Molecular Oncology Test Requisition Form

M Diagnostics
POWERED BY MIRXES

PATIENT INFORMATION (or paste Patient Label)

Name: Gender: ☐F ☐M

Date of birth: Identity No.:

Address:

Ethnicity: ☐Chinese ☐Malay ☐Indian
☐Thai ☐Others:

CLINIC INFORMATION (or stamp)

Clinic name:
☐ Bill to Clinic ☐ Bill to Parkway Lab Services
Address:

SG HCI Code:
Email:
Phone:

PATIENT CLINICAL INFORMATION

Primary cancer:

☐ Non-Small Cell Lung Cancer (NSCLC)
☐ Colorectal Cancer (CRC)
☐ Breast Cancer
☐ Brain Cancer
☐ Gastrointestinal Stromal Tumor (GIST)
☐ Cholangiocarcinoma
☐ Metastatic Cancer of Unknown Primary (mCUP)
☐ Other: ***please specify***

_____

Cancer stage: ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Supporting documents:

☐ Patient Informed Consent obtained. *Please attach.*
☐ (Optional) IHC/FISH/molecular reports.

Relevant History/ Findings/ treatment:

☐ No treatment received.
☐ Treatment received:

1st line:
☐ Chemotherapy
☐ Targeted therapy
☐ Immunotherapy
☐ Hormone therapy

2nd line:
☐ Chemotherapy
☐ Targeted therapy
☐ Immunotherapy
☐ Hormone therapy

Insufficient/inaccurate clinical information may affect clinical interpretation/recommendation.

TEST INFORMATION

☐ 10000666 **APEX Tissue 50 Genes**
(Mutations/amplifications/fusions in 50 genes)

☐ 10000501 **COMPASS Tissue 1021 Genes**
(Mutations/amplifications/fusions/MSI/TMB*)*
**Ongoing validation*

ORDERING PHYSICIAN (or stamp)
Name:
MCR:

Report to be sent to:
☐ Email:

_____

☐ Histopathology laboratory email:

_____

Physician signature

Date: _____

Samples From Pathology Lab

☐ Tissue Memo from Pathology Lab accompanies the FFPE samples.

Check:
- 2 Patient identifiers are present
- 1 matching H&E slide with tumour region marked out (≥ 30% tumor cellularity)
- Histopathology report attached
- 10 unstained sections (Tumor area ≥ 25 mm^2) or 15 unstained sections (Tumor area 5 - 25 mm^2) of 5 - 10 µm thickness on uncoated/uncharged slides
- Idylla MSI test: Additional 2 unstained sections (Tumor area ≥ 25 mm^2) of 5 - 10 µm thickness

☐ I declare that the FFPE sections and/or thickness do not meet the specimen requirements. Please proceed with nucleic acid extraction and inform us if sample amount is insufficient.

For MDX Lab Use Only

Accession ID:
Order ID:
Notes:

Section _____ slides
Date and Time Received: _____
Received By: _____
Verified By: _____

Slide Review: _____

M Diagnostics POWERED BY MiRXES	Patient Information (or paste patient ID label) Name: NRIC/Passport number: DOB: Race:
INFORMED CONSENT FORM FOR GENETICS/GENOMICS TESTING	

Purpose, Potential Risks and Limitations

1. Biological specimen(s) will be collected from you and sent to M Diagnostics by your healthcare professional for genetics/genomics testing at our laboratory.
2. The purpose of this test is to ascertain whether there are any specific genetic/genomic changes (mutations) in your biological specimen(s). The personalized information provided by the test may assist you and your doctor in determining a suitable treatment and management for your condition. However, the mutations identified by the test does not guarantee treatment success which depends on multiple factors, including but not limited to, type and extent of the disease, individual profile, and the type of treatment(s) received.
3. This test has been developed for detecting specific genetic changes, and it is possible that some mutations or genomic alterations may not be detected with the technology employed by this test.
4. The test is intended for detecting somatic mutations only, it should not be used to infer or exclude germline (heritable) mutations.
5. In certain circumstances (e.g., inadequate biological specimen(s)), the amount and/or quality of the DNA and/or RNA extracted from your specimen(s) may not be sufficient for processing in our laboratory. This might cause inaccurate results.
6. The decision to undergo this test is entirely voluntary, and your consent is required before we can proceed with the test. You should take the time to ask your physician or genetic counsellor any questions you may have about the test so that you can make an informed decision.
7. You may withdraw your consent to undergo the test at any time or postpone the disclosure of the test results to you or your physician by providing notice in writing to M Diagnostics. However, any amounts paid will not be refunded and M Diagnostics shall be entitled to charge you for any services already performed prior to being informed of the withdrawal of your consent.

Results and Implications

8. Your test results are strictly private and confidential. Your test results will only be reported to the referring physician who is named on the requisition form. Your test results will form part of your medical records and will be protected as required under Singapore law. M Diagnostics will have in place the necessary safeguards to ensure compliance with its obligations under the Personal Data Protection Act 2012, Private Hospitals and Medical Clinics Act and/or Healthcare Services Act.
9. Personal Data refers to information that relates to you and can be used to identify you. M Diagnostics may collect your Personal Data, which includes but is not limited to name, date of birth, race, sex, NRIC, passport numbers, any medical and health records, and all information contained within and accompanying the completed order form. Genetics/genomics data derived from your test results that can be used to identify you will also become part of your Personal Data.
10. Your Personal Data will be kept confidential in compliance with Singapore laws and regulations.
11. M Diagnostics may collect, use, disclose, process, retain and transfer your Personal Data in compliance with applicable Singapore laws and regulations, to fulfil the following purposes:
    i. Provide you with services, including diagnostic healthcare and customer services for the purposes of conducting the test(s), and/or provision of medical treatment and management; and/or
    ii. To allow M Diagnostics and its affiliates and service providers to discharge their legal obligations under applicable Singapore laws and regulations.
12. Your genetics/genomics data will be retained by M Diagnostics and will be used for the purposes of conducting the test(s) and/or provision of medical treatment and management and/or discharging its obligations under applicable local laws. Save for the purposes set out in the preceding paragraph, the disclosure of confidential health information revealed by

the test to any other third party other than your referring physician, except as otherwise required by law, is at your sole discretion.

13. There is a possibility of secondary findings, which are additional results that are intended to be sought by the referring physician but are not the primary purpose of the test.
14. There is also a low possibility of incidental findings, which are results that are not related to the initial reason for which the test was ordered.
15. Some findings are not medically actionable (i.e., do not guide treatment or have therapeutic implication). In recognition of this, M Diagnostics will not report findings, unless (i) the mutation is within the test gene panel ordered by your physician and/or (ii) the laboratory has sufficient and clear evidence of a mutation with clinical utility.
16. Unused biological specimen(s) (if any) will be stored in accordance with M Diagnostics' sample storage and data protection protocols for a reasonable period in accordance with applicable Singapore laws and regulations.
17. The remaining unused de-identified biological specimen(s) may be used at the sole discretion of M Diagnostics and its affiliates and service providers for purposes of maintaining clinical operations in M Diagnostics including validation, process development, product development, medical education and/or quality control.

Patient or Guardian or Legal Representative

I have read and understood the above information. I acknowledge that the nature, purpose, limitations, benefits and potential risks of the genetics/genomics testing have been explained to me and that my questions and concerns raised to my doctor have been answered to my satisfaction. I therefore consent to the selected genetics/genomics testing on the terms as set out above in this consent form.

Patient's Name: _____ NRIC/Passport number: _____

Signature: _____ Date: _____

Guardian / Legal Representative's (*delete whichever not applicable) Name: _____

NRIC/Passport number: _____

Signature: _____ Date: _____

Witness (if applicable):

Witness' Name: _____NRIC/Passport number: _____

Signature: _____ Date: _____

Referring Physician

I, _____ (Physician's name) have explained the above and answered the patient's / guardian's / legal representative's questions to his / her / their satisfaction.

Signature: _____ MCR No: _____ Date: _____

Tissue Submission Memo Form

M Diagnostics
POWERED BY MiRXES

FOR CLINIC TO FILL IN

Requesting Date: Ordering Clinic Information/Stamp: Ordering Physician Name/Stamp:	Patient Information/Sticker Test Ordered: ☐ APEX Tissue 50 Genes ☐ COMPASS Tissue 1021 Genes ☐ Idylla MSI Test

FOR PATHOLOGY LAB TO FILL IN

Dear Pathology Lab,

Please kindly prepare the FFPE slides according to the requirements below. Thank you.

- **1 H&E stained slide** with tumour region 5-25 mm² marked out, and tumour cellularity ≥30%;
- **APEX/COMPASS: Matching 10 unstained sections** (Tumor area > 25 mm²) or **15 unstained sections** (Tumor area 5 - 25 mm²) of 5 µm thickness on uncoated/uncharged slides.
- **MSI:** Total tumor area 50mm² [**Matching 2 unstained sections** of tumor area ≥25mm² or max up to **Matching 5 unstained slides** of tumor area ≥ 10mm²] of 5 µm thickness on uncoated/uncharged slides
- Histology report must accompany the slides.

To be completed by Pathology Lab

Specimen ID	FFPE Block ID _____
Original specimen **COLLECTION** date	D D / M M M / Y Y Y Y
COLLECTION time	H H : M M HR 24-hr time ☐No time info available
Specimen source (eg. Left lung)	
1 H&E **stained** slide	☐ Tumour region of interest (ROI) is 5-25 mm². ☐ Tumour region of interest (ROI) is > 25 mm². ☐ ≥30% tumour cellularity in ROI, specify: _____ %
Unstained slides	No. of slides: ___ slides Thickness: ___ µm **(≥5µm required)**
Slides **SECTIONED** date	D D / M M M / Y Y Y Y
Histology report	☐ Histology report attached

Please send the slides to the Ordering Clinic once the slides are prepared.

Please call M Dx lab at +65-6950 3210 if you need any clarification.