Startup Contest Application

High-Sensitivity Point-of-Care Cardiac Troponin Testing Device for Non-ST-Elevation Myocardial Infraction Diagnosis

1. Venture Name. M.EARLY

2. Team Leader and Primary Contact Information.

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3. Additional Team Members.

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4. Describe the business opportunity.

We have validated that cardiac troponin (cTn) testing under the prehospital setting for patients can result in (1) rule-out of non-ST-elevation myocardial infraction (NSTEMI) and avoidance of unnecessary visits to emergency department (ED); and (2) rule-in NSTEMI and immediate triaging and destination plans. In other words, prehospital diagnosis of NSTEMI can be clinically and economically beneficial. Central laboratory testing (CLT) in hospital is still preferred for NSTEMI owing to the superior sensitivity of the CLT. However, CLT is unavailable in the prehospital setup. Accordingly, delayed diagnosis of NSTEMI can be responsible for the high mortality and increased cost burden. Our target is to develop point-of-care (POC) cTn testing module with comparable sensitivity and specificity to the CLT for the prehospital NSTEMI diagnosis. 5.4 million patients visit ED annually due to the chest pain and the average cost is $37,000. AMI only accounts for 7% of all circulatory system-related diagnoses. 38.6% of visits are discharged without severe disease diagnosis. Our module can provide prehospital diagnosis of NSTEMI and reduce 35% ED visits of low-risk patients with non-ST elevation and negative cTn test results. For the high-risk NSTEMI patients, our module can expedite the clinical treatments by 1.5 hours and reduce false negative results by 14.9%.

5. Describe your technological solution.

Our team has demonstrated rapid high-sensitivity POC immunoassay incorporating nano-plasmonic and two-dimensional (2D) semiconductor transducers. (**Figure 1**) Specifically, such device consists of three unique components: i) plasmonic nanoprobes; ii) a photodetector made of 2D

molybdenum disulfide (MoS_2) layers; and iii) an integrated optical structure. The high detection specificity of biofunctionalized nanoparticles and extremely low electronic noise characteristics of 2D semiconductors result in superior biosensing performance

6. Who is your competition and what are your product differentiators?

Currently, the i-STAT cTn POC platform lacked sensitivity and should not be used to exclude NSTEMI owing to the 28% sensitivity result compared to the higher sensitivity value of 67.9% under CLT testing setup. Once our POC assays with improved analytical sensitivity become available, further deployment of POC cTn testing in the prehospital (i.e., ambulance transport) setting will be warranted.

7. Describe the Market Opportunity.

Our target patient group is the pre-hospitalized patients who are experiencing chest pain with non-ST-elevation (without electrocardiogram (ECG) abnormalities). This group of patients typically ends up with 1) non-cardiac chest pain, 2) unstable angina, and 3) NSTEMI. In fact, many of such patients with acute myocardial infraction (AMI) also exhibit equivocal ECG patterns, which make prehospital ECG diagnosis very difficult. The key differentiator of AMI for the patients with non-ST elevation is the positive cTn assay result. Thus, our target market segment, which will be addressed by the proposed innovation and service, is the prehospital POC troponin testing to rule-in and rule-out AMI. (**Figure 2**)

8. Describe the Team.

Seungjun Ki has in-depth learning experiences in commercialization milestones throughout the national science foundation (NSF) I-CORP program. Dr. Xiaogan Liang has extensive experience in nanofabrication, nanomanufacturing, nanoelectronics, biosensing, nano/microfluidics, and microsystem integration. Dr. Park is a well-established expert in the field of optofluidics, functional nanomaterials, bioinspired active optics, and integrated molecular detection.

9. Describe any traction.

M.Early completed NSF I-CORP project and finished 150+ customer interviews. Furthermore, our team has applied for follow-up technology translation funding, NSF PFI proposal.

Figures and Additional Information

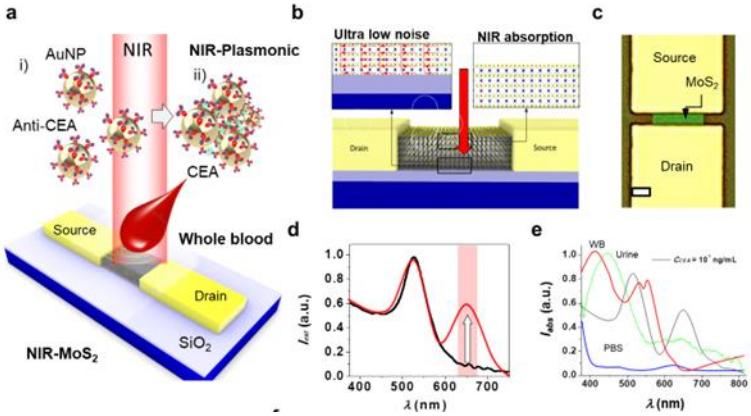

Figure 1: ***Integrated ultra-sensitive MoS_2 cancer biomarker detection by NIR plasmo-optoelectronic biosensing.*** ***(a)*** *Illustration of MoS_2 channel accompanying antibody-conjugated plasmonic AuNP aggregation driven by the presence of biomarkers.* ***(b)*** *Cross-sectional view of ultralow-noise MoS_2 photoconductive channel structure.* ***(c)*** *Optical micrographs of MoS_2 channel with electrodes;* ***(d)*** *Photocurrent Spectrum.* ***(e)*** *Photocurrent at zero biomarket concentration (black line) and 10 ng/mL (red line).*

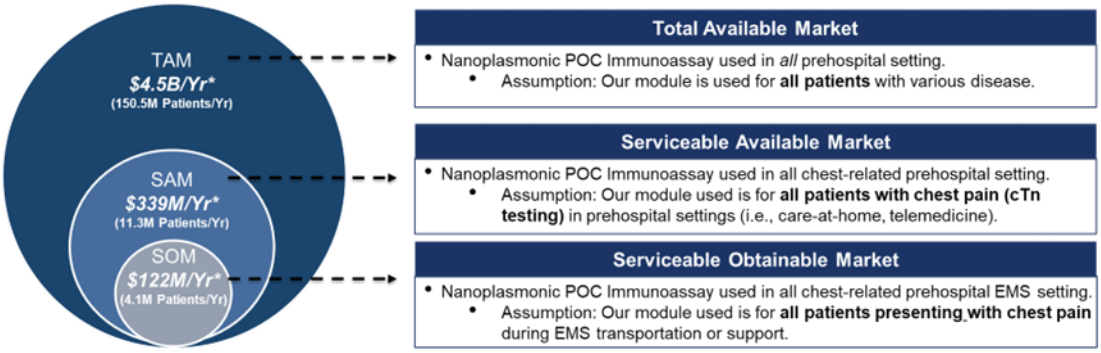

Figure 2: Market overview of POC diagnostic revenue in prehospital settings (presented market share ($) for 100% market penetration)