National Cancer Institute

DCTD Division of Cancer Treatment and Diagnosis

Validated Pharmacodynamic Assay Training Course: Immunofluorescence Assays for Circulating Tumor Cells

For more information on upcoming training dates please contact:

Katherine Ferry-Galow Phone: 301-228-4665; E-mail: ferrygalowkv@mail.nih.gov

The National Cancer Institute's Division of Cancer Treatment and Diagnosis (DCTD) invites investigators to receive training on validated immunofluorescence assays. One biomarker assays are currently supported: measurement of γH2AX-positive circulating tumor cells (CTCs) as a pharmacodynamic (PD) measure of DNA damaging agent drug effect.

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.

These immunofluorescence assays for CTCs use the CellSearch System and are being transferred to the cancer research community, with training and certification provided at the NCI-Frederick 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 immunofluorescence assays for CTCs using the CellSearch System employing quality-controlled commercial antibodies to γH2AX. This assay quantifies the number of biomarker-positive CTCs using the CellSearch System, to quantify drug effects. 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 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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Description

Training for the γH2AX immunofluorescence assay for CTCs using the CellSearch System will be conducted at the NCI-Frederick campus in Frederick, Maryland by senior scientific staff from PADIS, SAIC-Frederick, who developed and validated this immunofluorescence assay for CTCs on the CellSearch System. The training session will be tailored to the needs of a clinical research laboratory.

Pre-Course Requirement

Prospective assay trainees must have received training by Veridex, LLC in the use, operation, and maintenance of the CellSearch System, including the CellTracks AutoPrep System and the CellTracks Analyzer II. Equivalent training requires that the applicant work in a laboratory supervised by a board certified clinical chemist or pathologist; the certifier should provide a letter on institute letterhead stating that he/she has trained the applicant in ALL ASPECTS of Veridex CTC analysis including operation of the instrument and CTC identification (e-mail Katherine Ferry-Galow, ferrygalowkv@mail.nih.gov, to verify equivalence).

Qualified operator certification on the CellSearch System

is required prior to taking this course.

Learning Objectives

- Master step-by-step performance of the immunofluorescence assays for CTCs using the CellSearch System, 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
- 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