[Oncofocus] Patient Test Report

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Surname		**Requesting Clinician**	
Forename DOB		**Date requested**	
Gender	Female		
Histology #		**Tumour %**	55%
Primary site	Lung	**Tumour %**	n/a
Tumour subtype	Invasive Squamous Cell Carcinoma	**(macrodissected)**	
Tissue Type	Lung Pancoast		

Comment:
The DNA and RNA extracted from this sample were of optimal quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics.

221 genes were targeted using 2530 unique amplicons covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are linked to 466 anti-cancer targeted therapies.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Non-Small Cell Lung Cancer

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

Gene Variant	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG	✖	✖	✖	✖	● (11)
TP53 p.(V157F) c.469G>T	✖	✖	✖	✖	● (8)
FBXW7 p.(R441W) c.1321C>T	✖	✖	✖	✖	● (2)

EMA: European Medicine Agency, **US-FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **US-NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence. Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value(PPV) of 92%. Copy number variants; amplifications of CN> 6 with the 5% confidence value of ≥4 after normalization and deletions with 95% CI ≤1 are classified as present when the tumour% >50% with a sensitivity of 80% and PPV 100%. Gene Fusions are reported when occurring in >20 counts and meeting the thresholds of assay specific internal RNA quality control with a sensitivity of 92% and PPV of 99%. Supplementary technical information is available upon request.

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
everolimus	✖	✖	✖	✖	● (II)
GSK-2636771	✖	✖	✖	✖	● (II)
olaparib + vistusertib	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
AZD-5363	✖	✖	✖	✖	● (I)
AZD-5363 + olaparib	✖	✖	✖	✖	● (I)
AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib	✖	✖	✖	✖	● (I)
LY-3023414, LY-3023414 + midazolam	✖	✖	✖	✖	● (I)
MSC-2363318A	✖	✖	✖	✖	● (I)
palbociclib + pictilisib, palbociclib + taselisib	✖	✖	✖	✖	● (I)
PQR-309	✖	✖	✖	✖	● (I)

TP53 p.(V157F) c.469G>T

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
MK-1775 + olaparib	✖	✖	✖	✖	● (II)
nintedanib	✖	✖	✖	✖	● (II)
pazopanib	✖	✖	✖	✖	● (II)
ixazomib + vorinostat	✖	✖	✖	✖	● (I)
MK-1775	✖	✖	✖	✖	● (I)
pembrolizumab + p53MVA	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

TP53 p.(V157F) c.469G>T (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
SGT-53, SGT-53 + chemotherapy	✖	✖	✖	✖	● (I)
VX-970 + chemotherapy	✖	✖	✖	✖	● (I)

FBXW7 p.(R441W) c.1321C>T

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
palbociclib	✖	✖	✖	✖	● (II)
prexasertib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

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Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-12-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers.

Cancer type: Non-Small Cell Lung Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, TrialTroveID-265019, UKCRN ID:18725

Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

NCT01655225
A Phase I First-in-Human Dose Study of LY3023414 in Patients With Advanced Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 12-286, 13517, I6A-MC-CBBA, REFMAL 276, TrialTroveID-172222

Population segments: Estrogen receptor positive, Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), HER2 negative, Indolent, Other subtype, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Squamous Cell, Stage III, Stage IV, Untreated, Waldenstrom`s macroglobulinemia (WM)

Phase: I

Therapies: LY-3023414, LY-3023414 + midazolam

Locations: Italy, United States

US States: NY, OK, PA, TN

US Contact: Eli Lilly and Company [877-285-4559]

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PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (continued)

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER, TrialTroveID-200294

Population segments: Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: everolimus

Location: France

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH, TrialTroveID-258747

Population segments: (N/A), Aggressive, ALK, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: PTEN expression

Phase: II

Therapy: GSK-2636771

Location: United States

US States: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WV, WY

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (continued)

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

Population segments: First line, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: olaparib + vistusertib

Location: United States

US States: CT, MA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT01884285
A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Anti-tumour Activity of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB mutated/ amplified Advanced Solid Malignancies as Monotherapy and in Combination with Abiraterone Acetate or AZD2014

Cancer type: Unspecified Solid Tumor

Variant class: PTEN mutation

Other identifiers: 13-300, 20131275, D4620C00001, EudraCT Number: 2013-000703-17, IRAS ID: 129536, NCI-2013-02191, TrialTroveID-189056

Population segments: HER2 negative, Hormone refractory, Second line or greater/ Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapies: AZD8186, AZD8186 + abiraterone acetate + prednisone, AZD8186 + vistusertib

Locations: Canada, Spain, United Kingdom, United States

US States: MA, MI, WA, WI

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (continued)

NCT01971515
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PTEN aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334

Population segments: Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Exclusion criteria variant classes: AKT2 amplification, AKT2 mutation

Phase: I

Therapy: MSC-2363318A

Location: United States

US States: AL, CA, FL, MI, NY, TX, VT

US Contact: US Medical Information [888-275-7376]

NCT01226316
A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD5363 Under Adaptable Dosing Schedules in Patients with Advanced Solid Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 102084, 14-214, 14-430, 2014-0160, CR1322AZ, D3610C00001, EudraCT Number: 2010-022167-35, IRAS ID: 62131, JapicCTI-152844, M10AZD, NCI-2014-01803, NL33755.031.10, P1TGIVEN, TrialTroveID-136773

Population segments: Adenocarcinoma, Estrogen receptor positive, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Exclusion criteria variant classes: BRAF mutation, HRAS mutation, KRAS mutation, NRAS mutation

Phase: I

Therapy: AZD-5363

Locations: Canada, Denmark, France, Italy, Japan, Netherlands, Singapore, Spain, United States

US States: CA, CO, CT, NY, OK, PA, SC, TN, TX

US Contact: AstraZeneca Clinical Study Information [877-240-9479; information.center@astrazeneca.com]

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PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG (continued)

NCT02338622
A Phase I Multi-centre Trial of the Combination of Olaparib (PARP Inhibitor) and AZD5363 (AKT Inhibitor) in Patients With Advanced Solid Tumours

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: 14/LO/0103, CCR4058, ComPAKT, CRUKD/14/004, EudraCT number: 2013-004692-13, TrialTroveID-213474, UKCRN ID 16550

Population segments: HER2 negative, Hormone refractory, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: AZD-5363 + olaparib

Location: United Kingdom

NCT02389842
PIPA: A Phase Ib Study to Assess the Safety, Tolerability and Efficacy of the PI3K Inhibitors, Taselisib (GDC-0032) or Pictilisib (GDC-0941), in Combination With PAlbociclib, With the Subsequent Addition of Fulvestrant in PIK3CA-mutant Breast Cancers

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: CCR4191, EudraCT Number: 2014-002658-37, IRAS ID 159997, PIPA, TrialTroveID-253778

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapies: palbociclib + pictilisib, palbociclib + taselisib

Location: United Kingdom

NCT02483858
Phase I Study of Oral PQR309 in Patients With Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: PI3K/AKT/MTOR pathway

Other identifiers: EudraCT Number: 2015-003919-38, I 258914, IRAS ID: 193390, PQR309-003, REec-2016-2264, TrialTroveID-260655

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: PQR-309

Location: United States

US State: NY

US Contact: Dr. Alex Adjei [Alex.Adjei@RoswellPark.org]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

TP53 p.(V157F) c.469G>T

NCT02299141
A Pilot Study of Nintedanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)

Cancer type: Non-Small Cell Lung Cancer

Variant class: TP53 mutation

Other identifiers: 14-x346, 201412116, NCI-2014-02625, TrialTroveID-218546

Population segments: FGFR, First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: nintedanib

Location: United States

US State: MO

US Contact: Dr. Ramaswamy Govindan [314-362-5654; rgovindan@wustl.edu]

NCT02193152
A Pilot Study of Pazopanib in Molecularly Selected Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)

Cancer type: Non-Small Cell Lung Cancer

Variant class: TP53 mutation

Other identifiers: 14-X182, 201408009, 201566, NCI-2014-01760, PRMC 14-X182, TrialTroveID-213213

Population segments: First line, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: pazopanib

Location: United States

US State: MO

US Contact: Dr. Daniel Morgensztern [314-362-5737; danielmorgensztern@wustl.edu]

NCT02432963
A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab

Cancer type: Non-Small Cell Lung Cancer

Variant class: TP53 mutation

Other identifiers: 116634, 122284, 122771, 124524, 15002, NCI-2015-00653, TrialTroveID-256830

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative, Unresectable

Phase: I

Therapy: pembrolizumab + p53MVA

Location: United States

US State: CA

US Contact: Vincent Chung [800-826-4673]

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TP53 p.(V157F) c.469G>T (continued)

NCT02157792
An Open-Label, First-in-Human Study of the Safety, Tolerability, and Pharmacokinetics of VX-970 in Combination With Cytotoxic Chemotherapy in Subjects With Advanced Solid Tumors

Cancer type: Non-Small Cell Lung Cancer

Variant class: TP53 mutation

Other identifiers: 112876, 14-040, EudraCT Number: 2012-003126-25, NCI-2014-02042, OSU-13211, TrialTroveID-190735, VICCBRE1587, VX12-970-001

Population segments: First line, HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: VX-970 + chemotherapy

Locations: United Kingdom, United States

US States: CA, CO, GA, IL, MA, MI, MO, NY, OH, SC, TN, TX, VA, WA

US Contact: Medical Monitor [617-341-6777; medicalinfo@vrtx.com]

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

Population segments: First line, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: MK-1775 + olaparib

Location: United States

US States: CT, MA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02042989
A Phase I Study of MLN9708 and Vorinostat to Target Autophagy in Patients With Advanced p53 Mutant Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 2013-0511, NCI-2014-01091, TrialTroveID-201319

Population segments: Line of therapy N/A, Stage III, Stage IV

Phase: I

Therapy: ixazomib + vorinostat

Location: United States

US State: TX

US Contact: Dr. Siqing Fu [713-563-1930]

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TP53 p.(V157F) c.469G>T (continued)

NCT02610075
A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: D6015C00003, REFMAL 398, TrialTroveID-268385

Population segments: Liver mets, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MK-1775

Location: United States

US States: CO, TN

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

NCT02354547
A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1405-1316, SGT53-01-2, TrialTroveID-251586

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Location: United States

US State: TX

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

FBXW7 p.(R441W) c.1321C>T

NCT02873975
A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: FBXW7 mutation

Other identifiers: 16-281, TrialTroveID-284902

Population segments: Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shapiro@dfci.harvard.edu]

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FBXW7 p.(R441W) c.1321C>T (continued)

NCT01037790

Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Unspecified Solid Tumor

Variant class: G1/S cell cycle pathway

Other identifiers: NCI-2009-01467, Study 1006, TrialTroveID-120590, UPCC 03909, UPCC03909

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Metastatic, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

US Contact: Peter O'Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

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Appendix: Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

PTEN p.(V166fs) c.497_513delTAACTATTCCCAGTCAG

Variant Class	Evidence Items
PI3K/AKT/MTOR pathway	6
↳ PTEN aberration	1
↳ PTEN mutation	4

TP53 p.(V157F) c.469G>T

Variant Class	Evidence Items
TP53 mutation	8

FBXW7 p.(R441W) c.1321C>T

Variant Class	Evidence Items
G1/S cell cycle pathway	1
↳ FBXW7 mutation	1

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Appendix: Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
FBXW7	p.(R441W)	c.1321C>T	.	chr4:153249457	13.16%	NM_033632.3	missense
PTEN	p.(V166fs)	c.497_513delTAACTATTCCCAGTCAG	.	chr10:89711876	23.57%	NM_000314.4	frameshift Deletion
TP53	p.(V157F)	c.469G>T	COSM10670	chr17:7578461	15.30%	NM_000546.5	missense

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