

Date: March 1, 2010

To: Alberta Health and Wellness, MicroNet Partners, Senior Medical Officer of Health, TB Clinics, TB Physicians and TB Services

From: ProvLab

Re: Implementation of the BACTEC MGIT 960 System for Anti-tuberculosis Drug Susceptibility Testing

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#### **Key Message:**

Effective March 1<sup>st</sup>, 2010 ProvLab will implement the use of the BACTEC MGIT™ 960 system (Becton, Dickinson and Company, Sparks, MD) for routine drug susceptibility testing against first line anti-tuberculosis agents including rifampicin (RIF), ethambutol (ETB), pyrazinamide (PZA), isoniazid (INH) and ofloxacin.

#### **Why the change?**

The previously used radiometric BACTEC 460TB™ System (Becton, Dickinson and Company, Sparks, MD) has been employed by the ProvLab since the 1990's. However, the hazards arising from using radioisotopes as well as reagent delivery delays and sporadic unavailability of drugs compromises turn-around times for susceptibility testing affecting patient management. Use of the BACTEC MGIT™ 960 system will also align ProvLab methodology with many other TB labs throughout Canada and the United States.

#### **What is different?**

The BACTEC MGIT™ 960 system has obtained Health Canada approval for susceptibility testing of *M. tuberculosis* complex against INH, RIF, STR, ETB, and PZA (Health Canada, Medical Devices, 1999). The Mycobacterial Growth Indicator Tube (MGIT) contains a modified, non-radioactive 7H9 broth; in conjunction with a fluorescence quenching-based oxygen sensor it allows susceptibility testing, and overcomes the limitations of radiometry (including safety and regulatory mandates). Critical drug concentrations and interpretive criteria will not change; hence result reports will look similar.

The instrument was evaluated and validated in-house for routine use at ProvLab. Resistance detected toward any drug, as measured by the rapid BACTEC MGIT™ system, will be confirmed employing the reference agar dilution 1% method of proportion. Pyrazinamide resistance will be confirmed by repeat testing on the BACTEC MGIT™ as well as molecular genetic analysis.

#### **Questions?**

Contact:

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