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
SA00097459	TESTINGRNV, REPORT		2016-12-04	F	9 M
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00097459	SA00097459	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		20 Sep 2017 11:00			

cfDNA KRAS 12, 13, 61, 146 Blood

Result Summary MCR

NEGATIVE

Result MCR

Negative

Interpretation [1] MCR

A negative result with this test does not rule out the presence of a KRAS mutation in the patient's tumor. Analysis of the patient's tumor tissue for a KRAS mutation is recommended if the result is needed for clinical decision-making.

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 15:14 **Reported:** 29 Sep 2017 14:53

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