

# TUBEX® *TF*

For rapid detection of Typhoid Fever



# TUBEX®

TUBEX® **TF** is a rapid and sensitive *in vitro* diagnostic test for detection of acute typhoid fever, a disease caused by *Salmonella enterica* serovar Typhi. The test principle for TUBEX® **TF** is based on Inhibition Magnetic Binding Immunoassay (IMBI®) – a semi-quantitative colometric assay. TUBEX® **TF** can easily be performed in any laboratory setting as well as in the field. A positive TUBEX® **TF** result, together with typical clinical symptoms, is a strong indication of acute typhoid fever.

Typhoid fever is a water- and foodborne infectious feverish disease caused by *Salmonella* Typhi. The disease is endemic in large parts of Asia, Africa and Central and South America, and occasionally also causes epidemic spread. Symptoms include prolonged fever, fatigue, headache, nausea, abdominal pain and constipation or diarrhoea. Severe cases may lead to serious complications or even death, if not correctly treated. Due to its non-specific clinical indications, patients with typhoid fever are commonly misdiagnosed with malaria, dengue fever, gastroenteritis or pneumonia. Typhoid fever can be treated with antibiotics although the rate of typhoid cases resistant to available antibiotics is increasing globally. Thus appropriate antibiotic therapy is mandatory, typhoid mortality is high and ranges from 12-30 percent.

Blood culture, a commonly used diagnostic can be cumbersome, time-consuming, and even impossible without laboratory facilities.

Diagnostic alternatives must therefore deliver effective and reliable results, independent of laboratory facilities.

TUBEX® **TF** is an *in vitro* diagnostic test, based on early detection of *Salmonella* Typhi IgM anti-O9 antibodies in serum. It is based on IMBI® technology<sup>1,2</sup> a semi-quantitative assay technology, a simple assay technology based on visual interpretation. TUBEX® **TF** is characterized by high sensitivity and specificity. TUBEX® **TF** can be performed in any laboratory environment and the result is ready within 10 minutes.

TUBEX® **TF** Wash is a new product which enables analysis of colored samples (icteric, haemolytic). All components, including the wash buffer, are included in the kit.



	Catalogue Number	Assay Specification
TUBEX® <b>TF</b>	10-201	36 Tests/kit
TUBEX® <b>TF</b> Wash*	10-501	36 Tests/kit

\*To be used on colored serum samples



# Well documented

The awareness of the clinical benefits of TUBEX® **TF** in endemic settings is increasing. Some results from clinical trials from different parts of the world are presented below:

In a comparative study in the Philippines<sup>4</sup>, Kawano and co-workers evaluated four antibody detection tests for typhoid fever. The sensitivity of TUBEX® **TF** was 95% at a specificity of 80%. In this study TUBEX® **TF** performed best among the analysed tests.

Number of patients: 177 patients (75 patients with culture proven *S. Typhi* and 103 culture negative non-typhoidal patients).

	Sensitivity	Specificity
TUBEX® <b>TF</b>	95 %	80 %
SD Biolin IgM	69 %	79 %
SD Bioline IgG	71 %	76 %
Typhidot IgM	55 %	65 %
Typhidot IgG	73 %	46 %
Mega IgM	91 %	49 %
Mega IgG	96 %	39 %



In a prospective trial in Bangladesh by Rahman and co-workers<sup>5</sup>, a total of 243 febrile outpatients (mainly children and adolescents) and 57 healthy controls were enrolled. Based on culture results, TUBEX® **TF** was 91% sensitive and 82% specific in febrile subjects. Specificity increased to 90% in non-febrile healthy subjects, suggesting that some culture-negative patients were truly typhoidal. The Widal test demonstrated a sensitivity of 82 % and a specificity of 58%.

In an evaluation study from Zimbabwe by Tarupiwa and co-workers<sup>6</sup>, a total of 131 patients with typical symptoms and signs of typhoid fever were tested. Based on blood culture, TUBEX® **TF** had 100% sensitivity and 94% specificity. The results indicated that TUBEX® **TF** could be a useful tool for the rapid diagnosis of *Salmonella enterica* serovar typhi infection during typhoid outbreaks in Zimbabwe.



- Rapid IMBI® assay
- Accurate and reliable result within 10 minutes
- For any laboratory environment

#### References:

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3. Olsen S.J, et al. Evaluation of rapid diagnostic tests for typhoid fever. J Clin Microbiol. 2004;42: 1885-1889.
4. Kawano R.L., et al. Comparison of serological test kits for diagnosis of typhoid fever in the Philippines. J Clin Microbiol. 2007; 45:246-247.
5. Rahman M., et al. Rapid detection of early typhoid fever in endemic community children by the TUBEX O9-antibody test. Diagn Microbiol Infect Dis. 2007; 58:275-281.
6. Tarupiwa A., et al. Evaluation of TUBEX-TF and OnSite Typhoid IgG/IgM Combo rapid tests to detect *Salmonella enterica* serovar Typhi infection during a typhoid outbreak in Harare, Zimbabwe. BMC Researches Notes. 2015; 8:50
7. Mogasale et al. What proportion of *Salmonella* Typhi cases are detected by blood culture? A systematic literature review Ann Clin Microbiol Antimicrob. 2016; 15:32
8. WHO. Background document. The diagnosis treatment and prevention of typhoid fever. 2003; 11-16. WHO/V&B/03.07

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