[Oncofocus] Patient Test Report

Oncologica UK Ltd
Suite 15-16, The Science Village
Chesterford Research Park
Cambridge, CB10 1XL, UK
Tel: +44(0)1223 785327
Email: info@oncologica.com

ONC17			
Surname		**Requesting Clinician**	
Forename			
DOB		**Date requested**	
Gender	Female		
Histology #		**Tumour %**	20-25%
Primary site	Lung	**Tumour %**	-
Tumour subtype	Adenocarcinoma	**(macrodissected)**	
Tissue Type	Soft Tissue		

Comment:

237 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 582 anti-cancer targeted therapies.

The RNA extracted from this sample was of optimal quality. The DNA extracted form the sample was of borderline quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics for detecting oncogenes, fusion genes and tumour suppressors, however, copy number variation analysis was not possible.

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
ERBB2 **p.(Ala775_Gly776insYVMA) c.2313_2324dup** (also known as p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC)	✖	✖	✖	● (2)	● (15)

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.

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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

ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
afatinib	✖	✖	✖	●	● (II)
trastuzumab	✖	✖	✖	●	✖
ado-trastuzumab emtansine	✖	✖	✖	✖	● (II)
afatinib + chemotherapy	✖	✖	✖	✖	● (II)
AZD-8931, erlotinib + chemotherapy	✖	✖	✖	✖	● (II)
erlotinib + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
luminespib	✖	✖	✖	✖	● (II)
neratinib	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)
pyrotinib	✖	✖	✖	✖	● (II)
AP32788	✖	✖	✖	✖	● (I/II)
pirotinib	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)
varlitinib + chemotherapy	✖	✖	✖	✖	● (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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Current US-NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-NCCN information is current as of 2016-12-01. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC

● afatinib

Cancer type: Non-Small Cell Lung Cancer **Variant class:** ERBB2 mutation

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 3.2017]

● trastuzumab

Cancer type: Non-Small Cell Lung Cancer **Variant class:** ERBB2 mutation

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- NSCLC (Not specified)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 3.2017]

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.

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'.

ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC

No NCT ID - see other identifier(s)
A Study of Trastuzumab Emtansine in Patients With HER2-Positive, Recurrent Metastatic Non-Small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 exon 20 insertion

Other identifiers: HER2-CS-2, TrialTroveID-258506, UMIN000017709

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

Phase: II

Therapy: ado-trastuzumab emtansine

Location: Japan

NCT02369484
Afatinib in Pretreated Patients With Advanced NSCLC Harbouring HER2 Exon 20 Mutations

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 exon 20 mutation

Other identifiers: 1200.230, ETOP 7-14, ETOP 7-14 - NICHE, EudraCT Number: 2014-005098-35, NICHE, REec-2015-1543, TrialTroveID-252749

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

Phase: II

Therapy: afatinib

Locations: Germany, Netherlands, Spain, Switzerland

NCT01922583
A Multi-center Phase II Study of AUY922 in Patients with Stage IV Non-small Cell Lung Cancer (NSCLC) With Driver Molecular Alterations Other Than Sensitive EGFR Mutation, Who have Progressed after one Line of Systemic Therapy

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 exon 20 mutation

Other identifiers: 1020009413, CAUY922ATW02T(201302063MIPD), TrialTroveID-192154

Population segments: ALK, EGFR, KRAS, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: luminespib

Location: Taiwan

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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT01953926
An Open-label, Multicenter, Multinational, Phase II Study Exploring the Efficacy and Safety of Neratinib Therapy in Patients With Solid Tumors With Activating HER2, HER3 or EGFR Mutations or With EGFR Gene Amplification.

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 activating mutation

Other identifiers: 13-140, 13-615, CTA733, EudraCT Number: 2013-002872-42, IRAS ID: 171670, NCI-2014-00495, PUMA-NER-5201, REec-2014-0843, SUMMIT, SUMMIT basket, TrialTroveID-191740

Population segments: EGFR, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: neratinib

Locations: Australia, Finland, Israel, Italy, Republic of Korea, Spain, United Kingdom, United States

US States: CA, FL, MA, MO, MS, NJ, NY, TN, TX

US Contact: Puma Biotechnology Clinical Operations [424-248-6500; ClinicalTrials@pumabiotechnology.com]

NCT02597946
A Phase II Study of Afatinib in Patients With Advanced NSCLC Harboring HER2 Mutations, Previously Treated With Chemotherapy

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 mutation

Other identifiers: CTR20160453, 1200.222, TrialTroveID-267515

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

Phase: II

Therapy: afatinib + chemotherapy

Location: Malaysia

NCT02535507
Single Arm Phase II Clinical Trial to Investigate the Efficacy and Safety of Pyrotinib as a Single Agent in HER2 Mutation Advanced Non-small Cell Lung Cancer Patients Who Failed to Previous at Least 2nd Line Treatments

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 mutation

Other identifiers: FK1406, TrialTroveID-263775

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

Phase: II

Therapy: pyrotinib

Location: China

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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT02117167
Intergroup Trial UNICANCER UC 0105-1305/ IFCT 1301: SAFIR02_Lung - Evaluation of the Efficacy of High Throughput Genome Analysis as a Therapeutic Decision Tool for Patients With Metastatic Non-small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 aberration

Other identifiers: EudraCT Number: 2013-001653-27, IFCT-1301 SAFIR02 Lung, SAFIR02 Lung ITTC-1301, SAFIR02_Lung, TrialTroveID-207256, UC 0105-1305 / IFCT 1301

Population segments: Adenocarcinoma, First line, Large Cell, Maintenance/ Consolidation, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV

Phase: II

Therapies: AZD-8931, erlotinib + chemotherapy

Location: France

NCT02716116
A Phase I/II Study Of The Safety, Pharmacokinetics, And Anti-Tumor Activity Of The Oral EGFR/HER2 Inhibitor AP32788 In Non-Small Cell Lung Cancer

Cancer type: Non-Small Cell Lung Cancer

Variant class: ERBB2 exon 20 insertion

Other identifiers: 16-143, AP32788-15-101, NCI-2016-00587, TrialTroveID-262671

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

Phase: I/II

Therapy: AP32788

Location: United States

US States: CA, CO, MA, NY, TN, VA

US Contact: Dr. Shuanglian Li [617-503-7148; Shuanglian.Li@ariad.com]

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: ERBB2 aberration

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

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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT02675829
A Phase II Trial of Ado-Trastuzumab Emtansine for Patients With HER2 Amplified or Mutant Cancers

Cancer type: Lung Cancer

Variant class: ERBB2 activating mutation

Other identifiers: 15-335, TrialTroveID-256389

Population segments: First line, Stage III, Stage IV

Phase: II

Therapy: ado-trastuzumab emtansine

Location: United States

US State: NY

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

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 activating 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

Phase: II

Therapy: afatinib

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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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT02091141
My Pathway: An Open Label Phase IIa Study Evaluating Trastuzumab/ Pertuzumab, Erlotinib, Vemurafenib/ Cobimetinib, and Vismodegib in Patients Who Have Advanced Solid Tumors With Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 activating mutation

Other identifiers: 1403013519, 2014-0459, AAAN9701, J1480, ML28897, ML28897/PRO 02, ML28897PRO/02, My Pathway, NCI-2014-01811, TrialTroveID-205033

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

Phase: II

Therapy: pertuzumab + trastuzumab

Location: United States

US States: AR, AZ, CA, CO, FL, GA, IL, MD, MN, NC, ND, NY, OH, OK, OR, PA, SD, TN, TX, VA, WA

US Contact: Hoffmann-La Roche, Study Director [888-662-6728; global.rochegenentechtrials@roche.com]

NCT02689336
Phase II Clinical Trial Treating Relapsed/ Recurrent/Refractory Pediatric Solid Tumors With the Genomically-Targeted Agent Erlotinib in Combination With Temozolomide

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 201604002, NCI-2016-00549, TrialTroveID-273560

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

Phase: II

Therapy: erlotinib + chemotherapy

Location: United States

US State: MO

US Contact: Dr. Robert Hayashi [314-454-6018; Hayashi_R@kids.wustl.edu]

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: ERBB2 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: lapatinib

Location: France

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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT02442414
A Phase 1 Study of KBP-5209 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB aberration

Other identifiers: 2014-0891, 5209-CPK-1001, NCI-2015-00881, TrialTroveID-195201

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

Phase: I/II

Therapy: pirotinib

Location: United States

US States: IN, TX, UT

US Contact: Matthew S. Hunt [608-332-8641; Matthew.hunt2@covance.com]

NCT02152943
Combination Treatment With Everolimus, Letrozole and Trastuzumab in Hormone Receptor and HER2/Neu-positive Patients With Advanced Metastatic Breast Cancer and Other Solid Tumors: Evaluating Synergy and Overcoming Resistance

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 2014-0119, NCI-2014-01615, TrialTroveID-210119

Population segments: First line, HER2 positive, Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive and/or PR positive

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Location: United States

US State: TX

US Contact: Dr. Filip Janku [713-563-1930]

No NCT ID - see other identifier(s)
Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 5209-CPK-1002, CTR20150792, TrialTroveID-269399

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

Phase: I

Therapy: pirotinib

Location: China

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ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC (continued)

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: SHRUS 1001, TrialTroveID-261429

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

Phase: I

Therapy: pyrotinib

Location: United States

US State: TX

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

NCT02435927
Phase I Study to Evaluate the Safety and Tolerability of ASLAN001 in Combination with Oxaliplatin and Capecitabine or Oxaliplatin and 5-FU with Leucovorin

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifiers: ASLAN001-002SG, TrialTroveID-254374

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

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.

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.

ERBB2 p.(E770_A771insAYVM) c.2324_2325insATACGTGATGGC

Variant Class	Evidence Items
ERBB aberration	1
↳ ERBB2 aberration	3
↳ ERBB2 mutation	9
↳ ERBB2 activating mutation	4
↳ ERBB2 exon 20 insertion	2
↳ ERBB2 exon 20 mutation	2
↳ ERBB2 exon 20 insertion	2

Appendix: Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Allele Frequency	Transcript	Variant Effect	Gene Class	Variant Class
ERBB2	p.(E770_A771insAYVM)	c.2324_2325insATACGTGATGGC	COSM682	11.43%	NM_004448.3	nonframeshift Insertion	Gain of Function	Hotspot

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The following paragraph on Liability is an extract from the Oncologica Tests' Terms and Conditions. The extract is to draw your attention to particular terms applicable to you but nothing set out here is intended to supersede or override our Terms and Conditions, which can be found on our website at www.oncologica.com under the title Oncologica Tests' Terms and Conditions. Please read these Oncologica Test Terms and Conditions carefully before you submit an order for the Oncologica Tests, as you will be bound by these Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.

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6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

6.3 Information compiled in the Oncologica Test Report includes is from publicly available as well as proprietary sources. By updating the source database, Oncologica makes every effort to provide the most accurate and up-to-date information. However, Oncologica does not warrant or represent that the information in the Oncologica Test Report is accurate, timely or complete.

6.4 The Oncologica Test Report contains drug and clinical trial information. However, Oncologica does not warrant or represent that any drug or clinical trial identified by the Oncologica Test will guarantee a therapeutic response for a particular Patient. The drugs listed in an Oncologica Test Report are ranked on clinical evidence as to the predicted efficacy or appropriateness for the Patient. The Patient shall ensure that its physician shall evaluate and interpret the Oncologica Test Report, along with all other available clinical information about the Patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, nor solely on the information contained in the Oncologica Test Report.

6.5 Subject to paragraph 6.10, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Tests, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient's physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient's physician's professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician's use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient's physician.

6.6 Oncologica does not warrant or represent or guarantee that the Oncologica Tests will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Tests are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patient's cancer. In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.

6.7 The Oncologica Test identifies genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

6.8 Subject to Clause 6.8, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:
(a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;
(b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;
(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

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6.9 Subject to the provisions of this Clause 6, Oncologica's total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Test that is the subject of the claim.

6.10 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.11 If the Patient is a consumer (and not a business), the Patient expressly acknowledges and agrees that the Test is supplied to the Patient's specification and therefore there is no right to cancel the Test following acceptance under Clause 2.2. If the Patient is a consumer, then notwithstanding any other provisions of the Contract, none of the Patient's consumer statutory rights are affected.

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