

Validated Pharmacodynamic Assay Training Course: γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides

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) invites investigators to receive training for image capture and data analysis on a validated immunofluorescence assay. This immunofluorescence assay quantifies percent γ H2AX-positive tumor cells as a pharmacodynamic (PD) measure of DNA damaging agents.

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 SAIC-Frederick to develop and validate PD assays suitable for Phase 0, I, and II clinical trial applications with molecular-targeted agents.

The γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides using the Bond-Max System, a validated PD assay for DNA damaging agents, is being transferred to the cancer research community, with training and certification provided at the Frederick National Laboratory for Cancer Research 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 γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides, an assay employing quality-controlled commercial antibodies to γ H2AX. Because other staining systems may be used once qualified at certified assay sites, this course focuses on the SOPs for imaging and data analysis to quantify the percentage of γ H2AX-positive tumor cells as a biomarker for drug effect. Assay SOPs have 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 on γ H2AX levels 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 uniformity of imaging and data analysis across all sites conducting the assay.

Description

γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides training focuses on image capture and data analysis of tumor sections previously stained with the Bond-Max System. This course will be conducted at the Frederick National Laboratory for Cancer Research campus in Frederick, Maryland by senior scientific staff from DCTD's SAIC-Frederick PADIS and NCTVL laboratories who developed and validated the γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides. The training session will be tailored to the needs of a clinical research laboratory.

Learning Objectives

- Review specimen handling SOPs for frozen needle tumor biopsies and preparation of slides.
- Master step-by-step performance of image capture, data analysis, data reporting, troubleshooting, and quality control steps for tumor biopsy slides stained using the γ H2AX Immunofluorescence Assay for Tumor Biopsy Slides using the Bond-Max System.
- Instrument qualification strategies to be used if another automated staining system is used will be outlined.
- 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

E-mail Katherine Ferry-Galow, ferrygalowkv@mail.nih.gov, if you wish to be notified of upcoming training dates. 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](#)
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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