# TB NURSE NETWORK MEETING

January 20, 2016 10:00-12:00 PM

Conference call in number: 1-888-557-8511

Passcode: 2544873

### Agenda

- Announcements (15 min)
- TB Pilot Program with T-SPOT (30 min)
  - Pete Kinney, Danielle Watson; Oxford Immunotec
- Case Presentation (30 min)
  - Dr. Dana Kissner; Wayne State University Physician Group
- Open Forum (30 min)
- Close and Adjourn

### Announcements

- Next TBNN meeting
  - Wednesday April 20<sup>th</sup>, 2016
  - 10-12 PM EST
  - Capitol View Building, 5<sup>th</sup> floor conference room

### Announcements: Upcoming Webinars

- Southeastern National Tuberculosis Center (SNTC)
  - Jan 27, 2016 1-3 PM EST
    - Grand Rounds: "Maximizing Rifamycins" Charles Peloquin, Pharm.D.
  - Register for this event here
- TB Education and Training Projects: Updates from the Field
  - Jan 28, 2016 1-2 PM EST
    - "A Manual for DOT Aides" Karen Martinek, RN, MPH
    - "TB New Staff Orientation Program" Shelly Robichaux, RN, MPH
    - "Key Messages for TB & Diabetes: Flipchart & Toolkit" Denise Dodge, RN
  - Register for this and other webinars from this program here
- TB Nursing Webinar NTCA
  - Save the Date: April 14, 2016
  - Additional info to follow

### Announcements: Upcoming Events

- NTCA 2016 TB Conference
  - February 25-27<sup>th</sup>
  - Pre-conference meetings 23<sup>rd</sup>-24<sup>th</sup> 8-5 PM MT
  - Sheraton Denver Downtown Hotel, Denver, CO
  - Partnering with the UNION-North America Region (International Union Against Tuberculosis and Lung Disease)
  - Registration is open until February 5th
- 2016 World TB Day Conference: Migration & Tuberculosis
  - Friday, April 8<sup>th</sup>
  - Kellogg Hotel and Conference Center, East Lansing, MI
  - 8:30-4:45 PM
  - Registration is open!

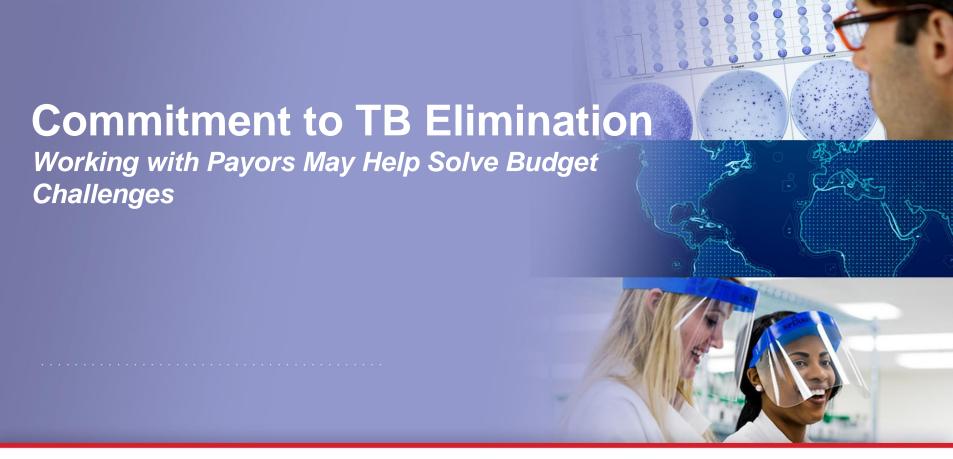
#### AGENDA

8:00—8:30	Registration, Exhibitors & Posters, Light Continental Breakfast (non-CME)				
8:30—8:45	Welcome and Opening Remarks: Migration & Tuberculosis	Jevon McFadden , MD, MPH	Medical Epidemiologist, Michigan Department of Health and Human Services (MDHHS), CDC Ca- reer Epidemiology Field Officer		
8:45—9:30		Jinga Rao	TB Patient		
	Panel: Personal Experience with	Krutika Jariwala	TB Patient		
	Tuberculosis	Denise Wisner, BSN, MSN	TB Public Health Nurse, Macomb County Health Department		
9:30—10:00	Transmission and Pathogenesis of Tu- berculosis	Pamela Hackert, MD, JD, MPH	Chief Medical Services, Oakland County Health Department		
10:00—10:10		Break (non-CME)			
10:10—10:55	Laboratory Testing & Case Study	Angie Schooley, MT, ASCP	Mycobacteriology Supervisor, MDHHS, Bureau of Laboratories		
10.10—10.55	Laboratory resump at Case Study	James Sunstrum, MD	TB Clinical Consultant, Medical Director; MDHHS; Wayne County TB Clinic		
10:55—11:40	Radiology	Dana Kissner, MD, MS	Critical Care Pulmonologist, Associate Professor; Wayne State University Physicians Group, Wayne State University School of Medicine		
11:40—11:50	Qu	estion and Answer: 2 Floor	Microphones		
11:50—1:00	Lu	unch, Exhibitors & Posters (	non-CME)		
1:00—1:30	Breakout I: Updated TB Testing Requirements for Facilities Licensing	Larry Horvath, BEd	Director, Michigan Department of Licensing and Regulatory Affairs, Bureau of Community and Health Systems		
1:00—1:30	Breakout II: TB Clusters in MI & the TB GIMS System	Shona Smith, MPH	TB Epidemiologist, MDHHS		
1:30—2:00	Breakout III: New Technologies in La- boratory Testing	Angie Schooley, MT, ASCP	Mycobacteriology Supervisor, MDHHS, Bureau of Laboratories		
		Laurel Vibber, MS	Microbiologist, MDHHS, Bureau of Laboratories		
1:30—2:00	Breakout IV: 3HP Treatment Regimen for Latent TB Infection	Dana Kissner, MD, MS	Critical Care Pulmonologist, Associate Professor; Wayne State University Physicians Group, Wayne State University School of Medicine		
2:00-2:10	Break (non-CME)				
2:10—3:10	Connections between Tuberculosis and Diabetes	Richard Brostrom, MD	TB Control Program Manager, Hawaii State Department of Health		
3:10-3:40	Epidemiology of Tuberculosis	Shona Smith, MPH	TB Epidemiologist, MDHHS		
3:40—4:25	Panel: Cultural Competencies of Tuber- culosis	Aimmee Mullendore, RN	CD Nurse and TB Coordinator, Branch-Hillsdale- St. Joseph Community Health Agency		
		Ricardo Garay, BBA	Health Network Manager, Migrant Clinicians Networks		
4:25—4:35	Question and Answer: 2 Floor Microphones				
4:35-4:45	35—4:45 Concluding Remarks, Evaluation Instructions, Adjournment				
Funding for this conference was made possible (In part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect					

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### TB Pilot Program

- Pete Kinney & Danielle Watson
  - T-SPOT, Oxford Immunotec





# New WHO Post-2015 Guidelines recommend testing high-risk populations for LTBI and treating to prevent progression to active TB

"Further progress towards elimination will require better access to high-quality **diagnosis and care** and more effective TB prevention, including addressing the social determinants of TB, with special attention to groups at the highest risk for TB."

### Improved **Diagnosis** Advanced tests, such as the T-SPOT.TB test, help identify patients with LTBI Increased LTBI **Eliminating TB Treatment** Completion New LTBI treatments, such as 3HP short-course therapy, help reduce active TB cases and improve treatment completion rates

**Budget** 

**Availability** 

Oxford Immunotec's insurance

Public Health offer advanced TB

tests within existing test budgets

billing capabilities may help

# CDC guidelines recognize advances in TB diagnostics and treatment



#### **Targeted Testing Specific Recommendations**

- "An IGRA is preferred for testing persons who have received BCG (as a vaccine or for cancer therapy)1."
- "An IGRA is preferred for testing persons from groups that historically have low rates of returning to have TSTs read<sup>1</sup>."

#### **Contact Tracing**

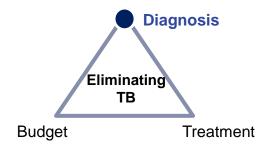
• "An IGRA or a TST may be used without preference to test recent contacts of persons known or suspected to have active tuberculosis with special considerations for follow-up testing<sup>1</sup>."

#### **Treatment**

"The new regimen is recommended as an equal alternative to the 9-month INH regimen for otherwise healthy patients aged ≥12 years who have LTBI and factors that are predictive of TB developing¹."



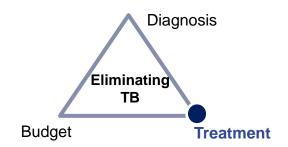
# Diagnosis – You need a TB test that improves your LTBI diagnosis



TB Diagnostic Challenge	T-SPOT®. <i>TB</i>
Accurately diagnosing immunosuppressed patients, such as individuals with HIV	The T-SPOT. TB test has been tested in immunosuppressed patients.
BCG vaccinated individuals may not believe a positive TST results	BCG does not cross-react with the T-SPOT. TB test.
High risk populations, such as homeless persons or drug users, may not return for TST reading	The T-SPOT. TB test can be completed in one visit



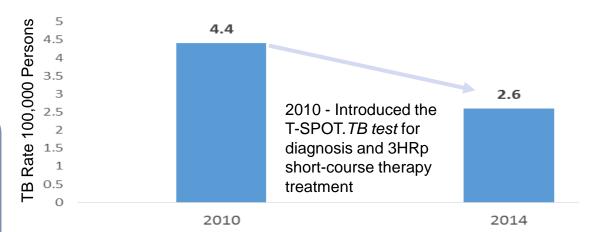
# Treatment – New, short-course therapy can improve LTBI treatment completion rates



#### CDC Recommends Short-Course Therapy as Equal Alternative to INH

"The new regimen is recommended as an equal alternative to the 9-month INH regimen for otherwise healthy patients aged ≥12 years who have LTBI and factors that are predictive of TB developing (e.g., recent exposure to contagious TB). The new regimen also can be considered for other categories of patients when it offers practical advantages²."

### Louisiana TB Control Program Reduced TB Rates 59% by Improving Diagnosis and Treatment<sup>1</sup>

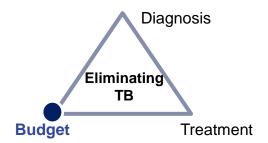


<sup>2.</sup> http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm? s cid=mm6048a3 w



<sup>1.</sup> http://dhh.louisiana.gov/index.cfm/newsroom/detail/3332

### **TB Elimination Program**

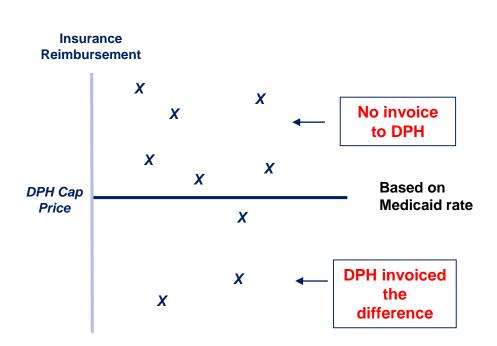


DPH Capped price (based on state Medicaid rate)

- Maximum the DPH can be invoiced
- Introductory 12 month DPH Cap

ODL submits insurance claim:

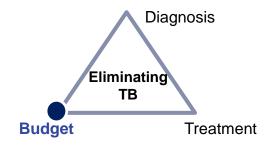
- Tests reimbursed > DPH cap:
- Tests reimbursed < DPH cap:</li>
- No insurance provided:
  - DPH invoiced at DPH cap





<sup>\*\*</sup>Individual will never receive an invoice, bill, co-pay

# Oxford Immunotec will bill insurance when available, allowing you to use the T-SPOT. TB test within your existing TB test budget



### **State Public Health Implementation**

Data collected July - December, 2014

### **Budget Results**

Average Public Health cost/test = \$8.88

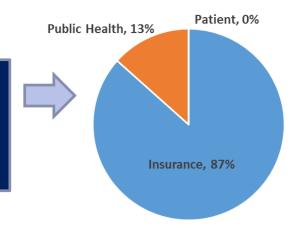
### 575 Patients tested with T-SPOT. TB

 Contact investigations managed through Oxford Immunotec's SPOTLIGHT service



Oxford Immunotec invoiced patients' insurance

- Uninsured patients covered by Public Health





### **TB Test Budget Examples**

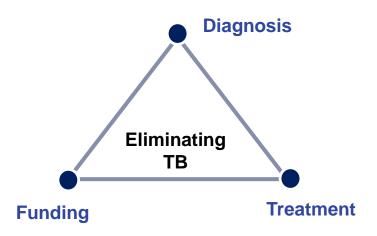
Example:	Patient #1	Patient #2	Patient #3	Patient #4
Insurance Plan	Α	В	С	D
Public Health Capped Price	\$74.00	\$74.00	\$74.00	\$74.00
Insurance Reimbursement	\$102.00	\$50.00	\$90.00 <sup>1</sup>	\$0 <sup>2</sup>
Public Health Responsibility for Specific Patient	\$0	\$24.00	\$0	\$74.00
Patient Responsibility for Test	\$0	\$0	\$0	\$0

<sup>1. \$10</sup> co-pay indicated

<sup>2. \$100</sup> payment authorized, applied to patient's deductible



# Public Health organizations benefit from Oxford Immunotec's cost-effective approach to TB Screening



- Your organization can start immediately
- Oxford handles all insurance billing
- Customer agreement:
  - No test volume commitment
  - No long-term contract



### Questions





### Case Presentation

- Dr. Dana Kissner
  - Wayne State University Physician Group TB Elimination and Control Program

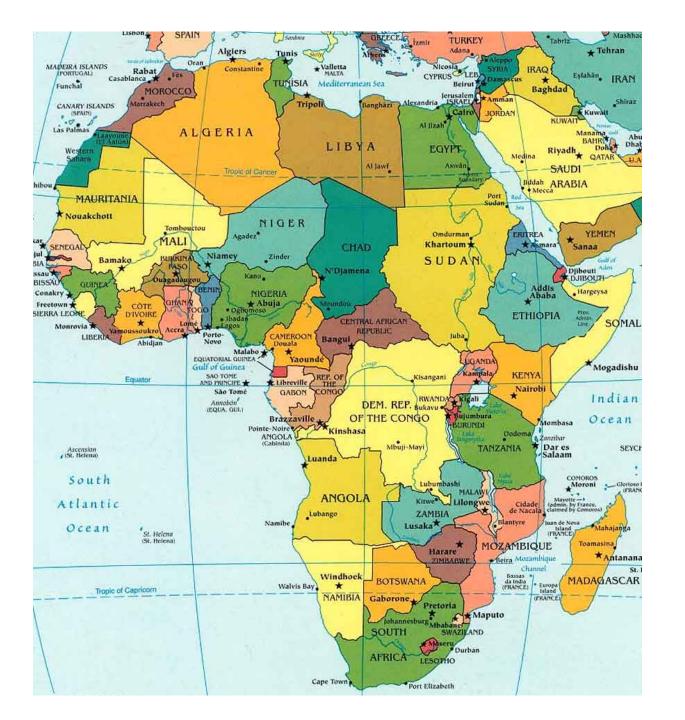
# 14 month old from Yemen: To Detroit via Djibouti

TB Nurse Network Webinar 1/20/2016
Dana Kissner, MD
Medical Director Detroit TB
Associate Professor Wayne State University



### Journey

- Born end of October 2014 in Yemen
  - 11/11/14 given BCG vaccination
- Age 10 months traveled to Djibouti with 29 year old mom and 9 year old brother
  - Lived in large house, very hot outside, many women and children
  - Owner's wife played with children every day, constantly coughing
- September arrived in Chicago=>Detroit







#### DJIBOUTI

#### **FACTSHEET**

September 2015

#### HIGHLIGHTS

25,219 Arrivals from Yemen to Djibouti since 26 March

4,318 Households provided with cash grants in Ali Sabieh

140 Children from Yemen benefitted from catch up classes

#### Gulf of Aden DIPOUTI Bosaso Berbera Boroma SOMA ILAND PUNTLAND Disputed area Hargelsa Garowe ETHIOPIA Galkayo/

#### Population of concern

A total of 18,234 people of concern

#### By country of origin

Country	Total PoC
Somalia	12,044
Yemen	2,818
Ethiopia	2,424
Eritrea	896
Other	52
Total	18,234

#### **Funding**

USD 37,477,643 million requested

#### **UNHCR Presence**

#### Staff:

- 29 national staff
- 12 international staff
- 7 united nations volunteers
- 2 consultants/contractors

- 1 office in Diibouti
- 1 field office in Ali Sabieh
- 1 field unit in Obock



### Offices:

### In Hamtramck

- Sickly on arrival
  - Grandfather noted swelling in left neck
- Pediatrician noted enlarged submandibular lymph node
  - Pediatrician treats with Augmentin
  - Another enlarged lymph node appears in preauricular area

### At CHM

- Brought to CHM on 12/17/15
  - Healthy appearing, afebrile
  - Chest x-ray is normal
  - 2 enlarged lymph nodes, firm, tender in left neck / face, no skin lesions
  - Coughing in ER TB is considered
  - What testing should be done?
    - PPD or IGRA (QuantiFERON Gold TB, T-Spot) or none?
    - Does the BCG vaccination matter?

### BCG: Live Attenuated form of M bovis

- Shares antigens with PPD, but not those in IGRAs.
- Can give a false + PPD skin test.
- Cannot give a false + QFT or T-Spot.
- Can cause infections in immune deficient people and in babies
  - Can cause lymphadenitis

### Situations in Which IGRA Preferred

- IGRA preferred in
  - Persons with low rates of return for TST reading (homeless, drug users)
  - BCG-vaccinated or treated (for cancer) individuals
- TST preferred in children < 5 years old, but IGRA acceptable

 Administer the vaccine in the deltoid region (Figure 1). Position the arm to maintain a horizontal surface where the vaccine is to be placed.

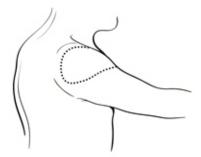


Figure 1

 Drop the immunizing dose of 0.2-0.3 mL of BCG VACCINE from the syringe and needle onto the cleansed surface of the skin (Figure 2) and spread over a 1" by 2" area using the edge of the multiple puncture device (Figure 3).



Figure 2



Figure 3



Grasp the arm firmly from underneath, tensing the skin. Center the multiple puncture device over the
vaccine and apply firm downward pressure such that the device points are well buried in the skin
(Figure 4).

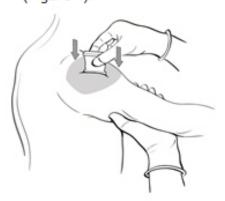
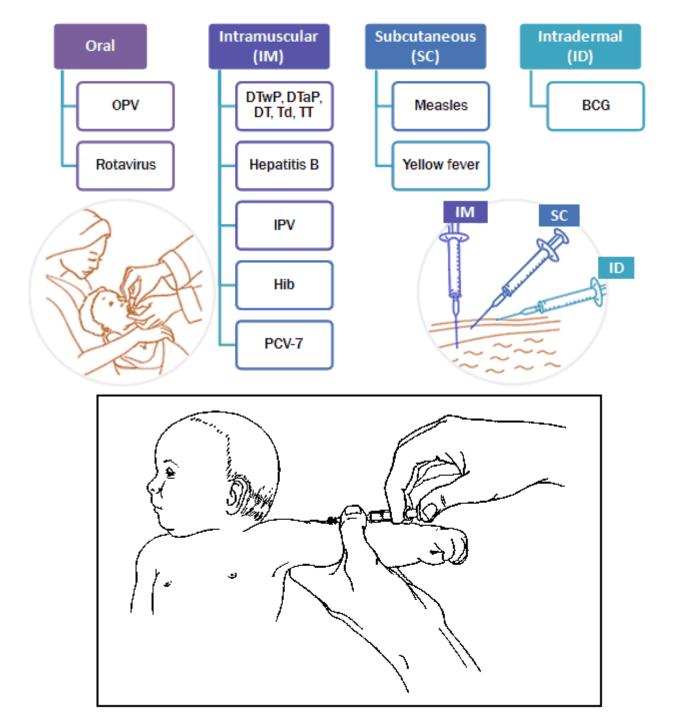


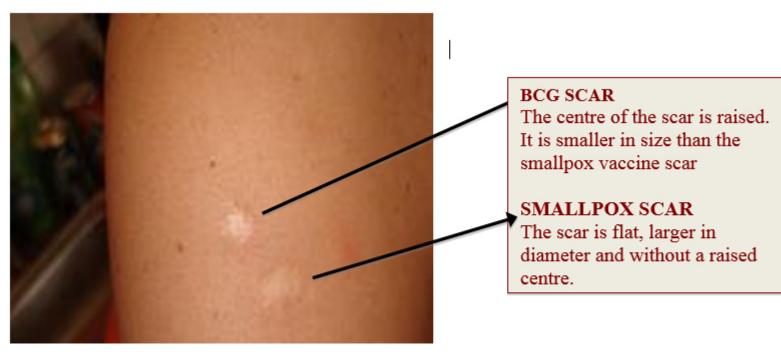


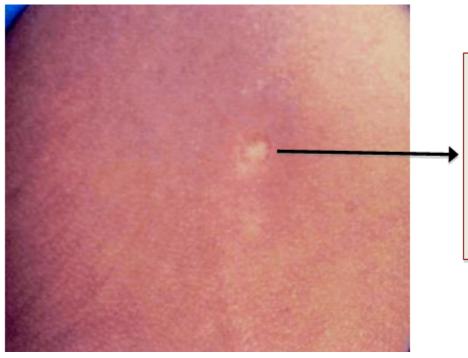
Figure 4

- Maintain pressure for 5 seconds. Do not "rock" the device. Release the pressure underneath the arm and remove the device. In a successful procedure the points puncture the skin. If the points do not puncture the skin, the procedure must be repeated.
- After successful puncture, spread vaccine as evenly as possible over the puncture area with the edge
  of the device. An additional 1–2 drops of BCG VACCINE may be added to ensure a very wet
  vaccination site.
- Use the multiple puncture device once and discard in a standard biohazardous sharps container.
- Loosely cover the site and keep dry for 24 hours.
- Advise the patient that the vaccine contains live organisms. Although the vaccine will not survive in a dry state for long, infection of others is possible.

Tuberculin reactivity resulting from BCG vaccination should be documented. A vaccinated person should be tuberculin skin tested 2–3 months after BCG administration, and the test results, in millimeters of induration, should be recorded in the person's medical record. [9] Vaccination should be repeated for those who remain tuberculin negative to 5 TU of tuberculin after 2–3 months.







• Small scar typically left upper arm in deltoid region.

•This scar has a central raised area, which is often best felt rather than seen.







### Diagnosing TB Infection

QuantiFERON@-TB Gold In-Tube test (QFT-GIT)



FDA Approved 10/07

T-SPOT®. TB test (T-Spot)



FDA Approved 7/08

### QFT Gold In-Tube TB

- Patient's immune cells are mixed with a cocktail of synthetic peptides that represent 3 antigens unique to MTB\* (& M kansasii, M szulgai, M marinum)
- If the cells have been exposed to TB and sensitized they produce excess Interferon Gamma
- Negative (nil) and Positive Controls (mitogen)



\* ESAT-6 & CFP-10 + parts of TB7.7 (RD4)

### Interpretation (FDA): QFT-GIT

Interpretation	NIL	TB Response	Mitogen Response
Positive	<u>&lt;</u> 8	≥.35 IU/ml & ≥25% of Nil	Any
Negative	<u>&lt;</u> 8	<.35 IU/ml or <25% of Nil	<u>&gt;</u> 0.5
Indeterminate	<u>&lt;</u> 8	<.35 or <25% of Nil	<0.5
Indeterminate	>8	Any	Any

NIL = plasma IFN-gamma concentration

TB Response = plasma IFN-gamma concentration *minus* Nil

Mitogen Response = plasma IFN-gamma concentration *minus* Nil

## Interpretation (FDA): QFT-GIT\*

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Indeterminate	<u>≤</u> 8	<.35 or <25% of Nil	<0.5
Indeterminate	>8	Any	Any

NIL = plasma IFN-gamma concentration

TB Response = plasma IFN-gamma concentration *minus* Nil

Mitogen Response = plasma IFN-gamma concentration *minus* Nil

<sup>\*</sup>QFT-G is different

## Interpretation (FDA): QFT-GIT\*

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Indeterminate (	>8	Any	Any

NIL = plasma IFN-gamma concentration

TB Response = plasma IFN-gamma concentration *minus* Nil

Mitogen Response = plasma IFN-gamma concentration *minus* Nil

<sup>\*</sup>QFT-G is different

#### Tests Ordered: TB QUANTIFERON GOLD (326751)

#### TB QUANTIFERON GOLD (Collection Date: Mon Dec 28 13:58:00 GMT-03:00 2015, Status: Final)

Specimen Collection Date/Time - Start: Hon Dec 28 21:41:00 GHT-05:00 2015

#### Result Units Flag Range Comment

TB QUANT Positive

GOLD

Result Status: Final

Observed On: Hon Jan 04 07:41:00 GMT-05:00 2016

0.34 IU/mL or less: N. tuberculosis infection unlikely, but cannot be completely excluded.

0.35 IU/ml or greater: M. tuberculosis infection (latent) or disease

(active) likely.

**TB-nil 4.93** 

Reference range: Negative Unit: not reported

QUANTIFERDN 4.93

IU/mLH : x0.35 TH MINUS NIL -

Result Status: Final

Observed On: Mon Jan 04 07:41:00 GMT-05:00 2016

Reference range: 0.00 to 0.34

QUANTIFERDN>10.00 IU/mL

MITOGEN MINUS NIL Result Status: Final

Observed On: Mon Jan 04 07:41:00 GMT-05:00 2016

QUANTIFERON 0.06 IU/mL

NIL

Result Status: Final

Observed On: Mon Jan 04 07:41:80 GMT-05:00 2016

Performed at ARUF Labs, 500 Chipeta Way, Salt Lake City, Utah 84108

Tests	Results Flag	Reference Range	Units
Quantiferon	Detected	(Not Detected)	
Nil	0.07		IU/mL
Mitogen-Nil	>10.00		IU/mL
TB Ag-Nil	>10.00		IU/mL

## T-Spot

Uses single tube of blood

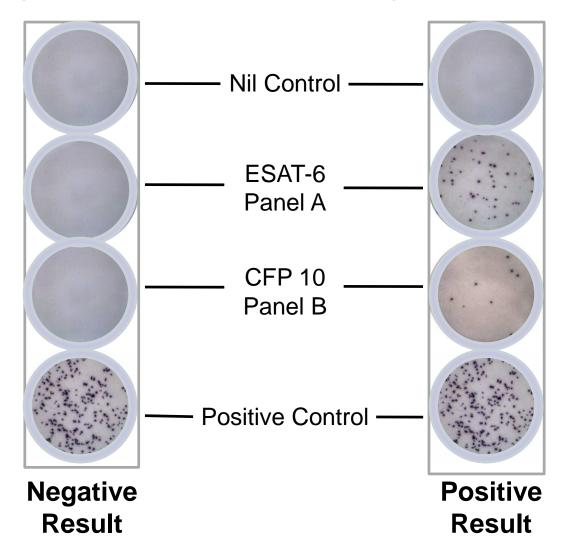
 Mixes patient's blood immune cells separately with ESAT-6 & CFP-10

- Spots are counted.
  - Made up of the immune cell secreting
     Interferon gamma





# Interpretation of T-Spot Results



# Interpretation (FDA) T-Spot

	r	Y	1

Interpretation	Nil	TB Response	Mitogen Response
Positive	<10 spots	≥8 spots	Any result
Borderline – repeat test	<10 spots	5, 6, or 7 spots	Any result
Negative	<10 spots	<4 spots	≥20 spots
Invalid – repeat test	>10 spots	Any result	Any result
Invalid – repeat test	≤10 spots	<5 spots	<20 spots

Nil = # spots

TB Response = the greatest # spots (ESAT-6 or CFP-10) *minus* Nil spots Mitogen Response = # spots *minus* Nil spots



#### Oxford Diagnostic Laboratories 23

5846 Distribution Drive Memphis, TN 38141 1-877-598-2522

CLIA ID& 44D2035267 Clustes Handorf, MD PhD, Medical Director

Robinson, Calesto Previder: Patient Name: Campus Health Center in Detroit Location: 08/16/1982 Patient ID: CHCOS Customer Number: Sex 154653527 Sample 1D: 8/16/1982 DOB: Received Date/Time: 1/9/2016 04:00 Collection Date/Time: 1/8/2016 10:16 1/10/2016 16:24 Approvak AND CONTRACTOR OF THE PROPERTY T-SPOTSTB Test Results

The test result is Rositive because the spot count in (Penel A minus Nil Control) and/or (Fanel B minus Nil Control) is greater than or equal to S.

Note: Diagnosing or esuinding tuberpulosis [75] discuss, and assessing the probability of latent TB infection (1751), requires a combination of spidemiological, historical, medical and diagnostic findings that should be taken into account when interpreting 7-6707.78 tast results. Rader to the most recent CDC guidence (http://www.odq.gov/tb/publications/guidalines/default.htm; for detailed recommendations on diagnosing TB infection (including disease) and exicoting persons for testing.

Positive

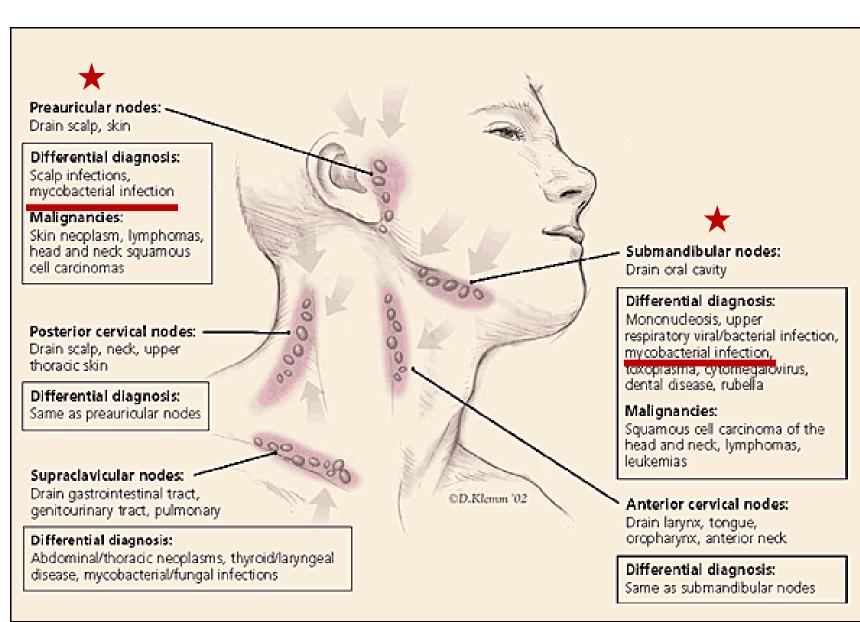
1-01-01-10	
Nii (Neg) Control Spot Count	2
Panel A Spot Count	>50
Panel B Spot Count	>50
Positive Control Spot Count	>20

TERROT TR.

### At CHM

- Brought to CHM on 12/17/15
  - Healthy appearing, afebrile
  - Enlarged lymph nodes, firm, tender, no skin lesions
  - Coughing in ER TB is considered
    - PPD 25 mm.
    - Nasal swab rhinovirus
  - Admitted, treated with IV Clindamycin
  - QFT done on discharge day
    - Positive, >10
    - Referred to health department
  - Now what?







# Mycobacterial diversity causing multi- and extensively drug-resistant tuberculosis in Djibouti, Horn of Africa

**Authors:** Millán-Lou, M. I.<sup>1</sup>; Ollé-Goig, J. E.<sup>2</sup>; Tortola, M. T.<sup>3</sup>; Martin, C.<sup>4</sup>; Samper, S.<sup>4</sup>

**Source:** The International Journal of Tuberculosis and Lung Disease, Volume 20, Number 2, 1 February 2016, pp. 150-153(4)

Publisher: International Union Against Tuberculosis and Lung Disease

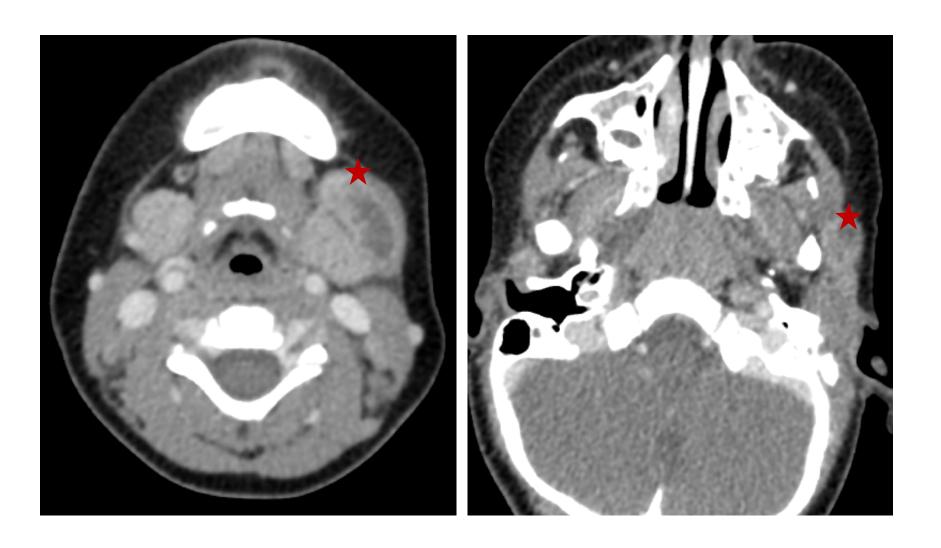
#### Abstract:

On detecting a high prevalence of multidrug-resistant tuberculosis (TB) in Djibouti, 32 *Mycobacterium tuberculosis* isolates of patients hospitalised in the TB referral centre of the capital were genotyped. A high variety of *M. tuberculosis* lineages, including lineage 1, Indo-Oceanic, lineage 2, East-Asian, lineage 3, East-African Indian and lineage 4, Euro-American, were detected.

# Health Department Perspective

- This cannot be latent TB infection
  - Defined as absence of TB symptoms / signs
    - Unless TB is excluded and an alternative cause is found
  - This kind of lymphadenopathy is classic for TB
- If resistance is not an issue a clinical diagnosis of TB can be considered and standard treatment begun
  - Biopsy in order to test for drug susceptibility
- Only mother, pregnant, has + QFT, CXR normal

# Hospital Admission





## Tissue and Fluid

- AFB smear +
- Sent to state lab
  - A PCR they are validating was +
  - Awaiting cultures

# **Teaching Points**

- The decision to treat for TB is very frequently a clinical one
  - This is TB and needs to be treated as TB
  - But, this child was infected in a country where drug resistance is possible
  - Mom is pregnant and has a + QFT and effective treatment is important
- Drug susceptibility is the most important test needed here







# Thank you!

- Meeting notes will be sent to everyone on the TB Nurse Network list
- If you have questions/comments regarding TBNN, please contact:

Helen McGuirk mcguirkh@michigan.gov 517-335-8050