SAPIENS SG GENETIC DISEASES DIAGNOSTIC CENTER
MEDICAL ANALYSIS REPORT
LABORATORY LICENSE NO: GHDM-SM/34.39/01

Patient Name	:	**Sampling Location**	:
Gender	:	**Test Request Date**	:
Date Of Birth	:	**Sample Collection Date**	:
ID Number	:	**Sample Acceptance Date**	:
Protocol Number	:	**Report Approval Date**	:
Sample Number	:	**Report Release Date/Report Number**	:
Sample Type	:		

Refering Center / Physician :

Reason For Referral :

Genetic Test: *EGFR* exon 18-21 Somatic Mutations

Method: Real-Time PCR Analysis

Platform Used: Bio-Rad CFX96

Kit Used: AmoyDx®EGFR29 Mutations Detection Kit

RESULT

NEGATIVE,

No therapeutic, diagnostic and/or prognostic biomarker was detected within the scope of this test.

RECOMMENDATIONS:

The result should be evaluated together with clinical and other laboratory findings and recommended not for decision-making alone. Please refer to the technical features and restrictions section. Therapy decisions should be planned with a multidisciplinary approach.

TECHNICAL SPECIFICATIONS AND LIMITATIONS:

The mutation details examined within the scope of the test were shown in the table below.

Qualitative detection of 29 Real-Time PCR was performed on the DNA sample isolated from the paraffin block sections sent from the Pathology Department of our hospital, using the IVD certified AmoyDx®EGFR29 Mutations Detection Kit. The kit has been validated for FFPE tumor tissue and plasma/serum DNA. The content of the pathological section affects the results of the genetic test. The kit can only detect listed EGFR mutations. With the two-step PCR amplification procedure patented with ADx-ARMS technology and the fluorescent probe design, the mutation detection sensitivity in genomic DNA is 1%. The method may give false-negative results for

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mutations present in less than 1% of the sample examined. To finalize the test, external laboratory service can be used in accordance with the Regulation on Genetic Diseases Evaluation Centers (For example, 'Düzen Laboratories Group_ISO 15189 Medical Laboratory' is within the scope of Accreditation). Also, wet laboratory and device using stages can be carried out in different in-house locations. Reliable results depend on proper sample handling, transport and storage. The sample obtained from the Formalin fixed-paraffin-embedded (FFPE) containing degraded DNA can negatively affect the success of the test.

This test was performed from the above-mentioned material type. This sample was sent to our center with the record of the patient mentioned above. It is recommended to consider the influencing factors involved in preanalytical errors before the material arrives at our institution. The responsibility of this process does not belong to our institution. The test does not include sample verification. There is the possibility of false positive-negative results within the technical characteristics - limitations of the method used. As with all laboratory tests, clinical findings should be prioritized; If necessary, additional tests/retests should be requested in case of clinical suspicion. As with all laboratory tests, it should not be used alone as a clinical decision-maker. No comment can be made on the adequacy of the analysis, in patients for whom sufficient clinical data is not shared, and additional interpretation/recommendations cannot be made. Genetic counseling should be recommended before and after the test in all genetic screening.

General Information:

The epidermal growth factor receptor (EGFR) plays a central role in tra nsmitting signals that promote cell growth and proliferation . Due to its association with malignancies, EGFR has become the target of an expanding class of anticancer therapies, such as gefitinib , erlotinib and afatinib , which are tyrosine kinase inhibitors (TKIs). The TKIs target the EGFR tyrosine kinase domain. These drugs work best on non small cell lung cancer (NSCLC) patients whose cancer is driven by abnormal EGFR signaling. Lung cancer patients who experienced rapid, durable, complete or par tial responses to TKI therapy have been found to harbor somatic mutations in EGFR gene. NSCLC patients with sensitizing EGFR mutations treated with TKI therapy have shown longer progression free survival and higher response rate, compared with conventional chemotherapy. Resistance to TKI therapy, either in the primary tumor or acquired after TKI treatment , is associated with EGFR T790M mutation. Therefore, assessment of EGFR mutation status facilitates personalized treatment to lung cancer patients.

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References:

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Reason For Referral :

Dr. Ceyhan Sayar, MD
Medical Geneticist

Assoc. Prof. Dr. Kanay YARARBAŞ, MD
Medical Geneticist

Verification Link:

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