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

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN, JR.
Governor

April 22, 2013 AFL 13-08

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 for the Developmentally Disabled - Habilitative
Psychiatric Health Facilities
Adult Day Health Centers
Chemical Dependency Recovery Hospitals

SUBJECT: Nationwide Shortage of Tuberculin Skin Test Antigens

The California Department of Public Health (CDPH) has recently been made aware of a nationwide shortage of Tuberculin Skin Test Antigens. In an effort to adapt to this shortage, this All Facilities Letter (AFL) is being issued so that health facilities may request program flexibility for the use of an alternate method for testing.

CDPH has developed proposed regulations that allow for the use of any test for tuberculin infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA). These regulations have been submitted to the Office of Administrative Law (OAL) for final review. In the meantime, attached is a template letter for health facilities to use to request program flexibility from the District Offices. In light of the current situation the District Offices will do their best to expedite these program flexibility requests.

For additional information regarding the shortage of Tuberculin Skin Test Antigens and CDC recommendations for addressing the shortages of tuberculin skin test antigens, please visit the CDC Health Alert Network at:

http://emergency.cdc.gov/HAN/han00345.asp

One of the recommendations of the CDC to address the shortage is to substitute the Interferon Gamma Release Assay (IGRA) blood tests to identify tuberculosis (TB). The Clinical Guidelines for IGRA in California can be found at:

http://www.ctca.org/fileLibrary/file_374.pdf

Please contact your local District Office if you have further questions.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality

Attachment

Template for Requesting Program Flexibility to Screen Health Care Workers with IGRA

Letterhead of your Organization

Date

(Name), District Administrator

California Department of Public Health (CDPH), Licensing & Certification (L&C)

(Address of the CDPH L&C District Office for your county)

Subject: Expedited Request for Program Flexibility for the Use of Interferon Gamma Release Assay (IGRA) Blood Tests to Identify Tuberculosis (TB) Infection in Health Care Workers

Dear (name):

(Name of your Facility) is requesting program flexibility for Section XXXX in Title 22, California Code of Regulations, to use Interferon Gamma Release Assay (IGRA) blood tests to detect tuberculosis infection in health care staff. IGRAs, approved by the federal Food and Drug Administration (FDA) and recommended by the Centers for Disease Control & Prevention (CDC), are QuantiFERON ® – TB Gold-In- Tube (QFT-GIT) manufactured by Qiagen and T-Spot ® manufactured by Oxford Immunotech Limited.

Current policy states that IGRA will only be used to screen for TB infection as follows:

(Mark all that apply)

____New employee screening

____Annual screening for employees with prior documented negative TB test

____Post-exposure screening for employees with prior documented negative TB test

Additionally, facilities are expected to be aware of the limitations for the use of IGRA in accordance with the most recent recommendations of the CDC (MMWR; 59 [No. RR-5]: 1-25) as well as recommendations of the California TB Controllers Association. Employees will be informed in writing of these limitations.

Due to an acute nationwide shortage of TB skin testing product we ask that program flexibility be granted as soon as possible.

Signature & Title of Facility Administrator