



Solid tumour somatic mutation testing | Request form

FOR THE DOCTOR

Patient details

Form for patient details including fields for First name, Surname, Date of birth, Sex, Address, Phone (mobile), and 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? Hospital patient in a recognised hospital? Private patient in a recognised hospital? Outpatient of a recognised hospital? Hospital Ward

Test/s requested

Form for test/s requested including Full FIND IT panel, Focused FIND IT panels, Focused FISH panels, and Other somatic mutation or FISH test.

Clinical information

REQUIRED

A copy of the histology report is essential

Clinical information form including sections for ALL fields must be completed for testing to proceed, REASON FOR REFERRAL, DIAGNOSIS & CLINICAL HISTORY, and ADDITIONAL INFORMATION.

Requesting doctor

Form for requesting doctor including fields for Name, Address, Phone, and Provider No., with a DOCTOR SIGNATURE box.

Copy reports to

Form for copy reports to including fields for Name and Address.

Holding laboratory and sample details

Form for holding laboratory and sample details including fields for Pathology laboratory holding patient sample block, Laboratory reference number, Sample block number, and Procedure date.

FOR THE PATIENT - Patient and Financial Consent

Form for patient and financial consent including sections for ACCOUNT STATEMENT, MEDICARE ASSIGNMENT, and a PATIENT SIGNATURE box.



# 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 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, vemurafenib or encorafenib 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 or consultant physician, that: (a) is for 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: (a) is for the detection of chromosome 1p/19q co-deletion; and (b) is for 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.

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