ONCOHELIX

Please send completed form to the C3:
ATTN: Christine Lafontaine
Email: c3@ohri.ca
Phone:+1(613)798-5555 ext 73860
Fax: +1(613)737-8659

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..... Is the Physician an Expert member of the C3? ☐ **YES** ☐ **NO** ☐ **No, but interested**

Location/Facility: ..... Report delivery method: ☐ Email ☐ Fax

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

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

DIAGNOSIS & ELIGIBILITY CRITERIA

Biliary Tract Cancer Diagnosis (select all that apply)

☐ Intrahepatic ☐ Extrahepatic ☐ Perihilar ☐ Distal ☐ Gallbladder ☐ Unconfirmed

Required Eligibility Criteria:

1. Age 18 or older ☐ **YES**
2. Unresectable locally advanced OR Metastatic ☐ **YES**
3. Patient agrees to contact the C3 (c3@ohri.ca) ☐ **YES**

Conditional Eligibility Criteria (See page 2 for more details)

1. Being considered for clinical trials? ☐ YES ☐ NO
2. Has already had molecular testing? ☐ YES ☐ NO
   (if yes, a copy of report is required)

TEST REQUEST

GENOMIC PANEL ORDERING:

☐ **OncoHelix-2**
170 genes CGP Panel (Tissue: DNA & RNA)

CGP Assay uses the **Illumina TST-170 panel** **see page 3 for details*
SNVs & Indels: 133 cancer-related genes (DNA); Fusions: 55 RNA fusion genes; CNV: 59 targets

SPECIMEN RETRIEVAL

OncoHelix Navigator will contact Pathology Lab to obtain specimen

Pathology Details to be provided by Ordering Oncologist

Copy of pathology report attached: ☐ **YES (required)**

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 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 funder of the program C3/OHRI ("Funder") for use in reporting, submissions, publication, research or commercial purposes or to improve this program. The Funder may modify or terminate the program at any time in its sole discretion.

☐ I acknowledge that I need to contact the C3 before testing can be completed. Should I not reach out in a timely manner, I permit the C3 to contact me.

....
Patient's signature **Printed Name** **Contact information (email or phone number)** **Date**

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

ONCOHELIX

Pathology Details

SAMPLE REQUIREMENT & GUIDELINES

Nucleic Acid and Tissue for Solid Tumor Genomic Analysis Panels

Panel	DNA	RNA	Biopsy	FFPE	Guidelines for 170 panel
OncoHelix-2 170 genes CGP Panel	250 ng	150 ng	120 µm or 4 mm^3	✓	• 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 mm^3; or 4 mm^3 FF tissue. For DNA only panels, the requirements are reduced to half

Specimen Type (select all that apply)

- **Biopsy Type:** ☐ FFPE Tissue ☐ FF Tissue ☐ 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 must acid be extracted from a minimum of 1 ml of biopsy in EDTA, 120 µm or of FFPE tissue or 4 mm^3 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	• Ship at -20°C (use dry ice)	• **Suboptimal quantity/quality** • **FFPE/FF: Tissue content < 40%; Tumor cellularity < 10%**
FF Tissue		
FFPE Tissue	• 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:**

FFPE: Formalin Fixed Paraffin Embedded tissue or block; FF Tissue: Fresh Frozen tissue

C3 Policy on Molecular Testing and Retesting Eligibility

Retesting will not be conducted on samples that have undergone prior molecular testing using a validated assay that is capable of detecting fusions, rearrangements, and covers the majority of mutations that are clinically actionable and relevant for biliary tract cancers. Additionally, retesting may not be conducted if a targetable mutation has already been identified, including but not limited to: KRAS, NRAS, BRAF, and IDH1/2 mutations. Furthermore, retesting may not be conducted if a patient is currently on a clinical trial with a targeted therapy for a mutation that was previously identified.

Please note, each test requisition will be evaluated on a case-by-case basis to determine eligibility for retesting. This assessment will include the criteria outlined above, as well as consideration of external factors such as the availability of funding.

The determination of test eligibility is at the sole discretion of the C3. Please be aware that these conditions may be subject to change or updates in the future.

ONCOHELIX

SOLID TUMOR NGS PANEL DESCRIPTION

OncoHelix-2 : 170 genes CGP Panel (DNA +/- RNA)

CGP Assay uses Illumina TST-170 panel*

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, 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, 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

*OncoHelix-2/3: 170 Gene CGP Panel uses the Illumina TST170 to provide comprehensive genomic profiling. The research use only 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

Testing Site & Shipping Address	For HTL Laboratory Use Only
ATTN: Dr. Faisal Khan **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.# .....