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Introduces a new
test for TB**

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Introduction of the Cepheid Xpert® MTB/RIF Test

The Microbiology Laboratory at Hamilton General Hospital is pleased to introduce the Cepheid Xpert® MTB/RIF test for *Mycobacterium tuberculosis* (MTB) which runs on the GeneXpert system.

Globally, about 2 billion people are infected with MTB. Every year almost 9 million people develop active disease, and 2 million people die of the illness. Active MTB, which is predominantly pulmonary in nature, is a highly infectious airborne disease. Given the infectious nature of MTB, fast and accurate diagnosis is an important element of MTB treatment and control.

The Xpert® MTB/RIF Assay is intended for use with specimens from untreated patients for whom there is clinical suspicion of tuberculosis (TB). Use of the Xpert MTB/RIF Assay for the detection of MTB or determination of rifampin susceptibility has not been validated for patients who are receiving treatment for tuberculosis.

Treatment involves prolonged administration of multiple drugs and is usually highly effective. However, MTB strains can become resistant to one or more of the drugs, which makes cure difficult to achieve. Four common first-line drugs used in anti-tuberculosis therapy are:

- Isoniazid (INH)
- Rifampin (RIF or Rifampicin)
- Ethambutol (EMB)
- Pyrazinimide (PZA)

RIF resistance rarely occurs in isolation and usually indicates resistance to a number of other anti-TB drugs. RIF resistance is most commonly seen in multi-drug resistant (MDR-TB) strains and has a reported frequency of greater than 95% in such isolates. MDR-TB is defined as a tuberculous disease caused by a bacterial strain that is resistant to at least INH and RIF. Resistance to RIF or other first-line drugs usually indicates the need for full susceptibility testing, including testing against second-line agents.

Prior to the consolidation of Microbiology at the Hamilton General site, HRLMP maintained a TB lab at the McMaster site. More stringent regulatory requirements have made it impossible to maintain a TB lab at any site. This means that concentrating and decontaminating specimens, as was done previously to make

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a smear, is no longer possible. Without these steps the sensitivity of Acid Fast Bacilli (AFB) staining of smears is <40% and has therefore been abandoned.

To replace the highly insensitive smear we have acquired the FDA and Health Canada approved Cepheid GeneXpert system and the MTB/RIF® assay to test for TB. The World Health Organization's (WHO) endorsement of the Xpert MTB/RIF test follows 18 months of rigorous assessment of its field effectiveness in the early diagnosis of TB, as well as multidrug-resistant TB (MDR-TB) and TB complicated by HIV infection, which is more difficult to diagnose.

The Xpert® MTB/RIF test provides on-demand capability for STAT results from sputum specimens for potential new TB cases. The test has excellent sensitivity even for smear negative / culture positive specimens and no concentration is required. Each test takes approximately 2 hours which is faster than the smear method (1-3 days) and certainly faster than culture which can take up to 8 weeks. The GeneXpert Dx system integrates and automates sample processing, nucleic acid amplification, and detection of the target sequences in samples using real-time PCR and reverse transcriptase PCR. The system utilizes single-use disposable GeneXpert cartridges that hold the PCR reagents and host the PCR process. The cartridges are self-contained, eliminating cross-contamination between samples.

The limit of detection of the assay is stated by the manufacturer to be 131 CFU/mL with a 95% confidence interval ranging from 106.2 CFU to 176.4 CFU/mL. Results from international studies indicate that when considering a composite of the results from three



sputum samples per patient, the Xpert MTB/RIF Assay demonstrated a sensitivity among culture positive specimens of 97.3%. In Smear+ Culture+ patients, the Xpert MTB/RIF Assay sensitivity was 99.8%, in Smear- Culture+ patients the sensitivity was 72.5%. The Xpert MTB/RIF Assay specificity in non-TB patients was 97.9%.

Although this test demonstrates excellent results for RIF resistance detection using External Quality Assurance DNA, the Microbiology Laboratory cannot fully validate this part of the assay due to low prevalence of resistance in Ontario. These results will be made available to the Microbiologists who will discuss them with the attending or specialist physicians on a case by case basis.

The Xpert test will be available for inpatients with suspected respiratory tuberculosis, who are in airborne precautions and have sputum or BAL samples submitted for AFB staining and culture. We will continue to send the specimens to the Public Health Laboratory for staining, culture and susceptibility testing. A minimum of three specimens should be submitted for Public Health testing; only the first of these will be tested by the Xpert.

News from HRLMP

Congratulations to Tom Dorland who will take on the role of **Supervisor of Laboratory Medicine** for Haldimand War Memorial Hospital in Dunnville on **March 3, 2014**. Tom will continue in his role of Quality Specialist for the HRLMP.

News from HRLMP

HRLMP Morbidity and Mortality Rounds Coming this Spring!

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The HRLMP will be launching **Morbidity and Mortality rounds** this May. Laboratory case studies that impact patient care will be reviewed, followed by a facilitated investigation of key factors that may have contributed to the undesired outcome. Laboratory staff, physicians and other healthcare practitioners will come together to discuss system-wide and process issues, as well as develop solutions for process improvements. Rounds will be held quarterly, span all laboratory disciplines, and rotate across all sites. Stay tuned for more information about the HLRMP Morbidity and Mortality rounds.

Education News

New Program Director, General Pathology Residency Program

We are pleased to announce that **Dr. Vidhya Nair** has accepted the role of Director of our General Pathology Postgraduate Program **effective February 1, 2014**.

Dr. Nair is a member of our Forensic Pathology team at the Hamilton General Hospital.



We would like to take this opportunity to thank Dr. Tariq Aziz, our outgoing Director, for his dedicated and enthusiastic service over the past five years.

As a result of Dr. Aziz's hard work and commitment, the General Pathology program achieved accreditation in 2009 and has continued to grow and prosper, providing our residents with a strong academic curriculum and a diverse variety and excellent volume of clinical cases.

Congratulations to our **Medical Biochemistry** residents who have completed their training and moved on to exciting new careers. **Li Wang** will be working as a Medical Biochemist at BC Children's Hospital, Vancouver. **John Sievenpiper**, will be working as a Scientist, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto.

For information and the latest news on our residency training programs follow the link: <http://fhs.mcmaster.ca/pathres/news/index.html>

Information on the postdoctoral fellowship: <http://fhs.mcmaster.ca/pathology/education/postdoctoralfellowshiptraining.html>

News from Hematology

Effective January 6th 2014, the von Willebrand Factor (VWF) ristocetin cofactor activity, our current method for measuring VWF activity, was replaced with an automated assay, Siemen's Innovance® VWF Activity. The Innovance® VWF Activity assesses VWF binding to recombinant glycoprotein Ib (activation mutant). This method does not require ristocetin and it has an improved sensitivity, which is helpful for von Willebrand disease assessment. The change to an automated method will shorten the turnaround times for VWF investigations, including the assessment of VWF activity

for peri-operative monitoring of patients with von Willebrand disease.

Our validation studies have demonstrated that Innovance® VWF Activity assay gives comparative results to the VWF ristocetin cofactor assay, with improved sensitivity. However, some subjects with type 2 von Willebrand disease have much lower activity by the Innovance® VWF Activity than by the ristocetin cofactor method.

The reference interval for the Innovance® VWF Act is 0.48 – 1.80 U/mL, with a lower limit of measurement of 0.04 U/mL.

If you have any questions regarding this assay or any other coagulation laboratory issue, please contact Karen Moffat, Technical Specialist, Coagulation at 905 521 2100 ext. 73124 or moffat@hhsc.ca.

Hemolytic Screen testing will be limited to one sample per patient per week, unless approved by a Hematologist, **effective February 15, 2014**.

Osmotic fragility testing will only be available for samples drawn Monday through Wednesday, **effective February 1, 2014**. Specimens must arrive in the Red Cell Disorders by noon on Thursday at the latest.

News from Microbiology

The LHIN Laboratory Medicine Network continues its plan to develop a **Regional Microbiology Service** through the consolidation of Microbiology testing in Hamilton. On January 27th, Microbiology and Reference



Testing from the Niagara Health System transferred to the Hamilton Regional Laboratory Medicine Program. This work was previously serviced by a private laboratory in the Niagara region. The **Niagara Health System (NHS)** serves 434,000 residents in 6 sites across the Niagara Region. The NHS provides a wide range of inpatient and

outpatient clinics/services at six sites, including Acute Care, Surgical Care, Emergency and Urgent Care, Kidney Care, Complex Care, Mental Health and Addiction, Long Term Care and Cancer Care.

Annual volumes of approximately 161,000 Microbiology tests and 25,000 laboratory reference tests are sent to Hamilton for processing. The samples are delivered multiple times per day. Orders are placed and results returned via an interface directly into the Meditech systems at both organizations.

The leadership teams at both the HRLMP and the NHS have been working together for months to make the transition for patients and clinicians a smooth one. The staff in our Microbiology departments at the Hamilton General and St. Joseph's Healthcare Hamilton have responded to the added workload with extreme professionalism, positive attitudes and effective teamwork!

The implementation of urine screening using the Alfred 60 and HB&L system from Alifax has been delayed temporarily while Microbiology focuses on Regional Microbiology services and total laboratory automation. Stay posted for a new implementation date!

The virology laboratory will be performing testing for respiratory viruses three times per day Monday through Sunday during influenza season.

Automation Update

We are operating one of the front end pieces (WASP) as a stand-alone instrument that is interfaced to Meditech for demographics and sample information only. This has made a positive impact on the workflow as we can load the samples on, walk away, and it does the work. By the way, WASP stands for 'Walk Away Specimen Processor'. All renovations are complete and the full WaspLab system has been delivered and installed in Microbiology. We are now in the process of validating, training, and creating a full bi-directional Meditech interface to allow us to use the system to its full capacity. We are aiming for a spring go-live of the entire system.

News from Pathology

Forensic Pathology Update

New Staff:

We are pleased to announce the addition of one new Forensic Pathologist at Hamilton Health Sciences. The new addition is **Dr. Allison Edgecombe**. Dr. Edgecombe received her medical degree from the University of Newfoundland, pathology training in anatomic pathology at the University of Ottawa and then fellowship (PGY-6) in Dallas Texas at Southwestern Institute of Forensic Sciences. She joined our staff in August 2013. Please join us in welcoming her to our department. Already Dr. Edgecombe has taken on not only service work providing excellent forensic pathology case work but also a significant teaching commitment to McMaster University pathology residents and medical students and University of Toronto Forensic Science undergraduate students.

We have been successful in recruitment of a PGY 6 for the start of the academic year **July 2015**. Watch for more details when the time nears.

Forensic Pathology has had a busy 2013 with 838 cases done in the department through the cooperation of our staff, the ancillary laboratories and facilities and our allied partners in death investigation.