Tuberculosis Investigative Guidelines

1. DISEASE REPORTING

A. Purpose of reporting and surveillance
   1. To identify and treat persons with tuberculosis (TB) disease.
   2. To identify and evaluate the contacts to TB cases. To treat infected contacts for latent TB infection (LTBI).
   3. To prevent transmission of TB from cases to contacts.

B. Laboratory and physician reporting requirements
   1. Health care providers and health care facilities
      a. Report all confirmed and suspected cases to the Local Public Health Authority (LPHA) within one working day of making a presumptive TB diagnosis. (OAR 333-018-0000)
      b. Cooperate with local public health authorities in the investigation and implementation of appropriate TB control measures. (OAR 333-019-0002)
   2. Laboratories
      a. Report all test results suggestive of TB to the LPHA within one working day (OAR 333-018-0015). This includes positive acid-fast smears, positive cultures identified as *Mycobacterium tuberculosis* or *M. tuberculosis* complex, or positive nucleic acid amplification test results for *M. tuberculosis*.
      b. Forward primary *M. tuberculosis* complex isolates to the Oregon State Public Health Laboratory (OSPHL). (OAR 333-018-0018)

C. Local Public Health Authority reporting and follow-up responsibilities
   1. Reporting
      Report all confirmed and suspected cases to the TB Program, Oregon Health Authority (OHA), within 5 business days of initial notification of the suspected or confirmed case. (OAR 333-018-0020). See TB Case Reporting in Orpheus
   2. Follow-up
      The LPHA is responsible for investigating reportable diseases (including TB) and following procedures outlined in these Investigative Guidelines (ORS 433.006, OAR 333-019-0000).
Basic requirements include:

- Assigning a TB Case Manager (TB-CM) for each suspected or confirmed TB case.
- Using directly observed therapy (DOT) for suspected or confirmed TB cases for and extrapulmonary cases.
- Monitoring therapy and treatment response for all TB cases.
- Initiating a contact investigation within 72 hours of confirming the case has TB disease (as appropriate).
- Evaluating contacts and initiating therapy (as appropriate).

2. THE DISEASE

A. Pathogenesis

TB is caused by Mycobacterium tuberculosis complex. This complex includes M. tuberculosis, M. africanum, M. bovis, M. microti, M. pinipedi and M. canetti.

When a person inhales air containing droplet nuclei with M. tuberculosis, most of the larger droplets become lodged in the upper respiratory tract (the nose and throat), where infection is unlikely to develop. However, smaller droplet nuclei may reach the small air sacs of the lung (alveoli), where infection can begin.

In the alveoli, some tubercle bacilli are killed, but a few may multiply and enter the lymph nodes and bloodstream spreading throughout the body. Bacilli can reach any part of the body, where TB disease can develop. Within 2 to 8 weeks, the body’s immune system usually intervenes, halting multiplication and preventing further spread. At this point, the person has latent TB infection (LTBI). When a person has LTBI the tubercle bacilli are in the body, but the body’s immune system is able to keep the bacilli contained. The immune system does this by producing special immune cells which surround the tubercle bacilli. The cells form a shell that acts as a barrier.

TB disease can develop very soon after infection or many years later. In the United States, unless treated, about 5% of recently infected people will develop TB disease in the first year or two after infection. Another 5% will develop TB disease later in their lives. The remaining 90% will remain disease free for the rest of their lives.

Some conditions increase the risk that LTBI will progress to disease. The risk may be about 3 times higher (as with diabetes) to more than 100 times higher (as with HIV infection) for people who have these conditions than for those who do not.
While most patients are infected with TB via an inhalational route, infection can also occur by the ingestion of raw milk products containing *M. bovis* or *M. tuberculosis*.

**B. TB disease signs and symptoms**

Although most patients with TB have pulmonary disease, TB disease can develop in any body part including bone, meninges, organs and skin. TB disease outside of the lungs is called “extrapulmonary”. The symptoms of pulmonary TB typically include cough, chest pain, and hemoptysis. The symptoms of extrapulmonary TB depend on the site of disease. Systemic symptoms consistent with TB include fever, chills, night sweats, appetite loss, weight loss, and fatigue.

**C. TB transmission**

TB is spread from person to person through the air. When a person with pulmonary or laryngeal TB coughs, sneezes, speaks, or sings, droplet nuclei containing *M. tuberculosis* can become airborne. Depending on the environment, these tiny particles (1–5 microns in diameter) can remain suspended for hours. If another person inhales air containing droplet nuclei, transmission may occur. The probability TB will be transmitted depends on multiple factors including the infectiousness of the person with TB disease (the number of organisms expelled into the air), the immune competency of the person exposed, the environment in which exposure occurred, the duration of exposure, and the virulence of the organism.

Persons at highest risk for becoming infected with *M. tuberculosis* are those who had prolonged, frequent, or intense contact. These close contacts may be family members, roommates, friends, coworkers, or others.

Extrapulmonary TB is rarely contagious (except for laryngeal and pleural TB); however, transmission from extrapulmonary sites can occur during aerosol-producing procedures, such as autopsies and tissue irrigation. TB disease can occur in more than one site in the body. Because of this, all patients should have a chest x-ray and sputum collected.

**D. Need for respiratory isolation of patients with pulmonary, pleural or laryngeal TB disease**

1. **Latent TB Infection (LTBI)**
   Persons with LTBI are not infectious.

2. **Pulmonary TB disease**
   Any patient with pulmonary TB is potentially capable of infecting others. However, studies have shown this risk is higher when the patient has AFB positive sputum smears. See section 5, “Preventing Further Spread of Disease” for details on isolation decisions.
3. **Extrapulmonary TB**
Exclusively extrapulmonary TB is not considered communicable except laryngeal TB and pleural TB. However, because TB disease can be in more than one site in the body all patients should have a chest x-ray and sputum collected.

**E. Overview of treatment**

1. **LTBI**
See [Treatment Regimens for Latent TB Infection (LTBI)](#) and [Latent Tuberculosis Infection Resources](#) for detailed treatment information.

a. **Three recommended regimens for treating LTBI**

- **Rifampin (RIF) daily 4 months (4R)**
  4 months daily RIF is recommended for all adults and children unless there is a potential for severe or unmanageable drug interactions.

- **Isoniazid (INH) and Rifampin (RIF) daily 3 months (3HR)**
  3 months daily INH and RIF is recommended for all adults and children unless there is a potential for severe or unmanageable drug interactions.

- **INH and Rifapentine (3HP)**
  INH and Rifapentine (3HP) taken once a week for 12 weeks is appropriate for patients 2 years or older unless there is a potential for severe drug interactions. DOT is advised for children 2 – 17 years old and may also be appropriate for other patients who have barriers to self-administration.

b. **One alternate regimen for treating LTBI**

- **Isoniazid (INH)**
  9 months daily INH is an alternate LTBI regimen that should be used when there’s a possibility of severe drug interactions with the above regimens or the patient is unable to tolerate the above regimens. 6 months daily INH is not preferred but considered adequate to treat LTBI for immunocompetent adults.

b. **Adolescent and adult patients taking INH should be supplemented with B6 (pyridoxine).** Standard dosing is 25-50 mg daily.
Supplement exclusively breast-fed infants with ¼ of 25 mg tab crushed B6. B6 supplementation for other children is optional. If supplementing children dose:
- babies with ¼ of 25 mg tab crushed B6
- toddlers- preschoolers with ½ of 25 mg tab crushed B6
- older children with 25 mg B6.
c. Some patients may require baseline and ongoing liver function tests (LFTs/CMP). Seek consultation or see Patient Monitoring and Education During Treatment.
d. Monitor patients monthly during treatment for side effects and compliance with treatment.
e. Educate patients about the signs and symptoms of hepatotoxicity, thrombocytopenia and other side effects. Stop medication when patients have adverse effects until further evaluation.

2. TB Disease
See:
See:
Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children for detailed information on diagnosis of TB disease.
a. DOT is the standard of care for all TB cases in Oregon. See Program Element #03-Tuberculosis Services located at: Technical Assistance for LPHAs - Program Elements
b. HIV, Hepatitis B and Hepatitis C screening, CMP, CBC, are required when starting treatment for TB disease. If the patient is on ethambutol (EMB), baseline vision testing (Snellen and color perception) is needed. See: TB Treatment Chart
c. Most TB cases will start on 4 drugs: isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB), pending drug susceptibility results.
d. Drug dosing is based upon the patient’s ideal body weight.
e. Patients with drug resistance, treatment failure, hepatic disease, HIV, pregnancy, advanced age, renal insufficiency or end stage renal disease may require alternate regimens. Expert consultation is strongly advised.
f. If the patient’s isolate is susceptible to INH, RIF and PZA:
   − EMB may be discontinued when susceptibility is known.
   − PZA may be discontinued at the end of the initial phase. The initial phase is complete after the first two months of treatment (40 doses).

g. All patients will be treated with daily DOT (Monday-Friday) in the intensive phase. Most patients will be treated with three times a week DOT or daily DOT (Monday-Friday) in the continuation phase. Patients with comorbidities or high disease burden upon diagnosis, may need daily treatment in the continuation phase.

h. Most patients require 6 months total treatment.
i. Some patients will require longer treatment (e.g. pulmonary cavitary TB with culture conversion after 2 months, extensive disease and comorbidity, TB meningitis).
j. For details on dosing and drug regimens see ATS/CDC/IDSA Clinical Practice Guidelines for Drug Susceptible TB

3. DIAGNOSIS AND LABORATORY SERVICES

A. Case definitions
   1. Laboratory confirmed case
      Case has nucleic acid amplification test (NAAT, PCR, MTD, GeneXpert MTB/RIF assay) or culture positive specimen identified as *M. tuberculosis*.
   2. Clinical case
      NAAT and culture negative cases meeting the below criteria:
      a. Positive tuberculin skin test (TST) or positive Interferon Gamma Release Assay (IGRA) result. IGRA are Quantiferon and T-SPOT.
      b. Signs and symptoms of TB.
      c. A complete evaluation for TB disease, including collection of appropriate specimen(s) sent for AFB smear, NAAT and culture.
      d. Started on four drug therapy for TB disease and have clinical improvement in response to treatment.

B. Diagnosis
   1. Follow the appropriate CDC guidelines on diagnosis available at: Clinical Practice Guidelines: Treatment of Drug Susceptible Tuberculosis

C. Laboratory services
   OSPHL performs tests and provides results for mycobacterial smear, NAAT (GeneXpert MTB/RIF), culture, and susceptibilities. For more information on
shipping and tests, refer to OSPHL’s Submitting Samples Menu at: OSPHL Communicable Disease Testing

1. **AFB smear**
   Staining and microscopic examination of sputum or other specimens. All species of mycobacteria appear essentially the same on smear.

2. **Nucleic Acid Amplification Test (NAAT)**
   Identifies genetic material unique to TB. NAAT may be called PCR, MTD, or GeneXpert MTB/RIF. The first AFB smear positive sputum sent to OSPHL is tested by GeneXpert MTB/RIF. Smear negative sputum may be tested upon request from OSPHL.

3. **AFB culture**
   The specimen is inoculated into both rapid test (liquid) media and standard culture media for growth, isolation, and identification. OSPHL identifies only *M. tuberculosis* complex and *M. avium* complex from specimens with AFB growth. Therefore, a culture may be reported as AFB positive, but negative for *M. tuberculosis* complex.

4. **Drug susceptibility**
   The TB isolate's susceptibility or resistance to TB drugs.

5. **CDC Molecular Detection of Drug Resistance (MDDR) Service**
   Available upon request. It is used to rapidly identify genetic mutations associated with drug resistance. This test is only available for specimens NAAT or culture positive for MTB.

6. **Genotyping**
   The analysis of TB genetic components to determine strain type. OSPHL sends an isolate from every culture positive TB patient to a CDC contracted laboratory for testing. Genotyping can assist in determining the relatedness between TB cases, which is useful for contact and outbreak investigations.

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**4. ROUTINE INVESTIGATION**

**A. Contact Investigation**
 Conducting a TB contact investigation (CI) includes identifying individuals who had contact with the case during the infectious period, determining whether the individual contact is high or low risk and deciding which contacts need evaluation based upon case characteristics, the type of exposure, and contact relationships and characteristics.

See: [Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis](#) and [TB Case Reporting Manual](#).
1. **Timeline for completion**
   Begin CIs within 72 hours of reported pulmonary (including pleural) or laryngeal TB. Consult with the TB Program, OHA for CI in congregate settings or when the exposure occurred on an airplane. Evaluate high risk contacts by history and screening test (TST or IGRA). Assure appropriate medical evaluation (including chest x-ray) and treatment initiation of contacts within 30 days of positive screening test results.

   All contacts who test negative on their initial test must be re-tested with the same type of screening test 8-10 weeks after their last exposure to the case.

2. **Period of infectiousness of the case**
   Determining precisely when a TB case became infectious is not possible. Usually the infectious period is estimated to begin three months prior to the onset of symptoms and extends until the TB case has been on treatment for 5 days and has 3 consecutive negative or equivocal smear results. If the patient was asymptomatic, the infectious period is estimated to begin 3 months prior to the first clinical indication that the patient had TB (e.g. first abnormal chest x-ray or first smear positive sputum).

3. **Risk of transmission**
   The TB case manager (TB-CM) must identify household, work, and other contacts, and estimate the proximity and duration of exposure between the case and potential contacts within each setting. Risk factors for disease progression in all contacts (e.g. age less than 5 years, HIV+ and other immunosuppression) must be considered. The presumed infectiousness of the case also influences the number of contacts needing evaluation. CDC guidelines describing how to conduct CIs are at: [Guidelines for the Investigations of Contacts of Persons with Infectious Tuberculosis](https://www.cdc.gov/tb/publications/guidelines/index.html)

4. **Evaluation of contacts**
   a. **Assess each contact for symptoms of TB disease and TB risk factors.**
      
      Symptomatic contacts, children less than 5 years old and/or those who are otherwise highly immunocompromised (e.g. HIV positive or on TNF alpha inhibitors) should be noted, as recommendations for follow-up differ for these groups. Symptomatic contacts need a CXR and possibly specimen collection.

   b. **Screen contacts with either a TST or IGRA.**
      
      − Do not use an IGRA alone for children less than 2 years old.
Before utilizing Quantiferon in any large contact investigation, coordinate with OSPHL.

If the contact is symptomatic for TB and/or has an abnormal CXR indicative of TB, TB disease must be ruled out by obtaining sputum or other appropriate respiratory, tissue or fluid specimens for lab testing. Do not start LTBI treatment until culture results are known to be negative.

If the contact has a documented past positive TST or IGRA, repeat testing is not needed. In this situation, a CXR may be needed if the TB exposure was extensive or the contact is immunocompromised.

c. Contacts who have a negative test should be tested again 8-10 weeks after their last exposure.

d. Contacts under 5 years old, HIV+, and others who are immunocompromised require different follow-up. CXR and window prophylaxis may be needed regardless of screening results. Consultation with a TB expert is advised.

e. For contacts who have LTBI or need window prophylaxis see:
Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis
and/or
Latent Tuberculosis Infection: A Guide for Primary Health Care Providers

5. Ongoing CI follow-up
Re-interview cases for additional contact information and expand the investigation to low risk contacts if evidence of transmission exists.

6. CI for extrapulmonary TB
A CI is not necessary unless there is evidence of pulmonary, pleural or laryngeal TB.

B. Source case finding (for TB cases less than 5 years old)
Source case finding is an investigation to determine the source of TB disease in an index case. This process is a “reverse” contact investigation. Source case finding should be undertaken for children age less than 5 years diagnosed with TB disease.

C. Environmental evaluation
Consider the environment where the exposures took place when classifying contacts as high or low risk. In general, closed or poorly ventilated spaces increase the chances of transmission.
5. **AIRBORNE ISOLATION**

A. **Isolation measures**
Infectious cases should be in airborne infection isolation at home or in a hospital until no longer considered infectious. Educate the patient about the need for airborne infection isolation. Complete a home isolation agreement when the case is isolated at home or in another non-health care setting (e.g. motel). The home isolation agreement is available here: [Isolation Agreement Form (pdf)](#) also available in [Spanish (pdf)], [Russian (pdf)], and [Vietnamese (pdf)].

B. **Initiation** of airborne infection isolation should occur immediately for patients suspected or newly confirmed to have pulmonary, pleural or laryngeal TB disease.

C. **Discontinuation of airborne infection isolation: suspected case of TB disease**
Discontinue airborne infection isolation for suspected cases of TB disease when any of the below criteria are met:
- Another diagnosis is made that explains the clinical syndrome or
- 3 consecutive negative AFB sputum smear results collected a minimum of 8 hours apart or 1 negative smear and two negative NAAT results or
- AFB sputum smear is positive and two GeneXpert MTB RIF or NAAT results are negative

D. **Discontinuation of airborne infection isolation: confirmed case of drug susceptible TB disease**
If the patient works in a high-risk setting (healthcare, daycare, other congregate setting) or lives with persons at high risk for TB (children under age 5, HIV+, other immunocompromised) consult a TB expert.

Discontinue airborne infection isolation for confirmed cases of drug susceptible TB disease when the below criteria are met:
- The patient has 3 consecutive negative or equivocal AFB sputum smear results collected a minimum of 8 hours apart or the patient has a negative culture result.
  and
- The patient has been on 4 drug TB treatment given by DOT a minimum of 5 days
E. Discontinuation of airborne infection isolation: suspected or confirmed case of drug resistant TB disease
If the patient has RIF resistance on GeneXpert MTB/RIF or multidrug resistant TB, consult a TB expert prior to discontinuing airborne infection isolation.

6. TB CASE MANAGEMENT

Each LPHA must have at least one designated TB case manager (TB-CM). The responsibility of the TB-CM is to assure suspected and confirmed TB cases and their contacts are managed according to current guidelines. Staff newly assigned as TB-CM should complete, at minimum, the CDC TB Self Study Modules 1-9 or attend the TB Case Management and TB Contact Investigation classes given by the TB Program, OHA.

CDC Self Study Modules

Responsibilities and activities for the TB-CM are outlined in Program Element #03

7. MANAGING SPECIAL SITUATIONS

A. Medical situations
The following medical situations are specifically addressed in the CDC treatment guidelines: common adverse side effects, culture negative TB (clinical case), drug resistance, advanced age, diabetes, hepatic disease, HIV, pregnancy and breastfeeding, renal insufficiency and end stage renal disease, treatment failure and relapse, and treatment interruptions. See: ATS/CDC/IDS Clinical Practice Guidelines: Treatment of Drug – Susceptible Tuberculosis

In these situations, expert consultation is advised. Obtain consultation by contacting the TB Program, OHA at 503-358-8516 or Curry International TB Center Warmline at 877-390-6682 or currytbcenter@ucsf.edu.

B. Legal issues in TB
Document all efforts to gain voluntary cooperation of suspected and confirmed TB cases before pursing legal action (i.e., Public Health Measure). Document patient education, treatment plans, episodes of nonadherence, and attempts to resolve problem. Written agreements and orders are necessary to establish clear expectations and provide evidence when pursuing legal action.
Taking a progressive approach to legal interventions is recommended as found in: Legal Interventions and When to Use Them in Oregon

Implementing Legal Interventions for the Control of Tuberculosis

Oregon Revised Statutes about Isolation and Quarantine can be found here: Chapter 433 – Disease and Condition Control; Mass Gatherings, Indoor Air
Obtaining local legal counsel is strongly advised.

B. Inter-jurisdictional coordination and transfers

Congregate Setting Contact Investigation
When a TB case lives in one county but works, goes to school, worships, etc. in a different one, the contact investigation should be referred to the county where the congregate setting is located. Call the jurisdiction to alert them of the referral and discuss significant factors about the case.

In State transfers
To transfer cases, contacts, LTBI and B-waivers within the state of Oregon, see TB Transfer Instructions.

Transferring TB cases and contacts to other states and U.S. territories
For complete directions on how to transfer cases out of Oregon to another U.S. state or territory, see the TB Transfer Instructions. U.S. territories include American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Marshall Islands, Republic of Palau and U.S. Virgin Islands.

International transfer of TB cases and contacts
Attempts should be made to transfer all TB cases and contacts who are leaving the U.S. Review the CDC DTBE's Process for International Notification of TB Cases. Contact heidi.behm@state.or.us if there are questions. A note should be left in Orpheus regarding the international transfer of a case or contact.

Obtaining medical records for TB patients who enter the United States
Information on obtaining international medical records is available at CDC DTBE's Process for International Notification of TB Cases.
TB cases and contacts transferred to Oregon from other states and U.S. territories

If a case of TB disease is transferred from another state or country to your jurisdiction, create a new case in Orpheus. When you receive a transfer to your jurisdiction, you must inform the referring jurisdiction about the outcome. Complete and forward the Interjurisdictional TB Notification Follow-Up Form to the referring jurisdiction.

REFERENCES AND RESOURCES

A. References

1. TB diagnosis

   • ATS/CDC/CDC Clinical Practice Guideline: Diagnosis of Tuberculosis in Adults and Children. Clinical Infectious Diseases 2016;00(0); 1-33.


2. TB treatment


3. LTBI diagnosis and treatment


• CDC. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection, United States, 2010. MMWR 2010; 59 (RR05); 1-25.

4. Contact investigation
• CDC. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. December 16, 2005 / 54(RR15); 1-37.

5. Health care facilities
• CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 2005. MMWR 2005; 54 (No. RR-17)


• OAR 333-019-041

B. TB resources

1. **CDC Tuberculosis Website:**
   • Self-Study Modules on TB

2. **TB Program, OHA:**
   • Forms
   • Case management tools
   • Patient education materials in multiple languages
   • Data
   • Rules and statutes

3. **Curry International Tuberculosis Center:**
   • TB warmline. Telephone: 877-390-6682 (toll-free) or 415-502-4600. Email: CurryTBcenter@ucsf.edu
# ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AFB</td>
<td>acid fast bacilli</td>
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<tr>
<td>CBC</td>
<td>complete blood count</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CI</td>
<td>contact investigation</td>
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<td>CMP</td>
<td>comprehensive metabolic pane</td>
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<td>CXR</td>
<td>chest x-ray</td>
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<td>DOT</td>
<td>directly observed therapy</td>
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<td>EMB</td>
<td>ethambutol</td>
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<td>IGRA</td>
<td>interferon gamma release assay (Quantiferon or TSPOT)</td>
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<td>isoniazid</td>
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<td>LFTs</td>
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<td>LTBI</td>
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<td>MTD</td>
<td>Gen Probe MTD test, type of NAAT</td>
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<td>nucleic acid amplification test</td>
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<td>TB Program, Oregon Health Authority</td>
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<td>Oregon State Public Health Laboratory</td>
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<td>Polymerase Chain Reaction</td>
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<td>RIF</td>
<td>rifampin</td>
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<td>3HP</td>
<td>12 dose once weekly isoniazid (INH) and rifapentine (RPT) used to treat latent TB infection</td>
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<tr>
<td>3HR</td>
<td>Isoniazid (INH) and Rifampin (RIF) daily 3 months (3HR)</td>
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