Sonic Genetics
Quality is in our DNA

INSTRUCTIONS FOR THE DOCTOR
Fax this form and a **copy of the histology report** to 1800 952 202 or email to oncology@sonicgenetics.com.au.
All enquiries, please contact 1800 010 447.

Solid tumour somatic mutation testing | Request form

FOR THE DOCTOR

Patient details

First name _____
Surname _____
Date of birth ___/___/___ Sex _____
Address _____
_____
_____
Phone (mobile) _____
Medicare No. ☐☐☐☐☐☐☐☐☐☐

PATIENT STATUS AT TIME OF SERVICE OR SPECIMEN COLLECTION
(Required by law for all patients) Was the patient a:

Private patient in a private hospital or approved day hospital?	☐ Yes	☐ No
Hospital patient in a recognised hospital?	☐ Yes	☐ No
Private patient in a recognised hospital?	☐ Yes	☐ No
Outpatient of a recognised hospital?	☐ Yes	☐ No

Hospital _____ Ward _____

Test/s requested

Full FIND IT panel
☐ Full panel (≥30 genes, including genes in focused panels below)
Tumour type: _____
☐ Tick here if full panel required for a sample which has had a focused panel reported

Focused FIND IT panels
☐ Colorectal panel (BRAF, KRAS, NRAS, PIK3CA)*
☐ Melanoma panel (BRAF, KIT, NRAS)*
☐ NSCLC panel (BRAF, EGFR, ERBB2, KRAS, MET + ALK/ROS1 by IHC/FISH)*
☐ Glioma panel (BRAF, IDH1, IDH2, TP53)*
☐ Breast panel (AKT1, ERBB2, ESR1, PIK3CA)
☐ Endometrial panel (CTNNB1, PIK3CA, POLE, TP53)
☐ Gastrointestinal stromal tumour panel (BRAF, KIT PDGFRA)

Focused FISH panels
☐ Glioma FISH (1p/19q co-deletion)*
☐ Glioma FISH (EGFR amplification)

Other somatic mutation or FISH test
_____

Please refer to test list, available on www.sonicgenetics.com.au/solid
Medicare criteria met ☐ Yes ☐ No (see overleaf)
*Medicare rebates available, subject to criteria being met.

Clinical information REQUIRED

A copy of the histology report is essential

ALL fields must be completed for testing to proceed
Please note: Comprehensive information regarding clinical history and diagnosis is essential in the interpretation of genomic findings and drug therapy recommendations.

REASON FOR REFERRAL
☐ Therapeutic target identification _____
☐ Acquired resistance to drug _____
☐ Other _____

DIAGNOSIS & CLINICAL HISTORY
Diagnosis _____
Stage _____

ADDITIONAL INFORMATION (INDICATE ALL THAT APPLY)
☐ Primary tumour ☐ Pre-treatment ☐ Undergoing treatment
Chemotherapy drugs _____
Previous molecular test results _____
☐ SD

Requesting doctor

Name _____
Address _____
_____
_____
Phone _____ Provider No. _____

I confirm that the patient has been informed about the purpose, scope and limitations of the test, that there may be a private fee for testing if Medicare criteria are not met and that, if a FIND IT panel is being tested, de-identified clinical and genomic data will be shared with Contextual Genomics in Canada and used for quality assurance and test improvements.

DOCTOR SIGNATURE
X

Copy reports to

Name _____
Address _____
_____
_____

Holding laboratory and sample details

Pathology laboratory holding patient sample block _____
_____
Laboratory reference number _____
Sample block number _____
Procedure date for tissue to be analysed ___/___/_____

FOR THE PATIENT – Patient and Financial Consent

I confirm that I have been informed about the purpose, scope and limitations of the test. I understand that the test requested may not be eligible for a Medicare rebate and I may receive an account which I will pay in full. I also understand that, if a FIND IT panel is being tested, de-identified clinical and genomic data will be shared with Contextual Genomics in Canada and used for quality assurance and test improvements.

If I do not fulfil the Medicare criteria

ACCOUNT STATEMENT
I understand that as the test requested is not eligible for a Medicare rebate, I will pay in full prior to the sample being tested.

If I do fulfil the Medicare criteria

MEDICARE ASSIGNMENT (Section 20A of the Health Insurance Act 1973):
I offer to assign my right to benefits to the Approved Pathology Practitioner who will render the requested pathology service(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.

PATIENT SIGNATURE
X

Practitioner's Use Only (Reason for patient being unable to sign)

For pricing, please refer to our website – www.sonicgenetics.com.au
For any enquiries, please contact Sonic Genetics on 1800 010 447.

ISSUE MAY 2020
SHG-REQ-0006-00.6

Sonic Genetics
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Solid tumour somatic mutation testing

Information for patients

Purpose

Every cancer is different. We now know that there are combinations of genetic mutations that arise in certain types of cancer. These are known as the cancer's 'molecular signature' because they are specific to the individual cancer.

We now have tests to identify some of these cancer-causing genetic mutations. Genomic testing of cancer provides information that gives your doctor a better understanding of your cancer. This helps in making decisions about potential treatments.

Sonic Genetics uses a variety of tests to look for mutations and determine the cancer's 'molecular signature'. These tests are regularly updated to include more mutations and genes.

Limitations

Our tests are designed to detect some of the most common mutations that are currently known in cancer. If no mutations are found, it may be advisable to have further testing done to look for mutations elsewhere in the DNA of the cancer cells. Some types of genomic testing may not work if the DNA is of low quality – for example, DNA quality is lower in samples stored for more than two years before testing. Sometimes another biopsy is requested if you have been on other therapy since the last biopsy was done.

Financial consent

By consenting overleaf, you confirm that you have been informed about the purpose, scope and limitations of the test(s) by your doctor. You understand that this test is performed from histopathology samples collected previously, that the sample will be requested from the holding laboratory, and that the result should be reviewed by your doctor in light of other findings. You consent to the test being performed in whole, or part, as requested by your doctor, and are aware that the laboratory could contact you for prepayment by credit card over the phone if Medicare or other reimbursement criteria are not met. You also understand that if your original tissue sample is held by a histopathology laboratory that is not part of the Sonic Healthcare network, a sample retrieval and processing fee may be applied by that laboratory and invoiced to you directly. Sonic Genetics has no control over the time taken for the sample to be sent to us from the holding laboratory.

Medicare criteria (as of May 2020)

Indication	Item #	MBS rebate requirements
Colorectal	**73338**	A test of tumour tissue from a patient with metastatic colorectal cancer (stage IV), requested by a specialist or consultant physician, to determine if the requirements relating to rat sarcoma oncogene (RAS) gene mutation status for access to cetuximab or panitumumab under the Pharmaceutical Benefits Scheme (PBS) are fulfilled, if: (a) the test is conducted for all clinically relevant mutations on KRAS exons 2, 3 and 4 and NRAS exons 2, 3 and 4; or (b) a RAS mutation is found.
Melanoma	**73336**	A test of tumour tissue from a patient with unresectable stage III or stage IV metastatic cutaneous melanoma, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to BRAF V600 mutation status for access to dabrafenib or vemurafenib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
NSCLC	**73337**	A test of tumour tissue from a patient diagnosed with non-small cell lung cancer, shown to have non-squamous histology or histology not otherwise specified, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to erlotinib, gefitinib or afatinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
NSCLC relapse	**73351**	A test of tumour tissue that is derived from a new sample from a patient with locally advanced (stage IIIb) or metastatic (stage IV) non-small cell lung cancer (NSCLC), who has progressed on or after treatment with an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI). The test is to be requested by a specialist or consultant physician, to determine if the requirements relating to EGFR T790M gene status for access to osimertinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
NSCLC ALK	**73341**	Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with locally advanced or metastatic non-small cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of anaplastic lymphoma kinase (ALK) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score >0, and with documented absence of activating mutations of the epidermal growth factor receptor (EGFR) gene, requested by, or on behalf of, a specialist or consultant physician to determine if requirements relating to ALK gene rearrangement status for access to an anaplastic lymphoma kinase inhibitor under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
NSCLC ROS1	**73344**	Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with locally advanced or metastatic non-small-cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of ROS proto-oncogene 1 (ROS1) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score of 2+ or 3+; and with documented absence of both activating mutations of the epidermal growth factor receptor (EGFR) gene and anaplastic lymphoma kinase (ALK) immunoreactivity by IHC, requested by a specialist or consultant physician to determine if requirements relating to ROS1 gene rearrangement status for access to crizotinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
Glioma	**73372**	Analysis of tumour tissue, requested by a specialist of consultant physician, that is for: (a) the identification of IDH1/2 pathological variant status; and (b) is for a patient with: (i) negative IDH1 (R132H) immunohistochemistry; and (ii) clinical or laboratory evidence, including morphological features of glial neoplasm. Maximum one test per lifetime.
Glioma FISH	**73371**	Analysis of tumour tissue, requested by a specialist or consultant physician, that is for: (a) the detection of chromosome 1p/19q co-deletion; and (b) a patient with clinical or laboratory evidence, including morphological features, of glial neoplasm with probable oligodendroglial component. Maximum one test per lifetime.

PRIVACY NOTE The information provided will be used to assess any Medicare benefit payable for the services rendered and to facilitate the proper administration of government health programs, and may be used to update enrolment records. Its collection is authorised by provisions of the Health Insurance Act 1973. The information may be disclosed to the Department of Health and Ageing or to a person in the medical practice associated with this claim, or as authorised/required by law.