HRG HIBM Research Group
Non-profit molecular laboratory

T-SPOT.*TB*®
Information for Clinicians

The New Effector T-Cell Based Blood Test for the Detection of Latent and Active M. tuberculosis

T-SPOT.*TB* is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations. The T-SPOT.*TB* test has been tested in some patient groups indicated for screening for TB infection according to current ATS/CDC Guidance[1]: such as, **human immunodeficiency virus (HIV) positive persons, recent contacts of TB case patients, residents and employees of high-risk congregate settings, chronic renal failure, children younger than 4 yr of age or infants, children, and adolescents exposed to adults at high-risk and immunosuppressed patients.**

THE NEW TB TEST FOR:

Immunosupressed Patients:

- **HIV**
- **Rheumatoid arthritis/ TNF-alpha**
- **End-stage renal disease**
- **Children, elderly**
- **Organ transplants**
- **Diabetes**

High Risk for Transmission:

- **Healthcare Workers**
- **Prisoners**
- **Immigrants**
- **Military**
- **TB Contacts**
- **Chronic Care Residents**

TEST PERFORMANCE:

	True Sensitivity	Reported Sensitivity		
	Sensitivity	Sensitivity	Indeterminate excluded (n)	Indeterminate (%)
T-SPOT.TB	92.1% (849/922)	92.8%	7	0.8%
QFT –Gold	78.1% (985/1262)	82.2% (985/1199)	63	5.6%
QFT-Gold In-Tube	76.4% (697/912)	81.0% (697/861)	51	8.2%
TST / PPD* ≥5mm	81.0% (295/364)	NA	NA	NA

Analysis based on all peer-reviewed articles published as of July 3, 2008 and 54 study data points, including results in 3096 patients
* Quantitative summary of all head:head studies between T-SPOT or QFN and TST in active TB as of July 3,2008

- **95.6% Sensitivity**[2]
- **97.1% Specificity**[2]
- **Results unaffected by BCG vaccination, age or immunosuppression**[3]

SPECIMEN REQUIREMENTS:

Age	Tube	Blood Volume (min.)
10 yr and older	Lithium or Sodium Heparin Tube	(1) 6 mL
2-9 yrs old	Same as above	(1) 4 mL
2 yrs and younger	Lithium Heparin Pediatric Tube	(1) 2 mL

TEST AVAILABILITY / RESULTS TAT:

******* SPECIMENS SHOULD BE KEPT AT ROOM TEMPERATURE ********

- **Sample collection should be performed *Monday - Thursday*.**
- **Specimen should be shipped Priority Overnight at Room Temperature**

Results reported as "Positive", "Borderline", or "Negative" within 48 hours of receipt

REFERENCES:

1. CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis. MMWR weekly, June 09, 2000; 49(RR06): 1-54.
2. T-SPOT.*TB* Pivotal Clinical Trial. Sensitivity of 95.6%. Specificity of 97.1% (PI-TB-US-V1)
3. T-SPOT.*TB* Pivotal Clinical Trial. T-SPOT.*TB* results were not associated with immunocompromised status or BCG vaccination. T-SPOT.*TB* was not impacted by age. (PI-TB-US-V1)

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