Patient, Sample (A00023XX)
Patient MRN: 55555 | DOB: JAN-01-1967 | Gender: Female
Diagnosis: Colorectal adenocarcinoma | Test Number 4

GUARDANTREVEAL
Residual Disease and Recurrence Monitoring

REPORTING

Report Date:	JAN-08-2021
Surgery Date:	DEC-11-2019
Receipt Date:	JAN-02-2021
Collection Date:	JAN-01-2021
Specimen:	Blood
Status:	FINAL

PHYSICIAN
Testing Physician
Account: Sample Account
Address: 123 Test St, Redwood City, CA, 95131, United States
Ph: (555) 123-4567 | Fax: (555) 765-4321
Additional Recipient: N/A

Key ☐ Current Test Results

Guardant Reveal™ Result ⊖ **ctDNA NOT DETECTED**

Timeline

Time Elapsed Since Surgery*	+16 weeks	+29 weeks	+42 weeks	+55 weeks
Guardant Reveal™ Result	⊖ ctDNA Not Detected	⊖ ctDNA Not Detected	⊖ ctDNA Not Detected	⊖ ctDNA Not Detected
Collection Date	APR-01-2020	JUL-01-2020	OCT-01-2020	JAN-01-2021

*Time elapsed since the surgery date is calculated using the date of surgery provided on test requisition form

Interpretation

The absence of ctDNA after treatment has been associated with a lower risk of cancer recurrence; however, it does not eliminate the possibility of recurrence entirely. Clinical correlation is recommended with consideration for repeat Guardant Reveal™ testing when appropriate.

Method and Limitations

Guardant Reveal™ is a next generation sequencing (NGS)-based assay for the detection of cancer-derived circulating tumor DNA (ctDNA) in patients with colorectal cancer (CRC). Cell-free DNA (cfDNA) is extracted from plasma, sequenced, and the data analyzed for the presence of genomic and epigenomic alterations in CRC. Based on this analysis, the Guardant Reveal™ test returns a result of either: *ctDNA detected* or *ctDNA not detected*. In CRC patients, the sensitivity for recurrence detection is 91% with surveillance. Based on a single landmark timepoint (~4 weeks post-therapy) in Stage II/III CRC patients (n=57 patients), Sensitivity is 63%, Specificity is 100%, PPV is 100%, and NPV 82%. The Guardant Reveal™ test is not designed to provide comprehensive genomic profiling results. Certain biological and clinical factors can impact the sensitivity and/or specificity of this test including treatment history, second primary tumor, rate of any residual tumor growth, tumor size, number of somatic alterations in the tumor, vascularization, and/or location.

About the Test

Guardant Reveal™ is a minimal residual disease and recurrence monitoring test for the detection of cancer-derived circulating tumor DNA (ctDNA) in patients with CRC following definitive treatment. The Guardant Reveal™ test was developed and its performance characteristics were determined by Guardant Health, Inc. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test may be used for clinical purposes and should not be regarded as investigational or for research only. Guardant Health's clinical reference laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

Testing performed at: Guardant Health
Laboratory Director: Martina Lefterova, MD PhD | CLIA ID: 05D2070300 | CAP #: 8765297 | 505 Penobscot Drive, Redwood City, CA, 94063, USA