ONCOHELIX

FOR USE BY ALBERTA PRECISION LABS ONLY

Testing site & Shipping Address:
Hematology Translational Lab (HTL)
HMRB336, 3330, Hospital Drive NW, Calgary, AB. T2N4N1

ATTN: Cindy Miskolczi
Email: Precision.Diagnostics@oncohelix.org; htl@ucalgary.ca
Phone +1 (403) 210-3935; +1 (403) 220-7671

PATIENT INFORMATION

Name (Last, First) .....

Medical Record # .....

Date of Birth (YYYY/MM/DD):..... Gender: M ☐ F ☐

Address:..... City:.....

Province: ..... Country: ..... Postal/Zip code.....

ORDER INFORMATION

Requesting Physician..... Copy to Physician .....

Location/Facility: .....

Phone: ..... Fax: ..... Email:.....

Secondary contact (office assistant/nurse) Phone: ..... Email:.....

DIAGNOSIS

Diagnosis:..... Cancer Status (Metastatic): Yes ☐ No ☐

Other Details (if applicable) .....

Has already had molecular testing (supply report, if yes) YES ☐ NO ☐

TEST REQUEST

GENOMIC PANEL ORDERING:

☐ **OncoHelix-4**

Tumour Cell-Free DNA NGS Testing - LAB9486

FOR ALBERTA PRECISION LABS USE ONLY

Liquid Biopsy ctDNA CGP Assay uses the **MSK-ACCESS® panel** **see pg3 for details*
SNVs & Indels: 147 genes; **CNV**: 38 genes; **Fusions**: 10 genes

SPECIMEN DETAILS

Specimen ID:	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 in the US and Europe with final analysis in Canada (b) retain de-identified test results as required or permitted by law for internal quality assurance / operational improvement, (c) use/disclose de-identified results and sequencing data for ongoing/future unspecified research and development purposes, (d) share de-identified aggregate data to the sponsor of the test Alberta Precision Laboratories ("Sponsor") for use in reporting, submissions, publication, research or commercial purposes or to improve this program. The Sponsor may modify or terminate the program at any time in its sole discretion.

....
Patient's signature **Printed Name** **Date**

☐ **OR Patient Verbal Consent Obtained from Ordering Oncologist**

ONCOHELIX

SAMPLE REQUIREMENT & GUIDELINES

Nucleic Acid and Tissue for Solid Tumor Genomic Analysis Panels

Panel	cfDNA	gDNA	Guidelines for MSK-ACCESS® panel
OncoHelix-4 Tumor cfDNA NGS Profiling	30 ng	50 ng	• 2 x 10 ml peripheral blood collected in STRECK Tubes (Tan-top Cell-Free DNA BCT tube) • 1 x 5 ml peripheral blood collected in EDTA Tubes (Lavender-Top EDTA BCT tube) • Extracted cfDNA from plasma and gDNA from WBCs are accepted • For MSK-ACCESS® (evaluation of somatic status), paired tumor-normal analysis is performed and both cfDNA and gDNA is assessed.

Specimen Type (select all that apply)

- BCT Type: ☐ cfDNA BCT (Streck Tubes) ☐ EDTA BCT
- ☐ cfDNA …… (ng) ☐ gDNA …… (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 10 ml of plasma separated from Streck tube Blood (cfDNA) and 3 ml EDTA Blood (gDNA)
- All nucleic acids will be tested for quality as per laboratory thresholds prior to processing

Plasma and cfDNA Recommendations

- Plasma separated from Blood collected in Streck tubes must be stored in -80 °C freezers until DNA extraction
- All blood collection tubes must be delivered to lab within 7 days of blood collection
- cfDNA must be extracted within 10 days of collection of sample (not applicable to genomic DNA extraction)

SPECIMEN TYPE	SHIPPING & HANDLING INSTRUCTIONS	REJECTION CRITERIA
DNA	• Ship at -20°C (use dry ice)	• **Suboptimal quantity/quality** • **Hemolyzed plasma specimen**
Plasma		
Peripheral Blood (Streck Tube)	• Ship at room temperature	
Peripheral Blood (EDTA)		

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

Shipping Address	For HTL Laboratory Use Only
ATTN: Cindy Miskolczi **Hematology Translational Lab (HTL)** HMRB 336, 3330, Hospital Drive NW, Calgary, AB, CANADA T2N 4N1	Sample Received …… (YYYY-MM-DD) …… (AM/PM) Specimen type …… # Tubes/amount …… Lab Acc.# ……

ONCOHELIX

cfDNA NGS PANEL DESCRIPTION

OncoHelix-4 : Tumour Cell-Free DNA NGS Testing - LAB9486 (APL Use Only)

cfDNA CGP Assay uses MSK-ACCESS panel*

Specimen compatibility: cfDNA extracted from Plasma paired with gDNA extracted from EDTA Bloodx`

APC	FOXL2	RB1	RET	CIC	FOXA1	KIT	NPM1	PPP2R1A	SMARCB1
AR	GATA3	SMAD4	ROS1	CREBBP	FOXO1	KNSTRN	NRAS	PPP6C	SOS1
ARID1A	HIST1H3B	STK11	ETV6	CTNNB1	FOXP1	MAP2K1	NTRK2	PRKCI	SRSF2
ASXL1	KDM6A	TET2	AKT1	CTCF	FUBP1	MAP2K2	NTRK3	PTPN11	STAT3
ATM	KEAP1	TP53	ARAF	DICER1	GNA11	MAPK1	NUP93	RAC1	STK19
BAP1	KRAS	TSC1	ARID2	DIS3	GNAQ	MAX	PAK5	RAD54L	TCF7L2
BRCA1	MLH1	TSC2	B2M	EIF1AX	GNAS	MED12	PDGFRA	RAF1	TGFBR1
BRCA2	MSH2	VHL	BCL2	EP300	H3F3A	MSH3	PHF6	RHOA	TGFBR2
CDK12	MSH6	ALK	BCOR	ERBB2	HRAS	MTOR	PIK3CA	RIT1	TP63
CDK4	NF1	BRAF	CARD11	ERBB3	IDH1	MYC	PIK3CB	RRAS2	U2AF1
CDKN2A	PALB2	EGFR	CBFB	ESR1	IDH2	MYCN	PIK3R1	RXRA	XPO1
CHEK2	PMS2	FGFR2	CBL	EZH2	IKZF1	MYD88	PIK3R2	SETD2	TERT
DNMT3A	PPM1D	FGFR3	CCND1	FGFR1	INPPL1	MYOD1	PIM1	SF3B1	
ERCC2	PTCH1	MET	CD79B	FGFR4	JAK1	NFE2L2	POLE	SMAD3	
FBXW7	PTEN	NTRK1	CDH1	FLT3	JAK2	NOTCH1	POT1	SMARCA4	

*OncoHelix-4: cfDNA comprehensive NGS profiling uses the MSK-ACCESS Panel. The assay was validated, and its performance characteristics were determined by OncoHelix and its partner lab – Hematology Translational Lab. The panel is not approved by Health Canada, as is the case for all cancer genomic panel. Both OncoHelix and HTL laboratories are clinically accredited by CPSA to perform high-complexity molecular testing. Any decisions related to patient care and treatment choices should be based on the independent judgement of the treating physician

- SNV and Indels
- Copy Number Variation (amplification and deletion)
- Fusions
- Promoter