

The **Idylla™ EGFR Mutation Assay**, performed on the Biocartis Idylla™ System, is a molecular assay for the qualitative detection of **exon 18** (G719A/S/C), **exon 21** (L858R, L861Q), **exon 20** (T790M, S768I) mutations, **exon 19 deletions** and **exon 20 insertions** of the *EGFR* gene. The Idylla™ EGFR Mutation Assay, from sample-to-result, starts with formalin-fixed, paraffin-embedded (FFPE) human tissue from metastatic non-small cell lung cancers to liberate DNA for subsequent real-time PCR amplification and detection.



Features

| EGFR mutation detection | | |
|-------------------------|-------|---|
| Exon 18 | G719A | (c.2156G>C) |
| | G719S | (c.2155G>A) |
| | G719C | (c.2155G>T; c.2154_2155delinsTT) |
| Del9 | | c.2238_2248delinsGC |
| | | c.2239_2248delinsC |
| | | c.2240_2248del c.2239_2247del |
| Del12 | | c.2239_2251delinsC |
| | | c.2240_2251del |
| | | c.2235_2249del c.2236_2250del c.2239_2253del c.2240_2254del |
| Exon 19 | Del15 | c.2238_2252del c.2237_2251del c.2235_2252delinsAAT c.2237_2252delinsT c.2234_2248del c.2236_2253delinsCTA c.2237_2253delinsTA c.2237_2253delinsTC c.2235_2251delinsAG c.2236_2253delinsCAA c.2230_2249delinsGTCAA |

| | | |
|--|---|--------------------------------|
| Exon 19 | Del18 | c.2240_2257del |
| | | c.2237_2255delinsT |
| | | c.2239_2256del |
| | | c.2236_2253del |
| | | c.2239_2258delinsCA |
| | | c.2237_2254del |
| | | c.2238_2255del |
| | | c.2237_2257delinsTCT |
| | | c.2236_2255delinsAT |
| | | c.2236_2256delinsATC |
| c.2237_2256delinsTT | | |
| c.2237_2256delinsTC | | |
| c.2235_2255delinsGGT | | |
| Del21 | (c.2238_2258del; c.2236_2256del) | |
| Del24 | (c.2253_2276del) | |
| Exon 20 | T790M | (c.2369C>T) |
| | S768I | (c.2303G>T) |
| | insG | (c.2310_2311insGGT) |
| | insASV9 | (c.2308_2309insGCCAGCGTG) |
| | insASV11 | (c.2308_2311delinsCCAGCGTGGAT) |
| | insSVD | (c.2311_2312insGCGTGGACA) |
| Exon 21 | L858R | c.2573T>G |
| | | c.2573_2574delinsGT |
| | L861Q | c.2573_2574delinsGA |
| EGFR Total (acting as Sample Processing Control) | | |
| Specimen requirements | | |
| Sample Type | 1 x 5µm FFPE tissue section | |
| Neoplastic cells | ≥10%, if less macrodissection is required | |
| Total turnaround time | | |
| Time | 150 minutes | |

Idylla™ EGFR Posters & Publications

- Tronccone G. et al. EGFR mutation detection on lung cancer cytological specimens by the rapid and fully integrated Idylla™ molecular diagnostics system. Poster ASCO 2016.
- De Luca C. et al. EGFR mutation detection on lung cancer cytological specimens by the novel fully automated PCR-based Idylla EGFR Mutation Assay. J Clin Pathol 2016.

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