siParadigm diagnostic informatics
888-599-5227 / 201-599-9044
USA 201-599-9066
888-890-4774 (Toll-free fax)
PR 888-782-5430
866-369-4114

Requisition Number: _____
Pick-up Confirmation # _____

☐ RUSH
☐ Call Results
☐ Need Results by: ____ / ____ / ____

SOLID TUMOR REQUISITION FORM

PATIENT INFORMATION (REQUIRED)

Name Last _____ First _____

Gender ☐ Male ☐ Female Date of Birth ____ / ____ / ____ (mm / dd / yyyy)

Street _____

City _____ State _____ ZIP _____

MRN / Patient ID# _____

Phone# _____

SPECIMEN INFORMATION-TISSUE BIOPSY (REQUIRED)

Specimen ID _____ Block ID _____

Retrieval date from archive ____ / ____ / ____ (mm / dd / yyyy) Sent date ____ / ____ / ____ (mm / dd / yyyy)

Collection date ____ / ____ / ____ (mm / dd / yyyy) Time _____ ☐ AM ☐ PM

☐ Primary ☐ Metastatic If Metastatic, List primary _____

☐ Slides # _____ Unstained _____ Stained _____ ☐ H&E _____

☐ Paraffin Block (S) # _____

☐ Choose best block.

FFPE block, or 4-10 of unstained slides, 5-micron thickness, shipped at room temperature. Minimum tissue area: at least 5 mm x 5 mm (preferred but not essential).

For packaging conditions, please check our website: https://www.siparadigm.com/physician-support/specimen-requirements

SPECIMEN INFORMATION-LIQUID BIOPSY (OPTIONAL)

Specimen ID _____

Collection date ____ / ____ / ____ (mm / dd / yyyy) Time _____ ☐ AM ☐ PM

Sent date ____ / ____ / ____ (mm / dd / yyyy)

PAXgene (blue top) specimen collection tubes and DeepSight collection kits must be utilized. Preferred minimum blood volume: >20-30 ml. For additional details, please visit our website.

REQUIRED *Pathology report and clinical notes.*

PHYSICIAN INFORMATION (REQUIRED)

Referring MD _____

Attending MD _____

Account Information _____

BILLING INFORMATION (BOTH SIDES REQUIRED)

☐ Insurance
☐ Client
☐ Patient

SPECIMEN COLLECTION LOCATION
☐ Non-hospital/office patient
☐ Out-patient hospital
☐ In-patient hospital Discharge Date ____ / ____ / ____ (mm / dd / yyyy)
☐ Independent ambulatory clinic/surgical center

Please attach an Advance Beneficiary Notice (ABN) for all Medicare patients **Available at www.siparadigm.com**

ICD-10 Code (REQUIRED)

Notes: _____

MOBILE PHLEBOTOMY REQUEST

Patient Phone (mobile preferred): _____

Patient Email (optional): _____

Patient Home Address: _____

City, ST, ZIP: _____

siParadigm Liquid Biopsy collection and shipping kit was provided to the patient. Please fax this completed requisition, pathology report, and insurance information to 888-890-4774 | By completing this section, Client represents it has obtained patient's consent to be contacted by third-party service.

THIRD-PARTY SPECIMEN LOCATION (REQUIRED)

Hospital/Facility _____ Phone # _____

Address _____

Fax # _____

Attach clinical notes, patient information, and insurance card (REQUIRED)

ORGANS (REQUIRED)

☐ Bladder	☐ Gastric/GIST	☐ Pancreatic
☐ Brain	☐ Hepatocellular and Biliary tract	☐ Prostate
☐ Breast	☐ Head and Neck	☐ Thyroid
☐ Colorectal	☐ Lung	☐ Unknown Origin
☐ Endometrial	☐ Skin	☐ Others _____
☐ Esophageal	☐ Ovarian	

ORGAN-BASED SPECIFIC TESTS (REQUIRED)

See website www.siparadigm.com/compendium/ for detailed panel content

Note: Any additional genomic alterations outside the specific gene list with strong clinical significance will also be reported.

☐ Multi-Omics

Includes NGS Comprehensive Panel, TMB, MSI, and HRD*, plus all required FISH and/or IHC studies as determined by our pathologists in light of NCCN guidelines.

PD-L1 (22C3 - KEYTRUDA®) (CDx) will be performed by default unless an alternative is specifically requested from below:

☐ PD-L1 (28-8 - OPDIVO®), FDA
☐ PD-L1 (SP142 - TECENTRIQ®), FDA
☐ PD-L1 (SP263 - IMFINZI®), FDA

INDIVIDUAL TESTS

(If you select Muti-Omics, do not select INDIVIDUAL TEST below)

Molecular Tests

☐ Focused NGS panel
☐ Comprehensive NGS panel +TMB+MSI+HRD*
☐ *HRD for selected organs: breast, pancreatic, prostatic, ovarian and cancers of unknown primary.
☐ DPYD Genotyping _____ PGx
☐ Others _____

IHC Tests

☐ ALK	☐ HER-2/neu
☐ BRAF	☐ Ki-67
☐ c-MET	☐ MMR
☐ CLDN18	☐ PD-L1 (22C3)
☐ ER	☐ PR
☐ FOLR1	☐ ROS1

☐ Others _____

FISH Tests

☐ 1p36/19q13	☐ RET
☐ ALK	☐ ROS1
☐ HER-2/neu	
☐ MET/CEN7	
☐ PTEN/CEN10	

☐ Others _____

ADDITIONAL TISSUE TESTING OPTIONS

☐ Concurrent Tissue and Liquid Testing

PHYSICIAN SIGNATURE (REQUIRED)

Confirmation of Informed Consent & Statement of Medical Necessity: I affirm each of the following: 1) Testing is medically necessary for the diagnosis of a disease or syndrome. 2) The results will be used in the patient's medical management and treatment decisions. 3) The person listed as the ordering physician is authorized by law to order the test(s) requested herein. 4) I have provided genetic testing information to the patient and the patient has consented to such testing (if applicable).

I am certified to order the test(s) listed above, such that these test(s) are medically necessary and I have obtained informed consent for the requested test(s) when pertinent.

☐ For DPYD Pharmacogenomics (fluoropyrimidine) testing: I confirm that the patient has been informed of the germline nature of this test and has received appropriate counseling regarding the Genetic Information Nondiscrimination Act (GINA, Pub. L. 110-233) and applicable state genetic privacy regulations, including the New Jersey Genetic Privacy Act (N.J.S.A. 10:5-43).

Signature *(MANDATORY FOR TESTING) _____ **Date** _____

PATIENT SIGNATURE: (REQUIRED)

I, the undersigned, authorize the holding facility to release my pathology material (paraffin blocks, slides, pathology report, etc.) to siParadigm Diagnostic Informatics Laboratory for additional testing.

Patient's signature: _____

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TEST DESCRIPTIONS: (COMPREHENSIVE NGS AND OTHER BIOMARKERS ANALYSED BY TUMOR TYPE)

*Gene is also included in the RNA gene-fusion panel.

BLADDER CANCERS Bladder Multi-Omics™ 37 Genes MSI and TMB

*ALK, AKT1, *AR, ATM, BAP1, *BRAF, BRCA1, BRCA2, CDKN2A, CCND1, CREBBP, *EGFR, ERBB2, ERBB3, ERBB4, FANCA, FBXW7, *FGFR1, *FGFR2, *FGFR3, HRAS, KDM6A, KMT2A, KMT2C, KMT2D, KRAS, MAP2K1, NF1, NRAS, PIK3CA, PTEN, RB1, *RET, SMARCA4, STAG2, TERT, TP53.

IHC Tests: MMR, PD-L1 (22C3).

BRAIN/CNS CANCERS Brain Multi-Omics™ 34 Genes MSI and TMB

APC, ATRX, BRAF, CDK4, CTNNB1, CDKN2A, CDKN2B, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, H3F3A, HRAS, IDH1, IDH2, NRG1, KIT, KRAS, MET, MTOR, MYCN, MYD88, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, TP53, TSC1,TSC2.

FISH Tests: 1p36/19q13, PTEN/CEN10. **IHC Tests:** MMR, PD-L1 (22C3).

BREAST CANCERS Breast Multi-Omics™ 43 Genes TMB, MSI and HRD for PARPi efficacy

*AR, AKT1, ATM, *BRAF, BRCA1, BRCA2, CCNE1, CDH1, CDK12, CHEK1, CHEK2, *EGFR, ERBB2, ERBB3, ERBB4, *ESR1, FANCA, FANCL, *FGFR1, *FGFR2, *FGFR3, KRAS, MLH1, MRE11A, MSH2, MSH6, MUTYH, MYC, NBN, *NTRK1, *NTRK2, *NTRK3, PALB2, PIK3CA, PMS2, PTEN, RAD50, RAD51, RB1, *RET, STK11, TERT, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** ER, HER-2/neu, Ki-67, MMR, PD-L1 (22C3), PR.

COLORECTAL CANCERS Colorectal Multi-Omics™ 38 Genes MSI and TMB

AKT1, APC, ATM, AXIN2, *BRAF, CHEK1, CHEK2, ERBB2, ERBB3, ERBB4, *EGFR, FANCA, FBXW7, HRAS, KRAS, MAP2K1, *MET, MLH1, MSH2, MSH6, MUTYH, *NTRK1, *NTRK2, *NTRK3, NRAS, PIK3CA, PMS2, POLD1, POLE, PTEN, *RET, SMAD4, STK11, TERT, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** BRAF, MMR, PD-L1 (22C3).

ENDOMETRIAL CANCERS Endometrial Multi-Omics™ 39 Genes MSI and TMB

AKT1, APC, ARID1A, ARID2, ATM, *BRAF, BRCA1, BRCA2, CDK12, CDK4, CHEK2, CTNNB1, EPCAM, ERBB2, *ESR1, FBXW7, KRAS, MDM2, MLH1, MSH2, MSH6, NBN, NRAS, *NTRK1, *NTRK2, *NTRK3, PALB2, PIK3CA, PMS2, POLE, POLD1, PPP2R1A, PTEN, *RET, RNF43, SAMD4, STK11, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** BRAF, MMR, PD-L1 (22C3).

ESOPHAGEAL CANCERS Esophagus Multi-Omics™ 34 Genes MSI and TMB

AKT1, *AR, ARAF, ARID1A, *BRAF, CDK12, CDK6, CCNE1, CCND1, CDKN2A, *EGFR, ERBB2, ERBB3, *FGFR1, *FGFR2, *FGFR3, KIT, KRAS, MCL1, MAP2K1, *MET, MLH1, MSH2, MSH6, MTOR, *NTRK1, *NTRK2, *NTRK3, *NRG1, NRAS, PMS2, PIK3CA, *RET, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** HER-2/neu, MMR, PD-L1 (22C3).

GASTRIC/GIST CANCERS Gastric/GIST Multi-Omics™ 40 Genes MSI and TMB

*AR, APC, ATM, *BRAF, CD274, CDH1, CCNE1, CTNNB1, ERBB2, ERBB4, *EGFR, FBXW7.*FGFR1, *FGFR2, *FGFR3, KRAS, *MET, MDM2, MEN1, MLH1, MSH2, MSH6, NF1, *NRG1, NRAS, *NTRK1, *NTRK2, *NTRK3, PDGFRA, PIK3CA, PMS2, PTEN, *RET, RB1, SAMD4, SDHA, SDHB, SDHC, SDHD, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** HER-2/neu, MMR, PD-L1 (22C3).

HEAD AND NECK CANCERS Head and Neck Multi-Omics™ 34 Genes MSI and TMB

*AR, ATM, ARAF, *BRAF, CD274, CDKN2A, *EGFR, ERBB2, ERBB3, *FGFR1, *FGFR2, *FGFR3, HRAS, IDH1, IDH2, KRAS, *MET, MTOR, MLH1, MSH2, MSH6, NOTCH1, NRAS, *NRG1, *NTRK1, *NTRK2, *NTRK3, PIK3CA, PMS2, PTEN, *RSPO2,*RET, TERT, TP53.

IHC Tests: MMR, PD-L1 (22C3).

HEPATOCELLULAR & BILIARY TRACT CANCERS Liver Multi-Omics™ 43 Genes MSI and TMB

AKT1, ARAF, ARID1A, ATM, *BRAF, BAP1, BRCA1, BRCA2, CTNNB1, *EGFR, ERBB2, ERBB3, ERBB4, *ESR1, *FGFR1, *FGFR2, *FGFR3, FGFR4, GNA11, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, *MET, MLH1, MSH2, MSH6, MTOR, NRAS, *NRG1, *NTRK1, *NTRK2, *NTRK3, PALB2, PIK3CA, PMS2, PTEN, *RET, RAD51D, TERT, TP53.

IHC Tests: MMR, PD-L1 (22C3).

LUNG CANCERS Lung Multi-Omics™ 38 Genes MSI and TMB

AKT1, *ALK, ARAF, ATM, *BRAF, ARID2, CCND1, CD274, CDK4, CDKN2A, CHEK2, ERBB2, ERBB3, *EGFR, *FGFR1, *FGFR2, *FGFR3, HRAS, KEAP1, KRAS, MAP2K1, *MET, MYCL, MTOR, NFE2L2, *NRG1, NRAS, *NTRK1, *NTRK2, *NTRK3, *NUTM1, PIK3CA, *RET, RICTOR, *ROS1, RB1, STK11, TP53.

FISH Tests: ALK, MET/CEN7, RET, ROS1. **IHC Tests:** ALK, BRAF, MMR, PD-L1 (22C3), ROS1.

MELANOMA Melanoma Multi-Omics™ 37 Genes MSI and TMB

APC, ARID2, ATM, *BRAF, BAP1, BRCA2, CCND1, CDK4, CDKN2A, CHEK2, CTNNB1, EIF1AX, FBXW7, GNA11, GNAQ, GNAS, IDH1, KIT, MAP2K1, MAP2K2, NF1, NRAS, *NTRK1, *NTRK2, *NTRK3, PALB2, PDGFRA, PIK3CA, PTEN, RB1, *RET, *ROS1, SF3B1, SMO, SRC, TERT, TP53.

IHC Tests: BRAF,MMR, PD-L1 (22C3).

OVARIAN CANCERS Ovarian Multi-Omics™ 43 Genes TMB, MSI and HRD for PARPi efficacy

AKT1, ARAF, ATM, ARID1A, BARD1, *BRAF, BRCA1, BRCA2, BRIP1, CCNE1, CDK12, CHEK1, CHEK2, CTNNB1, ERBB2, *ESR1, FANCA, FANCL, *FGFR1, *FGFR2, *FGFR3, FOLR1, KIT, MAP2K1, *MET, MLH1, MSH2, MSH6, MTOR, *NTRK1, *NTRK2, *NTRK3, NF1, *NRG1, PALB2, PIK3CA, PMS2, PPP2R1A, PTEN, RAD51C, RAD51D, RAD54L, RET, TP53.

FISH Tests: HER-2/neu. **IHC Tests:** FOLR1, MMR, PD-L1 (22C3).

PANCREATIC CANCERS Pancreas Multi-Omics™ 29 Genes TMB, MSI and HRD for PARPi efficacy

*ALK, ATM, *BRAF, BRCA1, BRCA2, CDKN2A, ERBB2, *FGFR1, *FGFR2, *FGFR3, FANCL, IDH1, IDH2, KRAS, MLH1, MSH2, MSH6, *NRG1, *NTRK1, *NTRK2, *NTRK3, PALB2, PMS2, PIK3CA, *RET, *ROS1, SMAD4, STK11, TP53.

IHC Tests: MMR, PD-L1 (22C3).

PROSTATE CANCERS Prostate Multi-Omics™ 42 Genes TMB, MSI and HRD for PARPi efficacy

AKT1, *AR, ARID1A, ATM, ATR, BARD1, *BRAF, BRCA1, BRCA2, BRIP1, CCND1, CDK12, CHEK1, CHEK2, CTNNB1, FANCA, FANCD2, FANCL, HRAS, IDH1, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, *NTRK1, *NTRK2, *NTRK3, PALB2, PIK3CA, PMS2, PPP2R2A, PTEN, RAD51B, RAD51C, RAD51D, RB1, *RET, SPOP, TERT, TP53.

FISH Tests: PTEN/CEN10. **IHC Tests:** MMR, PD-L1 (22C3).

THYROID CANCERS Thyroid Multi-Omics™ 28 Genes MSI and TMB

*ALK, AKT1, *BRAF, BRCA1, BRCA2, CDKN2A, CTNNB1, *FGFR1, *FGFR2, *FGFR3, HRAS, IDH1, IDH2, KRAS, MET, *NTRK1, *NTRK2, *NTRK3, NRAS, *RET, MLH1, MSH2, MSH6, PMS2, PALB2, PIK3CA, PTEN, TERT.

IHC Tests: BRAF, MMR, PD-L1 (22C3).

TUMOR OF UNKNOWN ORIGIN AND OTHERS Unknown Origin Multi-Omics™ 48 Genes MSI and TMB

AKT1, ALK, AR, ARAF, BRAF, CD274, CDK4, CDKN2A, CHEK2, CTNNB1, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, NRG1, NTRK1, NTRK2, NTRK3, NUTM1, PDGFRA, PIK3CA, PTEN, RAF1, RET, ROS1, SMO, TP53

IHC Tests: MMR, PD-L1 (22C3).

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FOCUSED NGS PANEL

DNA hotspots					CNVs		RNA level gene fusions		Intra-genetic fusions
AKT1	CHEK2	FGFR3	KIT	NTRK3	ALK	FGFR3	ALK	NTRK2	AR-V7
AKT2	CTNNB1	FGFR4	KRAS	PDGFRA	AR	KRAS	BRAF	NTRK3	EGFR VIII
AKT3	EGFR	FLT3	MAP2K1	PIK3CA	CD274	MET	ESR1	NUTM1	MET exon 14 skipping
ALK	ERBB2	GNA11	MAP2K2	PTEN	CDKN2A	PIK3CA	FGFR1	RET	
AR	ERBB3	GNAQ	MET	RAF1	EGFR	PTEN	FGFR2	ROS1	
ARAF	ERBB4	GNAS	MTOR	RET	ERBB2		FGFR3	RSPO2	
BRAF	ESR1	HRAS	NRAS	ROS1	ERBB3		MET	RSPO3	
CDK4	FGFR1	IDH1	NTRK1	SMO	FGFR1		NRG1		
CDKN2A	FGFR2	IDH2	NTRK2	TP53	FGFR2		NTRK1		

DPYD PHARMACOGENOMICS INFORMED CONSENT

1. PURPOSE AND DESCRIPTION OF TESTING

- DPYD (dihydropyrimidine dehydrogenase) gene testing is a germline pharmacogenomic test that identifies inherited variants affecting your ability to metabolize fluoropyrimidine chemotherapy agents (5-fluorouracil [5-FU], capecitabine, tegafur).
- Results are used to guide safe dosing or selection of alternative therapy in accordance with CPIC (Clinical Pharmacogenomics Implementation Consortium) and FDA prescribing recommendations.
- This test analyzes clinically actionable DPYD variants including DPYD*2A (c.1905+1G>A, rs3918290), DPYD*13 (c.1679T>G, rs55886062), c.2846A>T (rs67376798), and DPYD HapB3 (c.1129-5923C>G, rs75017182). Additional DPYD variants may be analyzed depending on the assay performed. The variants assessed and testing methodology are specified in the laboratory report.
- Because DPYD variants are inherited (germline), results may have implications for biological relatives. Genetic counseling is available upon request.

2. POTENTIAL BENEFITS AND LIMITATIONS

- **Benefits:** Identification of reduced-function variants may allow dose reduction or therapy modification to prevent severe or life-threatening fluoropyrimidine toxicity (e.g., mucositis, myelosuppression, neurotoxicity, hand-foot syndrome).
- **Limitations:** A negative result does not eliminate all risk of fluoropyrimidine toxicity; other genetic and non-genetic factors may contribute. Current panels do not detect all known DPYD variants.
- **Testing failure:** In rare cases, the assay may yield indeterminate results requiring repeat testing.

3. PRIVACY RIGHTS AND LEGAL PROTECTIONS

- GINA (Genetic Information Nondiscrimination Act, 2008, Pub.L. 110-233): Federal law prohibits health insurers and employers from discriminating based on genetic information. GINA does not apply to life insurance, disability insurance, or long-term care insurance.
- New Jersey Genetic Privacy Act (N.J.S.A. 10:5-43 et seq.): NJ law provides additional protections against genetic discrimination in insurance and employment. Disclosure of your genetic information requires your written authorization except as permitted by law.
- HIPAA: Your genetic test results are protected health information (PHI) and will be handled in accordance with applicable federal and state privacy regulations.
- Results will be reported to your ordering physician and incorporated into your medical record. Results will not be shared with third parties without your authorization except as required by law.

4. VOLUNTARY PARTICIPATION AND RIGHT TO DECLINE

- Participation in DPYD pharmacogenomic testing is voluntary. You may decline testing without penalty, though your physician may discuss how this affects your treatment plan.
- You have the right to withdraw consent at any time prior to sample processing. Once the sample has been analyzed, results cannot be recalled.
- If you choose not to undergo DPYD testing, standard fluoropyrimidine dosing per your physician's clinical judgment will apply.

5. SPECIMEN HANDLING AND STORAGE

- Testing will be performed on the peripheral blood specimen submitted with the accompanying siParadigm Solid Tumor Requisition Form.
- Residual specimen and/or extracted DNA may be retained for quality assurance purposes in compliance with CLIA/CAP retention requirements. Specimens will not be used for research without separate written consent.

PATIENT / LEGAL GUARDIAN CONSENT STATEMENT

I have read (or had read to me) the information above regarding DPYD pharmacogenomic testing. I have had the opportunity to ask questions and my questions have been answered to my satisfaction. I understand that this is a germline genetic test and that results may have implications for my biological relatives. I understand my rights under GINA and the New Jersey Genetic Privacy Act. I voluntarily consent to DPYD pharmacogenomic testing as ordered by my physician.

Patient / Legal Guardian Signature _____ *(MANDATORY FOR TESTING) Date _____

Relationship to Patient (if guardian) _____ Printed Name _____ Phone Number _____

ORDERING PHYSICIAN ATTESTATION

I have explained the nature, purpose, benefits, limitations, and privacy implications of DPYD pharmacogenomic testing to the patient or legal guardian. Informed consent has been obtained prior to specimen collection.

Ordering Physician Signature _____ *(MANDATORY FOR TESTING) Date _____

NPI Number _____ Printed Name _____ Specialty / Credentials _____

⚠ INSTRUCTIONS: This completed consent form must accompany the siParadigm Solid Tumor Requisition Form when DPYD pharmacogenomic testing is ordered. Results will be delayed if consent signature is missing. A copy should be retained in the patient's medical record.

Regulatory basis: New Jersey Genetic Privacy Act (N.J.S.A. 10:5-43); GINA (Pub.L. 110-233); CPIC DPYD Guideline (v1.4, 2023); FDA Table of Pharmacogenomic Biomarkers in Drug Labeling; CAP Molecular Pathology Checklist; CLIA 42 CFR §493.