# ONCOHELIM

# Testing site & Shipping Address:

# **Hematology Translational Lab (HTL)**

ATTN: Dr. Faisal Khan

HMRB336, 3330, Hospital Drive NW, Calgary, AB. T2N4N1

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

	7671, +1(403)210-393 76, Email: HTL@ucalga		Prov./State: Co	untry: Posta				
		ORD	ER INFORMATION					
Requesting Physician			Location/Facility					
Address		City	Prov./State	Country:	. Postal/Zip code			
Phone	Fax	, Email	·		y method: Email Fax			
			DIAGNOSIS					
Solid Tumor	Bladder Breast Prostate Lung		rectal Cholangio Noma Ovarian	Gastric Glioma Pancreatic Renal cell	Head/neck Neuroendocrine			
Disease status:	Metastatic YES NO	OTHER DETAI	LS:					
			TEST REQUEST					
		SOLID T	TUMOR GENOMIC PANEL	S: All tissu	e panels are FFPE Compatible			
Comprehensive 170	genes (Tissue: DNA & RNA	۸)	DNA: 133 cancer-related g	enes, 59 targets of CNV, <u>55 R</u>	NA fusion genes.			
Comprehensive 170	genes (Tissue: DNA Only)		DNA: 133 cancer-related g	enes, 59 targets of CNV. <u>NO</u> I	RNA fusion genes.			
AVENIO Pan-Cand	er panel matched to Fou	ındationONE® CDx	306 DNA target genes, 36 RNA fusion genes in solid tumors. FFPE Compatible.  Powered by FoundationONE® CDx Analysis Platform					
Pan Cancer Focus (1	Tissue)		35 DNA target genes, 19 ta	rgets of CNV and 23 RNA fus	ion genes			
Follow It® ctDNA Fo	ocused Panel (Blood DNA)		DNA: 38 cancer-related ge	nes, 146 Hotspots, 23 Ex.s. B	Blood sample only.			
SELF-PAYMENT DETAILS								
Contact Name: Patient	or patient support person	Email: (Required)		Phone:				
		SPE	ECIMEN RETRIEVAL	Path report inclu	ded with TRF (Required)			
OncoHelix can co	ontact Pathology Lab to o			Path report inclu				
OncoHelix can co				l arrange the specimen sh				
		btain specimen	Cancer Clinic wi	l arrange the specimen sh	nipment Fax:			
Pathologist Name:		Pathology Lab: Specimen Site:	Cancer Clinic wi	l arrange the specimen sh Date of Collection (YY/M	nipment Fax:			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ice	patient's treating physician a to the patient and have ob dentified test results as requ	Pathology Lab: Specimen Site:  TEST AUTHORIZA  and that results from the stained informed consecutived or permitted by lace.	Cancer Clinic wi Phone:  ATION, CONSENT & SIGNA his test/s may inform the parent, to the extent legally req	Date of Collection (YY/M  TURES  cient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvements	nipment  Fax:  M/DD):  ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ic (without identifiable p	patient's treating physician a to the patient and have ob dentified test results as requ atient information) results a	Pathology Lab:  Specimen Site:  TEST AUTHORIZA  and that results from the patained informed consecutived or permitted by lace and sequencing data for the patained se	Cancer Clinic wi Phone:  ATION, CONSENT & SIGNA his test/s may inform the parent, to the extent legally request for internal quality assur	Date of Collection (YY/M  TURES  cient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvements	nipment  Fax:  M/DD):  ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ic (without identifiable p  Ordering Physic I permit OncoHelix & Canada with final anal assurance/operational	patient's treating physician as to the patient and have obtained test results as requatient information) results as a signature partner lab HTL to (a) perfysis and clinical interpretati	Pathology Lab:  Specimen Site:  TEST AUTHORIZA  and that results from the total informed consecutive or permitted by lace and sequencing data form.  Printed or more than the test of the specified in	Cancer Clinic wing Phone:  Phone:  ATION, CONSENT & SIGNATION, CONSENT &	Date of Collection (YY/M  TURES  Tient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvement research and development  de-identified sequencing dast results as required or per	ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified purposes.			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ic (without identifiable posterior of the part	patient's treating physician as to the patient and have obtained test results as requatient information) results a signature partner lab HTL to (a) perfeysis and clinical interpretation;	Pathology Lab:  Specimen Site:  TEST AUTHORIZA  and that results from the total informed consecuired or permitted by lace and sequencing data for the test/s specified ions by OncoHelix/HTL submissions, publications esearch and development.	Cancer Clinic wing Phone:  ATION, CONSENT & SIGNATION, CONSENT & SIGNATION, to the extent legally required away for internal quality assurer ongoing/future unspecified away include team in Canada (b) retain team, research or to improve ent purposes.	Date of Collection (YY/M  TURES  Tient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvement research and development  de-identified sequencing dast results as required or per	nipment  Fax:  M/DD):  ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified purposes.  Date  ta analysis performed outside of mitted by law for internal quality			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ic (without identifiable posterior of the part	patient's treating physician as to the patient and have obtained test results as requatient information) results a signature partner lab HTL to (a) perfeysis and clinical interpretati improvement, reporting, angoing/future unspecified results.	Pathology Lab:  Specimen Site:  TEST AUTHORIZA  and that results from the trained informed consecuted or permitted by lace and sequencing data form.  Printed form the test/s specified ions by OncoHelix/HTL submissions, publications by OncoHelix/HTL submissions, publications and development Printed on Printed on Printed on Printed on Printed Oncoment Printed Oncoment Printed	Cancer Clinic wing Phone:  ATION, CONSENT & SIGNATION, CONSENT & SIGNATION, to the extent legally required away for internal quality assurer ongoing/future unspecified away include team in Canada (b) retain team, research or to improve ent purposes.	Date of Collection (YY/M  TURES  Tient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvement research and development  de-identified sequencing dast results as required or per	nipment  Fax:  M/DD):  ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified purposes.  Date ta analysis performed outside of mitted by law for internal quality lisclose de-identified results and			
Pathologist Name:  Specimen ID:  I certify that I am the pand purpose of testing herein, (b) retain de-ic (without identifiable particular of the particular	patient's treating physician as to the patient and have obtained test results as requatient information) results a signature partner lab HTL to (a) perfeysis and clinical interpretati improvement, reporting, angoing/future unspecified results.	Pathology Lab:  Specimen Site:  TEST AUTHORIZA  and that results from the total informed consecutive or permitted by lace and sequencing data for the test/s specified ions by OncoHelix/HTL submissions, publications by OncoHelix/HTL submissions, publications esearch and development Printed IMPO	Cancer Clinic wing Phone:  Phone:  ATION, CONSENT & SIGNATION, to the extent legally required and for internal quality assured to the extent legally required and for internal quality assured to the extent legally required and for internal quality assured to the extent legally required to the extent legally re	Date of Collection (YY/M  TURES  Tient's ongoing/future treatmuired, to permit OncoHelix trance/operational improvement research and development  de-identified sequencing dast results as required or per	nipment  Fax:  M/DD):  ment. I have explained the nature o (a) perform the test/s specified ent, (c) use/disclose de-identified purposes.  Date ta analysis performed outside of mitted by law for internal quality lisclose de-identified results and			



#### **SAMPLE REQUIREMENT & GUIDELINES**

Nucleic Acid and Tissue for Solid Tumor Genomic Analysis Panels									
Panel	DNA	RNA	Biopsy	FFPE	Blood		Guidelines for 35 to 306+ gene panels		
Comprehensive 170 gene panel  Avenio Pan-Cancer panel matched to FoundationONE®  CDx panel  Pan Cancer Focus Panel	250 ng	150 ng	120 μm or 4 mm <sup>3</sup>	<b>✓</b>		paraffin emb • 120 μm of minimum of FFPE cores of requirement	nucleic acids and fresh frozen (FF) or formalin fixed pedded (FFPE) tissue samples are accepted f FFPE tissue section (4 scrolls of 30 µm thickness) with a f 40% tissue content & 20% tumor cellularity*; or 2-4 of 1-2 mm <sup>3</sup> ; or 4 mm <sup>3</sup> FF tissue. For DNA only panels, the ts are reduced to half HTL lab is tumor cellularity is <20% and >10%		
Focused Follow It ® ctDNA 38- gene panel	✓				<b>✓</b>		tion: 2 Streck blood tubes collected within 14 days of op off to HTL genomic diagnostic lab		
Specimen Type (select all that apply)  Biopsy Type: FFPE Tissue Blood Other (specify)									
<ul> <li>General Notes and Quality Recommendations:</li> <li>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)</li> <li>Nucleic must acid be extracted from a minimum of 1 ml of biopsy in EDTA, 120 μm or of FFPE tissue or 4 mm³ of FF tissue</li> <li>All nucleic acids will be tested for quality as per laboratory thresholds prior to processing</li> <li>For FF tissue Recommendations</li> <li>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</li> <li>For both FF and FFPE samples, H&amp;E slides must be analyzed by the pathologist and estimation of tumor cellularity must be provided</li> </ul>									
SPECIMEN TYPE		SH	IIPPING & HANDLING	INSTRUCT	IONS		REJECTION CRITERIA		
DNA & RNA  FF Tissue  FFPE Tissue	• DNA only specimens may be shipped at 4 °C  • Ship at room temperature			t 4 ºC	• FFP	optimal quantity/quality E/FF: Tissue content < 40%; Tumor cellularity <20%			
2 Blood Streck Tubes  • Ship at room temperature  • Collected > 14 days ago									
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 cellular	Tumor cellularity:			Pathologist's Name:			

Shipping Address

For HTL Laboratory Use Only

Sample Received (YYYY-MM-DD) (AM/PM)

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 (YYYY-MM-DD) (AM/PM)

# 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

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, CTNNB1, DDR2, DNMT3A, EGFR, EP300, ERBB2, ERBB3, ERBB4, ERCC1, ERG, ESR1, EZH2, FAM175A, FANCI, FANCL, FBXW7, FGF1, FGF10, FGF2, FGF3, 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, 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, TFR

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

## **AVENIO Pan-Cancer panel matched to FoundationONE® CDx panel**

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

Small variants (306): ABL1, ACVR1B, AKT1, AKT2, AKT3, ALK, ALOX12B, AMER1, APC, AR, ARAF, ARFRP1, ARID1A, ASXL1, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, BAP1, BARD1, BCL2, BCL2L1, BCL2L2, BCL6, BCOR, BCORL1, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTG1, BTG2, BTK, C11orf30, CALR, CARD11, CASP8, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD22, CD274, CD70, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CHEK1, CHEK2, CIC, CREBBP, CRKL, CSF1R, CSF3R, CTCF, CTNNA1, CTNNB1, CUL3, CUL4A, CXCR4, CYP17A1, DAXX, DDR1, DDR2, DIS3, DNMT3A, DOT1L, EED, EGFR, EP300, EPHA3, EPHB4, ERBB2, ERBB3, ERBB4, ERCC4, ERG, ERRF11, ESR1, EZH2, FAM46C, FANCA, FANCC, FANCL, FAS, FBXW7, FGF10, FGF12, FGF14, FGF19, FGF23, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT3, FOXL2, FUBP1, GABRA6, GATA3, GATA4, GATA6, GID4 (C17orf39), GNA11, GNA13, GNAQ, GNAS, GRM3, GSK3B, H3F3A, HDAC1, HGF, HNF1A, HRAS, HSD3B1, ID3, IDH1, IDH2, IGF1R, IKBKE, IKZF1, INPP4B, IRF2, IRF4, IRS2, JAK1, JAK2, JAK3, JUN, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KLHL6, KMT2A (MLL), KM72D (MLL2), KRAS, LTK, LYN, MAF, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAPK1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, METTK, MET, MITF, MKNK1, MLH1, MPL, MRE11A, MSH3, MSH6, MST1R, MTAP, MTOP, MUTYH, MYC, MYCN, MYCN, MYD88, NBN, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NT5C2, NTRK1, NTRK2, NTRK3, P2RY8, PALB2, PARK2, PARP1, PARP2, PARP3, PAX5, PBRM1, PDCD1, PDCD1LG2, PDGFRA, PDGFRB, PDK1, PIK3C3B, PIK3C3G, PIK3C3A, PIK3C1, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1, RARA, RB1, RBM10, REL, RET, RICTOR, RNF43, RO51, RPTOR, SDHA, SDHB, SDHC, SDHO, SETD2, SF3B1, SGK1, SMAD2, SMAP4, SMARCA4, SMARCB1, SMO, SNCAIP, SOCS1, SOX2, SOX9, SPEN, SPOP, SRC, STAG2, STAT3, STK11, SYK, TBX3, TEK, TET2, TIPARP, TNFAIP3, TNFRSF14, TP53, TSC1, TSC2, TYRO3, U2AF1, VEGFA, VHL, WHSC1, WHSC11, WT1, XPO1, XRCC2, ZNF217, ZNF703;

RNA fusion (36): ALK, BCL2, BCR, BRAF, BRCA1, BRCA2, CD74, EGFR, ETV4, ETV5, ETV6, EWSR1, EZR, FGFR1, FGFR2, FGFR3, KIT, KMT2A (MLL), MSH2, MYB, MYC, NOTCH2, NTRK1, NTRK2, NUTM1, PDGFRA, RAF1, RARA, RET, ROS1, RSPO2, SDC4, SLC34A2, TERC, TERT, TMPRSS2

#### **Pan Cancer Focus Panel**

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

Small variants (133): AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1, SMO; DNA amplification (59): ALK, AR, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, KIT, KRAS, MET, MYC, MYCN, PDGFRA, PIK3CA; RNA fusion (55): ABL1, ALK, AKT3, AXL, BRAF, EGFR, ERBB2, ERG, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, MET, NTRK1, NTRK2, NTRK3, PDGFRA, PPARG, RAF1, RET, ROS1

### 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, Ex 15 (V600-M620), G606, **CCNE**: Amplification, **CTNNB1**: D32, S33, G34, I35, H36, S37, T41, S45, **DDR2**: L239, I638, S768, **DICER1**: D1705-D1709, G1809, D1810-E1813, **EGFR**: R108, A289, S492, P596, G598, Ex.18, Ex.19, Ex.20, Ex.21, & Amplification, **ERBB2**: G309, S310, K753, L755, I767, D769, Ex. 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, S59, V560, L576, K642, V654, T670, D816, D820, N822, Y823, A829, Ex.9, Ex.11, Ex.13, & 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, Ex.13, Ex.14 (-50 to +25), Ex.18, & 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, Ex.6 [start to P377], C420, E453, P539, E542, E545, Q546, D549, E970, E978, M1043, N1044, A1046, H1047, G1049, & Amplification, **POLE**: Ex.9, Ex.10, Ex.11, Ex.12, Ex.13, Ex.14, (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, Ex

FFPE: Formalin Fixed Paraffin Embedded tissue or block

FF Tissue: Fresh Frozen tissue

