Alberta Innovates Technology Futures

Alberta Innovates Health Solutions

DynaLIFEDx Diagnostic Laboratory Services

Alberta Small Business Innovation & Research Initiative

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HEALTH

PROGRAM CHALLENGE

Point-of-Care Detection for Patients with Acute Myocardial Infarction

OPEN CHALLENGE DATE: **JUNE 27, 2016** **CLOSE CHALLENGE DATE:** **AUGUST 7, 2016**

Overview

DynaLIFEDx provides diagnostic laboratory services to Albertans in a variety of healthcare settings. Among the services provided are tests for heart attacks, known clinically as myocardial infarction (MI). The most common analyte for identifying MI is Troponin, a protein that is released when the heart muscle has been damaged from an event such as a heart attack.

There are currently many commercially available Cardiac Troponin (cTn) assays that can be used to identify patients that have experienced a MI event. These existing assays require a series of blood specimens to be taken over many hours to accurately diagnose a positive or negative result or they need to be paired with a large analyzer, which typically are not found in smaller rural settings. Therefore, there exists a need for a High Sensitivity cTn assay requiring only a single test to generate a diagnostic result that can be used by small labs and in near-patient settings such as Emergency Departments and Ambulatory Care.

Together, Alberta Innovates - Tecnology Futures, Alberta Innovates - Health Solutions, and DynaLIFEDx have set a goal to identify technologies with the potential of providing a high-sensitivity point-of-care (POC) cTn device. A point-of-care (POC) High Sensitivity cTn assay would be beneficial to both patients and the healthcare system. A POC format would enable critical treatment to begin sooner; thereby improving patient outcomes while simultaneously freeing up resources as this assay would have rapid rule-out triage capabilities. In addition, such a POC devise would reduce healthcare disparities experienced by regional, rural, and remote communities.

Desired Technology Performance Characteristics

- Small form format:
  - Ideally, would be handheld.
  - Portable.
  - Battery powered is advantageous.
- High-sensitivity analytical criteria:
  - Imprecision of <10% concentration of variation (CV) at the 99th percentile.
  - Analyte measurability in >50% of healthy individuals.
- Other desired characteristics
  - Electronic transmission capabilities to other healthcare information systems.
  - A simple user interface so that a wide variety of healthcare professions can use it with minimal training.
  - Ability to measure a variety of blood specimen types, such as fingerstick blood, venous plasma, or serum.

Desired Solution Provider Attributes

A strong solution provider would possess:

- Expert scientific knowledge in the measurement of biomarkers.
- Technical expertise in assay development and instrumentation design.
- ISO 13485 certification or strong relationships with a manufacturer that does.
- Knowledge of medical device licensing requirements by Health Canada and the United States Food and Drug Administration
- Professional relationships with key opinion leaders in the cardiology community.

Selection Criteria

As part of Alberta Innovates standard due diligence process, we will opportunities from the following perspective:

- Technology readiness and IP strategy.
- Market competitiveness and addressable market size.
- Business capacity, capabilities, and sustainability.
- Project implementation plan (high-level).

As the solution will ultimately require Health Canada licensing, the solution provider must be prepared to provide evaluation data that meets regulatory requirements. This may include as part of this program a clinical trial conducted jointly with Dynalife.