

> MOLECULAR DIAGNOSTICS INDUSTRY

- The molecular diagnostic testing market represents the fastest growing and most profitable area of the \$51.7 billion clinical laboratory industry in the United States (Washington G-2 Reports' 2nd Annual Molecular Diagnostics Conference, 2007).
- The molecular diagnostics market was valued at \$4.1 billion in the U.S. in 2007. It is estimated that it will continue to grow by approximately 19% per year for the next three years (Washington G-2 Reports' 2nd Annual Molecular Diagnostics Conference, 2007).

TB AND MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)

- TB remains a massive global public health problem, with nearly 9 million new cases and more than 1.5 million deaths each year (WHO, 2008).
- One third of the world's total population is infected with the tuberculosis bacillus; an estimated 5,000 people die of the disease every day (WHO, 2008).
- Today's most commonly used TB diagnostic, sputum microscopy, has been in use for more than a century and lacks sensitivity (WHO, 2008).
- A total of 13,293 TB cases were reported in the United States in 2007 (CDC, 2007).
- According to the WHO, nearly half a million new cases of MDR TB emerge each year, yet only 2% are diagnosed and given appropriate treatment. MDR TB patients are those infected with TB strains resistant to the two most powerful "first-line" anti-TB drugs available: isoniazid and rifampicin.
- According to the WHO, about 2.8% of new TB cases in Southeast Asia are MDR-TB, and 18.8% of cases among people who have previously received TB treatment for at least one month are MDR-TB.
- Fewer than 5% of existing MDR-TB patients are currently being diagnosed due to serious laboratory capacity constraints and the availability of diagnostic tools (WHO, 2008).

PANDEMIC AND SEASONAL INFLUENZA

- By 2010, the worldwide influenza diagnostics market is likely to reach \$7.1 billion, with average annual growth estimated at 19.8% (BCC Research, 2007).
- Worldwide, more than 3.5 million people die annually of influenza (BCC Research, 2007).
- Every year in the United States, 5% to 20% of the population suffers from influenza. More than 200,000 people are hospitalized from flu complications, and about 36,000 people deaths are directly attributable to influenza.

HOSPITAL-ACQUIRED INFECTIONS (HAIs):

- The WHO defines HAIs as those occurring in a patient in a hospital or other health care facility, and where the infection was not yet present or incubating at the time of admission (WHO, 2008).
- HAIs affect at least 7 million people worldwide each year (First World Forum on Healthcare-Associated Infections, 2007).
- On average, one of every 20 patients entering U.S. hospitals acquires a serious drug-resistant infection (Mayer PT. Catheter related blood infections. *Medical Laboratory Observer*, 2007).
- HAIs are responsible for longer hospital stays, rising healthcare costs, and for generating nearly \$8 billion in extra healthcare-related expenses each year (First World Forum on Healthcare-Associated Infections, 2007).
- 70% of organisms causing HAIs are resistant to at least one antibiotic (First World Forum on Healthcare-Associated Infections, 2007). > IF | 004.01 | 10.10