Melanoma

Background

- An estimated 68,000 people were diagnosed with melanoma in the US in 2010, and approximately 8,700 individuals died of the disease.1
- At least 12% of melanomas are diagnosed at an advanced stage.1
- Historically, treatment options for patients with advanced melanoma have been associated with modest response rates.2
- The recent approval of Zelboraf® (vemurafenib), a targeted BRAF inhibitor, provides a new treatment option with demonstrated clinical effectiveness.2

BRAF Mutations and Melanoma

- BRAF is a protein kinase involved in cell signaling. Specific mutations cause BRAF to become constitutively active, promoting uncontrolled cell growth.2
- BRAF mutations have been found in 40% to 60% of metastatic melanoma, with the V600E mutation accounting for up to 90% of BRAF mutations.2
- The V600E BRAF mutation has not been shown to have any significant association with time to metastasis, although it may be associated with shorter survival after metastasis has occurred.4

BRAF Inhibitors

- Vemurafenib is a drug developed by Roche Pharmaceuticals and Plexxikon that was shown in published preclinical studies to specifically target and inhibit BRAF with the V600E mutation.2
- In a Phase III study presented at ASCO (BRIM3), patients treated with vemurafenib showed greatly improved response rates (48%) compared to patients treated with the standard of care treatment dacarbazine (5%).2,3
- In addition, patients treated with vemurafenib also showed a significant reduction in risk of death (56%) or disease progression (74%) compared to standard therapy.2,3

BRAF Testing

- The cobas® 4800 BRAF V600 Mutation Test is a PCR-based diagnostic test developed by Roche Molecular Systems and validated in the BRIM2 and BRIM3 clinical trials to identify tumors that carry the V600E mutation.2 This test was approved by the FDA as a companion diagnostic for vemurafenib.
- LabCorp’s Center for Molecular Biology and Pathology (CMBP) has significant experience with BRAF mutation testing procedures and was one of the central labs that performed testing to support both the drug and diagnostic assay clinical trials.
BRAF Gene Mutation Assay, Melanoma

CPT Code(s)
83907; 83891; 83898; 83912; 88381

Specimen Requirements:
FFPE block containing greater than or equal to 15% tumor; or a minimum of four pre-cut FFPE unstained slides in 5 μM sections (minimum 2 mm² tumor area) and one H&E reference slide

Special Instructions:
Please provide a copy of the pathology report

REFERENCES