Liquid Biopsy RAS Biomarker Test

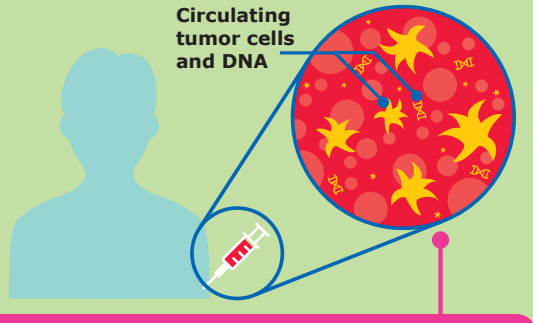
January 2016
Merck Oncology

FACT SHEET

Merck, in separate collaborations with Sysmex Inostics and Biocartis respectively, will introduce two novel liquid biopsy RAS biomarker tests that can enable precision medicine for patients with metastatic colorectal cancer.

What is the liquid biopsy RAS biomarker test?

The liquid biopsy RAS biomarker test is a method for determining the RAS mutation status of a tumor, using a simple blood draw.



Advanced tumors constantly shed genetic material into the bloodstream. A blood draw allows us to gain a 'snapshot' of the tumor status in real-time.[1]

Who should be tested via a liquid biopsy?

Patients who have been diagnosed with **metastatic colorectal cancer**, where the primary tumor has spread to other areas of the body, such as the lungs and/or liver.[1]

Unlike conventional tissue-based testing methods, the liquid biopsy RAS biomarker test removes the need to refer back to archived samples of the patient's tumor, which may have quality issues as a result of the preservation and storage processes.[1,2]

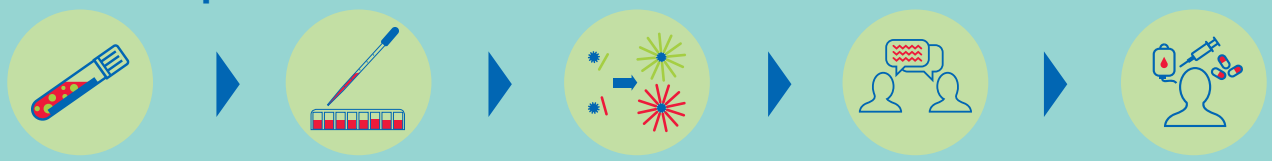
In cases where the tumor is difficult to reach, or the patient cannot tolerate an invasive procedure, the liquid biopsy RAS biomarker test still offers these patients the opportunity for a personalized treatment approach.[1]

When should testing take place?

Patients should receive a RAS biomarker test at the **point of being diagnosed** with metastatic colorectal cancer; tumor DNA fragments are found at relatively high concentrations in the circulation of most patients with metastatic disease.[1]

Knowing the RAS mutation status is critical to selecting the **most appropriate 1st line therapy**[3] and to improving the chances for successful treatment.

What is the process?



1. A blood sample (7–10mL) is taken
2. The tumor DNA is isolated in the lab
3. Highly sensitive PCR-based technologies identify the RAS status of the tumor
4. The physician and patient discuss treatment options based on results
5. Patient starts treatment

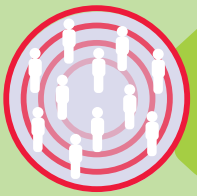
The results of a liquid biopsy RAS biomarker test can be made available to the patient in less than 1 week

Benefits of liquid biopsy testing[1]

- Potential to provide **faster results** than conventional tissue-based biopsies
- **Reduces** the need for **additional procedures** to obtain a sample of the tumor tissue
- The Liquid Biopsy RAS biomarker test provides the RAS mutation status in **real-time**, and can circumvent issues with tumor heterogeneity
- Rapid results enable **optimal 1st line decision making**, allowing efficacious treatment initiation

Why should patients be tested?

The test results enable the physician to select the most appropriate treatment for each mCRC patient[3], thereby **avoiding unnecessary toxicity** for the patient and ultimately **improving chances of overall survival.**[4-7]



The liquid biopsy RAS biomarker test can help expand the delivery of precision medicine to more patients with metastatic colorectal cancer[1]

Biomarker testing is a central part of precision medicine and critical to the delivery of personalized treatment.

Launch of a CE-marked in vitro diagnostic for RAS, using liquid biopsies, by Sysmex Inostics, in collaboration with Merck is expected in 2016 (a 'research use only' kit is already available).

Launch of a CE-marked in vitro diagnostic for RAS, using liquid biopsies, by Biocartis, in collaboration with Merck is expected in 2017.

For media information on request.

Merck KGaA Frankfurter Strasse 250 64293
Darmstadt
media.relations@merckgroup.com

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References

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For more information on the liquid biopsy RAS biomarker test, which has been developed in collaboration with Sysmex Inostics, please visit www.sysmex-inostics.com

For more information on the liquid biopsy RAS biomarker test, which is being developed in collaboration with Biocartis, please visit www.biocartis.com

For more information on biomarker testing and mCRC, please refer to the following additional fact sheets available on www.globalcancernews.com or visit www.targetmycancer.com

- 'Colorectal Cancer'
- 'Metastatic Colorectal Cancer: Treatments and Personalized Medicine'
- 'The Journey of Predictive Biomarkers in Metastatic Colorectal Cancer'

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