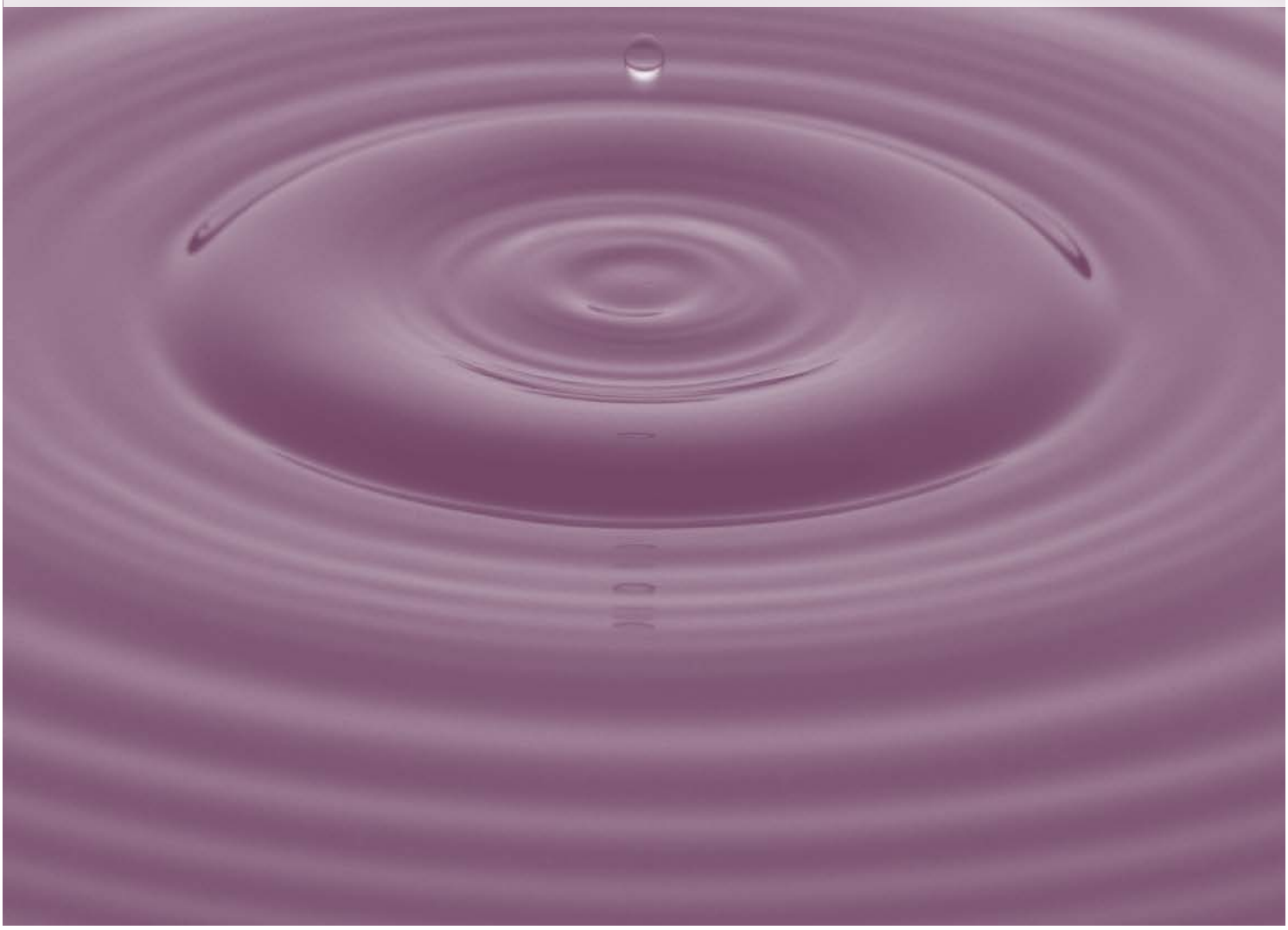
TUBEX® *TF*

Rapid typhoid detection



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TUBEX®

TUBEX® ***TF*** is a rapid and sensitive in vitro diagnostic test for detection of acute typhoid fever, a disease caused by *Salmonella 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 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. It causes high fever, flu-like symptoms, and severe symptoms in the digestive system that causes systemic disease, which is potentially life threatening 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. A definitive diagnosis depends on the isolation of *S. typhi* from bone marrow, blood, or stool, a process that is cumbersome, time-consuming, and even impossible without laboratory facilities. Diagnostic alternatives must therefore deliver effective and reliable results, independent of laboratory facilities. Typhoid fever is normally treated with antibiotics; however studies show that multi-drug resistant (MDR) typhoid strains have become much more common in typhoid high burden communities.

Thus appropriate antibiotic therapy is mandatory, typhoid mortality is high and ranges from 12-30 percent.

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 [1,2] 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 preformed in any laboratory environment and the result is ready within 10 minutes.

TUBEX® Wash Buffer is a product that is recommended to be used as a complement to TUBEX® ***TF*** to analyze colored serum samples. Colored serum samples can be difficult to test and interpret in TUBEX® ***TF***, but by adding an extra washing step with TUBEX® Wash Buffer it is possible to accurately interpret these problematic samples.

Product	Catalogue Number	Assay Specification
TUBEX® ***TF***	10-201	36 Tests/kit
TUBEX® Wash Buffer	10-932	Additional buffer solution* 120 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[3], 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.

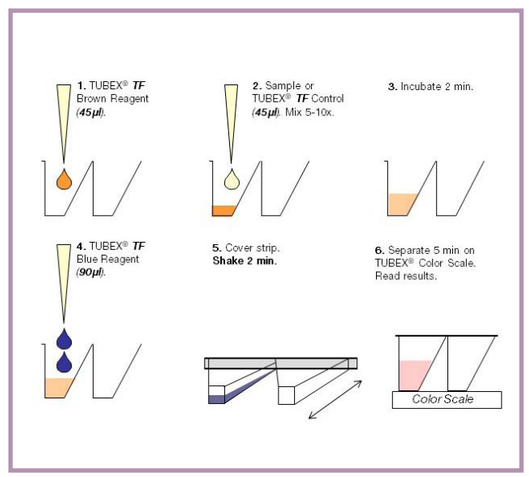
In a prospective trial in Bangladesh by Rahman and co-workers[4], a total of 243 febrile outpatients (mainly children and adolescents) and 57 healthy controls were enrolled. Based on culture results, TUBEX ***TF*** was 91% sensitive and 82% specific in febrile subjects. Specificity increased to 90% in 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%.

	Sensitivity	Specificity
TUBEX® ***TF***	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 %

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

Assay procedure

1. Add 45µl TUBEX® ***TF*** Brown Reagent (detector) to the TUBEX® Reaction Well Strip.
2. Add 45µl patient sample, TUBEX® ***TF*** Positive Control or TUBEX® ***TF*** Negative Control. Mix 10 times by pipetting.
3. Incubate on the bench for 2 minutes.
4. Add 90 µl TUBEX® ***TF*** Blue Reagent (indicator).
5. Cover the TUBEX® Reaction Well Strip using the TUBEX® Sealing Tape. Tilt and shake the TUBEX® Reaction Well Strip for 2 minutes.
6. Place the TUBEX® Reaction Well Strip on the TUBEX® Color Scale. Allow separation for 5 minutes. Read and score the results by comparing the color of each supernatant to the TUBEX® Color Scale. The color scale range from score 0 (negative test) to 10 (positive test).



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

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References:

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2. Tam FCH., et al. The TUBEX typhoid test based on particle-inhibition immunoassay detects IgM but not IgG anti-O9 antibodies. J Imm Meth. 2003; 282:83-91.
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4. Rahman M., et al. Evaluation of rapid detection of early typhoid fever in endemic community children by the TUBEX O9-antibody test. Diagn Microbiol Infect Dis. 2007; 58:275-281
5. Ley B., et al. Assessment and comparative analyziz of a rapid diagnostic test (TUBEX®) for the diagnosis of typhoid fever among hospitalized children in rural Tanzania. BMC Infectious Diseases. 2011; 11:147.
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