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| TITLE: Protocol and Standing Orders for Evaluation and  Management of Tuberculosis Infection and Disease with Tuberculin Skin Test (TST), Interferon Gamma-Release Assay Test (IGRA), and chest Xray (CXR) | EFFECTIVE DATE: |
| APPROVED BY:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Local Public Health Agency Medical Director (Print Name and Signature) (Date)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  LPHA Director (Print Name and Signature) (Date) | REVISION DATE: |

**CONDITION FOR PROTOCOL:** To detect *Mycobacterium tuberculosis* (TB) infection in individuals who meet the criteria for targeted testing as defined by the Colorado TB Risk Assessment.

* [Adult Tuberculosis Risk Assessment Form](https://drive.google.com/file/d/1wgtRX81C3EBqZLE08z3WLl5bkwu2ic6g/view)
  + [User Guide](https://drive.google.com/file/d/0B2o0IwpCuPw7VWJ4SDhYRXVFaFU/view?resourcekey=0-QCKjlL3rSnOviMeRYsHmtg)
* [Pediatric Tuberculosis Risk Assessment Form](https://docs.google.com/document/d/1KJf9FPJXwP8N_h2s8vqI8hsHIxGHb6ts96prOFFxjh0/edit)
  + [User Guide](https://docs.google.com/document/d/1ApAO11j3NHCLvjcl7PswWQqqScHBU8IucPtg13XYFe0/edit)

**PURPOSE:** To provide clinical staff with medical guidelines for evaluating and managing patients who present for Tuberculosis screening. The RN is the agent of the prescriber delegated to refill medications or Purified Protein Derivative (PPD) as per the following procedure. This document is intended to complement consultation from the TB medical consultant/control officer where appropriate.

**Rules and Regulations Scope of Practice and Delegation:**

* [Licensed Medical Doctor](http://www.aama-ntl.org/docs/default-source/legal/co-bome-rule-800.pdf?sfvrsn=4)
* [Registered Nurses](https://dpo.colorado.gov/Nursing/Laws)
* [Licensed Practical Nurse](https://dpo.colorado.gov/Nursing/Laws)
* [Certified Nurse Assistant](https://casetext.com/regulation/colorado-administrative-code/department-700-department-of-regulatory-agencies/division-716-division-of-professions-and-occupations-board-of-nursing/rule-3-ccr-716-1-nursing-rules-and-regulations/section-3-ccr-716-1-119-rules-and-regulations-for-the-certified-nurse-aide-in-relation-to-medication-aide-authority)
* Medical Assistant: See Medical Assistants under “Personnel”

**Definitions:**

**Chest X-ray (CXR):** Imaging test that uses X-rays to look at the structures and organs in the chest

**Delegation:** Involves the assignment of the performance of activities or tasks related to patient care to unlicensed assistive personnel while retaining accountability for the outcome.

**Interferon Gamma-Release Assay Test (IGRA):** Whole blood test that can aid in the diagnosis of TB infection. White blood cells from most persons who are infected with TB will release interferon-gamma (IFN-G) when mixed with antigens derived from *Mtb*. There are two FDA-approved tests: QuantiFERON and T-Spot.

**Purified Protein Derivative (PPD):** a sterile aqueous solution of a purified protein fraction for intradermal administration as an aid in the diagnosis of tuberculosis.

**Standing orders:** Written policy and authorization for nurses and in some cases, medical assistants (within their scope of practice and as delegated by the medical doctor) to complete certain tasks without first obtaining a physician order.

**Tuberculin skin test (TST):** Medical test to determine whether a person is infected with mycobacteria and is one method to detect tuberculosis infection.

* The terms Mantoux, TB skin test, tuberculin skin test, and PPD are often used interchangeably. Mantoux refers to the technique for administering the test. Tuberculin (also called purified protein derivative or PPD) is the solution used to administer the test, not the test. The preferred term for the test is tuberculin skin test or TST.

**Personnel**  **[Colorado TB Program Scope of Practice Guidance](https://drive.google.com/file/d/0B2o0IwpCuPw7SU5iR0tVQUtDVzQ/view?resourcekey=0-HSeGtHXWainvTV_fkqvM1Q)**

1. [**Medical Director (Medical Doctor [MD] or Doctor of Osteopathic Medicine [DO]**](https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=6459&fileName=6%20CCR%201014-6)
2. **Registered Nurse:** This includes various categories of licensed nurses: 1) Nurses in Advanced Practice: a) Advanced Practice Nurse, b) Clinical Nurse Specialist, c) Nurse Practitioner; 2) Registered Nurse. Administer medications under their own or delegated authority. In addition to public and private clinical settings, nurses may practice in a broad range of community locations.

[**Board of Nursing: Practice Act and Laws**](https://dpo.colorado.gov/Nursing/Laws): The statute defines delegated medical function to include the RN implementation of a medical plan, "a written plan, verbal order, standing order, or protocol - whether patient-specific or not, that authorizes specific or discretionary medical action, which may include but is not limited to the selection of medication." The amount of physician oversight would be determined by the physician and nurse involved in this process.

1. **Medical Assistant:** work alongside physicians, mainly in outpatient or ambulatory care facilities, such as medical offices and clinics. Colorado has **not** set forth a scope of practice for medical assistants. Colorado law states that unlicensed personnel cannot perform any duties that require licensing; Colorado medical assistants carry out basic non-invasive routine technical/clinical services and administrative tasks under the delegation and supervision of a licensed medical doctor. An unlicensed person may not diagnose, treat or perform any invasive task or require assessment. Per Colorado state statute, "Delegated services cannot be re-delegated to another party by the delegatee."

**Condition-specific criteria and prescribed actions:**

***For persons adopting these protocols:*** *The criteria listed below include indications, contraindications, and precautions for implementing the TST protocol. However, the criteria must be reviewed* ***and further delineated according to the licensed prescriber’s parameters. Additional criteria and prescribed actions may be necessary****. The prescribed actions are examples and may not suit your agency’s clinical situation and do not include all possible actions. A licensed prescriber must review the criteria and actions and determine the appropriate action to be prescribed. An annual review of this protocol is suggested.*

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|  | **Criteria** | **Prescribed Action** |
| I  nd  i  ca  t  i  on | Contact to an infectious case of TB | Administer the baseline TST or draw for an IGRA. Repeat using the same test 8-10 weeks post the last exposure to the person, while that person with TB disease was deemed infectious. |
| Targeted testing of persons at high risk for TB infection (e.g., foreign-born or travel to countries with medium or high incidence of TB; persons with HIV infection; history of drug or alcohol abuse; those started a TNF-inhibitor; and those who have experienced homelessness) | Administer TST or draw for an IGRA |
| Admission to a nursing home or boarding care home | Administer two-step TST or draw for an IGRA |
| Admission to a correctional facility (i.e., jail, prison) | Administer 2-step TST or one IGRA. |
| Pre-employment screening for healthcare workers and correctional facility staff | Administer two-step TST or one IGRA |
| Pregnant/lactating women at high risk for TB infection | Administer TST. Pregnancy and lactation are not contraindications for TSTs. If a woman declines TST, arrange for her to have an IGRA. |
| BCG-vaccinated persons | IGRA is the recommended test. If not available, administer TST. Prior BCG vaccination is not a contraindication for TST; however, a small number of persons (estimated at < 10%) have false-positive TSTs from the BCG, which is why the IGRA is recommended. |
|  |  |  |
| Con  t  r  a  i  nd  i  ca  t  i  on | Previous severe adverse reaction to tuberculin or any of its components (e.g., necrosis, blistering, anaphylactic shock. pr ulcerations). | Do **not** administer TST. Arrange for the patient to have an IGRA |
| **Documented** previous positive TST or IGRA | Do **not** administer. Repeat testing yields no meaningful information. Repeating the IGRA is recommended in some situations (i.e., if the person has absolutely no risk factors for TB infection but has one positive IGRA). This may require consultation with the State TB Nurse Consultant. |
| **Documented** history of previous active TB disease or latent TB infection | Do **not** administer TST. Repeat testing yields no meaningful information. |
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| Pr ecau  t  i  on  s | < 6 months old | Some infants < 6 months old who are infected with *M. tuberculosis* maynot react to a TST. A negative result may be a false negative if performed on someone younger than 6 months of age. A positive reading indicates infection and warrants further workup. |
| Immunization with a live, attenuated virus vaccine within the past 6 weeks | Defer TST until 4 - 6 weeks after immunization with the live, attenuated virus vaccine. If able to arrange TST prior to the vaccinations, schedule vaccine administration for the date of the TST reading. |
| Suspected active TB disease (based on signs, symptoms, and risk factors) | Administer TST and refer for immediate medical evaluation. A negative TST(or IGRA) result **does not** **rule out TB** **disease**. |
| Low risk for TB infection or active TB | Testing of low-risk persons is discouraged. |

**SUPPLIES:**

* A vial of refrigerated PPD
* A single-dose disposable tuberculin syringe
* Gauge-25-29 • Length-1/4 to ½ inch • Amount - 0.1 ml • Angle-15 degrees • DO NOT ASPIRATE
* Ruler with millimeter (mm) measurements
* 2x2 gauze pads or cotton balls
* Alcohol swabs
* Puncture-resistant sharps disposal container
* Record-keeping forms for the patient and provider
* Black pen.

**ALERT: Only appropriately trained staff who can perform this task under their scope of practice or license shall perform this medical test. Please see the** [**CDC website**](https://www.cdc.gov/tb/education/mantoux/default.htm) **on TST training and materials for a complete guide and video. Administering and Storage & Handling information is detailed in the PPD packaging insert**

**STORAGE:**

* **Do not** store the vial in the door of the refrigerator. When not in use, keep the vial stored in the Pharmacy/Vaccine Refrigerator.
  + CDC does **not** recommend **storage** of **any vaccine** in a **dormitory**-**style (or bar**-**style**) refrigerator. Vaccines and PPD should not be kept in the door of the refrigerator.
  + A unit dedicated to the storage of vaccines only. **Food and beverages must not be stored** in a vaccine storage unit. This practice results in frequent door opening and a greater chance for temperature instability and excessive exposure to light. It may also result in spills and contamination inside the refrigerator.

**ADMINISTRATION:**

* Skin tests should **not** be administered on a day that will cause the 48-72 hour reading date to fall on a weekend or holiday unless a specific plan has been established to permit a reliable reading.
* If the patient is having their skin test result read, measured, or interpreted by another healthcare agency, it is advised to have this confirmed prior to administering the PPD solution. It is recommended to fax the form to the facility that will be providing that service and request a copy be faxed back once completed.
* The usual site for injection is the left lateral forearm (aka, volar aspect of the forearm). Choose a site free of lesions, excess hair, scarring, tendons, and veins.
  + Alternative sites include the opposite lateral forearm or the posterior aspect of either scapula.
* Clean injection site with an alcohol swab. Allow the area to air dry completely before the injection.
* Storage and Handling:

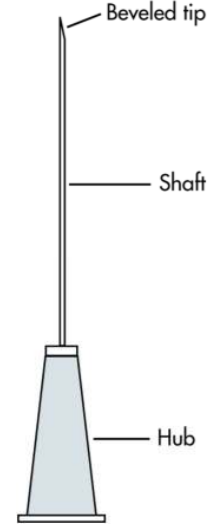
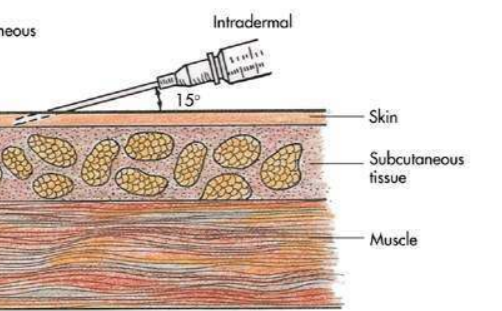
Read instructions that are available in the box that contains the PPD solution to familiarize yourself with all of the nuances.

It is advised **not** to pre-draw the solution, even when single-use. In mass testing, do **not** pre-draw the solution into syringes.

Remove from refrigerated vial **just prior** to the test. Keep the vial and solution-filled needle away and protected from light **at all times**. Return the vial to the refrigerator immediately after drawing it into the syringe. Do not store bottles in the door of the refrigerator.

**NOTE:** Check the vial for open and expiration date to ensure the viability of the solution. If opened, the bottle shall be marked with the date the bottle was accessed. PPD solution is not viable after one month from initial access. PPD solution that has gone beyond this date shall be discarded and a new bottle opened and marked.

* At a 15-degree angle, intradermally inject all of the tuberculin (0.1 ml ) using a tuberculin needle, 3/8 to 5/8 inch 25- 29 gauge needle with a short bevel tip. The bevel should be facing up. This will produce a 6-10 mm wheal.
  + When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter.If a wheal of >6 mm is *not* produced, **another test shall be done immediately at a site at least 2 inches from the original site**.

* Use a cotton ball to dab the area lightly and to wipe off any drops of blood. **Do not** apply pressure or use a bandage on the test site as this will siphon the PPD solution from the injection site, potentially affecting the validity of the test result. Instruct the patient to avoid scratching the test site and to avoid putting a bandage on after leaving the clinic.
* Document:
  + Printed name and signature of person administering test
  + Date **and time** test administered
  + Location of the test (e.g., right forearm, left forearm, alternate site)
  + Tuberculin manufacturer, lot number, **and** expiration date
* Provide a written reminder to the patient to return for reading in 48 to 72 hours.

**Measuring and Interpreting the Induration:**

* The following is **inappropriate**:
  + Patient measuring and reporting their own skin test result
  + To read or interpret anything other than the patient’s skin (i.e., photo, image, or verbalized description)
  + Read a negative anytime after 72 hours from planting the PPD
  + Read a positive after one week from planting the PPD
  + Have staff member measure without the appropriate training or outside of their scope of practice
* Confirm that TST was applied within 48 to 72 hours prior to reading by reviewing documentation from placement.
  + If < 48 hours, the patient must return after 48 hours and before 72 hours.
  + If the patient returns up to 7 days after the test was administered and the size of induration meets the criteria for a positive result, the result can be accepted. If reading the TST after 72 hours and there is no induration or the size of the induration does not meet the criteria for a positive result, the TST must be repeated.
* Use a millimeter ruler to measure the diameter of induration **perpendicular to the long axis of the arm**.
* Categorize results using the table below.
* Document:
  + Print name, title, and signature of the person reading test
  + Date and time test read
  + Exact number of mm of induration (if no induration, document "0" mm)
  + Interpretation
    - Interpretation includes an assessment and takes critical thinking skills (i.e., positive or negative, based on individual's risk factors)
    - See Table: Classification of TST Results
* Caution: Persons with symptoms of active TB disease or who are HIV infected or severely immunocompromised may have a false negative TST.

**TWO-STEP TST:**

If the first TST is negative, give a second 0.1 mL of 5TU tuberculin (Tubersol® or Aplisol®) ID 7 – 21 days following the first TST. This can be performed on the same arm or opposite arm. Documentation requirements are the same. Have the patient return in 48 to 72 hours and use the table “Classification of TST results” to determine the result.

**FOLLOW-UP OF PATIENTS WITH A NEWLY-POSITIVE TST:** Persons with a newly identified positive TST should be referred to a provider for a physical examination and chest x-ray to rule out active TB disease immediately. Chest x-ray and medical evaluation shall be completed within 72 hours.

**Table: Classification of TST Results**

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| --- | --- | --- | --- | --- |
| **Category of Person Tested** | **Tuberculin Skin Test (TST) Result (induration)** | | | |
| **< 5 mm** | **≥ 5 mm** | **≥ 10 mm** | **≥ 15 mm** |
| Recent contact of infectious TB case  (regardless of age) | Negative | Positive | Positive | Positive |
| HIV-infected | Negative | Positive | Positive | Positive |
| Immunosuppressed or organ transplant recipient | Negative | Positive | Positive | Positive |
| Fibrotic changes or scarring on chest x-ray | Negative | Positive | Positive | Positive |
| Foreign-born from (or extensive travel to) high-prevalence country1 | Negative | Negative | Positive | Positive |
| Injection drug user | Negative | Negative | Positive | Positive |
| Resident/employee of high-risk congregate setting or health care worker2 | Negative | Negative | Positive | Positive |
| Mycobacteria lab personnel2 | Negative | Negative | Positive | Positive |
| High-risk clinical conditions 3 | Negative | Negative | Positive | Positive |
| Child < 4 years of age | Negative | Negative | Positive | Positive |
| Child or adolescent exposed to high-risk adults | Negative | Negative | Positive | Positive |
| No risk factors (TB screening discouraged) | Negative | Negative | Negative | Positive |

1. BCG vaccination is not a contraindication for TST; disregard BCG history when interpreting TST result.
2. In instances of repeated testing (other than contacts), an increase in TST result of ≥ 10 mm within 2 years is considered a TST conversion indicative of recent infection.
3. Substance abuse, diabetes mellitus, silicosis, cancer of the head or neck, hematologic or reticuloendothelial disease such as Hodgkin’s disease or leukemia, end-stage renal disease, intestinal bypass or gastrectomy, chronic malabsorption syndromes, low body weight (i.e., 10% or more below ideal for the given population).
4. **Medical emergency or** [**anaphylaxis**](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf)**:** *[Depending on clinic staffing, including one of the two options below.]*
   * When exposed to something they’re allergic to, some people experience a potentially life-threatening reaction called anaphylaxis. As a result, their immune system releases chemicals that flood the body. This can lead to anaphylactic shock. Anaphylaxis symptoms occur suddenly and can progress quickly. The early symptoms may be mild, such as a runny nose, a skin rash, or a "strange feeling." These symptoms can quickly lead to more serious problems. That’s why it’s critical for people with severe allergies to know the symptoms of anaphylaxis and be prepared with an emergency action plan.
     + [Adults](https://www.immunize.org/catg.d/p3082.pdf)
     + [Pediatrics](https://www.immunize.org/catg.d/p3082a.pdf)

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| In the event of a medical emergency (described below) related to the administration of a TST, RN will call 911.  In the event there are some minor complaints in the absence of abnormal vital signs, the RN will update and provide the assessment data and summarize the situation for the Medical Director. | | |
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| In the event of an onset of symptoms of anaphylaxis including: | | |
| * + - **Respiratory:**difficulty breathing, rapid breathing, shortness of breath, or wheezing | * + - **Skin:**hives, swelling under the skin, blue skin from poor circulation, or rashes | * + - **Gastrointestinal:**nausea or vomiting |
| * + - **Whole body:**fainting, lightheadedness, low blood pressure, dizziness, or flushing | * + - **Also common:**fast heart rate, feeling of impending doom, itching, tongue swelling, difficulty swallowing, facial swelling, mental confusion, nasal congestion, or impaired voice |  |
| \_\_Fill in with Medical Provider directions (e.g., call 911, administer epinephrine) See CDC link “[**anaphylaxis**](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf)” \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

**Standing Orders for Obtaining Radiographic Studies of the Chest**

A. Indications

* New positive skin test or IGRA
* Past positive skin test or IGRA with no chest radiograph since positivity was first documented
* Contacts of patients with pulmonary tuberculosis disease if the contact is (PA/Lateral):
  + <5 years of age **or**
  + HIV infected **or**
  + immunosuppressed
* Reports of any abnormality on civil surgeon exams
* Persons immigrated with Class B notification
* Persons (age 6 and above) seeking treatment for latent TB infection whose last chest radiograph is more than three months old or unavailable
* Persons with signs and symptoms consistent with active TB disease. (i.e. productive cough greater than three weeks in duration, night sweats, hemoptysis, anorexia, lost weight, fatigues, etc.)
* End-of-therapy for active TB that included pulmonary, pleural, or other intrathoracic components (e.g., hilar or mediastinal lymphadenopathy).
* As otherwise directed by the Colorado Department of Public Health and Environment’s TB nurse consultant

Notes:

1. Patients undergoing administrative screening (e.g., for healthcare employment or school) who have a history of both a previous positive skin test AND a subsequent normal chest radiograph should be referred to the provider who conducted these examinations for the appropriate documentation to provide to their employer. These patients may be invited to return with this documentation when considering treatment for TB infection if they are interested in treatment and meet the criteria for targeted testing and do not have insurance.
2. Pregnancy and lactation are not contraindications for CXR and it is imperative that active pulmonary disease is ruled out prior to delivery. If the patient is asymptomatic (confirmed on physical assessment), the CXR can be delayed until the second trimester. If the patient has symptoms of pulmonary disease, the CXR should be performed immediately.

**Questions or concerns:**

In the event of questions or concerns, call Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**This protocol shall remain in effect for all patients of** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**until rescinded or until** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Name of prescriber:**

**Signature:**

**Date:**