



## Somatic Mutation Testing Request Form (page 1 of 3)

### INSTRUCTIONS FOR CLINICIANS:

- Please complete page 1 and the "Laboratory and Sample Details" section of page 2 in FULL. Incomplete forms will not be processed.
- Send one copy of both pages to the pathology laboratory holding the patient sample.
- 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](mailto:molecularoncology@snp.com.au)
- For any enquiries, please phone (07) 3377 8789

### COMPLETE THE FOLLOWING DETAILS:

**Patient Details**

Name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Gender: \_\_\_\_\_

Address: \_\_\_\_\_

Medicare No: \_\_\_\_\_

Patient's Health Fund: \_\_\_\_\_ Fund no: \_\_\_\_\_

**Patient status at time sample was collected:**

private patient in a private hospital, or approved day hospital facility

private patient in a recognised hospital

outpatient of a recognised hospital

Hospital name: \_\_\_\_\_

**Clinical Information**

Is this a new diagnosis?  Yes  No

Has the patient been treated with systemic anti-tumour therapy\*  Yes  No

Patient Stage\*: \_\_\_\_\_

Tumour type:  Melanoma

Colorectal carcinoma

Non-small cell lung cancer

Other \_\_\_\_\_

\* 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.

**Test Required (for fresh tissue samples, please also perform standard histopathology testing):**

Gene Target	Tick if Required	Test Set	Medicare Criteria Met?*		Other source of reimbursement (please state below)
EGFR	<input type="checkbox"/>	EGFR	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
ALK rearrangement screen: IHC +/- FISH**	<input type="checkbox"/>	ALKIHC	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
RAS testing (clinically relevant codons in KRAS and NRAS)	<input type="checkbox"/>	KRAS	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
BRAF	<input type="checkbox"/>	BRAF	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Other Somatic Test	<input type="checkbox"/>				

\*Refer to page 3 for Medicare criteria and private payment information if criteria not met.

\*\* ALK IHC screening is available for non-squamous NSCLCs. If EGFR mutations are negative and ALK IHC is equivocal or positive, further testing by FISH will be carried out.

**Referring Clinician Details**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Email: \_\_\_\_\_ Phone: \_\_\_\_\_

Fax: \_\_\_\_\_ Mobile: \_\_\_\_\_

Date requested: \_\_\_\_\_ Provider No: \_\_\_\_\_

Referring Clinician Signature: \_\_\_\_\_

**Copy Doctor Details**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Mobile: \_\_\_\_\_ Provider No: \_\_\_\_\_



## Somatic Mutation Testing Request Form (page 2 of 3)

### INSTRUCTIONS FOR LABORATORY HOLDING THE PATIENT SAMPLE:

- |          |  |   |
|----------|--|---|
| <b>1</b> | Please provide the sample as:  | <ul style="list-style-type: none"><li>10 x 4µM sections mounted on charged/coated slides. Please clean the microtome, eg with paraclean, between patients (due to the sensitivity of PCR analysis). Please stain the first section with H&amp;E. The remaining sections should be unstained and <b>dried overnight at 37°</b>.</li><li>Please label each slide with date of sectioning, along with patient and block identifiers, and label the unstained sections sequentially (ie slides 2-10).</li></ul> |
| <b>2</b> | Please send the sample, a copy of this form and a copy of the original histopathology report in a padded bag to: | Molecular Pathology Department<br>Sullivan Nicolaides Pathology<br>134 Whitmore Street<br>Taringa QLD 4068  |

### 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 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

EGFR Mutation Test Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 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 or gefitinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
2	Private Payment**	For patients where the above eligibility criteria are not met, the private fee for EGFR mutation testing will be \$400.

RAS Test Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 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.
2	Private Payment**	For patients where the above eligibility criteria are not met, the private fee for RAS mutation testing will be \$310.

BRAF Mutation Test Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 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 under Pharmaceutical Benefits Scheme (PBS) are fulfilled.
2	Private Payment**	For patients where the above eligibility criteria are not met, the private fee for BRAF mutation testing will be \$230.

ALK Rearrangement Screen Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 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 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.
2	Private Payment**	For patients where the above eligibility criteria are not met (e.g. EGFR mutation positive and/or ALK IHC negative), ALK FISH can be carried out on request. The private fee for ALK FISH testing will be \$355.

\*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 February 1<sup>st</sup> 2015 and may be subject to change.

\*\*\*From July 1<sup>st</sup>, 2015

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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