

SOMATIC MUTATION/ENDOPREDICT® TESTING IN SOLID TUMOURS REQUEST FORM

INSTRUCTIONS FOR CLINICIANS:

- 1 Please complete this page in FULL
- 2 EMAIL this form and a copy of the original histopathology report to Mellab.Genetics@clinicallabs.com.au (alternatively FAX: 03 9594 8571)
- 3 For any enquiries, please phone: 03 9538 2259 or 1300 134 111

COMPLETE THE FOLLOWING DETAILS:

Patient Details

Name:
 Date of Birth:
 Gender: Male Female Mobile:
 Address:
 Medicare No:
 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:
 Signature: Date:

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: Colorectal carcinoma
 Non-small cell lung cancer
 Metastatic melanoma
 Other

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.

Test Required

Gene Target	Tick if Required	Medicare Criteria Met?	
Colorectal Panel (KRAS, NRAS, BRAF, PIK3CA, PTEN & AKT1)	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Lung Panels DNA Panel (EGFR, KRAS, BRAF, ERBB2, NRAS, PIK3CA, AKT1, MAP2K1, & MET) Comprehensive Lung Panel DNA & RNA (EGFR, KRAS, BRAF, ERBB2, NRAS, PIK3CA, AKT1, MAP2K1, MET, ALK, ROS1, RET, NTRK1, NTRK2, & NTRK3) RNA Fusion Panel (MET, ALK, ROS1, RET, NTRK1, NTRK2, & NTRK3) MET Exon 14 skipping (RNA testing) <i>Provided suitability of sample for testing.</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> YES <input type="checkbox"/> YES <input type="checkbox"/> YES <input type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> NO <input type="checkbox"/> NO <input type="checkbox"/> NO
Melanoma Panel (BRAF, NRAS, cKIT)	<input type="checkbox"/>	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Breast Panel (PIK3CA, AKT1, ERBB2, TP53 & PTEN)	<input type="checkbox"/>	Please see clinicallabs.com.au/cancer-services for current pricing.	
Comprehensive Somatic Gene Panel (see over page for pay by phone) (Visit clinicallabs.com.au/cancer-services for a current list of genes included.)	<input type="checkbox"/>	Please see clinicallabs.com.au/cancer-services for current pricing.	
EndoPredict (see over page for EndoPredict test pre-payment information and Medicare eligibility criteria) (Multi gene assay for female patients with early stage, newly diagnosed, primary breast cancer, ER+ HER2-)	<input type="checkbox"/>	<input type="checkbox"/> YES <input type="checkbox"/> NO Please see clinicallabs.com.au/endopredict for current pricing. A partial Medicare rebate of \$1,101.30 is available under item 73306. Please note: Patients are required to pay for the test in full upfront prior to claiming the rebate. See over page for payment information.	

Referring Clinician Details

Name:
 Address:
 Email:
 Phone: Fax:
 Mobile:
 Date Requested:
 Provider No:
 Referring Clinician Signature:

Specimen to be Tested ID

SPECIMEN LOCATION:
 LAB NO:
 BLOCK NO:
 Date of Collection:

Copy Doctor Details

 Name:
 Address:
 Phone:

EndoPredict in Breast Cancer Test Funding Information		Criteria
1	Medicare Eligibility Criteria (Item 73306)	<p>Gene expression profiling testing using EndoPredict, for the purpose of profiling gene expression in formalin-fixed, paraffin-embedded primary breast cancer tissue from core needle biopsy or surgical tumour sample to estimate the risk of distant recurrence of breast cancer within 10 years, if:</p> <ul style="list-style-type: none"> (a) the sample is from a new primary breast cancer, which is suitable for adjuvant chemotherapy; and (b) the sample has been determined to be oestrogen receptor positive and HER2 negative by IHC and ISH respectively on surgically removed tumour; and (c) the sample is axillary node negative or positive (up to 3 nodes) with a tumour size of at least 1 cm and no more than 5 cm determined by histopathology on surgically removed tumour; and (d) the sample has no evidence of distal metastasis; and (e) pre-testing of intermediate risk of distant metastases has shown that the tumour is defined by at least one of the following characteristics: (i) histopathological grade 2 or 3; (ii) one to 3 lymph nodes involved in metastatic disease (including micrometastases but not isolated tumour cells); and (f) the service is not administered for the purpose of altering treatment decisions <p>Applicable once per new primary breast cancer diagnosis for any particular patient</p>
2	Private Payment	Where patients do not meet the eligibility criteria, a private fee will be charged. Please see clinicallabs.com.au/endopredict for current pricing.

EndoPredict Test Pre-Payment

Patients are required to pay for EndoPredict prior to our laboratory conducting the test. Clinical Labs will contact your patient via SMS or phone call with payment instructions—please advise them to expect this communication in the days following the test request. After making the payment online, Clinical Labs will send your patient a receipt, which they can use to claim the partial Medicare rebate directly from Medicare. Please see clinicallabs.com.au/endopredict for current pricing.

EGFR Mutation in Lung Cancer 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	Where patients do not meet the eligibility criteria, a private fee will be charged. Please see clinicallabs.com.au/cancer-services for current pricing.

MET Exon 14 Skipping in Lung Cancer 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	Where patients do not meet the eligibility criteria, a private fee will be charged. Please see clinicallabs.com.au/cancer-services for current pricing.

KRAS Mutation in Colorectal Cancer 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: <ul style="list-style-type: none"> (a) The test is conducted for all clinically relevant mutations on KRAS exons 2, 3 and 4 and NRAS exons 2, 3 and for; or (b) A RAS mutation is found
2	Private Payment	Where patients do not meet the eligibility criteria, a private fee will be charged. Please see clinicallabs.com.au/cancer-services for current pricing.

BRAF Mutation in Melanoma 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	Where patients do not meet the eligibility criteria, a private fee will be charged. Please see clinicallabs.com.au/cancer-services for current pricing.

Pay by phone for Somatic Mutation Tests:

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. Patients who do not meet the Medicare eligibility criteria may be charged an out-of-pocket fee.

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.

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