NEU Jetzt verfügbar

FOUNDATIONONE®CDx

Durchführung des Service in der Schweiz

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[1–7]

Wesentliche Unterschiede zu FoundationOne®

Companion Diagnostics (CDx)
Umfangreiche analytische und klinische Validierung anhand von 6 300 Proben[8,9]

Aktualisierte GEN-LISTE

Umfassendes Tumorprofiling
Analyse genetischer Alterationen von 324 bekannten tumorassoziierten Genen[1]

Gemeinsamkeiten mit FoundationOne®

DNA-Sequenzierung mit NGS-Technologie
Abdeckung einer Vielzahl von klinisch relevanten Mutationen.[1–7] Messung von TMB- und MSI-Status mit hoher Präzision[1]

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.[10] Nutzen Sie FoundationOne®CDx, um Ihre Patienten für eine zielgerichtete Therapie zu qualifizieren.[1]

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 (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.

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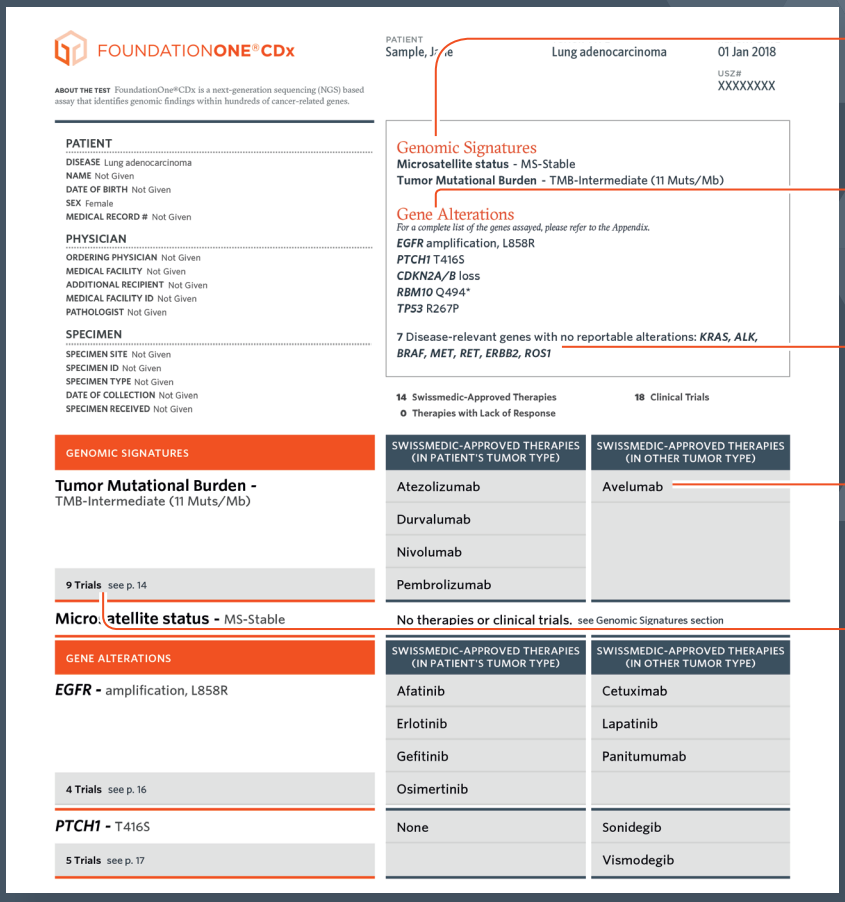
Therapierelevante Erkenntnisse in einem übersichtlichen Bericht



FOUNDATIONONE®CDx

PATIENT
Sample, J...e | Lung adenocarcinoma | 01 Jan 2018
USZ# XXXXXXXX

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

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
0 Therapies with Lack of Response
18 Clinical Trials

GENOMIC SIGNATURES	SWISSMEDIC-APPROVED THERAPIES (IN PATIENT'S TUMOR TYPE)	SWISSMEDIC-APPROVED THERAPIES (IN OTHER TUMOR TYPE)
Tumor Mutational Burden - TMB-Intermediate (11 Muts/Mb)	Atezolizumab	Avelumab
	Durvalumab	
	Nivolumab	
9 Trials see p. 14	Pembrolizumab	
Micro...atellite status - MS-Stable	No therapies or clinical trials. see Genomic Signatures section	

GENE ALTERATIONS	SWISSMEDIC-APPROVED THERAPIES (IN PATIENT'S TUMOR TYPE)	SWISSMEDIC-APPROVED THERAPIES (IN OTHER TUMOR TYPE)
EGFR - amplification, L858R	Afatinib	Cetuximab
	Erlotinib	Lapatinib
	Gefitinib	Panitumumab
4 Trials see p. 16	Osimertinib	
PTCH1 - T416S	None	Sonidegib
5 Trials see p. 17		Vismodegib

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
RBM10 - Q494* ..... p. 5
TP53 - R267P ..... p. 6

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.swissmedicinfo.ch.

1. Genomsignaturen
TMB- und MSI-Status ermöglichen fundierte Entscheidungen zum Einsatz von Immuntherapien[11–14]

2. Genveränderungen
Analysiert klinisch relevante Mutationen in 324 bekannten tumorassoziierten Genen[1]

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. Um FoundationOne®CDx für Ihre Patienten zu bestellen, nutzen Sie bitte das neue Bestellformular auf www.pathologie.usz.ch/fone-cdx.aspx.

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