

TECHNICAL SHEET IDYLLA™ GeneFusion ASSAY

The Idylla™ GeneFusion Assay is an assay for the **qualitative detection** of defined **gene fusions** for **ALK, ROS1, RET**, as well as **MET Exon 14 skipping** and **expression imbalance** for **ALK, ROS1, RET** and **NTRK1/2/3**. The Idylla™ GeneFusion Assay has been optimized for the use of formalin-fixed, paraffin-embedded (FFPE) tumor tissue sections. The Idylla™ GeneFusion Assay uses the Biocartis Idylla™ Platform and covers the entire process from **sample-to-result**, including fully integrated sample preparation, liberation of nucleic acids, reverse transcription of mRNA, real-time PCR amplification and detection, data analysis, and result reporting as applicable.

The Idylla™ GeneFusion Assay covers a panel of defined gene fusion variants for ALK, ROS1 and RET based on their occurrence in NSCLC, although detection of these gene fusion variants can be applied pan-cancer.

FEATURES

| Fusion specific detection | | |
|---------------------------|---------------------------|----------------------------|
| ALK fusions (17) | EML4-ALK | EML4 exon 2; ALK exon 20 |
| | | EML4 exon 6a; ALK exon 20 |
| | | EML4 exon 6b; ALK exon 20 |
| | | EML4 exon 13; ALK exon 20 |
| | | EML4 exon 15; ALK exon 20 |
| | | EML4 exon 17; ALK exon 20 |
| | | EML4 exon 18; ALK exon 20 |
| | EML4 exon 20; ALK exon 20 | |
| | KIF5B-ALK | KIF5B exon 15; ALK exon 20 |
| | | KIF5B exon 17; ALK exon 20 |
| | | KIF5B exon 24; ALK exon 20 |
| | HIP1-ALK | HIP1 exon 28; ALK exon 20 |
| | | HIP1 exon 30; ALK exon 20 |
| | KLC1-ALK | KLC1 exon 9; ALK exon 20 |
| | TPR-ALK | TPR exon 15; ALK exon 20 |
| | TFG-ALK | TFG exon 4; ALK exon 20 |
| | | TFG exon 6; ALK exon 20 |

| Fusion specific detection - continued | | |
|---------------------------------------|---|-------------------------------|
| ROS1 fusions (13) | CD74-ROS1 | CD74 exon 6; ROS1 exon 32 |
| | | CD74 exon 6; ROS1 exon 34 |
| | SDC4-ROS1 | SDC4 exon 2; ROS1 exon 32 |
| | | SDC4 exon 4; ROS1 exon 32 |
| | SLC34A2-ROS1 | SDC4 exon 4; ROS1 exon 34 |
| | | SLC34A2 exon 4; ROS1 exon 32 |
| | | SLC34A2 exon 13; ROS1 exon 32 |
| | EZR-ROS1 | EZR exon 10; ROS1 exon 34 |
| | TPM3-ROS1 | TPM3 exon 8; ROS1 exon 35 |
| | GOPC-ROS1 | GOPC exon 4; ROS1 exon 36 |
| GOPC exon 8; ROS1 exon 35 | | |
| LRIG3-ROS1 | LRIG3 exon 16; ROS1 exon 35 | |
| RET fusions (7) | KIF5B-RET | KIF5B exon 15; RET exon 11 |
| | | KIF5B exon 15; RET exon 12 |
| | | KIF5B exon 16; RET exon 12 |
| | | KIF5B exon 22; RET exon 12 |
| | | KIF5B exon 23; RET exon 12 |
| | KIF5B exon 24; RET exon 11 | |
| CCDC6-RET | CCDC6 exon 1; RET exon 12 | |
| MET Exon 14 skipping | MET Exon 14 skipping transcript detection at the exon 13-exon 15 junction | |

Expression imbalance detection

- ALK Expression imbalance
- ROS1 Expression imbalance
- RET Expression imbalance
- NRTK1 Expression imbalance
- NRTK2 Expression imbalance
- NRTK3 Expression imbalance

Measures if expression imbalance is present between the 5' PCR and 3' PCR of the kinase gene. Expression imbalance shows kinase domain expression, and is indicative for the presence of a fusion.

Internal GeneFusion controls

| | |
|-------------------------|---|
| RNA Housekeeping gene 1 | ERCC3 |
| RNA Housekeeping gene 2 | TMUB2 |
| RNA MET Wild-type | Detection of the wild-type MET isoform mRNA containing the MET Exon 14 sequence |
| DNA control | KIF11 |

Minimum specimen requirements

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|------------------|--|
| Sample type | 1 x 5 µm FFPE tissue section if tissue area ≥ 20 mm ² 3 x 5 µm FFPE tissue sections if tissue area < 20 mm ² |
| Neoplastic cells | $\geq 10\%$, if less macro-dissection is required |

Total turnaround time

| | |
|------|---------------------|
| Time | Approx. 180 minutes |
|------|---------------------|

Catalog number

| | |
|--------------------------|---------|
| Idylla™ GeneFusion Assay | A0121/6 |
|--------------------------|---------|



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