schistosoma mansoni IgG ELISA is intended for the qualitative determination of IgG class antibodies against Schistosoma mansoni in human serum or plasma (citrate, heparin). [From NovaTec website]</i>	NovaTec Immundiagnostica GmbH, Waldstraße 23A, 63128 Dietzenbach, Germany NovaTec website
	Schistosoma mansoni IgM	<i>S. mansoni</i>	Serum or plasma	IgM	NovaTec Immundiagnostica	(1)	<i>The Schistosoma mansoni IgM ELISA is intended for the qualitative determination of IgM antibodies against Schistosoma mansoni in human serum or plasma (citrate or heparin). [From NovaTec website]</i>	NovaTec Immundiagnostica GmbH, Waldstraße 23A, 63128 Dietzenbach, Germany NovaTec website
	Schistosoma mansoni ELISA IgG / Schistosoma mansoni ELISA Testkit	<i>S. mansoni</i>	Serum or plasma	IgG	Viramed Biotech AG	(1)	<i>Enzyme-linked immunosorbent assay for the detection of specific antibodies against Schistosoma mansoni in human serum. [From Viramed website]</i> <i>The Schistosoma mansoni IgG-ELISA is intended for the qualitative determination of IgG class antibodies against Schistosoma mansoni in human serum or plasma (citrate). [From Viramed's manufacturer User's Manual, DRG Instruments GmbH]</i>	Viramed Biotech AG, Behringstraße 11, 82152 Planegg, Germany Viramed website
	Schistosoma mansoni IgG ELISA	<i>S. mansoni</i>	Serum	IgG	DRG Diagnostics	(1)	(1) <i>[List of products available at DRG website]</i>	DRG Instruments GmbH, Frauenbergstrasse 18 D-35039 Marburg Germany DRG website

Schistosoma mansoni IgM ELISA (1)	<i>S. mansoni</i>	Serum	IgM (1)	DRG Diagnostics	(1)	(1) [List of products available at DRG website , availability of IgM ELISA listed but to be confirmed]	DRG Instruments GmbH, Frauenbergstrasse 18 D-35039 Marburg Germany DRG website
IVD Schistosoma Serum Antibody Detection Microwell ELISA	(1)	Serum	(1)	IVD Research	(1)	The IVD Schistosoma Serum Antibody Detection Microwell ELISA test kit provides accurate, reliable detection of Schistosoma antibodies in human serum samples. [From IVD website]	IVD Research Inc, 5909 Sea Lion Pl, Carlsbad, CA 92010, United States IVD Research website

(1) Companies have been contacted. Waiting for response

(2) Cost/info not known

* non species specific (may also work for other species *S. intercalatum*, *S. guineensis*, *S. japonicum*, *S. mekongi* and the *S. haematobium* group hybrids)

** contact supplier for more information and bulk buying savings

Table 1c: Commercially available diagnostic tests for schistosomiasis diagnosis – Antigen

Type	Product	Species	Sample type	Type of diagnostic	Company	Estimated Cost (refers to material only, may vary based on quantity and inflation) \$ = USD £ = GBP € = Euro (prices do not include VAT)	Manufacturers intended use (taken directly from manufacturers website where available)	Product and manufacturer information
Antigen	Schisto POC-CCA®	<i>S. mansoni</i> *** (and all other intestinal species)	Urine	CCA antigen	Rapid Medical Diagnostics	\$1.5-1.75 (per test) but further price reductions negotiable for large orders**	INDICATIONS FOR USE: The urine-CCA (Circulating Cathodic Antigen) cassette test is for the qualitative presumptive detection of an active Schistosoma infection, more specific <i>S. mansoni</i> , but also other species e.g. <i>S. haematobium</i> and <i>S. japonicum</i> . For endemic studies	Rapid Medical Diagnostics, 423A Sussex Avenue, Lynnwood, Pretoria 0081, RSA Rapid Medical Diagnostics website.

							<p>involving <i>S.mansoni</i> infections, a single CCA urine test demonstrates closely the true prevalence predicted by models based on multiple egg count determinations. Accuracy in urogenital schistosomiasis is variable, and also seems to differ between regions. In general, some medium to high level infections with <i>S. haematobium</i> can be diagnosed using the urine CCA strip. This test should be used for patients with clinical signs and symptoms that are consistent with a <i>Bilharzia</i> infection. [From Rapid Medical Diagnostics Brochure]</p>	<p>Manufactured under license of RMD, by ICT Diagnostics, 271 De Goede Hoop Estate, Village Lane, Noordhoek, Cape Town, RSA http://www.ictdiagnostics.co.za/</p> <p>For international orders, quotations and distribution contact ICT Diagnostics via http://www.ictdiagnostics.co.za/</p>
	Urine CCA (Schisto) ECO Teste	<i>S. mansoni</i>	Urine	CCA antigen	ECO Diagnóstica Ltda	(2)	<p>Qualitative detection of schistosomiasis more specifically caused by <i>Schistosoma mansoni</i> and by other species such as <i>S. haematobium/ haematobica</i> and <i>S. japonicum</i> [Translated from ECO Diagnostica by www.deepl.com]</p>	<p>Manufactured and distributed by ECO Diagnóstica Ltda. Rua das Acácias 1338, Sl. 906, Vale do Sereno, CEP: 34006-003, Nova Lima, Minas Gerais, Brazil ECO Diagnostica website</p>

(1) Companies have been contacted. Waiting for response

(2) Cost/info not known

* non species specific

** contact supplier for more information and bulk buying savings

*** (N.B. Schisto POC-CCA® detects *S. mansoni* and *S. japonicum* infections. It has not been fully tested for the intestinal species *S. intercalatum*, *S. guineensis*, *S. japonicum*, *S. mekongi*. It has variable results for *S. haematobium* infections, showing geographical variation. This could be due to the occurrence of *S. haematobium* group hybrids).