

EGFR Mutation Analysis

ONCOLOGY

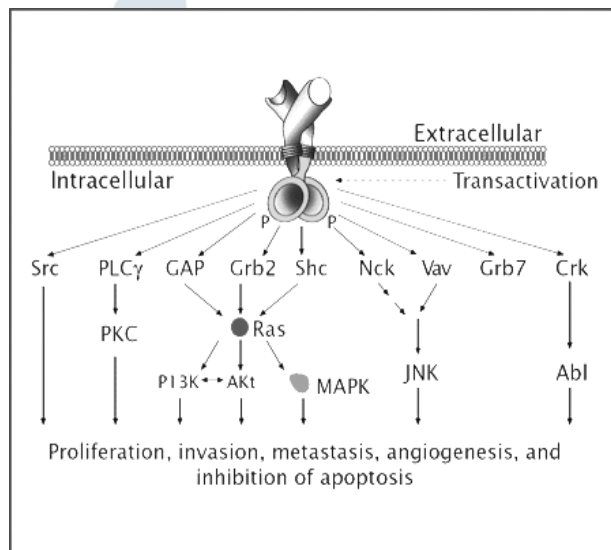
EGFR Mutations and Cancer

Epidermal growth factor receptor (EGFR) is a membrane protein that plays a central role in transmitting signals that promote cell growth and proliferation. Its tyrosine kinase (TK) domain activates several downstream effectors that lead to activation of the Ras-Raf-MAPK pathway. Overexpression and oncogenic mutations that constitutively activate the TK domain of EGFR have been found in various solid tumors. Additionally, excessive activation of EGFR has been shown to be associated with advanced stages of cancer and a poor prognosis.

Testing Procedure

EntroGen's EGFR mutation analysis kit is a real-time polymerase chain reaction (PCR)-based assay that uses mutant-specific primers to identify the presence of EGFR mutations. The testing procedure involves three (3) simple steps, which can be completed in approximately 2 hours from isolation of DNA to test results:

- Isolation of DNA from tumor biopsies, paraffin-embedded sections (FFPE), or fresh frozen tumors
- PCR setup with reagents included in the kit
- Amplification (8 reactions per sample) and detection using a real-time PCR instrument



Specifications

EntroGen's EGFR mutation analysis kit detects the following EGFR mutations:

Exon 18

G719A - 2156G>C
G719S - 2155G>A
G719C - 2155G>T
G719D - 2156G>A

Exon 20

T790M - 2369C>T
S768I - 2303G>T
2307-2308 ins GCCAGCGTG
2319-2320 ins CAC
2310-2311 ins GGT

Exon 19

2235-2249 del 15
2235-2252>AAT del 18
2236-2253 del 18
2237-2251 del 15
2237-2254 del 18
2237-2255>T del 19
2236-2250 del 15
2238-2255 del 18
2238-2248>GC del 11

Exon 19 (continued)

2238-2252>GCA del 15
2233-2247 del 15
2234-2248 del 15
2235-2246 del 12
2235-2248>AATC
2235-2251>AATC
2235-2252>AAT
2236-2248>AGAC
2236-2248>CAAC
2236-2256 del 21
2237_2251>TTC
2237-2252>T
2239-2247 del 9
2239-2256 del 18
2239-2248>C del 10
2239-2258>CA del 20
2240-2251 del 12
2240-2257 del 18
2240-2254 del 15
2239-2251>C del 13
2237-2253>TC
2237-2253>TTCCT

Exon 19 (continued)

2237-2253>TTGCT
2237-2256>TC
2237-2256>TT
2237-2257>TCT
2238-2252 del 15
2239-2252>CA
2239-2253 del 15
2239-2256>CAA
2239-2257>T
2239-2262 del 24
2246-2260 del 15
2248-2273>CC
2252-2275 del 24
2252-2276>A
2252-2277>AT
2253-2276 del 24
2254-2277 del 24

Exon 21

L858R - 2573T>G
L861Q - 2582T>A

* Expansion kit available for E709, L858M, and L861R mutations.

Limitations

EntroGen's *EGFR* mutation analysis kit requires 40-80 nanograms of genomic DNA (5-10 nanograms per reaction) and can detect a mutation load of less than 1%. This sensitivity greatly depends on the extent of fragmentation and quality of the isolated DNA.

Equipment and Materials

EntroGen's *EGFR* mutation analysis kit requires a real-time PCR instrument capable of detecting FAM and VIC fluorescent probes.

This test includes reagents required for the PCR amplification/detection, as well as validated reaction controls. Columns and reagents for DNA isolation are not included.

Intended Use

EntroGen's *EGFR* mutation analysis kits are available for Research Use Only (RUO) in the United States and for In Vitro Diagnostic use (CE-IVD) in Europe.

Ordering Information

Product Name	Cat. No.
EGFR 59 Mutation Detection Kit for Real-Time PCR - 52 Reactions	EGFR-RT52
EGFR Expansion Kit	EGFRX-RT52