

# **Therapeutic Drug Monitoring: The Role of the State Laboratory.**

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# **TDM Basics:**

- **Measure of active metabolites of anti-TB drugs in patient's blood at specific times after dosing.**
- **Poor clinical response or certain comorbidities may prompt TDM.**
- **Seek advice from TB Control regarding appropriateness.**

# **TDM not performed by DHMH Laboratory!**

- **Performed at Charles Peloquin's lab at the University of Florida.**
- **We can assist in the processing and shipping of specimens.**

# **Special handling of TDM specimens:**

- **Many of the anti-TB drugs will continue to break down at room temp even after blood is collected.**
- **There are many Federal regulations regarding shipping potentially infectious materials which must be met.**

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### Division of Microbiology



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### Latest News:

- [Newborn Screening for Severe Combined Immunodeficiency Memo](#)
- [Discontinuing Influenza A Virus Surveillance Memo \(March 14 2016\)](#)
- [Zika Virus Guidance and Instruction Memo \(January 2017\)](#)
- [TB Collection Memo \(February 12, 2016\)](#)
- [Instructions- Serological Testing Form with HIV](#)
- [Testing for Suspected Travel-Associated a and Dengue Virus Infections Memo August 1, 2014](#)
- [Middle Eastern Respiratory Syndrome s \(MERS-CoV\) July 25, 2013](#)

# [http://dhmh.maryland.gov/ laboratories/pages/Home.aspx](http://dhmh.maryland.gov/laboratories/pages/Home.aspx)

The screenshot shows the website for the Maryland Public Health Laboratory Division. At the top, there is a navigation bar with links for Maryland.gov, Phone Directory, State Agencies, and Online Services. Below this is a header section featuring the Maryland state logo and the text 'DEPARTMENT OF HEALTH AND MENTAL HYGIENE'. A search bar is located on the right side of the header. Below the header is a yellow banner with a black border containing a notice: 'The Maryland Public Health Laboratory in Baltimore located at 1770 Ashland Avenue does not accept patients or provide phlebotomy service for specimen collection for testing. Please contact your healthcare provider or local Health Department to order Zika or related lab tests.' Below the banner is a blue navigation bar with links for HOME, DIVISIONS, CERTIFICATES OF LICENSURE, and LABORATORY ADVISORY COMMITTEE. The main content area is divided into two columns. The left column contains three sections: 'Quick Links' with links to Lab Hours, Holiday Schedule, Influenza Webpage, Zika Webpage, and About the Labs; 'Laboratory Guides' with links to Guide to Public Health Laboratory Services and Guide to Environmental Laboratory Services; and 'Laboratory Testing & Order Forms' with a link to Infectious Agents Culture Detection. The right column features a large heading 'Maryland Public Health Laboratory Division's' followed by 'Robert Myers, Ph.D. - Director' and a list of two offices: 'Office of the MPHL Director' and 'Office of Laboratory Emergency Preparedness & Response'. Below this is another heading 'Scientific Divisions and Services' followed by 'Prince Kassim, Ph.D. - Deputy Director' and a list of six services: 'Clinical and Environmental Microbiology', 'Environmental Chemistry', 'Molecular Biology', 'Newborn and Childhood Screening', 'Virology and Immunology', and 'Eastern Shore and Western Maryland Labs'.

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## Maryland Public Health Laboratory Division's

### Robert Myers, Ph.D. - Director

- [Office of the MPHL Director](#)
- [Office of Laboratory Emergency Preparedness & Response](#)

### Scientific Divisions and Services

#### Prince Kassim, Ph.D. - Deputy Director

- [Clinical and Environmental Microbiology](#)
- [Environmental Chemistry](#)
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### Laboratory Guides

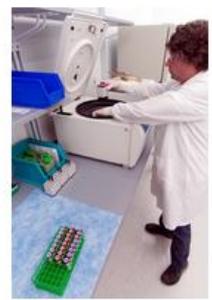
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- > [Guide to Environmental Laboratory Services](#)

### Laboratory Testing & Order Forms

- > [Infectious Agents Culture](#)

### Division of Microbiology

- Vacant
- 443-681-3941



- Office Admin:
- [Denise Brightful](#)
- 443-681-3941

- Fax:
- 443-681-4506

### Microbiology Labs:

- [Bioterrorism](#)
- [Clinical Microbiology](#)
- [Dairy Microbiology](#)
- [Enteric, Diarrheal & Foodborne Diseases](#)
- [Food/Shellfish Microbiology](#)
- [Gonorrhea\(GC\)](#)
- [Tuberculosis \(TB\)](#)
- [Water Microbiology](#)

### Public Health Microbiology:

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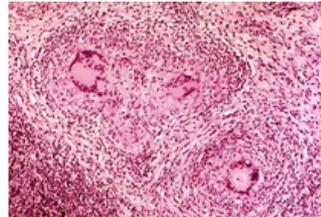
## Laboratory Testing & Order Forms

- › [Infectious Agents Culture Detection](#)
- › [Serological Testing](#)
- › [Testing Supplies Order Form](#)

TB/  
Mycobacteriology  
Lab:  
443-681-3942

Laboratory Scientist  
Supervisor:  
Rich Oatis  
443-681-3944

Laboratory Scientist Lead:  
Michele Plehn  
443-681-3950



The main focus of our work in the Mycobacteriology Laboratory is to provide testing to aid in the diagnosis and control of TB in the State of Maryland. As a secondary goal, our lab also acts as a reference lab, assisting area hospital labs in the identification of a wide range of mycobacterial species.

Testing offered Monday through Friday includes:

§ *Culture and Smear:* We process a wide range of clinical specimens for AFB smear and culture. All smears are read by Fluorochrome staining with positives confirmed by Kinyoun. Culture is performed in both MGIT broth and Lowenstein-Jensen slants and held for seven (7) weeks incubation.

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[Clinical Microbiology](#)

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[Enteric, Diarrheal & Foodborne Diseases](#)

[Food/Shellfish Microbiology](#)

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- [Univ. of Florida TDM Request Form](#)
- [MDPHL TDM Submission Instructions](#)
- [MDPHL TDM Request Form](#)
- [TDM Shipment Schedule](#)

# **Scheduling patients.**

- **Schedule patients to have blood drawn for TDM on Tuesdays or Wednesdays.**
- **Bloods must be to State Lab by 3:30 PM on date collected!**
- **Call State Lab when issues with scheduling a patient arise.**

# **Scheduling with Lab.**

- **Fill out the State Lab request form as completely as possible and fax to State Lab.**
- **Lab requests at least 5 working day notification of specimen submission!**

# MDPHL TDM Request Form

## Therapeutic Drug Monitoring – Maryland State Laboratory Assistance Request

Patient Name	<input type="text"/>
Patient DOB	<input type="text"/>
Submitting Health Department	<input type="text"/>
Contact Person	<input type="text"/>
Contact Phone Number	<input type="text"/>
FAX Number	<input type="text"/>

### Drugs to be tested

<input type="text"/>				
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Estimated Date of Collection	<input type="text"/>
Estimated Time of Delivery	<input type="text"/>

**Please fax this form to the State laboratory at (443) 681-4506 at least 5 business days prior to submitting blood specimens.**

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For State laboratory Use Only

Date received	<input type="text"/>
Comments	<input type="text"/>

# **Collecting blood specimens.**

- **Must use “red top” collection tube (no anticoagulant).**
- **Recommended that one tube be collected per drug to be tested.**
- **Be sure to label tubes with time of collection if levels are being tested at multiple collection times.**

# **University of Florida request form.**

- **Must be filled out completely and accompany blood specimens to the lab.**
- **Originating health department should be listed under the “results mailed to” and billing sections.**
- **A separate form must be used for each collection time, but up to 4 drugs can be listed per form.**

# Univ. of Florida TDM Request Form.

## INFECTIOUS DISEASE PHARMACOKINETICS LABORATORY

1600 SW Archer Rd., P4-30  
 Gainesville, FL 32610  
 Phone: 352-273-6710 Fax: 352-273-6804  
 E-mail: [peloquinlab@cop.ufl.edu](mailto:peloquinlab@cop.ufl.edu)  
 Website: <http://idpl.cop.ufl.edu>



Patient Last, First Name, MI. (Required)		Male Female	Mail results to: (Required)
Date of Birth:	Patient ID:		
Referring Physician:	Physician NPI #	Physician Phone #	
Fax #	Facility Phone #		

**COMPLETE SECTION BELOW ONLY IF BILLING INFORMATION DIFFERS FROM "MAIL RESULTS TO" INFORMATION**

Bill to / Contact Name :

Billing Address:

City State Zip

Telephone #

(Please submit a separate requisition for each sample collection time) Most assays require 4-7 days to complete.

Specimen source (circle one): serum cerebrospinal fluid other: \_\_\_\_\_

REQUIRED	Drug 1	Drug 2	Drug 3	Drug 4
Drug name to be Assayed				
ICD-9 Code				
Drug Dose (mg) (Specify: PO, IV, IM)				
# Doses per week				
Date of last dose				
Time of last dose (For IV: Start/End)				
Date blood drawn				
Time blood drawn				

The number of hours after the dose to collect concentrations are shown in parentheses after each drug name below. To test for delayed drug absorption, a second sample may be collected 4 hours after the "peak". Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.

Drug(s) to be assayed (provide 2 ml serum per test)

AMPL	Amprenavir (trough & 2-3 H)	EFVL	Efavirenz (trough & 5 H)	LOPV	Lopinavir (trough & 4-6H)	RBN	Rifabutin (3 H & 7 H)
ATAZ	Atazanavir (trough & 2 H)	EMBH	Ethambutol (2-3 H & 6-7 H)	MVC	Maraviroc (trough & 1-2H)	RIFH	Rifampin (2 H & 6 H)
AZL	Azithromycin (2-3 H & 6-7 H)	ETAH	Ethionamide (2 H & 6 H)	MXFL	Moxifloxacin (2 H & 6 H)	RFPTN	Rifapentine (3 H & trough)
CMH	Capreomycin (2 H & 6 H)	ETRA	Etravirine (trough & 3-4 H)	NLFL	Neftinavir(trough & 2-3 H)	RTVL	Ritonavir (trough & 2-3 H)
CIPH	Ciprofloxacin (2 H & 6 H)	FLUCZ	Fluconazole (trough & 2 H)	NEV	Nevirapine trough & 2 H)	SAQL	Saquinavir (trough & 2-3 H)
CLART	Clarithromycin(2-3 H & 6-7 H)	INDL	Indinavir (trough & 1-2 H)	OFLHL	Ofloxacin (2 H & 6 H)	SMH	Streptomycin (2 H & 6 H)
CFH	Clofazimine (2-3 H & 6-7 H)	INH	Isoniazid (1-2 H & 6 H)	PASH	p-Aminosalicylic acid (6 H)	TIPV	Tipranavir (trough & 3 H)
CSH	Cycloserine (2-3 H & 6-7 H)	ITRL	Itraconazole (trough & 3-4 H)	POSA	Posaconazole(trough& 3H)	VITD	Vitamin 25(OH) D (random)
DARU	Darunavir (trough & 2-4 H)	LFLHL	Levofloxacin (2 H & 6 H)	PZAH	Pyrazinamide (2 H & 6 H)	VORL	Voriconazole (trough& 2 H)
DELV	Delavirdine (trough & 2 H)	LNZL	Linezolid (trough & 2 H)	RALT	Raltegravir (trough & 3 H)		

**Sample preparation and shipment:** Collect in a plain red top, 8-10 ml tube. Allow the sample to clot and separate serum from cells by centrifugation and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample inside tube. Freeze at -70°C if possible (otherwise -20°C). Ship for overnight delivery on a 5 lbs. dry ice. **SHIP SAMPLES TO BE RECEIVED MONDAY THROUGH FRIDAY. DO NOT SHIP ON FRIDAY OR SATURDAY.**

List other medications patient is currently taking: \_\_\_\_\_

**For UFL Use Only**

Date Received: \_\_\_\_\_  
 Time Received: \_\_\_\_\_  
 Condition: (circle one)  
 Frozen Partially Frozen Thawed

# **Transporting Specimens to State Lab.**

- **Should be expedited on ice to State Lab by private courier/health department employee.**
- **First collected blood can be held on ice until second blood collection if absolutely necessary.**
- **Call the TB Lab upon arrival and deliver specimens directly to lab employee.**

# **Shipping to Florida.**

- **State Lab batches serums and ships to Florida about every 2 to 3 weeks.**
- **Shipment schedule released quarterly via memo and posted to TDM Instructions web page.**
- **May be able to expedite shipment in emergency situations – staff allowing.**
- **Emergency or unusual TDM requests should first be addressed to TB Control.**

**Questions?**