

## Circulating Tumor Cell Assay Frequently Asked Questions

### **LHTP003.8.1                    $\gamma$ H2AX IMMUNOFLUORESCENCE ASSAY FOR CIRCULATING TUMOR CELLS USING THE CELLSEARCH SYSTEM**

1. *Do I need any prior experience before applying for the training course with DCTD?*

Yes. The primary operator and reviewer for this Laboratory procedure should have at least a PhD and 3 years or an MS and 5 years of experience in immunoassay validation and have worked in a clinical testing laboratory setting. In addition, training and certification on the CellSearch System with Veridex, LLC is required prior to training on the  $\gamma$ H2AX IFA using the CellSearch System with DCTD.

### **LHTP003.8.1.1                    $\gamma$ H2AX IMMUNOFLUORESCENCE ASSAY ANTIBODY QUALIFICATION AND LABORATORY PROFICIENCY TESTING**

1. *What is proficiency testing and why are we required to do this even though we have been trained on the SOP?*

- a. Proficiency panels are widely used in clinical laboratory testing; their purpose is to demonstrate that an assay being run in a specific laboratory is yielding accurate and reliable results. Because the  $\gamma$ H2AX Immunofluorescence Assay for CTCs is the equivalent of a "home brew" assay, there is no manufacturer's (Veridex) procedure for assay control. Therefore, laboratories are required to perform proficiency testing when the assay is first set up in their laboratory, each time a new certified assay operator is added to the laboratory, and each time a new batch of custom antibody is qualified.
- b. The proficiency panel for this test is simply healthy donor blood spiked with topotecan-treated or untreated MCF7 cells assayed using the CellSearch system as if they were clinical samples. A set of performance criteria are provided, and if met, provide some assurance that the operator and the assay system are working properly.