

## ARUP Launches Two FDA-Approved Companion Diagnostic Tests

ARUP Laboratories recently launched two new FDA-approved companion diagnostic tests for determining Gleevec eligibility in several oncology indications:

- *KIT* D816V by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)
- *PDGFRB* FISH for Gleevec Eligibility in Myelodysplastic Syndrome/Myeloproliferative Disease (MDS/MPD)

These are the first laboratory-developed tests to be approved by the FDA under the humanitarian device exemption (HDE) program. Both tests were developed and validated at ARUP, where they will be offered exclusively.

Gleevec (imatinib mesylate) is one of first targeted therapeutics to be developed. Initially approved for the treatment of Philadelphia-chromosome positive chronic myelogenous leukemia (CML), it has since obtained approval for other cancer indications, including rare diseases such as ASM and MDS/MPD. The *KIT* D816V and *PDGFRB* FISH tests are indicated as aids in the selection of ASM and MDS/MPD patients for whom Gleevec treatment is being considered.

The companion diagnostic tests were developed through the collaborative efforts of a multidisciplinary team led by ARUP's PharmaDx group and consisting of members of R&D, technical operations, compliance and quality systems (CQS), and purchasing.

The PharmaDx group provides customized test development and validation services, as well as clinical research and commercial testing, for numerous pharmaceutical and biotech partners. As a part of the PharmaDx program, ARUP implemented an augmented quality-management system so selected diagnostic tests may receive FDA approval.

Since its inception, the PharmaDx program has entered into several collaborative agreements spanning a variety of common and rare disease areas in addition to oncology, including infectious diseases and genetic disorders. ARUP expects that these first FDA approvals will provide a foundation for many more productive partnerships with members of the pharmaceutical industry.