EGFR CE IVD

# TECHNICAL SHEET IDYLLA™ EGFR MUTATION TEST

The **Idylla™ EGFR Mutation Test**, performed on the Biocartis Idylla™ System, is an *in vitro* diagnostic test for the qualitative detection of **exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions** in the *EGFR* oncogene. The Idylla™ EGFR Mutation Test, from **sample-to-result**, starts with formalin-fixed, paraffin-embedded (FFPE) human tissue from non-small cell lung cancer (NSCLC) to liberate DNA for subsequent real-time PCR amplification and detection.

## FEATURES

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

| | | |
|---|---|---|
| **Exon 19** | Del18 | c.2240_2257del<br>c.2237_2255delinsT<br>c.2239_2256del<br>c.2236_2253del<br>c.2239_2258delinsCA<br>c.2237_2254del<br>c.2238_2255del<br>c.2237_2257delinsTCT<br>c.2236_2255delinsAT<br>c.2236_2256delinsATC<br>c.2237_2256delinsTT<br>c.2237_2256delinsTC<br>c.2235_2255delinsGGT |
| | Del21 | c.2238_2258del<br>c.2236_2256del |
| | Del24 | c.2253_2276del |
| **Exon 20** | T790M | c.2369C>T |
| | S768I | c.2303G>T |
| | insG<br>insASV9<br>insASV11<br>insSVD<br>insH | c.2310_2311insGGT<br>c.2308_2309insGCCAGCGTG<br>c.2308_2311delinsCCAGCGTGGAT<br>c.2311_2312insGCGTGGACA<br>c.2319_2320insCAC |
| **Exon 21** | L858R | c.2573T>G<br>c.2573_2574delinsGT<br>c.2573_2574delinsGA |
| | L861Q | c.2582T>A |

EGFR Total (acting as Sample Processing Control)

| **Specimen requirements** | |
|---|---|
| Sample Type | 1 x 5 µm FFPE tissue section |
| Neoplastic cells | ≥10%, if less macrodissection is required |
| **Performance** | |
| Analytical Sensitivity | LOD ≤ 5% for most prevalent *EGFR* mutations |
| Between Laboratory Reproducibility (600 results at 3 sites) | 100% agreement for 10% EGFR G719S<br>100% agreement for 10% EGFR Del15<br>100% agreement for 10% EGFR T790M<br>100% agreement for 10% EGFR L858R<br>100% agreement for 10% EGFR L861Q |

| | |
|---|---|
| | 100% agreement for 10% EGFR G719S |
| Between Lot | 100% agreement for 10% EGFR Del15 |
| Reproducibility | 100% agreement for 10% EGFR T790M |
| (300 results on 3 lots) | 100% agreement for 10% EGFR L858R |
| | 100% agreement for 10% EGFR L861Q |

| **Total turnaround time** | |
|---|---|
| Time | 150 minutes |

## ACCURACY - CLINICAL PERFORMANCE EVALUATION

95.9% overall agreement for the *EGFR* gene was obtained during the clinical performance evaluation comparing Idylla™ with Therascreen (Qiagen), a PCR-based reference method.

**95.9% overall concordance**

| Therascreen / Idylla™ | DelEx19 | DelEx19, T790M | L858R | L867Q | G719X | G719X, S768I | L858R, T790M | InsEx20 | No mutation detected | Totals without invalids | Invalids | Totals |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DelEx19 | 18 | | – | – | – | – | – | – | – | 18 | 8 | 26 |
| InsEx20 | – | – | – | – | – | – | – | – | – | – | 1 | 1 |
| DelEx19,T790M | – | 4 | | – | – | – | – | – | – | 4 | – | 4 |
| L858R | – | – | 20 | | – | – | 1 | – | – | 21 | 2 | 23 |
| L861Q | – | – | – | 2 | – | – | – | – | – | 2 | – | 2 |
| G719X | – | – | – | – | 1 | – | – | – | – | 1 | – | 1 |
| G719X,S768I | – | – | – | – | – | 1 | – | – | – | 1 | – | 1 |
| L858R,T790M | – | – | – | – | – | – | 1 | – | – | 1 | – | 1 |
| T790M | – | 1 | – | – | – | – | – | – | 1 | 2 | 2 | 4 |
| DelEx19, S768I | 1 | – | – | – | – | – | – | – | – | 1 | – | 1 |
| S768I | – | – | – | – | – | – | – | – | – | 0 | 1 | 1 |
| No mutation detected | – | 1 | 2 | – | 1 | – | – | 1 | 66 | 71 | 30 | 101 |
| Totals without invalids | 19 | 6 | 22 | 2 | 2 | 1 | 2 | 1 | 67 | **122** | – | / |
| Invalids | – | 1 | – | – | – | – | – | – | 2 | – | 10 | 13 |
| Totals | 19 | 7 | 22 | 2 | 2 | 1 | 2 | 1 | 69 | / | 54 | **179** |

After discordant analysis by NGS and/or ddPCR (excluding invalids) the **overall concordance** was **97.9%**.

EGFR CE IVD

## IDYLLA™ EGFR POSTERS & PUBLICATIONS

- Troncone 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.
- Reijans M. et al. Fully automated and sensitive detection of EGFR exon 18, 19, 20 and 21 mutational status in less than 2.5 hours from a single FFPE slice. Poster ESMO 2016.
- Laetitia Lambros et al. Evaluation of a fast and fully automated platform to diagnose EGFR and KRAS mutations in formalin-fixed and paraffin-embedded non-small cell lung cancer samples in less than one day. J Clin Pathol 2017.
- Mirko Marabese et al. Comparison of technologies for EGFR analysis within a subset of a randomized clinical trial. Poster AACR 2017.
- Vincent Thomas De Montpréville et al. EGFR and KRAS molecular genotyping for pulmonary carcinomas: Feasibility of a simple and rapid technique implementable in any department of pathology. Pathology Research and Practice 2017. http://www.sciencedirectcom/science/article/pii/S0344033817302947
- Marius Ilie et al. Optimization of EGFR mutation testing by the fully-automated qPCR-based Idylla on whole slide and biopsy tumor tissue of non-small cell lung cancer. Abstract e20632, 2017 ASCO Annual Meeting. http://abstracts.asco.org/199AbstView_199_191634.html




GL.FL009.EN.R2.10/2018