SBio SLIM S. typhi Test

DIPSTICK

Rapid test for detection of IgM antibodies to *S. typhi* in serum/plasma/whole blood

REF	90720020
Σ	20 T

CE

	Temperature Limitation	⬆⬆	This side up	DIPSTICK	Dipstick	Xn	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
	Use by		Consult Instructions for use	PIPETTE	Disposable Plastic Sample Applicator	NaN₃, R22, S23-46-61	
	Date of Manufacture	REF	Catalogue Number	BUF	Sample Running Buffer		Do not use if package is damaged
LOT	Batch Number / Lot Number	IVD	*In vitro* Diagnostic Medical Device	CAP	Test Tube Caps		
Σ	Contains sufficient for <n> tests		Do not reuse	TUBE	Test Tubes	EC REP	Authorised Representative in the European Community

INTENDED USE

SBio SLIM S. typhi Test is a rapid, qualitative, sandwich immunoassay for the detection of IgM antibodies to *S. typhi* in human serum/plasma or whole blood specimen.

SUMMARY

A febrile condition, Typhoid fever, is a bacterial infection caused by Salmonella serotypes including *S. typhi, S. paratyphi A, S. paratyphi B* and *Salmonella sendai.* The symptoms of the illness include high fever, headache, abdominal pain, constipation and appearance of skin rashes. Accurate diagnosis of typhoid fever at an early stage is not only important for etiological diagnosis but to identify and treat the potential carriers and prevent acute typhoid fever outbreaks. The conventional WIDAL Test usually detects antibodies to *S. typhi* in the patient serum from the second week of onset of symptoms. Early rising antibodies to Lypopolysaccharide (LPS) O are predominantly IgM in nature. Detection of *S. typhi* specific IgM antibodies instead of IgG or both IgG & IgM (as measured by the Widal test) would serve as a marker for recent infection.

SBio SLIM S. typhi Test qualitatively detects the presence of IgM class of Lypopolysaccharide (LPS) specific to *S. typhi* in human serum/plasma or whole blood specimens.

PRINCIPLE

SBio SLIM S. typhi Test utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad contains two components - Agglutinating sera for human IgM conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane test assembly, the Agglutinating sera for human IgM - colloidal gold conjugate complexes with the *S. typhi* specific IgM antibodies in the specimen and travels on the membrane due to capillary action. This complex moves further on the membrane to the test region (T2) where it is immobilized by the *S. typhi* specific LPS antigen coated on the membrane leading to formation of a pink to pink- purple coloured band. The absence of this coloured band in the test region indicates a negative test result.

The unreacted conjugate and unbound complex, if any along with the rabbit globulin - colloidal gold conjugate move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C), forming a pink to pink-purple coloured band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

SBio SLIM S. typhi Test kit contains:

A. Individual pouches, each containing:
 1. Dipstick: Membrane assembly pre-dispensed with Agglutinating sera for human IgM - colloidal gold conjugate, rabbit globulin - colloidal gold conjugate, *S.typhi* LPS antigen and Agglutinating sera for rabbit globulin coated at the respective regions.
 2. Desiccant pouch.
 3. Disposable Plastic Sample Applicator.
B. Sample running buffer bottle.
C. Package insert.
D. Test tube with result reading marked area.
E. Test tube caps.

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4°C to 30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE. After first opening of the sample running buffer bottle, it can be stored between 4°C to 30°C for the remaining duration of its shelf life.

NOTES

Read the instructions carefully before performing the test. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only. Do not use the kit beyond expiry date. Test dipstick, reading tube are for single use only. Do not intermix reagents from different lots. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a

minimum. Inhalation / swallowing may cause harm. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test dipstick must be run. Sample running buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxide. Flush with large volumes of water to prevent azide build-up in the plumbing.
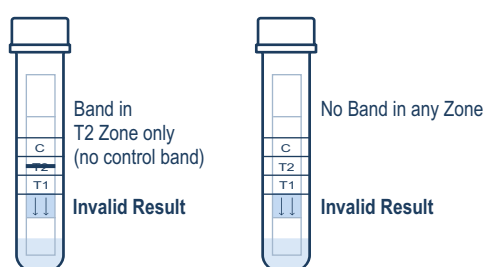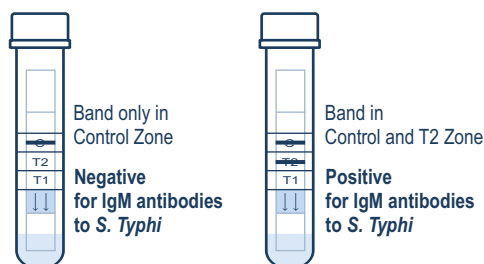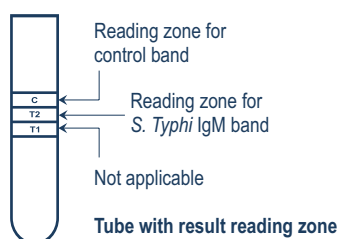
SPECIMEN COLLECTION AND PREPARATION
1. SBio SLIM S. typhi Test uses human serum / plasma / whole blood as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. For whole blood, collect blood with a suitable anticoagulant such as EDTA or Heparin or Oxalate and use the freshly collected blood. Finger prick whole blood also can be used.
4. Whole blood should be used immediately and not to be stored.
5. For serum or plasma, fresh specimen is preferable but in case of delay in testing, it may be stored at 2°C to 8°C for maximum up to 24 hrs. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Do not use turbid, lipaemic and hemolysed serum/plasma.
8. Do not use hemolysed, clotted, contaminated, viscous/turbid specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only should be used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS
1. Bring the SBio SLIM S. typhi Test kit components to room temperature before testing.
2. Open the pouch and retrieve the dipstick (taking care not to touch the membrane area), sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the dipstick and use another dipstick. *Once opened, the dipstick must be used immediately.*
3. Take the result area marked test tube provided with the kit and label it with patient's identity and number.
4. Tighten the cap of the sample running buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
5. Carefully dispense 5µl of the whole blood/serum/plasma on the sample pad just below the arrows on the dipstick using a micropipette. In case of whole blood the sample applicator can be used for sample dispensing by dipping the sample applicator in the sample container and blot the sample on the dipstick just below the arrows.

NOTE : Use of applicator is recommended only for whole blood sample, not for serum/plasma. Incase of serum/plasma use precision micropipette.
6. Dispense **four drops** of sample running buffer into the labeled test tube by holding the plastic buffer bottle vertically straight.
7. Put the test tube vertically straight in the test tube stand.
8. Place the dipstick with the sample into the tube, with the arrows on the dipstick pointing downwards and ensuring that the buffer level is below the blood sample for the entire duration of the test and close the test tube with cap.
9. Read the results at the end of **20 minutes** as follows based on the marking of T1/T2/C on the test tube.

Reading zone for control band

Reading zone for *S. Typhi* IgM band

Not applicable

Tube with result reading zone

Band only in Control Zone
Negative for IgM antibodies to *S. Typhi*

Band in Control and T2 Zone
Positive for IgM antibodies to *S. Typhi*

Band in T2 Zone only (no control band)
Invalid Result

No Band in any Zone
Invalid Result

PERFORMANCE CHARACTERISTICS
Internal Evaluation
In an in-house study, the performance of SBio SLIM S. typhi Test was evaluated using a panel of sixty-five specimens of WIDAL-positive (of varying reactivity) and WIDAL-negative sera in comparison with a commercially available DOT ELISA

test kit. The results of the evaluation are as follows:

SPECIMEN DATA	WIDAL	SBio SLIM S.Typhi Test	Commercially available DOT ELISA
No. of specimen tested	65	65	65
No. of positive specimens	15	15	15
No. of negative specimens	50	49	50

Based on this evaluation:
Sensitivity of SBio SLIM S. typhi Test : 100%, Specificity of SBio SLIM S. typhi Test : 95.5%.

LIMITATIONS OF THE TEST

1. Presence of a band at the test region even if low in intensity or formation is a positive result.
2. The deliberate slow reaction kinetics of SBio SLIM S. typhi Test is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
3. Most positive results develop within 20 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read the test results after 30 minutes.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. SBio SLIM S. typhi Test should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions.
6. In some studies, it has been reported that low titre IgM antibodies to *S.typhi* may persist for about 4 months post infection. Therefore, in endemic area, samples positive yet with low signal intensity should be interpreted with caution, preferably in light of patient history.
7. The following chart would explain the IgM seroresponse in *S.typhi* infected subjects after onset of fever.

Detectable IgM Response	
Onset of fever	Percent positive
4-6 days	43.50 %
6-9 days	92.90 %
>9 days	100 %

8. A negative result, i.e., the absence of detectable IgM antibody does not rule out recent or current infection, as the positivity is influenced by the time elapsed from the onset of fever and immunocompetence of the patient. However, if *S. typhi* infection is still suspected, obtain a second specimen 5-7 days later and repeat the test.
9. Specific IgG may compete with the IgM for sites and may result in a false negative. Conversely, high titer Rheumatoid factor may result in a false positive reaction.
10. A low extent of cross reactivity may be observed with *S. paratyphi* infection.

WARRANTY
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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