

## Preclinical results for infectious disease test, 2/13:110

Akonni Biosystems recently announced results from three preclinical studies verifying the efficacy of its TruDiagnosis molecular diagnostic platform. Akonni TruArray tests are for mid-multiplex molecular diagnostics deployed in near point-of-care settings.

These studies, including those for methicillin-resistant *Staphylococcus aureus* (MRSA), multi-drug resistant *Mycobacterium tuberculosis* (MDR-TB), and influenza subtyping, were funded and developed over the past six years by the National Institutes of Health, Centers for Disease Control and Prevention, National Science Foundation, and the Department of Defense.

In collaboration with Johns Hopkins University, Akonni conducted a retrospective study on 87 clinical isolates and 246 nasal swab samples acquired from a non-random, high-risk patient population. Of the 87 isolates, the TruArray test accurately classified 86 (98.8 percent) and correctly identified 14 *mecA* dropout specimens that were falsely positive in other tests. The overall prevalence of MRSA in the clinical sample set was 16.7 percent.

In collaboration with researchers from Johns Hopkins, Akonni conducted a study with 185 *M. tuberculosis* isolates representing a worldwide distribution of rifampin, isoniazid, streptomycin, and ethambutol resistance genotypes. The simplified TruArray test containing 96 unique probes for 39 drug-resistant mutations in five genes enabled a single technician to run up to 24 samples in under six hours, using a thermal cycler and a microarray imager. Of 196 mutations in the culture set that were also represented on the microarray, the TruArray test correctly detected 193 (98.4 percent success rate).

In collaboration with the CDC and others, Akonni developed a TruArray test for influenza detection, subtyping, and neuramidase resistance detection from nasopharyngeal swabs. Limits of detection in clinical nasopharyngeal swab samples were about 100 RNA gene copies per test, regardless of influenza subtype. The most sensitive probes were those targeting seasonal and pandemic influenza A H275Y variants. Using a CDC surveillance and reporting guideline, definitive identification was provided for 164 of 178 samples (92 percent) and 328 of 342 hybridizations (95.9 percent). No false positives were detected.

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