

Testing site & Shipping Address:

Hematology Translational Lab (HTL)

ATTN: Dr. Faisal Khan
 HMRB336, 3330, Hospital Drive NW, Calgary, AB. T2N4N1
 Phone: +1(403)220-7671, +1(403)210-3935,
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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 (select applicable) Metastatic Diagnostic **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; FGFR 1, FGFR 2, FGFR 3, FGFR 4.
<input type="checkbox"/> Follow It® ctDNA Focused Panel (Blood DNA)	DNA: 38 cancer-related genes, 146 Hotspots, 23 Exons. Blood sample only

PAYMENT OPTIONS

Facility* Name of the facility Address:
 Self Pay Contact Name: Phone: Email:
 *If a contract between OncoHelix and your facility is not in place, please contact: precision@oncohelix.hush.com

SPECIMEN RETRIEVAL

OncoHelix can contact Pathology Lab to obtain specimen Clinic/Patient will arrange the specimen shipment
 Pathologist Name: Pathology Lab: Phone: Fax:
 Specimen ID: Specimen Site: Date of Collection (YYYY/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 Canada with final analysis and clinical interpretations done 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 Printed Name Date

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

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 and RNA extracted from fresh frozen and FFPE tissues

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

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		
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.#