



California
Department of
Health Services

SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

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TO: GENERAL ACUTE CARE HOSPITALS
ACUTE PSYCHIATRIC HOSPITALS
SKILLED NURSING FACILITIES
INTERMEDIATE CARE FACILITIES
HOME HEALTH AGENCIES
PRIMARY CARE CLINICS
PSYCHOLOGY CLINICS
INTERMEDIATE CARE FACILITIES FOR THE DEVELOPMENTALLY
DISABLED
INTERMEDIATE CARE FACILITIES/DEVELOPMENTALLY DISABLED-
HABILITATIVE
PSYCHIATRIC HEALTH FACILITIES
ADULT DAY HEALTH CENTERS
CHEMICAL DEPENDENCY RECOVERY HOSPITAL

SUBJECT: PROCEDURE FOR REQUESTING PROGRAM FLEXIBILITY FOR THE
USE OF QUANTIFERON-TB GOLD BLOOD TEST TO IDENTIFY
LATENT MYCOBACTERIUM TUBERCULOSIS INFECTION IN
CALIFORNIA HEALTHCARE WORKERS

What is QuantiFERON – TB Gold?

For many years the tuberculin skin test (TST) or PPD has been the basic screening test for detecting latent tuberculosis infection (LTBI) in healthcare workers. Limitations include the need to measure the response (induration) within 48-72 hours after the application of the TST as well as inaccuracies and errors in determining if the response meets the definition of a positive TST. In 2005, the Food and Drug Administration approved an in vitro laboratory diagnostic test to diagnose LTBI. Guidelines for using QuantiFERON – TB Gold are available from the Centers for Disease Control and Prevention (CDC) at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm>.

Use of a blood test for screening healthcare workers for LTBI requires a grant of program flexibility from the California Department of Health Services, Licensing and

Certification, since the TST is required by regulation (California Code of Regulations, Title 22, all chapters – see below). Use of QuantiFERON – TB Gold for screening patients, residents or clients on admission to a health care facility does not require program flexibility because the test method is not specified in the regulation. Therefore the facility may choose either the QuantiFERON – TB Gold or the TST for patient, resident and client LTBI screening.

Requirements for Submitting a Request for Program Flexibility to Use QuantiFERON – TB Gold

1. The facility must submit a letter to the Licensing and Certification district office with jurisdiction over the facility signed by the hospital administrator or designee requesting that program flexibility be granted for the use of QuantiFERON –TB Gold for LTBI healthcare worker screening.
2. The facility must submit a policy specifying that QuantiFERON – TB Gold is to be used for screening healthcare workers for LTBI. The policy must comply with current standards of practice for LTBI screening as defined by the California Occupational Safety and Health Administration (Cal-OSHA) for new employee, annual and post-exposure testing. The policy must stipulate that QuantiFERON – TB Gold will be used exclusively for new employee LTBI screening or, in addition, the test will also be used for annual and post-exposure screening.
3. The policy must include a statement that employees will be informed in writing of the limitations of using QuantiFERON – TB Gold as defined by most current recommendations by the Centers for Disease Control and Prevention (CDC) or the California Tuberculosis Controllers Association (if applicable). The CDC currently identifies the following limitations:
 - (a) As with a negative TST result, negative QuantiFERON – TB Gold results should not be used alone to exclude *M. tuberculosis* infection in persons with symptoms or signs suggestive of TB disease. The presence of symptoms or signs suggestive of TB disease increases the likelihood that *M. tuberculosis* infection is present, and these circumstances decrease the predictive value of a negative QuantiFERON – TB Gold or TST result. Medical evaluation of such persons should include a history and physical examination, chest radiograph, bacteriologic studies, serology for human immunodeficiency virus (HIV), and, when indicated, other tests or studies.
 - (b) The performance of QuantiFERON – TB Gold, in particular its sensitivity and its rate of indeterminate results, has not been determined in persons who, because of impaired immune function, are at increased risk for *M. tuberculosis* infection progressing to TB disease. Impaired immune function can be caused by HIV infection or acquired immunodeficiency syndrome (AIDS); current treatment with immunosuppressive drugs including high-dose corticosteroids, tumor necrosis factor-alpha (TNF-a) antagonists, and drugs used for managing organ transplantation; selected hematologic disorders (e.g., myeloproliferative disorders, leukemias, and lymphomas); specific malignancies (e.g., carcinoma of the head, neck, or lung); diabetes; silicosis; and chronic renal failure.

Each of these conditions or treatments is known or suspected to decrease responsiveness to the TST, and they also might decrease production of IFN-g in the QFT-G assay. Consequently, as with a negative TST result, negative QuantiFERON – TB Gold results alone might not be sufficient to exclude *M. tuberculosis* infection in these persons.

(c) Published data are relatively limited concerning the use of QuantiFERON – TB Gold among persons recently exposed to TB (e.g., contacts) and other populations at high risk for LTBI. No published data document the performance of QFT-G in children aged <17 years.

(d) With any of the testing methods, persons who have a negative test result can still have LTBI. Those who have a negative result but who are likely to have LTBI and who are at greater risk for severe illness or poor outcomes if TB disease occurs might need treatment or closer monitoring for disease. Potential examples include close contacts who are aged <5 years, those who are immunocompromised because of HIV infection, or those who will undergo treatment with TNF-a antagonists (which increase the risk for progression from LTBI to TB disease)”.

For questions regarding this letter, please contact Patricia DeWan-Duran at (916) 440-7360.

Sincerely,

Original Sign by Patricia DeWan-Duran for Brenda Klutz

Brenda G. Klutz
Deputy Director

Attachment

ATTACHMENT

The following Title 22 chapters require the use of the TST (PPD) for screening employees for LTBI

Chapter 1. General Acute Care Hospitals.
§ 70723. Employee Health Examinations and Health Records.

(b)(1) Initial examination for tuberculosis shall include a tuberculin skin test using the Mantoux method using a 5 Tuberculin Unit dose of PPD tuberculin stabilized with Tween-80, the result of which is read and recorded in millimeters of induration. If the result is positive, a chest film shall be obtained. A skin test need not be done on a person with a documented positive reaction to PPD but a baseline chest X-ray shall be obtained

Chapter 2. Acute Psychiatric Hospitals.
§71523. Employee Health Examinations and Health Records.

(b) A health examination performed under the direction of a physician shall be required as a requisite for employment and must be performed within one week after employment. Written examination reports signed by the physician which verify that employees are able to perform assigned duties shall be maintained. Repeat examinations shall be performed whenever necessary to ascertain that employees are free from symptoms indicating the presence of an infectious disease and are able to perform their assigned duties. Upon initial examination, and at least annually, the employee shall have a skin test for tuberculosis using Purified Protein Derivatives intermediate strength or a chest X-ray. Positive reactions to the skin test shall be followed by a 35.56 cm x 43.18 cm (14 "x 17") chest X-ray.

Chapter 3. Skilled Nursing Facilities.
§ 72535. Employees' Health Examination and Health Records.

(b) The initial health examination and subsequent annual examination shall include a purified protein derivative intermediate strength intradermal skin test for tuberculosis. A chest X-ray is indicated if the employee has previously had a positive reaction to a tuberculosis skin test or is currently being treated for tuberculosis. Positive reaction to the skin test shall be followed by a 35.56 cm x 43.18 cm (14 " x 17 ") chest X-ray. Evidence of tuberculosis screening within 90 days prior to employment shall be considered as meeting the intent of this Section.

Chapter 4. Intermediate Care Facilities.
§73525. Employees' Health Examination and Health Records.

(b) The initial health examination and subsequent annual examination shall include a protein purified derivative intermediate strength intradermal skin test for tuberculosis or a chest X-ray. Positive reaction to the skin test shall be followed by a 35.56cm x 43.18cm (14" x 17") chest X-ray.

Chapter 6. Home Health Agencies.
§74723. Employee's Health Examinations and Health Records.

(d) An employee shall not be required to undergo the tuberculosis screening requirements of (b)(3) if a physician certifies in writing that neither a skin test nor a chest x-ray needs to be performed as a prerequisite of employment, and the rationale for such an exemption is in accordance with applicable federal, state and local requirements and established professional standards.

Chapter 7. Primary Care Clinics.
§75051. Health Examinations and Health Records of Persons Working in the Clinic.

(b) The initial health examination and subsequent annual examination shall include a protein purified derivative intermediate strength intradermal skin test for tuberculosis or a chest X-ray. Positive reaction to the skin test shall be followed by a 35.56cm x 43.18cm (14" x 17") chest X-ray. Evidence of tuberculosis screening with 12 months prior to employment shall be considered as meeting the intent of this regulation.

Chapter 7.2. Psychology Clinics.
§75335. Employee Health Examinations and Health Records.

(a) The initial health examination shall include a tuberculosis screening test consisting of a purified protein derivative intermediate strength intradermal skin test and a chest X-ray if the skin test is positive. The psychology clinic shall establish a policy regarding subsequent health examinations and tuberculosis screening tests based on an assessment of the following:

Chapter 8. Intermediate Care Facilities for the Developmentally Disabled.
§76539. Employee' Health Examination and Health Records.

(b) The initial health examination and subsequent annual examination shall include a protein purified derivative intermediate strength intradermal skin test for tuberculosis or a chest X-ray. Positive reaction to the skin test shall be followed by a 35.56cm x 43.18cm (14" x 17") chest X-ray.

Chapter 8.5. Intermediate Care Facilities/Developmentally Disabled – Habilitative.
§76919. Employees' Health Examination and Health Records.

(b) At the time of employment, testing for tuberculosis shall consist of a purified protein derivative intermediate strength intradermal skin test. If a positive reaction is obtained from the skin test, the employee shall be referred to a physician to determine if a chest X-ray is necessary. Annual examinations shall be performed only when medically indicated.

Chapter 9. Psychiatric Health Facilities.
§77121. Employee Health Examinations and Health Records.

(b) The initial health examination shall include a tuberculosis screening test consisting of a purified protein derivative intermediate strength intradermal skin test and a chest X-ray if the skin test is positive. The facility shall establish a policy regarding subsequent health examinations and tuberculosis screening test based on an assessment of the following:

Chapter 10. Adult Day Health Centers.
§78429. Employee Records.

(b) Each employee record shall contain at least the following:

(A) A chest X-ray or purified protein derivative intermediate strength test performed not more than 12 months prior to employment or with 7 days of employment.

Chapter 11. Chemical Dependency Recovery Hospital Licensing Regulations.
§79331. Employee Health Examinations and Health Records.

(b) A health examination performed by a person lawfully authorized to perform such an examination shall be required as a prerequisite for employment and shall be performed within one week after employment. The written health examination shall be signed by the person performing the examination and shall verify that the employee is able to perform assigned duties and is free from symptoms indicating the presence of an infectious disease. Repeat health examinations shall be performed whenever necessary to ascertain that employees continue to be free of symptoms indicating the presence of an infectious disease and are able to perform their assigned duties. Upon initial examination, and at least annually, the employee shall have a skin test for tuberculosis using purified protein derivatives, intermediate strength or a chest x-ray. Positive reactions to the skin test shall be followed by a 35.56cm x 43.38cm (14" x 17") chest x-ray.

Chapter 12. Correctional Treatment Centers.
§79795. Employee Health Examinations and Health Records.

(b) The initial health examination shall include a tuberculin skin test using the Mantoux method using a 5 Tuberculin Unit dose of Purified Protein Derivative (PPD) stabilized with Tween-80, the result of which is read and recorded in millimeters of induration. If the result is positive, a chest film shall be obtained. A tuberculin skin test need not be done on a person with a documented positive reaction to PPD but a baseline chest X-ray shall be obtained.