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OCTOBER 2023

MOLECULAR TESTING OF TUMOR TISSUE SAMPLES

NUCLEIC ACID EXTRACTION

Macrodissection and DNA extraction from FFPE tissue
Macrodissection and RNA extraction from FFPE tissue

COMBINED STUDIES

SOLID TUMOR (*Recommended for* LUNG, MELANOMA, BREAST and other Solid tumors) **CS-T-001** **NGS Somatic QIAseq DNA Custom Extended Panel (30 genes)** Genes: *ALK, ARID1A, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FAT1, FGFR1, FGFR2, FGFR3, IDH1, IDH2, KEAP1, KIT, KRAS, MET, MYC, NFE2L2, NRAS, PDGFRA, PIK3CA, POLD1, POLE, RET, ROS1, SETD2, STK11, TP53* **nCounter RNA Pangaea Solid Tumor Panel*** Fusions: *ALK, FGFR1,2,3, NRG1, NTRK1, RET, ROS1* Splicing variant*: METΔ14, EGFRvIII* Gene expression analysis: *ALK, ATM, BARD1, BID, BRCA1, BRCA2, CCNE1, CD274, CD4, CD8A, CDK2, EGFR, FGFR1,2,3, FOXP3, GZMM, IFNG, KRAS, NRG1, NTRK1,2,3, PDCD1, PTEN, RET, ROS1, STK11, TP53*
CS-T-002 **Combined study CS-T-001 and PD-L1 IHC**

**The nCounter RNA Pangaea Solid Tumor Panel could be replaced by the NGS RNA Fusion XP Lung Panel (ask for prices)*

UROTHELIAL carcinoma study **CS-T-003** **NGS Somatic QIAseq DNA Custom Extended Panel (30 genes)** **nCounter RNA Pangaea Urothelial Carcinoma Panel** Fusions*: FGFR2 and FGFR3* **Identification of the variants: *FGFR2-BICC1, FGFR2-CASP7, FGFR3ex17-TACC3ex10*** *FGFR3ex17-TACCex11, FGFR3-BAIAP2L1*
COLON study **CS-T-004** ***KRAS*, *BRAF*, *NRAS* sequencing (NGS Custom Panel) (19 genes)** Genes: *ALK, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FGFR1, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, ROS1, STK11, TP53* **Mismatch Repair (MMR) status (IHC)** Genes*: MLH1, MSH2, MSH6, PMS2*
GIST study ***c-KIT, PDGFR* sequencing (NGS Custom Panel) (19 genes)**

TISSUE SAMPLE SHIPMENT: All molecular assays in solid tumors require the shipment of Formalin Fixed Paraffin-Embedded (FFPE) blocks. Please contact us if the FFPE block is not available.

MULTIGENIC MOLECULAR PANELS

NGS Somatic QIAseq DNA Custom Extended Panel (30 genes) Genes: *ALK, ARID1A, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FAT1, FGFR1, FGFR2, FGFR3, IDH1, IDH2, KEAP1, KIT, KRAS, MET, MYC, NFE2L2, NRAS, PDGFRA, PIK3CA, POLD1, POLE, RET, ROS1, SETD2, STK11, TP53*
NGS RNA Fusion XP Lung Panel (13 genes) Fusions: *ALK, BRAF, EGFR, FGFR1,2,3, MET, NRG1, NTRK1,2,3, RET, ROS1* Splicing variant*: METΔ14*
NGS Somatic QIAseq DNA Repair Genes Panel (28 genes) Genes: *APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, CTNNB1, EPCAM, FANCA, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PIK3CA, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, STK11, TP53*
nCounter RNA Pangaea Solid Tumor Panel Fusions: *ALK, FGFR1,2,3, NRG1, NTRK1, RET, ROS1* Splicing variants*: METΔ14, EGFRvIII* Gene expression analysis: *ALK, ATM, BARD1, BID, BRCA1, BRCA2, CCNE1, CD274, CD4, CD8A, CDK2, EGFR, FGFR1,2,3, FOXP3, GZMM, IFNG, KRAS, NRG1, NTRK1,2,3, PDCD1, PTEN, RET, ROS1, STK11, TP53*
nCounter RNA Pangaea Urothelial Carcinoma Panel Fusions*: FGFR2 and FGFR3* **Identification of the variants: *FGFR2-BICC1, FGFR2-CASP7, FGFR3ex17-TACC3ex10*** *FGFR3ex17-TACCex11, FGFR3-BAIAP2L1*
PROSIGNA Genetic prognostic signature for breast cancer

INDIVIDUAL GENE MUTATIONS (TaqMan® allelic discrimination qPCR assay)

***EGFR* exon 19 del and *EGFR* exon 21 (L858R, L861Q) mutations**
***EGFR* exon 19 del, *EGFR* exon 21 (L858R, L861Q) and *EGFR* exon 20 T790M mutations**
***EGFR* exon 20 resistance mutation T790M**
***EGFR* exon 20 resistance mutation C797S**
***KRAS* hotspot mutations (codons 12, 13 and 61)**
***BRAF* hotspot mutations (V600E, V600K, V600R)**
***PIK3CA* hotspot mutations (codons 542, 545 and 1047)**
One hotspot mutation (*EGFR, KRAS, BRAF, PIK3CA*)

TISSUE SAMPLE SHIPMENT: All molecular assays in solid tumors require the shipment of Formalin Fixed Paraffin-Embedded (FFPE) blocks. Please contact us if the FFPE block is not available.

SPLICING VARIANTS AND FUSIONS

ALK-EML4 **by RT-PCR (variants 1, 2 and 3)**
ALK-EML4 **by RT-PCR (one known variant)**
MET **splicing variants 7/8-14**
EGFR **vIII splicing variant**
MET **splicing variant 14**

ANATOMIC PATHOLOGY

ANATOMICAL PATHOLOGY DIAGNOSIS

Anatomical pathology diagnosis (H&E and 4 IHC analysis)
Confirmation of anatomical pathology diagnosis (Previous AP report required)

MAIN FISH ASSAYS*

HER-2/neu amplification**
ALK **fusions****
ROS1 **fusions**
RET **fusions**
MET **amplification**
EGFR **amplification**
KRAS **amplification**
NTRK1 **fusions**
NTRK2 **fusions**
NTRK3 **fusions**
FGFR1 **fusions**
FGFR1 **amplification**

TISSUE SAMPLE SHIPMENT: All molecular assays in solid tumors require the shipment of Formalin Fixed Paraffin-Embedded (FFPE) blocks. Please contact us if the FFPE block is not available.

FGFR2 **fusions**
FGFR2 **amplification**
FGFR3 **fusions**
FGFR3 **amplification**
BCL2 **fusions**
BCL6 **fusions**
NRG1 **fusions**
MYC **fusions**
MYC **amplification**
1p/19q loss

** Ask for other IHC or FISH assays if required*
*** FDA approved*

MAIN PRONOSTIC AND PREDICTIVE INMUNOHISTOCHEMISTRY (IHC) ASSAYS*

ALK **(D5F3) ****
PDL1 **(22C3)**
Mismatch Repair (MMR) status (*MLH1, MSH2, MSH6, PMS2*)
MET **(SP44)**

** Ask for other IHC or FISH assays if required*
*** FDA approved*

EXTERNALIZED SERVICES

ONCOPDO 3D Organoid Test (Invitrocue)
Oncotype DX
Foundation ONE CDx

TISSUE SAMPLE SHIPMENT: All molecular assays in solid tumors require the shipment of Formalin Fixed Paraffin-Embedded (FFPE) blocks. Please contact us if the FFPE block is not available.

MOLECULAR TESTING OF TUMOR LIQUID BIOPSY SAMPLES

NUCLEIC ACID EXTRACTION

cfDNA extraction from liquid biopsies
cfRNA extraction from liquid biopsies
DNA extraction from white blood cells

COMBINED STUDIES

CS-BL-001 (Recommended for all type of tumors) **NGS Somatic QIAseq DNA Custom Panel (19 genes)** Genes: *ALK, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FGFR1, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, ROS1, STK11, TP53* **nCounter RNA Pangaea Solid Tumor Panel for liquid biopsies (6 genes)** Fusions*: *ALK, NRG1, NTRK1, RET, ROS1* Splicing variants*: METΔ14* **More frequently found fusions*

MULTIGENIC MOLECULAR PANELS

NGS Somatic QIAseq DNA Custom Panel (19 genes) Genes: *ALK, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FGFR1, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, ROS1, STK11, TP53*
NGS Somatic QIAseq DNA Custom Extended Panel (30 genes) Genes: *ALK, ARID1A, BRAF, CDK4, CDK6, EGFR, ERBB2, ERBB4, FAT1, FGFR1, FGFR2, FGFR3, IDH1, IDH2, KEAP1, KIT, KRAS, MET, MYC, NFE2L2, NRAS, PDGFRA, PIK3CA, POLD1, POLE, RET, ROS1, SETD2, STK11, TP53*
nCounter RNA Pangaea Solid Tumor Panel for Liquid Biopsies (6 genes) Fusions: **ALK, NRG1, NTRK1, RET, ROS1* Splicing variants*: METΔ14* **More frequently fusions*

LIQUID BIOPSY SAMPLE SHIPMENT: Three EDTA tubes of blood and one of serum are routinely required for most liquid biopsy assays. Please contact us for assays in other types of biological fluids.

INDIVIDUAL GENE MUTATIONS (TaqMan® allelic discrimination qPCR assay)

EGFR **exon 19 del and** ***EGFR*** **exon 21 (L858R, L861Q) mutations**
EGFR **exon 19 del,** ***EGFR*** **exon 21 (L858R, L861Q) and** ***EGFR*** **exon 20 T790M mutations**
EGFR **exon 20 resistance mutation T790M**
EGFR **exon 20 resistance mutation C797S**
KRAS **hotspot mutations (codons 12, 13 and 61)**
BRAF **hotspot mutations (V600E, V600K, V600R)**
PIK3CA **hotspot mutations (codons 542, 545 and 1047)**
One hotspot mutation (*EGFR, KRAS, BRAF, PIK3CA*)

SPLICING VARIANTS AND FUSIONS

ALK-EML4 **by RT-PCR (variants 1, 2 and 3)**
ALK-EML4 **by RT-PCR (one known variant)**
MET **splicing variants 7/8-14**
MET **splicing variant 14**
EGFR **vIII splicing variant**

LIQUID BIOPSY SAMPLE SHIPMENT: Three EDTA tubes of blood and one of serum are routinely required for most liquid biopsy assays. Please contact us for assays in other types of biological fluids.

GERMLINE MOLECULAR TESTING ASSOCIATED WITH INHERITED PREDISPOSITION SYNDROMES

MULTIGENIC MOLECULAR PANELS

NGS QIAseq Inherited Cancer Panel (28 genes, germline)
Genes: *APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, CTNNB1, EPCAM, FANCA, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PIK3CA, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, STK11, TP53*

INMUNOHISTOCHEMISTRY (IHC) ASSAYS (Recommended for Lynch syndrome)

Mismatch Repair (MMR) status (*MLH1, MSH2, MSH6, PMS2*)*

**Sample required: FFPE Block*

EXTERNALIZED SERVICES

CentoVision Panel (Inherited Diseases)

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