Incredible Hulk

Diagnosis
Lung adenocarcinoma

Accession No.
TL-22-5ACDEHVZ

IHC

AMENDED REPORT

Date of Birth
01/01/1990

Sex
Male

Physician
Test Physician

Institution
Test Institution 123456789

TEMPUS | IHC

DNA Mismatch Repair Panel: MLH1, PMS2, MSH2, MSH6 BIOCARE G168-15, A16-4, FE11, BC/44

Tumor specimen:
Lung, left
Test Institution Pathology Laboratory, S22-123456, A2
Collected 02/06/2021
Received 02/09/2021
Tumor Percentage: 70%

Notes
Any notes related to the report would appear here.

THIS AMENDMENT IS BEING ISSUED TO CORRECT THE SAMPLE INFORMATION

The previous report (TL-22-5ACDEHVY) was signed out by Test Pathologist, MD, PhD on 02/21/2022.

DNA MISMATCH REPAIR PROTEIN EXPRESSION

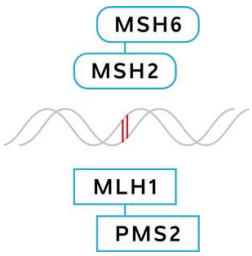
Abnormal

MLH1	Present
PMS2	Absent
MSH2	Absent
MSH6	Absent

Interpretation

The immunohistochemical staining profile is abnormal (MSH2/MSH6 DNA mismatch repair proteins are absent). This indicates that the tumor is DNA mismatch repair deficient (dMMR), and therefore may qualify for pembrolizumab under the tissue agnostic FDA approval[1] and/or dostarlimab-gxly under the FDA approval[2] for dMMR advanced solid tumors. Lynch syndrome should be ruled out with further genetic testing. Genetic counseling and cancer screening appropriate to Lynch syndrome is recommended for the patient and any potentially affected family members.

1. https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm560040.htm
2. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-advanced-solid-tumors test



Mismatch repair (MMR) genes are responsible for correcting errors in DNA by detecting and replacing bases that are wrongly paired (mismatched bases). Mismatch repair deficient cells (those lacking the expression of one or more of the four MMR proteins) usually have many DNA mutations, which may lead to cancer. MMR deficiency is commonly seen in colorectal and endometrial cancer, but it may also be found in other cancers. Discrepancies between MMR and MSI (microsatellite instability) testing results can occur and additional testing and/or counseling in these cases is recommended. (PMID 22086678)

Tempus Disclaimer

This test was developed and its performance characteristics determined by Tempus Labs, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration and should be considered a laboratory developed test (LDT). This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing. All controls were reviewed and show appropriate positive or negative reactivity. This assay has not been validated on decalcified tissue; results from decalcified tissue should be interpreted with caution. In reports containing photographic images, those images should be considered representative and should not be used for diagnostic purposes. These test results and Information contained within the report are current as of the report date.

Any decisions related to patient care and treatment choices should be based on the independent judgment of the treating physician and should take into account all information related to the patient, including without limitation, the patient and family history, direct physical examination and other tests. Tempus is not liable for medical judgment with regards to diagnosis, prognosis or treatment in connection with the test results.

END OF AMENDED REPORT