TECHNOLOGY BRIEF

Diagnostic

A blood test for detection of congenital heart block in autoimmune-related maternal conditions

Lead Inventor:
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Business Development Director:
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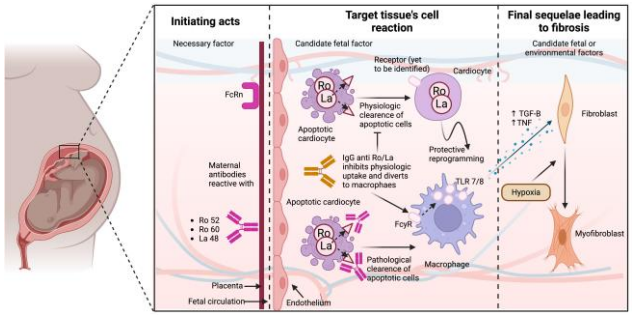
Background

Fetal heart block is a congenital arrhythmia caused by impaired conduction of electrical signals from atria to ventricles, leading to a slowed fetal heartbeat, life-long therapy, or potentially death. Autoimmune congenital heart block is a rare disease but affecting a non-rare population (autoimmune disease) (Lupus affects about 1.5 million Americans and at least 5 million people worldwide, with a higher prevalence in women of childbearing age.) **The population is large, the disease is rare, and prevention is currently weak.**

Description of the Invention

SickKids Hospital cardiologist, Dr. Robert Hamilton has identified a novel maternal autoantibody targeting the fetal AT1A1 cardiac protein as a potential biomarker for the early and accurate detection of fetal autoimmune congenital heart block in pregnant women who had not previously had an affected pregnancy.



Commercial Applications

ATP1A1 Changes the Entire Landscape:

- Replaces or reduces fetal echo surveillance by 98–99%.
- Identifies true at-risk pregnancies before disease onset, enabling targeted Plaquenil.
- Predicts CHB well in advance, providing a first-in-class companion biomarker for new therapies.
- Brings number-needed-to-treat/diagnose down to ~1:1.

This advancement might improve the maternal-fetal management of at-risk pregnancies through enhanced surveillance and timely and informed therapeutic interventions.

Current screening fails both sensitivity and specificity:

Anti-Ro Testing

- Misses ~20% of CHB cases.
- Only 1/50–1/100 anti-Ro positive pregnancies develop CHB → *very non-specific.*

Fetal Echocardiography

- Weekly scans from 16–24 weeks: stressful, expensive, unsustainable.
- Detects disease too late to prevent injury.
- Lifetime cost of pacing a child is extremely high.

Developmental Stage

In collaboration with a contract research organization, Dr. Hamilton is developing a robust clinical grade assay. Once developed, blood samples from pregnant women across several sites in Europe, Canada and the USA will be assayed in order to test the robustness and validate the accuracy of the assay to detect heart block from diverse ethnicities and genetic backgrounds.

Keywords: Diagnostic, Companion Diagnostic, Maternal, Fetal, Congenital Heart Block

Tech ID: 1364

Intellectual Property

Patent: Diagnosis of Congenital Heart Block

Abstract: A method of diagnosing congenital heart block or risk of congenital heart block in a fetal or infant subject is provided. The method includes the step of detecting in a biological sample obtained from the mother of the subject one or more maternal autoantibodies which bind to target cardiomyocyte proteins of the subject. A kit for use in to detect such maternal autoantibodies is also provided.

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National Phase: entered in Canada, United States, Europe, Australia

IP&C is seeking a partnership with either a diagnostic company to complete the development and commercialize the test or with a pharmaceutical company to license the test as a companion diagnostic

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