Tuberculosis Infection: Diagnosis and Recommendations

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Has the following disclosures to make:

- No conflict of interests
- No relevant financial relationships with any commercial companies pertaining to this activity

Tuberculosis Infection: Diagnosis and Recommendations

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TEXAS Health and Human Services | Texas Department of State Health Services

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Laws Affecting Tuberculosis

Laws Affecting TB

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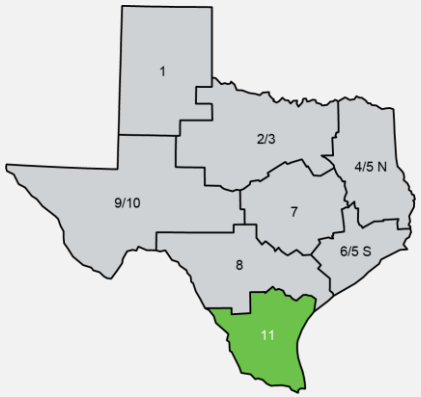
- Texas laws listed in the Texas Health and Safety Code, Chapters 81 and 89 require specific information regarding notifiable conditions be provided to the Texas Department of State Health Services (DSHS).
- Health care providers, hospitals, laboratories, schools, and others are required to report patients who are suspected of having a notifiable condition Texas Administrative Code Title 25, Part 1, Chapter 97.



The Texas Tuberculosis Manual

Sets performance standards for TB programs receiving state funding

TB manual

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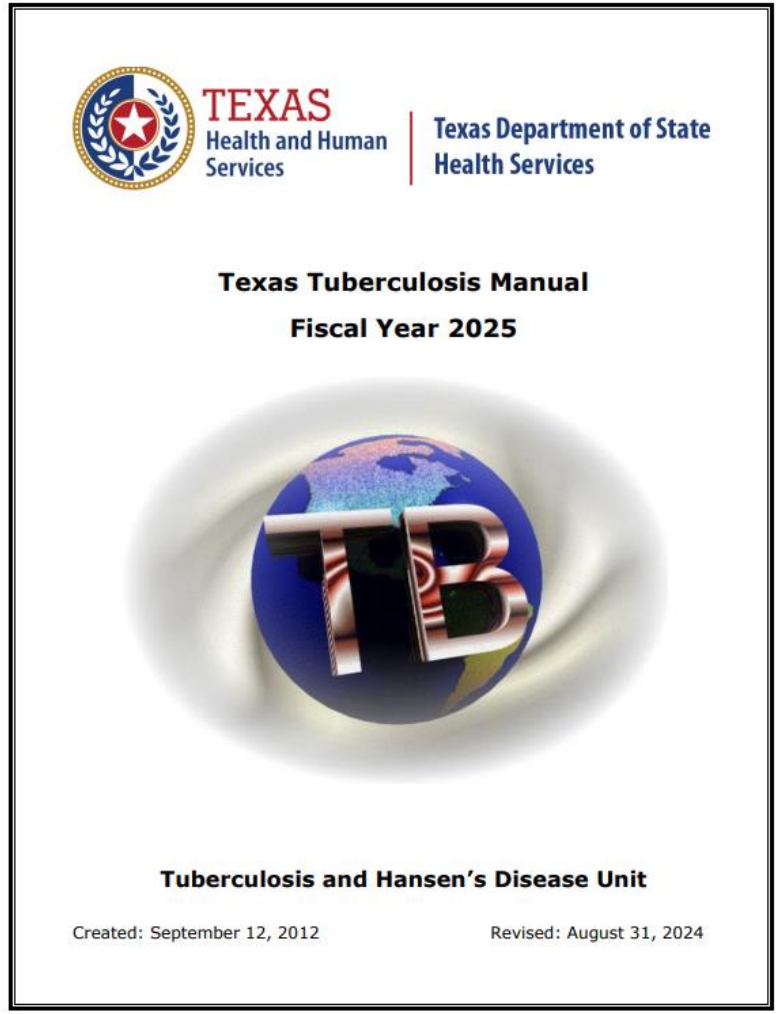
- Provide patient centered care
- Prioritize referrals and screen for TB disease and latent TB infection
- Ensure the availability of radiology services
- Implement location-appropriate isolation
- Ensure completion of specimen testing
- Initiate clinical evaluation and start treatment promptly
- Perform routine patient assessments
- Provide DOT
- Manage pediatric patients aged 17 and younger
- Seek expert consultation when indicated
- Ensure completion of adequate therapy
- Initiate contact investigations
- Clarify roles and responsibilities of TB program staff



Who do you test?

USPSTF Recommendations

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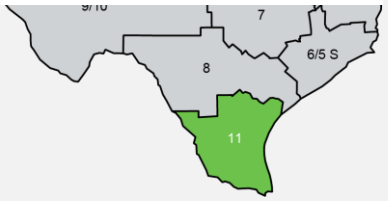
Recommendation Summary

Population	Recommendation	Grade
Asymptomatic adults at increased risk of latent tuberculosis infection (LTBI)	The USPSTF recommends screening for LTBI in populations at increased risk. See the "Assessment of Risk" section for additional information on adults at increased risk.	B

Pathway to Benefit

To achieve the benefit of screening, it is important that persons who screen positive for LTBI receive followup and treatment.



Visas & Permanent Residency

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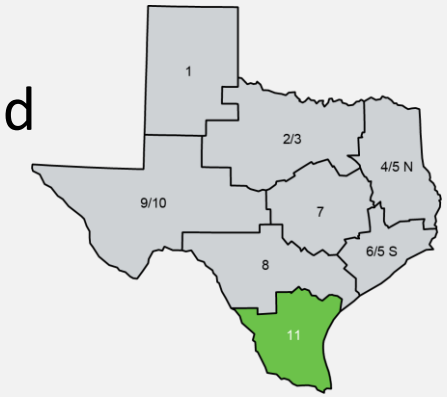
- **Immigrants seeking formal permanent residence, through visa process:**
  - Initial screening occurs overseas, will be referred through the EDN to R/LHD

- **People in the U.S applying for adjustment of status to a permanent resident of the U.S.**
  - Initial screening occurs via a Civil Surgeon domestically
  - Civil Surgeons are responsible for initial TB testing including CXRs and can treat for LTBI



Health Care Personnel

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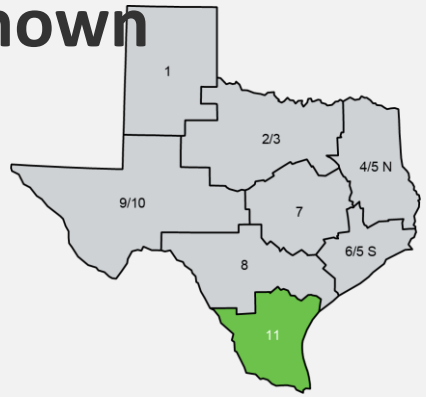
On May 17th, 2019 the CDC and the National Tuberculosis Comptroller Association updated their recommendations for TB screening and testing and treatment in the U.S. :

- **Follow TB infection control plans**
- **CDC recommends all U.S. health care personnel should be screened for TB upon hire**
- **Annual TB testing is not recommended unless there is known exposure or ongoing transmission**



Health Care Personnel (2)

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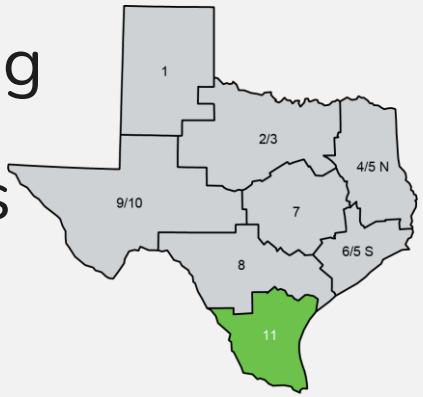
New hires:

- ✓ Baseline individual TB risk assessment
- ✓ Symptom screening
- ✓ TB test

In the U.S. there is no recommended annual testing.

Healthcare facilities may consider using annual TB screening for certain groups at increased risk for TB exposure (e.g., pulmonologists, respiratory therapists) or in certain settings if transmission has occurred in the past (e.g., emergency department)



Health Care Personnel (3)

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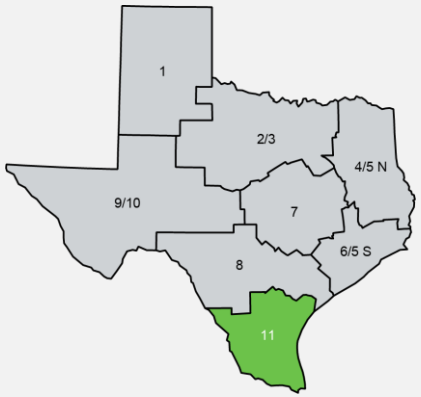
HCP with a positive TB result, should receive:

- ✓ A symptom evaluation
- ✓ A Chest X-Ray



Health Care Personnel (4)

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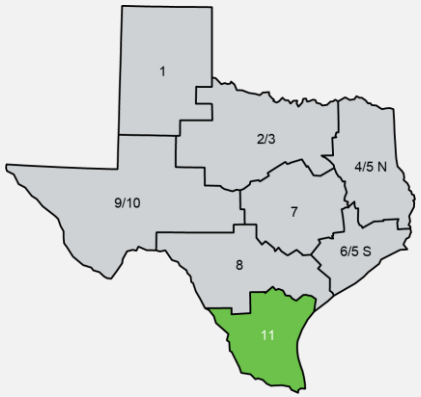
- Treatment for latent TB infection is strongly encouraged
- Untreated Latent TB infection: Annually screening for TB symptoms



School Districts

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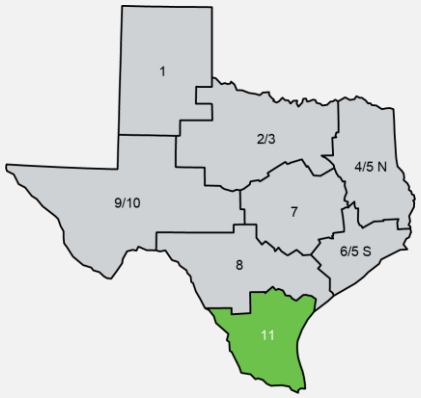
- In Texas, school districts in Region 6 (and across the state) generally don't require universal TB testing for all students.
- Instead they use a TB risk assessment questionnaire developed by DSHS to identify students who may be at higher risk for TB infection.
- Generally, testing occurs upon entry to pre-K.



How do we test for TB?

First option: TST

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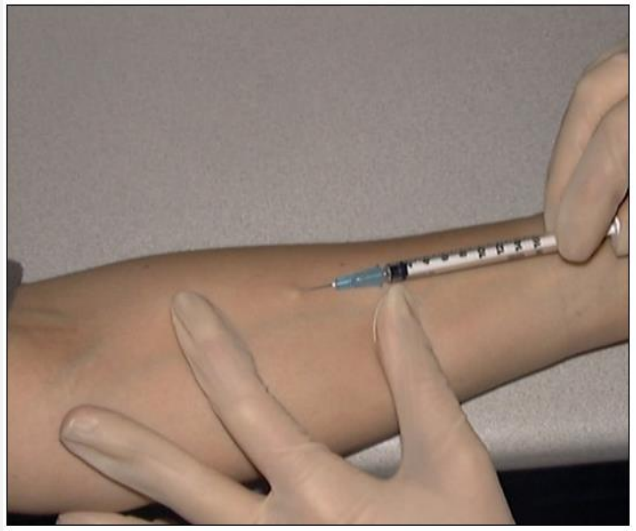
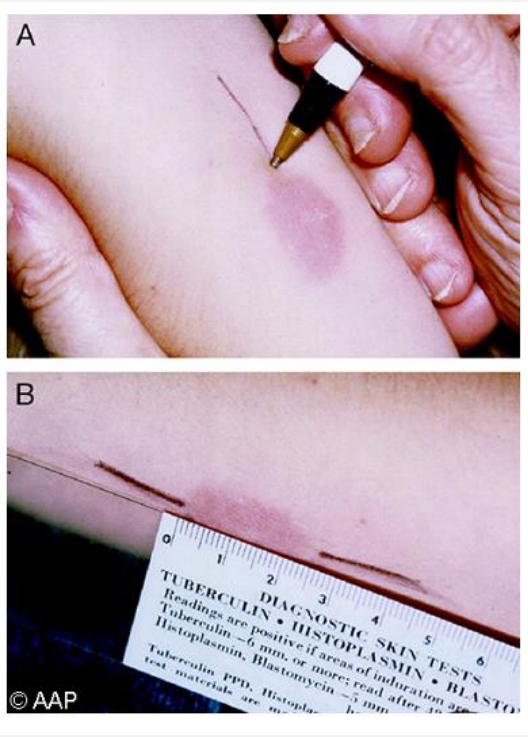
One option is via a Tuberculin Skin Test (TST)

-0.1 ml of 5 Tuberculin Units (TU) injected **intradermally**

- Patient returns 48-72 after placement for reading
  - Read is done in millimeters
  - Read is of **induration, NOT erythema**





TST: How to measure

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- Like many things TB related, there is no one answer to this.
- Positive Tests are defined based on a patient's individual risk factors.

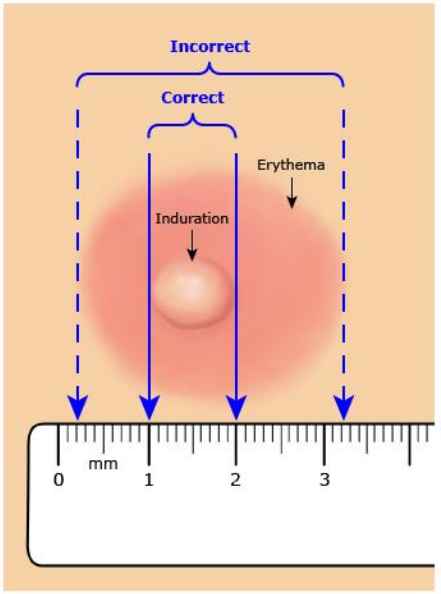
From smallest to largest…

1. An induration of 5mm is **positive** for High risk individuals such as
   - HIV/Immunocompromised
   - Recent contact (<8 weeks) to a person with active TB
   - History or Imaging suggestive of old disease

2. An induration of 10 mm is **positive** for individuals in high-risk settings
   - Immigrants from countries with high TB burden (>20/100,000)
   - Residents or Employees of congregate settings (jails, shelters, etc)

3. An induration of 15 mm is **positive** for ANY individual

Measuring a reaction to the tuberculin skin test



This figure shows the correct method for measuring a reaction to the tuberculin skin test. The size of the reaction is measured by the width of induration, not erythema. In the example shown, the reaction measures 10 mm.

Modified from: Testing for tuberculosis infection and disease. In: Core Curriculum on Tuberculosis: What the Clinician Should Know, 6th ed, Centers for Disease Control and Prevention 2013. https://www.cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis.html (Accessed on July 16, 2024).

TST: Pros and Cons

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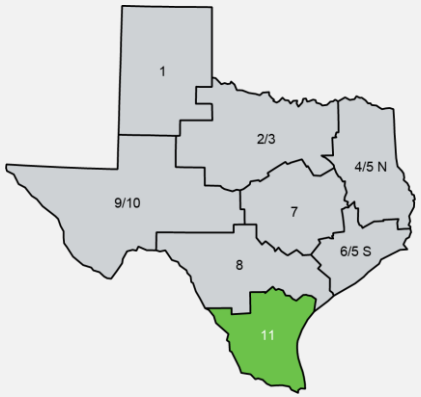
PROS

*Cheap!

* Easy! ….kind of

CONS

* Mandatory return visit (48-72 hours)
* The art of interpretation can be tricky
* Potential for false negatives
* Potential for false positives



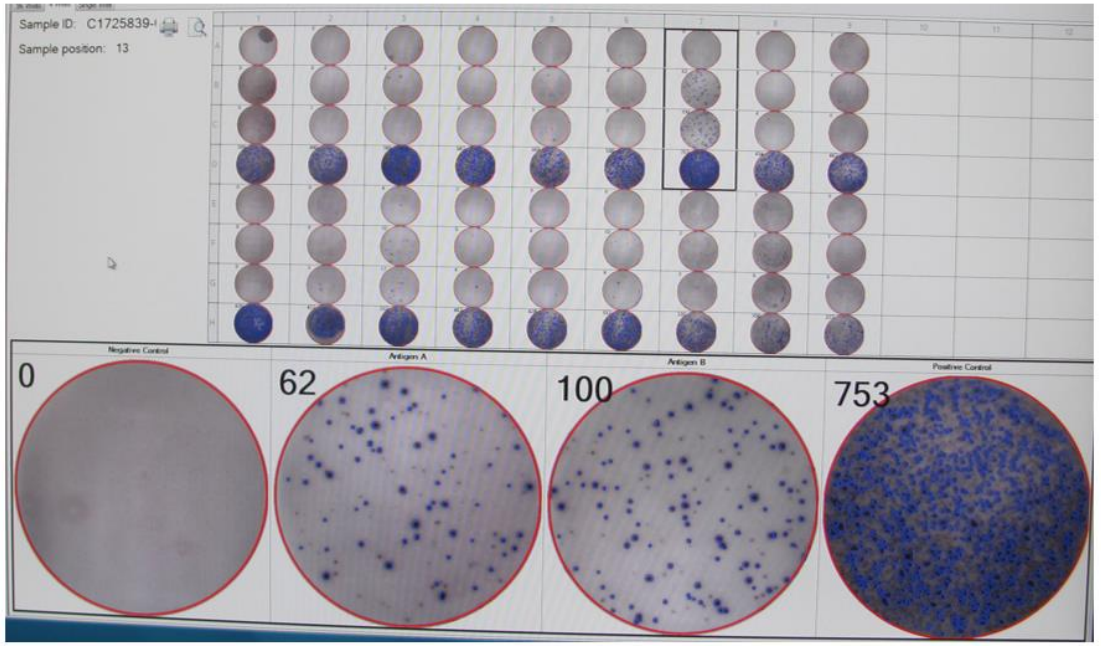
Second option: IGRAs

QuantiFERON®-TB Gold Plus

- **Mitogen – Positive Control**
  Low response may indicate inability to generate IFN-γ
- **Nil – Negative Control**
  Adjusts for background IFN-γ
- **TB1 – Primarily detects CD4 T cell response**
- **TB2 – Optimized for detection of CD4 and CD8 T cell responses**

- Essentially 2 tests in one blood draw
- TB1 and TB2 should be close in value

T-Spot.*TB*



Initial Process of Evaluating for TB via IGRAs

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Patient's blood sample

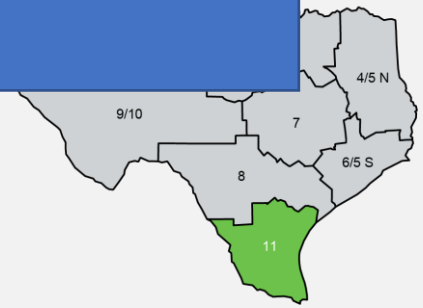
ESAT -6
CFP-10
TB7.7

Negative control/nil (filled with saline or heparin)

Positive Control/ mitogen (a non-specific immune stimulator)

TB1

TB2



IGRAs: What Number is Positive for a QFT

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Nil (IU/mL)	TB1 or TB2 Antigen minus Nil (IU/mL)	TB1 or TB2 (IU/mL)	Mitogen	Interpretation
≤ 8.0	≤ 0.35 or < 25% of Nil value	Negative	≥ 5.0	*M. tuberculosis* infection **unlikely**
≤ 8.0	≥ 0.35 and ≥ 25% of Nil value	Positive	ANY	*M. tuberculosis* infection **likely**
≥ 8.0	ANY	Indeterminate	ANY	Indeterminate
≤ 8.0	≤ 0.35 and or < 25% of Nil value	Indeterminate	< 5.0	Indeterminate

IGRAs: QFT Interpretation

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immunization or past orcurrent infection with rubella virus.

QuantiFERON-TB Gold Plus

MITOGEN-NIL	9.88	IU/ml	
NIL	0.05	IU/ml	
QUANTIFERONA (R)-TB GOLD PLUS,1T	Positive		Negative

In healthy persons who have a low likelihood ofM. tuberculosis infection, a single positive QFTresult should not be taken as reliable evidenceof M. tuberculosis infection. Repeat testing, witheither the initial test or a different test, maybe considered on a case-by-case basis.

TB1-NIL	0.55	IU/ml
TB2-NIL	0.87	IU/ml

QuantiFERON-TB Gold

TABLE 2. TEST SENSITIVITY AND SPECIFICITY FOR CFP-10 AND ESAT-6 AT VARIOUS CUTOFFS IN WHOLE-BLOOD IFN-γ ASSAY

Cutoff, IFN-γ	CFP-10		ESAT-6		CFP-10 and/or ESAT-6	
(*IU/ml*)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)
0.05	92.5	81.4	94.8	94.9	89.4	97.5
0.10	94.4	77.1	96.2	90.7	92.0	95.8
0.15	95.8	72.9	97.6	88.1	93.9	93.2
0.20	96.7	71.2	99.1	86.4	96.2	91.5
0.25	97.2	67.8	99.1	84.7	96.7	91.5
0.30	97.7	66.9	99.1	83.1	97.2	89.8
0.35	**98.6**	**65.3**	**99.5**	**81.4**	**98.1**	**89.0**
0.40	98.6	61.9	99.5	79.7	98.1	88.1
0.45	98.6	60.2	100.0	78.8	98.6	86.4
0.50	99.1	60.2	100.0	75.4	99.1	83.9

Sensitivity was determined on the basis of data from 118 patients with culture-positive tuberculosis, and specificity was determined on the basis of data from 213 low-risk subjects. The chosen cutoff (0.35) is in boldface.

Mori et al 2004 Am J Respir Crit Care Med ,170: 59–64

Interpretation Criteria for the T-Spot.TB

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Result	Nil*	TB Response##	Mitogen++	Interpretation+
Positive	≤ 10 spots	≥ 8 spots	Any	*M.tuberculosis* infection likely
Borderline	≤ 10 spots	5, 6, or 7 spots	Any	Uncertain likelihood of *M. tuberculosis* infection
Negative	≤ 10spots	≤ 4 spots		M Tb infection unlikely
Indeterminate	> 10 ≤ 10	Any < 5 spots	Any < 20 spots	Uncertain likelihood of *M. tuberculosis* infection

⚠ T-SPOT®.TB (FINAL)

Lab: V6O

Analyte	Value		
⚠ **T-SPOT.TB** (71773-6)	**POSITIVE**	Reference Range: SeeBelow	FINAL

Normal Value: Negative
Diagnosing or excluding tuberculosis (TB) disease and assessing the probability of latent TB infection (LTBI) requires a combination of epidemiological, historical, medical and diagnostic findings that should be taken into consideration when interpreting T-SPOT.TB test results. A positive test result does not rule in active TB disease caused by Mycobacterium tuberculosis (M. tuberculosis); active TB disease should be confirmed by other tests such as sputum smear and culture, PCR, and chest radiography. Uncommonly, a positive T-SPOT.TB result may be due to infection with other Mycobacterium species including M. kansasii, M. szulgai, M. gordonae, or M. marinum. Alternative tests would be required if these infections are suspected. The T-SPOT.TB test is qualitative and results are reported as positive, borderline or negative, given that the test controls perform as expected. In line with the Centers for Disease Control and Prevention's 2010 recommendation to report quantitative measurements alongside the qualitative result, the laboratory provides spot counts for informational purposes only. The T-SPOT.TB test should not be interpreted as a quantitative test.

PANEL A SPOT COUNT CORRECTED FOR NEG CONTROL (74278-3)	>50		FINAL
PANEL B SPOT COUNT CORRECTED FOR NEG CONTROL (74277-5)	42		FINAL
NEGATIVE CONTROL (74279-1)	Passed		FINAL
POSITIVE CONTROL (74280-9)	Passed		FINAL

IGRAs: Pros and Cons

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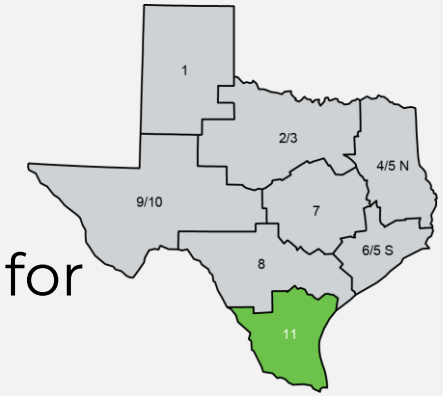
❿ Pros

* Objective
* (Should) only require one visit
* Is not impacted by BCG vaccine status

❿ Cons

* Though per the AAP IGRAs can now be performed on any age, a *negative* IGRA cannot be trusted until the child is at least 6m
* A more expensive test/ study
* Though results are more objective, can be indeterminate/ borderline, creating a need for further testing and potential for confusion for your patient



You have a positive test, now what?

Tuberculosis in Texas

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TB is a notifiable condition in Texas, reportable to your local or regional health department

Tuberculosis Disease (known/suspected): Reportable within 1 working day

Reportable tuberculosis disease includes the following: suspected tuberculosis disease pending final laboratory results; positive nucleic acid amplification tests; clinically or laboratory-confirmed tuberculosis disease; and all Mycobacterium tuberculosis (M. tb) complex including M. tuberculosis, M. bovis, M. africanum, M. canettii, M. microti, M. caprae, and M. pinnipedii.

Tuberculosis Infection: Reportable within 1 week

TB infection is determined by a positive result from an FDA-approved Interferon-Gamma Release Assay (IGRA) test such as T-Spot TB or QuantiFERON - TB GOLD In-Tube Test or a tuberculin skin test, and a normal chest radiograph with no presenting symptoms of TB disease. Please include documentation of all results and report skin test results in millimeters.

Ruling out TB disease

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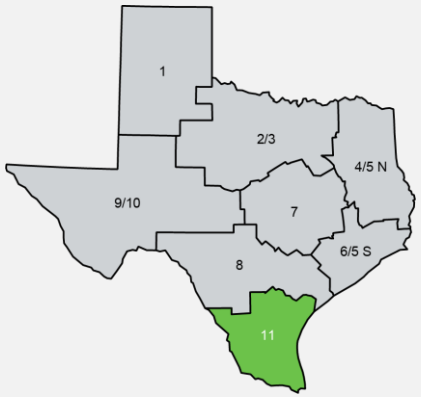
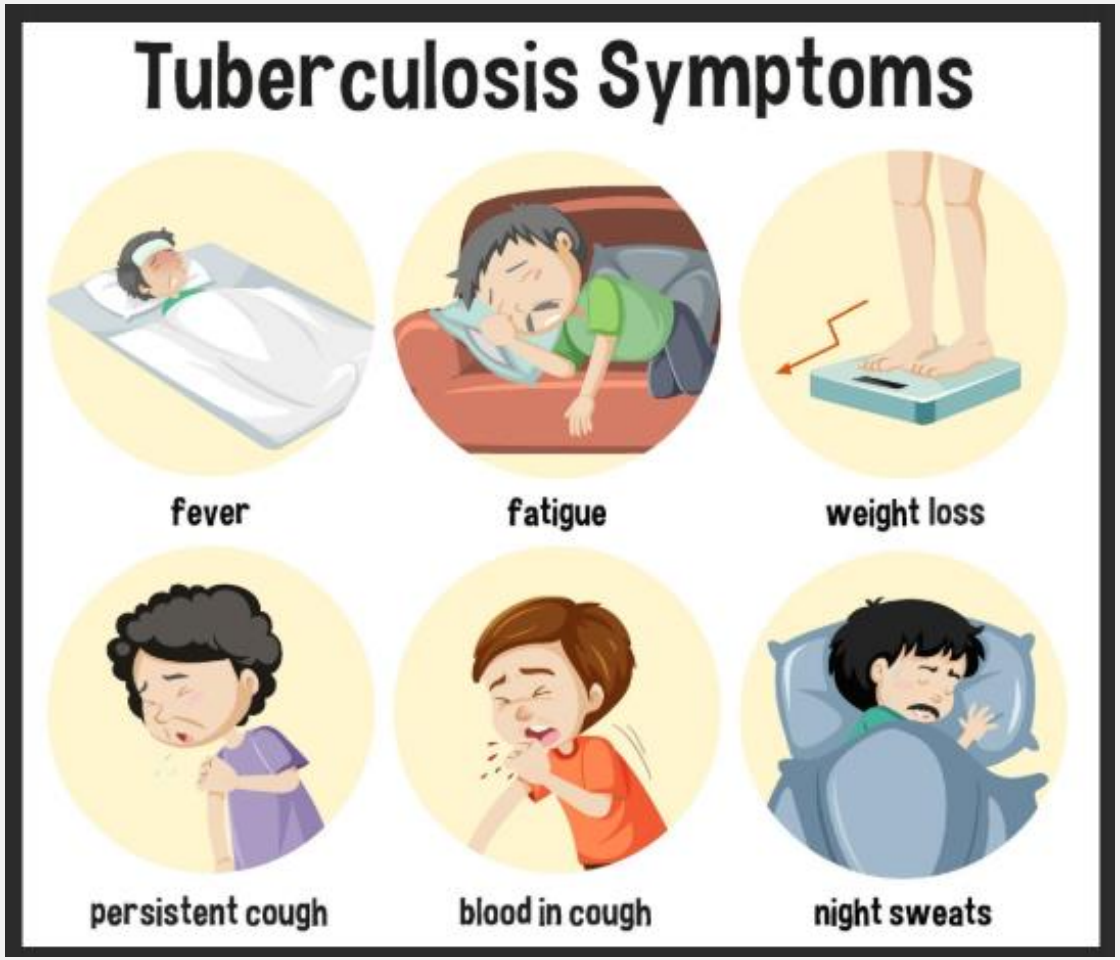
The 3 main components of determining TB disease (after a positive test or a negative test result in a patient of high risk) are:

1. History
2. Physical
3. Chest X-Ray



H & P



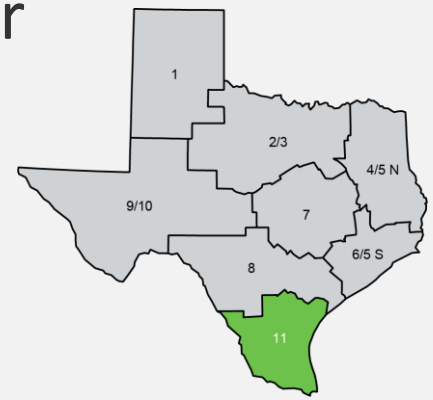
Physical Exam:

Appearance: Are they Frail, Cachectic, Clammy, Coughing

Lungs: Wheezing, Rhonchi, Rales, Lymph nodes

Lymph nodes: Lymphadenopathy

Abdomen: focus on the liver



Imaging

Typically a **chest xray** or **CT** of the chest (without contrast)

*Looking for evidence of active disease

*Looking for clear imaging

* Looking for evidence of old disease/ stable abnormalities over a 3 month period

Additional (ie, always get a chest xray!) imaging may be needed if concern for extrapulmonary disease

* Sites include: bone and joints, lymph, skin, kidneys, miliary (disseminated)

Imaging in Pregnancy

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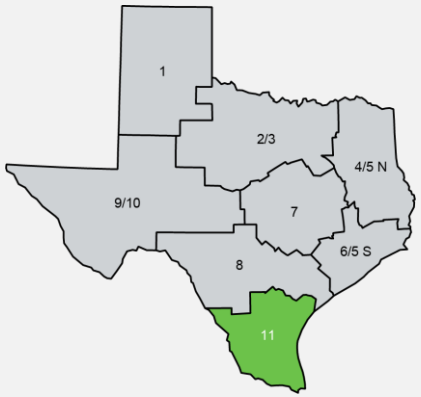
Being pregnant and having TB is not safe for the mom or the baby

- **Therefore, priority is to evaluate for TB**



ACOG

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The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 723 • October 2017 *(Replaces Committee Opinion Number 656, February 2016)*

Committee on Obstetric Practice

This document is endorsed by the American College of Radiology and the American Institute of Ultrasound in Medicine. This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Member contributors included Joshua Copel, MD; Yasser El-Sayed, MD; R. Phillips Heine, MD; and Kurt R. Wharton, MD. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Table 2. Effects of Gestational Age and Radiation Dose on Radiation-Induced Teratogenesis

Gestational Period	Effects	Estimated Threshold Dose*
Before implantation (0–2 weeks after fertilization)	Death of embryo or no consequence (all or none)	50–100 mGy
Organogenesis (2–8 weeks after fertilization)	Congenital anomalies (skeleton, eyes, genitals)	200 mGy
	Growth restriction	200–250 mGy
Fetal period	**Effects**	**Estimated Threshold Dose***
8–15 weeks	Severe intellectual disability (high risk)†	60–310 mGy
	Intellectual deficit	25 IQ-point loss per 1,000 mGy
	Microcephaly	200 mGy
16–25 weeks	Severe intellectual disability (low risk)	250–280 mGy*

*Data based on results of animal studies, epidemiologic studies of survivors of the atomic bombings in Japan, and studies of groups exposed to radiation for medical reasons (eg, radiation therapy for carcinoma of the uterus).

†Because this is a period of rapid neuronal development and migration.

Modified from Patel SJ, Reede DL, Katz DS, Subramaniam R, Amorosa JK. Imaging the pregnant patient for nonobstetric conditions: algorithms and radiation dose considerations. Radiographics 2007;27:1705–22.

Table 3. Fetal Radiation Doses Associated With Common Radiologic Examinations

Type of Examination	Fetal Dose* (mGy)
Very low-dose examinations (<0.1 mGy)	
Cervical spine radiography (anteroposterior and lateral views)	<0.001
Head or neck CT	0.001–0.01
Radiography of any extremity	<0.001
Mammography (two views)	0.001–0.01
Chest radiography (two views)	0.0005–0.01
Low- to moderate-dose examinations (0.1–10 mGy)	
Radiography	
Abdominal radiography	0.1–3.0
Lumbar spine radiography	1.0–10
Intravenous pyelography	5–10
Double-contrast barium enema	1.0–20
CT	
Chest CT or CT pulmonary angiography	0.01–0.66
Limited CT pelvimetry (single axial section through the femoral heads)	<1
Nuclear medicine	
Low-dose perfusion scintigraphy	0.1–0.5
Technetium-99m bone scintigraphy	4–5
Pulmonary digital subtraction angiography	0.5
Higher-dose examinations (10–50 mGy)	
Abdominal CT	1.3–35
Pelvic CT	10–50
^{18}F PET/CT whole-body scintigraphy	10–50

Putting it all together

Next steps

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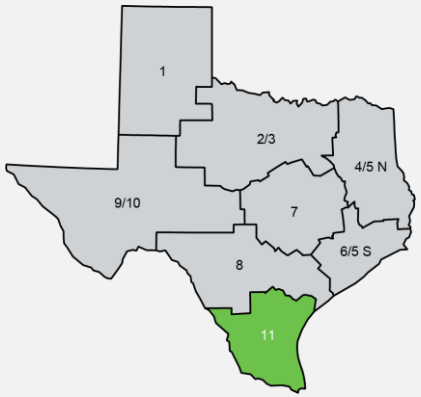
- **A patient has a positive IGRA/TST**
- **AND they have an abnormal or concerning CXR**

What next?? Depends….do they have symptoms?

- If NO symptoms: Collect 3 sputum samples for both smears and cx
  - if smear and culture negative, can repeat imaging (this is approx. 2-3 months wait).
  - MTB PCR or NAAT can be of great benefit here!

-If YES symptomatic, refer to PHD

- We may consider fast start on RIPE after sputum collected



Summary

Now you are a Pro!

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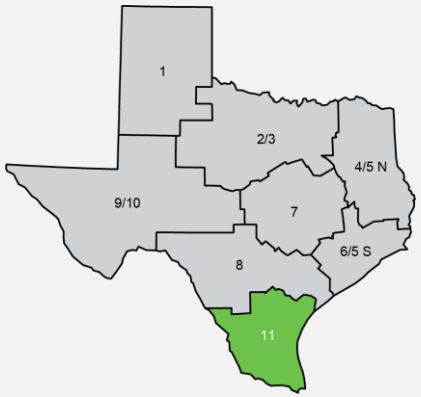
- Now you know how to test for TB exposure via blood or skin test
- If positive, pursue imaging and an exam
- If imaging or exam is suspicious, pursue sputum collection (assuming pulmonary site)
- If sputa are positive - treat for TB!



Thank you!
Any Questions?

Emilie Prot DO MPH

Email: emilie.prot@dshs.texas.gov