

**Validated Pharmacodynamic Assay Training
Course: γ H2AX Immunofluorescence Assay
for Tumor Biopsy Slides
August 14 – 15, 2012**

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

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

Registration Form: γH2AX Immunofluorescence Assay for Tumor Biopsy Slides Using the Bond-Max System Training, Frederick National Lab, Ft Detrick, MD

Today's Date: _____ Training Date Requested: _____ (Please print of type)

Trainee Information

<hr/> Last Name	<hr/> First Name	<hr/> Middle (opt)
<hr/> Occupation	<hr/> Employer	
<hr/> Street Address		
<hr/> City	<hr/> State	<hr/> Zip Code
<hr/> Contact Phone #	<hr/> Contact E-mail	Date of Birth <input type="checkbox"/> M <input type="checkbox"/> F Gender
<hr/> Employer Phone #	<hr/> Employer E-mail	<hr/> Employer Fax #
<hr/> *Driver's License #	<hr/> *Passport #	
<hr/> State/Country Issued	<hr/> Country Issued	<hr/> *Alternate Photo Identification
<p>*IMPORTANT: Two (2) forms of photo identification are required for access to the Frederick National Laboratory for Cancer Research campus at Fort Detrick where the training will be conducted.</p>		

Training

Environmental Health and Safety Training (informational only, previous training not required)

Bloodborne Pathogens	<input type="checkbox"/> Yes	<input type="checkbox"/> No
OSHA Laboratory Standards	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Laboratory Equipment Decontamination	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Medical Waste Management	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Additional Information

Hepatitis B Vaccination	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Laboratory Coat Size:	<input type="checkbox"/> S <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> XL <input type="checkbox"/> XXL <input type="checkbox"/> Other _____	

Indemnification

The TRAINEE shall indemnify, defend and hold harmless SAIC-Frederick (SAIC-F), Frederick National Laboratory for Cancer Research, and any persons acting on their behalf, (and its successors, officers, directors, and employees) from any and all liabilities, claims, and expenses of whatever kind and nature for injury to or death of any person or persons, and for property loss or damage to any real or tangible personal property arising out of SAIC-F's performance of the training, except to the extent such death, injury, loss, or damage was caused by the negligent acts or omissions of SAIC-F or Frederick National Laboratory for Cancer Research. SAIC-F shall promptly notify the TRAINEE, in writing, of any claim and shall reasonably cooperate with the TRAINEE in the defense and settlement of the claim. This Section shall survive completion of the training.

Emergency Contact

<hr/> Name of Friend or Relative	<hr/> Relationship	<hr/> Home Phone #	<hr/> Work Phone #
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Signature

<hr/> AGREED BY (signature above)	<hr/> Date
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Print Name

Send completed registration form Katherine Ferry-Galow by e-mail ferrygalowkv@mail.nih.gov (fax: 301-846-5206).

Visiting Frederick National Laboratory for Cancer Research

Frederick National Laboratory for Cancer Research is located within Fort Detrick in Frederick, Maryland. Please be aware that you will be required to provide two (2) forms of photo identification in order to enter Fort Detrick. Van transportation for trainees will be provided to and from the preferred hotel and the Frederick National Laboratory for Cancer Research campus. If you provide your own transportation, please allow extra time for security inspection upon entering Fort Detrick.

Driving directions to Frederick National Laboratory for Cancer Research in Frederick, Maryland and a map of the campus are provided below. The following links can also be used:

- [Driving Directions](#)
- [Campus Map](#)

Fort Detrick

810 Schreider Street
Fort Detrick, Maryland 21702-5000
Directory assistance (operator): (301) 619-8000

Directions from Baltimore, Maryland:

Total Distance: Approximately 53 miles

- I-695 west towards Towson to I-70 west (approximately 20 miles).
- I-70 west (exit 16) to Frederick (approximately 45 miles).
- As you approach Frederick, you will exit at Rt. 15 north to Frederick/Gettysburg, PA.
- Follow Route. 15 North to the Fort Detrick/Rosemont Avenue Exit
- Bear right at the bottom of the ramp onto Rosemont Avenue;
- Follow straight to Old Farm Drive; turn right into the Old Farm Gate;
- Follow through gate to yield sign at 3-way intersection and turn right onto Doughten Drive;
- At the 4-way stop, turn right onto Sultan Drive and then an immediate left onto Miller Drive;
- Protective Services, Bldg. 426, and the NCI Administrative Offices, Building 427, will be on the right.
- Parking is available in the Building 371/372 and Building 549 parking lots.

Directions from Washington, DC:

Total Distance: Approximately 55 miles

- I-270 north to Frederick
- As you approach Frederick, I-270 ends and becomes Rt. 15 north to Frederick/Gettysburg, PA.
- Follow Route. 15 North to the Fort Detrick/Rosemont Avenue Exit
- Bear right at the bottom of the ramp onto Rosemont Avenue;
- Follow straight to Old Farm Drive; turn right into the Old Farm Gate;
- Follow through gate to yield sign at 3-way intersection and turn right onto Doughten Drive;
- At the 4-way stop, turn right onto Sultan Drive and then an immediate left onto Miller Drive;
- Protective Services, Bldg. 426, and the NCI Administrative Offices, Building 427, will be on the right.
- Parking is available in the Building 371/372 and Building 549 parking lots.

Directions from Northern Virginia/Leesburg area (Dulles Airport):

Total Distance: Approximately 44 miles

- Rt. 28 north to Rt. 7 west and Leesburg.
- As you approach Leesburg, you will exit at the Rt. 15 bypass around the city and continue towards Point-of-Rocks/Frederick, MD.
- You will cross the Potomac River at Point-of-Rocks and continue north on Rt. 15 to Frederick (road bears left after crossing the bridge).
- Follow Route. 15 North to the Fort Detrick/Rosemont Avenue Exit
- Bear right at the bottom of the ramp onto Rosemont Avenue;
- Follow straight to Old Farm Drive; turn right into the Old Farm Gate;
- Follow through gate to yield sign at 3-way intersection and turn right onto Doughten Drive;
- At the 4-way stop, turn right onto Sultan Drive and then an immediate left onto Miller Drive;
- Protective Services, Bldg. 426, and the NCI Administrative Offices, Building 427, will be on the right.
- Parking is available in the Building 371/372 and Building 549 parking lots.

Directions from Baltimore-Washington International Thurgood Marshall Airport (BWI):

Total Distance: Approximately 54 miles

- West on I-195 W
- Merge onto MD-295 S via EXIT 2B toward WASHINGTON
- Merge onto MD-100 W toward Ellicott City.
- Merge onto US-29 N / Columbia Pike toward I-70.
- Merge onto I-70 W via exit 25B toward Frederick.
- Merge onto US-40 W via exit 53B toward Gettysburg. US-40 W will become US-15 N.
- Follow Route. 15 North to the Fort Detrick/Rosemont Avenue Exit
- Bear right at the bottom of the ramp onto Rosemont Avenue;
- Follow straight to Old Farm Drive; turn right into the Old Farm Gate;
- Follow through gate to yield sign at 3-way intersection and turn right onto Doughten Drive;
- At the 4-way stop, turn right onto Sultan Drive and then an immediate left onto Miller Drive;
- Protective Services, Bldg. 426, and the NCI Administrative Offices, Building 427, will be on the right.
- Parking is available in the Building 371/372 and Building 549 parking lots.

Directions from Ronald Reagan Washington National Airport (DCA):

Total Distance: Approximately 52 miles

- Start out going NORTH on ramp.
- Merge onto George Washington Memorial Pkwy N (Passing through District of Columbia - then crossing into VA)
- Merge onto I-495 N / Capital Beltway toward MD (Crossing into MD).
- Keep LEFT to take I-270 SPUR N via exit 38 toward Rockville / Frederick.
- I-270 Spur N becomes I-270 N.
- I-270 N becomes US-40 W.
- US-40 W becomes US-15 N.
- Follow Route. 15 North to the Fort Detrick/Rosemont Avenue Exit
- Bear right at the bottom of the ramp onto Rosemont Avenue;
- Follow straight to Old Farm Drive; turn right into the Old Farm Gate;
- Follow through gate to yield sign at 3-way intersection and turn right onto Doughten Drive;
- At the 4-way stop, turn right onto Sultan Drive and then an immediate left onto Miller Drive;
- Protective Services, Bldg. 426, and the NCI Administrative Offices, Building 427, will be on the right.
- Parking is available in the Building 371/372 and Building 549 parking lots.

