



CDPH - CTCA Joint Guidelines

Guidelines for Prevention and Control of Tuberculosis In California Long Term Health Care Facilities

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Introduction

The guidelines for the *Prevention and Control of Tuberculosis in California Long-Term Health Care Facilities* were developed jointly by the California Department of Health Services (CDPH)(Licensing and Certification Program and Tuberculosis Control and Infectious Diseases Branches of the Division of Communicable Disease Control) and the California Tuberculosis Controllers Association (CTCA). Long-term care facilities are those health care facilities licensed by the Licensing and Certification (L&C) Program under Section 1418 of the Health and Safety (H&S) Code, including Skilled Nursing Facilities (SNF), Acute Care Hospital Distinct Part SNFs (DP/SNF) and all types of Intermediate Care Facilities for the Developmentally Disabled (ICF-DD), congregate living health facilities as well as pediatric day health and respite care facilities licensed pursuant to Chapter 8.6 of the H&S Code.

The recommendations contained in these guidelines are intended to be advisory. However, requirements of the California Code of Regulations (CCR), Title 22, and of the California Occupational Safety and Health Administration (Cal/OSHA) are cited when applicable. These guidelines replace *Guidelines on Prevention and Control of TB in California Long Term Health Care Facilities* issued in 2005.

The purpose of these guidelines is to provide persons responsible for infection control and HCW health with sufficient information with which to: (1) design and implement a program for screening residents and employees for tuberculosis; (2) reduce transmission through the prompt detection and management of active tuberculosis disease; (3) request consultation from the local health department, and (4) comply with state and federal regulations.

Questions related to long term care TB screening programs should be directed to:

Healthcare-Associated Infections Program
Phone: 510-412-6060
cdphhaiprogram@cdph.ca.gov

Questions related to the medical management of tuberculosis infection or disease should be referred to the tuberculosis controller at the local county health department.

1. Overview of Tuberculosis

Tuberculosis (TB) is a disease caused by *Mycobacterium tuberculosis* bacteria (M. tb). These bacteria primarily cause disease in the lungs but just about any organ of the body can be infected. In 2011 there were 2,317 cases of TB in California, the third highest rate in the United States. In 2011 43 active TB cases (1.9% of all cases) were residents of long-term health care facilities.

1.1 Transmission of Tuberculosis

Transmission occurs when a person inhales air contaminated with *M. tb* bacteria that have been forced from the lungs of persons with active TB pulmonary disease when they talk, cough, sing, or shout. Most of the inhaled bacteria that reach the alveoli of the lungs are ingested and destroyed by macrophages (white blood cells). TB can also cause disease in the kidneys, spine, bones, and other organs. Unless the person also has lung disease, *M. tb* cannot be transmitted to other persons from these infected, extra-pulmonary, body sites.

1.2 Latent Tuberculosis Infection (LTBI)

M. tb bacteria that survive macrophage ingestion remain dormant in the lungs (and other organs) but viable (alive) for many years. This is referred to as latent tuberculosis infection (LTBI). LTBI generally results in the conversion of the tuberculin skin test (TST) and/or Interferon gamma release assay (IGRA) from negative to positive. Ten to 15% of persons with LTBI eventually progress to active TB disease sometime years to decades after the initial infection. Persons with LTBI are asymptomatic (have no symptoms of disease), have a normal chest radiograph (CXR), and cannot transmit *M. tb* bacteria to other persons. However, infected persons are at risk of progressing from LTBI to active disease, but this risk can be decreased if they receive LTBI treatment.

1.3 Active TB Disease

1.3.1 Persons at Increased Risk of Progression to TB Disease if infected:

- Children < 5 years of age
- Recent (within 2 years) TST/IGRA conversion from negative to positive.
- Persons with medical conditions associated with an increased risk of progression to active TB Disease, including:
 - Human immunodeficiency virus (HIV) infections (including persons at risk for HIV infection who have not been tested).
 - Diabetes mellitus, especially if insulin dependent or poorly controlled.
 - End-stage renal disease, chronic renal failure, hemodialysis.
 - Injection drug use, even if HIV negative.
 - Cancer of the head and neck.
 - Immunosuppressive treatment, including chronic corticosteroids, anti TNF-alpha agents, post-transplant therapy and cancer chemotherapy.
 - Other diseases characterized by immunosuppression, such as lymphoma or leukemia.
 - Intestinal bypass or gastrectomy.
 - Low body weight (> 10% below ideal body weight).
 - Malnutrition and clinical situations associated with rapid weight loss.
 - Silicosis.
 - Tobacco use.

1.3.2 Symptoms of Active Pulmonary TB Disease

The symptoms of active pulmonary TB disease may develop slowly and be difficult to differentiate from other lung diseases such as pneumonia and exacerbation of chronic obstructive lung disease. The symptoms of active pulmonary TB disease include, but may not be limited to:

- Cough, generally producing sputum, that lasts longer than three weeks,
- Unexplained or new onset of fever, hemoptysis (coughing up blood), sweating at night, weight loss, anorexia (loss of appetite), fatigue, chest pain,
- A recurrent diagnosis of pneumonia or a pneumonia that does not improve within two weeks after antibiotic therapy is initiated.

1.3.3 Diagnosis of Active Pulmonary TB Disease

Persons with active pulmonary TB disease usually have: (1) one or more symptoms, (2) an abnormal CXR, and (3) a positive sputum (acid fast bacilli or AFB) smear and/or culture. The TST/IGRA may be negative in those with suppressed immune systems. A sputum smear may or may not be positive depending on the extent of active disease. A positive smear also may, on occasion, be due to infection with other non-tuberculosis *Mycobacterium* species such as *Mycobacterium avium-complex* or *Mycobacterium kansasii*. A positive sputum culture is the gold standard for diagnosis of active TB. Nucleic acid amplification testing (NAAT) and other molecular tests for *M. tb* can provide rapid preliminary identification of active TB facilitating rapid initiation of treatment and infection control procedures. Rapid testing is recommended on all AFB samples.

1.3.4 Exposure to Active Pulmonary TB Disease

LTCFs should be aware that any resident, employee, volunteer, family member or visitor may, at any time, develop active disease and expose many persons in the facility to TB. A HCW or resident is considered exposed if there has been significant or prolonged contact (shared air space) with a person whose sputum culture, NAAT or other molecular test is positive for *M. tb* and who has not received adequate anti-tuberculosis treatment.

Factors that influence the significance of the exposure include:

- The affected person's infectiousness. Infectiousness is positively correlated with the following factors:
 - Disease in the lungs, airways or larynx.
 - Presence of cough.
 - Presence of a positive AFB smear in the sputum.
 - Extent of infiltration on CXR.
 - Cavitation on CXR.
 - Failure of the patient to cover the mouth and nose when coughing.
 - Inappropriate or short duration of TB drug treatment.

- Non-adherence to TB drug treatment.
- Poor clinical or bacteriologic response to TB treatment.
- The environment where the potential exposure took place.
 - Environmental factors which increase the risk of transmission include:
 - Potential that others will share air with the case (either in the same room or via the building ventilation system). Use of HEPA filtration or ultraviolet germicidal irradiation (UVGI) may reduce the risk.
 - Poor supply of fresh air.
 - Larger number and higher density of persons in setting.
 - Longer duration of time spent in the setting.
 - Transmission of *M. tb* has been documented in a variety of settings. At a minimum, the following types of settings, should be considered high risk:
 - Health Care Facilities (HCF) such as LTCFs.
 - Correctional facilities (CFs).
 - Drug treatment residential facilities.
 - Other congregate living sites, especially those housing persons at increased risk of progression to TB disease if infected including shelters for homeless person, board and care facilities, and residential treatment facilities.
 - Public living accommodations, including single room occupancy hotels, if air is shared in common areas or through the building ventilation system
 - Transmission of TB by AFB smear-negative cases prior to treatment can occur and is well-documented. Consequently, in certain circumstances, the determination of infectiousness may require the application of more stringent criteria; for example, consistently negative sputum cultures in at least two consecutive respiratory specimens would indicate low infectiousness.
- Drug resistance of patient’s TB isolate. Patients with drug-resistant TB and their contacts may be more difficult to treat and have poorer outcomes.

1.4 Tuberculosis Skin Test (TST)

Persons with LTBI generally have a positive TST within two to ten weeks after they have been exposed to someone with active pulmonary TB disease. The TST is performed using the Mantoux method of intradermally injecting five (0.1 cc) tuberculin units (TU) of purified protein derivative (PPD) into the volar aspect (palm side) of the forearm. Multiple puncture skin testing devices should never be used. Persons previously vaccinated with bacille Calmette-Guerin (BCG) should be included in the TST screening program. The effect of prior BCG vaccination on TST results is variable and is not a contraindication to testing. BCG vaccine does not protect against LTBI so persons with a positive TST and prior BCG vaccine should be considered to have LTBI. IGRA testing can distinguish between prior BCG vaccine and TB infection – see section 1.7 for more information.

A **two-step TST** should be administered to new HCWs and residents who have never been tested **or** if more than 12 months have elapsed since the last documented negative TST. This requires that the first TST, if interpreted as negative, be followed by a second TST administered one to three weeks after the first. This method of screening is recommended because the immune response of persons previously infected with M. tb may wane decline over time and the second TST acts as an immune system "booster." The results of the second test should be the reported result, i.e., those persons with a positive reaction on the second test should be considered to be previously infected, and those with a negative reaction on the second test should be considered uninfected. In these uninfected persons, a positive result on any future TST should be interpreted as a skin test conversion. Persons who have documentation of a single negative TST within the previous 12 months only need a single TST.

1.5 TST procedures

- The TST should be administered by a licensed health care professional specifically trained to apply and interpret the results.
- The TST is recorded in millimeters of induration (not negative or positive). A documented prior TST means there is written documentation of all the following: date administered and read, millimeters of induration, test method (i.e., Mantoux), and provider's name.
- HCWs should be given written notification of the interpretation of the TST results. The notification should include a statement conveying that:
 - HIV infection and other medical conditions may cause a TST to be negative, even though you may be infected with tuberculosis. Please consult with your healthcare provider should you have concerns.
- TST positive new HCWs and residents classified as reactors (TST conversion date undetermined) or converters should be referred to their healthcare provider or the local health department for LTBI treatment recommendations.
- TST positive HCWs and residents classified as converters should be reported to the local health department, if required by local ordinance.
- HCW TST conversions should be recorded on the OSHA 300 log. New HCWs classified as TST reactors do not have to be recorded on the OSHA Log.

1.6 Interpreting TST Results

A TST reaction of five millimeters (mm) or more of induration is considered positive in persons who meet any of the following criteria:

- Recent contact with a case of active pulmonary TB disease,
- Fibrotic changes on CXR consistent with prior TB,

- Known or suspected to be infected with HIV, and
- Immunosuppression (persons who have had recent organ transplant, take TNF-alpha antagonists or who require immunosuppressive medication equivalent to or greater than 15 mg of prednisone by mouth every day for one or more months).

A TST reaction of 10 mm or more induration is considered positive for all other persons.

A TST conversion is defined as a documented increase in induration of at least 10 mm within a 2-year period. However, for persons in recent contact with a case of active pulmonary TB disease, a TST conversion is defined as an increase of from less than 5 mm induration on the first TST to a reaction of greater than or equal to 5 mm on the second TST administered 8-10 weeks after the last date of exposure.

As with any test there is a risk of false negative results and a negative TST may not exclude LTBI. Regardless of the TST results, if a HCW or resident is symptomatic, a CXR and, if indicated, bacteriological studies of sputum should be obtained.

1.7 Interferon Gamma Release Assay (IGRA)

For years the TST has been the basic screening test for tuberculosis infection. Limitations of the TST include the need to measure the response within 48-72 hours after application as well as inaccuracies and errors in measurement. In 2001, Quantiferon* (QFT) became the first interferon gamma release assay (IGRA) to be approved by the Food and Drug Administration as an aid in diagnosing LTBI. Advantages over TST are that it is more specific, needs only a single contact, and it eliminates of reader inaccuracies in measurements. Limitations of this initial in vitro laboratory test included the need to draw blood and process it within 12 hours after collection as well as current limited laboratory and clinical experience with the test. In July 2008 the fourth IGRA test was approved by the FDA. The subsequent IGRA's have improved in specificity, sensitivity, blood draw and processing limitations from the earlier assays. Guidelines for using the in vitro test are available from the Centers for Disease Control and Prevention (CDC) (see references). Effective May 30, 2013 the use of the IGRA test for screening HCWs no longer requires a grant of program flexibility from L&C, (All Facilities Letter 13-15). Revised California Code of Regulation, Title 22 (Sections 70723, 71523, 71835, 72535, 73525, 74723, 75051, 76539, 76874, 76919, 78429, 79331, 79781, 79795) allows the use of TB blood tests and TB skin tests if the test is licensed by the Federal Food and Drug Administration (FDA) and recommended by the CDC. Use of the in vitro test for screening residents on admission requires only approval by the patient care policy committee [CCR, Title 22, 72523 (c) (2) (C)].

* The use of commercial names is not an endorsement of a product.

1.8 Interpreting IGRA Results

Using a sample of whole blood, the interferon-gamma release assays (IGRA'S) measure how the immune system reacts to the bacteria that cause tuberculosis. Because the current FDA approved IGRA tests in use each measure different aspects of the immune response and use different antigens and interpretation criteria, test results might not be interchangeable. Different tests may yield different results.

These assays do not differentiate LTBI from active TB disease. A diagnosis of LTBI requires that TB disease be excluded by medical evaluation. This should include checking for signs and symptoms suggestive of TB disease, a CXR, and when indicated, examination of sputum or other clinical samples for the presence of M.tb. Decision about a diagnosis of M.tb infection should also include epidemiological information.

- Positive IGRA: This suggests that the person's blood did react to the test and has most likely been infected with M. tb.
- Negative IGRA: This suggests that the person's blood did not react to the test and that M. tb infection is not likely but cannot be excluded especially when illness is consistent with TB disease and likelihood of progression to TB disease is increased.
- Indeterminate IGRA or Borderline T-Spot: An indeterminate result means test failure due to lack of responses to controls and in general does not provide useful information regarding M. tb infection. For persons with an indeterminate IGRA or borderline T-spot, providers should consult a healthcare provider who is knowledgeable and experienced in managing TB disease.

When using IGRAs in HCWs who require annual testing, only a single step test is needed at baseline, unlike the two-step testing used in skin testing. If the test changes from a negative to a positive result within a 2-year period, the person is considered a "converter" or newly infected. In addition to a positive or a negative result, the test may be reported as "indeterminate." In these situations, the IGRA can be repeated or a TST can be used to avoid getting another indeterminate result.

Note: There is no problem with repeated IGRAs causing a booster effect.

2. Reporting Requirements

The local health department should be consulted for guidance on evaluating and managing exposed residents and HCWs following the identification of a suspected or confirmed case of active TB disease in the LTCF.

The local health department (CCR, Title 17, Section 2500) and the L&C district office with jurisdiction over the facility (CCR, Title 22, Section 72541) must be notified within one working day of identifying any HCW or resident with suspected or confirmed active

pulmonary TB disease. The facility medical director or other professional designee must implement respiratory precautions and make the appropriate notifications (e.g., advising the person's healthcare provider that the person may have active TB). He/she should also document all recommendations made by the local health department.

If required by local ordinance, persons who convert their TST/IGRA from negative to positive should be reported to the local health department. Upon a report of a suspect or confirmed case of active disease or a cluster of recent conversions, the local health department may initiate an investigation in order to:

- Identify those persons who are at risk for infection due to exposure and to ensure adequate evaluation and/or treatment, and
- Identify the source person with active pulmonary TB disease when a cluster(s) of TST/IGRA conversions occur.

The H&S Code, Section 121365 states that each local health officer, or designee, is directed to use every available means to ascertain the existence of, and immediately investigate all suspected or confirmed cases of TB disease in their jurisdiction, and to ascertain the sources of those infections.

3. Resident Screening Program

3.1 New Admission Screening Program

New admissions are required by CCR, Title 22, Section 72523 to be screened for TB. However, these regulations vary depending upon the type of licensed facility. Screening for Skilled Nursing Facility (SNF) residents is required by CCR, Title 22, Section 72523(c)(2)(C). Screening for intermediate care facilities is required by CCR, Title 22, Section 73519(c).

These regulations state that all patients regardless of length of stay are screened for TB upon admission. These screening procedures shall be determined by the patient care policy committee. (See sample assessment questionnaire, Appendix 12.1)

A TB screening procedure may not be required if there is satisfactory written evidence available that a TB screening procedure has been completed within 90 days of the date of admission to the LTCF. Subsequent TB screening procedures shall be determined by the attending physician.

All TB screening information must be retained in the resident's medical record.

3.2 Admissions for patient/residents with known or suspected TB disease

Patients/residents who are known or suspected to have TB disease and are hospitalized or are residents of other healthcare facilities may only be admitted when a formal discharge plan is approved by the local health department. Section 121361 of

the H&S Code requires all healthcare facilities to obtain written approval of the local health officer or TB Controller **prior to** discharging or transferring a patient with suspected or verified active TB.

Patients/residents who are known or suspected to have TB disease may only be admitted when they are non-infectious according to the following criteria:

- Those patients/residents with **previously positive sputum smears** must meet all of the following criteria to be admitted:
 - Three consecutive negative sputum AFB smear results from sputum (see Definition of Terms in this guideline, Sputum), and
 - Fourteen daily doses of appropriate drug treatment for TB, taken and tolerated, and
 - Clinical improvement, and
 - Continued close medical supervision, including directly observed therapy (DOT), and
 - Continued treatment for TB, even if another pulmonary process is diagnosed, pending culture results from the 3 sputum specimens.

- Those patients/residents with **initially negative sputum smear results** must meet all of the following criteria to be admitted:
 - Three consecutive negative sputum AFB smear results from sputum (see Definition of Terms in this guideline, Sputum), and
 - Five daily doses of appropriate drug treatment for TB, taken and tolerated, and
 - Clinical improvement, and
 - Continued close medical supervision, including DOT, and
 - Continued treatment for TB, even if another pulmonary process is diagnosed, pending culture results from the 3 sputum specimens.

3.3 General Admission Screening

Patients/residents with a documented history of positive (TST) recorded in mm or positive IGRA or history of active TB disease:

- No further TST/IGRA required.

- TB Symptom Screen and CXR.
 - TB symptom screen must be performed upon admission.
 - CXR must be performed. If the patient/resident can provide a written report of a negative CXR done in the United States within 90 days prior to admission, a CXR is not necessary.
 - If patient/resident has TB symptoms (productive cough for greater than 3 weeks, fever, anorexia, weight loss, etc.) a new CXR must be performed as soon as possible.

- In the case of an abnormal CXR, the patient/resident must be referred to their

healthcare provider for evaluation.

- The patient/resident will not be allowed admission until s/he is considered not to have infectious TB and provides a medical clearance.
 - If the patient/resident has been admitted to the facility, the resident must be isolated in his/her room with the door closed and be transferred within one working day to a facility with negative pressure isolation rooms. While awaiting transfer, instruct HCWs entering the room to wear an N-95 respirator or a surgical mask if an N-95 respirator is not available. The resident must wear a surgical mask during transport. Report all suspected or confirmed TB cases to the local health department.
- All patients/residents with a positive TST/IGRA and no history of LTBI treatment should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

3.3.1 Patients/Residents with documented history of negative TST/IGRA:

- Admission TST/IGRA
 - If documentation of a previous negative TST is done and recorded in millimeters (e.g. 0 mm) within prior 12 months, only a single TST is needed. The single TST is acceptable if done within 90 days of admission. If no documentation is available, a two-step TST should be done to satisfy the two-step admission requirement to eliminate the question of false boosting with future TST's.
 - If documentation of a previous IGRA done (e.g. negative) within 90 days of admission is available, no additional IGRA test is needed. If **no documentation** is available, a single IGRA should be done.
 - If TST/IGRA is positive, patient/resident must have a CXR performed as soon as possible.
- TB Symptom Screen and CXR
 - TB symptom screen must be performed upon admission. If an adequate screen cannot be obtained and there is no documentation of CXR within 90 days prior to admission, an admission CXR should be obtained.
 - Persons with TB symptoms (productive cough for greater than 3 weeks, fever, anorexia, weight loss, etc.) must have a CXR performed as soon as possible.
- In the case of an abnormal CXR, the patient/resident must be referred to their healthcare provider for evaluation.
 - The patient/resident will not be allowed admission until s/he is considered not to have infectious TB and provides a medical clearance.
 - If the patient/resident has been admitted to the facility, the resident must be isolated in his/her room with the door closed and be transferred within one working day to a facility with negative pressure isolation rooms. While awaiting transfer, instruct HCWs entering the room to wear an N-95 respirator or a surgical mask if an N-95 respirator is not available. The

resident must wear a surgical mask during transport. Report all suspected or confirmed TB cases to the local health department.

- All patients/residents with a positive TST/IGRA, normal CXR and no history of treatment for LTBI should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

3.3.2 No documented history of TST/IGRA:

- Admission TST/IGRA
 - A two-step TST procedure is required as part of the admission health screening. If IGRA is used, only a single test is required.
 - If TST/IGRA is positive, patient/resident must have a CXR performed as soon as possible.
- TB Symptom Screen and CXR
 - TB symptom screen must be performed upon admission. If an adequate screen cannot be obtained and there is no documentation of CXR within 90 days prior to admission, an admission CXR should be obtained.
 - Persons with TB symptoms (productive cough for greater than 3 weeks, fever, anorexia, weight loss, etc.) must have a CXR performed as soon as possible.
- In the case of an abnormal CXR, the patient/resident must be referred to their healthcare provider for evaluation.
 - The patient/resident will not be allowed admission until s/he is considered not to have infectious TB and provides a medical clearance.
 - If the patient/resident has been admitted to the facility, the resident must be isolated in his/her room with the door closed and be transferred within one working day to a facility with negative pressure isolation rooms. While awaiting transfer, instruct HCWs entering the room to wear an N-95 respirator or a surgical mask if an N-95 respirator is not available. The resident must wear a surgical mask during transport. Report all suspected or confirmed TB cases to the local health department.
- All patients/residents with a positive TST/IGRA and no history of treatment for LTBI should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

3.4 Readmission Screening

- For patients/residents who have been discharged from a facility for less than 90 days:
 - Perform TB Symptom Screen
 - Repeat TST/IGRA, unless previously positive or there is documentation of a TST/IGRA given within the preceding 90 days

- A CXR is required for all patients/residents with symptoms and newly positive TST/IGRA results.
- For patients/residents discharged for longer than 90 days, follow guidance in the appropriate section of Resident Screening Program.

4. Resident Recordkeeping

All TST/IGRA and CXR results should be recorded in the resident's medical record. It is recommended that a separate log also be maintained. This log may be invaluable if a case of active TB is identified and a contact investigation is necessary. The log should be easily retrievable for reference by licensed nurses working in the facility, local health department investigators, and L&C health facility evaluator nurses, and include:

- Resident's name,
- Resident's date of birth,
- Date of admission and discharge,
- Date and results of admission TST (in millimeters of induration) and/or IGRA results,
- Date and results of annual or periodic TST/IGRA results,
- Date and results of the admission chest CXR and any follow-up CXR related specifically to diagnosing active TB disease, and
- Dates and results of sputum smears and cultures, if applicable.
- History of prior LTBI or TB treatment and if available year of this diagnosis, state of diagnosis, medications (dose and duration)

5. HCW Screening Program

The CCR, Title 22, Section 72535 requires that all HCWs working in health care facilities, including LTCFs, be screened for TB within 90 days prior to employment or within seven days after employment and at least annually thereafter by a person lawfully authorized to perform such a procedure.

CAL/OSHA issued an updated Aerosol Transmissible Disease Standard (ATD) in August 2009 requiring all health facilities to establish, implement and maintain an effective written TB exposure control plan which is specific to the work place or operation(s), that is reviewed annually and revised as necessary. (CCR, Title 8, Section 5199, (d) Aerosol Transmissible Diseases Exposure Control Plan). With the goal to protect HCWs against aerosol transmissible diseases, this plan should include the following key elements: name(s) or title(s) of persons(s) responsible for administering the plan, source control plan,

exposure incident procedures, requirements for annual TB screening and medical evaluation, personal protective equipment (PPE) use and availability, airborne isolation room set-up and maintenance, communication, recordkeeping and training requirements. The exposure control plan is to be available to HCWs at all times.

Annual TB screening permits any test approved by FDA and recommended by CDC.

5.1 New HCW TB Symptom Screen Questionnaire

To exclude active disease, all new HCWs (permanent, temporary, and contract staff) must have a TB symptom screen questionnaire completed PRIOR TO the first day of employment. If the questionnaire is positive, (i.e., HCW has one or more unexplained TB related symptoms), the new HCW should be excluded from work until active TB disease is ruled out by a medical evaluation.

5.2 New HCW TST/IGRA

Initial Screening: All HCWs working in the facility are required to have a health examination within 90 days prior to employment or within 7 days after employment.

All TB screening information must be retained in the employee's medical record.

5.2.1 Documented history of positive TST recorded in mm or positive IGRA or history of active TB Disease:

- HCWs with a history of active TB disease must provide documentation of completion of an adequate course of treatment and have medical clearance prior to start of employment.
- No further TST/IGRA is required
- TB Symptom Screen and CXR
 - TB Symptom Screen must be performed prior to employment.
 - CXR must be performed. If the HCW provides a written report of a negative CXR done in the United States within 90 days of hire, a CXR is not necessary.
 - Persons with TB symptoms (productive cough for greater than 3 weeks, fever, anorexia, weight loss, etc.) must have a new CXR performed as soon as possible to rule out active TB disease.
- In the case of an abnormal CXR, the HCW must be promptly referred to their healthcare provider for evaluation. The HCW must not be allowed to work until s/he is determined not to have infectious TB and provides a written medical clearance.
- All HCWs with a positive TST/IGRA, normal CXR and no history of treatment for latent tuberculosis infection (LTBI) should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

5.2.2 Documented history of negative TST/IGRA:

- Employment TST/IGRA
 - TST: If documentation of a previous TST done and recorded in millimeters (e.g. 0 mm) within 12 months of employment is available, a single test will be needed prior to time of hire to eliminate the question of false boosting with future TST's. The single TST is acceptable if done within 90 days prior or 7 days after hire. If no documentation is available, a two-step TST should be done.
 - If the second TST is positive, the HCW should be restricted from working until CXR is obtained and the result is available. In the case of an abnormal CXR, the HCW must be referred to their healthcare provider for further evaluation to rule out TB. The HCW must not be allowed to work until s/he is determined not to be infectious and provides a medical clearance. Report all suspected or confirmed TB cases to the local health department within one working day.
 - IGRA: Only a single IGRA test is required. If documentation of a previous negative IGRA done within 90 days prior to employment is available, no additional IGRA test is needed.
- TB Symptom Screen and CXR
 - TB Symptom Screen must be performed prior to employment.
 - If the HCW has symptom(s) consistent with TB (productive cough greater than 3 weeks, fever, anorexia, weight loss, night sweats, etc.) then a CXR and a medical evaluation to rule out active disease must be completed.
- All HCWs with a positive TST/IGRA, normal CXR and no history of LTBI treatment should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

5.2.3 No documented history of TST/IGRA:

- Employment TST/IGRA
 - TST: A two-step TST procedure is required as part of the health screening.
 - IGRA: Only a single test is required.
 - If the initial TST is negative and the HCW is asymptomatic, the HCW may start working prior to the administration of second TST.
 - If the second TST or single IGRA is positive, the HCW should be restricted from working until a CXR is obtained to rule out active disease.
- TB Symptom Screen and CXR
 - Symptom Screen must be performed prior to employment.
 - Any HCW with TB symptoms (productive cough for greater than 3 weeks, fever, anorexia, weight loss, etc.) must have a CXR performed and a medical evaluation to rule out active disease.

- In the case of an abnormal CXR, the HCW must be referred to their healthcare provider for evaluation. The HCW must not be allowed to work until s/he is determined not to have infectious TB and provides written medical clearance.
- All HCWs with a positive TST/IGRA, normal CXR and no history of treatment for LTBI should be encouraged to see their healthcare provider for evaluation and treatment recommendations.

5.3 Annual HCW Screening Program

TST/IGRA negative HCWs should have a single TST/IGRA and a symptom-screen questionnaire annually by face-to-face interview. TST/IGRA positive HCWs should receive a symptom-screen questionnaire annually by face-to-face interview. If the questionnaire is positive, (i.e., HCW has one or more unexplained symptoms) the HCW must be excluded from work until active TB disease is ruled out by a medical evaluation. An annual CXR for TST/IGRA-negative or asymptomatic TST/IGRA-positive employees is no longer required.

5.4 Post-exposure HCW Screening

Following notification of the local health department (see 3. Reporting Requirements, above), at a minimum, all HCWs who have an exposure to a confirmed case of active pulmonary TB disease must receive a symptom-screen questionnaire. Symptomatic HCWs must have a CXR immediately and be referred for medical evaluation. Asymptomatic TST/IGRA-negative HCWs should be tested as follows:

- If a TST/IGRA was negative within 3 months prior to the last exposure date, test the HCW in 8-10 weeks following the last exposure date.
- If a TST/IGRA was negative greater than 3 months prior to the last exposure date, administer a TST/IGRA as soon as possible. If the new TST/IGRA is negative, repeat the TST/IGRA in 8-10 weeks following the last exposure date.

5.5 HCW TST/IGRA Conversions

HCWs who convert their TST/IGRA from negative to positive during employment must have a symptom-screen questionnaire and a CXR within one week and be promptly referred to a healthcare provider or the local health department for treatment recommendations. Symptomatic HCWs (i.e., HCW has one or more unexplained TB related symptoms) must be excluded from work until active TB disease is ruled out by a medical evaluation.

5.6 HCWs with Suspected or Confirmed Active TB Disease

If the HCW's healthcare provider or the local health department suspects or diagnoses active pulmonary disease, all of the following criteria must be met before the employee returns to work:

- If the HCW was initially AFB smear positive and now has 3 consecutive respiratory specimens that are AFB smear negative, must have completed at least 14 daily doses of treatment for TB, and
- If the HCW was initially and always AFB smear negative, s/he must have completed at least 5 daily doses of treatment for TB, and
- Has 3 consecutive negative AFB sputum smears collected for smear and culture, and
- Exhibits clinical improvement, and
- Has continued, close medical supervision, and
- Adheres to the treatment regimen approved by the local health department, and
- Has written clearance to return to work from the local health department.

6. HCW Training and Education

All HCWs should be trained annually in methods to identify, prevent, and control the transmission of TB. The training should be conducted by a health care professional using current literature such as guidelines published by the CDC or recommendations made by the local health department and the CTCA. (Contact the local health department for train-the-trainer class offerings.) All HCWs should have the opportunity for interactive questions and answers with the person conducting the training session. The training should be appropriate to the education level, literacy skills, and language ability of each employee. Cal/OSHA (CCR, Title 8, Section 3203(a)(7) requires the following topics to be included:

- An accessible copy of the regulatory text of this standard and an explanation of its contents.
- A general explanation of ATDs including the signs and symptoms of Aerosol Transmissible Pathogen (ATPs) or ATP-Laboratories (ATP-Ls) and applicable source control procedures.
- An explanation of the employer's ATD Exposure Control Plan and/or Biosafety Plan, and the means by which the HCW can obtain a copy of the written plan and how they can provide input as to its effectiveness.
- An explanation of the appropriate methods for recognizing tasks and other activities that may expose the HCW to ATPs or ATPs-L.

- An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs or ATPs-L including appropriate engineering and work practice controls, decontamination and disinfection procedures, and respiratory and personal protective equipment (PPE).
- An explanation of the basis for selection of PPE, its uses and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the items of PPEs HCWs will use.
- A description of the employer's TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI.
- Training meeting the requirements of Section 5144(k) of these orders for HCWs whose assignment includes the use of a respirator.
- An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available, and post-exposure evaluation.
- Information on the employer's surge plan as it pertains to the duties that HCWs will perform. As applicable, this training shall cover the plan for surge receiving and treatment of patients, patient isolation procedures, surge procedures of handling of specimens, including specimens from persons who may have been contaminated as the result of a release of a biological agent, how to access supplies needed for the response including PPE and respirators, decontamination facilities and procedures, and how to coordinate with emergency response personnel from other agencies.

7. Retention of Records

7.1 Training Records

Cal/OSHA requires that training records be maintained for a period of not less than 3 years from the date the training occurred. The records should include the employee's name, the dates of training, a summary of the training material, and the name of the professional who provided the training.

7.2 HCW Health Record (Related to Tuberculosis)

Cal-OSHA requires that HCW health records be confidentially maintained for at least the duration of employment plus 30 years in accordance with Section 3204, Access to HCW Exposure and Medical Records Information. The HCW health records related to HCWs TB status should include, but not be limited to, the following:

- The employee's name and any other identifier used in the workplace;

- Date(s) of hire and termination,
- Date (approximate) of BCG vaccination (if applicable),
- Date(s) of TST/IGRA,
- Result(s) of TST in millimeters of induration,
- Copies of result(s) of IGRA tests
- Copies of CXR reports and other diagnostic reports (if applicable),
- Copies of medical recommendations (if applicable), and
- Copies of clearance to return to work (if applicable).
- A copy of all written opinions provided by a physician or other licensed healthcare professional (PLHCP) in accordance with this standard and the results of all TB assessments, and,
- A copy of the information regarding an exposure incident that was provided to the PLHCP as required by subsection (h)(7)(B) of ATD Standard.

References

1. CAL-OSHA ATD Standard – California Code of Regulations, Title 8, Section 5199 Aerosol Transmissible Disease.
2. CDPH/CTCA Guidelines for the Targeted Testing of Latent TB Infection in Adults and Children. Revised 2006. This guideline is available at <http://www.ctca.org>.
3. CDPH/CTCA Contact Investigations Guidelines. 2011. This guideline is available at <http://www.ctca.org>.
4. CDPH/CTCA Guidelines for Source Case Investigation for Latent Tuberculosis Infection. 2011. This guideline is available at <http://www.ctca.org>.
5. CDPH/CTCA Guidelines for the Treatment of Active TB Disease. 4/15/03. This guideline is available at <http://www.ctca.org>.
6. Centers for Disease Control and Prevention. Prevention and control of tuberculosis in facilities providing long-term care to the elderly. MMWR 1990;39 (No RR-10).
7. Centers for Disease Control and Prevention. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health care settings, 2005. MMWR 2005;54(No. RR-17).
8. Centers for Disease Control and Prevention. Guidelines for environmental infection control in health care facilities. MMWR 2003;52(No. RR-10).
9. Guidelines for Using the QuantiFERON-TB Gold Test for Detecting Mycobacterium tuberculosis Infection, United States MMWR 2005; 54 (No. RR-15, 49-55)
10. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection — United States, 2010 MMWR 2010; 59 (RR-5); 1-25
11. CDPH/CTCA Guideline for Interferon Gamma Release Assays Clinical Guidelines in California, 2012.
12. Curry International Tuberculosis Center, medical consultation service: <http://www.currytbcenter.ucsf.edu/index.cfm> (follow link to Medical Consultation) or by phone at 877-390-6682.

Definition of Terms

Acid-fast bacilli (AFB): an AFB examination involves microscopic examination of a stained smear of a patient specimen (usually sputum) to determine if mycobacteria are present. The relative concentration of AFB per unit area on a slide (the smear grade) is associated with infectiousness.

Airborne Infection Isolation Room (AIIR): (formally called a negative pressure isolation room) a single-occupancy room used to isolate persons with suspected or confirmed infectious TB. The room's ventilation system should be designed to provide

- negative pressure in the room (so that air flows under the door gap into the room);
- air flow rate of six to twelve air changes per hour; and
- direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter

BCG: bacille Calmette-Guerin vaccine used in many parts of the world. BCG is rarely used in the United States.

Baseline tuberculin skin test: a TST provided to HCWs or residents to determine if the person was previously infected with *M. tuberculosis*.

Boosted TST reaction: some persons who have had LTBI for many years have a negative reaction on an initial or first TST, followed by a positive (boosted) TST reaction on a subsequent test. This occurs because the immune system has developed decreased ability to recognize the TST material (PPD) over time. See two-step tuberculin skin testing (TST).

Clinical or medical evaluation: an evaluation by a physician or advanced practice practitioner to: (1) diagnose active or latent TB disease, (2) select the appropriate treatment for TB disease, and/or (3) determine if the disease is responding to anti-TB therapy. The evaluation may include the following:

- Medical history and TB symptom review
- Clinical and/or physical examination
- Screening and diagnostic tests (such as tuberculin skin tests, IGRA blood tests, CXRs, bacteriological examination, and HIV testing)
- Counseling
- Treatment referrals

Contact: a person who has been exposed to (shared air space with), (see Exposure, below) a person who has active pulmonary TB disease.

Contact investigation: procedures used to identify and clinically evaluate those exposed to (contacts of, see above) persons with active TB disease, in order to determine if they have been infected and have developed latent or active TB disease.

Converter (TST or IGRA converter): a person whose TST induration increases at least ten millimeters (mm) from less than ten mm to ten mm or greater within a two-year period,

regardless of age. For contacts to a TB case, a TST conversion is defined as a change from less than five mm induration on the initial TST to a reaction of greater than or equal to five mm on the second test.

Converter (Interferon Gamma Release Assay (IGRA)): a person with documented IGRA results that have changed from negative result to positive result within 24 months.

Culture: see Mycobacterium tuberculosis culture.

Exposure: sharing air space with a person with active pulmonary TB disease so that there is an opportunity to inhale air containing M. tb bacteria.

False-negative TST reaction: a negative TST reaction in a person who is infected with M. tb. This can occur because: (1) the immune system has lost the ability to respond (anergy) to the TST material (PPD), (2) the infection occurred recently (within the past eight to ten weeks), or (3) the person is very young (less than six months old) and the immune system is underdeveloped.

False-positive TST reaction: a positive TST reaction in a person who is not infected with M. tb. This is generally caused by (1) infection with a nontuberculosis Mycobacterium species (e.g., M avium complex, M kansasii) or (2) previous vaccination with BCG. However, the TST cannot distinguish between these different Mycobacterium species.

Healthcare Worker: HCWs refer to all paid and unpaid persons working in health care settings who have the potential for exposure to M. tuberculosis through air space shared with persons with infectious TB disease. Part time, temporary, contract, and full-time HCWs should be included in TB screening programs. All HCWs who have duties that involve face-to-face contact with patients with suspected or confirmed TB disease (including transport staff) should be included in a TB screening program. For a complete list of who to include, refer to Centers for Disease Control and Prevention, Guidelines for preventing the transmission of Mycobacterium tuberculosis in health care settings, 2005. MMWR 2005;54(No. RR-17).

HEPA filter respirator (mask): a mask used to reduce to number of M. tb infectious particles inhaled by a health care worker.

High efficiency particulate air (HEPA) filter: a filter that removes particles in the size range that contain the M. tb bacterium.

Human immunodeficiency virus (HIV) infection: infection with the virus that causes acquired immunodeficiency syndrome (AIDS). HIV infection is the most important risk factor for the progression from LTBI to active TB disease.

Immunosuppression: a condition in which the immune system is functioning less effectively than normal. Immunosuppressed individuals are at increased risk of rapidly progressing from LTBI to active TB disease. The most common causes of immunosuppression are diseases such as HIV/AIDS and the administration of drugs such as steroids (e.g., prednisone) and cancer chemotherapy.

Index case: a person with active disease who is identified as the first case and who may be a source of exposure to others.

Induration: swelling that can be palpated (felt) at the TST injection site; the reaction size is the diameter of the indurated (swollen) area excluding redness and is measured in millimeters of induration.

Infectious: having the potential to cause transmission to other persons.

Interferon Gamma Release Assays (IGRA): a test on whole blood that detects an immunologic response to *Mycobacterium tuberculosis* infection by measuring the release of interferon-gamma from leukocytes in response to exposure to M. tb antigens.

Intradermal: TST is injected within the dermal layers of the volar aspect of the forearm skin.

Isolation: the separation of persons with active disease from other persons to prevent transmission, such as the placement of a person in a separate private room. In a health care facility this is usually accomplished by placing the patient in an Airborne Infection Isolation Room (AIIR) (see above).

Latent tuberculosis infection (LTBI): a condition in which living M. tb bacteria are present in the body without producing disease. Persons with LTBI are not contagious, have no symptoms, and generally have a positive TST.

Mantoux tuberculin skin test: (see tuberculin skin test below).

Mycobacterium tuberculosis (M. tb): the name of the bacterium that causes tuberculosis.

Mycobacterium tuberculosis culture: a laboratory test to determine the presence of *Mycobacterium tuberculosis*. A positive culture confirms the diagnosis of TB disease.

Negative pressure isolation room: see Airborne Infection Isolation Room (AIIR).

Nucleic Acid Amplification test (NAAT): a laboratory method used to target and amplify a single deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence for detecting and identifying (typically) a microorganism. NAATs for *M. tuberculosis* complex are sensitive and specific; they can accelerate confirmation of pulmonary TB disease. NAAT can be used as a diagnostic test for tuberculosis.

Purified protein derivative (PPD): a commercial preparation of TST antigen.

QuantiFERON-TB-Gold(Qiagen.)*: is a commercial in vitro blood test to detect M. tb infection.

Reactor: a person with a positive TST.

Smear: (also acid-fast bacilli [AFB] smear) a laboratory test that is done to determine if the Mycobacterium species bacteria are visible in sputum (or other material) with a microscope.

Sputum: material that is coughed up from deep within the lungs (not saliva or nasal secretions). Sputum induction is a medical procedure used to obtain sputum from a patient who is unable to cough up a specimen spontaneously. Adequate sputum collection for assessing patient infectiousness (except for MDR_TB), sputum specimens will be collected at least 8 hours apart. At least one should be early AM, induced, and broncho-alveolar lavage, or collected post-bronchoscopy.

Transmission: the way in which a disease, or a disease-causing organism such as M. tb, is spread from one person to another. M. tb is spread from one person to another through the air when a person with active disease coughs, sings, shouts, or speaks.

T-Spot(Oxford Immunotec)*: a commercial blood test to detect M. tb infection.

Tuberculin skin test (TST): the intradermal injection of purified protein derivative (PPD) into the dermis of the skin for the purpose of detecting LTBI. The TST is performed using the Mantoux method of injecting five (0.1 cc) tuberculin units (TU) of protein purified derivative (PPD) into the volar aspect (palm side) of the dermis of the forearm. The currently available commercial solutions are Aplisol and Tubersol.*

TB disease (active TB disease): clinically active disease caused by M. tb. Persons who have active TB usually have symptoms, and about 80 percent have a positive TST. TB disease of the lungs or larynx can be transmitted when a person with the disease coughs, sings, laughs, speaks, or breathes.

Tuberculosis infection: M. tb bacteria are present in the individual without producing symptoms of disease; the infected person generally has a positive TST and a normal chest x-ray. The infection may be recent or may have been present for a long period of time.

Two-step TST: a series of two TSTs done one to three weeks apart if the first test is negative.

* The use of commercial names is not an endorsement of a product.

Appendix A Sample Tuberculosis Symptom-Screen Questionnaire

Name: _____	Date questionnaire administered: _____
Employee: YES NO	Resident: YES NO
New employment date: _____	Admission Date: _____
Healthcare worker ID number: _____	Resident medical record number: _____

1. In the last year, have you had any of the following symptoms?
YES NO
 Coughing up blood
 Hoarseness lasting three weeks or more
 Persistent cough lasting three weeks or more
 Unexplained, excessive fatigue
 Unexplained, persistent fever lasting three weeks or more
 Unexplained, excessive sweating at night
 Unexplained weight loss
2. Have you ever been told by a doctor or other health care provider that you have TB?
 Yes No Don't Know
3. Have you ever been treated for active TB?
 Yes No Don't Know
4. Have you ever been treated for latent TB infection (a positive skin test or blood test for TB)?
 Yes No Don't Know
5. Have you ever had the BCG vaccine?
 Yes No Don't Know
6. Have you ever been told by a doctor or other health care provider that your immune system is not working right or that you cannot fight infection?
 Yes No Don't Know
7. Have you had pneumonia in the past year?
 Yes No Don't Know
8. Have you ever lived with or had close contact with someone who has/had active tuberculosis disease?
 Yes No Don't Know
9. Have you ever been told that you have an abnormal chest x-ray?
 Yes No Don't Know
10. Have you ever worked where patients with active tuberculosis disease receive care or services?
 Yes No Don't Know
11. Have you ever worked, volunteered, or lived in any institution such as a jail, group home, or homeless shelter?
 Yes No Don't Know
12. Have you ever traveled outside the United States?
 Yes No If yes, identify city, country and approximate year: _____
13. Were you born in the United States?
 Yes No If no, identify country you were born in: _____

Appendix B

Category		Symptom screen	Tuberculin Skin Test (TST)*	IGRA*	Chest X-Ray (CXR)
Resident	New Admission	Upon Admission	Upon admission unless documentation of prior positive TST which requires an admission CXR be performed. (See CXR column) 2-Step TST required unless documentation of negative TST result within prior 12 months, then only 1 TST required upon or within 90 days of admission	Upon admission a single IGRA is needed unless documentation of a prior positive IGRA which requires an admission CXR be performed. No IGRA required if documentation of prior negative test results done within 90 days prior to admission date is available.	Immediate if has TB symptoms upon screen. Within 90 days prior to admission if (1) a history of active TB, (2) a history of positive TST/IGRA, (3) admission TST/IGRA is positive, or (4) adequate symptom-screen questionnaire cannot be obtained. None if TST/IGRA negative
	Annual	Annually	Annually, if last TST was negative.	Annually, if last IGRA was negative.	Not routinely required. Immediate if TB symptoms upon screen or within 7 days if resident has TST/IGRA conversion.
Employee Healthcare Worker (HCW)	New Hire	Complete on first day of employment	Upon hire unless documentation of prior positive TST which requires a CXR be performed. (See CXR column) 2-Step required unless documentation of negative TST result within prior 12 months, then only 1 TST required upon or within 90 days prior or 7 days after hire date.	Upon hire a single IGRA is needed unless documentation of a prior positive IGRA which requires a CXR be performed. No IGRA required if documentation of prior negative test results done within 90 days prior to or 7 days after hire date is available	Immediate, if has TB symptoms upon screen. Within 90 days prior to or within 7 days after hire if: (1) a history of active TB, (2) a history of positive TST/IGRA, (3) admission TST/IGRA is positive, or (4) adequate symptom-screen questionnaire cannot be obtained None if TST/IGRA negative.
	Annual	Annually	Annually, if last TST was negative.	Annually if last IGRA was negative.	None routinely Immediate if TB symptoms upon screen or within 7 days if HCW has TST/IGRA conversion.
HCW and Resident Post-Exposure		After exposure to "infectious" active TB disease	If TST negative less than 90 days prior to last exposure date, repeat single TST in eight to ten weeks after last exposure date. If TST negative greater than 90 days after last exposure date, do new baseline TST and a second TST eight to ten weeks after the exposure ended.	If IGRA negative less than 90 days prior to last exposure date, repeat IGRA in eight to ten weeks after last exposure date. If IGRA negative greater than 90 days after last exposure date, obtain new baseline IGRA and a second IGRA eight to ten weeks after the exposure ended.	Immediate, if symptomatic

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Louise McNitt, MD, MPH, TB Controller, San Bernardino County Department of Public Health

Cynthia Haines, PHN, MA, TB Program Manager, TB Prevention and Control Program, Santa Clara Public Health Department

Barbara Cole, RN, PHN, MSN, TB Controller, Program Manager, Private Provider Liaison, and Director, Disease Control, Riverside County Department of Public Health

Lisa Goozé, MD, TB Controller, San Mateo County Health System

Jan Young, RN, MSN, Program Development Section, Chief, CA Department of Public Health

Rebecca Siiteri, RN, MPH; Dr. Kavita Trivedi, Healthcare Associated Infections Program, California Department of Public Health

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Robert Benjamin, MD, MPH, TB Controller, Medical Director and Private Provider Liaison, Alameda County Public Health Department

Sarah Royce, MD, MPH, Chief TB Control Branch, California Department of Public Health

John Rosenberg, MD, CA Department of Public Health, Infectious Diseases Branch

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