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Patient Name:	Sample Patient	**Ordering Physician:**	Smith, Jane
D.O.B & Sex:	01/01/19XX - Male	**Ordering Facility:**	John Doe Medical Center
Collection Date:	01/05/2015	**Account Number**	00000-00
Received Date:	01/05/2015	**VantagePoint ID #:**	00000
Report Date:	01/07/2015	**VantagePoint Case #:**	MOL12-000000
Specimen Type:	FFPE Tissue	**Medical Record #:**	

BRAF Mutation Analysis by PCR

Results: BRAF Mutation Detected (V600D).

Analytical Results:

Mutation Regions	Result
V600D	**Detected**
V600E	**Not Detected**
V600K	**Not Detected**

Methodology: A pathologist identifies and marks the area of tumor in the collected specimen. This area in particular is targeted to enrich the cell populations before testing. DNA is isolated from this area of the formalin fixed, paraffin embedded tissue (FFPE) using a column based extraction. The ***BRAF*** mutation analysis involves the isolation of DNA from the formalin-fixed paraffin-embedded (FFPE) tissue and is subjected to allele specific real-time PCR which amplifies exon 15 of the ***BRAF*** gene. The assay identifies both the wild type, used as an endogenous control, and the V600E, V600K or V600D ***BRAF*** mutations by utilizing separate probes for wild type and 3 mutant forms of the gene. Utilizing TaqMan® chemistry this assay can detect mutant DNA as low as 1% in a background of wild type DNA. This assay cannot detect variants of ***BRAF*** other than V600E, V600K or V600D.

Intended Use: The ***BRAF*** mutation analysis PCR assay is able to detect the presence of codon 600 mutations in the ***BRAF*** gene in FFPE tissue samples. In cancer patients, 90% of ***BRAF*** mutations found are the V600E variant[1]. BRAF is downstream of EGFR and therefore has an effect on drugs that target EGFR. The presence of a ***BRAF*** mutation is supportive of an expected poor response to anti-EGFR therapy[2, 3].

BRAF mutations have been detected in other disorders such non-Hodgkin lymphoma, colorectal cancer, malignant melanoma, papillary thyroid carcinoma, non-small cell lung carcinoma, and adenocarcinoma of lung[4]. The results of this study should be interpreted in the context of all clinical and laboratory findings. No therapeutic action should be taken based solely upon these results. A "Not Detected" result may indicate the presence of a ***BRAF*** mutation below the detection limit of this assay.

References:

1. Tan YH, Liu Y, Eu KW, Ang PW, Li WQ, Salto-Tellez M, Iacopetta B, Soong R (April 2008). "Detection of BRAF V600E mutation by pyrosequencing". Pathology 40 (3): 295–8.
2. Kohne C, Stroiakovski D, Chang-chien C, et al. (2009). "Predictive biomarkers to improve treatment of metastatic colorectal cancer (mCRC): Outcomes with cetuximab plus FOLFIRI in the CRYSTAL trial." J Clin Oncol. 27 (15S): 4068
3. Flaherty KT, Yasothan U, Kirkpatrick P. (Oct 2011). "Vemurafenib." Nat Rev Drug Discov. 10(11):811-2.
4. NCBI. (March 2012). "BRAF V-Raf Murine Sarcoma Viral Oncogene Homolog B1 [Homo Sapiens]." NCBI. Gene ID: 673.

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Electronically Signed by:

Anand Kunda, M.D.

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END OF REPORT