MAYO CLINIC LABORATORIES

1-800-533-1710

KRASD

Cell-Free DNA KRAS 12, 13, 61,146, Blood

Patient ID	Patient Name		Birth Date	Gender	Age
SA00097461	TESTINGRNV, REPORT		2015-07-06	F	26 M
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00097461	SA00097461	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		20 Sep 2017 09:00			

cfDNA KRAS 12, 13, 61, 146 Blood

Result Summary MCR

POSITIVE

Result MCR

KRAS status: Mutant

Interpretation [1] MCR

KRAS mutations result in constitutive activation of the RAS/MAPK signaling pathway. The most prevalent KRAS mutations in colorectal tumors involve KRAS codons 12, 13, 61, and 146; other mutations in KRAS are rare (<1%).

Current data suggests that the efficacy of EGFR-targeted therapies in colorectal cancer is limited to patients with tumors lacking KRAS mutations. Thus, the detection of a KRAS activating mutation within this specimen suggests that EGFR-targeted therapies may have limited therapeutic value for this patient (2). Note, this assay does not distinguish between the listed (see method) mutations within codons 12, 13, 61, and 146.

This test has been evaluated by our laboratory as an alternative to accessing paraffin embedded tumor specimens for KRAS mutations in patients with colorectal cancer.

REFERENCES:

1. cancer.snager.ac.uk/cancergenome/projects/cosmic/
2. Ann Oncol. 2013 Aug;24(8):2062–7 (PMID 23666916)

ADDITIONAL INFORMATION

Cell-free DNA was isolated from the plasma and evaluated for the presence KRAS G12A, G12C, G12D, G12R, G12S, G12V, G13D, Q61K, Q61L, Q61R, Q61H, and A146 mutations using digital droplet PCR analysis. The limit of detection of this assay for the detection of the KRAS mutations (G12A, G12C, G12D, G12R, G12S, G12V, G13D, Q61K, Q61L, Q61R, Q61H, and A146T) is influenced by the amount of cfDNA in the blood. This is a biological variable that cannot be controlled.

This assay was designed to detect the KRAS G12A, G12C, G12D, G12R, G12S, G12V, G13D, Q61K, Q61L, Q61R, Q61H, and A146 mutations.

This test has been evaluated by our laboratory as an alternative to assessing paraffin embedded tumor specimens for KRAS mutations in patients with advanced colorectal cancer. Those studies revealed that this assay has a high positive predictive value (100% in our study) for the presence of a KRAS mutation in the patient's tumor and high concordance in the specific mutation type observed in the patient's plasma and tumor.

Patients with a negative test result may still harbor a KRAS mutation at codons 12, 13, 61, or 146, and mutation testing of a tissue specimen for KRAS mutations is recommended.

This test has not been clinically validated for use as a tool to monitor response to therapy or for early detection of tumors.

Specimen MCR

WB Whole Blood

Released By MCR

Benjamin R. Kipp, Ph.D.

Received: 20 Sep 2017 15:12 **Reported:** 29 Sep 2017 14:54

Laboratory Notes

[1] This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292