

The Impact of Molecular Testing on Public Health.

By Steven Hinrichs M.D., Director, NPHL

While we have heard for many years about the potential of molecular testing in the clinical laboratory, most new tests did not use prepackaged kits approved by the Food and Drug Administration (FDA) and required in house validation. Amplification tests that used PCR were practical only in the research or academic laboratory but when probe based tests became available for sexually transmitted diseases such as Chlamydia, they had a major impact. Within the past year, commercial amplification tests have been released that use molecular amplification technologies with kits approved by the FDA, most notably tests for Methicillin (oxacillin) resistant *Staphylococcus aureus* and Group B Streptococcus. These tests also have been developed for single use applications, meaning they don't have to be batched and can be run on a STAT basis when needed. It is now being predicted that molecular approaches will replace many of the tests used by the microbiology laboratory. Therefore, all microbiologist may want to gain at least a basic level of understanding in the field of molecular biology. Two articles in this issue of the newsletter were written to provide examples of the importance of molecular approaches.

Dr. Peter Iwen has reviewed one of the applications of molecular technology that can be used to identify virtually any type of bacteria. His laboratory has applied this technology to determine the species of bacteria that cannot be identified using standard biochemical tests or phenotypic assays. This is the same technology being used to identify new species of organism as illustrated by the recent identification of *Mycobacterium* named after our state.

Dr. Paul Fey has summarized the key principles and methods that are used in pulse field gel electrophoresis studies. These approaches are one of the best approaches to support epidemiologic investigations and trace the origin of a strain of bacteria that is capable of moving from patient to patient.

Taken together, these articles provide some of the framework needed to understand the basic technologies behind these tests. The information is a primer toward a working knowledge of molecular approaches. Both of these authors are more than happy to provide educational opportunities beginning with MRSA and bacterial susceptibility and will be participating as speakers in the next round of the Center for Biopreparedness Education (formerly Nebraska Center for Bioterrorism Education) 2005 Symposia (see details on page 3). Those laboratorians participating in the symposia will again be invited to join us for a laboratory advisory committee meeting during lunch on day two of the symposia. We look forward to seeing you at the upcoming meetings throughout the state.