



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH**

Steven L. Beshear
Governor

275 East Main Street, HS2GW-C
Frankfort, Kentucky 40621
(502) 564-3261
(502) 564-9626 Fax
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary

October 8, 2013

Dear Health Care Facility Operator or Long Term Care Administrator:

Employee health programs at health care facilities and long term care facilities (LTCFs) continue to be impacted by the nationwide shortages of some medications used in tuberculosis (TB) infection control programs. Shortages of some formulations of Tubersol® brand of Tuberculin Purified Protein Derivative (tuberculin), which is used for tuberculin skin tests (TSTs), may not be resolved before 2014.

A blood assay for *Mycobacterium tuberculosis* (BAMT) is a recommended option for TB testing in health care facilities and LTCFs during the tuberculin shortage. The QuantiFERON®-TB Gold In-Tube test and the T-SPOT®.TB test are the two BAMTs marketed in the United States. Both tests are interferon-gamma release assays (IGRAs). An IGRA may be used in place of, but not in addition to, a TST in all situations in which CDC recommends tuberculin skin testing as an aid to diagnosing *M. tuberculosis* infection, with preferences and special considerations noted in the full text of the 2010 Centers for Disease Control and Prevention (CDC) Guidelines about IGRAs, <http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf>. The attached joint letter from the Department for Public Health and Office of Inspector General, dated February 2013, also has additional information for health care facilities and or LTCFs that elect to use BAMTs in lieu of TSTs for TB screenings, as well as guidelines from CDC about tuberculin for TB screening in health care settings.

The two BAMT tests are not identical. Healthcare facilities and LTCFs should critically compare both products based upon test price, amounts of blood drawn for testing, and other steps needed in the BAMT testing process. BAMT test costs are directly related to test volume; the price for the laboratory test rapidly declines when larger numbers are tested. For your convenience, please see contact information below for BAMT representatives.

QuantiFERON®-TB Gold In-Tube test
Brad Gosky
Manager, Sales, Great Lakes Region
Cellestis, a QIAGEN company
661-414-9064
Brad.Gosky@qiagen.com
www.quantiferon.com
www.qiagen.com

T-SPOT®.TB test
Mark Honore
Territory Manager NC, KY
Oxford Immunotec
616-540-2782
MHonore@oxfordimmunotec.com
www.tspot.com

Dear Health Care Facility Operator or Long Term Care Administrator:
October 8, 2013
Page 2

To continue TB screening in your facility during this ongoing tuberculin shortage, the Kentucky Tuberculosis Program **DOES** recommend the following:

- Substitute the BAMT for a TST, per CDC guidelines, if feasible.
- Allocate Tubersol for priority use for TB cases, TB suspects and contact investigations.
- Stagger serial TB testing throughout the year for those employees or residents required to have TSTs or BAMTs, so that some TB testing occurs each month.

The Kentucky Tuberculosis Program **DOES NOT** recommend:

- That health care facilities or long term care facilities experiencing shortages of Tubersol switch to Aplisol®, the other brand of tuberculin marketed in the United States. CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005," <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>, recommended that "TB screening programs should use one antigen consistently and should realize that changes in products might make serial changes in TST results difficult to interpret. In one report, systematic changes in product use resulted in a cluster of pseudoconversions that were believed to have erroneously indicated a health-care-associated outbreak."
- Deferment of any health care facility or LTCF resident or employee required to have TB screening per existing state regulations, such as new hires, employees who have annual testing, new residents in LTCFs, or residents in LTCFs who have annual testing.

One specific special consideration when using either TSTs or BAMTs occurs during a TB contact investigation. Repeat testing with the same test format will minimize the number of conversions that occur as a result of test differences. Additionally, the local health department should be notified when a TB contact investigation is needed in health care facilities and long term care facilities.

Please contact the Kentucky TB Prevention and Control Program at 502-564-4276 if you or your staff have questions about TB screening, TSTs, or BAMTs.

Sincerely,



Robert L Brawley, MD, MPH, FSHEA
Chief, Infectious Disease Branch
Division of Epidemiology and Health Planning

Cc: Kraig Humbaugh, MD, MPH
Maria Dalbey, RN, BSN, MA, MBA
Emily Anderson, RN, BSN
Mary Reinle Begley (OIG)
Connie Payne (OIG)



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275 East Main Street, HS1GWA
Frankfort, Kentucky 40621
502) 564-3970
(502) 564-9377
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary

February 19, 2013

Dear Health Care Facility Operator or Long Term Care Administrator:

Health care facility and long term care facility employee health programs may be impacted by two nationwide shortages of medications used in your Tuberculosis (TB) Infection Control Program. First, the Centers for Disease Control (CDC) announced a nationwide shortage of 300 mg isoniazid (INH) tablets in the MMWR issue of December 21, 2012, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6150a4.htm?s_cid=mm6150a4_w. Since that time, shortages of 100 mg INH tablets have also been reported. These INH shortages may not be resolved before late March 2013. Second, in late January 2013, the Association of Health System Pharmacists announced shortages of some formulations of Tubersol[®] brand of Tuberculin Purified Protein Derivative (tuberculin) produced by Sanofi Pasteur that is used for tuberculin skin tests (TSTs). The Tubersol shortage may also not be resolved before late March 2013, <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=973>.

The Kentucky Tuberculosis Program does not recommend that health care facilities or long term care facilities experiencing shortages of Tubersol switch to Aplisol[®], the other brand of tuberculin marketed in the United States. CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005," <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>, recommended that "TB screening programs should use one antigen consistently and should realize that changes in products might make serial changes in TST results difficult to interpret. In one report, systematic changes in product use resulted in a cluster of pseudoconversions that were believed to have erroneously indicated a health-care-associated outbreak." The shortage of INH that can be used to treat either active TB disease or latent TB infection diagnosed during TB screening would further magnify the impact of any false-positive test results or pseudoconversions on your employee health programs.

A Blood Assay for *Mycobacterium tuberculosis* (BAMT) would be another option for TB screening in health care facilities and long term care facilities and would remove some of the administrative and logistic problems associated with using tuberculin. The QuantiFERON[®]-TB Gold In-Tube test and the T-SPOT[®].TB test are the two BAMTs marketed in the United States, and both those tests are interferon-gamma release assays (IGRAs). In 2010, CDC recommended in "Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection – United States, 2010," <http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf>, that "An IGRA may be used in place of (but not in addition to) a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing *M. tuberculosis* infection, with preferences and special considerations noted [in those guidelines]. . . Despite the indication of a preference in these instances, use of the alternative test (FDA-approved IGRA or TST) is acceptable medical and public health practice."



Dear Health Care Facility Operator or Long Term Care Administrator
February 19, 2013
Page 2

A CDC Fact Sheet titled "TB Elimination: Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection," lists advantages and disadvantages of these tests and is available online, <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf>.

Presently, BAMTs (IGRAs) are not listed as TB screening options in Kentucky regulations for health care facilities and long term care facilities. Regulation changes have been drafted to permit health care facilities and long term care facilities to use either TSTs or BAMTs (IGRAs) for TB screening, and the Cabinet anticipates that those changes should be submitted to the Legislature in April, 2013.

Additionally, the Office of Inspector General will not cite any health care facility or long-term care facility in violation of regulatory requirements for skin testing if the facility elects to use BAMTs in lieu of TSTs for TB screening. This policy is consistent with forthcoming regulatory changes and is effective as of the date of this letter.

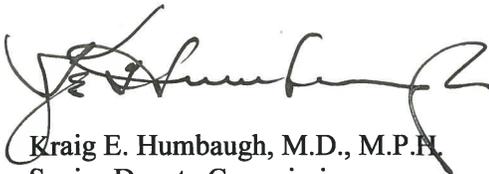
The Kentucky Department for Public Health and the Office of Inspector General hope that the information provided in this letter will aid your employee health programs.



Stephanie Mayfield Gibson, MD, FCAP
Commissioner
Department for Public Health



Mary Reine Begley
Inspector General
Cabinet for Health and Family Services



Kraig E. Humbaugh, M.D., M.P.H.
Senior Deputy Commissioner
State Epidemiologist
Department for Public Health