

Specialty Laboratory Testing at TGH

Ray Widen, Ph.D., Manager, Esoteric Testing

The TGH Clinical Laboratory is committed to developing advanced laboratory testing capabilities to provide cutting edge testing for our medical staff and patient populations. It became apparent in several recent meetings with different physician groups that the medical staff may not be aware of the types of testing available. We decided to put together a summary for **Outcomes In Perspective** to help inform the TGH health care team concerning the testing menu.

The Clinical Laboratory offers a variety of specialized testing in each of the departments (Chemistry, Hematology, Histology and Microbiology) that would be found in most hospitals. Each of these departments offers a level of testing that exceeds their counterparts in other regional hospitals. An example of a test for which we have received questions is procalcitonin, currently being performed in the Chemistry Department, which may have utility in detection of early sepsis/infection. In order to develop a broader menu of tests, we established another laboratory department, the Esoteric Testing/R&D Department. This section includes the disciplines of molecular diagnostics, flow cytometry and special/cellular immunology. The Esoteric Testing section's goal is to continuously monitor developments in these disciplines and incorporate the tests that match the needs of TGH physicians in the test menu. This department has implemented an array of in-house developed assays as a complement to numerous commercially available tests to bring on board a menu of assays not available at any other hospital in the region. The Esoteric Testing/R&D lab was the first lab in the region to offer a number of molecular diagnostics assays, including PCR assays for HIV viral load and proviral DNA, MRSA, CMV, HSV along with several other targets. More recently, the TGH Esoteric Lab was the first regional lab to offer influenza virus PCR and typing of the 2009 H1N1 virus. A list of currently available tests is shown in Table 1, with tests available only at TGH listed in **bold italics**.

Table 1. TGH Esoteric Testing/R&D Section

Currently Offered Testing

Flow Cytometry

- Leukemia/lymphoma immunophenotyping
- Lymphocyte quantitation (CD4/8,T,B,NK)
- Transplant CD3 and CD19/CD20 counts
- Fetal hemoglobin detection in maternal blood
- Cell-Cycle DNA Ploidy Analysis
- PNH (CD55/CD59) assay

Special Immunology

- Heparin-induced platelet antibodies by ELISA
- Anti-Nuclear Antibody Titer
- HIV Western blot
- Quantiferon TB Gold
- CSF VDRL

IL-6 quantitative ELISA



Molecular Diagnostics

CMV PCR– quantitative cytomegalovirus DNA detection
HSV PCR– Herpes simplex virus DNA detection and typing
HIV Viral Load– HIV RNA quantitative by PCR

HIV proviral DNA PCR

HCV Viral Load by quantitative PCR
Chlamydia trachomatis PCR
Neisseria gonorrhoeae PCR
Factor V Leiden mutation
Factor II mutation
MTHFR mutation

DNA fingerprinting of bacterial/fungal strains by Rep PCR

MRSA PCR
MRSA PVL Toxin PCR
MRSA Mec Cassette typing

***Mycobacterium species, M. avium/intracellulare and M. tuberculosis* PCR**

EBVPCR– Epstein-Barr Virus Quantitation by PCR
B and T-cell rearrangements by PCR/Fragment Analysis

BK and JC polyomavirus PCR

Bordetella pertussis PCR

Parvovirus B19 PCR

Enterovirus PCR
Influenza A/B PCR
Typing of influenza A by PCR
RSV PCR
Human metapneumovirus PCR
Parainfluenzavirus PCR

Adenovirus PCR

Rhinovirus PCR

Group B streptococcus PCR

***Mycoplasma pneumoniae* PCR**

JAK2 mutation PCR

KPC resistance factor PCR

***Burkholderia cepacia* complex PCR**

Fluorescent in Situ Hybridization (FISH)

Urovision bladder cancer

Hematopoietic translocations by FISH

t11;14

t8;14

t14;18

t9;22

t8;21

t15;17

PathVysion Her2/Neu amplification by FISH



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EGFR**1p19q deletion**

The testing menu historically has evolved to support the Transplant and Infectious Disease services, with more recent additions to support Oncology services as well. As noted in the name of the department, R&D plays a major role in Esoteric Testing. The Esoteric Testing lab operates under the scientific direction of Ray Widen, Ph.D, with strong support from Suzane Silbert, Ph.D. Dr. Widen and Dr. Silbert work with Vicki Healer, MT (ASCP), team leader and the medical technologists in the Esoteric lab to design and implement in-house developed assays and collaborate with vendors to evaluate commercial assays to potentially bring in-house. The most recent completed assay validation is for a molecular assay to detect *Clostridium difficile*, which will be available for testing this month. The molecular assay for *C. difficile* toxin DNA is more sensitive than available rapid antigen assays. The types of tests under investigation and that are being considered are summarized in Table 2. One of the priority assays is development of a respiratory viral panel PCR assay to allow simultaneous detection of influenza A/B, RSV, Parainfluenza 1-3, HMPV, Adenovirus, Rhinovirus, Bocavirus and Coronaviruses. The advantage of this multiplex approach is that it will take less labor time and will be less expensive than setting up so many individual tests.

Table 2. Tests being investigated and current research priorities**Under investigation or planned**

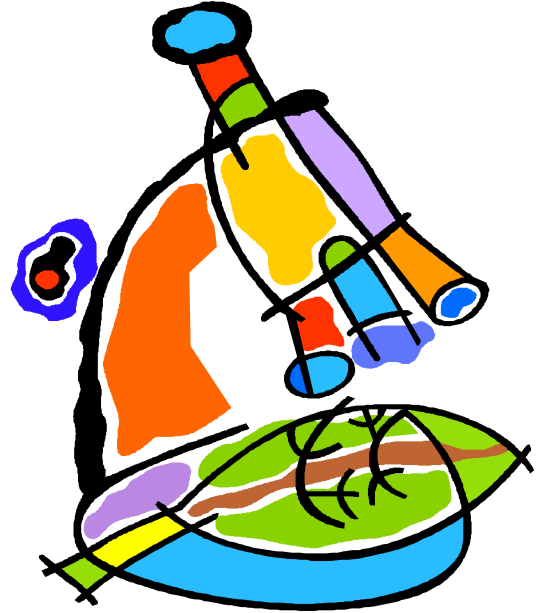
- *Clamydophila pneumonia* and *Legionella pneumophila* PCR
- Respiratory viral panel PCR using an array based multiplex assay
- *Toxoplasma gondii* PCR
- HHV6 PCR
- *Varicella zoster* PCR
- KRAS and BRAF mutation analysis
- BCR/ABL quantitative PCR
- HPV screen and genotyping
- PCR screen for metallo beta lactamases and ESBL associated genes
- PCR assays for mutations in the liver drug metabolizing genes associated with processing of Plavix which can have significant impact on dosing and efficacy

**Research Priorities**

- Molecular assays for rapid detection of bacterial, fungal and viral antimicrobial resistance
- Sequencing or array based assays for rapid detection of microorganisms-bacteria, mycobacteria and fungi
- Molecular assays to support select oncology diagnostic and targeted therapy
- Cellular immunology, flow cytometry and gene expression assays to monitor transplant status

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The Esoteric Testing/R&D lab also participates in contract research activities. One of the projects is the SENTRY program, an international study involving the collection of bacterial isolates to search for new mechanisms of antimicrobial resistance. TGH is one of 140 labs participating worldwide. Another project is with a molecular diagnostics company where we function as a clinical trial site for FDA clearance of CMV quantitative PPCR assay. A similar study for EBV will follow. We also anticipate starting an FDA trial of a multiplexed respiratory pathogen test in the fall. A study to evaluate the performance of a bacterial collection/transport system in maintaining viability of specific “fragile” bacteria is set to start soon. Such studies are important as revenue sources for TGH and provide us with information to help make decisions as to which tests perform well.



In addition to the contract research activities, the Esoteric lab has an education role, with two students from the USF College of Medicine performing their doctoral research projects here and several Masters level students working on research projects with the Esoteric department staff. This fall we will be hosting a Post Doctoral Fellow from Brazil for a one year study researching antimicrobial resistance factor assays and learning the operations and management of a Molecular Diagnostics lab. This program is fully funded by an award she received through the Brazilian government.

Our goal in the TGH Esoteric Testing/R&D Laboratory is to continue to provide our physicians and our patients with the highest level of cost effective diagnostic, prognostic and therapy guiding testing to help continually improve the patient outcomes here at TGH. Please feel free to contact us concerning testing you might find useful for your practice so we can investigate the feasibility of bringing the testing in-house.

Contact Information:

Raymond Widen, Ph.D., Manager, Esoteric Testing/R&D 844-7882 or rwiden@tgh.org

Suzane Silbert, Ph.D., Clinical Scientist 844-4261 or ssilbert@tgh.org

Vicki Healer, MT (ASCP), Team Leader 844-7284, ext 65737 or vhealer@tgh.org

New Residents Welcomed to TGH

On June 28th, TGH welcomed 210 new residents to the hospital. This was a few less than last year's class that numbered 216. There are 128 PGY 1 residents.



Of interest:

The residents range in age from 19 to 60

There are 93 females and 117 males

There are 40 residents from USF

Largest specialties: Internal Medicine, Pediatrics, Surgery and Emergency Medicine



Foreign countries of birth:

South Africa, Cuba, Egypt, Hong Kong, Pakistan, Lebanon, Russia, South Korea, Turkey, Uzbekistan, Viet Nam, and Nigeria

All residents attended a one-day orientation sponsored by Dr. Sally Houston, TGH Sr. VP/Chief Medical Officer. Administrative information was provided from a number of hospital departments and included a special presentation of "Showtime", the hospital's demonstration of how a culture of service, safety and patient satisfaction is incorporated into patient care and staff activities.



Elaine Adams, USF Senior Education Coordinator

Chuck Bombard, Director, Quality Improvement

TGH Pharmacy & Therapeutics (P & T) Committee UPDATE: May 2010

**Please visit Micromedex – FORMULARY ADVISOR for more details of the latest formulary decisions and access to the TGH Formulary. Micromedex – FORMULARY ADVISOR is available on any computer in the hospital with an internet browser!*

Hydroxyethyl Starch 6% (130/0.4) (Voluven®)

Hydroxyethyl starch (130/0.4) (Voluven) is a volume expander indicated for the treatment and prophylaxis of hypovolemia. The 130/0.4 designation refers to the molecular weight, which is a smaller molecule compared to the more commonly known volume expander (Hespan) hydroxyethyl starch with a molecular weight of 600/0.75. Similar efficacy has been noted with Voluven, Hespan, and Albumin. However Voluven has been associated with lesser coagulopathies at higher doses (>3,000mL) compared to Hespan, and lesser financial impact compared with Albumin. Voluven was approved for addition to formulary with the preferred usage in settings where albumin would be used secondary to coagulopathy concerns with Hespan.



Rifaximin (Xifaxan®)

Rifaximin (Xifaxan) is a structural analog of rifampin that is minimally absorbed orally and inhibits bacterial RNA synthesis. The agent concentrates in the gastrointestinal tract and has broad-spectrum in vitro activity against gram-positive and gram-negative aerobic and anaerobic enteric bacteria which lowers the amount of ammonia producing bacteria. Xifaxan is indicated for prophylaxis of hepatic encephalopathy and was approved for addition to formulary based on this indication.

FDA Pancreatic Enzyme Advisory

The FDA has focused on standardization of pancreatic enzyme products (PEPs) in 2010 by requiring manufacturers to submit new drug applications (NDAs) for previously marketed PEPs in order to continue marketing these products. The deadline for submission to the FDA was April 28, 2010. Some manufacturers have complied and received approval, while others have not. Currently, only three formulations have been FDA approved: Creon, Zenpep, and Pancreaze. The committee approved limiting the TGH formulary to these FDA approved products.

Pharmaceutical Shortage Update-Coral Snake Antivenin



Coral snake antivenin is no longer being produced. Current stock consists of out of date (expired) vials as well as in-date vials. At present, Pfizer pharmaceuticals is seeking a two year extension on the current lot numbers and have inventory of expired drug to last approximately 12 months. The medical staff will be updated when more information is made available.

Please visit Micromedex – FORMULARY ADVISOR for a complete and current list of pharmaceutical shortages



SAVE THE DAY!



*The Medical Staff 2010 Annual Meeting
will be held Wednesday, September 22nd
at the Westin Harbor Island Hotel beginning at 6:00 pm.*

*Headlining the meeting will be:
Voting for Medical Staff Officers and Medical Staff Recognition!
MARK YOUR CALENDAR NOW!*



WE'RE ON THE WEB
WWW.TGH.ORG

TGH Welcomes our new Physicians



The physicians below were added to TGH staff: 6/30/2010

Michael J. Adler, MD	Orthopaedic Surgery	Justin R. Kunes, MD	Orthopaedic Surgery
Jaron R. Andersen, MD	Orthopaedic Surgery	Candice F. Mateja, DO	Internal Medicine
Melanie L. Aya-Ay, MD	Plastic Surgery	Jason A. Nydick, MD	Orthopaedic Surgery
Michael E. Billhymer, MD	Orthopaedic Surgery	Christina Pelaez-Velez, MD	Pediatrics
Eric E. Coris, MD	Family Practice	Tran C. Phung, MD	Internal Medicine/ Infectious Diseases
Jennifer E. DePerio, MD	Orthopaedic Surgery		
Riley W. Hale, MD	Orthopaedic Surgery		
Kevin L. Herreld, MD	Orthopaedic Surgery		
Kavita Kalidas, MD	Neurology		
Dan D. Kemper, MD	Orthopaedic Surgery		
Shiraz A. Khaiser, MD	Internal Medicine		
Aslam M. Khan, MD	Internal Med/Card		

This newsletter is produced by Tampa General Hospital's Quality Improvement Department. All comments, responses or suggestions are welcome and should be directed to:

Sally H. Houston, M.D.
Sr. V.P. &
Chief Medical Officer
Tampa General Hospital,
P.O. Box 1289,
Tampa, Florida 33601

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### **KUDOS TO OUR PHYSICIANS!**

**Congratulations to the following physicians who were recognized by their patients in the form of personal letters to TGH leadership.**



**Dr. Jennifer Cox , Michelle Bonfe, ARNP,  
Dr. Thomas Bernasek, Dr. Vincent Perron,  
& June Resident of The Month: Dr. Rohit Neal Sharma**