

BECAUSE  
TIME MATTERS

# IDYLLA™ EGFR MUTATION ASSAY



THINK IDYLLA™  
BECAUSE TIME MATTERS

Idylla™ EGFR Mutation Assay is for Research Use Only (RUO), not for use in diagnostic procedures.

# IDYLLA™ EGFR MUTATION ASSAY

## FAST & RELIABLE INFORMATION ON EGFR MUTATION STATUS



Comprehensive assay covering 46 mutations in EGFR exons 18, 19, 20, 21



Directly from 1 FFPE tissue section



145 minute assay turnaround time



Highly sensitive & standardized platform



< 2 minutes hands-on time



Fully automated solution - suitable for any lab

## IDYLLA™ EGFR MUTATION ASSAY TISSUE SPECIMEN REQUIREMENTS

One of the biggest challenges in oncology biomarker testing is the ability to obtain samples of sufficient size and quality. The Idylla™ assay is designed to work with a minimal amount of sample:

- 1 x 5  $\mu\text{m}$  FFPE tissue section
- Neoplastic cell content  $\geq 10\%$   
*- If < 10%, macrodissection needed*



# IDYLLA™ EGFR MUTATION ASSAY EXCELLENT PERFORMANCE



The Idylla™ EGFR Mutation Assay shows high concordance to reference methods across a variety of different sample types

| STUDY   | # SAMPLES | REFERENCE METHOD | SAMPLE   | CONCORDANCE |
|---|-----------|------------------|--|-------------|
| Arcila et al. (2020)<br>MSKCC                                   | 222       | NGS              | FFPE tissue, DNA, cytological samples (cell pellets, smears), touch preps, NGS libraries | 96.2%       |
| Huang et al. (2019)<br>Medical College of Wisconsin             | 47        | NGS              | FFPE tissue  | 96.2%       |
| Al-Turkmani et al. (2018)<br>Dartmouth-Hitchcock Medical Center | 8         | NGS              | Fresh touch preps  | 100%        |
| Al-Turkmani et al. (2018)<br>Dartmouth-Hitchcock Medical Center | 34        | NGS              | FFPE tissue  | 100%        |



The Idylla™ EGFR Mutation Assay significantly reduces the time until the biomarker test result becomes available

| STUDY   | REFERENCE METHOD                        | TIME TO RESULT VS. REFERENCE METHOD   |
|---|---|---|
| Arcila et al. (2020)<br>MSKCC                               | NGS                                     | Average time to result of 2 days vs. 2-4 weeks  |
| Huang et al. (2019)<br>Medical College of Wisconsin         | NGS                                     | The turnaround time was shortened by 7 days on average  |
| Dagogo-Jack et al. (2023)<br>Massachusetts General Hospital | Routine workflows not including Idylla™ | Median time between biopsy and EGFR results was 1 days vs. 7 days<br>Median time to treatment initiation was 5 days vs. 23 days |



The Idylla™ EGFR Mutation Assay analyzes samples which do not have sufficient quantity or quality for NGS testing or have failed on previous NGS testing platforms

| STUDY   | REFERENCE METHOD | VALID RESULTS ON SAMPLES WITH INSUFFICIENT MATERIAL FOR NGS |
|---|------------------|---|
| Huang et al. (2019)<br>Medical College of Wisconsin             | NGS              | 100% (n=25)   |
| Al-Turkmani et al. (2020)<br>Dartmouth-Hitchcock Medical Center | NGS              | 100% (n=6)  |

# IDYLLA™ EGFR MUTATION ASSAY FOR SPEED AND SIMPLICITY BECAUSE TIME MATTERS

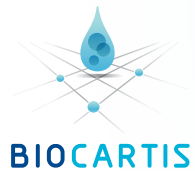


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