

Texas Department of State Health Services

Considerations for Using Therapeutic Drug Monitoring

Providers may order drug levels on tuberculosis patients not responding to adequate therapy, or those with risk factors for poor absorption. Testing is performed at the University of Florida's Infectious Disease Pharmacokinetics Laboratory (IDPL). DSHS will cover the cost of drug levels based on below criteria. Programs may draw drug levels using funds outside of the TB and Hansen's Disease Branch if requests fall outside this criteria.

Note: Only rifamycin and isoniazid levels will be covered, unless patient is on second-line medications or a consultation from a DSHS-recognized TB medical consultant recommends otherwise.



Bacteriological Criteria (consider at 8 weeks of therapy)	Medical Criteria (consider at 2-4 weeks of therapy)	Clinical Criteria (consider at 8 weeks of therapy)	Criteria based on TB Diagnosis**
 Slow response to adequate therapy at 8 weeks of treatment, evidenced by the following: Patient remains AFB sputum smear positive 2+ or greater (unless easily 	 TB/poorly controlled diabetes comorbidity Mal-absorption due to chronic or acute co-morbidity Chronic or excessive vomiting or diarrhea 	 No improvement of TB symptoms (i.e. no weight gain, no reduction in cough, etc.) at 8 weeks Worsening CXR anytime during course of adequate therapy 	• Patient Relapse: When signs and symptoms of TB return within two years of a prior episode of disease and there was a good possibility that relapse was due to low drug levels (exclude previous poor adherence,
 explained) And/or Sputum smear results not decreasing as expected (4+ to 3+, 2+, etc.) 	 HIV infection and CD-4 count <100** Low or high body mass index (>10% above or below ideal body weight) 	 New clinical deterioration, likely related to TB (i.e. new evaluation for TB relapse or concern for drug resistance**) 	 missed doses, or N/V) When second line drugs need monitoring, as per consult recommendations TB meningitis

* Therapeutic Drug Monitoring should be reserved for patients who are not responding to adequate therapy, and not necessarily for patients who meet some of the stated criteria and are otherwise doing well.

** Consultation recommended by a DSHS-recognized TB medical consultant, see list here: dshs.texas.gov/idcu/disease/tb/consultants/



Texas Department of State Health Services

Supplies Needed

TB programs may need to purchase additional supplies for collecting and shipping.







- □ **Pipettes:** For aliquoting serum from the red top tubes into polypropylene tubes.
- □ **Polypropylene tubes:** Used for the aliquoted serum that will be frozen and shipped.
- □ **Dry Ice:** Must be purchased locally; typically found at local grocery stores. Five pounds (5lbs) is required for shipping.





- □ **Cold Boxes:** A vaccine-size cold box is recommended.
- Labels: Biological Substances Category B Label UN 3373 and Dry Ice Label UN 1845
- □ **IDPL Laboratory Requisition**: See page 6 for details



Texas Department of State Health Services

Prepare for Specimen Collection

Review IDPL requisition for specimen collection times: idpl.pharmacy.ufl.edu/forms-and-catalog/idpl-requisition/

Review specimen shipping and collection details: idpl.pharmacy.ufl.edu/forms-and-catalog/sample-handling-instructions/



Perform Directly Observed Therapy (DOT) of TB medications being tested, ensuring that the blood draw can occur at the indicated time *after* the dose of medication is observed.

The number of hours after the dose to draw the samples are shown in parentheses after each drug on the IDPL requisition. It shows the peak time of absorption first and then 4 hours post peak, which may help indicate if there is delayed absorption.

Providers may choose to collect a peak, or <u>both</u> peak and post-peak levels. When collecting post-peak levels, and it is not possible to collect at 4 hours after the first draw, consideration may be made to shorten to at least 2 hours after peak (i.e. collect at 4 hours after DOT). Consult with the ordering physician first to determine which levels are needed; IDPL staff may serve as a resource for drug and patient-specific questions by phone (352) 273-6710 or email <u>peloquinlab@cop.ufl.edu</u>.

For example: If testing both rifampin and isoniazid peak levels, DOT would be provided, and a peak level would be drawn at 2 hours after DOT. A second draw may also be recommended 6 hours after DOT for a post-peak level. Ensure a new laboratory requisition is completed for each timed draw.





Texas Department of State Health Services

<u>Step 2</u>

Perform phlebotomy and collect at least 1 mL of blood per drug to be tested in a plain Red Top tube.

- Required volume of serum once blood is centrifuged is *at least* 0.5 mL.
- Document timing of the blood draw on the requisition; include time DOT was provided.
- Use a separate tube for each test. (Consider drawing an extra tube to freeze serum and save if needed.)

<u>Step 3</u>

Centrifuge blood and aliquot the separated serum into a labeled polypropylene or similar plastic tube, using one tube per test; or, coordinate processing with a local laboratory.

- Draw blood, allow 20 minutes to clot, and then centrifuge. Centrifuging should occur <u>within 2 hours of</u> <u>collection</u>. If blood will be processed in a local laboratory and not by collector, it can be kept on ice while in transport. Coordinate with the lab to ensure timely processing.
- A pipette can be used to harvest out the separated serum and aliquot into the polypropylene tube.
- Label the tube with patient name, date of birth, date/time of collection, and drugs to be tested.

<u>Step 4</u>

Keep separated serum frozen (or refrigerated until it can be frozen) to prepare for shipping.

- Freeze at -70C if possible, but at minimum -20C. Serum that is frozen above -20C is stable for 31 days.
- If an ultralow freezer is unavailable, the serum can be frozen in a regular freezer; do not allow it to go through a defrost cycle.
- Alternately, the tube with decanted serum can be placed on a rack and stored on dry ice (the rack should prevent direct contact between the tube and the ice; the serum will slowly freeze without being shocked by contact with the dry ice).



Texas Department of State Health Services

Shipping Details



Receiving Results and Interpretations

The treating provider will determine if medication dosages will need to be changed based on the results of the serum drug level testing. Each result will be interpreted by Charles Peloquin, Pharm D, at the IDPL who may also be consulted *upon request*. Contact <u>peloquinlab@cop.ufl.edu</u>, phone: (352) 273-6710.



Texas Department of State

Health Services

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	70°C if possible (others	vise -20°C.) Ship	for overnig	ht delivery on ≥ 5 lbs. dry ice.	SHIP SAMP	LES TO BE	Date Recei	ived:					<i>, ,</i> ,
List other medications patient is currently taking: Kings and the set of the set	RECEIVED MONDAY	THROUGH FR	UDAY, DO	NOT SHIP OF FRIDAY OR	CATERON				,		nter	preta	tions

(Revised 04.20)