

# SOMATIC MUTATION / ENDOPREDICT® TESTING REQUEST FORM

## INSTRUCTIONS FOR CLINICIANS

- 1 Please complete this page in FULL
- 2 FAX this form and a copy of the original histopathology report to: Fax: 03 9594 8571
- 3 For any enquiries, please phone: 03 9538 2259 or 1300 134 111

## COMPLETE THE FOLLOWING DETAILS:

Patient Details		Clinical Information	
Name: ..... Date of Birth: ..... Gender: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE Address: ..... Medicare No: ..... Health Fund: ..... 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: ..... Signature ..... Date: .....		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"/> Colorectal carcinoma <input type="checkbox"/> Non-small cell lung cancer <input type="checkbox"/> Metastatic Melanoma <input type="checkbox"/> Other .....	
<p>** Clinical stage and/or treatment status may determine eligibility for funding by Medicare or pharmaceutical access programs (see back of form). If this information is not indicated, the patient may be privately billed. Testing of samples that fall outside of the Medicare Eligibility Criteria will be billed privately to the patient.</p>			
Test Required			
Gene Target	Tick if Required	Medicare Criteria Met?	
<b>Colorectal Panel</b> (KRAS, NRAS, BRAF, PIK3CA, PTEN & AKT1)	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Lung Panel</b> (EGFR, KRAS, NRAS, BRAF, PIK3CA & AKT1) • All EGFR neg are ALK (IHC) tested, if over expressed ALK (FISH) MET Exon 14 skipping (RNA testing)* *Provided suitability of sample for testing.	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Melanoma Panel</b> (BRAF, NRAS, cKIT)	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>ALK (IHC)</b>	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Breast Panel</b> (PIK3CA, AKT1, ERBB2, TP53 & PTEN)	<input type="checkbox"/>	\$400.00	
<b>Comprehensive Gene Panel</b> (***) see over page for pay by phone) (Visit <a href="http://clinicalabs.com.au/cancer-services">clinicalabs.com.au/cancer-services</a> for a current list of genes included.)	<input type="checkbox"/>	\$750.00	
<b>EndoPredict</b> (***)see over page for pay by phone) (Multi gene assay for early stage breast cancer, ER+ HER2-)	<input type="checkbox"/>	\$2980.00	
Referring Clinician Details		Specimen to be tested ID	
Name: ..... Address: ..... Email: ..... Phone: ..... Fax: ..... Mobile: ..... Date requested: ..... Provider No: ..... Referring Clinician Signature: .....		SPECIMEN LOCATION: ..... LAB NO: ..... BLOCK NO: ..... Date of Collection: .....	
		Copy Doctor Details	
		Name: ..... Address: ..... Phone: .....	

# SOMATIC MUTATION / ENDOPREDICT® TESTING REQUEST FORM

## MEDICARE ELIGIBILITY 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 ( <i>EGFR</i> ) 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 <i>EGFR</i> mutation testing will be \$400.00

MET Exon 14 skipping Test Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 73436)	A test of tumour tissue from a patient diagnosed with locally advanced or metastatic non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician to determine if the requirements relating to MET proto-oncogene, receptor tyrosine kinase (MET) exon 14 skipping alterations (METex14sk) status for access to tepotinib are fulfilled under the Pharmaceutical Benefits Scheme.
2	Private Payment**	For patients where the above eligibility criteria are not met, the private fee for MET Exon 14 skipping testing will be \$400.00

KRAS Mutation 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 <i>KRAS</i> 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 <i>KRAS</i> mutation testing will be \$400.00

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 <i>BRAF</i> 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 <i>BRAF</i> mutation testing will be \$230.00

ALK Rearrangement Test Funding Information		Criteria
1	ALK IHC – Medicare Rebate/Private Payment **	<i>ALK</i> IHC will be available as a screening test for samples that return a negative <i>EGFR</i> mutation result. This test may be rebated by Medicare; a separate request will be required following <i>EGFR</i> reporting. If the test is not rebated by Medicare, a private fee of \$75 may be applied. If <i>ALK</i> over expression is detected by IHC, confirmation of an <i>ALK</i> rearrangement by <i>FISH</i> is recommended.
2	ALK (FISH) – Medicare Eligibility Criteria (Item 73341) (referred out test)	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 ( <i>ALK</i> ) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score > 0, and with documented absence of activating mutations of the epidermal growth factor receptor ( <i>EGFR</i> ) gene, requested by a specialist or consultant physician to determine if requirements relating to <i>ALK</i> gene rearrangement status for access to crizotinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.

### Pay over phone (call centre) Receipt # \_\_\_\_\_

Please call 1300 369 762 and select option 3 to make your payment over the phone. Lines are open Mon-Fri 9am-5pm (AEST).  
For patients in WA, please call (08) 9442 7646. Lines are open Mon-Fri 8am-4pm (AWST).

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

\*\* Private Payment Fees are correct as at 15/08/17 and may be subject to change.

PRIVACY NOTE: This 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 or to a person in the medical practice associated with this claim or as authorised/required by law.