Tubex® TF (RAP-4724)

USA: RUO

As of 25 Oct. 2007

INTENDED USE

TUBEX® TF is a 10 minute semi-quantitative in vitro serum assay for the detection of current typhoid fever caused by Salmonella typhi.

A positive TUBEX® TF result, together with typical clinical symptoms of typhoid fever, is highly suggestive of a typhoid infection.

PRINCIPLE OF THE ASSAY

TUBEX® TF detects the presence of anti-O9 antibodies in the patient's serum by assessing their ability to inhibit the reaction between the antigen-coated brown and antibody-coated blue reagents. The level of inhibition is proportional to the concentration of anti-O9 antibodies in the sample. Separation is enabled by magnetic force. Result is read visually against a color scale.

ASSAY SPECIFICITY

TUBEX® TF specifically detects IgM antibodies to the S. typhi O9 lipopolysaccharide antigen. This antigen is highly specific to S. typhi and other Salmonella serogroup D bacteria by its extremely rare sugar (α-D-tyvelose). IgM anti-O9 antibodies are normally not present in healthy individuals. No detectable cross reactivity to antibodies of other specificities prevails.

SPECIMENS

Use clear serum samples or Heparin plasma.

Do not use EDTA or Citrate plasma.

Avoid grossly lipemic, icteric or hemolyzed samples. Colored samples will disturb the color in the reaction and result in indeterminate assay results, e.g. by hemoglobin (red color) and bilirubin (greenish color).

The serum samples should be stored at 2 - 8 °C or frozen (≤-18 °C), if not used immediately.

PRECAUTIONS FOR USERS

1. TUBEX® TF is for in vitro use only.
2. Wear protective gloves and protective goggles.
3. Do not use the kit after expiry date.
4. Do not mix reagents from different lots.
5. All patient specimens should be regarded as contagious and handled and disposed of according to appropriate regulations.
6. Avoid microbiological contamination of reagents.
7. If reagents come in contact with eyes, flush with plenty of water and seek medical advice.
8. Caution! Strong magnets inside the TUBEX® TF Color Scale.

9. Reading of results requires a normal color vision.
10. ProClin 300 (60 ppm) used as a preservative in this product might be allergenic. In case of contact flush with plenty of water and seek medical advice.
11. Material Safety Data Sheets are available on request.

MATERIALS REQUIRED BUT NOT PROVIDED

Device to obtain serum.

Preferably common laboratory equipment, such as precision pipettes, vortex and timer.

COMPONENTS IN TUBEX® TF

Materials supplied for 30 determinations.

1. **TUBEX® TF Blue Reagent:** 1 vial, 3 ml, antibody coated particles in protein stabilized buffer, pH 8.2. Preservative added. Ready for use.
2. **TUBEX® TF Brown Reagent:** 1 vial, 1.5 ml, antigen coated particles in protein stabilized buffer, pH 8.2. Preservative added. Ready for use.
3. **TUBEX® TF Negative Control:** 1 vial, 0.4 ml, protein stabilized buffer, pH 8.2. Yellow colored. Preservative added. Ready for use.
4. **TUBEX® TF Positive Control:** 1 vial, 0.4 ml, control antibody in protein stabilized buffer, pH 8.2. Preservative added. Ready for use.
5. **TUBEX® Color Scale:** 1 piece, with embedded magnets. Strong magnet, handle with caution.
6. **TUBEX® Colored Stickers:** Self-adhesive colored stickers for labeling of reagents and controls (bottle and cep), optional use.
7. **TUBEX® Pipette:** 32 pieces, plastic, single-use dropper Do not mix the use of TUBEX® Pipettes with precision pipettes in the same reaction well.
8. **TUBEX® Reaction Well Strip:** 5 strips (6 reaction wells per strip). Single-use.
9. **TUBEX® Sealing Tape:** 8 strips, sealing tape for reaction wells. Single-use.

ASSAY PROCEDURE

Carefully read the assay procedure instructions below before starting the analysis (also see Figure 1).

The assay should be performed at room temperature (RT 18-35°C). Inclusion of controls are recommended at every test occesion, but not required for every Reaction Well Strip used. The assay can be performed either by using a precision pipette or the provided TUBEX® Pipettes. Never mix the use of precision pipettes with TUBEX® Pipettes in the same reaction well strip.

Results are dependent on the right proportion between the volume of the reagents and serum samples, to ensure the correct results always use only one kind of pipette consistently.

TUBEX® Reaction Well Strips, TUBEX® Sealing Tapes and TUBEX® Pipettes should only be used once due to risk of contamination and false positive results.

1.1 Preparations

Bring all reagents and samples to RT. Color label the components (optional).

Vortex or shake all reagents thoroughly prior to use.

Check visually that all sediments have dispersed into solution.

1.2 Procedure

The accuracy of the test is related to adherence to the assay procedure and accurate volume pipetting.

Use TUBEX® Pipettes or precision pipettes consistently.

1. Place the TUBEX® Reaction Well Strip upright on the bench (*do not place the strip on the color scale yet*). Add **45 µL** (1 drop) TUBEX® TF Brown Reagent to each well.
2. Add **45 µL** (1 drop) sample, TUBEX® TF Positive Control or TUBEX® TF Negative Control to appropriate wells, and carefully mix by pipetting up and down 10 times. Thorough mixing is essential. Avoid foaming. Use a new pipette for each sample.
3. Incubate on the bench for **2 min**.
4. Add **90 µL** (2 drops) TUBEX® TF Blue Reagent, to each well.
5. Cover the TUBEX® Reaction Well Strip with a TUBEX® Sealing Tape. Press the tape hard against the plastic to prevent leakage.

   Important!

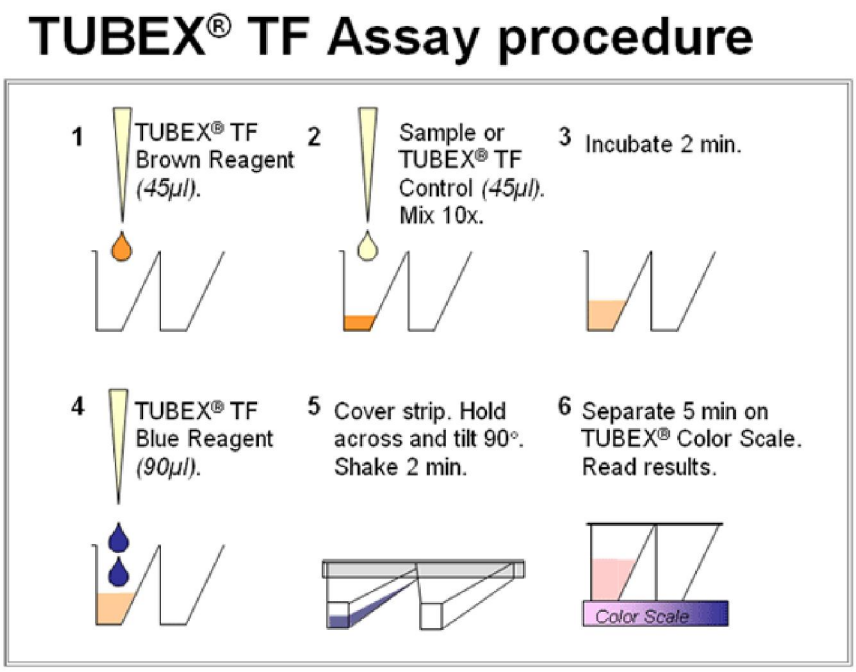
   Mix thoroughly for 2 min using the following procedure:

   - Hold the Reaction Well Strip across at one end (well number face-front) using one hand's thumb and forefinger.
   - **Tilt** the Reaction Well Strip horizontally (90°) to expose maximum well surface for the mixture.
   - **Shake** the Reaction Well Strip **rapidly** backwards and forwards. Make sure that the contents flow across the entire exposed surface of the well.
6. Place the TUBEX® Reaction Well Strip on the TUBEX® Color Scale as far left as possible. Allow separation for 5 min to obtain a clear supematant.

Do not interpret results if reaction is disturbed after separation time.

Read and score the results by comparing the color of each supernatant to the color scale provided. Reading should be performed at good light conditions within 30 minutes after separation, although results are stable for hours if not disturbed. The scores range from 0 (clear pink) to 10 (intense blue). Intermediate scores of 1, 3, 5, 7, and 9 are not shown on the TUBEX® Color Scale but can be extrapolated.

Figure 1. Assay. For detailed description see Procedure above.



INTERPRETATION OF RESULTS

A general guide to the interpretation of TUBEX® TF scores is presented in Table 1. Interpretation should focus on detection of any blue tone in the supernatant, particularly important regarding the lower scores.

Disturbed reactions after separation time should not be re-separated and interpreted. The disturbance of already separated reactions may cause false results.

To indicate a correct performance of the kit, TUBEX® TF Negative Control should score ≤ 2 and TUBEX® TF Positive Control should score ≥ 8.

Table 1

Score	Interpretation Guide
≤ 2	NEGATIVE - Does NOT indicate current typhoid fever infection. TUBEX® TF Negative Control
3	Borderline, inconclusive score. Repeat analysis. If still inconclusive, repeat sampling at a later date.
4	WEAK POSITIVE - Indication of current typhoid fever infection.
6-10	POSITIVE- Strong indication of current typhoid fever infection. TUBEX® TF Positive Control
INDETERMINATE	No clear score obtained due to: 1) Poor adherence to assay protocol. Repeat analysis. 2) Poor specimen quality. Repeat sampling and analysis.

If the TUBEX® TF result indicates current typhoid fever but the culture is negative, the following may be the reasons:

- Patient truly has typhoid fever. Culture is commonly positive in only 50 - 80% of affected patients.
- Patient has a subclinical or asymptomatic infection, but is not a chronic typhoid carrier. Presumably the latter is negative in TUBEX® TF due to the absence of relevant IgM antibodies (but in whom IgG antibodies may be found).
- Patient has another Salmonella Group D infection.
  Theoretically, all organisms belonging to this group, in particular S. enteriditis, can stimulate the immune response and yield a positive TUBEX® TF score. However, many of these infections may not be common, or are confined to the gut only, and hence may not induce a detectable systemic response.
- The TUBEX® TF result is false. Repeat sampling and analysis at a later occasion. In a true typhoid fever case, the TUBEX® TF score is likely to change (increase or decrease); while the score remain constant if the result is due to non-specific factors.

REAGENTS STORAGE

The kit should be stored at 2-8°C. **Do not freeze!**

Store the reagents upright in their original containers if not used at once.

ASSAY CHARACTERISTICS

TUBEX® TF has an analytical sensitivity of 15 - 20 µg/mL.

LIMITATIONS OF THE PROCEDURE

TUBEX® TF results should be interpreted in conjunction with all available clinical information.

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Although TUBEX® TF specifically detects acute phase antibodies, IgM-dominant, it may also detect convalescent phase IgG antibodies. IgG antibodies, although not reactive by themselves, can synergistically bind to the antigen coated particles.

TUBEX® TF may not detect cases where IgM antibodies are present in extremely low levels, such as early in the infection when culture is positive, but the immune system has not yet been sufficiently stimulated.

The use of EDTA or Citrate plasma may cause false positive results.

Insufficient mixing during the second incubation may cause false positive results.

ADDITIONAL MATERIALS

Additional TUBEX® Reaction Well Strips and Sealing Tape can be ordered if needed (TUBEX® Well Package REF 10-929).

WARRANTY

The performance data presented here were obtained using the procedure indicated. Any change or modification in the procedure, not recommended by DRG, may affect the results. In such event, DRG disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

REFERENCES

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SYMBOLS USED WITH DRG ELISA´S

Symbol	English	Deutsch	Francais	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Ussage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Temperature de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Distributeur	Distributeur	Distribuidor	Distributtore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..