

Clinical Report for Mutation Testing Service

PATIENT AND ORDER INFORMATION

Name: JANUS, MARY	Pathwork Case ID: MOL11-000025
DoB: 11 Aug 1965 Age: 46 Sex: Female	Test Report Date: 22 Dec 2011
Biopsy Site: Lymph Node	Specimen ID: LN-250-4056 -1B
Specimen Collected: 15 Dec 2011	
Specimen Received: 18 Dec 2011	

TREATING PHYSICIAN	SUBMITTING PHYSICIAN
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MUTATION TEST RESULTS

TEST PERFORMED	RESULT (Positive or Not Detected)	MUTATION DETECTED
BRAF – Melanoma	POSITIVE	V600E

INTERPRETATION & REFERENCES

BRAF gene is mutated in approximately 45% of cutaneous melanomas. Some studies suggest that melanomas with the BRAF V600E mutation are more aggressive and less sensitive to chemotherapy. Recent studies have shown drugs in development which inhibit BRAF activity resulting in a reduction in risk of death and in disease progression. Clinical practice guidelines from National Comprehensive Cancer Network state genetic analysis such as BRAF may be useful in assessing patients with metastatic melanoma for targeted therapy (inhibitors of protein kinase BRAF), such as vemurafenib.

Flaherty KT, et al. N Engl J Med 2010;363-809.
 Lin et al. Genes & Cancer May 2010 1 5): 409-420.
 NCCN Guidelines Ver 3.2012 Melanoma

TEST METHOD DESCRIPTION

Prior to DNA extraction, submitted tissues are reviewed by a pathologist and tumor areas are selected for microdissection, if needed, to enrich for tumor cells. All DNA samples are assessed for adequacy by real-time PCR assay utilizing Amplification Refractory Mutation System (ARMS) and Scorpions technology prior to mutation testing. The test can detect the presence of V600E mutation (1799T>A), and will also detect V600E (1799_1800TG>AA) complex and V600D (1799_1800TG>AT) complex, but will not distinguish between them. All the mutations are found in exon 15 of the BRAF oncogene. The level of detection for all mutations is 1% against a background of wild-type genomic DNA.

Estimated Percent Tumor Tissue in Sample Tested: _____% Comment: _____

CLIA Number: 05D1080859
Laboratory Director: Meredith Halks Miller, M.D.

The performance characteristics of this test were determined by Pathwork Diagnostics Laboratory. This test has not been approved by the US Food and Drug Administration. This laboratory is CAP accredited and regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as certified to perform high complexity clinical testing. This assay is used for clinical purposes and the results should be interpreted in reference to other laboratory and clinical findings.