

# EGFR RT-PCR

CRM ID : 0000000  
Name : DUMMY  
Sex/Age : NA  
Bill. Loc. : NA  
Ref. By : NA

Sample Type : NA  
Date & Time Collected : DD-MM-YYYY  
Date & Time Received : DD-MM-YYYY  
Date & Time Reported : DD-MM-YYYY

## CLINICAL HISTORY

NA

## Results

G719X	<b>ΔCt-8.608 Detected [Cutoff ΔCt value-09]</b>
Exon 19 deletion	<b>ΔCt-15.53 Not Detected [Cutoff ΔCt value-12]</b>
S768I	<b>ΔCt-16.199 Not Detected [Cutoff ΔCt value-10]</b>
Exon 20 insertion	<b>ΔCt-17.237 Not Detected [Cutoff ΔCt value-13]</b>
L858R	<b>ΔCt-18.549 Not Detected [Cutoff ΔCt value-12]</b>
L861Q	<b>ΔCt-12.776 Not Detected [Cutoff ΔCt value-11]</b>
T790M	<b>ΔCt-13.835 Not Detected [Cutoff ΔCt value-09]</b>
C797S	<b>ΔCt-17.669 Not Detected [Cutoff ΔCt value-11.8]</b>

## CLINICAL SIGNIFICANCE

EGFR Mutation status is useful in identifying patient eligibility for tyrosine kinase inhibitor (TKI) therapy. Specific oncogenic EGFR mutations in pulmonary adenocarcinomas are associated with clinical response or resistance to certain TKIs.

## METHODOLOGY

In the EGFR PCR Kit, mutation-specific reactions use ARMS (amplification-refractory mutation system) and clamp designs to detect and identify the mutations in EGFR gene. DNA extracted from FFPE sample using the deparaffinization and for purification use silica membrane based extraction method.

## RECOMMENDATION

- Please correlate clinically.
- If the above results do not correlate completely with patient phenotype, additional testing like NGS based test is highly advised based on clinician's recommendation
- For about this report, or for assistance in locating nearby genetic counseling services, please contact the Laboratory: geneticcounselors@redcliffelabs.com, or ccsupport@redcliffelabs.com.

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List of mutations covered in the assay				
Exon	Mutation	COSMIC ID*	Base change	
18	G719A	6239	c.2156G>C	
	G719S	6252	c.2155G>A	
	G719C	6253	c.2155G>T	
19	Deletions	26038	c.2233_2247del15	
		13550	c.2235_2248>AATTC	
		6223	c.2235_2249del15	
		6225	c.2236_2250del15	
		18427	c.2237_2257>TCT	
		6220	c.2238_2255del18	
		12367	c.2237_2254del18	
		12384	c.2237_2255>T	
		12678	c.2237_2251del15	
		13551	c.2235_2252>AAT	
		13552	c.2235_2251>AATTC	
		12386	c.2237_2252>T	
		12416	c.2237_2253>TTGCT	
		12728	c.2236_2253del18	
		12422	c.2238_2248>GC	
		12382	c.2239_2248TTAAGAGAAG>C	
		Deletions	6218	c.2239_2247delTTAAGAGAA
			12387	c.2239_2258>CA
			12370	c.2240_2257del18
			12403	c.2239_2256>CAA
			6255	c.2239_2256del18
			12383	c.2239_2251>C
			12419	c.2238_2252>GCA
		6210	c.2240_2251del12	
		23571	c.2238_2252del15	
		12369†	c.2240_2254del15	
		13556	c.2253_2276del24	
		12385	c.2235_2255>AAT	
20	S768I	6241	c.2303G>T	
	Insertions	12376	c.2307_2308insGCCAGCGTG	
		12378	c.2310_2311insGGT	
		12377	c.2319_2320insCAC	
		13428	c.2311_2312insGCGTGGACA	
		13558	c.2309_2310AC>CCAGCGTGGAT	
	T790M	6240	c.2369C>T	
	C797Sa	6493937	c.2389T>A	
	C797Sb	5945664	c.2390G>C	
21	L858R	6224	c.2573T>G	
	L861Q	6213	c.2582T>A	

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**Comment-**

The EGFR mutation status is useful to identifying patient eligibility for tyrosine Kinase inhibitor(TKI) therapy. EGFR gene (exons 18, 19, 20, and 21), G719X (with X = A, S or C; exon 18), T790M (exon 20), C797Sa and C797Sb (exon 20), S768I (exon 20), L858R (exon 21), and L861Q (exon 21).

- G719X in exon 18 detects G719S, G719A, or G719C, but does not distinguish between them
- 28 deletions in exon 19 (detects the presence of any of the 28 deletions but does not distinguish between them)
- S768I, T790M, C797Sa and C797Sb in exon 20 (detects all four mutations, but does not distinguish between C797Sa and C797Sb)
- Five insertions in exon 20 (detects the presence of any of the five insertions, but does not distinguish between them)
- L858R and L861Q in exon 21 (detects the two mutations)

**Limitations**

1. The tissue should contain at least 10% of tumor content for the assay.
2. This assay does not detect mutations other than the mutation listed in the table (List of mutations covered in the assay).
3. The assay does not distinguish between the mutation at the same codon positions as mention in the comment section.

**Disclaimer**

- Test results released pertain to the specimen submitted .
- All test results are dependent on the quality of the sample received by the Laboratory .
- Laboratory investigations are only a tool to facilitate in arriving at a diagnosis and should be clinically correlated by the Referring Physician .
- Certain tests may require further testing at additional cost for derivation of exact value. Kindly submit request within 72 hours post reporting.
- Test results may show inter laboratory variations.
- If Sample collection date is not stated on test requisition form, the current date will be printed by default as the date of collection.
- Test results are not valid for medico legal purposes.



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2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.
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**Disclaimer: Method given in report are only indicative and can be changed depending upon type of machine and kit available at time of testing.  
Not all tests at all locations are under NABL scope. Availability of tests under NABL scope varies from lab to lab.**