siParadigm diagnostic informatics

PR 888-782-5430 / 866-369-4114

USA 888-599-5227 / 201-599-9044 / 201-599-9066 / 888-890-4774 (Toll-free fax)

Requisition Number: _____

Pick-up Confirmation # _____

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

# LIQUID BIOPSY 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-LIQUID BIOPSY (REQUIRED)

Specimen ID _____

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

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

A pathology report is **required**

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.

## MOBILE PHLEBOTOMY REQUEST (ONCOLOGY OFFICE TO COMPLETE IF NEEDED)

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.**

## PHYSICIAN INFORMATION (REQUIRED)

Referring MD _____

Attending/Ordering MD _____

Account Information _____

## THIRD-PARTY SPECIMEN LOCATION (REQUIRED)

Hospital/Facility _____ Phone # _____

Address _____

Fax # _____

## 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)

ICD-10 CODE _____

## SPECIMEN INFORMATION - TISSUE BIOPSY (OPTIONAL)

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

*For global molecular/NGS testing only. Submit ≤4 FFPE blocks. Blocks will be combined for molecular testing when necessary.*

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).

A pathology report is **required**

## DIAGNOSIS (REQUIRED)

Date of Original Diagnosis ____ / ____ / ____ (mm / dd / yyyy)

**BREAST**
- ☐ Breast Carcinoma
- ☐ Other Breast Tumor _____

**GENITOURINARY**
- ☐ Prostate Adenocarcinoma
- ☐ Other Genitourinary Tumor _____

**GYNECOLOGIC**
- ☐ Endometrial Carcinoma
- ☐ Ovarian Carcinoma
- ☐ Other Gynecologic Tumor

**LUNG**
- ☐ Adenocarcinoma (NSCLC)
- ☐ Large Cell Carcinoma (NSCLC)
- ☐ Squamous Cell Carcinoma (NSCLC)
- ☐ Small Cell Lung Carcinoma
- ☐ Other Lung Tumor _____

**GI**
- ☐ Cholangiocarcinoma
- ☐ Colorectal Adenocarcinoma
- ☐ Gastric Adenocarcinoma
- ☐ Esophageal/Gastroesophageal Junction Adenocarcinoma
- ☐ Pancreatic Ductal Adenocarcinoma
- ☐ Pancreatic Neuroendocrine Tumor
- ☐ Other Gastrointestinal Tumor _____

**SKIN**
- ☐ Melanoma
- ☐ Other Skin Tumor _____

**BRAIN**
- ☐ Glioblastoma
- ☐ Other Brain Tumor _____

**OTHER**
- ☐ Carcinoma of Unknown Primary (CUP)
- ☐ Other _____

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

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

**Authorized Signature:** _____ **Date:** _____

## CONCURRENT LIQUID AND TISSUE TESTING OPTIONS

☐ **DeepSight™ on Liquid + siPortfolio Multi-Omics™ on Tissue** — TAT 7-10 Days
- On Liquid: DeepSight™ Comprehensive Liquid Biopsy (523 genes mutations and fusions)
- On Tissue:
  - NGS (500+ genes, TMB, MSI)
  - HRD for PARPi therapy
  - IHC, FISH (as clinically pertinent and necessary)

☐ **DeepSight™ on Liquid +NGS 500-Genes on Tissue** — TAT 7-10 Days
- On Liquid: DeepSight™ Comprehensive Liquid Biopsy (523 genes mutations and fusions)
- On Tissue:
  - NGS (500+ genes, TMB, MSI)
  - HRD for PARPi therapy

## CONCURRENT SOMATIC AND GERMLINE TESTING OPTIONS

☐ **DeepSight™ Comprehensive 523 genes Liquid Biopsy (Somatic) + Neovare Portfolio testing (Germline)**

**Concurrent ctDNA and Germline Reporting from Liquid Biopsy**

**For PARPi treatment:** ☐ Breast ☐ Prostate ☐ Ovarian ☐ Pancreatic

## LIQUID ONLY TESTING OPTIONS

☐ **DeepSight™ Comprehensive Liquid Biopsy (523 genes mutations and fusions) including TMB and MSI** — TAT 7-10 Days

☐ **DeepSight™ Focused Liquid Biopsy (50 genes mutations and fusions)** — TAT 4-5 Days
Indicated only for lung, colon, and melanoma

## REFLEX TESTING OPTIONS

☐ **Reflex Liquid to Tissue**
If liquid biopsy is negative or QNS reflex to siPortfolio Multi-Omics™ 500 genes testing on tissue

☐ **Reflex Tissue to Liquid**
If the tissue is unattainable in 3 working days reflex to DeepSight™ Comprehensive 523 genes liquid biopsy testing on liquid

## INDIVIDUAL TESTS

☐ **HRD Germline on Liquid**

**Tissue Biopsy Block is REQUIRED**

☐ **PD-L1, SP263, FDA** IMFINZI®
☐ **PD-L1, 22C3, FDA (DEFAULT)** KEYTRUDA®
☐ **PD-L1, SP142, FDA** TECENTRIQ®
☐ **PD-L1, 28-8, FDA** OPDIVO®

## PHYSICIAN (REQUIRED FOR GERMLINE TESTING ONLY)

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

**Signature** *(**MANDATORY FOR TESTING** – Results will be delayed if consent signature is missing) _____ **Date** _____

## PATIENT/LEGAL GUARDIAN (REQUIRED FOR GERMLINE TESTING ONLY)

- Consent: I give permission to Neovare by siParadigm to perform genetic testing as requested by my physician. In the event that one of the following apply.
  1) I do not have health insurance - Attach Check
  2) I do not qualify for testing based on nationally recognized clinical criteria for medical necessity for hereditary cancer testing - Attach Check
  3) I do not qualify for testing based on my insurance company's medical necessity policy for hereditary cancer testing and will be responsible to make payment of $250.00 upon receipt of bill
- I authorize Neovare by siParadigm to perform testing to determine my risk for hereditary cancer AND I understand that I will personally pay $250.00 out of pocket for testing (to include extra shipping and handling) for these services.

***This self pay rate is NOT available to those patients with Medicare/Medicaid due to governmental guidelines.

**Signature** *(**MANDATORY FOR TESTING** – Results will be delayed if consent signature is missing) _____ **Date** _____

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## NEOVARE PORTFOLIO

*APC, CDH1, MLH1, PALB2, RET, ATM, CDK4, MRE11A, PDGFRA, SDHA, AXIN2, CDKN2A, MSH2, PMS2, SDHB, BAP1, CHEK2, MSH3, POLD1, SDHC, BARD1, EPCAM, MSH6, POLE, SDHD, BMPR1A, HOXB13, MUTYH, PTEN, SMAD4, BRIP1, KIT, NBN, RAD50, STK11, BRCA1, MEN1, NF1, RAD51C, TP53, BRCA2, MITF, NTHL1, RAD51D, VHL.*

## 523 GENE COMPREHENSIVE PANEL (LIQUID BIOPSY)

**ABL1, ABL2, ACVR1, ACVR1B, AKT1,* ***AKT2,*** *AKT3,* ****ALK,*** *ALOX12B, ANKRD11, ANKRD26, APC,* ***AR,*** *ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2,* ***ATM,*** *ATR, ATRX, AURKA, AURKB, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BBC3, BCL10, BCL2, BCL2L1, BCL2L11, BCL2L2, BCL6, BCOR, BCORL1, *BCR, BIRC3, BLM, BMPR1A,* ****BRAF, BRCA1, BRCA2,*** *BRD4, BRIP1, BTG1, BTK, C11orf30, CALR, CARD11, CASP8, CBFB, CBL,* ***CCND1,*** *CCND2,* ***CCND3, CCNE1,*** *CD274 (PD-L1), CD276, *CD74, CD79A, CD79B, CDC73, CDH1, CDK12,* ***CDK4, CDK6,*** *CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CHD2, CHD4,* ***CHEK1, CHEK2,*** *CIC, CREBBP, CRKL, CRLF2, CSF1R, CSF3R, CSNK1A1, CTCF, CTLA4, CTNNA1, CTNNB1, CUL3, CUX1, CXCR4, CYLD, DAXX, DCUN1D1, DDR2, DDX41, DHX15, DICER1, DIS3, DNAJB1, DNMT1, DNMT3A, DNMT3B, DOT1L, E2F3, EED, EGFL7, *EGFR, EIF1AX, EIF4A2, EIF4E, EML4, EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1,* ***ERBB2 (HER2), ERBB3,*** *ERBB4,* ***ERCC1, ERCC2,*** *ERCC3, ERCC4, ERCC5, ERG, ERRFI1,* ***ESR1 (ER),*** *ETS1, *ETV1, *ETV4, ETV5, *ETV6, *EWSR1, EZH2, FAM123B (AMER1), FAM175A, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FAS, FAT1, FBXW7,* ***FGF1, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, *FGFR2, *FGFR3, FGFR4,*** *FH, FLCN, FLI1, FLT1, FLT3, FLT4, FOXA1, FOXL2, FOXO1, FOXP1, FRS2, FUBP1, FYN, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GEN1, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GPR124, GPS2, GREM1, GRIN2A, GRM3, GSK3B, H3F3A, H3F3B, H3F3C, HGF, HIST1H1C, HIST1H2BD, HIST1H3A, HIST1H3B, HIST1H3C, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HIST2H3A, HIST2H3C,HIST2H3D, HIST3H3, HLA-A, HLA-B, HLA-C, HNF1A, HNRNPK, HOXB13, HRAS, HSD3B1, HSP90AA1, ICOSLG, ID3, IDH1, IDH2, IFNGR1, IGF1, IGF1R, IGF2, IKBKE, IKZF1, IL10, IL7R, INHA, INHBA, INPP4A, INPP4B, INSR, IRF2, IRF4, IRS1, IRS2, JAK1,* ***JAK2,*** *JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIF5B,* ***KIT,*** *KLF4, KLHL6, KMT2B, KMT2C, KMT2D,* ***KRAS, LAMP1,*** *LATS1, LATS2, LMO1, LRP1B, LYN, LZTR1, MAGI2, MALT1, MAP2K1 (MEK1), MAP2K2 (MEK2), MAP2K4, MAP3K1, MAP3K13, MAP3K14, MAP3K4, MAPK1, MAPK3, MAX, MCL1, MDC1,* ***MDM2, MDM4,*** *MED12, MEF2B, MEN1,* ****MET,*** *MGA, MITF, MLH1, MLL (KMT2A), MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MST1, MST1R, MTOR, MUTYH, MYB,* ***MYC, MYCL1, MYCN,*** *MYD88, MYOD1, *NAB2, NBN, NCOA3, NCOR1, NEGR1, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NKX3-1, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1,* ***NRAS, NRG1,*** *NSD1, *NTRK1, *NTRK2, *NTRK3, NUP93, *NUTM1, PAK1, PAK3, PAK7, PALB2, PARK2, PARP1, *PAX3, PAX5, PAX7, *PAX8, PBRM1, PDCD1, PDCD1LG2,* ***PDGFRA, PDGFRB,*** *PDK1, PDPK1, PGR, PHF6, PHOX2B, PIK3C2B, PIK3C2G, PIK3C3,* ***PIK3CA, PIK3CB,*** *PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PLCG2, PLK2, PMAIP1, PMS1, PMS2, PNRC1, POLD1, POLE, *PPARG, PPM1D, PPP2R1A, PPP2R2A, PPP6C, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRSS8, PTCH1,* ***PTEN,*** *PTPN11, PTPRD, PTPRS, PTPRT, QKI, RAB35, RAC1, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L,* ***RAF1,*** *RANBP2, RARA, RASA1, RB1, RBM10, RECQL4, REL,* ****RET,*** *RFWD2, RHEB, RHOA,* ***RICTOR,*** *RIT1, RNF43, *ROS1, RPS6KA4,* ***RPS6KB1,*** *RPS6KB2, RPTOR, RUNX1, RUNX1T1, RYBP, SDHA, SDHAF2, SDHB, SDHC, SDHD, SETBP1, SETD2, SF3B1, SH2B3, SH2D1A, SHQ1, SLIT2, SLX4, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCD1, SMC1A, SMC3, SMO, SNCAIP, SOCS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, SRSF2, STAG1, STAG2, STAT3, STAT4, STAT5A, STAT5B, STK11, STK40, SUFU, SUZ12, SYK, TAF1, TBX3, TCEB1, TCF3, TCF7L2,* ***TERC,*** *TERT, TET1, TET2, *TFE3, TFRC, TGFBR1, TGFBR2, TMEM127, *TMPRSS2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TP63, TRAF2, TRAF7, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, VTCN1, WISP3, WT1, XIAP, XPO1, XRCC2, YAP1, YES1, ZBTB2, ZBTB7A, ZFHX3, ZNF217, ZNF703, ZRSR2.*

***Bold*** = Copy number variants (59)

*** = Genes targeted for DNA based fusion detection

## 50 GENE FOCUSED PANEL (LIQUID BIOPSY)

*AKT1, AKT2, AKT3,* ****ALK,*** ***#AR,*** *ARAF, *BRAF,* ***CD274,*** *CDK4,* ***CDKN2A,*** *CHEK2, CTNNB1,* ***#EGFR, ERBB2, ERBB3,*** *ERBB4, *ESR1,* ****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, *RSPO2, *RSPO3, SMO, TP53.*

***Bold*** =Copy number variants (14)

*** = Genes targeted for RNA based inter-genetic fusion

*#* =Genes targeted for RNA based intra-genetic fusion

Please see separate solid tumor requisition for solid tumor NGS test gene lists

25 Riverside Drive, Suite #2, Pine Brook, NJ 07058
www.siparadigm.com

CLIA CERTIFIED

cap ACCREDITED