

Validated Pharmacodynamic Assay Training

Course: Tumor Biopsy Fractionation for the Apoptosis Multiplex Immunoassay Panels

For more information on upcoming training dates please contact

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The National Cancer Institute's Division of Cancer Treatment and Diagnosis (DCTD) invite investigators to receive training on a validated tumor biopsy extraction procedure. DCTD has supported the development and validation of multiplex immunoassays for 15 cytosolic and membrane-associated proteins indicative of the induction, onset, and commitment to apoptosis in human tumors (Srivastava, A.K. et al, 2015, Clin. Can. Res. 14: 3156). These immunoassay kits, constructed on the Luminex multiplex technology platform, are now commercially available.

DCTD-sponsored research emphasizes both drug development and molecular target identification and assessment. Validated PD assays standard operating procedures (SOPs) are integral to obtain accurate information about drug effect on intended molecular targets in early clinical trials and inform clinical development.

DCTD has established the Pharmacodynamic Assay Development and Implementation Section (PADIS) and the National Clinical Target Validation Laboratory (NCTVL) at Leidos Biomedical Research, Inc. to develop and validate PD assays suitable for Phase 0, I, and II clinical trial applications with molecular-targeted agents.

The Tumor Biopsy Lysate Fractionation for the Apoptosis Multiplex Immunoassay Panels SOP is a validated procedure for preparing tumor biopsies in preparation of multiplex analysis, is being transferred to the cancer research community, with training and certification provided at the Frederick National Laboratory for Cancer Research (FNLCR) campus. Additional training and certification sessions, including sessions on validated assays and SOPs for new drug targets, will be scheduled in the future. For further information see the DCTD Biomarkers Web site at <http://dctd.cancer.gov/ResearchResources/ResearchResources-biomarkers.htm>.

DCTD announces training for the cancer research community on its validated procedure for fractionation of tumor biopsies in preparation for use of the apoptosis multiplex immunoassay panels that are now commercially available. The procedure involves the preparation of cytosolic and combined nuclear/mitochondrial cell fraction lysates from frozen needle tumor biopsies to enable quantification of analyte levels of proteins involved in apoptosis using the multiplex immunoassay kits on the Luminex platform. This biopsy extraction SOP has been developed to ensure inter-operator, inter-site, and inter-day precision.

The goals of the training are as follows:

- i) Achieve user proficiency via NCI-led training and certification.
- ii) Maintain performance during transfer of the extraction procedure to outside sites.
- iii) Ensure uniformity across all sites conducting the extraction procedure.

Description

Training on Tumor Biopsy Lysate Fractionation for the Apoptosis Multiplex Immunoassay Panels will be conducted at the FNLCR campus in Frederick, Maryland by senior scientific staff from DCTD's Leidos Biomedical Research, Inc. PADIS and NCTVL scientists that developed and validated the procedure and supported the development of the commercially available multiplex kits will provide the training. The training session will be tailored to the needs of a clinical research laboratory.

Learning Objectives

- Review Specimen Handling SOPs and master step-by-step performance of the fractionated tumor biopsy extract SOP and perform protein quantitation and quality control evaluation of the lysates.
- Gain an overview of the development, validation and preclinical and clinical applications of the apoptosis multiplex immunoassay panels.
- A demonstration of the use of a multiplex immunoassay kit on the Luminex platform will be provided.

Registration Information

Please complete the attached registration form and send by e-mail to Katherine Ferry-Galow, ferrygalowkv@mail.nih.gov (fax: 301-846-5206). All registrants will be notified once training dates have been selected with admittance prioritized according to receipt of registration and preference given to individuals from site participating in NCI clinical trials.

There will be no charge for registration, training, and transportation between the preferred hotel and the training site. The trainees will be responsible for their accommodations, meals, transportation to and from Frederick, Maryland, and any other costs incurred during training. For additional information please contact Katherine Ferry-Galow by phone 301-228-4665 or e-mail (ferrygalowkv@mail.nih.gov).

Preferred Hotel

Those interested in staying at a hotel convenient to the training site, with free transportation to and from the training site, may contact the Hampton Inn & Suites.

Hampton Inn & Suites Frederick-Fort Detrick

1565 Opossumtown Pike
Frederick, Maryland, 21702
Phone: (301) 696-1565 **Fax:** (301) 696-1545

<http://hamptoninn.hilton.com/en/hp/hotels/index.jhtml?ctyhocn=FDRHSHX>

Airport Transportation

Airport-specific Transportation Links

- [Reagan National Airport \(DCA\) Ground Transportation Information](#)
- [Dulles International Airport \(IAD\) Ground Transportation Information](#)
- [Baltimore/Washington International \(BWI\) Ground Transportation Information](#)

Shuttle/Limousine Services

- [Airport Quick Connection](#)
- [America Limousine & Bus Service](#)
- [Atlas Limousine & Sedan](#)
- [BWI Car Service](#)
- [KV Limo](#)
- [Super Shuttle](#)

Restaurants

Below are links to Frederick restaurants. The hotel Web site has listings for nearby restaurants under their dining tab. Note that some restaurants may require reservations at least 1 week in advance.

- [Eat in Frederick.com](#) Restaurant Guide – restaurants in Frederick arranged by cuisine type and searchable by restaurant name.
- [Frederick.com](#) Restaurant Guide – restaurants in Frederick arranged by cuisine type.
- [Google Maps link](#) – Frederick, Maryland restaurants