ImmunoScience INDIA

ImmunoQuick

S. Typhi IgG/IgM

Rapid S. Typhi IgG/IgM Test – Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

Typhoid fever is a life-threatening infection caused by the bacterium Salmonella Typhi. That spreads through contaminated food and water. An estimated 11–20 million people get sick from typhoid and between 128 000 and 161 000 people die from it every year. Symptoms include prolonged fever, fatigue, headache, nausea, abdominal pain, and constipation or diarrhea. Some patients may have a rash. Severe cases may lead to serious complications or even death. Typhoid fever can be treated with antibiotics although increasing resistance to different types of antibiotics is making treatment more complicated.

INTENDED USE

Rapid S. Typhi IgG/IgM test is an immunochromatographic assay for the qualitative Detection of S. Typhi specific IgG/IgM antibodies in human serum/plasma or whole blood.

PRINCIPLE

After addition of the sample and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant S. Typhi specific antigens and streptavidin. If the sample contains detectable levels of the S. Typhi specific IgM and IgG antibodies, it reacts with the gold conjugated recombinant S. Typhi specific antigens to form a complex. This complex moves further and S. Typhi specific IgM antibodies conjugate complex reacts with anti-human IgM test line and the S. Typhi specific IgG antibodies react with the anti-human IgG antibodies test line on the nitrocellulose membrane area to form colored band/s. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT

1. Test Device with desiccant and plastic dropper in individual pouch
2. Assay Buffer
3. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Timer
2. Sample container
3. Micro pipette
4. Disposable Gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the used test components hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

SPECIMEN COLLECTION

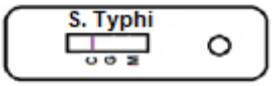
Testing should be performed as early as possible after collection. Do not leave serum/Plasma/blood samples at room temperature for prolonged periods.

TEST PROCEDURE

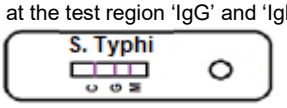
1. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test device, desiccant and plastic dropper from the pouch and use it as early as possible.
3. Put the device on plain surface and add 10 µl of serum / plasma or 20 µl whole blood sample in sample well and add 2 drops (Approx. 60 µl) of assay buffer in sample well.
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

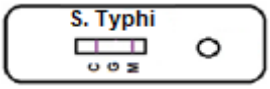
Negative: Only one colored line appears at the control region 'C' only



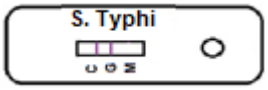
Positive: A) A distinct colored line appears at the control region 'C' and at the test region 'IgG' and 'IgM'.



B) A distinct colored line appears at the control region 'C' and at the test region 'IgM'

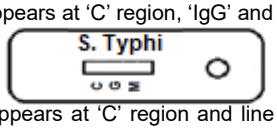


C) A distinct colored line appears at the control region 'C' and at the test region 'IgG'

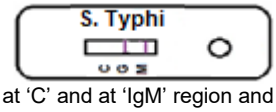


Invalid: The test should be considered invalid if,

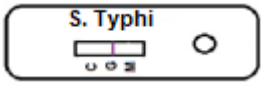
A) no line appears at 'C' region, 'IgG' and 'IgM' region



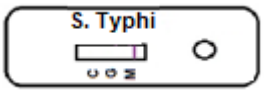
B) No line appears at 'C' region and line appear at 'IgM' and 'IgG' region



C) No line appears at 'C' and at 'IgM' region and line appear at 'IgG' region



D) No line appears at 'C' and at 'IgG' region and line appear at 'IgM' region



NOTE: The intensity of the color of test lines will vary depending upon the antibodies present in specimen.

PERFORMANCE CHARACTERISTICS

1. Total 185 samples are evaluated for specificity, sensitivity. sensitivity was found 100% (60/60) and relative specificity was observed to be 100% (125/125).
2. The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.
3. No cross reactivity found with HIV, HCV, Dengue, HBsAg and syphilis Ab positive samples.
4. Lowest detection limit is observed up to 1:128 titre of positive sample.

Sample	ImmunoQuick S.Typhi IgG/IgM		Reference Kit		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	60	0	60	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	25	0	25	No cross reactivity observed			
Total	60	125	60	100	-			

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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