

ELITechGroup

Development of Rapid Systems for the Detection of Antibiotic Resistance

Antibiotic resistance has become a major health issue. The ELITechGroup solution consists of two different approaches utilizing the strengths of academia and industry. ELITechGroup will address the Inpatient Solution and the Bioengineering Department of University of Washington (UW) will address the Outpatient Solution in sections A and B respectively. ELITechGroup and the UW have collaborated closely for 10 years on a Gates Foundation Grand Challenge and a DARPA grants where both projects lead to the development of a molecular diagnostics point of care instrument and assays, the former work was sold to Sony Inc.

Inpatient Solution: A commercially available PCR instrument-based approach that performs 12 assays from extraction to result with no hands-on time in about 2.5 hours is now available from ELITechGroup. The Elite InGenius® instrument (www.elitechgroup.com/product/elite-ingenius/) has the ability to measure 6 different fluorescent wavelengths, perform melting curve analysis and has been validated to extract nucleic acid (DNA and RNA) from the following sample types: whole blood, plasma, CSF, urine, nasal swab, throat swab, stool, rectal swab, serum and nasopharyngeal swab. ELITechGroup has 6 commercially available antibiotic resistance assays. These include 5 CE-IVD assays; CRE (VIM, IMP, OXA, NDM1, KPC and IC), ESBL (CTXM group1, 9 and 14/15), MRSA (*mecA*, *mecC*, *ldh1*), *Mycobacterium tuberculosis* and *C. difficile*. The assays use ELITech's Minor Groove Binding (MGB) and modified base technologies which allow the use of shorter probes with improved specificity. MGB-Pleiades probes are not degraded and allow post amplification melting curve analysis.

Outpatient Setting: The University of Washington Department of Bioengineering (Drs Yager and Lutz) has collaborated with ELITechGroup to develop the Multiplexable Autonomous Disposable NAAT (MAD NAAT) system – a rapid, instrument-free, disposable NAAT platform that performs lysis, amplification, and detection for bacterial or viral targets. The MAD NAAT includes all reagents stored on board in a dry form that is shelf-stable without refrigeration and does not require any reagent handling by the user. User steps are very simple, and all processes are automated inside the disposable device. In the fifth year of a \$20M DARPA project, we have demonstrated prototype devices for detection of methicillin-resistance *Staphylococcus aureus* (MRSA, via two DNA gene targets) and respiratory syncytial virus (RSV) from nasal swab samples. The device uses an isothermal (constant temperature) amplification method developed by ELITechGroup that is very fast and sensitive (in benchtop conditions, it can detect 10 copies in about 15 minutes). The University of Washington and ELITechGroup will adapt their Elite InGenius antibiotic resistance assays into the isothermal amplification format and demonstrate such assays on the MAD NAAT platform.