MYPG | CancerSelect™ Report

REPORT DATE: 6/14/2016
TUMOR TYPE: PANCREATIC NEUROENDOCRINE

PATIENT NAME
[redacted]

PATIENT INFORMATION

DATE OF BIRTH	PATIENT GENDER	PGDX NUMBER	MEDICAL RECORD NUMBER	PATIENT PHONE NUMBER
10/26/1943	Male	PGDX7392T3	JHH MR#3-631-64-21	[redacted]
PATIENT EMAIL [redacted]			INSTITUTION Johns Hopkins	
PHYSICIAN Christopher Wolfgang M.D.			TUMOR SAMPLE RECEIVED 5/25/2016	NORMAL SAMPLE RECEIVED 4/26/2016

TEST INFORMATION AND SEQUENCING CHARACTERISTICS

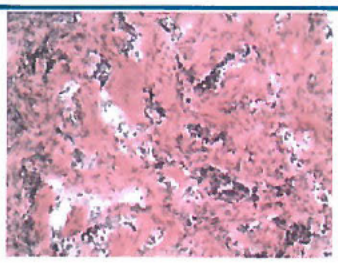
TEST PERFORMED	NUMBER OF GENES SEQUENCED	BASES IN TARGET GENES
CancerSelect	88	478,861
SEQUENCED BASES (TUMOR) 1,264,014,600	NUMBER OF SEQUENCES AT EACH BASE (TUMOR) 1,109	NUMBER OF DISTINCT SEQUENCES AT EACH BASE (TUMOR) 706
SEQUENCED BASES (NORMAL) 763,723,200	NUMBER OF SEQUENCES AT EACH BASE (NORMAL) 741	NUMBER OF DISTINCT SEQUENCES AT EACH BASE (NORMAL) 496

SAMPLE CHARACTERISTICS

DIAGNOSIS
Pancreatic Neuroendocrine

PRIMARY TUMOR SITE	HISTOLOGY
Pancreas	Neuroendocrine
SPECIMEN SITE Pancreas	PATHOLOGICAL TUMOR PURITY 50%
SPECIMEN TYPE Frozen	SOURCE OF NORMAL DNA Saliva
TUMOR COLLECTION DATE 4/6/2016	SPECIMEN ID S16-21646

TUMOR HISTOLOGY



MICROSATELLITE ANALYSIS

MSS - Microsatellite Stable (0 of 5 markers positive for MSI)

SEQUENCE MUTATIONS

No Sequence Mutations Identified

AMPLIFICATIONS OR TRANSLOCATIONS

No Amplifications or Translocations Identified

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CLINICALLY ACTIONABLE INFORMATION ASSOCIATED WITH SOMATIC ALTERATIONS

No Clinically Actionable Information Identified

CLINICAL TRIALS SPECIFIC TO MUTATION AND TUMOR TYPE

No Clinical Trials Identified

GENES EVALUATED IN TARGETED CANCER GENE ASSAY

Sequence Analyses

ABL1	ERBB4	GNAQ	MTOR	RET
AKT1	EZH2	GNAS	NF1	ROS1
ALK	FANCA	HNF1A	NF2	SMAD4
APC	FANCC	HRAS	NOTCH1	SMARCB1
ATM	FANCD2	IDH1	NPM1	SMO
BRAF	FANCE	IDH2	NRAS	SRC
BRCA1	FANCF	JAK2	NTRK1	STK11
BRCA2	FANCG	JAK3	PALB2	TERT
BRIP1	FANCL	KDR	PDGFRA	TP53
CDH1	FBXW7	KIT	PDGFRB	TSC1
CDKN2A	FGFR1	KRAS	PIK3CA	TSC2
CSF1R	FGFR2	MET	PMS2	VHL
CTNNB1	FGFR3	MLH1	PTCH1	
DDR2	FLT3	MPL	PTEN	
EGFR	FOXL2	MSH2	PTPN11	
ERBB2	GNA11	MSH6	RB1	

Copy Number Analyses

ALK	ERBB3	FGFR3	MYC	RET
EGFR	FGFR1	KIT	MYCN	
ERBB2	FGFR2	MET	PDGFRA	

Rearrangement Analyses

ABL1	EGFR	ETV6	PDGFRA	ROS1
ALK	ETV1	EWSR1	PDGFRB	TMPRSS2
BCL2	ETV4	MLL	RARA	

Microsatellite Analyses

BAT-25	BAT-26	NR-21	NR-24	MONO-27

ADDENDUM

Disclaimer and Limitations of Approach

In validation studies, the analytical sensitivity and specificity of the targeted cancer gene assay were > 99% and > 99.9%, respectively. These may be lower for structural alterations and vary depending on the quality of the specimen. Next generation sequencing approaches may provide incorrect sequence or mutational data due to insufficient coverage in specific regions of the genome, inability to distinguish highly related human sequences, and sequencing errors. The analysis of sequence specific alterations can also be hampered by three aspects related to the tumor DNA. First, the quality of tumor DNA obtained from formalin-fixed samples is generally of poor quality and can result in degraded and damaged DNA. Second, the quantity of DNA obtained can be very low, limiting the amount of DNA molecules that can be successfully analyzed by next generation sequencing. Third, the purity of tumor DNA can be a factor, as a significant portion of the DNA analyzed in the tumor sample may be derived from contaminating normal tissues. These three aspects can reduce the chance of detecting somatic sequence and copy number alterations and rearrangements.

Sequence mutations, including single base and small insertions/deletions, are evaluated where the allele frequency is ≥2.0% and amplifications are evaluated when the fold-change is ≥4-fold. Specific amplifications are marked as "indeterminate" in situations where there is evidence of amplification ≥3-fold, but a definitive determination cannot be made.

Genetic alterations are defined as clinically significant based on published literature and other evidence. Literature references are not comprehensive and there may be other studies that relate to the test results.

Results presented in this report are intended for use solely by a qualified health care professional. Any diagnosis, counseling, or treatment determination made as a result of data presented in the report should be made by a qualified health care professional in conjunction with other individual patient health information, including clinical presentation and other test reports. Information contained within the report is current as of the report date; a qualified health professional should reassess these data as relevant literature becomes available.

This test was developed and its performance characteristics determined by Personal Genome Diagnostics. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

Somatic vs. Germline mutations

Except for BRCA1, BRCA2, PALB2 and ATM, this test is meant to identify only somatic mutations and is not designed to detect the presence or absence of germline mutations. For BRCA1, BRCA2, PALB2 and ATM, the presence of either a somatic or germline change will be included in this report. Our analyses do not determine whether a mutation is somatic or germline, and patients in whom an alteration in these genes is reported may benefit from additional germline testing.

Microsatellite Instability Testing

The microsatellite instability (MSI) phenotype may indicate a deficiency in normal DNA mismatch repair function within the tumor, and may suggest that this individual has an inherited cancer syndrome due to defective DNA mismatch repair (e.g. HNPCC/Lynch syndrome). However, the finding of tumor MSI does not distinguish between somatic and germline alterations leading to MSI. Furthermore, it is also possible that MSI status can be influenced by neoadjuvant chemotherapy, which may lead to a false positive result (Int J Radiat Oncol Biol Phys. 2007 68(5):1584).

Source of Clinical Information

N-of-One, Inc has provided to PGDx research, analysis and interpretation, on a patient specific basis, of peer-reviewed studies and publically available databases. This information may include the association between a specific molecular alteration and clinical benefit, or lack thereof, from FDA-approved therapies and therapies under clinical investigation. Additional information from N-of-One is available on its website at www.n-of-one.com.

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All positions below use the Human Reference genome hg19

SEQUENCE MUTATION DETAILS

No Sequence Mutations Identified

AMPLIFICATION DETAILS

No Amplifications Identified

TRANSLOCATION DETAILS

No Translocations Identified

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