

Testing site & Shipping Address: Hematology Translational Lab (HTL)

ATTN: Dr. Faisal Khan
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PATIENT INFORMATION

Name (Last, First)
Medical Record #
Date of Birth (YYYY/MM/DD):..... Gender: M F
Address:..... City:.....
Prov./State: Country: Postal/Zip code.....

ORDER INFORMATION

Requesting Physician.....Location/Facility
Address.....City Prov./State Country: Postal/Zip code
Phone Fax Email Report delivery method: Email Fax

DIAGNOSIS

Solid Tumor Bladder Breast Cervical Colorectal Cholangio Gastric Glioma Head/neck
 Prostate Lung Thyroid Melanoma Ovarian Pancreatic Renal cell Neuroendocrine
Disease status: Metastatic YES NO **OTHER DETAILS:**

TEST REQUEST

SOLID TUMOR GENOMIC PANELS: *All tissue panels are FFPE Compatible*

<input type="checkbox"/> Comprehensive 170 genes (Tissue: DNA & RNA)	DNA: 133 cancer-related genes, 59 targets of CNV, 55 RNA fusion genes.
<input type="checkbox"/> Comprehensive 170 genes (Tissue: DNA Only)	DNA: 133 cancer-related genes, 59 targets of CNV. NO RNA fusion genes.
<input type="checkbox"/> GU Panel: Prostate, Bladder+ NET, Cholangio (Tissue: DNA)	DNA: BRCA 1, BRCA 2, ATM; FGF1, 10, 2, 23, 3, 4, 5, 7, 9 (<i>not FGF RNA Fusion</i>)
<input type="checkbox"/> Follow It® ctDNA Focused Panel (Blood DNA)	DNA: 38 cancer-related genes, 146 Hotspots, 23 Exons. Blood sample only.

SELF-PAYMENT YES OR **INSTITUTION PAYMENT YES** INSTITUTION NAME:

Contact Name: Patient / Patient Support or Institution **Email: (Required)** **Phone:**

SPECIMEN RETRIEVAL **Path report included with TRF (Required)**

OncoHelix can contact Pathology Lab to obtain specimen Cancer Clinic will arrange the specimen shipment
Pathologist Name: Pathology Lab: Phone: Fax:
Specimen ID: Specimen Site: Date of Collection (YY/MM/DD):

TEST AUTHORIZATION, CONSENT & SIGNATURES

I certify that I am the patient's treating physician and that results from this test/s may inform the patient's ongoing/future treatment. I have explained the nature and purpose of testing to the patient and have obtained informed consent, to the extent legally required, to permit OncoHelix to (a) perform the test/s specified herein, (b) retain test results indefinitely for internal quality assurance/operational improvement, and (c) use/disclose de-identified (without identifiable patient information) results and sequencing data for ongoing/future unspecified research and development purposes.

.....
Ordering Physician signature Printed Name Date

I permit OncoHelix & partner lab HTL to (a) perform the test/s specified herein, that may include de-identified sequencing data analysis performed outside of Canada with final analysis and clinical interpretations by OncoHelix/HTL team in Canada (b) retain test results indefinitely for internal quality assurance/operational improvement, (c) use/disclose de-identified results and sequencing data for ongoing/future unspecified research and development purposes.

.....
Patient's signature OR Check for Patient Verbal Consent Printed Name Date

IMPORTANT INFORMATION

Panels Refer to Genomic panel descriptions for list of Genes on page 3
Specimens Refer to sample requirements, guidelines and shipping instructions on page 2

SAMPLE REQUIREMENT & GUIDELINES

Nucleic Acid and Tissue for Solid Tumor Genomic Analysis Panels

Panel	DNA	RNA	Biopsy	FFPE	Blood	Guidelines for 170 and 500+ gene panels
Comprehensive 170 gene panel GU Somatic Panel	250 ng	150 ng	120 µm or 4 mm ³	✓	--	<ul style="list-style-type: none"> Extracted nucleic acids and fresh frozen (FF) or formalin fixed paraffin embedded (FFPE) tissue samples are accepted 120 µm of FFPE tissue section (4 scrolls of 30 µm thickness) with a minimum of 40% tissue content & 10% tumor cellularity; or 2-4 FFPE cores of 1-2 mm³; or 4 mm³ FF tissue. For DNA only panels, the requirements are reduced to half
Focused Follow It [®] ctDNA 38-gene panel	✓	--	--	--	✓	Blood Collection: 2 Streck blood tubes collected within 14 days of delivery / drop off to HTL genomic diagnostic lab

Specimen Type (select all that apply)

- Biopsy Type: FFPE Tissue FF Tissue Blood Other (specify)
- PARAFFIN BLOCK – no prepped scrolls or extracted nucleic acids
- DNA (ng) RNA (ng)

General Notes and Quality Recommendations:

- Minimum required nucleic acid concentrations are based on fluorometric estimation with Qubit reagents. A spectrophotometric method (nanodrop) overestimates the amount of nucleic acid and may only be used for the determination of sample purity (260/280 ≥ 1.8 for DNA and ≥ 1.9 for RNA)
- Nucleic acid must be extracted from a minimum of 1 ml of biopsy in EDTA, 120 µm or of FFPE tissue or 4 mm³ of FF tissue
- All nucleic acids will be tested for quality as per laboratory thresholds prior to processing

FF and FFPE Tissue Recommendations

- For FF tissue, samples must be flash-frozen in liquid nitrogen as quickly as possible after removal from patients and immediately delivered to the laboratory. Samples must be kept in -80°C freezers until DNA and RNA extraction
- For both FF and FFPE samples, H&E slides must be analyzed by the pathologist and estimation of tumor cellularity must be provided

SPECIMEN TYPE	SHIPPING & HANDLING INSTRUCTIONS	REJECTION CRITERIA
DNA & RNA	<ul style="list-style-type: none"> Ship at -20°C (use dry ice) DNA only specimens may be shipped at 4 °C 	<ul style="list-style-type: none"> Suboptimal quantity/quality FFPE/FF: Tissue content < 40%; Tumor cellularity < 10%
FF Tissue	<ul style="list-style-type: none"> Ship at room temperature 	
FFPE Tissue	<ul style="list-style-type: none"> Ship at room temperature 	<ul style="list-style-type: none"> Collected > 14 days ago
2 Blood Streck Tubes	<ul style="list-style-type: none"> Ship at room temperature 	

CHECKLIST

- A completed requisition has been sent with the specimen/s
- A pathology report has been sent with the specimen/s
- Any available genomic (single gene or panel) profile report/s has been sent with the specimen/s

Please provide the following information:

Tissue content:	Tumor cellularity:	Pathologist's Name:
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Shipping Address

ATTN: Dr. Faisal Khan
Hematology Translational Lab (HTL)
 HMRB 336, 3330, Hospital Drive NW,
 Calgary, AB, CANADA T2N 4N1

For HTL Laboratory Use Only

Sample Received (YYYY-MM-DD) (AM/PM)
 Specimen type
 # Tubes/amount
 Lab Acc.#

SOLID TUMOR NGS PANEL DESCRIPTION

Comprehensive Somatic 170 Gene Panel (DNA +/- RNA)

Specimen compatibility: Genomic DNA & RNA extracted from fresh frozen and FFPE tissues

DNA GENES ALONE:

Small variants and indel (148): AKT1, AKT2, AKT3, ALK, APC, AR, ARID1A, ATM, ATR, BAP1, BARD1, BCL2, BCL6, BRAF, BRCA1, BRCA2, BRIP1, BTK, CARD11, CCND1, CCND2, CCNE1, CD79A, CD79B, CDH1, CDK12, CDK4, CDK6, CDKN2A, CEBPA, CHEK1, CHEK2, CREBBP, CSF1R, CTNNA1, DDR2, DNMT3A, EGFR, EP300, ERBB2, ERBB3, ERBB4, ERCC1, ERG, ESR1, EZH2, FAM175A, FANCI, FANCL, FBXW7, FGF1, FGF10, FGF2, FGF23, FGF3, FGF4, FGF5, FGF7, FGF9, FGFR1, FGFR2, FGFR3, FGFR4, FLT1, FLT3, FOXL2, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, INPP4B, JAK2, JAK3, KDR, KIT, KRAS, MAP2K1, MAP2K2, MCL1, MDM2, MDM4, MET, MLH1, MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MTOR, MUTYH, MYC, MYCN, MYD88, NBN, NF1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NRG1, PALB2, PDGFRA, PDGFRB, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PMS2, PTCH1, PTEN, PTPN11, RAD51B, RAD51C, RAD54L, RB1, RET, RICTOR, ROS1, SLX4, SMAD4, SMARCB1, SMO, STK11, TET2, TP53, TSC1, TSC2

DNA amplification target genes (59): AKT2, ALK, AR, ATM, BRAF, BRCA1, BRCA2, CCND1, CCND3, CCNE1, CDK4, CDK6, CHEK1, CHEK2, EGFR, ERBB2, ERBB3, ERCC1, ERCC2, ESR1, FGF1, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, FGFR2, FGFR3, FGFR4, JAK2, KIT, KRAS, LAMP1, MDM2, MDM4, MET, MYC, MYCL1, MYCN, NRAS, NRG1, PDGFRA, PDGFRB, PIK3CA, PIK3CB, PTEN, RAF1, RET, RICTOR, RPS6KB1, TFRC

OR

DNA GENES LISTED ABOVE PLUS RNA GENES:

RNA fusion target genes (55): ABL1, AKT3, ALK, AR, AXL, BCL2, BRAF, BRCA1, BRCA2, CDK4, CSF1R, EGFR, EML4, ERBB2, ERG, ESR1, ETS1, ETV1, ETV4, ETV5, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT1, FLT3, JAK2, KDR, KIF5B, KIT, KMT2A (MLL), MET, MLLT3, MSH2, MYC, NOTCH1, NOTCH2, NOTCH3, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFRA, PDGFRB, PIK3CA, PPARG, RAF1, RET, ROS1, RPS6KB1, TMPRSS2

GU Somatic Panel

Specimen compatibility: Genomic DNA extracted from fresh frozen and FFPE tissues NO RNA FUSIONS FOR FGF

DNA amplification target genes: BRCA 1, BRCA2, ATM, FGFR 1, FGFR 2, FGFR 3, FGFR 4

FOLLOW IT® ctDNA Liquid Biopsy Focused Panel Powered by Canexia Health™

Specimen compatibility: Genomic DNA extracted from fresh blood sample

SNVs, deletions and insertions (up to 24bp):

AKT1: E17, **ALK:** T1151, L1152, C1156, F1174, L1196, L1198, G1202, D1203, S1206, G1269, R1275, Y1278 **AR:** L702H, V716, S741, W742, Q784, H875, F877, T878, M896 **BRAF:** Q201, G464, G466, F468, G469, Y472, D594, F595, G596, L597, V600, K601, part of Exon 15 (V600-M620), G606, **CCNE:** Amplification, **CTNNA1:** D32, S33, G34, I35, H36, S37, T41, S45, **DDR2:** L239, I638, S768, **DICER1:** D1705-D1709, G1809, D1810-E1813, **EGFR:** R108, A289, S492, P596, G598, Exon18, Exon19, Exon20, Exon21, & Amplification, **ERBB2:** G309, S310, K753, L755, I767, D769, Exon 20, & Amplification, **ESR1:** K303, E380, S463, V534, P535, L536, Y537, D538, **FGFR1:** N546, K656, & Amplification, **FGFR2:** S252, P253, W290, A315, S372, Y375, C382, N549, K659, E731, E777, & Amplification, **FGFR3:** R248, S249, G370, S371, Y373, G380, A391, 650, **FOXL2:** C134, **GNA11:** Q209, **GNAQ:** Q209, **GNAS:** R201, **HRAS:** G12, G13, Q61, **IDH1:** R132, **IDH2:** R140, R172, **KIT:** S476, Y553, W557 559, V560, L576, K642, V654, T670, D816, D820, N822, Y823, A829, Exon9, Exon11, Exon13, & Amplification, **KRAS:** K5, A11, G12, G13, L19, Q22, A59, G60, Q61, K117, A146, & Amplification, **MAP2K1(MEK1):** F53, Q56, K57, K59, V0, D67, I103, I111, C121, N122, P124, P387, **MAP2K2(MEK2):** F57, Q60, K61, L119, H123, G132, **MET:** T1010, V1112, H1112, G1181, L1213, D1246, Y1248, Y1253, Exon13, Exon 14 (-50 to +25), Exon18, & Amplification, **NRAS:** G12, G13, A59, G60, Q61, K117, A146, **NTRK1:** F589, G595, G667, **NTRK3:** G623, G696, **PDGFRA:** R560-E571, P577, N659, D842, L839-Y849, **PIK3CA:** R88, C90, R93, P104, G106, N107, R108, K111, R115, N345, R357, G364, E365, Exon6 [start to P377], C420, E453, P539, E542, E545, Q546, D549, E970, E978, M1043, N1044, A1046, H1047, G1049, & Amplification, **POLE:** Exon9, Exon10, Exon11, Exon12, Exon13, Exon14, (P286R, M295R, S297F, F367S, D368Y, V411L, L424I, M444K, A456P, S459F), **PTCH1:** W844, G1093, **PTEN:** A126, G129, R130, R173, R233, K254-K267, **RET:** G533, K603, C609, C611, C618, C620, C630, D631, C634, G691, E768, L790, Y791 V804, Y806, A886, S904, M918, A919, Exon10, Exon13, Exon15, **ROS1:** S1986, L2026, G2032, **STK11:** Q37, P281, **TP53:** Exon4, Exon5, Exon6, Exon7, Exon8, Exon9; **MSI:** 21 Loci

FFPE: Formalin Fixed Paraffin Embedded tissue or block

FF Tissue: Fresh Frozen tissue