DIAGNOSTIC LABORATORY SERVICES,INC.

Date: March 25, 2005

Memo To: DLS Clients

From: Microbiology Department

Re: Change of Methodology and Reporting Format for *Mycobacterium tuberculosis Susceptibility* panel

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DLS microbiology is changing its *M. tuberculosis* (TB) susceptibility testing methodology from the BD BACTEC 460 to the BD BACTEC MGIT 960. Along with the new testing protocol, there will also be a change to the reporting format for this susceptibility panel.

The MGIT 960 protocol is a rapid (3-13 days) qualitative test, and is based on the growth of a patient's *M. tuberculosis* isolate in a drug-containing tube compared to a drug-free (growth control) tube. The instrument monitors the growth and reports results as "Sensitive" or "Resistant" at established concentrations.

The MGIT 960 is cleared by the U.S. FDA for the use of Streptomycin 1.0 ug/ml, Isoniazid 0.1 ug/ml, Rifampin 1.0 ug/ml, Ethambutol 5.0 ug/ml and Pyrazinamide 100 ug/ml. The concentrations that are tested are called the "critical concentration", and are the lowest concentrations that inhibit 95% of "wild-type" strains of *M. tuberculosis* strains that have not been exposed to the drug. Note that these concentrations do not inhibit strains of *M. tuberculosis* considered resistant which are isolated from patients who are not responding to therapy. The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) recommends that every lab should test the susceptibility of *M. tuberculosis* to the critical concentration of the drugs.

DLS will report its M. tuberculosis susceptibility panel as follows:

M. Tuberculosis Complex Panel: (DLS)

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|---|---|
| Status: | Final |
| Comments: | |
| Streptomycin (1.0 ug/ml) | S/R |
| Isoniazid (0.1 ug/ml) | S/R |
| Rifampin (1.0 ug/ml) | S/R |
| Ethambutol (5.0 ug/ml) | S/R |
| Pyrazinamide (100 ug/ml) | S/R |

S=Susceptible R=Resistant

Note: This isolate was tested by the BACTEC MGIT 960, using critical (lowest) concentrations established by the United States Public Health Service and recommended by the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS).