

## Overview

### Useful For

Identifying non-small cell lung cancers that may respond to epidermal growth factor receptor-targeted therapies

### Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
SLIRV	Slide Review in MG	No, (Bill Only)	Yes

### Testing Algorithm

When this test is ordered, slide review will always be performed at an additional charge.

### Method Name

Polymerase Chain Reaction (PCR)

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Necessary Information

Pathology report must accompany specimen in order for testing to be performed.

### Specimen Required

#### Preferred:

**Specimen Type:** Tissue, smear stained with Diff Quik, fine needle aspirate (FNA), or pleural fluid in cell blocks

**Container/Tube:** Tissue block

**Collection Instructions:** Submit a formalin-fixed, paraffin-embedded (FFPE) tissue block.

#### Acceptable:

**Specimen Type:** Tissue, smear stained with Diff Quik, fine needle aspirate, or pleural fluid in cell block or cytology blood smear

**Container/Tube:** Slides

**Specimen Volume:** 1 Stained and 5 unstained

#### Collection Instructions:

1. For FFPE tissue, FNA or pleural fluid: Submit 1 slide stained with hematoxylin and eosin and 5 unstained, non-baked slides with

5-10-micron thick sections of the tumor tissue.

2. For cytology blood smear: Submit up to 2 slides stained with Diff Quik

**Specimen Minimum Volume**

Formalin-fixed, paraffin-embedded tissue block or Slides: see Specimen Required

Cytology smear stained with Diff Quik: >1000 cells

**Reject Due To**

Specimens that have been decalcified (all methods)	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	0 hours	
	Refrigerated	0 hours	

**Clinical & Interpretive****Clinical Information**

[Targeted cancer therapies are defined as antibody or small molecule drugs that block the growth and spread of cancer by interfering with specific cell molecules involved in tumor growth and progression. Multiple targeted therapies have been approved by the FDA for treatment of specific cancers. Molecular genetic profiling is often needed to identify targets amenable to targeted therapies and to minimize treatment costs and therapy-associated risks.](#)

Epidermal growth factor receptor (EGFR) protein is activated by the binding of specific ligands, resulting in activation of the RAS/MAPK pathway. Activation of this pathway induces a signaling cascade ultimately leading to cell proliferation. Dysregulation of the RAS/MAPK pathway is a key factor in tumor progression for many solid tumors. Targeted therapies directed to tumors harboring activating mutations within the *EGFR* tyrosine kinase domain (exons 18-21) have demonstrated some success in treating a subset of patients with non-small cell lung cancer.

As a result, the mutation status of *EGFR* can be a useful marker by which patients are selected for EGFR-targeted therapy.

**Reference Values**

An interpretive report will be provided.

**Interpretation**

An interpretive report will be provided.

**Cautions**

A negative (wildtype) result does not rule out the presence of a mutation that may be present but below the limits of detection for this assay (approximately 10%).

A negative (wildtype) result does not rule out the presence of other activating mutations in the EGFR gene.

Not all patients that have activating EGFR mutations detected by this assay respond to EGFR-targeted therapies.

Rare polymorphisms exist that could lead to false-negative or false-positive results.

### Clinical Reference

- Sharma SV, Bell DW, Settleman J, Haber DA: Epidermal growth factor receptor mutations in lung cancer. *Nat Rev Cancer*. 2007 Mar;7(3):169-181. doi: 10.1038/nrc2088
- Gao G, Ren S, Li A, et al: Epidermal growth factor receptor-tyrosine kinase inhibitor therapy is effective as first-line treatment of advanced non-small-cell lung cancer with mutated EGFR: a meta-analysis from six phase III randomized controlled trials. *Int J Cancer*. 2012 Sep 1;131(5):E822-829. doi: 10.1002/ijc.27396
- Mok TS: Personalized medicine in lung cancer: what we need to know. *Nat Rev Clin Oncol*. 2011 Aug 23;8(11):661-668. doi: 10.1038/nrclinonc.2011.126
- Lee CS, Sharma S, Miao E, Mensah C, Sullivan K, Seetharamu N: A comprehensive review of contemporary literature for epidermal growth factor receptor tyrosine kinase inhibitors in non-small cell lung cancer and their toxicity. *Lung Cancer (Auckl)* 2020 Oct 7;11:73-103. doi: 10.2147/LCTT.S258444

### Performance

### Method Description

All ordered specimens will undergo *EGFR* testing. [The EGFR test is a qualitative polymerase chain reaction \(PCR\)-based assay employing fluorescently labeled probes that are used to detect exon 18 \(G719A/C/S\), exon 21 \(L858R, L861Q\), exon 20 \(T790M, S768I\) mutations, exon 19 deletions and exon 20 insertions of the EGFR gene.](#)

Exon	Mutation	Protein change	Nucleotide change	Genotype
18	G719A	p.Gly719Ala	c.2156G>C	G719A/C/S
	G719C	p.Gly719Cys	c.2155G>T	
	G719C	p.Gly719Cys(2)	c.2154_2155delinsTT	
	G719S	p.Gly719Ser	c.2155G>A	
19	Deletion 9	p.Leu747_Ala750delinsPro	c.2238_2248delinsGC	Exon 19 deletion
			c.2239_2248delinsC	
		p.Leu747_Ala750delinsSer	c.2240_2248del	
		p.Leu747_Glu749del	c.2239_2247del	
	Deletion 12	p.Leu747_Thr751delinsPro	c.2239_2251delinsC	
		p.Leu747_Thr751delinsSer	c.2240_2251del	
	Deletion 15	p.Glu746_Ala750del	c.2235_2249del	
			c.2236_2250del	
		p.Leu747_Thr751del	c.2239_2253del	
			c.2240_2254del	
			c.2238_2252del	
	p.Glu746_Thr751delinsAla	c.2237_2251del		

	p.Glu746_Thr751delinslle	c.2235_2252delinsAAT	
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A pathology review and macro dissection to enrich for tumor cells is performed prior to slide scraping

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available

5 days

### Specimen Retention Time

Unused portions of blocks will be returned. Unused slides are stored indefinitely.

### Performing Laboratory Location

Rochester

## Fees & Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

### CPT Code Information

81235-EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)

88381-Microdissection, manual

### LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
EGFRS	EGFR Gene, Mutation Analysis, Tumor	21665-5

Result ID	Test Result Name	Result LOINC® Value
616123	Result Summary	50397-9

616124	Result	21665-5
616125	Interpretation	69047-9
616126	Specimen	31208-2
616127	Source	31208-2
616128	Tissue ID	80398-1
616129	Released By	18771-6