

## Diagnostic Assay for Determining Patient Response to Apoptosis-related Cancer Therapy

### Summary (1024-character limit)

Researchers at the National Cancer Institute (NCI) developed a multiplex assay to determine the efficacy of apoptosis-related drugs targeting the Bcl2 family of proteins or aid in the selection of cancer patients likely to respond. The NCI seeks partners for co-development or licensees for commercialization of novel immunoassays for determining or predicting patient response to cancer therapy.

### NIH Reference Number

E-195-2018

### Product Type

- Diagnostics

### Keywords

- Apoptosis, Bcl-2, Immunoassay, Pro-Apoptotic, Prognostic, Pharmacodynamic Biomarkers, Srivastava

### Collaboration Opportunity

This invention is available for licensing.

### Contact

- John D. Hewes  
NCI - National Cancer Institute

240-276-5515

[John.Hewes@nih.gov](mailto:John.Hewes@nih.gov)

### Description of Technology

Many known chemotherapeutic drugs kill abnormal cells through a process called apoptosis. Bcl-2 proteins are negative regulators of apoptosis that control cell survival and death. Increased expression of anti-apoptotic Bcl-2 proteins commonly occurs in up to 30% of all cancers, providing cancer cells a pro-survival advantage to evade cell death, grow, and proliferate. Drugs targeting these specific anti-apoptotic proteins are potential anti-cancer therapeutics. A need exists for improved methods to select patients that may benefit from drugs targeting apoptotic pathway, such as Bcl-2 homology domain-3 (BH3) mimetics.

Researchers at the NCI developed a multiplex assay to determine the efficacy of apoptosis-related drugs targeting the Bcl2 family of proteins or aid in the selection of cancer patients likely to respond. The immunoassay quantitatively measures heterodimer protein complexes of specific Bcl-2 family proteins. Traditional assays performed in needle biopsies only measure individual Bcl-2 family proteins and do not

capture the protein-protein interactions.

The assay was confirmed using tumor tissue biopsy samples and has the potential to predict drug efficacy. The assay may be useful as a companion diagnostic in conjunction with apoptosis-inducing agents. The assay also has the potential to aid in the selection of cancer patients likely to respond to drugs targeting the apoptosis pathway.

### **Potential Commercial Applications**

- Companion diagnostic to determine efficacy of anti-apoptotic therapies such as BH3 mimetics
- Diagnostic for the selection of appropriate drug therapy for cancer patients

### **Competitive Advantages**

- Novel assay to simultaneously measure multiple indicators of apoptosis in a single sample compared to traditional assays
- Quantitative measurement of pro-apoptotic drug efficacy

### **Inventor(s)**

Apurva K Srivastava Ph.D. (NCI/Leidos), Dominic Esposito Ph.D. (NCI/Leidos), Jeevan Prasaad Govindharaju Ph.D. (NCI/Leidos), Ralph E Parchment Ph.D. (NCI/Leidos), [James H Doroshaw MD \(NCI\)](#)

### **Development Stage**

- Clinical

### **Publications**

Srivastava AK, et al. Effect of a Smac Mimetic (TL32711, Birinapant) on the Apoptotic Program and Apoptosis Biomarkers Examined with Validated Multiplex Immunoassays Fit for Clinical Use. [[PMID 26446940](#)]

### **Patent Status**

- **U.S. Provisional:** U.S. Provisional Patent Application Number 62/798,615 , Filed 30 Jan 2019

### **Therapeutic Area**

- Cancer/Neoplasm
- Infectious Diseases
- Immune System and Inflammation