

Modaplex FGFR

C O P Y N U M B E R

V A R I A T I O N

G E N E E X P R E S S I O N

G E N E F U S I O N

M U T A T I O N

THE FGFR CHALLENGE

PROVIDING MEANINGFUL DATA IN A COMPLEX ENVIRONMENT

The fibroblast growth factor receptor family consists of four signaling tyrosine kinase receptors (FGFR1–FGFR4) that interact with eighteen secreted FGF proteins⁽¹⁾. They are expressed in nearly all tissues and play essential roles in a wide range of physiological mechanisms, like embryonic development, cell proliferation, differentiation, migration, angiogenesis, wound healing, inflammation and cell survival⁽²⁾.

Dysregulation of FGFR signaling can occur through a variety of molecular mechanisms including chromosomal translocation, mutations and gene amplification, which lead to receptor and ligand over-expression. Abnormalities of FGFs and FGFRs have been observed in many cancer types such as breast, bladder, head and neck, colon, lung and haematological malignancies; and reported to have different meanings according to tumor type^(3, 4).

The complexity of the FGFR signaling and signaling aberrations paves the way for new approaches for therapeutic strategies in human cancer⁽⁵⁾. Targeted therapies such as non-selective, selective tyrosine kinase inhibitors, monoclonal anti-FGFR antibodies and small molecules are continuously evaluated through diverse clinical trials considering FGFs and FGFRs abnormalities^(2, 6).

REFERENCES

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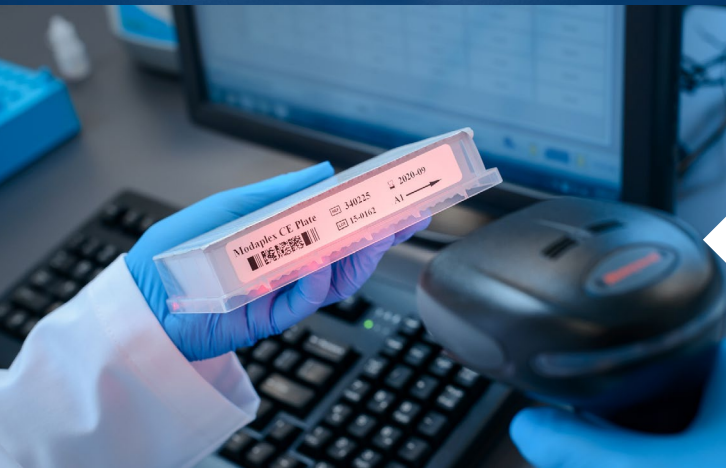
DECIPHER COMPLEXITY IN FGFR

ADDRESSING THE CHALLENGE
WITH MULTI - ANALYTE FGFR ASSAYS



MERGE COMPREHENSIVE FGFR ANALYSIS WITH FLEXIBLE APPLICATION

- Analysis of FGFR1, FGFR2, FGFR3, FGFR4, FGF3, FGF4 and FGF19 genes
- Simultaneous detection of copy number variations, gene fusions, mutations and gene expressions
- Up to 44 parameters tested per sample



PROVIDE TRUSTWORTHY RESULTS

- Developed under ISO 9001:2015 and FDA's Design Control Guidance
- Comprises a comprehensive control concept
- Tested with archived FFPE material



STREAMLINE LABORATORY OPERATIONS

- Efficient workflow through automation
- Rapid result interpretation with Biotype's Moda-RA (Modaplex Result Analyzer) software
- Cost effective detection of all relevant genetic FGFR variations

MODAPLEX FGFR ANALYSIS KITS

MERGE COMPREHENSIVE FGFR ANALYSIS WITH FLEXIBLE APPLICATION

To help laboratories addressing all molecular testing requirements in FGFR trials, Biotype developed a Modaplex FGFR panel. It comprises 4 FGFR assays to analyze FGFR 1, FGFR 2, FGFR 3, FGFR 4, FGF 3, FGF 4, FGF 19 relevant genetic alterations.

Together with Modaplex technology, tests can be set up individually or simultaneously in combination with other FGFR tests.

COMPREHENSIVE TARGETED FGFR PANEL

FGFR CNV



FGFR1
FGFR2
FGFR3
11q

FGFR Gene Fusion



BAG4:FGFR1 (e2:e6)
BAG4:FGFR1 (e1:e8)
FGFR2:CIT (e17:e23)
FGFR3:TACC3 (e17:e4)
FGFR3:TACC3 (e17:e8)
FGFR3:TACC3 (e17:e10)
FGFR3:TACC3 (e17:e11)
FGFR3:TACC3 (e17:e4intra)

FGFR Mutation



FGFR1 (2 mutations)
FGFR2 (14 mutations)
FGFR3 (9 mutations)

FGFR Gene Expression



FGFR1
FGFR2
FGFR3
FGFR4
FGF3
FGF4
FGF19

PROVIDE TRUSTWORTHY RESULTS

Modaplex FGFR Analysis Kits support laboratories to provide results with confidence. For this purpose, the kits have been designed and developed according to customer requirements resulting into assays which are robust, safe and flexible to use at the same time.



ROBUST TEST PERFORMANCE

In order to provide safe products with a robust test performance, Modaplex FGFR Analysis Kits have been developed under ISO 9001:2015 and FDA's Design Control Guidance for medical device manufacturers.



RELIABLE RESULTS

Each FGFR assay is endowed with a comprehensive control concept. It comprises internal controls like migration size standard and internal controls as well as external positive and negative controls. In addition, the result interpretation software Moda-RA assists laboratories with a user-friendly interface. It enables the recognition of incorrect runs immediately and prevents wrong manual result interpretation.

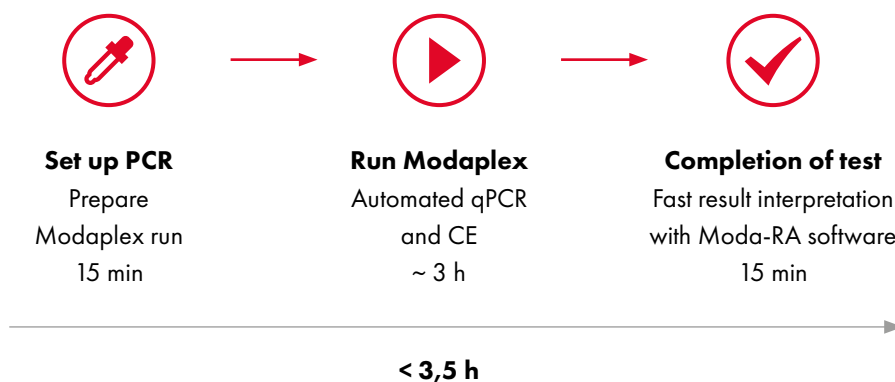


TAILORED TO LABORATORY REQUIREMENTS

FFPE archival material has been tested with the Modaplex FGFR Analysis Kits in order to address the limitations of poor quantity and quality DNA and RNA in a formalin-fixed, paraffin-embedded environment.

MODAPLEX FGFR ANALYSIS KITS

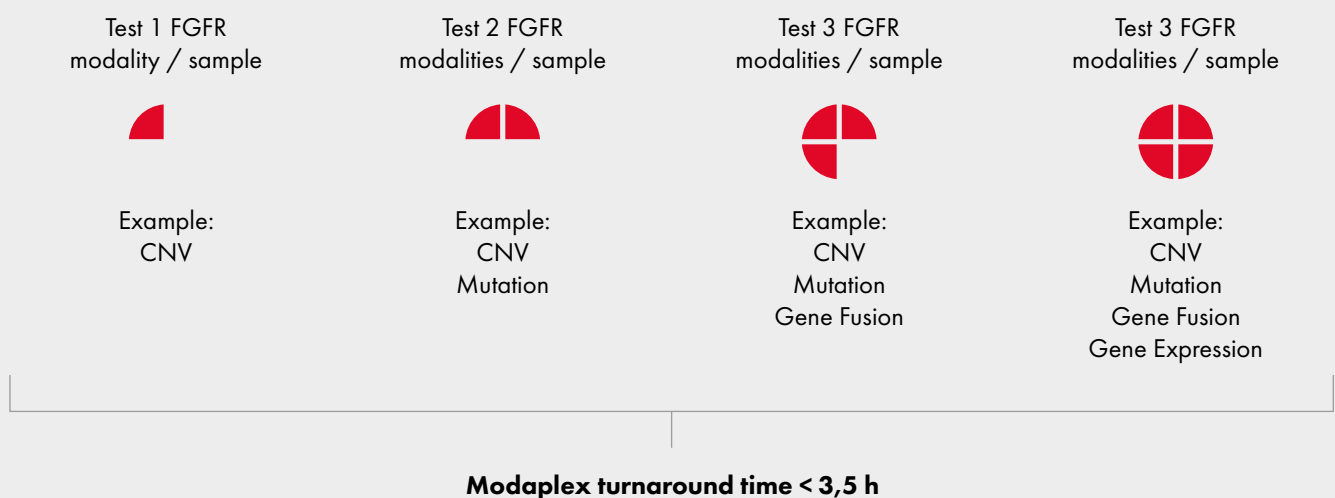
STREAMLINE LABORATORY OPERATIONS



The Modaplex workflow comprises three steps, which are identical for all FGFR tests.

A single user can complete a Modaplex FGFR run (up to 44 FGFR tests, inclusive controls) in less than 4 hours with 0,3 hours total hands-on time.

ADDRESSING COMPLEX FGFR TESTING REQUIREMENTS WITH A COMMON PROTOCOL



The universal PCR amplification profile of the Modaplex instrument allows the simultaneous analysis of various molecular alterations. Modaplex FGFR tests can be therefore combined individually according to the testing requirements and performed in a single run in less than 3,5 hours. For all combination of tests, the workflow remains as simple as setting up a single qPCR.

MODAPLEX TECHNOLOGY

ENHANCE LABORATORY EFFICIENCY WITH
MULTIPLEX, MULTIMODAL ANALYSIS



The Modaplex FGFR Analysis Kits are performed with the Modaplex instrument, a multiplex PCR benchtop system. It combines qPCR with capillary electrophoresis (CE) in an automated process and allows to detect, differentiate and quantify up to 50 DNA and RNA targets in a single well and run. With a 48-capillary cartridge, the Modaplex enables the simultaneous analysis of various samples for FGFR / FGF copy number variations, gene fusions, mutations and gene expressions.

ADDITIONAL MODAPLEX AND MODAPLEX FGFR KIT ADVANTAGES

48

Capillaries enabling high flexibility by scalable sample processing. Setup of 1 Modaplex run with up to 44 samples tested for 1 FGFR/FGF alteration (incl. controls) or set up of up to 9 samples tested for all 4 different alterations (incl. controls).

20

Minutes or less hands-on-time are required only for comprehensive FGFR testing.

4

Genetic FGFR variations can be analyzed simultaneously in a single run.

1

Modaplex run to decipher complexity in FGFR.

ORDER INFORMATION

Product	Cat. no.	Application
Modaplex FGFR CNV Analysis Kit	BTI-C001-A1-2-0050	RUO
Modaplex FGFR Gene Fusion Analysis Kit	BTI-C001-B1-2-0050	RUO
Modaplex FGFR Mutation Analysis Kit*	BTI-C001-C1-2-0050	RUO
Modaplex FGFR Gene Expression Analysis Kit	BTI-C001-D1-2-0050	RUO
Modaplex instrument	00-04901-0001	

*This product is available upon request

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