



Somatic Mutation Testing Request Form (page 1 of 3)

INSTRUCTIONS FOR CLINICIANS:

- 1 Please complete page 1 and the "Laboratory and Sample Details" section of page 2 in FULL. Incomplete forms will not be processed.
- 2 Send one copy of both pages to the pathology laboratory holding the patient sample.
- 3 Send a second copy of both pages AND a copy of the original histopathology report to:

	Sullivan Nicolaides Pathology
	- Fax (07) 3371 9846 or
	- Scan and email to: molecularoncology@snp.com.au
- 4 For any enquiries, please phone (07) 3377 8789

COMPLETE THE FOLLOWING DETAILS:

Patient Details	Clinical Information
Name: _____ Date of Birth: _____ Gender: _____ Address: _____ Medicare No: _____ Health Fund & No: _____ Patient status at time sample was collected: <input type="checkbox"/> private patient in a private hospital, or approved day hospital facility <input type="checkbox"/> private patient in a recognised hospital <input type="checkbox"/> outpatient of a recognised hospital Hospital name: _____	Is this a new diagnosis? <input type="checkbox"/> Yes <input type="checkbox"/> No Has the patient been treated with systemic anti-tumour therapy* <input type="checkbox"/> Yes <input type="checkbox"/> No Patient Stage*: _____ Tumour type: <input type="checkbox"/> Melanoma <input type="checkbox"/> Colorectal carcinoma <input type="checkbox"/> Non-small cell lung cancer <input type="checkbox"/> Other _____ <div style="border: 1px solid gray; padding: 5px; margin-top: 10px; font-size: small;"> * Clinical stage and/or treatment status may determine eligibility for funding by Medicare or pharmaceutical access programs. If this information is not indicated, the patient may be privately billed. </div>

Test Required (for fresh tissue samples, standard histopathology and immunohistochemistry will be performed):

Gene Panels*	Tick if Required	Medicare Criteria Met? **	Other source of reimbursement (please state below)	Test Set
NSCLC Panel: EGFR, BRAF, KRAS, ERBB2 ALK by IHC+/-FISH ***	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>		LNGDNA ALKIHC
NSCLC: ROS1 FISH	<input type="checkbox"/>	no MBS item		PETFISH
Colorectal Panel: KRAS, NRAS, BRAF, PIK3CA	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>		CRCDNA
Melanoma Panel: BRAF, KIT, NRAS	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>		MELDNA
Other Somatic Mutation Test: _____	<input type="checkbox"/>	N/A		
Other FISH test (Cytogenetics): _____	<input type="checkbox"/>	N/A		PETFISH

* A small proportion of samples are not suitable for panel testing and targeted testing for the rebated gene(s) will be carried out.
 ** Refer to page 3 for Medicare criteria and private payment information if criteria not met.
 *** ALK IHC screening will be performed on non-squamous NSCLCs. If ALK IHC is equivocal or positive, further testing by FISH will be carried out.

Referring Clinician Details	Copy Doctor Details
Name: _____ Address: _____ Email: _____ Phone: _____ Fax: _____ Mobile: _____ Date requested: _____ Provider No: _____ Referring Clinician Signature: _____	Name: _____ Address: _____ Email: _____ Phone: _____ Fax: _____ Mobile: _____ Provider No: _____

Somatic Mutation Testing Request Form (page 2 of 3)

INSTRUCTIONS FOR LABORATORY HOLDING THE PATIENT SAMPLE:

- | | |
|--|--|
| <p>1 Please provide the sample as:</p> | <ul style="list-style-type: none"> 10 x 4µM sections mounted on charged/coated slides. Please clean the microtome, e.g. with paraclean, between patients (due to the sensitivity of PCR analysis). Please stain the first section with H&E. The remaining sections should be unstained and dried overnight at 37°. Please label each slide with date of sectioning, along with patient and block identifiers, and label the unstained sections sequentially (ie slides 2-10). |
| <p>2 Please send the sample, a copy of this form and a copy of the original histopathology report in a padded bag to:</p> | <p>Molecular Pathology Department
Sullivan Nicolaides Pathology
24 Hurworth Street
Bowen Hills Qld 4006</p> |

COMPLETE THE FOLLOWING DETAILS:

Laboratory and Sample Details

Pathology Laboratory holding patient sample block: _____

Patient Name: _____

Date of Birth: ____ / ____ / ____ Gender: _____

Sample Block Number: _____

Laboratory Reference Number: _____

Referring Clinician's Signature: _____ Date: ____ / ____ / ____

By signing this form I confirm to the best of my knowledge that I have the consent of the patient to request somatic mutation testing on their tumour tissue, and that the patient is aware that they may receive a bill if they do not meet criteria for Medicare or other reimbursement.

COMPLETE THE FOLLOWING DETAILS FOR MEDICARE-FUNDED TESTS ONLY:

Patient Advisory Statement

Referring clinician to tick if SNP required

Your treating practitioner has recommended that you use a Sonic laboratory, Sullivan Nicolaides Pathology. You are free to choose your own pathology provider. However, if your doctor has specified a particular pathologist named on this form on clinical grounds, a Medicare rebate will only be performed if that pathologist performs the service. You should discuss this with your doctor.

Concession

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 services(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.

Patient Signature: _____ Date: ____ / ____ / ____

REFERRING CLINICIAN'S USE ONLY

Patient unable to sign: (Reason patient cannot sign):

Somatic Mutation Testing: Medicare criteria and private payment details*

NSCLC Panel Funding Information	Criteria
<p>Medicare Eligibility Criteria (Item 73337) NSCLC NGS Panel: EGFR (plus BRAF, KRAS, ERBB2, ALK IHC) requested by a clinician or pathologist.</p> <p>Medicare Eligibility Criteria (Item 73341) ALK FISH Testing requested by a clinician</p>	<p>a. EGFR Testing: 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 or gefitinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.</p> <p>b. ALK FISH Testing: 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 a specialist or consultant physician to determine if requirements relating to ALK gene rearrangement status for access to crizotinib under the pharmaceutical benefits scheme (PBS) are fulfilled.</p>
Private Payment**	For patients where the above eligibility criteria are not met, the private fee for the NSCLC mutation panel will be \$397.35. The private fee for ALK FISH testing will be \$355.

Colorectal Panel Funding Information	Criteria
<p>Medicare Eligibility Criteria (Item 73338) CRC NGS Panel: KRAS and NRAS (plus BRAF, PIK3CA) requested by a clinician.</p>	<p>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:</p> <p>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</p> <p>b. a RAS mutation is found.</p>
Private Payment**	For patients where the above eligibility criteria are not met, the private fee for the colorectal panel will be \$362.59.

Melanoma Panel Funding Information	Criteria
<p>Medicare Eligibility Criteria (Item 73336) Melanoma NGS Panel: BRAF (plus KIT, NRAS) requested by a clinician or pathologist.</p>	<p>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 under Pharmaceutical Benefits Scheme (PBS) are fulfilled.</p>
Private Payment**	For patients where the above eligibility criteria are not met, the private fee for BRAF mutation testing will be \$230.95.

Solid Tumour FISH Funding Information	Criteria
<p>ROS1 FISH and other FISH tests ordered by a clinician</p>	<p>There is currently no Medicare funding for ROS1 and other solid tumour FISH testing. The private fee for single target solid tumour FISH testing is \$355. If more than one FISH probe is required, the fee is \$410**.</p>

*Please note: For patient samples held by histopathology laboratories that are not part of the Sonic network, a sample retrieval and processing fee may be applied and invoiced to the patient by the laboratory holding the sample block.

**Private Payment Fees are correct as at July 1st 2016 and may be subject to change.

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.

SULLIVAN NICOLAIDES PTY LTD ABN 38 078 202 196, a subsidiary of Sonic Healthcare Limited APA ABN 24 004 196 909, 14 Giffnock Ave, Macquarie Park NSW 2113

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