FDA approves Qiagen CDx for GIST

November 2023—Qiagen announced FDA approval of its Therascreen PDGFRA RGQ PCR kit, a companion diagnostic intended for use to aid clinicians in identifying patients with gastrointestinal stromal tumors (GIST) who may be eligible for treatment with avapritinib (Ayvakit, Blueprint Medicines). Ayvakit is approved in the United States for the treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Qiagen says its kit is the first PDGFRA assay to receive FDA approval as a companion diagnostic.

The Therascreen PDGFRA kit uses genomic DNA extracted from a patient's formalin-fixed, paraffin-embedded tumor tissue. FFPE tumor specimens are processed using the QIAamp DSP DNA FFPE tissue kit for sample preparation and the Rotor-Gene Q MDx instrument for DNA amplification and mutation detection.

Qiagen, 240-686-7700