

# Personalisierte Therapie durch umfassendes genomisches Tumorprofiling

Das Verständnis von Krebs entwickelt sich stetig weiter – unsere Diagnostik auch **FoundationOne®CDx bietet eine umfassende Analyse des Tumorgenoms, welche eine Vielzahl von klinisch relevanten Mutationen abdeckt**<sup>1-7</sup>

## Wesentliche Unterschiede zu FoundationOne®

## Gemeinsamkeiten mit FoundationOne®



### Companion Diagnostics (CDx)

Umfangreiche analytische und klinische Validierung anhand von 6 300 Proben<sup>8,9</sup>



### DNA-Sequenzierung mit NGS-Technologie

Abdeckung einer Vielzahl von klinisch relevanten Mutationen.<sup>1-7</sup> Messung von TMB- und MSI-Status mit hoher Präzision<sup>1</sup>



### Umfassendes Tumorprofiling

Analyse genetischer Alterationen von 324 bekannten tumorassoziierten Genen<sup>1</sup>



### Strukturierter, ausführlicher Bericht

Umfasst von Swissmedic zugelassene Therapieoptionen sowie relevante Literatur und mögliche klinische Studien

## Treffen Sie die bestmögliche Entscheidung für Ihre Patienten

Die regelmässige Aktualisierung der analysierten Gene ermöglicht die Abdeckung neuester klinisch relevanter Mutationen.<sup>10</sup> Nutzen Sie FoundationOne®CDx, um Ihre Patienten für eine zielgerichtete Therapie zu qualifizieren.<sup>1</sup>

NGS = Next-Generation-Sequencing; TMB = Tumormutationslast; MSI = Mikrosatelliteninstabilität

#### Referenzen:

**1** FoundationOne®CDx: Technical Information Version 02. <https://www.rochefoundationmedicine.com/f1cdxtech> (Letzter Zugriff: 04.12.2018). **2** Frampton GM et al. Development and validation of a clinical cancer genomic profiling test based on massively parallel DNA sequencing. *Nat Biotechnol* 2013;31(11):1023-1031. **3** Suh JH et al. Comprehensive genomic profiling facilitates implementation of the national comprehensive cancer network guidelines for lung cancer biomarker testing and identifies patients who may benefit from enrollment in mechanism-driven clinical trials. *Oncologist* 2016;21(6):684-691. **4** Drilon A et al. Broad, hybrid capture-based next-generation sequencing identifies actionable genomic alterations in lung adenocarcinomas otherwise negative for such alterations by other genomic testing approaches. *Clin Cancer Res* 2015;21(16):3631-3639. **5** Rankin A et al. Broad Detection of Alterations Predicted to Confer Lack of Benefit From EGFR Antibodies or Sensitivity to Targeted Therapy in Advanced Colorectal Cancer. *Oncologist* 2016;21(11):1306-1314. **6** Ross JS et al. Nonamplification ERBB2 genomic alterations in 5605 cases of recurrent and metastatic breast cancer: An emerging opportunity for anti-HER2 targeted therapies. *Cancer* 2016;122(17):2654-2662. **7** Hirshfield KM et al. Clinical Actionability of Comprehensive Genomic Profiling for Management of Rare or Refractory Cancers. *Oncologist* 2016;21(11):1315-1325. **8** FoundationOne®CDx. <http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx> (Letzter Zugriff: 26.11.2018). **9** Department of Health, New York. Next Generation Sequencing (NGS) guidelines for somatic genetic variant detection, Stand: 2015. [https://www.wadsworth.org/sites/default/files/WebDoc/1300145166/NextGenSeq\\_ONCO\\_Guidelines.pdf](https://www.wadsworth.org/sites/default/files/WebDoc/1300145166/NextGenSeq_ONCO_Guidelines.pdf) (Letzter Zugriff: 26.11.2018). **10** Singal G et al. Development and validation of a real-world clinicogenomic database. *J Clin Oncol* 2017;35(15\_Suppl):2514-2514. **11** Chalmers ZR et al. Analysis of 100,000 human cancer genomes reveals the landscape of tumor mutational burden. *Genome Med* 2017;9(1):34. **12** Johnson DB et al. Targeted next generation sequencing identifies markers of response to PD-1 blockade. *Cancer Immunol Res* 2016;4(11):959-967. **13** Carbone DP et al. First-line nivolumab in stage IV or recurrent non-small-cell lung cancer. *N Engl J Med* 2017;376(25):2415-2426. **14** Gatalical Z et al. High microsatellite instability (MSI-H) colorectal carcinoma: a brief review of predictive biomarkers in the era of personalized medicine. *Fam Cancer* 2016;15(3):405-412.



**FOUNDATIONONE® CDx**

ABOUT THE TEST FoundationOne®CDx is a next-generation sequencing (NGS) based assay that identifies genomic findings within hundreds of cancer-related genes.

**PATIENT**

DISEASE Lung adenocarcinoma  
NAME Not Given  
DATE OF BIRTH Not Given  
SEX Female  
MEDICAL RECORD # Not Given

**PHYSICIAN**

ORDERING PHYSICIAN Not Given  
MEDICAL FACILITY Not Given  
ADDITIONAL RECIPIENT Not Given  
MEDICAL FACILITY ID Not Given  
PATHOLOGIST Not Given

**SPECIMEN**

SPECIMEN SITE Not Given  
SPECIMEN ID Not Given  
SPECIMEN TYPE Not Given  
DATE OF COLLECTION Not Given  
SPECIMEN RECEIVED Not Given

PATIENT Sample, Name Lung adenocarcinoma 01 Jan 2018  
USZ# XXXXXXXX

**Genomic Signatures**

Microsatellite status - MS-Stable  
Tumor Mutational Burden - TMB-Intermediate (11 Muts/Mb)

**Gene Alterations**

For a complete list of the genes assayed, please refer to the Appendix.

**EGFR amplification, L858R**

**PTCH1 T416S**

**CDKN2A/B loss**

**RBM10 Q494\***

**TP53 R267P**

7 Disease-relevant genes with no reportable alterations: **KRAS, ALK, BRAF, MET, RET, ERBB2, ROS1**

**14** Swissmedic-Approved Therapies  
Therapies with Lack of Response

SWISSMEDIC-APPROVED THERAPIES (IN PATIENT'S TUMOR TYPE)	SWISSMEDIC-APPROVED THERAPIES (IN OTHER TUMOR TYPE)
Atezolizumab	Avelumab
Durvalumab	
Nivolumab	
Pembrolizumab	

**18** Clinical Trials

No therapies or clinical trials. see Genomic Signatures section

SWISSMEDIC-APPROVED THERAPIES (IN PATIENT'S TUMOR TYPE)	SWISSMEDIC-APPROVED THERAPIES (IN OTHER TUMOR TYPE)
Afatinib	Cetuximab
Erlotinib	Lapatinib
Gefitinib	Panitumumab
Osimertinib	
None	Sonidegib
	Vismodegib

**GENOMIC SIGNATURES**

**Tumor Mutational Burden - TMB-Intermediate (11 Muts/Mb)**

9 Trials see p. 14

**Microsatellite status - MS-Stable**

**GENE ALTERATIONS**

**EGFR - amplification, L858R**

4 Trials see p. 16

**PTCH1 - T416S**

5 Trials see p. 17

**GENE ALTERATIONS WITH NO REPORTABLE THERAPEUTIC OR CLINICAL TRIALS OPTIONS**

For more information regarding biological and clinical significance, including prognostic, diagnostic, germline, and potential chemosensitivity implications, see the Gene Alterations section.

**CDKN2A/B - loss** p. 5    **TP53 - R267P** p. 6  
**RBM10 - Q494\*** p. 5

NOTE: Genomic alterations detected may be associated with activity of certain drugs approved by applicable regulatory authorities (for example, the FDA, EMA, or country specific regulatory authorities); however, the agents listed in this report may have varied clinical evidence in the patient's tumor type. Neither the therapeutic agents nor the trials identified are ranked in order of potential or predicted efficacy for this patient, nor are they ranked in order of level of evidence for this patient's tumor type. This report includes scientific information. All treatment decisions remain the full and final responsibility of the respective treating physician. Foundation Medicine's genetic test and this genetic test report, including the information on therapies and clinical trials contained in this report, should not be used as the single basis for the therapy decision. The report should only be regarded and used as a supplementing source of information. All treatment decisions remain the full and final responsibility of the respective treating physician. For various reasons further explained below, both the therapies and the clinical trials listed in this report may not be complete and exhaustive. Please find the entire Swiss Prescribing Information on www.swissmedic.ch

- 1. Genomsignaturen**  
TMB- und MSI-Status ermöglichen fundierte Entscheidungen zum Einsatz von Immuntherapien<sup>11-14</sup>
- 2. Genveränderungen**  
Analysiert klinisch relevante Mutationen in 324 bekannten tumorassoziierten Genen<sup>1</sup>
- 3. Relevante negative Ergebnisse**  
Sequenzierte Gene, die im Tumortyp häufig mutiert sind, aber in dieser Biopsie nicht gefunden wurden
- 4. Von Swissmedic zugelassene Therapien**  
entsprechend des Tumorprofils Ihres Patienten
- 5. Klinische Studien**  
Mögliche relevante Studien, für die Ihre Patienten entsprechend ihres Tumorprofils infrage kommen
- 6. Weitere gefundene Mutationen,**  
die nicht gezielt mit einer personalisierten Therapie behandelt werden können. Um mit Sicherheit die bestmögliche Therapieentscheidung treffen zu können

Weitere Informationen finden Sie auf [www.foundationmedicine.ch](http://www.foundationmedicine.ch). Um FoundationOne® CDx für Ihre Patienten zu bestellen, nutzen Sie bitte das neue Bestellformular auf [www.pathologie.usz.ch/fone-cdx.aspx](http://www.pathologie.usz.ch/fone-cdx.aspx).

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12/2018