



# Tuberculosis Information

For Health Care Providers and Schools

# County of Santa Clara

## Public Health Department


Administration  
976 Lenzen Avenue, 2<sup>nd</sup> Floor  
San José, CA 95126



**DATE:** April 15, 2014

**TO:** District Superintendents  
School Nurses  
Health Care Providers

**FROM:** Sara H. Cody, MD   
Health Officer

Teeb Al-Samarrai, MD   
Tuberculosis Controller

**RE: Change in the Tuberculosis (TB) School Mandate:  
From Universal Testing to Universal Risk Assessment and Targeted Testing**

Beginning June 1, 2014, the Santa Clara County Tuberculosis (TB) School Mandate will change from a requirement for universal TB testing to a requirement for universal TB risk assessment.

Santa Clara County has required TB testing for students entering school since 1989. This Health Officer Mandate was implemented at that time because TB rates rapidly increased. It was intended to ensure that children with TB were diagnosed early and treated appropriately when the infection was latent or “silent.” The California Health and Safety Code, § 121515, gives the county Health Officer authority to implement such mandates.

As TB rates have declined in the US and California, the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP) and the California Tuberculosis Controller’s Association (CTCA) have revised their recommendations. In place of universal TB testing, these bodies now recommend that healthcare providers ask a series of questions to assess a child’s risk of exposure to TB and target TB testing for children at increased risk for TB exposure or developing TB disease. Although rates of TB have declined in Santa Clara County since the Mandate was put in place, we continue to have one of the highest rates of TB in the US. Santa Clara County has very few cases of active TB among children, however, children remain vulnerable to being exposed to TB from others and are at greater risk of progressing to active TB disease if latent or “silent” TB infection is not detected and treated early.

In February 2014, the Public Health Department convened a School Mandate Review Task Force — including school representatives and pediatricians from the community — to review our local TB data, the AAP/CDC/CTCA recommendations, the academic literature, the policies of similar jurisdictions across California and the US, as well as challenges and advantages of different policy

Board of Supervisors: Mike Wasserman, Cindy Chavez, Dave Cortese, Ken Yeager, S. Joseph Simitian  
County Executive: Jeffrey V. Smith

Change in the TB School Mandate

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changes. Based on this review and discussion, Santa Clara County will no longer require universal testing but will transition to a mandate for universal risk assessment and targeted testing.

**The new *Santa Clara County Public Health Department Risk Assessment for School Entry* form will be required for school registration effective June 1, 2014 for all children enrolling in kindergarten or transferring, at any grade level, from outside of Santa Clara County.**

Please discard all prior references to the TB School Mandate and replace with the following documents:

- **NEW:** TB Risk Assessment for School Entry form (to be completed by healthcare providers)
- **Revised:** Guidelines to Revisions to the School Mandate and Requirements
- **Revised:** Frequently Asked Questions
- **Revised:** Dear Parent Letter
- **Revised:** Santa Clara County School Mandate Flow Chart
- **Revised:** IGRA Fact Sheet
- **NEW:** List of school health clinics and FQHCs in Santa Clara County

Please reproduce this entire packet for each school in your district as well as any location where centralized registration is done for new and transfer students. Please also feel free to post on District or School websites. These materials will also be available at [www.sccphd.org/tb](http://www.sccphd.org/tb).

If you have questions about these changes, please contact the TB Prevention and Control Program at (408) 885-4214.

Thank you for helping us protect the health of children in Santa Clara County.

Child's Name: \_\_\_\_\_ Birthdate: \_\_\_\_\_ Male/Female School: \_\_\_\_\_  
Last, First month/day/year

Address \_\_\_\_\_ Phone: \_\_\_\_\_ Grade: \_\_\_\_\_  
Street City Zip

## Santa Clara County Public Health Department TB Risk Assessment for School Entry

**This form must be completed by a licensed health professional and returned to the child's school.**

1. Was your child born in Africa, Asia, Latin America, or Eastern Europe?  Yes  No
2. Has your child traveled to a country with a high TB rate\* (for more than a week)?  Yes  No
3. Has your child been exposed to anyone with tuberculosis (TB) disease?  Yes  No
4. Has a family member or someone your child has been in contact with had a positive TB test or received medications for TB?  Yes  No
5. Was a parent, household member or someone your child has been in close contact with, born in or traveled to a country with a high TB rate?  Yes  No
6. Has another risk factor for TB (i.e. one of those listed on the back of this page)?  Yes  No

\* This includes countries in Africa, Asia, Latin America or Eastern Europe. For travel, the risk of TB exposure is higher if a child stayed with friends or family members for a cumulative total of 1 week or more.

**If YES, to any of the above, the child has an increased risk of TB infection and should have a TST/ IGRA.**

**All children with a positive TST/IGRA result must have a medical evaluation, including a chest X-ray. Treatment for latent TB infection should be initiated if the chest X-ray is normal and there are no signs of active TB. If testing was done, please attach or enter results below.**

Tuberculin Skin Test (TST/Mantoux/PPD) Date given: _____ Date read: _____	Induration _____ mm Impression: <input type="checkbox"/> Negative <input type="checkbox"/> Positive
Interferon Gamma Release Assay (IGRA) Date: _____	Impression: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Indeterminate
Chest X-Ray ( <b>required with positive TST or IGRA</b> ) Date: _____	Impression: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal finding
<input type="checkbox"/> LTBI treatment (Rx & start date): _____	<input type="checkbox"/> Prior TB/LTBI treatment (Rx & duration): _____
<input type="checkbox"/> Contraindications to INH or rifampin for LTBI	<input type="checkbox"/> Offered but refused LTBI treatment

<b>Providers, please check one of the boxes below and sign:</b>	
<input type="checkbox"/> Child has no TB symptoms, none of the above or other risk factors for TB and does not require a TB test.	
<input type="checkbox"/> Child has a risk factor, has been evaluated for TB and is free of active TB disease.	
_____	_____
<b>Health Provider Signature, Title</b>	<b>Date</b>

**Name/Title of Health Provider:**

**Facility/Address:**

**Phone number:**

**Fax number:**

# County of Santa Clara

## Public Health Department

Tuberculosis Prevention & Control Program  
976 Lenzen Avenue, Suite 1700  
San José, CA 95126  
408.885.2440



### Risk Factors for Tuberculosis (TB) in Children

- Have clinical evidence or symptoms of TB
- Have a family member or contacts with history of confirmed or suspected TB
- Are in foreign-born families from TB endemic countries (including countries in Africa, Asia, Latin America or Eastern Europe)
- Travel to countries with high rate of TB
- Contact with individual(s) with a positive TB test
- Abnormalities on chest X-ray suggestive of TB
- Adopted from any high-risk area or live in out-of-home placements
- Live with an adult who has been incarcerated in the last five years
- Live among or frequently exposed to individuals who are homeless, migrant farm workers, residents of nursing homes, or users of street drugs
- Drink raw milk or eat unpasteurized cheese (i.e. queso fresco or unpasteurized cheese)
- Have, or are suspected to have, HIV infection or live with an adult with HIV seropositivity. See below for testing methods in children with HIV or other immunocompromised conditions.

### Testing Methods

A Mantoux tuberculin skin test (TST) or an Interferon Gamma Release Assay (IGRA) (for children aged 4 and older) should be used to test those at increased risk. A TST of  $\geq 10$ mm is considered positive. If a child has had contact with someone with active TB (yes to question 3 on reverse) then TST  $\geq 5$ mm is considered positive.

Screening should be performed by CXR in addition to a TST/IGRA (consider doing both) and symptom review in HIV infected or suspected HIV, other immunocompromised conditions or if a child is taking immunosuppressive medications such as prednisone or TNF-alpha antagonists.

### Referral, Treatment, and Follow-up of Children with Positive TB Tests

- All children with a positive TST or IGRA result should have a medical evaluation, including a chest X-ray.
- Report any confirmed or suspected case of TB disease to the TB Control Program within 1 day, including any child with an abnormal chest X-ray.
- If TB disease is not found, treat children and adolescents with a positive TST or IGRA for latent TB infection (LTBI).
- Isoniazid (INH) is the drug of choice for the treatment of LTBI in children and adolescents. The length of treatment is 9 months with daily dosing: 10-15mg/kg (maximum 300 mg).
- For management and treatment guidelines for TB or LTBI, go to: [www.cdc.gov/tb](http://www.cdc.gov/tb) or contact the TB Control Program at (408) 885-4214.

### References

American Academy of Pediatrics, Committee on Infectious Diseases. Tuberculosis. In L.K. Pickering (Ed.), 2009 *Red Book: Report of the Committee on Infectious Diseases*. 27<sup>th</sup> ed. El Grove Village, IL: American Academy of Pediatrics, 2009:680-701.

California Health and Safety Code Section 121515.

Pediatric Tuberculosis Collaborative Group. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents. *Pediatrics* 2004; 114 (14):1175-1201.

Pang J, Teeter LD, Katz DJ, et al. Epidemiology of Tuberculosis in Young Children in the United States. *Pediatrics*, 2014:494-504.

Board of Supervisors: Mike Wasserman, Cindy Chavez, Dave Cortese, Ken Yeager, S. Joseph Simitian,  
County Executive: Jeffrey V. Smith

# **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

## **Guidelines to Revisions to the School Mandate and Requirements**

### **1) What are the changes to the tuberculosis (TB) screening requirement for school entrance in Santa Clara County?**

Students are no longer required to have mandatory TB testing but must undergo a TB risk assessment prior to entering kindergarten or upon transfer to Santa Clara County schools. Each student must now be evaluated by a health care provider who will complete the *Santa Clara County Public Health Department TB Risk Assessment for School Entry* form.

TB risk assessment and test results (if indicated) must be submitted prior to school entry; documented TB screening and tests performed in the US **up to twelve months prior to registration for school are considered valid.**

Students who have a positive risk assessment should have a TB test. All children with a positive TB test should undergo medical evaluation, including a chest x-ray. The results of the chest x-ray should be included on the form. If the chest x-ray is normal and the child has no TB symptoms, they may start school. If the child has an abnormal chest x-ray, the child must undergo further evaluation and cannot enter school unless treatment has been initiated.

**Please fax any forms reporting an abnormal chest x-ray to the TB Prevention and Control Program at (408) 885-2331.**

### **2) How were the risk assessment questions chosen?**

The questions on the TB Risk Assessment for School Entry form were adapted from the American Academy of Pediatrics Guidelines and the Pediatric Tuberculosis Collaborative Group recommendations and based on the epidemiology of childhood tuberculosis in Santa Clara County.

### **3) Who needs to satisfy the requirements of the Santa Clara County TB Mandate?**

The requirement applies to the following students entering a public or private school in Santa Clara County beginning June 1, 2014 and later:

1. All students entering into kindergarten for the first time.
2. All students transferring to Santa Clara County schools into kindergarten through twelfth grade from a school outside of Santa Clara County.

### **4) Who is exempt from these requirements?**

1. All students who have previously met the TB screening requirements of Santa Clara County AND who have not been residing outside the county greater than 12 months; this includes students who entered Santa Clara County schools Transitional-Kindergarten (TK).

## **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

2. Students transferring from one school to another within Santa Clara County AND have previously met the TB screening requirements.

### **5) Who can enroll/register in a Santa Clara County school before TB screening requirements are complete?**

A student who falls under the provisions of the McKinney-Vento Homeless Assistance Act is not required to complete TB screening before school registration and may be immediately enrolled into school. TB screening is still required for these students and should be completed in a timely manner, e.g. within 20 calendar days of enrollment. Note: School district may extend time to complete screening for up to 45 calendar days.

### **6) What are acceptable TB tests?**

1. Mantoux Tuberculin Skin Test (TST), which must be done in the U.S. A 4-Pronged Tine multipuncture test is not acceptable.
2. Interferon Gamma Release Assay (IGRA) blood test, e.g. Quantiferon or T-spot, which must be done in the U.S. (generally recommended for children who are at least 4 years old at the time the blood test is done).

### **7) What is the definition of a positive TB test?**

1. A positive TST is 10 millimeters (mm) or more of induration (swelling). Redness alone at the skin test site is not considered a positive reaction.
2. A person who has had recent contact to an active infectious TB case will have a positive TST at 5mm or more of induration.
3. A positive IGRA result interpretation is included in the laboratory report.

### **8) What does a positive TB test mean?**

A positive TB screening test suggests that the student has been infected with TB. It is important for the student to undergo medical evaluation to determine that they are free of communicable disease and to be offered treatment for latent or “silent” TB infection. Occasionally, a positive TB screening test identifies students with active contagious TB disease. It is important to identify these students early on to prevent the spread of TB in the school system and to ensure that they receive the proper treatment.

### **9) What is the next step for a student with a positive TST or positive IGRA result? *Note: positive means past positive or current positive result***

1. Students with a positive TST or positive IGRA must submit evidence that they are free of pulmonary TB disease. This includes **one** of the following:
  - a. Report of chest x-ray done in the United States up to 12 months prior to school registration that shows no evidence of active pulmonary tuberculosis.
  - b. Written documentation of prior treatment for latent TB infection. See Table on pg. 7

## **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

- c. Written documentation of ongoing treatment for latent TB infection.
  - d. Written documentation of prior treatment for active TB disease.
  - e. Written documentation of current treatment for active TB disease.
2. If the student does not have any of the above and does not have signs or symptoms of active TB (as documented by a medical provider), he/she may be conditionally enrolled, pending the results of the chest x-ray in accordance with school policy. It is recommended that conditional enrollment and admittance be extended for no more than 20 calendar days. However, school districts may extend the time before excluding the student for up to 45 days.

### **10) What is the next step for a student with an indeterminate IGRA test?**

Students who have a positive TB risk assessment, an indeterminate IGRA result and a negative symptom review by a health care provider may enter school.

**Note to providers:** If result is indeterminate, consider placing a TST or repeating the IGRA test in 2 weeks.

### **11) What should schools do if a student does not have a health care provider?**

If a student does not have a source of regular care, refer to the Child Health and Disability Prevention (CHDP) program at 1(800) 689-6669 or the School Health Clinics of Santa Clara County at (408) 284-2280 to be evaluated.

### **12) What records must students provide to meet the requirements of the Revised TB Mandate?**

1. The *Santa Clara County Public Health Department TB Risk Assessment for School Entry* form completed by a health care provider.
2. Students who are currently being treated or have completed treatment for TB or latent tuberculosis infection (LTBI) must provide written documentation from their health care provider. This should include medication name, dosage, date started, and date completed. This student does NOT require an additional chest x-ray.

### **13) What is the process for obtaining a waiver that exempts a student with a positive risk assessment from the TB test?**

1. To initiate the process for an exemption for a TB test, a student who has a positive TB risk assessment must have the medical provider write a note on the Santa Clara County TB Risk Assessment for School Entry form. The provider should document that TB testing was deferred due to personal beliefs and that child has no TB symptoms.
2. Fax this form to the TB Prevention and Control Program at (408) 885-2331.

**Note:** The signed back of the blue card is not acceptable for use as a waiver for the TB screening mandate in Santa Clara County.



## **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

### **14) What is the process for obtaining a waiver that exempts a student from the TB screening Assessment?**

Students who lack health insurance or a health care provider and who cite these as reasons for obtaining a waiver must still fulfill the requirements of the TB screening before attending school. Refer student to CHDP or the School Health Centers of Santa Clara County.

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### **References**

American Academy of Pediatrics, Committee on Infectious Diseases. Tuberculosis. In L.K. Pickering (Ed.), 2009 *Red Book: Report of the Committee on Infectious Diseases*. 27<sup>th</sup> ed. El Grove Village, IL: American Academy of Pediatrics, 2009:680-701.

California Health and Safety Code § 121515.

Centers for Disease Control and Prevention Tuberculosis Information: <http://www.cdc.gov/tb/>

Pang J, Teeter LD, Katz DJ, et al. Epidemiology of Tuberculosis in Young Children in the United States. *Pediatrics*, 2014:494-504.

Pediatric Tuberculosis Collaborative Group. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents. *Pediatrics* 2004; 114 (14):1175-1201.

# **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

## **Frequently Asked Questions**

### **A child has history of BCG vaccination, should they have TST or IGRA?**

According to the American Academy of Pediatrics Red Book (2012), Interferon Gamma Release Assay (IGRA) is the preferred test for children  $\geq 5$  years of age that have a history of BCG vaccination. For children  $\leq 5$  years of age, TST is preferred but IGRA is acceptable.

Among TB experts, IGRA blood tests, e.g. QuantiFeron or T-spot, which must be done in the U.S., are reliable for children who are at least 4 years old at the time the blood test is done. There is insufficient data on the sensitivity of IGRA and reports of high indeterminate results among children 0-2 years of age.

Of note, effective March 1, 2014, Medi-Cal removed the age restriction on Medi-Cal reimbursement for IGRA tests for children under 5 years old. The California Department of Health Care Services posted this announcement on their website: "Effective for dates of service on or after March 1, 2014, the minimum patient age for reimbursement with CPT-4 codes 86480 (tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon) and 86481 (tuberculosis test, enumeration of gamma interferon-producing T-cells in cell suspension) is lowered from 5 to 0 years."

### **Are there ever indications for doing both a TST AND an IGRA?**

In general, a provider should choose the appropriate test and avoid doing both tests or using IGRA results to validate positive TST results. A child with a positive result for either TST or IGRA should have a chest X-ray and be treated appropriately.

There are some indications for doing both tests but this should not be routine. If an initial IGRA is indeterminate or borderline, do a TST. Or if an initial test (TST or IGRA) is negative AND there is clinical suspicion for TB disease or risk of infection, progression and poor outcome is higher. For children who are immunocompromised do both tests AND obtain a chest X-ray.

### **Okay, you said not to, but I did both TST and IGRA and get different results. What do I do now?**

Obtain a chest-X ray. If there is a high index of suspicion for active TB disease or risk of progression from infection (i.e. young child, immunocompromised) then treat if either test is positive. If you have questions, please call the TB Prevention and Control Program at (408) 885-4214.

### **The BCG vaccination may have affected the TST result. What do I do?**

Any new TST result  $\geq 10$  mm induration will be read as a positive TB screening result regardless of whether or not the child received a BCG vaccination. The student must demonstrate that they are free of communicable disease. In most cases, this will require a chest x-ray done in the United States up to 12 months prior to school registration.

# **Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014**

## **What if the student has a previous positive TST/IGRA from outside the country?**

The student will be required to obtain an IGRA and/or undergo a chest x-ray in the United States.

## **This student left the county for an extended vacation. Do they still need a TB screening test?**

If the student has traveled for greater than 1 week to a country in Africa, Asia, Latin America, or Eastern Europe they should be re-evaluated by a healthcare provider and evaluated for possible exposure to TB but this will not be required for school re-entry.

## **What is considered an adequate regimen for latent TB Infection?**

The recommended regimen for latent TB infection is isoniazid for 9 months, usually co-administered with vitamin B6. Children 12 years and older may be considered for weekly dosing of rifapentine and isoniazid by directly observed therapy (DOT) for 12 weeks. An alternate regimen, usually reserved for children exposed to drug resistant TB, is rifampin for six months. See Table on page 7

For review of LTBI treatment regimens other than isoniazid see the table below or contact the TB Prevention and Control Program at (408) 885-4214.

## **What will be the “Catch-Up” procedure for students who were deferred due to the Tuberculin shortage in 2013?**

Students who were tracked because they did not receive a TST or any TB risk assessment evaluation due to the tuberculin shortage should receive instruction to follow-up with their health care provider and undergo TB risk assessment screening assessment. These students should return TB Risk Assessment form prior to starting the 2014-2015 school year.

All other questions regarding the Mandate should be directed to the Public Health Department’s TB Prevention and Control Program at (408) 885-4214. Please follow the prompts below to speak with a PHD staff member:

- Press option 1 for English/2 for Spanish then,
- Press option 6 for “All other TB calls” and you will be connected with PH staff prepared to accept your call.

## Santa Clara County Tuberculosis Screening Requirement for School Entrance Effective June 1, 2014

**Table. Latent Tuberculosis Infection Treatment Regimens for Children**

Drug(s)	Duration	Dose	Frequency	Total Doses
Isoniazid (INH)	9 months	Children: 10-20 mg/kg** Maximum dose: 300 mg	Daily	270
Isoniazid (INH) and Rifapentine (RPT)	3 months	Adults and Children 12 and over: <b>INH*</b> : 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum <b>RPT*</b> : 10.0–14.0 kg 300 mg 14.1–25.0 kg 450 mg 25.1–32.0 kg 600 mg 32.1–49.9 kg 750 mg ≥50.0 kg 900 mg maximum	Once weekly by DOT †	12
Rifampin (RIF)	6 months	Children: 10-20 mg/kg*** Maximum dose: 600 mg	Daily	120

\*Isoniazid (INH) is formulated as 100 mg and 300 mg tablets. Rifapentine (RPT) is formulated as 150 mg tablets in blister packs that should be kept sealed until usage.

\*\* The American Academy of Pediatrics recommends an INH dosage of 10-15 mg/kg for the daily regimen.

† DOT: Directly observed therapy

\*\*\*In the United States, the recommended regimen for treatment of LTBI in children is a 9-month course of INH. For the treatment of LTBI in infants, children, and adolescents when INH could not be tolerated or the child has had contact with a case patient infected with an isoniazid-resistant but rifamycin-susceptible organism the American Academy of Pediatrics recommends 6 months of daily rifampin (RIF) (180 doses) at a dosage of 10-20 mg/kg.

### References

American Academy of Pediatrics, Committee on Infectious Diseases. Tuberculosis. In L.K. Pickering (Ed.), 2009 *Red Book: Report of the Committee on Infectious Diseases*. 27<sup>th</sup> ed. Elk Grove Village, IL: American Academy of Pediatrics, 2009:680-701.

Pang J, Teeter LD, Katz DJ, et al. Epidemiology of Tuberculosis in Young Children in the United States. *Pediatrics*, 2014:494-504.

Pediatric Tuberculosis Collaborative Group. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents. *Pediatrics* 2004; 114 (14):1175-1201.

Centers for Disease Control and Prevention Tuberculosis Information: <http://www.cdc.gov/tb/>

# County of Santa Clara

## Public Health Department

Administration  
976 Lenzen Avenue, 2<sup>nd</sup> Floor  
San José, CA 95126



April 15, 2014

Dear Parent/Guardian,

Santa Clara County continues to have one of the highest rates of tuberculosis (TB) in the United States. TB is a bacterial infection spread through the air and can affect the lungs, brain, bones, or any part of the body. Children can become infected when traveling, from household members, family, or visitors who are infected. Children exposed to someone with TB have a very high risk of developing active TB. If diagnosed early, TB is treatable and preventable.

Santa Clara County has required mandatory tuberculosis (TB) testing for students enrolling in school. However, **effective June 1, 2014, students enrolling into school will be required to undergo TB testing ONLY if their healthcare provider identifies a risk factor for TB exposure. Prior to school enrollment children will be required to have their healthcare provider complete the Santa Clara County Public Health Department Risk Assessment for School Entry form which is attached. Take this form to your provider to complete and return to your child's school.** This requirement applies to students attending both public and private schools in Santa Clara County and is based on the authority given the Santa Clara County Health Officer under the California Health and Safety Code, Section 121515.

This new policy will decrease unnecessary testing and allow healthcare providers to ensure that children who have TB infection are evaluated and treated promptly.

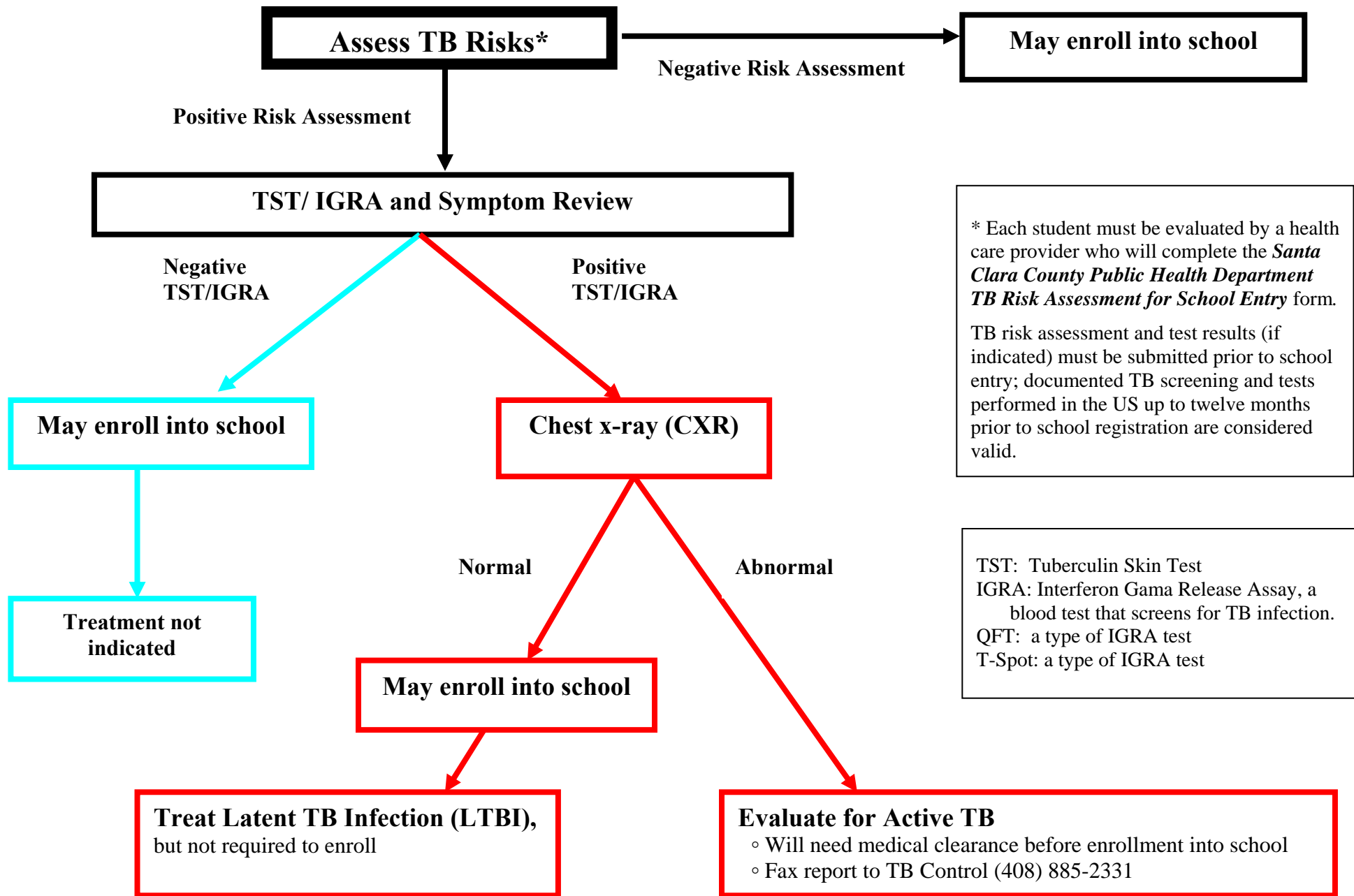
Thank you for helping us protect the health of your children.

Sincerely,

A handwritten signature in black ink, appearing to read "Teb Al-Samirai".

Teeb Al-Samirai, MD  
Tuberculosis Controller

**SANTA CLARA COUNTY TB SCREENING REQUIREMENT FOR SCHOOL ENTRANCE (K-12) EFFECTIVE JUNE 1, 2014**



## Interferon Gamma Release Assay (IGRA) TB Tests Provider Information and Guidelines for Interpretation

### What is it?

Interferon Gamma Release Assays (IGRAs) are blood tests for detection of infection to *M. tuberculosis*, as occurs in active tuberculosis (TB) and latent tuberculosis infection (LTBI).

If not detected and treated, LTBI may later develop into TB disease. The IGRA measures the patient's immune reactivity to *M. tuberculosis*, the bacterium that causes TB. The IGRA tests most commonly available are the QuantiFERON Gold In-Tube (QFT-IT) and T-SPOT tests.

### What are the advantages of IGRA?

Requires only a single patient visit to conduct the test.

Prior BCG (Bacillus Calmette-Guérin) vaccination does not cause a false-positive IGRA test result.

Does not cause booster phenomenon which can happen with repeat tuberculin skin tests (TSTs).

Is less subject to reader bias and error when compared to the TST.

### What are the disadvantages?

Blood samples must be processed within 8-30 hours after collection.

Errors in collecting or transporting the blood specimens or in running and interpreting the assay can decrease the accuracy of IGRAs.

Less sensitive in immunocompromised populations and young children < 5 years old.\*

\*Some experts report that IGRA is reliable in children as young as 3 or 4 years old.

***Like the TST, the IGRA is a useful but imperfect diagnostic aide. It should not replace clinical judgment.***

### When should I use IGRA?

IGRAs are the preferred TB screening test in the following situations:

- Children  $\geq$  5 years old; however, some experts report that IGRA tests can be used reliably in children as young as 3 or 4 years.
- Children who have received BCG vaccine.
- Children unlikely to return for the TST reading.

### When should I use both TST and IGRA?

***If there is an increased risk of progression of latent TB infection (such as in a patient who is immunocompromised either from a medical condition or medications) consider both IGRA and TST and take either positive as evidence of infection.***

Also consider using both TST and IGRA for:

- Patients with suspected TB or symptoms of TB.
- Patients with HIV infection or other immunosuppressed condition or medications.

### Is IGRA covered by Medi-Cal?

**YES!** As of March 1, 2014, Medi-Cal removed the age restriction on Medi-Cal reimbursement of IGRA tests for children under 5 years old. *"The minimum patient age for reimbursement with CPT-4 codes 86480 (tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon) and 86481 (tuberculosis test, enumeration of gamma interferon-producing T-cells in cell suspension) is lowered from 5 to 0 years."*

## How do you interpret IGRA test results?

*Negative:* Same interpretation as negative TST – no further TB evaluation unless indicated by clinical judgment.

*Positive:* Same interpretation as positive TST. Radiograph and medical evaluation indicated.

*Indeterminate:* Repeat IGRA or place TST per patient and provider preference.

## Can IGRAs be done at the same time as receiving vaccinations?

Similar to TST, live virus vaccines might affect IGRA test results. However, this effect has not been studied.

The CDC recommends that IGRA testing in the context of live vaccine administration be done as follows:

- Either on the same day as vaccination with the live-virus vaccine, OR
- 4 - 6 weeks after administration of the live-virus vaccine.

## How do IGRAs work?

IGRA measures a person's immune response to *M. tuberculosis*. White blood cells that are infected with *M. tuberculosis* will release interferon-gamma (IFN- $\gamma$ ) when mixed with antigens derived from *M. tuberculosis*.

The antigens include ESAT-6 and CFP-10, and TB7.7(p4) proteins specific to *M. tuberculosis complex*. These antigens are not found in BCG strains or *M. avium*.

The IGRA results are based on the amount of IFN- $\gamma$  that is released. Additional tests such as chest radiograph are needed to exclude TB disease and confirm the diagnosis of LTBI.

## Where can I get or order an IGRA?

IGRAs are now available through many commercial laboratories with provider prescription. You should advise patients to check with the individual draw stations of these laboratories, as they often have specific days that they draw and process the IGRA tests.

## Additional Information

Centers for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection, United States. *MMWR* 2010; 59 (No.RR-5)

Santa Clara County Public Health Department  
Tuberculosis Prevention & Control Program  
Phone: 408-885-4214  
Fax: 408-885-2331



# Tuberculosis Health Brief

## Santa Clara County

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### What is Tuberculosis?

Tuberculosis (TB) is an ancient disease that still affects many people in Santa Clara County. TB is caused by the bacteria *Mycobacterium tuberculosis* and is spread from person to person through the air when an individual with TB coughs, sneezes, or speaks. Individuals who breathe in infected droplets become infected with TB and are at risk for developing TB disease.

People who have TB can have two types of infection:

1. Latent or “silent” TB infection: Individuals with latent TB infection (LTBI) have a small amount of TB in their bodies that their immune system keeps under control. They do not have symptoms, are not contagious and may remain that way for years. Treatment of LTBI can prevent TB disease in the future.
2. Active TB disease: Occurs when TB bacteria multiply and a person develops symptoms such as cough, fever, or weight loss. They can also spread disease to others. Active TB disease can develop in people with LTBI when the immune system is weakened by stress or a medical illness, such as diabetes, cancer, kidney disease, or HIV. Certain behaviors, such as smoking, also increase an individual’s risk for developing TB disease.

TB usually affects the lungs, but can also affect any part of the body such as lymph nodes, bones and joints, kidneys, intestines, and the brain. TB can be treated but if untreated, can be fatal.

### TB in Santa Clara County

There were 181 cases of TB in Santa Clara County (SCC) in 2013<sup>1</sup> which is an increase from the downward trend through 2012 (N=176)<sup>2</sup>. This represents a rate of 9.8 cases per 100,000 residents in Santa Clara County<sup>1</sup> which is higher than the rate in California overall of 5.7 per 100,000 people<sup>3</sup> and more than three times the United States rate of 3.0 per 100,000 people<sup>4</sup>.

### Who’s at risk for TB infection and developing active TB disease?

People who were born in or travel to countries with high TB rates are at the highest risk for being exposed to TB. For people with LTBI, certain medical conditions such as diabetes, end stage renal and behaviors increase the risk of progression from latent TB infection to active TB disease<sup>4</sup>.

- People with LTBI and diabetes are three times more likely to develop active TB disease than non-diabetics with latent TB infection<sup>6</sup>.

- 20% (36/181) of Santa Clara County TB cases identified in 2013 also had diabetes<sup>1</sup>.
- People with LTBI who smoke are 2.5 times more likely to develop active TB disease than non-smokers with LTBI<sup>8</sup>. Studies have shown that people with LTBI who are exposed to secondhand smoke are also more likely to develop active TB disease compared to those with TB infection not exposed to second hand smoke<sup>10</sup>.
- According to a World Health Organization review, people with heavy alcohol use are almost 3 times more likely to develop active TB disease than those who do not drink alcohol<sup>11</sup>.
- Other risk factors that increase the likelihood of progression from LTBI to active TB disease include HIV or other immune-compromising conditions, chronic kidney disease, or immunosuppressant medications such as TNF- $\alpha$  inhibitors or steroids (Table 1).

**Table 1. Risk factors and comorbidities of TB cases, Santa Clara County, 2013<sup>1</sup>**

<b>Risk factors</b>	<b>Number of Cases N=181 (%)</b>
Diabetes mellitus	36 (20%)
Immunosuppression (not HIV/AIDS)	8 (4%)
Excess alcohol use in past year	6 (3%)
End-stage renal disease	6 (3%)
Homeless within the past year	6 (3%)
Contact of infectious TB patient	3 (2%)
Post-organ transplantation	3 (2%)
Incomplete LTB treatment	3 (2%)
HIV*	2 (1%)
Missed contact	2 (1%)
TNF-alpha antagonist therapy	1 (0.5%)
Contact of MDR-TB patient	1 (0.5%)

Source: California Reportable Disease Information Exchange, 2013;  
 \*163/181 (90%) of TB cases had documented screening for HIV infection

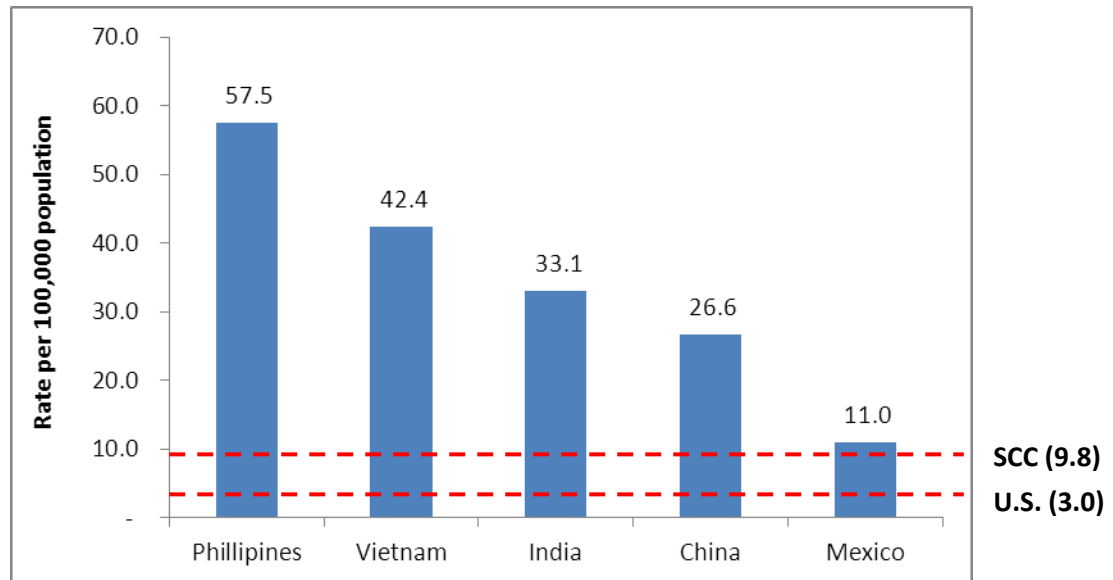
## Who had TB in Santa Clara County in 2013?

In 2013, the majority of TB cases (58%) were among people between 25 and 64 years of age. Children and young adults between 0 to 24 years of age accounted for 10% of TB cases. Almost 32% of people diagnosed with TB were older than 65 years of age<sup>1</sup>. The majority of SCC TB cases are of Asian or Hispanic race/ethnicity. Although the TB case rate among Asians in Santa Clara County has been trending downward from a peak of 37 per 100,000 people in 2007<sup>12</sup>, it remains eight times the overall rate of TB in the US at 24.7 per 100,000 people in Santa Clara County. This rate is higher among foreign-born residents from certain Asian countries (Figure 1).

In 2013, 91% of active TB cases were in foreign-born residents, primarily from the following countries: Vietnam, Philippines, India, Mexico and China. The majority (67%) of foreign-born

residents who developed active TB disease had lived in the United States for more than 5 years<sup>1</sup>.

**Figure 1: Tuberculosis case rates by country of origin, Santa Clara County, 2013<sup>1</sup>**



## How does TB make us sick?

When TB affects the lungs, it is called pulmonary TB and can be spread to others. In 2013, almost three quarters (73%) of TB cases in Santa Clara County had pulmonary TB<sup>1</sup>.

Five adults with TB died in Santa Clara County, 2 of whom were younger than 64 years of age and 3 were 65 years or older<sup>2</sup>. No children died of TB in Santa Clara County in 2013<sup>1</sup>.

## Drug Resistant TB

TB that is resistant to standard treatment is challenging to treat and can require 2 years of a complicated medication regimen. In 2013, 14% (21/145) of TB cases in Santa Clara County with known drug sensitivity results were resistant to at least one of the standard TB medications (rifampin, isoniazid, ethambutol, or pyrazinamide). Of those without a prior history of TB, 13% (17/135) were resistant to isoniazid<sup>1</sup>, which was higher than the national average in 2012 (8.9%)<sup>5</sup>. Multi-drug resistant TB, which is resistant to both isoniazid and rifampin accounted for 3.0% of culture confirmed TB cases in Santa Clara County in 2013<sup>1</sup>. No extensively drug resistant cases were identified in Santa Clara County in 2013.

## What should people do to know if they are at risk?

- If someone was born in or travels to countries where TB is endemic such as countries in Asia, Eastern Europe, Africa, or Latin America then they are at risk for having been exposed to TB and should ask their doctor about TB screening.
- If someone has a positive TB test then they should talk to their doctor about getting treated for latent TB infection in order to prevent the development of active TB disease.
- Treatment of latent TB infection is especially important for children, people with diabetes, HIV, people who smoke, a history of smoking, or exposure to tobacco smoke, chronic kidney disease, or who might be treated with immunosuppressant medications (e.g. prednisone, TNF- $\alpha$  inhibitors).

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1. California Reportable Disease Information Exchange, 2013

2. California Reportable Disease Information Exchange, 2012

3. California Department of Public Health Tuberculosis Control Branch

4. Centers for Disease Control and Prevention, Centers for Disease Control and Prevention. Trends in Tuberculosis – United States, 2013. MMWR 2014; 63:229-33

5. Centers for Disease Control and Prevention, Reported Tuberculosis in the United States 2012, <http://www.cdc.gov/tb/statistics/reports/2012/pdf/report2012.pdf>

6. Jeon CY, Murray MB. Diabetes mellitus increases the risk of active tuberculosis: a systematic review of 13 observational studies. PLoS Med. 2008 Jul 15;5(7):e152

7. Dooley, K.E., et al., Impact of diabetes mellitus on treatment outcomes of patients with active tuberculosis. Am J Trop Med Hyg, 2009. 80(4): p. 634-9.

8. Santa Clara County Department of Public Health Department, 2009 Behavioral Risk Factor Survey

9. Bates MN, Khalakdina A, Pai M, Chang L, Lessa F, Smith KR. Risk of tuberculosis from exposure to tobacco smoke: a systematic review and meta-analysis. Arch Intern Med. 2007 Feb 26;167(4):335-42.

10. Leung CC, Lam TH, Ho KS, Yew WW, Tam CM, Chan WM, Law WS, Chan CK, Chang KC, Au KF. Passive smoking and tuberculosis. Arch Intern Med. 2010 Feb 8;170(3):287-92.

11. Rehm, J., et al., The association between alcohol use, alcohol use disorders and tuberculosis (TB). A systematic review. BMC Public Health, 2009. 9: p. 450.

12. Tuberculosis Information Management System, 2007

# Clinics for Tuberculosis Screening

## **Valley Connection**

Call for appointment: 888-334-1000

Valley Health Center **Bascom**: 751 S. Bascom Avenue, San Jose, 95128

Valley Health Center **East Valley**: 1993 McKee Rd, San Jose, 95116

Valley Health Center **Gilroy**: 7475 Camino Arroyo, Gilroy, 95020

Valley Health Center **Milpitas**: 143 N. Main St., Milpitas, CA 95035

Valley Health Center **Moorpark**: 2400 Moorpark Ave, San Jose, 95128

Valley Health Center **Sunnyvale**: 660 Fair Oaks Ave., San Jose, 94086

Valley Health Center **Tully**: 500 Tully Rd., San Jose, 95111

## **Alviso**

### Alviso Health Center

1621 Gold Street, Alviso, 95002; 408-935-3900

Mon-Fri 8:00am-5:00pm

## **Daly City**

### RotaCare Bay Area, Inc.--Daly City Clinic

Seton Medical Center-Ground Floor;

1900 Sullivan Avenue, Daly City, 94015; 650-991-6046

Mon: 5:00pm-7:00pm

## **East Palo Alto**

### Ravenswood Family Health Center

1798 Bay Road, East Palo Alto, 94303; 650-330-7400

Mon 8:45am-7:00pm, Tue-Fri 8:45am-5:00pm,

Closed the 4<sup>th</sup> Friday of the month at 2:00pm

## **Gilroy**

### Planned Parenthood Mar Monte--Gilroy

760 Renz Lane, Gilroy, 95020;

Call for appointment: 408-847-1739

Mon 9:30am-5:30pm, Wed 10:00am-7:00pm,

Tue/Thu/Fri 9:00am-5:00pm, Sat 9:00am-2:00pm,

### Gardner South County Health Center

7526 Monterey St, Gilroy, CA 95020; 408-848-9400

M-F 8:00am-5:00pm, Sat 8:00am-4:30pm;

Accept insurance or fee: sliding scale, \$40 for established patients;

Accepts adults and children;

No X-rays at site - refer Chest X-rays to SLH and San Martin Clinic.

### Gilroy Neighborhood Health Clinic

7861 Murray Ave, Gilroy, CA 95020; 408-842-1017

M-F: 8:00am-4:00pm (closed 12pm-1pm); appointment preferred

\$25 for patients without insurance; can order QuantiFeron.

No X-rays at site, refers Chest X-rays to San Martin VHC Clinic, or

CHDP exam to VMC;

## **Half Moon Bay**

### RotaCare Bay Area, Inc.--Coastside Clinic

225 South Cabrillo Hwy, Suite 100A, Half Moon Bay, 94019;

650-573-3774;

Wed 5:00pm-7

No pediatric or radiology services on site

## **Los Altos**

### Planned Parenthood Mar Monte-Foothill College (Foothill Students & Staff Only)

12345 El Monte Road, Los Altos, 94022; 650-949-7243;

Mon-Thu 8:30am-4:30pm; Closed 1:00pm-2:00pm; Closed Every

4<sup>th</sup>Tue at 3:30pm

## **Menlo Park**

### Ravenswood at Bell Haven

100 Terminal Avenue, Menlo Park, 94025; 650-321-0980

Mon/Wed/Fri 8:00am-5:00pm, Tue 12:30pm-5:00pm,

Sat 8:00am-12:00pm

## **Milpitas**

### Alliance Occupational Medicine in Milpitas

315 S Abbott Avenue, Milpitas, CA 95035; 408-790-2900;

M-F 7:00am-7:00pm, No appointment is needed, just walk in;

\$20 for TST, do not accept any private insurance, \$100 for

Quantiferon;

X-rays at site, approved positive TB test shown as necessary;

X-rays time: M-F 8:00am-5:00pm.

## **Mountain View**

### MayView Community Health Center--Mountain View

100 Moffett Blvd., Suite 101, Mountain View, 94043;

650-963-3323

Mon, Wed, Fri 8:30am-5:00pm, Tue, Thu 8:30am-8:30pm,

Sat 9:00am-4:00pm

### Planned Parenthood, Mountain View

225 San Antonio Road, Mountain View, CA 94040; 650-948-0807;

Walk-in: 8:30am-4pm

Fee: sliding fee scale; Accept adults and children;

No X-rays at site - refer to VMC for CXR f/u if needed.

### Mayview Community Health Center at Mt. View

900 Miramonte Ave, 2<sup>nd</sup> Fl, Mountain View, CA 94040;

650-965-3323;

1:00-3:00pm (1<sup>st</sup> and 3<sup>rd</sup> Tuesday of the month);

Accept Healthy Kids, Healthy Families, or Fee: \$28.00;

Accept adults and children;

No appointment necessary, but accept first 20 patients.

### Mountain View Clinic @ El Camino Hospital (Rota Care Clinic)

2400 Grant RD, Park Pavilion Building, Mountain View, CA 94040;

650-988-820;

Mon: 5:00pm-7:00 pm, Tue: 9:00am-11am, Fri: 9am-noon

Accepts adult and children;

No appointment necessary

## **Palo Alto**

### Gardner Packard Children's Health Center

730 Welch Road, 1<sup>st</sup> Floor, Palo Alto, CA, 94304; 650-497-8820;

Mon-Fri 9:00am-5:00pm

### Mayview Community Health Center at Palo Alto

270 Grant Ave, Palo Alto, CA 94306; 650-327-8717;

No appointment necessary on 2<sup>nd</sup> and 4<sup>th</sup> Wednesday of the month

1:00 pm-3:00pm

Accepts Healthy Kids, Healthy Families, or Fee: \$28.00;

Accepts adults and children

## **San Mateo**

### Planned Parenthood Mar Monte--San Mateo

35 Baywood Avenue, San Mateo, 94401; 650-235-7940;

Mon 8:30am-4:00pm, Thu&Fri 10:30am-3:00pm

## **San Jose**

### Asian American for Community Involvement

2400 Moorpark Ave, Ste 319, San Jose, CA 95128;

408-975-2763;

M-F 8:30am-12:30pm, 1:30pm-5:30pm;

Appointment only, TST \$20 for all patients;

No X-rays at site, refers chest X-rays to SCCVMC.

## San Jose

### San Jose High Neighborhood Health Clinic

1149 E. Julian St, Bldg. H, San Jose, CA 95116; 408-535-6001;  
M-F 8:00am-4:00pm, appointment;  
**IZ/TST: Tuesday 1:00 pm-3:00 pm (Walk-in);**  
\$25 for people who do not have insurance;  
No X-rays on site - refers to Just X Rays and VMC

### CompreCare Health Center

3030 Alum Rock Ave, San Jose, CA 95127; 408-259-8400;  
M-Sat 8:00am-5:30pm with appointment, walk-in:8am-5pm (M-F);  
Fee: sliding scale, accept adult and children.

### San Jose Clinic

Washington School, 100 Oak Street (Clinic located on Edwards St.  
behind the school), San Jose, CA 95110; 408-295-0980;  
Appointment or walk-in;  
M-F: 8am-4:30pm (closed 12pm-1pm for lunch break);  
Visit Fee: \$25.00 for everyone;  
No X-rays at site, refers chest X-rays to Just X-Ray.

### Gardner Health Center

195 E. Virginia St, San Jose, CA 95112; 408-998-8814 for appointment;  
M-F 8:30am-4:30pm, by appointment only  
TST: Accepts insurance, Medical, or fee: \$15; Accepts adults and  
children; No X-rays at site, refers chest X-rays to JXR and VMC.

### St. James Health Center

55 E. Julian St., San Jose, CA 95112;  
408-918-2600, by appointment only, 408-918-2641  
M-F 8:30am-5:00pm;  
TST: Accepts insurance, Medical, or fee: \$15; Accepts adults and  
children; No X-rays at site, refers chest X-rays to JXR and VMC.

### San Jose Foothill Family Community Clinic

2880 Story Road, San Jose, 95127; 408-729-4282;  
M-F 8:00am-8:00pm, S-S 8:00am-5:00pm;  
Walk-in: 8am-11am, 1pm-3pm (M, T, W, F, S); Prefer appointment;  
Accept insurance, sliding fee scale, or \$35.00 for uninsured;  
Accept adult and children;  
No X-rays at site, refers CXR's to VRI/Just X-Ray.

### Indian Health Center

1333 Meridian Ave, San Jose, CA 95125; 408-445-3400;  
M-F 8:00am-5:00pm New patients need to register prior to  
appointment for TST;  
Fee: \$30.00 Accepts adult and children;  
No X-rays at site, refers to other sites for X-rays.

### Franklin McKinley School Center

645 Wool Creek Dr., San Jose, CA 95112; 408-283-6051;  
Call for appointment; \$25 for pts without insurance;  
No X-rays at site

### Overfelt Neighborhood Health Clinic

1835 Cunningham Ave, San Jose, 95122; 408-347-5988;  
Mon-Wed & Fri 8:00am-4:30 pm (closed 12pm-1pm for lunch);  
Immunizations/TST: Tuesday 8:00-10:30.

### Mar Monte Community Clinic

2470 Alvin Ave. Ste 60, San Jose, CA 95121  
Call for appointment: 408-274-7100; Sliding fee scale  
Mon, Tue, Thurs., Fri 8:45am-5:00pm, W 8:45am-  
6:30pm, Sat 8:45am-1:00pm.  
No X-rays at site - refer to VMC for CXR.

### Family Medicine Center at O'Connor

455 O'Connor Drive, Suite 200, San Jose, 95128; 408-283-7676;  
Mon-Fri 8:30am-5:30pm

### Foothill Health Center

2380 Montpelier Drive, Suite 200, San Jose, 95116; 408-254-1800;  
Mon-Fri 8:00am-12:00pm

### Gardner Downtown Health Center

725 East Santa Clara Street, San Jose, 95112;  
408-794-0500 or 408-794-0501;  
Mon-Fri 8:30am-5:30pm

### Independence High School Clinic (Pediatrics)

1776 Educational Park, Drive H Building, San Jose, 95133;  
408-928-9599;  
Mon-Fri 9:30am-1:30pm

### Indian Health Center--Silver Creek

1462 East Capital Expressway, San Jose, 95121;  
408-445-3431;  
Mon-Fri 8:30am-5:30pm

### Mount Pleasant High School Clinic (Pediatrics)

1650 South White Road, San Jose, 95127; 408-928-5250;  
Mon-Fri 8:00am-5:00pm

### North East Medical Services--Lundy Clinic

1715 Lundy Avenue, Suite 108-116, San Jose, 95131;  
408-573-9686;  
Mon-Sat 8:30am-5:00pm;  
Closed Mon-Fri 12:00pm-1:00pm, Sundays and Holidays

### Planned Parenthood Mar Monte--Blossom Hill

5440 Thornwood Drive, Suite G, San Jose, 95123; 408-281-9777;  
Mon-Wed 8:30am-6:30pm, Tue/Thu/Fri 8:30am-5:00pm

### Planned Parenthood Mar Monte--Eastside

3131 Alum Rock Avenue, San Jose, 95127; 408-729-7600;  
Mon&Thu 8:30am-7:00pm, Tue 8:00am-5:00pm, Wed-Fri 8:30am-  
5:00pm

### Washington Neighborhood Clinic

100 Oak St. San Jose, 95110; 408-295-0980  
Call for appointment Mon-Fri 8:00-4:30

### Yerba Buena High School Clinic (Pediatrics)

1855 Lucretia Avenue, Room 112, San Jose, 95122; 408-347-4752;  
Mon-Fri 11:30am-3:30pm Planned Parenthood, San Jose  
1691 The Alameda, San Jose, CA 95126; 408-287-7526;  
Fee: \$35.00 for established patients;  
No X-rays at site refer to VMC for CXR f/u if needed.

## Santa Clara

### Alliance Occupational Medicine in Santa Clara

2737 Walsh Avenue, Santa Clara, CA 95051; 408-228-8400;  
M-F 7:00am-7:00pm;  
No appointment is needed, just walk in;  
\$20 for TST, does not accept any private insurance, \$100 for  
Quantiferon;  
X-rays on-site, time: M-F 8:00am-5:00pm.

## Sunnyvale

### Mayview Community Health Center--Columbia Neighborhood Center

785 Morse Avenue, Sunnyvale, 94085; 408-746-0455;  
1st & 3<sup>rd</sup> Tuesday of the month

## Redwood City

### Planned Parenthood Mar Monte--Redwood City Express

2907 El Camino Real, Redwood City, 94063; 877-855-7526;  
Tue 8:30am-4:00pm