

# ICT International

## Schistosoma IgG Card Test

Rapid Detection of IgG Antibodies to  
Schistosoma in Human Serum/Plasma

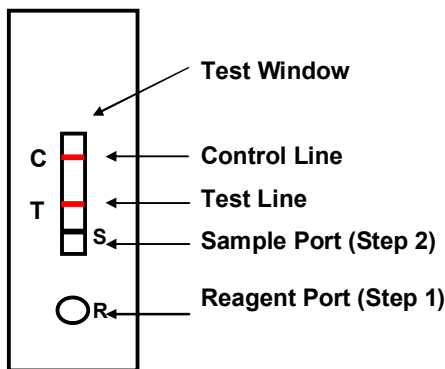
Catalog No.: SCHAb25

### SUMMARY OF TEST PROCEDURE

Step	Description	Time
1	Apply 2 drops of conjugate to the <b>reagent port (R)</b> to wet the membrane	Wait ~20 seconds
2	Apply 5 µl sample in the <b>sample port (S)</b>	
3	Read result	<b>5 minutes</b> after sample application

\*Refer to illustration 1 and the package insert for detail

**Illus. 1: Test Device (Card)**



### INTENDED USE

**Schistosoma IgG Antibody Test** (The Test) is a rapid immunoassay intended as a screening test for qualitative detection of IgG antibodies to **Schistosoma** in human serum or plasma. The Test is designed for investigational use only.

### INTRODUCTION

A genus of trematodes, **Schistosoma**, commonly known as **blood-flukes** and **bilharzia**, includes flatworms which are responsible for the most significant parasitic infection of humans by causing the disease schistosomiasis, and are considered by the World Health Organization as the second most important parasitic disease, next only to malaria, with hundreds of millions infected worldwide. Diagnosis of the disease is based on a series of laboratory studies including egg detection, complete blood count and coagulation studies, urinalysis, liver function tests, and serologic tests.

The Test is a rapid visual assay based on principles of immunochromatography and fluid dynamics to qualitatively detect the presence of **IgG** antibodies to **Schistosoma** in human serum or plasma specimen.

### PRINCIPLES OF THE TEST

The Test is based on a proprietary technology that combines the principles of immuno-chromatography and fluid dynamics. The

device of the Test has **Schistosoma** antigen immobilized on the membrane within the test zone. The liquid gold-Protein A conjugate applied to the device through the reagent port (marked "R") in the first step serves to prime the device and to facilitate the migration of samples applied in the sample port (marked "S") in the second step. As the sample migrates through the test zone, the **IgG** antibodies to the **Schistosoma** antigen present in the specimen are captured by the immobilized antigen and subsequently visualized by the conjugate in the form of a magenta test line. The absence of the test line indicates a negative test. In the control zone of the membrane, a magenta control line appears in every valid test indicating that the Test is properly performed and reagents are functional as specified.

### MATERIAL PROVIDED

1. Test Device (card)
2. Conjugate Reagent
3. 5ul sampler

### MATERIAL REQUIRED BUT NOT PROVIDED

1. Timer

### STORAGE AND STABILITY

Store the test cards at 2-30°C. Store the conjugate reagent at 2-8°C. **DO NOT FREEZE.** Do not use beyond the expiration date.

### PRECAUTIONS

1. Do not use the test device and reagent beyond expiration date.
2. Treat all specimens as infectious. Practice universal precautions and wear protective gloves throughout the procedure. Properly dispose of specimens and other testing materials according to standard procedures.
3. Bring testing materials including specimen to room temperature before testing.

### SPECIMEN COLLECTION AND PREPARATION

1. The Test can be performed on either serum or plasma. It is recommended that fresh specimens be used if possible. Specimens may be stored at 2-8°C for up to 3 days before testing. For long-term storage, specimens should be kept below -20°C.
2. Separation of serum or plasma from blood should be performed as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

### TEST PROCEDURE (see illustration 1)

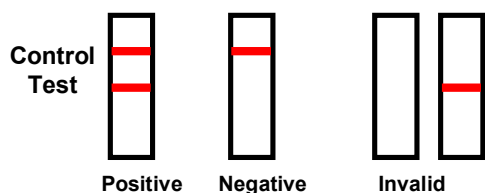
**Allow test card, reagent, specimen, and controls to equilibrate to room temperature (15-30°C) before testing.**  
**Place the test card on a clean and level surface.**

1. Hold the conjugate dropper bottle vertically and transfer 2 full drops (~100 µl) of conjugate into the reagent port (marked "R"). Wait for the conjugate to pass the sample port (marked "S") as indicated by the red liquid front passing through.
2. Transfer 5µl of sample onto the membrane in the sample port.
3. Read result within **5 minutes** after the sample application.  
**Do not attempt to interpret result after 10 minutes.**

### RESULT INTERPRETATION

(Please refer to illustration 2)

## Illus. 2: Result Interpretation



<b>Positive:</b>	<b>Both test and control lines appear.</b> Note: Low titres of antibody may result in a faint test line.
<b>Negative:</b>	<b>Only control line appears.</b>
<b>Invalid:</b>	<b>Control line fails to appear.</b> The test should be repeated on a new device.

### QUALITY CONTROL

The control line in the control zone is a built-in procedural control in the Test. The control line appearing as specified indicates that the test is properly performed and reagents are functional.

### LIMITATIONS

1. The Test (Serum/Plasma) is for *in vitro* use only.
2. The Test is a qualitative test.
3. Positive results should be confirmed by independent confirmatory tests.
4. In cases where the test result is negative while clinical symptoms persist, further consultation with a physician and additional tests of other methods should be followed.
5. Optimal assay performance requires strict adherence to the assay procedures described in this insert sheet. Deviations may lead to aberrant results.

### PERFORMANCE CHARACTERISTICS

The Test showed concordance with other commercial tests when tested with commercial performance panels.

### REFERENCES

1. Tie-Wu Jia; Xiao-Nong Zhou; Xian-Hong Wang; Jürg Utzinger; Peter Steinmann; Xiao-Hua Wu (June 2007). "Assessment of the age-specific disability weight of chronic schistosomiasis japonica". *Bulletin of the World Health Organization* (Geneva: World Health Organization) 85 (6): 458–465.
2. Larry S Roberts; Schmidt, Gerald D (2005). *Foundations of Parasitology* (7th ed.). pp. 247–261.
3. Ishii A; Tsuji M; Tada I (2003 Dec). "History of Katayama disease: schistosomiasis japonica in Katayama district, Hiroshima, Japan". *Parasitol Int.* (New York: Elsevier) 52 (4): 313–9.
4. Xiao-Nong Zhou; Guo-Jing Yang; Kun Yang; Xian-Hong Wang; Qing-Biao Hong; Le-Ping Sun; John B. Malone; Thomas K. Kristensen; N. Robert Bergquist; Jürg Utzinger (2008). "Potential Impact of Climate Change on Schistosomiasis Transmission in China". *Am. J. Trop. Med. Hyg* 78 (2): 188–194.
5. Chitsulo L, Engels D, Montresor A, et al. The global status of schistosomiasis and its control. *Acta Trop.* Oct 23 2000;77(1):41-51.