Molecular Diagnostic Testing OHSU Knight Diagnostic Laboratories

The Knight Diagnostic Laboratories (KDL) at the Oregon Health & Science University specializes in molecular diagnostic testing that may lead to targeted drug therapy options for patients based on the identification of DNA mutations in cancer samples. KDL is a leader in adapting next-generation sequencing technologies to meet the standards of clinical testing.

Screening for mutations in oncogenes and tumor suppressor genes is increasingly important in delivering personalized cancer care. The KDL GeneTrails® Solid Tumor Genotyping Panel delivers information on 37 genes commonly involved in solid tumors. GeneTrails® is especially suitable for squamous cell carcinoma of the lung, head and neck, esophagus, and cervix. It may also be used to screen for rare mutations in breast carcinoma and gliomas.

The OHSU Knight Cancer Institute, led by Dr. Brian Druker, KDL, and the Fanconi Anemia Research Fund have collaborated to make next-generation sequencing available to Fanconi Anemia patients who develop a malignancy. The process for obtaining this important testing is simple.

Test Order Process

The patient's oncologist completes a simple test order form (requisition), which is available through the Fanconi Anemia Research Fund or on the KDL website. This form can be faxed to KDL or shipped with the specimen and a copy of the original pathology report.

Specimen Acquisition

KDL Client Services can facilitate specimen acquisition. This is helpful when the pathology facility and oncology practice are in different locations. To request specimen acquisition services, the patient's oncologist can fax the requisition with a note indicating he or she would like KDL to obtain the specimen.

Specimen Requirements & Shipping

Although testing can be performed on almost any tumor material, KDL recommends DNA extracted from formalin-fixed, paraffin-embedded (FFPE) tumor tissue, which is very stable and can be tested long after the procedure. A paraffin block or 10 unstained sections (4-5 micron) should be packaged and shipped to remain cold, but not frozen, via FedEx overnight express. KDL Client Services can be contacted for shipping kits and FedEx billing account information. KDL accepts specimens from around the world.

Turnaround Time & Specimen Return

Test results are faxed to the patient's oncologist within 14 calendar days of specimen receipt. Paraffin blocks are returned to the pathology facility in a timely manner.

Billing Process

The Fanconi Anemia Research Fund will pay for the portions of the test fee not covered by the patient's insurance plan. If the insurance will not pay for the test, the Fund will cover the full cost of the test. If the insurance pays for the test, but co-insurance or a deductible applies, the Fund will cover these out-of-pocket expenses once the patient sends the bill to the Fund. To request funds, the patient must submit to the Fanconi Anemia Research Fund a copy of their insurance plan's Explanation of Benefits (EOB) and OHSU Patient Bill.

While KDL tests represent a novel approach in cancer diagnostics, there is no guarantee that any submitted tumor specimen will yield a mutation that can be targeted by drugs currently available or being tested in clinical trials. Regardless, screening Fanconi Anemia malignancies using the KDL GeneTrails® Solid Tumor Genotyping Panel will help researchers develop a more complete picture of what mutations are, or are not contributing to the growth and progression of these cancers.

Finally, please note that this testing option does not preclude our work with the National Disease Research Interchange (NDRI). When possible, the Fanconi Anemia Research Fund strongly encourages patients to also donate tissue to NDRI. These donations allow Fanconi Anemia researchers around the world to study the genetics and biology of Fanconi Anemia that, in turn, could lead to better treatments and a cure.

To order the KDL GeneTrails® Solid Tumor Genotyping Panel, please complete the KDL Molecular Oncology – Solid Tumor Test Requisition found on the KDL website (search on key term "Solid Tumor Panel"), and fax or ship with specimen to:

OHSU Knight Diagnostic Laboratories

2525 SW 3rd Avenue, Suite 350 Portland, OR 97201 USA Fax: (855) 535-1329 Web: www.knightdxlabs.com

For additional information or assistance, please contact:

OHSU Knight Diagnostic Laboratories

Phone: (855) 535-1522 Email: KDLClientServices@ohsu.edu

Fanconi Anemia Research Fund, Inc.

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