

Validated Pharmacodynamic Assay Training Course: Hypoxia-Inducible Factor 1 α (HIF-1 α) Immunoassay

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 immunoassay. This immunoassay quantifies total hypoxia-inducible factor 1 α (HIF-1 α) levels in patient tumor biopsies as a pharmacodynamic (PD) measure of drug action on total HIF-1 α . *Limitations:* Data generated using Phase I clinical trial samples suggest that this assay may not be sufficiently sensitive to measure HIF-1 α decreases in many human biopsy pre- and post-dose pairs (Park, S.R. et al., 2014, Anal Biochem).

DCTD-sponsored research emphasizes both drug development and molecular target identification and assessment. Validated PD assays with specimen handling 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 HIF-1 α Immunoassay, a validated PD assay for HIF-1 α inhibitors, 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 HIF-1 α Immunoassay, a chemiluminescent immunoassay employing quality-controlled, commercial antibodies and recombinant HIF-1 α standards. The assay quantifies changes in HIF-1 α levels as a means to quantify drug effects on the HIF-1 α molecular target. An assay SOP has been developed to ensure inter-operator, inter-site, and inter-day precision. Rigorous methodology and reference materials result in accurate and reproducible evaluation of drug effect in highly heterogeneous clinical specimens.

The goals of the training are as follows:

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

Description

HIF-1 α Immunoassay training will be conducted at the FNLCR campus in Frederick, Maryland by senior scientific staff from DCTD's Leidos Biomedical Research, Inc. PADIS and NCTVL laboratories who developed and validated the HIF-1 α Immunoassay and Specimen Handling SOPs. The training session will be tailored to the needs of a clinical research laboratory.

Learning Objectives

- Review Specimen Handling SOPs and prepare biopsy tumor extracts in compliance with SOPs.
- Master step-by-step performance of the HIF-1 α Immunoassay, including instrumentation, data analysis and reporting, troubleshooting, and quality control.
- Understand the importance of reagent quality and consistency for obtaining valid results as they pertain to the success of early-phase clinical trials.

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](#)
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- [BWI Car Service](#)
- [KV Limo](#)
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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