AUSTIN HEALTH
SOLID TUMOUR MOLECULAR TEST REQUEST FORM

LABORATORY NUMBER 2741

PATIENT INFORMATION

Surname:	Sex: M / F
First Name:	DOB:
Address:	
Medicare Number:	
Private Health Fund:	
Health Fund Number:	

Clinical Notes: ***(Attach a copy of the relevant Pathology Report if reported outside Austin Pathology)***

Lab number of biopsy to be tested:_____

SAMPLE TYPE: ❑ Resection ❑ Biopsy ❑ Cell block

REQUESTING CLINICIAN / PATHOLOGIST

Name:	Referrer Signature: _____ Date:_____
Address:	*Note that you are also accepting full responsibility for this pathology request including informing the patient of potential unexpected or incidental findings as outlined below (see PLEASE NOTE).*
Provider No:	Report Copy (Print CLEARLY):
Tel:	Dr _____
Fax:	Address _____
	_____
	Tel _____
	Fax_____

SELECT TEST(S)

- ❑ **Colorectal carcinoma NGS (KRAS, NRAS, BRAF, PIK3CA, ERBB2, POLE)**
- ❑ **Colorectal carcinoma Idylla automated real-time PCR (KRAS, NRAS, BRAF)**
- ❑ **Endometrial carcinoma NGS (POLE, PIK3CA and TP53)– Not covered by MBS**
- ❑ **Gastrointestinal stromal tumour NGS (KIT, PDGFRA) – Not covered by MBS**
- ❑ **Gastro-oesophageal junction or stomach adenocarcinoma HER2 SISH**
- ❑ **Glioma NGS panel (EGFR, IDH1, IDH2, TERT promoter, H3F3A, BRAF, TP53, PIK3CA)**
- ❑ **Glioma 1p/19q FISH**
- ❑ **Melanoma NGS (NRAS, BRAF, KIT, TERT promoter)**
- ❑ **Melanoma Idylla automated real-time PCR (BRAF)**
- ❑ **Non-small cell lung carcinoma NGS (EGFR, KRAS, BRAF, PIK3CA, ERBB2, MET, ALK, ROS1) (tick/select to include TP53 ❑)**
- ❑ **Non-small cell lung carcinoma EGFR cobas real-time PCR**
- ❑ **Non-small cell lung carcinoma EGFR Idylla automated real-time PCR**
- ❑ **Non-small cell lung carcinoma ALK FISH**
- ❑ **Ovarian granulosa cell tumour NGS (FOXL2)**
- ❑ **Tumour not otherwise specified above; full NGS panel – Not covered by MBS**
- ❑ **Tumour not otherwise specified above HER2 SISH**
- ❑ **Other specific genes on NGS panel (please list:_____) – Not covered by MBS**

PLEASE NOTE: Some patient samples referred for NGS (next generation sequencing) may fail tumour purity, DNA quality or adequacy criteria. In these circumstances relevant single gene testing with PCR (eg. Idylla or Cobas) may be attempted at the discretion of the molecular laboratory however the laboratory may also recommend that repeat biopsy be considered in some circumstances. Additional mutations/variants detected in the Archer 26 gene NGS panel, apart from those selected above may be reported at the pathologist's discretion or if specifically requested by the treating team (see full list of genes in the test description below**. This NGS panel cannot distinguish between somatic and germline mutations. In some rare instances germline testing may need to be considered in order to clarify the significance of some detected variants/mutations. This would require referral to a familial cancer clinic.** Note also that only ALK and ROS1 non-structural variants are detected by the Austin NGS assay.

Eligible criteria for MBS Rebate

❑ Colorectal cancer (stage IV) to determine RAS gene mutation status for access to cetuximab or panitumumab under the PBS. (item 73338)

❑ Gastro-oesophageal junction or stomach adenocarcinoma with evidence of HER2 overexpression by IHC (2+ or 3+) on the same tumour sample. Requested by or on the advice of a consultant physician managing the patient treatment to determine requirements for access to trastuzumab under PBS. (item 73342)

❑ Glial neoplasm for detection of chromosome 1p/19q co-deletion; and is for a patient with clinical or laboratory evidence, including morphological features, of a glial neoplasm with probable oligodendroglial component. Available once per lifetime. (item 73371).

❑ Glial neoplasm, negative for IDH1 (R132H) immunohistochemistry, for evaluation of IDH1/2 variant status. Available once per lifetime. (item 73372).

❑ Melanoma cutaneous (stage III or IV) to determine BRAF V600 mutation status for access to dabrafenib, vemurafenib or encorafenib under the PBS. (item 73336)

❑ Non-small cell lung carcinoma (non-squamous histology or histology not otherwise specified), to determine if the requirements relating to EGFR gene status for access to an EGFR TKI or pembrolizumab listed under the PBS are fulfilled. (item 73337)

❑ Non-small cell lung carcinoma (stage IIIB or IV), new sample following progression after treatment with an EGFR tyrosine kinase inhibitor. To determine EGFR T790M status for access to osimertinib (item 73351).

❑ Non-small cell lung carcinoma, locally advanced or metastatic, non-squamous histology or histology not otherwise specified, with ALK positive IHC and absence of activating EGFR mutation. (item 73341)

❑ Ovarian tumour with morphological features of granulosa cell tumour requiring detection of FOXL2 c.402 C>G status. (item 73377)

SELECT PAYMENT OPTION

❑ **Bill Referring Hospital/Pathology Provider Direct (<u>Also applicable to Austin Hospital Inpatients</u>)**

❑ **Bill Medicare** *(Patient must sign. Non-rebatable components will be billed to the pathology provider unless otherwise specified)*

If a test is being requested through Medicare the patient's hospital status at the time of the service or when the specimen was collected is required:

- ❑ Private Patient in a private hospital or approved day hospital
- ❑ Private Patient in a recognised hospital
- ❑ Public Patient in a recognised hospital
- ❑ Outpatient in a recognised hospital

Patient's Signature: _____ Date: _____

Medicare Assignment Form (Section 20A of the HIA 1973)
I offer to assign my right to benefits to the approved practitioner who will render the requested pathology service(s) and any eligible pathological determinable service(s) established necessary by the practitioner.

PROVIDE THE FOLLOWING:

- This completed form
- Appropriate sample (Please see requirements below)
- Copy of the Pathology Test Report (if reported outside Austin Pathology)

SEND TO:

Austin Pathology, Anatomical Pathology Laboratory
Austin Health; Level 6 HSB
145 Studley Road, Heidelberg, VIC 3084
Fax: (03) 9496 3437 Tel: (03) 9496 5285

Your doctor recommended that you use Austin Pathology. You are free to choose your own pathology provider.
However, if your doctor has specified a particular pathologist on clinical grounds, a Medicare rebate will only be payable if that pathologist performs the service.
You should discuss this with your doctor.
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 provision 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.

SAMPLE REQUIREMENTS (for pathology samples external to Austin Pathology):

- **Solid Tumour NGS Panel, Idylla and cobas PCR**
  1x H&E stained section containing at least 10% tumour nuclei
  6x unstained 5µm sections on uncoated slides

- **ALK FISH or HER2 SISH**
  1x H&E stained section
  2x unstained 4µm sections on coated slides (ideally TRAJAN series 2 slides)

- **1p/19q FISH**
  1x H&E stained section
  4x unstained 4µm sections on coated slides (ideally TRAJAN series 2 slides)

TEST DETAILS:

- **Archer 26 Gene NGS Panel:**

AKT1 (NM_005163.2; exons 3,6), **ALK** (NM_004304.4, exons 21, 22, 23, 24, 25), **BRAF** (NM_004333.4; exons 8, 11, 12, 13, 14, 15), **EGFR** (NM_005228.4; exons 2, 3, 6, 7, 8, 9, 15, 18, 19, 20, 21), **ERBB2** (NM_004448.3; exons 10, 19, 20, 21, 24), **FOXL2** (NM_023067.3; exon 1), **GNA11** (NM_002067.4; exon 5), **GNAQ** (NM_002072.4, exons 4, 5), **GNAS** (NM_000516.5; exons 6, 7, 8, 9), **H3F3A** (NM_002107.4, exon 2), **HRAS** (NM_002107.4; exons 2, 3), **IDH1** (NM_005896.3; exons 3, 4), **IDH2** (NM_002168.3; exon 4), **KIT** (NM_000222.2; exons 2, 8, 9, 10, 11, 13, 14, 15, 17, 18), **KRAS** (NM_033360.3; exons 2, 3, 4, 5), **MAP2K1** (NM_002755.3; exons 2, 3, 5, 6, 7), **MET** (NM_000245.3; exons 2, 11, 14, 16, 19, 21), **NRAS** (NM_002524.4; exons 2, 3, 4, 5), **PDGFRA** (NM_006206.5; exons 12, 14, 15, 18, 23), **PIK3CA** (NM_006218.3; exons 2, 5, 7, 8, 10, 12, 14, 19, 20, 21), **POLD1** (NM_002691.3; exons 8, 9, 10, 11, 12), **POLE** (NM_006231.4; exons 9, 10, 11, 12, 13, 14), **RET** (NM_020975.4; exons 10, 11, 13, 14, 15, 16), **ROS1** (NM_002944.2; exons 36, 37, 38, 39, 40, 41, 42), **TERT** (NM_198253.2; promoter), **TP53** (NM_000546.5; exons 2, 3, 4, 5, 6, 7, 8, 9, 10, 11).

- **EGFR Mutations Detected with Idylla PCR:** G719A, G719C, G719S, T790M, S768I, L858R, L861Q. exon 19 deletions and exon 20 insertions (refer also to technical sheet for details https://www.biocartis.com/sites/default/files/2019-09/techsheet-egfr-ivd-2019.pdf).
- **EGFR Mutations Detected with cobas EGFR PCR:** G719X substitution mutations in exon 18, deletion mutations in exon 19, T790M and S768I, substitution mutations in exon 20, insertion mutations in exon 20, and L858R and L861Q substitution mutations in exon 21.
- **KRAS Mutations Detected with Idylla PCR:** G12C, G12R, G12S, G12A, G12D, G12V, G13D, A59E, A59G, A59T, Q61K, Q61L, Q61R, Q61H, K117N, A146P, A146T, A146V.
- **NRAS Mutations Detected with Idylla PCR:** G12C, G12S, G12D, G12A, G12V, G13D, G13V, G13R, A59T, Q61K, Q61L, Q61R, Q61H, K117N, A146T, A146V
- **BRAF Mutations Detected with Idylla PCR:** V600E (c.1799T>A; c.1799_1800delinsAA), V600D, V600K, V600R, V600M

For further information, please contact Austin Pathology, Anatomical Pathology on (03) 9496 5285