New Streamlined, Platform Independent, Lymphocyte Response Diagnostic for Clinical Laboratories

Allen J. Norin, Ph.D.
Professor & Director, Transplant Immunology & Immunogenetics
SUNY Downstate Medical Center
Allen.Norin@downstate.edu

The Problem

Three major classes of lymphocytes, T cells, B cells and NK cells, play important roles in immunity to pathogens and cancers, in autoimmune diseases and in rejection of organ transplants.

However, only T lymphocyte function is assessed by commercially available assays.

The Commercial Solution

To address this need I developed the *"The Downstate Lymphocyte Function Test (DLFT) Kit"*, for assessing the function of B cells and NK cells, as well as T cells.

The Downstate Lymphocyte Function Test (DLFT) Kit

Advantage - 1

A kit that tests the function of B lymphocytes and NK cells as well as T cells would provide more detailed information for diagnosis and management of patients with inherited and acquired immune dysfunction including:

- **Immunodeficiency diseases (e.g., Di George's syndrome)**
- **Immunosuppression (e.g., organ transplantation, autoimmune diseases)**
- **Viral infections (e.g., HIV)**
- **Immunotoxicity e.g., industrial chemical accidents**

The Downstate Lymphocyte Function Test (DLFT) Kit

Advantage - 2

The DLFT kit is designed to simplify cell isolation, save time and reduce cost since the activating agent and the cell isolation agent are one and the same.

Important Data - 1

TABLE 1

Comparison of B Cell Stimulation with Pansorbin ® and T cell Stimulation with PHA*

	B cell Function Assay			T cell Function Assay		
Subject	Unstim	Pansorbin ®	Difference	Unstim	PHA	Difference
A.	127	429	302	36	362	326
B.	152	205	53	5	134	129
C.	608	>1000	>392	79	364	285
D.	117	473	356	3	473	470

*Results are reported in ng/ml ATP. Subject "A" is a normal adult subjects "B-D" are children <12.

Important Data - 2

TABLE 2

Comparison of B Cell Stimulation with Pansorbin ® and Protein A Magnetic Beads from the Same Adult Subject*

Stimulant	Unstimulated	Stimulated	Difference
Pansorbin ®	117	367	250
Protein A beads	108	503	395

*Results are reported in ng/ml ATP

Technology Development

- **Prototype has been developed and tested.**
- **All reagents are commercially available.**
- **Next steps, Distribution:**
  - **Model #1: manufacture of a kit to be sold directly to clinical laboratories**

    and/or
  - **Model #2: as a service provided by centralized commercial laboratory.**

Market/Intellectual Property Status

MARKET

- In 2012, an estimated 500,000 Americans were afflicted with Primary Immunodeficiency Diseases. (National Institute of Allergy and Infectious Disease).
- 16,844 solid organ transplants performed between January 2014 and July 2014. (U.S. Department of Health & Human Services – Organ Procurement and Transplant Network)
- Over 500 transplant centers and labs in the U.S. (Scientific Registry of Transplant Recipients – SRTR)

INTELLECTUAL PROPERTY

- U.S. Patent Number: 8,771,971, *"Methods and Kits for Measurement of Lymphocyte Function."*
- Issue Date: July 8, 2014

Contact Information

Alexandra Dudman

Senior Licensing Associate

Office of Technology Commercialization

SUNY Downstate Medical Center

450 Clarkson Avenue

Brooklyn, NY 11203

Phone: 718-613-8524

Email: alexandra.dudman@downstate.edu