

Texas Department of State Health Services Standing Delegation Orders for Tuberculosis Clinical Services Provided by Authorized Licensed Nurses, Fiscal Year 2021

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) clinical services described by the TB and Hansen's Disease Branch and under the authority of Rule Title 22, Texas Administrative Code §193.2, Standing Delegation Orders.

Standing delegation orders (SDOs) and standing medical orders (SMOs) are written instructions, orders, rules, regulations or procedures prepared by a physician. SDOs provide authority and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician. SMOs provide authority and direction for the performance of certain prescribed acts for patients which have been examined or evaluated by a physician. SDOs and SMOs are distinct from specific orders written for a particular patient. The Texas TB Work Plan should be used as a companion to this SDO in order to ensure all client care standards are met. The intended audience for these orders is authorized licensed nurses working in local health departments providing TB services, and in Texas Department of State Health Services (DSHS) Public Health Regions.

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Standing Delegation Orders

A. Definitions

1. Authorized Licensed Nurse: an employee or contractor of the Texas Department of State Health Services in a nursing position who has met the requirements of and signed this SDO.
2. Authorizing Physician: a physician licensed by the Texas Medical Board who executes this SDO.
3. Licensed Healthcare Provider: a licensed healthcare provider (physician assistant, advanced practice nurse, physician) who is responsible for the care of the client. The licensed healthcare provider may be another provider who is providing care for the client in the medical community or it may be the authorizing physician, if the client does not have another provider.

B. Method Used for Development, Approval, and Revision

This SDO and the relevant attachments shall be:

1. Developed by the TB and Hansen's Disease Branch.
2. Reviewed, updated, and signed at least annually by the authorizing physician who may re-name these Standing Delegation Orders for local use and write any additional orders, provide clarification or include updates as needed to reflect local practice, with the standards outlined in this document as the minimum orders.
3. Revised as necessary by the DSHS Infectious Diseases Medical Officer, the Regional Medical Directors, and/or the TB and Hansen's Disease Branch.
4. Reviewed (and revised as necessary) annually by Heartland National Tuberculosis Center heartlandntbc.org.

C. Level of Experience, Training, Competence, and Education Required

To carry out acts under this SDO, an authorized licensed nurse must:

1. Be an employee or contractor of the Texas Department of State Health Services.
2. Be currently licensed to practice by the Texas Board of Nursing.
3. Be currently certified in Basic Life Support.
4. Have reviewed, are familiar with, and able to readily access the recommendations within the following documents:
 - a. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases (2016) 63 (7): e147-e195.
cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf
 - b. Official American Thoracic Society/Infectious Diseases Society of America/ Centers for Disease Control and Prevention Clinical Practice

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- Guidelines: Diagnosis of Tuberculosis in Adults and Children (2016)
[cdc.gov/tb/publications/guidelines/pdf/cid_ciw694_full.pdf](https://www.cdc.gov/tb/publications/guidelines/pdf/cid_ciw694_full.pdf)
- c. Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020.
[cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf](https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf)
- d. Recommendations for Use of an Isoniazid–Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. MMWR. 2011; 60(48):1650–1653.
[cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=m_m6048a3_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=m_m6048a3_w)
Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection (2018)
[cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=m_m6725a5_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=m_m6725a5_w)
- e. American Academy of Pediatrics. Committee on Infectious Diseases. (2018). Red Book: Report of the Committee on Infectious Diseases. Red Book, 31st edition. American Academy of Pediatrics (AAP), 2018.
- f. Who Should Be Tested. CDC, 2016.
[cdc.gov/tb/topic/testing/whobetested.htm](https://www.cdc.gov/tb/topic/testing/whobetested.htm)
- g. Recommendations for Human Immunodeficiency Virus (HIV) Screening in Tuberculosis (TB) Clinics Fact Sheet.
[cdc.gov/tb/publications/factsheets/testing/HIVscreening.htm](https://www.cdc.gov/tb/publications/factsheets/testing/HIVscreening.htm)
- h. AIDSInfo Clinical Guidelines Portal. aidsinfo.nih.gov/guidelines
- i. Core Curriculum on Tuberculosis: What the Clinician Should Know, 6th Edition. CDC, 2013.
[cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf](https://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf)
Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection — United States, 2010. MMWR. 2010; 59(5):1-25.
[cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr59_05a1_e](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr59_05a1_e)
- j. Consensus statement on the use of Cepheid Xpert MTB/RIF assay in making decision to discontinue airborne infection isolation in healthcare settings. National Tuberculosis Controllers Association (NTCA) and Association of Public Health Laboratories (APHL), April 2016.
[tbcontrollers.org/docs/resources/NTCA_APHL_GeneXpert_Consensus_Statement_Final.pdf](https://www.tbcontrollers.org/docs/resources/NTCA_APHL_GeneXpert_Consensus_Statement_Final.pdf).
- k. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. MMWR. 2006; 55(RR14):1-17.
[cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm)
- l. An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy. Am J Respir Crit Care Med. 2006; 174:935-952.
[thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf](https://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf)

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- m. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005; 54(RR17):1-141.
cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr54_17a1_e
Update: Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR. May 17, 2019 / 68(19);439-443
cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=m_m6819a3_w
- n. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. MMWR 2005; 54(RR15): 1-55.
cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm
- o. Controlling Tuberculosis in the United States Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. MMWR. 2005; 54(RR12):1-81.
cdc.gov/MMWR/preview/MMWRhtml/rr5412a1.htm
- p. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR. 2000; 49(RR06):1-54.
cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm
Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003. MMWR. 2003; 52(31):735-739.
cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm
- q. Recommendations for Prevention and Control of Tuberculosis among Foreign-Born Persons. MMWR. 1998; 47(RR16):1-26.
cdc.gov/MMWR/preview/MMWRhtml/00054855.htm
- r. Tuberculosis Control Laws-United States, 1993 Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR.1993;42(RR15).
cdc.gov/mmwr/preview/mmwrhtml/00030715.htm
- s. Prevention and Control of Tuberculosis in Migrant Farm Workers Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR10).
cdc.gov/MMWR/preview/MMWRhtml/00032773.htm
- t. Prevention and Control of Tuberculosis Among Homeless Persons Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR5):001.
cdc.gov/MMWR/preview/MMWRhtml/00019922.htm

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5. Have undergone an initial or continuing evaluation of competence relevant to TB clinical services within 12 months prior to signing and providing TB clinical services under this SDO:
- Initial evaluation of competence is performed by the authorizing physician, the nurse’s supervisor, or clinical designee and consists of completion of 40 hours of continuing education and skills training (including the CDC’s “Self-Study Modules on Tuberculosis” <http://www.cdc.gov/TB/education/ssmodules/>), as approved by the TB program manager, and completion of a mentoring plan facilitated by an experienced TB nurse and/or licensed healthcare provider.

The authorized licensed nurse must receive an initial evaluation by the authorizing physician, the nurse’s supervisor, or clinical designee that documents the nurse’s ability to carry out these orders in the customary manner.

For authorized licensed nurses whose primary job duties are with the TB program, this training and evaluation of competence must occur within 90 days of employment. For other authorized licensed nurses, this training and evaluation of competence must occur before TB clinical services are independently provided by the nurse.

- Continuing evaluation of competence is performed annually by the authorizing physician, the nurse’s supervisor, or clinical designee and consists of completion of 16 hours of continuing education and skills training, as approved by the regional or local TB program manager.

The authorized licensed nurse must receive an annual evaluation by the authorizing physician, the nurse’s supervisor, or clinical designee that documents the nurse’s ability to carry out these orders in the customary manner.

6. Have reviewed and signed this SDO, **ATTACHMENT 1: *Attestation of Authorized Licensed Nurse***, within 12 months prior to providing services under this SDO.

D. Method of Maintaining a Written Record of Authorized Licensed Nurses

A record of the authorized licensed nurses who complete the required training and demonstrate competence shall be documented and maintained by the nurse’s supervisor in the Local Health Department or Public Health Region office.

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E. Authorized Delegated Acts

Authorized licensed nurses may evaluate and provide TB clinical services under this SDO to clients who are undergoing evaluation for TB disease or TB infection or are a contact to a confirmed or suspected TB disease case.

It is the intent of all parties that the acts performed under this SDO shall be in compliance with the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, and the rules promulgated under those Acts.

F. Procedures and Requirements to be Followed by Authorized Licensed Nurses

1. Adhere to all Standard Precautions, including bloodborne and respiratory precautions, when participating in TB clinical services.
2. Utilize interpreter services to facilitate client and provider communication as it relates to limited English proficient (LEP) clients. DSHS employees may use the service listed on the following website:
online.dshs.internal/languageservices/phone.aspx
3. Establish that the client requires evaluation for TB disease or TB infection or is a contact to a confirmed or suspected TB disease case.
4. Ensure, to the extent possible, that the client seen for TB clinical services is, in fact, who the person claims to be.
5. Ensure the client's consent, in the preferred language of the client, and signature have been obtained in accordance with agency policy and provide copies of the **DSHS Privacy Notice** and/or applicable signed consent forms.
 - **DSHS General Consent and Disclosure** (L-36), available at:
dshs.texas.gov/rls/pubs/GeneralConsentForm042010.pdf
 - **DSHS Privacy Notice**, available at:
dshs.texas.gov/hipaa/privacynotices.shtm
6. All clients undergoing evaluation for TB disease or TB infection will receive an initial evaluation to consist of:
 - a. A personal and medical history.
 - b. An appropriate physical examination.
 - c. An explanation of all test(s) to be performed and the risk and benefits of each one. Provide the opportunity for the client to ask questions.
 - d. The medical screening as described in **ATTACHMENT 2: Medical Screening**.
 - e. **TB screening tests:** Determine if the client has had a previous positive

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TB screening test performed in the United States and if there is written documentation of the results OR if the client has had previous TB disease and if there is written documentation of the treatment.

- 1) If not, perform a TB screening test with an interferon gamma release assay (IGRA), either T-SPOT®.TB test or QuantiFERON®-TB Gold Plus, as determined by the licensed healthcare provider; the tuberculin skin test (TST) may be used if client is unable to receive an IGRA or refuses phlebotomy, as described in **ATTACHMENT 3: TB Screening Tests**, if the client has no contraindications for the selected TB screening test.
 - 2) If so, do not administer another TB screening test, unless instructed by the licensed healthcare provider. Obtain a copy of the results or treatment and document in the client's medical record.
 - If the client has had any past treatment for TB infection, obtain a copy of the treatment, if able, and document in the client's medical record.
7. Obtain additional diagnostic tests appropriate to the services provided.
- a. **Laboratory Tests:** Determine the need for lab specimen collection, as described in **ATTACHMENT 4: Laboratory Tests (Labs)**. Determine if the client has had the appropriate lab specimens collected within the last 14 days and if there is written documentation of the results.
 - 1) If not, perform venipuncture and collect specimens in the proper tubes, according to laboratory submission requirements.
 - 2) If so, do not perform venipuncture or collect specimens, unless instructed by the licensed healthcare provider. Obtain a copy of the results and document in the client's medical record.
 - b. **Chest X-Ray:** Determine the need for a CXR, as described in **ATTACHMENT 5: Chest X-Ray (CXR)**. Determine if the client has had the appropriate CXR performed within the allowed time frame and if there is written documentation of the results.
 - 1) If not, refer for and obtain CXR within 14 calendar days if the client has no contraindications for CXR. TB programs with on-site radiograph equipment should obtain a CXR within ten (10) calendar days.
 - 2) If so, do not obtain another CXR, unless instructed by the licensed healthcare provider. Obtain a copy of results (and images, if available, for provider review) and document in the client's medical record.
 - c. **Sputum Collection:** Determine the need for sputum collection, as described in **ATTACHMENT 6: Sputum Collection**. Determine if the client has had the appropriate sputum collection(s) performed within the allowed time frame and if there is written documentation of the results.
 - 1) If not, collect sputum specimens, according to laboratory submission

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requirements. Otherwise, contact the licensed healthcare provider for instructions.

- 2) If so, do not collect sputum, unless instructed by the licensed healthcare provider. Obtain a copy of the results and document in the client's medical record.

8. Label and correctly package specimens, according to shipping requirements and regional or local procedures. Submit specimens to an approved laboratory for processing.

9. Document the following in the client's medical record:
 - All test collection dates, test types, circumstances affecting collection, and results.
 - That all diagnostic test results were reviewed.

10. For clients suspected or confirmed to have TB disease, provide the Order to Implement and Carry Out Measures for a Patient with Tuberculosis ("Control Order" or the TB 410 or equivalent dshs.texas.gov/IDCU/disease/tb/TB-Forms.doc), signed and dated by the local health authority, for the client to review at the beginning of treatment, if not provided already.

Explain the Control Order and risks of violation of the Control Order. Provide the opportunity for the client to ask questions. Have the client review and sign the Control Order.

Provide a copy of the Control Order to the client.

 - If the client has questions the nurse cannot answer, contact the local health authority.
 - If the client refuses to sign the Control Order, sign and date that the Control Order was given, and that the patient refused to sign it; this serves as documentation in the event the patient violates the order.
 - If the client violates the Control Order, immediately notify the licensed healthcare provider treating the client and the local health authority who signed the control order.

11. For clients suspected or confirmed to have TB disease, implement location-appropriate isolation (home-based or refer to a negative pressure air-borne infection isolation room (AIIR) if in a congregate setting).

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a. If the client has an AFB smear positive specimen, do NOT release from isolation until:

- The client has three consecutive negative AFB sputum smears, collected in 8- to 24- hour intervals; and
 - has symptomatic improvement; and
 - has been on multi-drug therapy for tuberculosis **for at least the equivalent of two weeks** given as directly observed therapy (DOT); and
 - has been completely adherent with DOT

Once the above criteria are met, the client may be released from isolation, with the date documented in the medical record.

b. If the client has never had an AFB smear positive sputum or other respiratory specimen, do NOT release from isolation until:

- The client has three consecutive negative AFB sputum smears, collected in 8- to 24- hour intervals; and
 - has symptomatic improvement; and
 - has been on multi-drug therapy for tuberculosis for **at least 5 days** given as directly observed therapy (DOT); and
 - Has been completely adherent with DOT.

Once the above criteria are met, the client may be released from isolation with the date documented in the medical record.

c. If the client has positive AFB sputum smears and the last two consecutive sputum specimens return AFB culture negative, they may be released from isolation if they meet the following criteria (*even if they remain smear positive, as these likely represent dead organisms*):

- have symptomatic improvement;
- have been on multi-drug therapy for tuberculosis for **at least the equivalent of two weeks**;
- given as directly observed therapy (DOT); and
- have been completely adherent with DOT.

12. Send all pertinent clinical information to the licensed healthcare provider for review and specific medication therapy orders before medications are administered or provided to the client.

For verbal or telephone orders, or for telephonic reporting of critical test results, verify the complete order or test result by recording the complete order or test result in the client's medical record and "reading-back" the complete order or test result. Receive confirmation from the licensed healthcare provider who gave the order or received the test result.

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All verbal or telephone orders should be reviewed and countersigned or confirmed by written communication as soon as possible, ideally within one week.

13. The authorized licensed nurse shall review the most recent TB medication regimen ordered by the licensed healthcare provider, a copy of which is placed in the medical record, ensuring that an updated medication consent form is updated in the chart as needed
 - a. Verify appropriate weight-based dosage calculations for all clients. For purposes of dosage calculations and treatment regimen selection, a client is considered a child if the client is less than 18 years old and should receive pediatric weight-based dosing of medications as described in **ATTACHMENT 7: Medications, Table 6.**

14. Determine whether the client is taking medications that interact when used with the prescribed TB medication regimen. Seek out/consult with a trusted drug information source (e.g., DSHS Library access to "Facts and Comparison," DSHS pharmacist, prescribing licensed healthcare provider) to verify possible medication interactions.
 - a. If so, do not administer or provide medications. Notify the licensed healthcare provider for instructions.
 - b. If not, administer (for directly observed therapy (DOT)) or provide (for self-administered therapy) medications consistent with the most recent licensed healthcare provider order.
 - 1) If medications are to be administered by **DOT**, verify the medications administered are the same as the medications ordered, provide the DOT packet(s) to the client, and observe the client ingesting all prescribed medication in each DOT dose packet.
 - 2) If medication(s) are to be **self-administered** by the client, complete the medication label and provide the medication(s) to the client.
 - i. As required by the Texas State Board of Pharmacy (Rule Title 22, Texas Administrative Code §291.93), the following information will be pre-printed on the medication label for self-administered medications:
 - The name, address, and telephone number of the clinic
 - The name and strength of the drug - if generic name, the name of the manufacturer or distributor of the drug
 - Quantity
 - Lot number
 - Expiration date

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- ii. The authorized licensed nurse will complete the labeling directions so that it contains the following information:
 - The client's name
 - Date medication is provided
 - The physician's name
 - Directions for use (per Texas State Board of Pharmacy rules, incomplete directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of provision)

See sample label:

DSHS Pharmacy Near You 123 Pharmacy Lane Pharmacy, TX 1231234 (512)555-5555		Date:
Name:	Exp:	01/01/19
Dir:	Lot:	111222
RIFAMPIN CAP 300 MG #60 Take ___ caps by mouth each day. Take 1 hour before or 2 hours after meals. May decrease effectiveness of birth control pills.		
VERSAPHARM		61748001860
STORE BELOW 86 DEGREES F.		

- 3) Counsel the client regarding possible side-effects, conditions under which medications should be stopped and the clinic contacted, and the need to prevent pregnancy, if applicable.
- 4) Provide patient with a Patient Education Sheet outlining the uses of the drug(s), potential side effects, and other precautions.
- 5) Document on Medication Provision Log patient's name or initials, drug(s) given (name, strength, quantity), and initials of nurse providing the medications;
- 6) The initial dose of each new TB medication should be given by an authorized licensed nurse with emergency supplies readily available, when possible. The client should remain for 30 minutes for observation of adverse reactions. Document how long the patient was observed.

15. The following *must* be provided via DOT until completion of therapy:

- a. All regimens for TB disease
- b. Intermittent regimens for TB infection (self-administration may be considered on select patients for 3HP; see **ATTACHMENT 7: Medications**, Table 5)
- c. All treatment for TB infection for contacts to multi-drug resistant (MDR)-TB, pre-extensively drug-resistant (pre-XDR) TB, or extensively-drug

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resistant (XDR)-TB

DOT for TB infection is *highly recommended* for the following:

- children less than 5 years old

16. If any of the following is true, contact the licensed healthcare provider. Do not initiate treatment until additional orders are given.
- a. The medication prescribed for TB disease or TB infection is not consistent with recommended regimens as described in **ATTACHMENT 7: Medications**.
 - b. The medication prescribed for a client co-infected with TB disease and HIV infection is ordered to be given twice-weekly.
 - c. The medication prescribed for TB disease or TB infection is not appropriate for the client's weight and/or age as described in **ATTACHMENT 7: Medications**.
 - d. The medication prescribed for TB disease or TB infection is not consistent with
 - Available and known drug susceptibilities for TB disease
 - Consult recommendations provided by a DSHS-recognized TB Medical Consultant
 - e. Contraindications or significant drug interactions exist with non-TB medications the client is currently taking, and the TB medication prescribed.
 - f. Client is suspected or known to be pregnant.
 - g. Client has active hepatitis or end stage liver disease.
 - h. Laboratory test results are not within the normal range.
 - i. Client meets indications for DOT but has been prescribed self-administered medications. Consultation with the authorizing physician must be obtained. An order or progress note in writing from the licensed healthcare provider must be placed in the client's medical record stating reasons for not providing medications by DOT, as expected by DSHS.
17. Immediately discontinue treatment if any of the following occurs. Obtain testing as described in **ATTACHMENT 4: Laboratory Tests** and consult the licensed healthcare provider before restarting any medications.
- a. Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and/or bilirubin level exceeds three times the upper limit of normal in the presence of symptoms.
 - b. AST, ALT, and/or bilirubin level exceeds five times the upper limit of normal (with or without symptoms).
 - c. Laboratory monitoring results reveal a significant change, *as defined by the licensed healthcare provider*, in white blood cell count, hemoglobin, or

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- platelet count.
- d. Laboratory monitoring results reveal a significant increase, *as defined by the licensed healthcare provider*, in alkaline phosphatase (alk phos) levels.
 - e. Client reports symptoms or has signs that could be attributed to medication toxicity.
 - f. Client is on treatment for TB infection and develops signs or symptoms of TB disease.
18. Notify the licensed healthcare provider for any interruptions of therapy, as defined in **ATTACHMENT 7: Medications**. Interruptions in treatment may have a significant effect on the duration of therapy. Reinstitution of treatment must take into account the bacillary load of the patient, the point in time when the interruption occurred, and the duration of the interruption. In general, the earlier in treatment and the longer the duration of the interruption, the more serious the effect and the greater the need to restart therapy from the beginning.
19. **Determine completion of therapy based on total number of doses administered (allowing for minor interruptions in therapy) - not on duration of therapy alone** - as described in **ATTACHMENT 7: Medications**.
- Every attempt should be made to help client *not* miss doses. Completion of treatment for initial phase must be documented before the client is permitted to begin therapy for continuation phase of treatment for TB disease. **Only after the minimum total number of DOT doses has been administered for the initial phase can DOT doses be counted towards the minimum total number of doses administered for the continuation phase.** Drug susceptibility testing should be known before discontinuing medications in the initial and continuation phases.
20. If the authorized licensed nurse has questions or concerns that the licensed healthcare provider is unable to answer, the question or concern should be referred to the regional TB program manager and/or the Regional Medical Director, when applicable. The DSHS TB and Hansen's Disease Branch may also be consulted for further information and direction.
21. If any of the conditions are met in **ATTACHMENT 9: DSHS-Recognized TB Medical Consultant Indications**, a DSHS-Recognized TB Medical Consultant should be consulted. See dshs.texas.gov/idcu/disease/tb/consultants/.

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Exceptions may be granted if made by the DSHS Regional Medical Director (RMD). In that case, the RMD must either write the medical orders for the patient or include a signed letter in the patient's medical record that the treatment prescribed meets criteria for adequate therapy. The RMD may also request a consult from a DSHS-Recognized TB Medical Consultant.

- All consults to a DSHS-Recognized TB Medical Consultant should include the specific question to be answered, adequate information regarding the history, physical, and diagnostic test results, and a cc: to the regional TB Program Manager, the Regional Medical Director, and the TB and Hansen's Disease Branch Nurse Consultant.

G. Client Record-Keeping Requirements

TB forms available at: texastb.org/forms

Authorized licensed nurses must accurately and completely report and document each client visit in a medical record prepared in accordance with local and DSHS policy or regional procedures, which will include:

1. Names of personnel involved in the evaluation and treatment at each visit, including the name of the interpreter (if an interpreter is used).
2. The client's personal health history, the client's status including signs and symptoms, and physical examination findings.
3. Actions carried out under these standing orders.
4. Any additional physician orders.
5. Medications administered, prescribed by the physician, or provided to the client.
6. Client response(s), if any.
7. Contacts with other healthcare team members (for example, the client's primary healthcare provider) concerning significant events regarding client's status.
8. Documentation that the appropriate forms are completed and included in the medical record, and copies, when applicable, are provided to the client.

H. Scope of Supervision Required

These Standing Delegation Orders give the authorized licensed nurse authority to perform the acts described in the SDOs in consultation with the authorizing physician as needed.

I. Specialized Circumstances to Immediately Communicate with the Authorizing Physician

Specific circumstances that the authorized licensed nurse providing services under this SDO should immediately contact the authorizing physician by phone include, but are not limited to:

1. Circumstances when medical direction or consultation is needed.

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2. Client has violated the signed *Order to Implement and Carry Out Measures for a Patient with Tuberculosis*.

In an emergency situation, the authorized licensed nurse is to call 911, provide emergency services as authorized in the regional or local emergency SDO, and contact his/her supervisor and/or the authorizing physician by phone as soon as possible.

J. Limitations on Setting

Authorized licensed nurses can provide services under these standing orders in the clinic setting, in the client’s home, or other field settings when the authorizing physician can be contacted by phone.

K. Date and Signature of the Authorizing Physician

This SDO shall become effective on the date that it is signed by the authorizing physician, below, and will remain in effect until it is either rescinded, upon a change in the authorizing physician, or at the end of business on the last day of the current DSHS fiscal year (August 31, 2021), whichever is earlier.

Authorizing Physician’s Signature:

Authorizing Physician’s Title:

Printed Name:

Effective Date:

Emergency Contact Information:

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ATTACHMENT 1: *Attestation of Authorized Licensed Nurse*

I, _____ have read and understand the
printed name of authorized licensed nurse

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2021 ("SDO") that was signed by Dr. _____

on _____ printed name of authorizing physician

date of authorizing physician's signature

- I agree that I meet all qualifications for authorized licensed nurses outlined in the SDO.
- I agree to follow all instructions outlined in the SDO.

Signature of Authorized Licensed Nurse

Date

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ATTACHMENT 2: Medical Screening

A. All clients undergoing initial screening for TB disease or TB infection:

1. Undergo a **clinical evaluation** that includes a signs and symptoms screening questionnaire and documentation of medical history.
2. **Screen for tuberculosis** with an approved TB screening test, as outlined in Attachment 3: *TB Screening Tests*. Perform venipuncture and collect specimens in the proper tubes, according to laboratory submission requirements.
3. For clients age 13 years and older, **screen for HIV infection** using an approved laboratory-based HIV immunoassay. For clients younger than 13 years old, screen for HIV infection using an approved laboratory-based HIV immunoassay **if risk factors for HIV infection are present** (including known or self-reporting of: mother with HIV infection and no documentation of child's status; history of blood transfusion outside the United States; history of sexually transmitted infection (STI), sexual activity, pregnancy, intravenous drug abuse).

cdc.gov/healthyouth/data/topics/index.htm;

pedaids.org/pages/about-pediatric-aids

- a. Note for testing of clients aged <24 months:

- HIV infection in infants should be diagnosed using HIV nucleic acid amplification virologic assays. (From: aidsinfo.nih.gov/guidelines/html/3/perinatal/188/initial-postnatal-management-of-the-neonate-exposed-to-hiv)
- Because children with perinatal HIV exposure aged 18 to 24 months may have residual maternal HIV antibodies, definitive exclusion or confirmation of HIV infection in children in this age group who are HIV antibody-positive should be based on a nucleic acid test. (From: aidsinfo.nih.gov/guidelines/html/2/pediatric-treatment-guidelines/0#)
- DSHS Laboratory does not perform HIV NAAT testing but can provide guidance where to send the specimen if needed; contact State Serology lab for details: dshs.texas.gov/lab/default.shtm

- b. If the client has a previously documented positive HIV test result, HIV testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.
- c. If the client has a documented negative HIV test result from a specimen collected within the last 14 days, HIV testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.

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B. All clients undergoing evaluation for TB disease or TB infection, once initially screened and diagnosed:

1. For clients age 13 years or older, **screen for diabetes** using a random plasma glucose.
 - a. If any of the following apply, do not screen for diabetes:
 - If the client is younger than 13 years old, routine screening is not recommended.
 - If the client has a previously documented positive diabetes test result, diabetes testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.
 - If the client has been prescribed medication for diabetes, diabetes testing does not need to be repeated. Obtain a copy of the most recent diabetes test results and document in the client's medical record.
 - If the client has a documented negative diabetes test result from a specimen collected within the last 14 days, diabetes testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.

2. For clients with any of the following risk factors for hepatitis B virus (HBV), **screen for HBV** using hepatitis B surface antigen (HBsAg):
 - All persons born in one of the following high-risk regions:
 - Western Pacific (includes China, Cambodia, Vietnam, the Philippines, Korea)
 - Africa (Democratic Republic of Congo, Ethiopia, Guinea, Kenya, Eritrea, Sierra Leone)
 - Southeast Asia (Bangladesh, Nepal, India, Myanmar/Burma)
 - Eastern Mediterranean (Afghanistan, Iraq, Kuwait, Pakistan, Yemen, Sudan, Syria)

Additional information can be found at:

wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-b

- US born persons not vaccinated as infants
- Persons with behavioral exposures to HBV (e.g., men who have sex with men, past or current injection drug users, history of incarceration)
- Persons receiving cytotoxic or immunosuppressive therapy
- Persons with liver disease or elevated ALT/AST of unknown etiology
- Pregnant women
- Household contacts and sex partners of HBV-infected persons
- Persons with HIV

If any of the following apply, do not screen for HBV:

- If the client has a previously documented positive HBV test result, HBV

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testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.

- If the client has a documented negative HBV test result from a specimen collected within the last 14 days, HBV testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.

3. For clients born during 1945 through 1965 (without prior ascertainment of hepatitis C virus (HCV) risk factors) or for clients with any of the following risk factors for HCV infection, **screen for HCV** using an FDA-cleared test for antibody to HCV (i.e., immunoassay, enzyme immunoassay (EIA) or enhanced chemiluminescence immunoassay (CIA) and, if recommended, a supplemental HCV test):

- Current or past injection drug use, including those who injected once or a few times many years ago
- History of incarceration
- Have certain medical conditions, including persons:
 - Who received clotting factor concentrates produced before 1987
 - Who were ever on long-term hemodialysis
 - With persistently abnormal ALT levels (if known/previously documented)
 - Who have HIV infection
- Were prior recipients of transfusions or organ transplants, including persons who:
 - Were notified that they received blood from a donor who later tested positive for HCV infection
 - Received a transfusion of blood, blood components or an organ transplant before July 1992
- Being born to a mother with HCV infection
- Intranasal drug use
- Receipt of an unregulated tattoo
- Other percutaneous exposures

If any of the following apply, do not screen for HCV:

- If the client has a previously documented positive HCV test result, HCV testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record.
- If the client has a documented negative HCV test result from a specimen collected within the last 14 days, HCV testing does not need to be repeated. Obtain a copy of the results and document in the client's medical record. Additional information can be found at:

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wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-c

4. Ask the client about his or her vaccination history. Obtain documentation and also confirm in ImmTrac. If the client's vaccination status is not current, determine if the client meets current DSHS or local Immunization Program eligibility criteria.
 - If so, immunization may be provided as authorized in the appropriate immunization SDO. Note the issue regarding administering live virus vaccines and the timing of TB screening tests in Attachment 3.
 - If not, refer client to an appropriate immunization provider resource for vaccination.

C. Clients suspected or confirmed to have drug susceptible TB disease and who are prescribed treatment will have the following medical screening:

1. **Baseline and monthly clinical monitoring** and evaluation for TB medication toxicity:
 - If client is taking **ethambutol** or **rifabutin**, this includes red/green color discrimination using Ishihara plates and visual acuity using Snellen chart.
 - If client is taking high dose isoniazid, this is to include screening for peripheral neuropathy.
2. **Clinical evaluation as soon as feasible** when signs or symptoms of medication toxicity develop. In this case, hold the medications, contact the licensed healthcare provider, do not resume until re-started by the provider.

D. Clients receiving treatment for TB infection (including clients on window prophylaxis) will have the following medical screening:

1. **Baseline and monthly clinical monitoring** and evaluation for TB medication toxicity.
 - If client is taking **rifabutin**, this is to include red/green color discrimination using Ishihara plates and visual acuity using Snellen chart. (See notation below Table 5 for indications of rifabutin usage.)
2. **Clinical evaluation as soon as feasible** when signs or symptoms of medication toxicity develop. In this case, hold the medications, contact the licensed healthcare provider, do not resume until re-started by the provider.

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ATTACHMENT 3: TB Screening Tests

A. The following clients may undergo TB screening testing:

1. All clients undergoing evaluation for, or diagnosed with, TB disease and there is not a documented previous positive tuberculin skin test (TST) or interferon-gamma release assay (IGRA) result performed in the United States or documented previous TB disease, *unless the criteria in #6 apply.*
2. All clients undergoing evaluation for TB infection and there is not a documented previous positive TST or IGRA result performed in the United States *unless the criteria in #6 apply.* Clients with history of severe reaction to a TST (i.e., blistering) should not have a repeat TST.
3. All contacts who meet criteria for testing, and there is not a documented previous positive TST or IGRA result or documented previous TB disease.
 - If the initial TB screening test is negative, administer a second TB screening test 8 to 10 weeks after the last exposure.
 - See **ATTACHMENT 7: Medications** for indications for window prophylaxis and recommendations to complete a full course of treatment for TB infection (beyond the window period) even if a TB screening test administered 8 weeks or more after the end of exposure is negative.
4. All clients who meet criteria for targeted testing, except screening in correctional facilities – monthly screening reports shall be submitted in accordance with TB and Hansen’s Disease Branch.
5. DSHS employees and contractors providing TB services, when TB screening is indicated.
6. Class B immigrants or other immigrants* (including refugees) undergoing immigration screening.

Exceptions: Immigrants who need evaluation for TB, including those who are reported from the Electronic Disease Notification (EDN) system with a classification of A or B, will have the following exceptions to repeat testing:

- a) Applicants with a documented positive IGRA test, even if performed overseas, do not need to have a repeat IGRA at the health department unless indicated by the licensed healthcare provider.
- b) For applicants under age 2 years old who have a TST performed overseas, the TST should not be repeated unless there is no specific documentation of a result (in mm induration), unless recommended by the licensed healthcare provider.
- c) For applicants over 2 years old, screen for TB with an IGRA if the

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last test done overseas was a positive TST only. Consideration of diagnosis should be made based on the IGRA result, however the licensed healthcare provider will need to consider items listed in B. 4., below.

**Applicants referred from a civil surgeon should not undergo a TB screening test initially at the health department; they should be referred to the health department only after a full evaluation has been done by the civil surgeon (that includes IGRA/TST and CXR).*

Refer to: [cdc.gov/immigrantrefugeehealth/exams/ti/civil/tuberculosis-civil-technical-instructions.html](https://www.cdc.gov/immigrantrefugeehealth/exams/ti/civil/tuberculosis-civil-technical-instructions.html).

B. TB screening tests may include TST OR IGRA:

1. It is important before applying a TB screening test that information is known about the client's risk for infection and risk for progression to disease if infected. The single test that is most appropriate for the client should be chosen and applied. More than one test should not be routinely performed.
2. **Routine testing with BOTH a TST and an IGRA is not recommended.** If an IGRA is chosen, it should be used in place of, NOT IN ADDITION TO, a TST.
3. Performing both a TST and an IGRA can be considered in the following situations after consulting with the licensed healthcare provider and receiving a patient-specific order for the additional test:
 - The initial test is negative and the risk for infection, the risk for progression, and the risk for a poor outcome are increased (e.g., when persons with HIV infection or children aged younger than five years are at increased risk for *Mycobacterium tuberculosis (M.tb)* infection), or
 - The initial test is negative and clinical suspicion exists for active tuberculosis disease (such as in persons with symptoms, signs, and/or radiographic evidence suggestive of active tuberculosis disease) and confirmation of *M.tb* infection is desired.
 - The initial test is positive and additional evidence of infection is required to encourage compliance or to confirm the positive test (e.g., in foreign-born health-care workers who believe their positive TST result is attributable to BCG). A positive IGRA might prompt greater acceptance of treatment for latent TB infection as compared with a positive TST alone.
 - The initial test is positive, and the client is considered a healthy person who has a low risk for both infection and progression.
4. **If both an IGRA and a TST are performed and discordant results are obtained**, the licensed healthcare provider will need to make a determination

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regarding whether or not the client should be considered to have TB infection, based on client's risk factors, examination, and epidemiology (such as exposure risk). The TB and Hansen's Disease Branch can assist but cannot make this determination in lieu of the licensed healthcare provider.

5. **If both an IGRA and a TST are performed because the initial test is negative**, a positive result from a second test increases detection sensitivity. If the repeat test is positive and the client is high risk, any positive test result should be considered evidence of TB infection and acted upon accordingly. If the second test is negative and the client is high risk, it still does not conclusively rule out *M.tb* infection. Multiple negative results from any combination of these tests cannot exclude *M.tb* infection.
6. **If both an IGRA and a TST are performed because the initial test is positive**, a positive result from the second test increases the likelihood that the test result reflects infection.
 - An alternative is to assume, *without additional testing*, that the initial result is a false positive or that the risk for disease does not warrant additional evaluation or treatment, regardless of test results. This should only be considered after careful assessment of the client's risk, physical exam findings and history of exposure.
 - Steps should be taken to minimize unnecessary and misleading testing of persons at low risk.
7. Repeating an IGRA or performing a TST should be considered when the initial IGRA result is indeterminate, borderline, invalid, or if interpretation results are in question and a reason for testing persists.
 - If an IGRA is to be repeated, a new blood sample should be used. In such situations, repeat testing with another blood sample usually provides interpretable results.
8. A TST is not recommended to be repeated unless the administration or reading of the TST is determined to be unreliable, the tuberculin PPD is determined to be expired, or if performed as 2nd round screening 8-10 weeks after a break in exposure.

C. Which TB screening test to choose:

1. IGRA is the preferred testing choice. Before a TB screening test is performed, the advantages and limitations of TST and IGRA must be evaluated for each client. Refer to *Figure 1* for choosing the appropriate TB test in children.

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2. An IGRA is *preferred* for testing the following groups or individuals aged **two (2) years and older**:
- High-risk individuals who have previously received BCG
 - Congregate settings, for employees and residents
 - Persons with diabetes or on dialysis
 - Immunocompromised persons
 - Persons undergoing contact investigation
 - Persons who work with TB clients
 - Persons anticipated to receive TNF- α inhibitors or other biologic response modifiers
- a. If an IGRA is used, there is no preference for the use of one IGRA over another.
- b. Do NOT administer IGRA if the client has received a live virus vaccine within the last 4 to 6 weeks. Contact the licensed healthcare provider for instructions. (From: cdc.gov/tb/publications/factsheets/testing/igra.htm)
- Until additional information is available regarding how live virus vaccines might affect IGRA test results, IGRA testing in the context of live virus vaccine administration should be done as follows:
 - Either on the same day as vaccination with live-virus vaccine or 4 to 6 weeks after the administration of the live-virus vaccine
 - At least one month after smallpox vaccination
- c. When IGRA testing is performed greater than 3 days after TST, the PPD injection should be expected to boost anamnestic immune responses measured by IGRA originating from *M.tb* infection (but not from BCG vaccination or in non-sensitized persons). The effect also appears to be more apparent in those individuals who are already IGRA positive. To date, there is no definitive data and some experts suggest waiting 3 months after TST before testing with IGRA, while others feel this is unnecessary. **Decisions to delay IGRA testing can only be made by the licensed healthcare provider.**
3. **TST is preferred for testing clients younger than 2 years old** and may be used if the client is unable to receive an IGRA or refuses phlebotomy. For infants younger than 6 months, a negative TST cannot be confirmed until the infant is 6 months old, or after the break in contact period, whichever is later. If the test is positive, then refer for medical evaluation. If negative, then retest at age 6 months or 8-10 weeks after the break in contact, whichever is later, to confirm a negative test.

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Any infant who is a contact to infectious tuberculosis should be placed on window prophylaxis until the TST can be confirmed. See **Attachment 7: Medications**, section B.

- a. Do NOT administer TST if any of the following apply*. Contact the licensed healthcare provider for instructions.
- Allergy to any component of TUBERSOL or APLISOL or an anaphylactic or other allergic reaction/hypersensitivity to a previous test of tuberculin purified protein derivative (PPD)
 - Severe reaction to previous TST such as ulceration, necrosis, blistering, bullae, anaphylaxis
 - Documented active TB
 - A documented history of treatment for TB infection or disease
 - Extensive burns or eczema
 - Immunization with a live virus vaccine that interacts with TST within the last 4 to 6 weeks
 - TST may be given on the same day as immunization with a live-virus vaccine; otherwise, TST testing should be delayed for 4 to 6 weeks after vaccination.
 - Live virus vaccines that interact with TST include: measles, mumps, rubella, varicella, zoster, yellow fever, intranasal influenza, oral polio.

*From:

[fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts / ucm114924.pdf](https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114924.pdf) and
[fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts / ucm114912.pdf](https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114912.pdf)

If TST is performed, provide instructions to the client regarding care of the injection site, then read and interpret the TST result within 48 to 72 hours.

b. Definition of TST Reaction:

- **Negative reaction:** An induration less than the specified criteria based on risk factors shows either a lack of tuberculin sensitivity or a low grade sensitivity that most likely is not caused by *Mycobacterium tuberculosis* complex (*M.tb*). A negative test does not rule out the presence of TB.
- **Positive Reaction:** An induration greater than or equal to the specified criteria based on risk factors indicates infection with *M.tb*.

c. TST Interpretation:

- 1) An induration of **5 mm or more** is considered to be positive for:
- HIV-infected persons

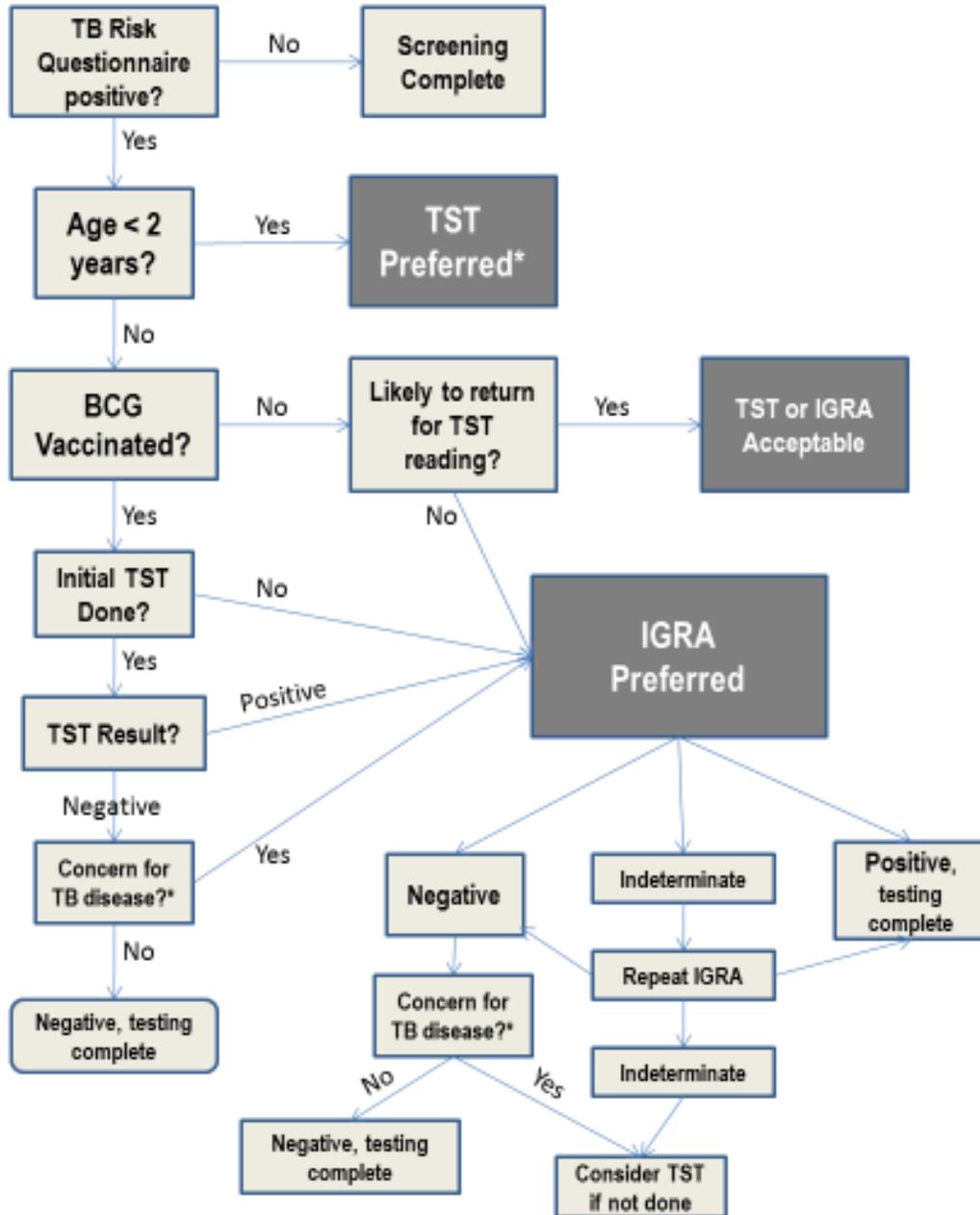
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- Recent contacts to a known TB case
 - Individuals with fibrotic changes on chest radiograph consistent with old TB
 - Persons with organ transplants and other immunosuppressed persons (such as taking the equivalent of greater than 15 mg/day prednisone for longer than 1 month or taking tumor necrosis factor- α antagonists)
- 2) An induration of **10 mm or more** is considered to be positive for:
- Individuals from high-prevalence countries
 - Injection drug users
 - Residents and employees of high-risk congregate settings: correctional facilities, nursing homes and other healthcare or long-term care facilities, residential facilities for AIDS patients, and homeless shelters
 - Mycobacteriology laboratory personnel
 - Persons with high-risk clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of > 10% of ideal body weight, gastrectomy, jejunioileal bypass
 - Children younger than 4 years of age
 - Infants, children, adolescents exposed to adults in high-risk categories
- 3) An induration of **15 mm or more** is considered to be positive for:
- Individuals with no known risk factors for tuberculosis.

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Figure 1: Algorithm for TB Testing in Children

Algorithm for TB Testing in Children



*Either positive TST or IGRA considered significant (indicative of TB infection or disease) if there is clinical suspicion of disease or high risk for progression or poor outcome in patients with latent TB infection
 Geltmeyer A, Smith KC. 16th Annual Conference of the IUATLD-North American Region, Feb 2012.

Algorithm courtesy of Heartland National Tuberculosis Center

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ATTACHMENT 4: *Laboratory Tests (Labs)*

A. Clients suspected or confirmed to have TB disease age 18 or older, will have the following labs collected under the following circumstances:

At Baseline:

1. Baseline measurements of complete blood count (CBC), and testing to include at least: AST, ALT, total bilirubin, alk phos, albumin, and creatinine.

Monthly:

1. Monthly measurements of CBC and testing that includes at least: AST, ALT, total bilirubin, alk phos, and/or creatinine if the baseline result is abnormal.
2. Monthly measurements of AST, ALT, total bilirubin, and alk phos for clients with risk factors for hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first three months postpartum
 - Clients with or at risk for HBV, HCV, or other liver disorder
 - Clients taking medications for other comorbidities or chronic medical conditions that may affect the liver or kidneys
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the liver

As Needed:

1. Measurement of AST, ALT, total bilirubin, and alk phos if AST, ALT and/or bilirubin level exceeds **more than three times the upper limit of normal in the presence of symptoms or more than five times the upper limit of normal with or without symptoms present**. Hold medication and contact the licensed healthcare provider for instructions.
2. Measurement of AST, ALT, total bilirubin, and alk phos if there is a significant increase, *as defined by the licensed healthcare provider*, compared to any prior measurements, in alk phos. Hold medication and contact the licensed healthcare provider for instructions.
3. Measurement of CBC if there is a significant change, *as defined by the licensed healthcare provider*, compared to any prior measurements, in white blood cell count, hemoglobin, or platelet count. Hold medication and contact the licensed healthcare provider for instructions.

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4. Measurement of CBC, AST, ALT, total bilirubin, alk phos, albumin, and creatinine if the client reports symptoms or has signs that could be attributed to medication toxicity. If symptoms or signs are compatible with hepatotoxicity, only measurements of AST, ALT, total bilirubin, alk phos, and albumin are necessary. Hold medication and contact the licensed healthcare provider for instructions.
5. Note: **Routine testing of serum uric acid is not recommended.** Acute gouty arthritis is a known adverse effect of pyrazinamide (PZA) and is rare except in patients with preexisting gout, which is generally a contraindication to the use of the drug. Non-gouty polyarthralgia may occur in up to 40% of patients receiving daily doses of PZA and rarely requires dosage adjustment or discontinuation of the drug. Asymptomatic hyperuricemia is an expected effect of the drug and is generally without adverse consequence. See [cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm) for additional information. If the client develops signs and symptoms consistent with acute gouty arthritis, hold medication and contact the licensed healthcare provider for instructions.
6. Therapeutic drug monitoring for clients who are slow to respond to therapy and/or who have risk factors for poor drug absorption as determined by the licensed healthcare provider. Refer to *Therapeutic Drug Monitoring Process* at: dshs.texas.gov/idcu/disease/tb/forms/#resources.

B. Clients receiving treatment for TB infection (including clients on window prophylaxis) age 18 or older will have the following labs collected under the following circumstances:

At Baseline:

1. Baseline measurements of AST, ALT, total bilirubin, alk phos, and albumin for all clients starting treatment for TB infection **AND** who have risk factors for potential hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first 3 months postpartum
 - Clients with or at risk for HBV, HCV, or other liver disorders
 - Clients with other comorbidities or chronic medical conditions
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the live
2. Baseline measurement of a complete blood count (CBC) if starting on a rifamycin.

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Monthly:

1. Monthly measurements of AST, ALT, total bilirubin, and/or alk phos if the baseline result is abnormal.
2. Monthly CBC if patient will be taking a regimen that includes a rifamycin, if the baseline CBC is abnormal.
3. Monthly measurements of AST, ALT, total bilirubin, and alk phos for clients with risk factors for hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first three months postpartum
 - Clients with or at risk for HBV, HCV, or other liver disorder
 - Clients with other comorbidities or chronic medical conditions
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the liver

As Needed:

1. Measurement of AST, ALT, total bilirubin, and alk phos if AST, ALT and/or bilirubin level exceeds **more than three times the upper limit of normal in the presence of symptoms or more than five times the upper limit of normal with or without symptoms present.** Hold medication and contact the licensed healthcare provider for instructions.
2. Measurement of AST, ALT, total bilirubin, and alk phos if there is a significant increase, *as defined by the licensed healthcare provider*, compared to any prior measurements, in alk phos. Hold medication and contact the licensed healthcare provider for instructions.
3. Measurement of CBC if there is a significant change, *as defined by the licensed healthcare provider*, compared to any prior measurements, in white blood cell count, hemoglobin, or platelet count. Hold medication and contact the licensed healthcare provider for instructions.
4. Measurement of CBC, AST, ALT, total bilirubin, alk phos, albumin, and creatinine if the client reports symptoms or has signs that could be attributed to medication toxicity. If symptoms or signs are compatible with hepatotoxicity, only measurements of AST, ALT, total bilirubin, alk phos, and albumin are necessary. Hold medication and contact the licensed healthcare provider for instructions.

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NOTE: **For clients younger than 18 years**, considerations can be made for laboratory testing of children who meet the following criteria: chronic medical conditions, those on medications chronically, with disseminated disease or who endorse substance use. Contact the licensed healthcare provider. Note: alk phos varies in children depending on growth cycles, ensure that consideration is made for interpreting pediatric laboratory values.

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ATTACHMENT 5: Chest X-Ray (CXR)

For clients younger than 18 years old, or clients with HIV infection, CXR should include posterior-anterior and lateral views.

For adult clients, CXR should include at least posterior-anterior view.

For pregnant clients evaluated for active TB disease, CXR should be done without delay and with appropriate shielding, even in the first trimester, if indicated.

A. The following clients will have an initial CXR:

1. Clients suspected or confirmed to have TB disease:

- a. All clients exhibiting signs and symptoms of active pulmonary TB disease.
- b. Clients with suspected or known extra-pulmonary TB to assess for the presence of pulmonary involvement.

2. Clients with TB infection:

- a. Clients exhibiting signs and symptoms of active pulmonary TB disease.
- b. Clients newly identified as infected with TB based upon a documented positive TST result or documented positive IGRA result.

3. Clients undergoing evaluation as part of a contact investigation:

- a. Clients exhibiting signs and symptoms of active pulmonary TB disease.
- b. Clients newly identified as infected with TB based upon a documented positive TST result or documented positive IGRA result.
- c. Clients who are contacts to a TB case and have documentation of a prior positive TB screening test but have not been treated for TB infection.
- d. Clients who are contacts to a TB case and are at high risk of progression to active TB disease regardless of their TB screening test result:
 - Children younger than 5 years old
 - Clients who have HIV infection or at high risk for HIV infection
 - Clients who have an immunocompromising condition
 - Clients receiving immunosuppressive therapy
- e. Clients who have a previous CXR showing pulmonary fibrotic lesions (presumed from prior TB) and have not been treated for TB.

4. Clients who have been referred to the health department for evaluation through the Electronic Disease Notification (EDN) system or who have self-referred for services, when indicated. EDN clients needing an *initial* CXR include:

- Any client with signs and symptoms of TB disease
- Any client with a positive IGRA or TST on **domestic** screening
- All clients with known HIV infection
- Any client classified as a Class A or B* whose overseas medical examinations are unavailable and/or there has been a change in clinical

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status (i.e., new signs or symptoms of pulmonary or extrapulmonary TB disease)

- Any EDN client *as determined by the licensed health care provider*

For full guidelines on screening immigrants referred from the Electronic Disease Notification (EDN), see:

[cdc.gov/immigrantrefugeehealth/guidelines/domestic/tuberculosis-guidelines.html](https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/tuberculosis-guidelines.html)

**Some providers may recommend repeating radiology domestically for any client with Class A or B TB classification if the CXR was performed overseas; contact the licensed healthcare provider.*

B. The following clients will have a follow-up CXR:

1. Clients suspected or confirmed to have TB disease:

- a. For all clients who started medication for TB, regardless of culture results, a CXR at completion of 2 months of treatment.
- b. All clients should have a CXR near or at the end of treatment to serve as a new baseline for future evaluations, unless a previous CXR is negative.

If any of the following apply, do not obtain a follow-up CXR:

- If a previous CXR (baseline or at 2 months) is negative, an end of treatment CXR is not necessary.
- Follow-up CXRs are not necessary for clients with extrapulmonary TB disease, if initial sputum collection results are negative and initial CXR is normal.

2. Clients with TB infection (including clients on window prophylaxis):

- a. Clients who report or begin to exhibit symptoms suggestive of TB disease should have a follow-up CXR before continuing on treatment for TB infection.
- b. Clients who have *not started treatment* for latent TB infection *within one month* of the initial CXR showing no abnormalities suggestive of TB disease AND are at high risk of progression to active TB disease must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the initiation of therapy.

The following clients are at **high risk of progression to** active TB disease:

- Children younger than 5 years of age
- Clients who have HIV infection or at high risk for HIV infection
- Clients who have an immunocompromising condition or other clinical

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condition that is associated with progression to active TB (such as substance abuse, silicosis, underweight by more than 5%, diabetes, chronic renal failure, gastrectomy, jejunioileal bypass, solid organ transplantation, head and neck cancer)

- Clients receiving immunosuppressive therapy
 - Clients with a documented change in TB screening test results from a negative to positive and other clients who have been recently infected with TB (such as close contacts of a person with infectious TB disease, clients who have immigrated from areas of the world with high rates of TB, clients within groups having high rates of TB transmission [homelessness, injection drug users] or within groups who work or reside with people who are at high risk for TB in facilities or institutions [hospitals, homeless shelters, correctional facilities, nursing homes, residential homes for those with HIV])
 - Clients with pulmonary fibrotic lesions seen on CXR (presumed to be from prior, untreated TB)
- c. Clients who have an *interruption* in latent TB infection treatment *longer than one month during the first 2 months of treatment* AND are at high risk of progression to active TB disease (see list above) must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the re-initiation of therapy. Otherwise, reimaging is not necessary unless the client has symptoms consistent with active TB disease.
- d. All other clients who are not at high risk of progressing to active TB disease who have *not started treatment for TB infection **within 6 months*** of the initial CXR showing no abnormalities suggestive of TB disease must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the initiation of therapy.
- e. All other clients who are not at high risk of progressing to active TB disease who have an *interruption* in latent TB infection treatment **and treatment needs to be re-started must have a repeat CXR** showing no abnormalities suggestive of TB before therapy is re-started.

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ATTACHMENT 6: Sputum Collection

Because sputum specimens may have culture results that fluctuate from positive to negative to positive over a period of time before true conversion occurs, collection dates for the last positive sputum culture and the first consistently negative sputum culture must be separated by at least 7 days.

When possible, all sputum specimens should be mailed to the laboratory on cold pack in order to preserve the specimen as long as possible.

A. Clients suspected or confirmed to have PULMONARY TB disease:

1. For all clients, collect 3 consecutive sputum specimens - ideally 24 hours apart, but at minimum 8 hours apart, ideally with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning. Sputum collection must occur within 7 days before (preferable) to 7 days after medication start date.
 - a. Submit 3 sputum specimens for acid-fast bacilli (AFB) smear and culture. The DSHS Laboratory will perform drug susceptibility testing (DST) reflexively on the initial *M.tb* culture positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture-positive 3 months or more after the initial specimen collection date, or upon physician request.
 - b. Submit all diagnostic sputum specimens on cold pack. For all clients who have no laboratory confirmation of a rapid test that shows rifampin resistance (i.e., GeneXpert), regardless of positive *M. tb* cultures, request nucleic acid amplification testing (NAA) on one of the first 3 diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" **unless drug susceptibility test (DST) results are known**. The lab will perform NAA on only the most suitable specimen.
2. For clients who have positive initial AFB smears at the time of diagnosis, collect 3 sputum specimens, with at least one specimen collection in early morning, for AFB smear every 2 weeks until 3 consecutive specimens are negative on AFB smear.
3. For all clients, collect up to 3 sputum specimens, with at least one specimen collection in early morning, for AFB smear and culture at least once a month until 2 consecutive specimens (at least one month apart) are negative on culture.
4. For clients who have completed < 80% of planned doses in the continuation

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phase of TB treatment and have an interruption of therapy, collect 3 sputum specimens, with at least one specimen collection in early morning, for AFB smear and culture.

5. For clients with MDR-TB, after culture conversion, continue to collect at least one sputum specimen for AFB smear and culture, with at least one specimen collection in early morning, at least once a month, until treatment completion.
6. For all clients, if possible, collect one final sputum specimen in early morning for AFB culture at completion of therapy.

B. Clients confirmed to have EXTRAPULMONARY TB disease:

1. For clients with suspected or known extrapulmonary TB, attempts should be made to collect 3 sputum specimens - ideally 24 hours apart, but at minimum 8 hours apart, with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning, even if the CXR is normal, in order to exclude concomitant pulmonary disease.
 - a. Submit 3 sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture positive 3 months or more after the initial specimen collection date, or upon physician request.
 - b. Submit all diagnostic sputum specimens on cold pack. For all clients who have no laboratory confirmation of a rapid test that shows rifampin resistance (i.e. GeneXpert), regardless of positive *M. tb* cultures, request nucleic acid amplification testing (NAA) on one of the first 3 diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" **unless DST results are already known**. The lab will perform NAA on only the most suitable specimen.
2. For clients whose initial sputum results are positive, collect follow-up sputum as described in section A. *Clients suspected or confirmed to have PULMONARY TB disease*.
3. If Gastrointestinal (GI) or genitourinary (GU) TB is suspected, stool or urine samples can be collected in addition to sputum (as above) and sent for NAA test, AFB smear and culture. Contact DSHS State Lab for submission criteria **prior** to shipping dshs.texas.gov/lab/myco_home.shtm

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C. Clients with TB infection (including clients on window prophylaxis):

1. For clients who develop signs and symptoms suggestive of TB disease, collect 3 consecutive sputum specimens - ideally 24 hours apart, but at minimum 8 hours apart, ideally with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning.
 - a. Submit 3 sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture positive 3 months or more after the initial specimen collection date, or upon physician request.
 - b. Submit all diagnostic sputum specimens on cold pack. For all clients who have no laboratory confirmation of a rapid test that shows rifampin resistance (i.e. GeneXpert), regardless of positive *M. tb* cultures, request nucleic acid amplification testing (NAA) on one of the first 3 diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" **unless DST results are already known**. The lab will perform NAA on only the most suitable specimen.
2. For clients with CXR findings suggestive of prior, healed TB disease, collect 3 consecutive sputum specimens - ideally 24 hours apart, but at minimum 8 hours apart, ideally with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning.
 - a. Submit 3 sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture positive 3 months or more after the initial specimen collection date, or upon physician request.
 - b. Submit all diagnostic sputum specimens on cold pack. For all clients who have no laboratory confirmation of a rapid test that shows rifampin resistance (i.e. GeneXpert), regardless of positive *M. tb* cultures, request nucleic acid amplification testing (NAA) on one of the first 3 diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" **unless DST results are already known**. The lab will perform NAA on only the most suitable specimen.
 - c. Results of all AFB smears and cultures must be negative before treatment for TB infection is started.

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3. For clients with HIV infection and respiratory symptoms, even if the CXR is normal.

Prior to the initiation of therapy, collect 3 consecutive sputum specimens - ideally 24 hours apart, but at minimum 8 hours apart, with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in early morning.

- a. Submit 3 sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture positive 3 months or more after the initial specimen collection date, or upon physician request.

- b. Submit all diagnostic sputum specimens on cold pack. For all clients who have no laboratory confirmation of a rapid test that shows rifampin resistance (i.e. GeneXpert), regardless of positive *M. tb* cultures, request nucleic acid amplification testing (NAA) on one of the first 3 diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" **unless DST results are already known**. The lab will perform NAA on only the most suitable specimen.

- c. Results of all AFB smears and cultures must be negative and respiratory symptoms must be explained by another etiology before treatment for TB infection is started.

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ATTACHMENT 7: Medications

A. Clients suspected or confirmed to have TB disease:

- Administer the following medications after verifying that a current order is written by the medical provider; that order should be implemented within 3 business days, or a new order must be received.

TABLE 1. Drug Regimens for Culture-Positive Pulmonary TB caused by Drug-Susceptible Organisms

Regimen	Intensive Phase		Continuation Phase			Range of total doses, (duration)	Comments	
	Drugs	Interval, Dose	Regimen	Drugs	Interval and Dose (Minimum Duration)			
1	INH* RIF** PZA EMB†	7 days/wk for 56 doses in 8 wks, or	1a	INH, RIF	If 6 months' total therapy: 7 days/wk for 126 doses in 18 wks or 5 days/wk for 90 doses in 18 wks	182-130 (26 weeks)	Preferred regimen for patients with newly diagnosed tuberculosis.	
		5 days/wk for 40 doses in 8 weeks	1b		If 9 months' total therapy: 7 days/wk for 217 doses in 31 wks or 5 days/wk for 155 doses in 31 wks			273-195 (39 weeks)
2	INH* RIF** PZA EMB†	7 days/wk for 56 doses in 8 wks, or 5 days/wk for 40 doses in 8 weeks	2a	INH, RIF	If 6 months' total therapy: 3 times/wk for 54 doses in 18 wks	110-94 (26 weeks)	May be used as an alternative regimen when daily DOT in the continuation phase is difficult.	
			2b		If 9 months' total therapy: 3 times/wk for 93 doses in 31 wks			149-133 (39 weeks)
			2c		If 6 months' total therapy: 2 times/wk for 36 doses in 18 wks or If 9 months' total therapy: 2 times/wk for 62 doses in 31 wks			92-76 (26 weeks) 118-102 (39 weeks)

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3 ‡	INH* RIF** PZA EMB†	3 times weekly for 24 doses in 8 weeks	3a ‡	INH, RIF	If 6 months' total therapy: 3 times/wk for 54 doses in 18 wks	78 (26 weeks)	Not preferred, consult recommended before use. Use with caution in patients with HIV and/or cavitory or extensive disease.
			3b ‡		If 9 months' total therapy: 3 times/wk for 93 doses in 31 wks	117 (39 weeks)	
4 ‡	INH* RIF** PZA EMB†	7 days/wk for 14 doses in 2 weeks, then twice weekly for 12 doses in 6 weeks	4a ‡	INH, RIF	If 6 months' total therapy: 2 times/wk‡ for 36 doses in 18 weeks	62 (26 weeks)	Not preferred, consult required before use. Do not use in patients w/: <ul style="list-style-type: none"> • HIV co-morbidity • Smear positive bacteriology at diagnosis • Cavitory disease
			4b ‡		If 9 months' total therapy: 2 times/wk ‡ for 62 doses in 31 weeks	88 (39 weeks)	

Definition of abbreviations: **INH** = Isoniazid; **RIF** = Rifampin; **PZA** = Pyrazinamide; **EMB** = Ethambutol

***INH:** Supplementation with pyridoxine (vitamin B6) is recommended in the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV/AIDS, alcohol use, diabetes).

****RIF:** Drug interactions with potentially serious consequences may occur when using Rifampin. Of particular concern are reductions, often to ineffective levels, in serum concentrations of common drugs, such as oral contraceptives, methadone, and warfarin. There are important bidirectional interactions between rifamycins and antiretroviral agents. Because information regarding rifamycin drug interactions is evolving rapidly, consult a trusted drug information resource to obtain the most up-to-date information.

†**EMB:** may be stopped once the isolate is susceptible to RIF, INH, and PZA.

‡**Regimens 2c, 3 and 4 are not preferred for most clients receiving treatment for tuberculosis, as they have lower efficacy than regimens 1 and 2a and b.** They should be used *only* after consultation from a DSHS-Recognized Medical TB Consultant. Not recommended for: HIV-infected patients or patients with smear-positive and/or cavitory disease. If it is difficult to treat daily or three times per week, the use of treatment two times per week after an initial two weeks of daily therapy may be considered in individuals with low risk of relapse (i.e. drug-susceptible TB organisms, that at the start of treatment is non-cavitory and/or smear negative, and those who are HIV negative.) Note: **highly intermittent regimens have a high rate of failure and should be used with caution.**

Table originally adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11) and includes updated guidelines from Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases (2016) 63 (7): e147-e195. [cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf](https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf)

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TABLE 2. Doses of First-Line Anti-Tuberculosis Drugs for Adults and Children

Drug	Preparation	Adults/ Children	Doses		
			Daily	2x/wk	3x/wk
Isoniazid*	Tablets (100 mg, 300 mg); elixir (50 mg/5 ml)	Adults (max.)	5 mg/kg (300 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)
		Children (max.)	10–15 mg/kg (300 mg) See TABLE 6	20–30 mg/kg (900 mg) See TABLE 6	**
Rifampin†	Capsule (150 mg, 300 mg); (powder may be suspended for oral use— Contact Pharmacy Branch)	Adults‡ (max.)	10 mg/kg (600 mg)	10 mg/kg (600 mg)	10 mg/kg (600 mg)
		Children‡ (max.)	15-20 mg/kg (600mg) See TABLE 6	15-20 mg/kg (600mg) See TABLE 6	**
Pyrazinamide	Tablet (500 mg, scored)	Adults	See TABLE 3	See TABLE 3	See TABLE 3
		Children (max.)	30-40 mg/kg (2.0 g) See TABLE 6	50 mg/kg (2.0 g) See TABLE 6	**
Ethambutol	Tablet (100 mg, 400 mg)	Adults	See TABLE 4	See TABLE 4	See TABLE 4
		Children (max.)	15–25 mg/kg (1.0 g) See TABLE 6	50 mg/kg (2.5 g) See TABLE 6	**

***Isoniazid:** Supplementation with pyridoxine (vitamin B6) is recommended in the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV/AIDS, alcohol use, diabetes).

†**Rifampin:** Drug interactions with potentially serious consequences may occur when using Rifampin. Of particular concern are reductions, often to ineffective levels, in serum concentrations of common drugs, such as oral contraceptives, methadone, and warfarin. There are important bidirectional interactions between rifamycins and antiretroviral agents. Because information regarding rifamycin drug interactions is evolving rapidly, consult a trusted drug information resource to obtain the most up-to-date information.

‡ **Rifampin Dosing:** Many experts recommend using a daily **rifampin dose of 20-30mg/kg/day** for infants and toddlers less than 2 years old, and for adults and children with serious forms of TB such as meningitis and disseminated disease. See American Academy of Pediatrics Red Book, 2018, 31st Edition for dosing.

****Thrice-weekly dosing:** The ATS guidelines, academic.oup.com/view-large/89047409, state “The optimal doses for thrice-weekly therapy in children and adolescents have not been established. Some experts use in adolescents the same doses as recommended for adults, and for younger children the same doses as recommended for twice-weekly therapy.” See American Academy of Pediatrics Red Book, 2018, 31st Edition for pediatric dosing.

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). cdc.gov/mmwr/pdf/rr/rr5211.pdf and includes Rifampin dosing recommendations from American Academy of Pediatrics Red Book, 2018, 31st Edition.

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TABLE 3. Suggested Pyrazinamide (PZA) Doses, Using Whole Tablets, for Adults Weighing 40–90 Kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	1,000 (18.2–25.0)	1,500 (20.0–26.8)	2,000† (22.2–26.3)
Thrice weekly, mg (mg/kg)	1,500 (27.3–37.5)	2,500 (33.3–44.6)	3,000† (33.3–39.5)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	3,000 (40.0–53.6)	4,000† (44.4–52.6)
*Based on estimated lean body weight. †Maximum dose regardless of weight.			

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). cdc.gov/mmwr/pdf/rr/rr5211.pdf

TABLE 4. Suggested Ethambutol (EMB) Doses, Using Whole Tablets, for Adults Weighing 40–90 Kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	800 (14.5–20.0)	1,200 (16.0–21.4)	1,600† (17.8–21.1)
Thrice weekly, mg (mg/kg)	1,200 (21.8–30.0)	2,000 (26.7–35.7)	2,400† (26.7–31.6)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	2,800 (37.3–50.0)	4,000† (44.4–52.6)
*Based on estimated lean body weight. †Maximum dose regardless of weight.			

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). cdc.gov/mmwr/pdf/rr/rr5211.pdf

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B. Clients with TB infection (including clients on window prophylaxis):

TABLE 5. Recommended Drug Regimens for Treatment of INH- and RIF-Susceptible TB Infection

Drug(s)	Duration	Dose	Frequency	Total Doses and Intervals Needed for Completion of Therapy
<p align="center">Isoniazid* and Rifapentine† (3HP)</p> <p>Not recommended for: -Children <2 years old -Clients with HIV taking antiretroviral therapy other than efavirenz- or raltegravir-based regimens -Clients who or expecting to become pregnant -Clients with TB infection or are contacts to a TB case that is resistant (or suspected to be) to INH or a rifamycin</p>	3 months	<p>Adults and children ≥ 12 years: INH: 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg max. RPT: 10.0–14.0 kg: 300 mg 14.1–25.0 kg: 450 mg 25.1–32.0 kg: 600 mg 32.1–49.9 kg: 750 mg ≥50.0 kg: 900 mg maximum Children 2-11 years: INH: 25 mg/kg rounded up to the nearest 50-100 mg; 900 mg max. RPT: 10.0–14.0 kg: 300 mg 14.1–25.0 kg: 450 mg 25.1–32.0 kg: 600 mg 32.1–49.9 kg: 750 mg ≥50.0 kg: 900 mg maximum Children under age 2 years: Contraindicated</p>	Once weekly, DOT strongly preferred‡	<p>12 doses (minimum of 11 doses acceptable)</p> <p>administered in no fewer than 12 weeks (but no more than 16 weeks)</p> <p>Doses must be separated by ≥72 hours to be counted</p>
Rifampin† (4R)	4 months	<p>Adults: 10 mg/kg Maximum dose: 600 mg Children ≥ 2ys-17ys: 15-20 mg/kg Maximum dose: 600 mg Infants and Toddlers <2ys: 20-30mg/kg Maximum dose: 600mg</p>	Daily	<p>120 (7 days/ week) OR 90 (for 5 days/week by DOT) within 6 months</p>

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Isoniazid* and Rifampin† (3HR)	3 months	Adult: INH: 5 mg/kg; Maximum dose: 300 mg RIF: 10 mg/kg Maximum dose: 600 mg Children: INH: 10-20 mg/kg**; Maximum dose: 300 mg RIF: 15-20 mg/kg; Maximum dose: 600 mg	Daily	90 (7days/week) within 4 months
Isoniazid* (6H/9H)	6 months	Adult: 5 mg/kg Maximum dose: 300 mg Children: 10-20 mg/kg** Maximum dose: 300 mg	Daily	180 (7 days/ week) OR 129 (for 5 days/week by DOT) within 9 months
		Adult: 15 mg/kg Maximum dose: 900 mg Children: 20-40 mg/kg** Maximum dose: 900 mg	Twice weekly	52 by DOT ONLY within 9 months
	9 months	Adult: 5 mg/kg Maximum dose: 300 mg Children: 10-20 mg/kg** Maximum dose: 300 mg	Daily	270 (7 days/ week) OR 195 (for 5 days/week by DOT) within 12 months
		Adult: 15 mg/kg Maximum dose: 900 mg Children: 20-40 mg/kg** Maximum dose: 900 mg	Twice weekly	76 within 12 months by DOT only

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Definition of abbreviations: **INH** = Isoniazid; **RIF** = Rifampin; **RPT** = Rifapentine

***INH:** Supplementation with pyridoxine (vitamin B6) is recommended in the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV/AIDS, alcohol use, diabetes).

†**RIF, RPT:** Both have drug interactions with potentially serious consequences. Of particular concern are reductions, often to ineffective levels, in serum concentrations of common drugs, such as oral contraceptives, methadone, and warfarin. There are important bidirectional interactions between rifamycins and antiretroviral agents. Because information regarding rifamycin drug interactions is evolving rapidly, consult a trusted drug information resource to obtain the most up-to-date information. **NOTE: Rifabutin (RBT) may be substituted for rifampin if rifampin cannot be used due to certain drug-drug interactions. Consultation from a DSHS-Recognized Medical TB Consultant is recommended for use.**

The American Academy of Pediatrics recommends an **isoniazid dosage of 10-15mg/kg for the daily regimen and 20-30mg/kg for the twice-weekly regimen in children. For more details refer to *Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020*: [cdc.gov/mmwr/volumes/69/rr/rr6901a1.htm?s_cid=rr6901a1_w&deliveryName=USCDCNPIN_151-DM19855](https://www.cdc.gov/mmwr/volumes/69/rr/rr6901a1.htm?s_cid=rr6901a1_w&deliveryName=USCDCNPIN_151-DM19855) and the American Academy of Pediatrics Red Book, 2018, 31st Edition.

‡Intermittent regimens of INH mono-therapy must be provided by directly observed therapy (DOT). It is recommended that 3HP also be administered via DOT unless specified by the licensed healthcare provider. Self-administration *may be considered* in select patients when DOT is not possible, and when mechanisms are in place to help patients adhere to treatment, as determined by the licensed healthcare provider. Refer to [cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w) and [cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w)

NOTE: Short course regimens are preferred to the 6 or 9-month regimens

Table adapted from Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020. MMWR 2020; RR-69.
[cdc.gov/tb/publications/lbti/lbtiresources.htm?deliveryName=USCDCNPIN_151-DM19855](https://www.cdc.gov/tb/publications/lbti/lbtiresources.htm?deliveryName=USCDCNPIN_151-DM19855)

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C. Pediatric Dosing (age 17 and younger):

TABLE 6. Pediatric Dosing Range for Daily, Twice Weekly, Maximum Doses, and Forms Available for the First-Line Anti-Tuberculosis Medications

DAILY DOSE RANGE*					
Child's Weight (kg)	Isoniazid (INH) 10-15 mg/kg/day Dose, mg Max dose: 300mg	Pyrazinamide (PZA) 30-40 mg/kg/day Dose, mg Max dose: 2000mg	Ethambutol (EMB) 15-25 mg/kg/day Dose, mg Max dose: 1000mg	Rifampin (RIF)** 15-20 mg/kg/day Dose, mg Max dose: 600mg	
				Weight (kg)	Dose, mg
3-5	50	125	50-100	Up to 5	75#
6-9	100	250	150	5.1-10	150
10-15	150	375-500	250	10.1-15	225#
16-20	200	500-750	300	15.1-20	300
21-25	300	750	400	20.1-30	450
26-45	300	1000-1500	600-700	Over 30kg	600
46-50	300	1500-2000	800		
51-66	300	2000	1000		
67+	300	2000	1000		
TWICE WEEKLY DOSE:	20-30 mg/kg/dose Max dose: 900 mg	50 mg/kg/dose Max dose: 2000 mg	50 mg/kg/dose Max dose: 2500 mg	15-20 mg/kg/dose Max dose: 600 mg	
Forms available:	Scored tablets: 100 mg 300 mg Syrup: 10 mg/ml†	Scored tablets: 500 mg	Tablets: 100 mg 400 mg	Capsules: 150 mg, 300 mg Suspension: #Specialty compounding is needed; contact DSHS regional or state offices	

*Note: there are many factors that can affect medication stability when tablets are broken or crushed/capsules are opened and then mixed with food or liquids. Consult a trusted drug reference before using food disguises. See American Academy of Pediatrics Red Book, 2018, 31st Edition for pediatric dosing ranges.

Refer to *Rifampin Dosing* footnote in **Table 2 regarding dosages for infants and toddlers.

†Many experts advise against using INH syrup because it is frequently associated with diarrhea.

Table adapted from American Academy of Pediatrics Redbook by Kim Smith, MD

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Indications for window prophylaxis for contacts to someone with confirmed or suspected TB disease:

1. Children younger than 5 years old. Note: Children <6 mo old should continue on window prophylaxis until they undergo a repeat TST at 6 mo of age.
2. Clients with HIV infection.*
3. Clients receiving immunosuppressive therapy for organ transplantation.*
4. Clients taking TNF- α inhibitors.*

**Indications for window prophylaxis WITH recommendations to complete a full course of treatment for TB infection (beyond the window period) even if a TB screening test administered \geq 8 weeks after the end of exposure is negative.*

D. Interruptions of Therapy for TB Disease:

1. When any interruption of less than 14 *cumulative* days occurs during the initial phase of treatment for TB disease, *the treatment can continue.*
 - If total initial phase treatment is not completed in 10 weeks, the treatment will need to be restarted. Contact the licensed healthcare provider for instructions.
2. When any interruption of 14 or more *cumulative* days occurs in the initial phase of treatment for TB disease, the treatment regimen will need to be restarted. Contact the licensed healthcare provider for instructions.
 - If treatment is discontinued for drug intolerances, the client must be on an empiric regimen considered adequate (RIP [RIF, INH, PZA], RIE [RIF, INH, EMB], or RPE [RIF, PZA, EMB]) for doses to count towards completion of therapy.
 - If susceptibilities are known and there is no resistance to INH or RIF, then once the client is on *both* INH *and* RIF, doses can count towards completion of therapy.
3. **If a patient misses a cumulative total of 3 months of doses during the continuation phase and less than 80% of planned doses in the continuation phase are completed**, the treatment will need to be restarted.
 - Collect 3 sputum specimens for AFB smear and culture and contact the licensed healthcare provider for instructions.
4. **If a patient misses a cumulative total of 3 months of doses during the continuation phase and 80% or more of planned doses in the continuation phase are completed**, additional treatment may not be necessary.
 - However, clients who initially had sputum smears positive for AFB should receive additional therapy. Contact the licensed healthcare provider.

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E. Interruptions of Therapy for TB Infection:

When an interruption occurs during treatment for *TB infection*, a CXR should be obtained in accordance with ATTACHMENT 5: *Chest X-Ray*.

- If a CXR is indicated, an examination and symptom screen to rule out active TB disease are also required before restarting therapy.
- If the client has symptoms consistent with active TB disease, a symptom screen, physical examination, CXR, and collection of 3 sputum specimens (if sputum can be produced) are required. Active TB disease must be excluded *before* treatment for TB infection is restarted.
- If the minimum number of doses cannot be completed within the maximum time frame allowed, as described in section G: *Completion of Therapy for TB Infection* of this attachment, treatment will need to be restarted from the beginning.

Contact the licensed healthcare provider for instructions.

F. Completion of Therapy for Drug Susceptible TB Disease:

Below are the **minimum** number of doses required, based on regimens listed in *Table 1* and the corresponding time frames for acceptable completion of therapy. The goal is to complete all doses within 12 months.

Six months (26 weeks) is generally the minimum duration of treatment; nine months (39 weeks) is recommended for clients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy (see additional indications in #4, below). These durations accurately indicate the amount of time the drugs are given *only if there are no interruptions in drug administration*.

NOTE: daily dosing throughout the course of therapy is preferred over intermittent dosing.

1. Initial phase to total 8 weeks:

Initial phase must be documented to be appropriately completed before client is permitted to count doses for continuation phase.

Regimen 1: 7 days per week for **56** doses administered by DOT in 8 weeks, OR
5 days per week for **40** doses administered by DOT in 8 weeks

Regimen 2: 7 days per week for **56** doses administered by DOT in 8 weeks, OR
5 days per week for **40** doses administered by DOT in 8 weeks

Regimen 3: 3 times weekly for **24** doses administered by DOT in 8 weeks

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Regimen 4*: 7 days per week for 14 doses administered by DOT in 2 weeks,
then twice weekly for 12 doses administered by DOT in 6 weeks for
a total of **26** doses in 8 weeks

**consultation required prior to use*

2. Continuation phase to total 18 or 31 weeks (INH/RIF):

Doses for continuation phase should **not** be counted until initial phase treatment has been documented to be appropriately completed.

Regimen 1a: 7 days per week for **126** doses administered by DOT in 18 weeks, OR
5 days per week for **90** doses administered by DOT in 18 weeks

Regimen 1b: 7 days per week for **217** doses administered by DOT in 31 weeks, OR
5 days per week for **155** doses administered by DOT in 31 weeks

Regimen 2a: 3 times weekly for **54** doses administered by DOT in 18 weeks

Regimen 2b: 3 times weekly for **93** doses administered by DOT in 31 weeks

Regimen 2c*: 2 times weekly for **36** doses administered by DOT in 18 weeks,
OR 2 times weekly for **62** doses administered by DOT in 31 weeks

Regimen 3a: 3 times weekly for **54** doses administered by DOT in 18 weeks

Regimen 3b: 3 times weekly for **93** doses administered by DOT in 31 weeks

Regimen 4a*: 2 times weekly for **36** doses administered by DOT in 18 weeks.

Regimen 4b*: 2 times weekly for **62** doses administered by DOT in 31 weeks.

**consultation required prior to use*

3. When regimens vary from above (i.e., are extended or change frequently) doses from each phase should be converted to "daily dose equivalents."

- Use the minimum numbers for daily dosing of each phase when making a determination of adequate number of doses to complete therapy. Consult the licensed healthcare provider, the local and/or regional TB program manager, or the TB and Hansen's Disease Branch TB Nurse Consultant for assistance, if needed.
- *For example, for 5 days per week dosing, 40 doses should be given for the initiation phase and 90 doses should be given for the continuation phase.*
 - If twice weekly doses were administered, multiply the total number of twice weekly doses by 2.5 (because 5 days per week ÷ 2 doses per week = 2.5) to convert twice weekly doses to daily dose equivalents.
 - If 3 times (thrice) weekly doses were administered, multiply total

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number of thrice weekly doses by 1.67 (because 5 days per week ÷ 3 doses per week = 1.67) to convert thrice weekly doses to daily dose equivalents.

- Add all daily dose equivalents together to calculate the total daily doses given.
- Numbers that are not whole numbers should be rounded down.

4. Exceptions to the length of therapy described above:

- If PZA cannot be included throughout the initial phase of treatment (minimum of 40 doses given 5 days/week by DOT), then the regimen should consist of INH, RIF *and* ethambutol (EMB)* for the initial phase (8 weeks) and the continuation phase of treatment with INH and RIF must be extended to 7 months (31 weeks) for a total minimum duration of treatment of 9 months (39 weeks).
 - NOTE: *M. bovis* is naturally resistant to PZA. Infection with *M. bovis* or PZA-resistant *M. tuberculosis*: minimum of 9 months (39 weeks) of treatment.

**EMB is given for the duration of the initial phase even when susceptibilities are known and there is no resistance identified, as it has some bactericidal effects.*

- Clients with cavitation or extensive pulmonary TB disease on initial CXR and a positive culture at the time of completion of 2 months (8 weeks) of treatment are *at substantially increased risk of relapse*. The continuation phase for these clients is recommended to be prolonged to 7 months (31 weeks), to complete a total treatment period of 9 months (39 weeks).
- The following extrapulmonary TB sites require a longer duration of treatment:
 - Bone and joint: 9 months (39 weeks) of treatment recommended
 - Meningitis: 9 - 12 months (39 - 52 weeks) of treatment recommended
 - Disseminated/miliary TB in children with HIV: 9 - 12 months (39 - 52 weeks) of treatment recommended
 - Any site that is slow to respond should be considered for prolongation of treatment
- Culture-negative pulmonary TB
 - Defined as symptomatic or radiographic improvement after 2 months of RIPE treatment in a client for whom
 - a. the clinical suspicion for active TB disease is high,
 - b. AFB cultures were collected and are negative, AND

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- c. an alternative diagnosis/etiology has not been found
 - For adult clients, treatment should be continued with INH, RIF, AND ethambutol for an additional 2 months to complete a total of 4 months (18 weeks) of treatment.
 - For pediatric clients with no identifiable source case, treatment should be continued with INH, RIF, AND ethambutol for an additional 4 months (18 weeks) to complete a total of 6 months (26 weeks) of treatment.
 - Ethambutol can be discontinued if the client with culture-negative pulmonary TB is a contact to a case and the susceptibilities of that case are known and no resistance is detected.

- Culture-negative extrapulmonary TB: treatment recommendations are determined by the licensed healthcare provider, preferably in consultation with a DSHS-recognized TB Medical Consultant.

- Clients newly diagnosed with HIV who are not started on ART during treatment for TB: treatment should consist of at least 8+ months of therapy or longer.

- If RIF cannot be included in the treatment regimen, the minimum duration of treatment is 18 months (78 weeks). **Medical consultation is required.**

G. Completion of Therapy for TB Infection:

Below are the *minimum* number of doses required, based on regimens listed in *Table 5* and the corresponding time frame for acceptable completion of therapy.

1. INH/RPT (3HP) =
12 doses (minimum of 11 doses acceptable) administered in no fewer than 12 weeks (but no more than 16 weeks) Doses must be separated by ≥ 72 hours to be counted.

2. 4 months of rifampin (4R) =
7 days per week for **120** doses taken within 6 months, OR
5 days per week for **90** doses administered by DOT within 6 months

3. 3 months of INH and RIF (3HR)=
7 days per week for **90** doses taken within 4 months

4. 6 months of daily INH (6H)=
7 days per week for **180** doses taken within 9 months, OR
5 days per week for **129** doses administered by DOT within 9 months

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5. 6 months of twice-weekly INH (6H)=
twice weekly for **52** doses administered by DOT within 9 months

6. 9 months of daily INH (9H)=
7 days per week for **270** doses taken within 12 months, or
5 days per week for **195** doses administered by DOT within 12 months

7. 9 months of twice-weekly INH (9H) =
twice weekly for **76** doses administered by DOT within 12 months

For persons treated empirically for TB disease with at least isoniazid, rifampin, and pyrazinamide for 2 months (40 doses given by DOT 5x/week or 56 doses given by DOT 7 days/week), this regimen can be considered effective treatment of TB infection in persons subsequently determined to have infection rather than TB disease.

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Attachment 8: Clients with Drug Resistant Tuberculosis (DR-TB)

This attachment outlines required activities, procedures, and orders to be performed *in addition to* those outlined in the previous sections of these SDOs.

A. Definitions

1. Isoniazid mono-resistant TB- resistance to isoniazid, a first line TB drug.
2. Rifampin mono-resistant TB (RR)- resistance to rifampin, a first line TB drug; this type of DR-TB is treated similarly to MDR-TB.
3. Multi-drug resistant TB (MDR-TB)- resistance to at least rifampin and isoniazid.
4. Pre-extensively drug resistant TB (Pre-XDR TB)- MDR, plus resistance to one of the second line injectable agents (amikacin, capreomycin, or kanamycin) *or* a fluoroquinolone.
5. Extensively drug resistant TB (XDR-TB)- MDR, plus resistance to one of the second line injectable agents (amikacin, capreomycin, or kanamycin) *and* a fluoroquinolone.

B. Level of Experience, Training, Competence, and Education Required

1. Have reviewed, are familiar with, and able to readily access the recommendations within the following document:
 - a. Treatment of Drug-Resistant Tuberculosis-An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline: Executive Summary, September 2019.
[cdc.gov/tb/publications/guidelines/pdf/executive_summary.pdf](https://www.cdc.gov/tb/publications/guidelines/pdf/executive_summary.pdf)

C. Procedures and Requirements to be Followed by Authorized Licensed Nurses Managing Clients with DR-TB

1. When resistance is identified by drug susceptibility testing (DST) or rapid testing (i.e. GeneXpert NAAT), whichever comes first, or if resistance is suspected due to patient risk factors, perform the following:
 - a. Contact the licensed healthcare provider.
 - b. Hold the current regimen if not consistent with current test results and the client is medically stable.
 - c. Initiate a consultation with a DSHS-recognized TB medical consultant within three (3) working days. Do not wait for final cultures to initiate consultation, as the consultant will assist in coordination of further testing, including Molecular Detection of Drug Resistance (MDDR).
 - d. Notify the TB and Hansen's Disease Branch's Nurse Consultant.
2. Respond to treatment and case management activities where indicated, unless otherwise noted by the treating physician or consultant.
 - a. **Release from airborne isolation:** Contact the licensed healthcare provider. Release may be made in consultation with a DSHS-recognized medical TB consultant. Considerations to release from isolation include:
 - where the client is being released to (i.e. congregate settings, household with small children, etc.)
 - client's response to therapy clinically, radiographically, and bacteriologically (some experts recommend two to three consecutive negative AFB sputum cultures prior to release from isolation.)

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Refer to:

heartlandntbc.org/assets/products/guidelines_home_hospital_infectious_patients.pdf and
currytbcenter.ucsf.edu/sites/default/files/tb_sg3_chap8_monitoring_and_cm.pdf#infectionctrl

b. **Medical Screenings:** Perform the following screening assessments at the following intervals and document on the TB 702 (or equivalent):

1) Baseline and monthly clinical monitoring of medication toxicity for clients on second-line medications:

- If client is taking **aminoglycosides** (most commonly **amikacin**), this is to include:
 - audiometry screening.
 - vestibular screening.
- If client is taking **cycloserine**, this is to include:
 - A mental health assessment to include depression screening. Also ask if they are experiencing nightmares, hallucinations, aggression or disorientation.
- If client is taking **clofazimine**, this is to include:
 - A mental health screening to focus on depression symptoms.
- If client is taking **linezolid**, this is to include:
 - red/green color discrimination using Ishihara plates.
 - visual acuity using Snellen chart or equivalent.
 - peripheral neuropathy screening.
- If client is taking **high dose isoniazid (adults 15mg/kg)**, this is to include:
 - peripheral neuropathy screening.
- If client is taking **bedaquiline (Situro)**, this is to include:
 - an ECG at baseline, 2 weeks after initiation of treatment, and monthly.
 - Perform ECG at the designated intervals (preferably Monday-Wednesday in case further interventions such as labs or consultations are needed).
 - ECG should be performed at the same time of day each time. ECGs exhibit diurnal variation of up to +/- 75ms during the course of a day.
 - **A client with elevated QTc intervals should have one repeat ECG done ≥ 30 minutes apart to confirm reading.**
 - Documentation of any symptoms* of prolonged QTc should be included when performing the ECG and results of both provided to the licensed healthcare provider.
 - Ensure the licensed healthcare provider reviews the symptoms and ECG results within 24 hours of test, unless otherwise specified, and documents response in the medical record.

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- Respond to the following based on the ECG results:
 - If QTc is greater than 450ms (in males) or greater than 470ms (in females) and patient is *asymptomatic****:
 - Draw CMP plus magnesium, TSH, CBC
 - Contact the licensed healthcare provider to review ECG results within 24 hours
 - Perform weekly ECGs until normal or until licensed healthcare provider orders otherwise
 - If QTc is greater than 450ms (in males) or greater than 470ms (in females) and patient is *symptomatic****:
 - Hold medications
 - Contact the licensed healthcare provider immediately
 - Draw CMP plus magnesium, TSH, CBC
 - If QTc is greater than 500ms in male or females, and patient is *asymptomatic****:
 - Hold medications
 - Draw CMP plus magnesium, TSH, CBC
 - Contact the licensed healthcare provider to review results within 24 hours
 - Request that the licensed healthcare provider consults cardiology or a DSHS-recognized medical TB consultant
 - Repeat ECG in 24-48 hours
 - Perform weekly ECGs until normal or the licensed healthcare provider orders otherwise
 - Do not resume regimen until instructed by the licensed healthcare provider
 - If QTc is greater than 500ms in male or females, and patient is *symptomatic* ***:
 - Hold medications
 - Contact the licensed healthcare provider immediately
 - Draw CMP plus magnesium, TSH, CBC
 - Refer patient to the Emergency Department (ED)- ensure there is a referral form that the patient may present to the ED already reviewed by the licensed healthcare provider which outlines at minimum: diagnosis, isolation status, current medications, baseline and current ECG results, symptoms, reason for referral to ED and TB physician contact information
 - Do not resume regimen until instructed by the licensed healthcare provider
 - If QTc is greater than 60ms above baseline and patient is *asymptomatic****:
 - Draw CMP plus magnesium, TSH, CBC
 - Contact the licensed healthcare provider to review ECG results within 24 hours for recommendations

**Symptoms of prolonged QTc include: palpitations, tachycardia, light-headedness, fainting/syncope, chest pain, loss of consciousness, shortness of breath*

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Considerations for the licensed healthcare provider:

Correcting the QT interval from ECG readings: The QTc interval is influenced by the heart rate. At a HR of 60, QT = QTc using any of the formulas (Bazett, Fridericia, Framingham or Hodges). As HR increases, the QTc increases. Most ECG machines in the US use the Bazett formula which at higher HR yields a more prolonged QTc than the Fridericia formula. It is recommended to use the Fridericia formula when calculating corrected QTc intervals as studies examining TB medications and QT prolongation used the Fridericia formula in their assessments and guidance. Consider online calculators (e.g. mdcalc.com/corrected-qt-interval-qt-c) or manual calculations.

Refer to algorithms for monitoring and managing corrected QT prolongation in patients with DR-TB here: "Guide for QTc Monitoring and management of Drug-resistant TB Patients with QT Prolonging Agents" available at: challengetb.org/publications/tools/pmdt/Guidance_on_ECG_monitoring_in_NDR_v2.pdf

It is recommended that the licensed healthcare provider interpret the ECG within 24 hours of the ECG test.

- c. **Laboratory tests:** Clients prescribed second line medications age 18 or older will have additional labs collected under the following circumstances:
- 1) At Baseline:
 - CBC and CMP.
 - A pregnancy test for females of child bearing age who are starting **clofazimine** and/or on an aminoglycoside, commonly **amikacin**.
 - For clients on **bedaquiline and amikacin**, include magnesium, which must be ordered in addition to the CMP.
 - For clients on **ethionamide, bedaquiline, and para-amino salicylic acid (PAS)**, include a TSH (thyroid stimulating hormone) level.
 - 2) Monthly:
 - CBC and CMP.
 - For clients on **amikacin**, include magnesium.
 - For clients on **bedaquiline**, include TSH and magnesium.
 - 3) Quarterly and as needed:
 - For clients on, **ethionamide** and **PAS**, include TSH.
- d. **Radiology:** Posterior-anterior (PA) view CXRs should be performed for clients over age 18; PA and lateral for clients younger than 18 and clients with HIV, in the following intervals:
- 1) Clients with RR/MDR/Pre-XDR/XDR pulmonary TB:
 - During treatment:
 - initially
 - at two months

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- at six months, then,
 - every six months until completion of therapy or as recommended by DSHS-recognized medical TB consultant
 - Post treatment:
 - Every six months for two years, accompanied with a TB signs and symptoms questionnaire.
- 2) For clients who are contacts to RR/MDR/Pre-XDR/XDR TB diagnosed with TB infection, regardless of whether they completed prophylaxis treatment for TB infection, every effort should be made to perform a TB signs and symptoms screening questionnaire and a CXR every six months for two years as this is the highest risk period for developing active disease. If symptoms of TB are present, follow up as indicated (refer to **Attachment 5**).
- e. **Sputum collection:** For clients with pulmonary disease, collect sputum in the following intervals after initial samples:
- 1) Collect at least three consecutive sputum specimens for AFB smear and culture monthly until culture conversion.
 - 2) Continue to collect at least one sputum specimen for AFB smear and culture after culture conversion, at least once a month, until treatment completion.
 - 3) Every effort should be made to collect at least one sputum every six months for two years after completion of therapy.
- f. **Completion of therapy:**
- 1) Clients with RR/MDR/Pre-XDR/XDR -TB:
 - Initial and continuation phases are different for clients with DR-TB. Refer to consult for dose counting and regimen changes based on response to therapy.
 - 2) Clients with isoniazid mono-resistant TB:
 - Seek consultation from a DSHS recognized medical TB consultant.
 - Once fluoroquinolone susceptibilities are known and no further resistance is identified, the addition of a later-generation fluoroquinolone (usually **moxifloxacin** or **levofloxacin**) may be added with a treatment duration of at least 6 months of daily **rifampin**, **ethambutol**, and **pyrazinamide (PZA)**.
 - If **PZA** is not tolerated for the entire course of treatment, PZA can be shortened to 2 months in selected situations.
 - If low-level INH resistance is identified, high dose INH may be included as part of the regimen.

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ATTACHMENT 9: DSHS-Recognized TB Medical Consultant Indications

Consultation from a DSHS-Recognized TB Medical Consultant is required or recommended in the situations described below. Exceptions to consultation requirements may be granted if made by the DSHS Regional Medical Director (RMD). In that case, the RMD must either write the medical orders for the patient or include a signed letter in the patient's medical record that the treatment prescribed meets criteria for adequate therapy.

Contact information for DSHS-Recognized TB Medical Consultants may be found at: dshs.texas.gov/idcu/disease/tb/consultants/

Consultation REQUIRED when:

1. Client is a contact to a case of MDR-TB, Pre-XDR-TB, or XDR-TB.
 2. Client has laboratory-confirmed drug resistance or is suspected to have drug resistant-TB.
 - a. Laboratory-confirmed drug resistance is defined as resistance to isoniazid and/or rifampin, or to any drug other than streptomycin* on drug susceptibility panel testing.
 - b. Consultation must occur within 3 days of laboratory notification.
 - c. Drug resistance should be considered in any client with:
 - Known exposure to an individual with drug-resistant TB
 - Residence in a setting with high rates of primary drug-resistant TB, such as a country or area with high rates of drug-resistant TB in newly diagnosed individuals
 - Persistently positive smear or culture results at or after four months of treatment
 - Previous TB treatment, particularly if it was not directly observed or was interrupted for any reason
- *If the organism is identified as *M. bovis* with PZA monoresistance, consult is not required.*
3. Client has positive sputum cultures for *M.tb* after 4 months of appropriate therapy for TB disease and is deemed a treatment failure.
 4. Client has been prescribed a second line medication.
 - Rifabutin can be used interchangeably with rifampin in clients with drug interactions. If rifabutin is used in place of rifampin due to drug interactions, consult is not required.
 5. Client has been prescribed a regimen for TB disease with highly intermittent therapy, as listed on Table 1 of Attachment 7: Medications.

Consultation RECOMMENDED when:

1. Client has HIV infection and is on or anticipates starting on antiretrovirals.
2. Client has complex medical comorbidities.
3. Client is under the age of 5 years.

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4. Client's symptoms or CXR have not improved after the first 2 months of treatment.
5. Client has a positive sputum smear for acid-fast bacilli and/or positive sputum culture for *M.tb* after 2 months of appropriate therapy for TB disease.
6. When therapeutic drug monitoring is being considered, and the client is not clinically, radiographically, or bacteriologically improving after 2 months of appropriate therapy for TB disease.
7. Client has treatment interrupted for more than 2 weeks in the initial phase of therapy for TB disease.
8. Client has treatment interrupted for more than 3 months in the continuation phase of therapy for TB disease.