Tuberculin Skin Testing (TST)

I. **TITLE:** Procedure for administering, reading, and interpreting Mantoux tuberculin skin tests to detect infection with *M. tuberculosis*.

II. **TYPE OF STANDARD:** Service

III. **OUTCOME**:

1. To ensure that only persons with a valid risk to progress from TB infection to disease are tuberculin skin tested.
2. To ensure that the Mantoux tuberculin skin test is applied consistently and correctly to every client.
3. To ensure that clients' skin test reactions are read and interpreted correctly.
4. To ensure that clients requiring further evaluation are referred to the appropriate providers of care.

IV. **PERSONNEL:** The following subsections address the classes of personnel who may perform the referenced activities within the constraints of their practice acts, job descriptions, and protocols.

1. Assessment of Risk: M.D., D.O., A.R.N.P., P.A., R.N., and L.P.N.
2. Preparation/Interviewing/Counseling/Education: M.D., D.O., A.R.N.P., P.A., R.N., L.P.N., and Health Service Representatives (H.S.R.)
3. Administration of the Mantoux Tuberculin Skin Test: M.D., D.O., A.R.N.P., P.A., R.N., L.P.N., and H.S.R.
4. Reading Mantoux TSTs: M.D., D.O., A.R.N.P., P.A., R.N., L.P.N, and H.S.R.
5. Interpretation: M.D., D.O., A.R.N.P., P.A., R.N., and L.P.N.
6. Referral: M.D., D.O., A.R.N.P., P.A., R.N., L.P.N., and H.S.R.
7. Emergency: M.D., D.O., A.R.N.P., P.A., and R.N.
8. Documentation: M.D., D.O., A.R.N.P., P.A., R.N., L.P.N., and H.S.R.

V. **COMPETENCIES:** Health care professionals and para-professionals must demonstrate knowledge, judgment, and performance of Mantoux tuberculin skin testing and related responsibilities according to the constraints of their individual practice acts, job descriptions, and protocols. Professional and para-professional personnel records should contain documentation of training as appropriate for their individual practice acts. This should include didactic, practicum, and clinical training; which cover pharmacology, clinical studies, identification of client risk, counseling, case management, and complications and side effects of medications. A nurse who has successfully completed the Tuberculin Skin Test (TST) Certification Course or the TST Train-the-Trainer Certification Course should certify each health care professional. The practitioner may practice independently in each skill area once proficiency is attained and documented in that skill area.

VI. **AREAS OF RESPONSIBILITY:**

1. Assessment of Risk
   a. The Mantoux tuberculin skin test is currently the best available test for detecting *M. tuberculosis* infection. However, the TST has significant

diagnostic value only in clients with **identifiable risk factors** for underlying TB infection or disease. (See *TA Guideline TB 3: Targeted Testing and Treatment of Latent TB Infection (LTBI)* for risk factors*).*

b. Persons with no identifiable risk factors for TB infection or disease should not be Mantoux tuberculin skin tested because many reactions will be false positives due to non-tuberculosis mycobacteria, e.g. *M. kansasii*.

2. Selection of the Appropriate TST:
   a. The Purified Protein Derivative (PPD) tuberculin skin test using the Mantoux method is the standard method for identifying persons infected with tuberculosis.
   b. Multiple puncture tests (e.g. tine tests) should not be used to identify persons with tuberculosis infection or disease. These tests are not standardized.

3. Storage precautions for PPD antigen:
   a. Date each PPD vial when opened and discard PPD vials 30 days after opening.
   b. Keep PPD vials refrigerated at all times or in a cooler with ice packs.
   c. Keep PPD vials protected from light. If the vial is exposed to light for extended or unknown period of time, it should be discarded.
   d. If PPD vial is accidentally frozen, it should be discarded.
   e. When a vial must be discarded, discard it following local county health department (CHD) protocol.

4. Administration precautions for PPD antigen:
   a. Do not draw PPD antigen into syringes until ready to administer.
   b. Never transfer PPD from one vial to another vial.
   c. Avoid administering PPD antigen to documented positive TST reactors as the severity of the reaction may increase.
   d. Avoid injecting PPD antigen subcutaneously. A general febrile reaction or acute inflammation around prior TB lesions may occur.
   e. If a live virus vaccine, especially measles, yellow fever, varicella, or measles, mumps, rubella (MMR), is administered before the TST, a waiting period of six weeks should be observed before the TST is administered, as a false reaction may occur. Other vaccines have not been studied. Oral live vaccines, e.g. TOPV and typhoid, are not included in this group. A live virus vaccine may be administered either at the time the TST is administered or after the TST is interpreted.
   f. See PPD antigen insert or the current Physician's Desk Reference for additional information.

5. How to administer a TST by the Mantoux method:

   a. Interviewing the client:
      (1) Elicit the following information from the client:
         (a) TB exposure history
         (b) His or her identifiable risk factor(s) for TB infection (See *TA Guideline TB 3: Targeted Testing and Treatment of Latent TB Infection (LTBI)* for risk factors)
         (c) Previous TST reactions

(d) Recent live virus immunizations, e.g. measles, mumps, rubella, varicella, yellow fever, or MMR
(e) History of BCG
(f) Allergies

(2) Explain the following to the client:
(a) Transmission, diagnosis, treatment of TB
(b) Mantoux skin testing procedure
(c) Two-step testing procedure, if appropriate
(d) The connection between TB and HIV/AIDS
(e) Importance of follow-up visit - provide the client with a written return date on the space available on the Department of Health (DOH) "The Tuberculin Skin Test - Tells Who Is Infected? What Does It Mean" pamphlet, DH 150-161.

(3) Provide the client with TB educational materials.

b. Procedure for Administering the Mantoux Tuberculin Skin Test

(1) Inject 0.1 ml (5 Tuberculin Units) PPD antigen intradermally keeping the bevel of a 26 or 27-gauge needle facing upward. This will produce a 6-10 mm wheal on the volar surface of the **left** forearm (lfa) in an area free of lesions and away from veins. If the left forearm is unable to be used, the right forearm (rfa) may be used.

(2) If a wheal of 6-10 mm is not produced, another test should be done immediately on the same arm at a site at least 5 centimeters or 2" from the original site.

(3). After administering the TST, advise the client not to rub or scratch the test site.

(4) Give the client a cotton ball to dab the area lightly and to wipe off any drops of blood, which may occur. Do not put a band-aid on the test site.

(5) Document the test site in the client's record.

Note: Follow the same infection control procedures as for all injections (including proper hand washing and the use of gloves and a sharps container). When water is not available for hand washing, use an appropriate skin-cleaning product, e.g. antibacterial towelettes or antiseptic liquid air-drying cleaner.

6. Two-Step Testing:

a. Some people with TB infection may have a negative skin test reaction when tested many years after their initial infection. The initial repeat skin test may stimulate ("boost") their ability to react to tuberculin antigen. Positive reactions to subsequent tests may be misinterpreted as new infection. These misinterpretations have resulted in inappropriate treatment for latent TB infection and investigations involving extensive tuberculin skin testing, particularly in congregate living situations.

b. Two-step testing is recommended for the initial skin testing of adults who cannot document a history of a negative TST within the past 12 months and who will be retested periodically. For example, serial (periodic) testing is

recommended for appropriate staff at county health departments, hospitals, and long-term care facilities, e.g. jails and prisons. In addition, two-step testing is also recommended for certain client populations, such as new nursing home residents.

c. Procedure for Two-Step TST:
   (1) For clients who test negative to the first TST, a second test should be administered within one to three weeks after the first test and read 48 to 72 hours after application.
   (2) If the second TST is positive, this probably represents a "boosted" reaction of a remote infection and may not be due to a recent infection.
   (3) If the second TST is negative, the client should be considered not infected.

Note: An alternative method which may decrease the number of required clinic visits is to interpret the initial TST one week after administration and, if negative, administer the second TST at that time. This method may assist in maximizing public health resources.

7. Anergy Testing
   a. Anergy is defined as non-responsiveness to delayed-type hypersensitivity-inducing antigens, such as PPD, mumps or *candida*.
   b. Anergy may be common among persons having an impaired immune system (e.g., persons infected with HIV).
   c. The Centers for Disease Control and Prevention (CDC) no longer recommends anergy testing as a routine component of TB testing among HIV-infected persons in the United States.
   d. If a clinician elects to use anergy testing as part of a multifactorial assessment of a person's risk for TB, the two FDA-approved Mantoux-method tests (mumps and *Candida*), used together with cut-off diameters of 5 mm induration, are recommended by CDC.

8. BCG (Bacille Calmette-Guérin vaccine)
   a. Many countries outside the United States use BCG vaccine as part of their TB control program, especially to prevent or lessen the effects of TB meningitis in infants.
   b. BCG scars are usually found on the left arm and look similar to a smallpox scar. The presence or absence of a scar does not indicate the degree of protection conferred by the vaccination.
   c. The size of the tuberculin skin test reaction caused by a BCG vaccination varies by strain and dose of vaccine as well as the age and nutritional status at the time of vaccination.
   d. Children vaccinated with BCG show tuberculin reactions ranging from 3 to 19 mm induration and within 5 to 10 years these reactions will wane. Therefore, an adult who was vaccinated as a child who has a positive Mantoux tuberculin skin test is likely to represent an infection with *M. tuberculosis* and not from the BCG vaccination.
   e. The reported efficacy of BCG vaccine is variable, ranging from 0% to 80%. The duration of protection is unlikely to persist more than 10 years after

vaccination. It should never be assumed that a person who has received BCG vaccination is completely protected from developing TB.

f. A history of a BCG vaccination is **not** a contraindication to administer a Mantoux tuberculin skin test.

9. TST of Pregnant Women

a. Tuberculin skin testing is safe and reliable for pregnant women. No teratogenic effects have been documented.

b. Routine testing of pregnant women is **not** necessary, unless they have conditions which suggest a high risk to progress from infection to disease:. These conditions include:

- Symptoms suggestive of active TB disease
- HIV infection
- Behavioral risk factors for HIV infection whose HIV status is unknown
- Medical conditions that have been reported to increase the risk of TB disease, e.g. diabetes mellitus, silicosis, prolonged corticosteroid therapy, other immunosuppressive therapy, hematologic reticuloendothelial diseases, e.g. leukemia and Hodgkin's disease, carcinoma of the head or neck and lung, end stage renal disease, intestinal bypass or gastrectomy, chronic malabsorption syndromes, or low body weight (10% or more below ideal weight)
- Close contact to someone with infectious laryngeal or pulmonary TB disease
- Recently arrived foreign-born from areas where TB disease is endemic, e.g. Latin America, Caribbean, Asia, Africa, Russia, etc.
- Organ transplant recipients

10. Reading of the Mantoux TST Results

a. Reaction to the test should be read by a **trained** health care worker (HCW) 48 to 72 hours after administration.

b. Significant TST reactions may still be measurable after 72 hours, and may remain measurable up to one week after administration.

c. Induration (raised area) should be palpated and inspected in both direct and indirect lighting. The diameter of the induration is measured transversely to the long axis of the arm and recorded in millimeters (mm). **Note: Erythema (redness) should not be included in the measurement.**

11. Interpretation of the Mantoux TST Results

a. The following persons are considered at increased risk for TB disease once infected and reactions of **5 mm** or more induration should be considered positive:

- Recent close contacts of persons known to have clinically active, infectious TB.

- Persons with known HIV infection.
- Persons with organ transplants and other immunosuppressed clients (e.g., persons receiving the equivalent of > 15 mg/d of prednisone for one month or more).
- Persons whose chest radiographs show fibrotic lesions consistent with prior TB.
- Persons at high risk for HIV infection whose HIV status is unknown (e.g. injecting drug users).

b. The following persons are considered at increased risk for TB infection or for progression to TB disease once infected. Reactions of **10 mm** or more induration in these persons should be considered positive:

- Persons with medical conditions known to increase the risk of TB disease, for example, silicosis, diabetes mellitus, prolonged corticosteroid therapy, other immunosuppressive therapy, post gastrectomy, some hematologic disorders (such as leukemias and lymphomas), other malignancies (e.g., carcinoma of the head or neck and lung), chronic renal failure, and 10% or more below ideal body weight.
- Recent Mantoux skin test converters are persons who have a documented TST increase of 10 mm or more within a two year period.
- Children younger than 4 years of age or infants, children, and adolescents exposed to adults at high-risk are assumed to be converters and are included in this category.
- Staff of facilities in which an individual with current TB disease would pose a risk to large numbers of susceptible persons, (e.g. correctional facilities, nursing homes, hospice, other health care agencies, schools, CHD personnel with a defined risk, mycobacterial laboratories, and child care facilities).
- Certain <u>locally identified</u> medically underserved low-income populations, including locally identified high-risk racial and ethnic populations, (e.g., homeless shelters, migrant workers).
- Recently arrived (within the last 5 years) foreign-born persons from TB endemic areas, (e.g. Latin America, Caribbean, Asia, Africa, former Yugoslavia, Russia, etc.). BCG status of foreign-born persons from high prevalence countries should be ignored in interpreting skin test reactions.
- Residents of facilities for congregate long-term care, (e.g. correctional institutions, nursing homes).

c. Persons with no risk factors for infection or disease should not be Mantoux TST tested. If testing is done, reactions of **15 mm** of induration, or more, should be considered positive.

d. <u>Vaccination with BCG and interpretation of the TST</u>:
A diagnosis of *M. tuberculosis* infection and the use of treatment for latent TB infection should be considered for any BCG-vaccinated person who has a significant tuberculin skin test reaction, especially if any of the following circumstances are present:

- The vaccinated person is a contact of another person who has infectious TB, particularly if the infectious person has transmitted *M. tuberculosis* to others;

- The vaccinated person was born or has resided in a country in which the prevalence of TB is high; or
- The vaccinated person is exposed continually to populations in which the prevalence of TB is high (e.g., some HCWs, employees and volunteers at homeless shelters, and workers at drug treatment centers).

12. Referral

a. Clients with positive skin test reactions should receive further evaluation to rule out the presence of TB disease.

b. Additional follow-up should be performed to identify potential candidates for treatment of latent TB infection. For more on treatment of latent TB infection, see *TA Guideline TB 3: Targeted Testing and Treatment of Latent TB Infection (LTBI)* for risk factors.

13. Documentation

a. Document exposure to TB, previous TST reactions, previous BCG, other immunizations, site of TST, and lot number of the PPD antigen vial on the Immunization Clinic Record/Signature Card, DH 687.

b. Give the DOH pamphlet, "The Tuberculin Skin Test - Tells Who Is Infected? What Does It Mean," DH 150-161 to the client with return clinic date and other TB educational materials.

c. Document TST results in mms. If positive, include date for chest x-ray on the pamphlet and on the immunization card.

d. Have client sign that he or she received the TST pamphlet on the Immunization Clinic Record/Signature Card with the return date indicated in the box on this record card.

e. Provide the client with copy of test results on the State of Florida Department of Health Immunization Record, DH 686.

f. Document all the above information on the appropriate state record forms:
Problem List DH Form 3115
Progress Notes DH Form 3056
Adult and Adolescent History DH Form 3113
Adult and Adolescent Physical Examination DH Form 3117
Child Health History Birth Through 10 Years DH Form 3105B
Child Health Physical Examination DH Form 3105A
Child Health Flow Sheet DH Form 3105D
Tuberculosis Record DH Form 3106
Tuberculosis Preventive Therapy (PT) Form DH Form 2046
Immunization Clinic Record DH Form 687
Immunization Record, DH 686

14. **SUPPORTIVE DATA:**

a. Chapter 392, Florida Statutes.
b. 64D-3.103 through 64D-3.108, Florida Administrative Code.
c. MMWR, September 8, 1995, Vol 44, No. RR-11 "Essential Components of a Tuberculosis Prevention and Control Program" and "Screening for Tuberculosis and Tuberculosis Infection in High-Risk Populations."
d. MMWR April 26, 1996,Vol 45, No. RR-4, "The Role of BCG Vaccine in the Prevention and Control of Tuberculosis in the United States."
e. CHD Guidebook Technical Assistance Guidelines "Targeted Testing and Treatment of Latent TB Infection (LTBI)" and local CHD policies & procedures.
f. Friedman, Lloyd N., M.D., editor, 1994, Tuberculosis - Current Concepts and Treatment Chapter 8, pp. 153-181, "Tuberculosis in Childhood and Pregnancy"; Chapter 13, pp. 285-306, "Skin Testing and Chemoprophylaxis," Chapter 14, pp. 307-333, "Control of Tuberculosis," Chapter 15, pp. 335-348, "BCG Vaccine."
g. Schlossberg, David, editor, 1994, Tuberculosis Chapter 2, pp. 30-31, "Effect of Vaccines on the Establishment of Pulmonary Tuberculosis Lesions (107)"; Chapter 5, pp. 63-68, "Tuberculin Skin Testing"; Chapter 7, pp. 89-91, "Prophylaxis."
h. Rossman, Milton D. and MacGregor, Rob Roy, 1995, Tuberculosis- Clinical Management and New Challenges, Chapter 5, pp. 73-88, "Tuberculin Skin Testing"; Chapter 7, pp. 109-128, "BCG Vaccination: An Old Idea Revisited."
i. American Thoracic Society, "Diagnostic Standards and Classification of Tuberculosis in Adults and Children," Am J Respir Crit Care Med, Vol161, pp 1376-1395, 2000.
j. "Prevention and Control of Pediatric Tuberculosis in New York City: Recommendations of the Expert Advisory Panel, Winter 1995, pp. 20-24
k. U.S. Department of Health and Human Services (CDC), Core Curriculum on Tuberculosis - What The Clinician Should Know, Chapter 4, pp. 25-33 "Testing for TB Disease and Infection," Fourth Edition, 2000.
l. Sbarbaro, John A., "Skin Testing in the Diagnosis of Tuberculosis," 1986, pp. 234-238
m. MMWR, September 5, 1997, Vol.46, No. RR-15, "Anergy Skin Testing and Preventive Therapy for HIV-Infected Persons: Revised Recommendations," pp. 1-8.
n. CDC. "Mantoux Tuberculin Skin Testing" video and poster.
o. Tubersol Information from Connaught.
p. Aplisol Information from Parke-Davis.
q. Current edition of Physician's Desk Reference - tubersol.
r. MMWR, August 20, 1999, Vol 48, RR-10, 1999, USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus.
s. NTNCC, Tuberculosis nursing: a comprehensive guide to patient care, Atlanta, 1997, pp.22-32.
t. NYC DOH Clinical Policies and Protocols, "Tuberculin Skin Testing."
u. MMWR, June 9, 2000, Vol. 49, No. RR-6, "Targeted Tuberculin Testing and Treatment for Latent Tuberculosis Infection."