

Requisition and Consent Form

NTRK Testing of Solid Tumours Program

For consultation/ assistance, please call Kingston Health Sciences Centre at 1-613-549-6666
Molecular Genetics (ext 4892) or Pathology (ext 6035) between 8 am and 4 pm EST

Shipping is included. Please contact your Bayer Representative or KHSC to receive the Purolator Account Number.

Send samples to: Attn: Pathology Laboratory Douglas 2, Kingston Health Sciences Center, Kingston General Hospital, 76 Stuart St, Kingston, ON, K7L2V7

Patient Information		For Laboratory Use Only
Last Name:	First Name:	
Address:		
Health card number:	Telephone:	
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Not specified	Date of birth: MM / DD / YYYY	
Ordering Physician Information		
Name:	Telephone:	Secured Fax # to Send Report: Copy to Fax # (optional):
Institution /Hospital:	Address:	
Physician CPSO#:	Email:	
Other Provincial #:		
Patient Eligibility Criteria		Sample Details
<p>All solid tumour types and histologies qualify for testing. Patients must meet <u>all</u> of the below:</p> <p><input type="checkbox"/> Primary reason for testing is suspicion of an NTRK gene fusion.</p> <p><input type="checkbox"/> Solid tumour is metastatic or surgical resection is likely to result in severe morbidity.</p> <p><input type="checkbox"/> No satisfactory treatment options.</p>		Tissue site:
Prior Testing		Tumour type:
<p>Is this a repeat sample for the same patient under the FastTRK program?</p> <p><input type="checkbox"/> Yes. If known, please provide the KHSC Accession Number: _____</p> <p><input type="checkbox"/> No</p> <p>Has the patient's sample tested positive for an NTRK gene fusion identified through prior testing under a non-validated test or been identified to stain positive for TRK protein through IHC? If so, this patient's sample will be sent straight for NGS testing.</p> <p><input type="checkbox"/> Yes (please include a copy of the prior testing results)</p> <p><input type="checkbox"/> No</p>		<p>For NGS, viable tumour cellularity is >10%? (This assay is not validated to work in samples with <10% cellularity).</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>

Test(s) Requested and Sample Preparation Instructions (CHOOSE ONE):

This testing program is supported by Bayer Inc. For most samples, testing is required to be initiated with a pan-TRK IHC to detect TRK protein.

If sample material is available, positive samples from IHC will be reflexed to molecular testing using the Oncomine Comprehensive Assay version 3 (OCAv3) panel when appropriate.

If sample material is limited, sufficient quantity of slides for only IHC can be sent. If the IHC is positive, additional slides and a new requisition form will be required for NGS testing. Blocks are preferred. If providing slides, Surgipath X-tra Adhesive or Fisherbrand Superfrost Plus slides are preferred. Blocks and any unused slides will be returned following completion of the case to the mailing address noted above.

OPTION #1

- ☐ **Pan-TRK IHC Only** - Expected turnaround time is 2-4 business days for IHC report.

Prepare 3 slides in total as follows:

- Serially section the tissue at 4 microns and mount 1 section each on 2 charged slides, and a third section on a plain slide. Please place tissue onto the lower 2/3rds of the slide.
- Stain plain slide with H&E or equivalent.
- Leave uncharged slide unstained.
- Air Dry at ROOM TEMPERATURE (not in oven).

OPTION #2

- ☐ **Pan-TRK IHC followed by NTRK1/ NTRK2/ NTRK3 gene fusion test by NGS if IHC is positive** - Expected turnaround time is up to 14 business days for NGS report.

Prepare 12 slides in total as follows:

- Serially section the tissue at 4 microns and mount 3 sections (1,2,12) on charged slides, place tissue onto the lower 2/3rds of the slide.
- Mount the remaining 9 sections (3-11) on uncharged slides.
- Stain slides #1 and #12 with H&E.
- Leave slides #2-11 unstained.
- Air Dry at ROOM TEMPERATURE (not in oven).

Additional Information (Optional)

Submission Checklist – Send submission directly to Kingston Health Sciences Centre.

- ☐ Completed and signed requisition (pages 1 and 2; all fields mandatory unless indicated otherwise).
- ☐ Specimen properly prepared for shipping (see above). Clinician must coordinate directly with their Pathology Department to locate sample.
- ☐ Pathology report(s) to accompany the sample (mandatory).

****PHOTOCOPY BOTH SIDES OF REQUISITION AND INCLUDE 1 COPY WITH SAMPLES****

Requisition and Consent Form

NTRK Testing of Solid Tumours Program

For consultation/ assistance, please call Kingston Health Sciences Centre at 1-613-549-6666
Molecular Genetics (ext 4892) or Pathology (ext 6035) between 8 am and 4 pm EST

Additional Prior Treatment Information (Required)			
<input type="checkbox"/> Chemotherapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Radioactive iodine therapy	<input type="checkbox"/> Biologic (non-immunotherapy) <input type="checkbox"/> Radiation	<input type="checkbox"/> Oral tyrosine kinase inhibitor <input type="checkbox"/> Surgery	<input type="checkbox"/> Other <input type="checkbox"/> No prior therapy
Declaration of Patient Consent			
<p>TESTING AND CONTACT WITH PHYSICIAN</p> <p>I consent to the carrying out of the immunohistochemistry and/or genomic analyses indicated on these pages, on myself or the person for whom I am custodian. My physician has told me about the condition(s) being investigated and its molecular basis. I have received and understand the explanation of genomic and molecular analyses.</p> <p>I agree to the collection, use, and disclosure of my personal data for the testing described in this Requisition and Consent Form and as further described below.</p> <p>I understand that my personal data includes my biological samples, my name, date of birth, gender, age, as well as details about my medical history and medication I have taken; the type of cancer with which I have been diagnosed and treatments I have had or am having; results of those treatments; and results from the testing of my biological samples.</p> <p>I agree that my biological samples and personal data will be sent to Kingston Health Sciences Centre (KHSC) at their laboratory and in some cases may be sent to another clinical laboratory for confirmatory testing.</p> <p>I agree that a copy of the results from the testing of my biological samples will be sent to my ordering physician.</p> <p>I understand that as per regulatory guidelines, once the requested test(s) has/have been completed, any remaining tumour sample will be returned to the referring institution, and any remaining genetic material will be stored at the testing laboratory for a minimum of two (2) years.</p> <p>I understand that KHSC will:</p> <ul style="list-style-type: none"> (i) Provide Bayer with information about the testing of my biological samples. This information will be coded with a unique identifier to protect my identity and will include information such as my sex, age range, type of cancer, and test results. This information will be used to optimize access to the NTRK Testing of Solid Tumours Program and to support improvement of the testing protocols. (ii) Notify Bayer if testing under this Program determines that I am positive for an NTRK gene fusion, without revealing my identity. Bayer may contact my physician to provide additional medical information about NTRK gene fusions. <p>KHSC will not provide information to Bayer that would allow Bayer to directly identify me. KHSC's full privacy statement can be found at: http://www.kgh.on.ca/about-kgh/privacy-and-access-information/my-healthcare-information</p> <p> <input type="checkbox"/> Yes, I consent to the terms noted above. <input type="checkbox"/> No, I do not consent to the terms noted above and choose not to be tested under this program. </p>			
SCIENTIFIC RESEARCH			
<p>I consent to KHSC providing Bayer with information about the testing of my biological samples for conducting scientific research. I understand that this information will be coded with a unique identifier to protect my identity and will include information such as my sex, age range, type of cancer, and test results. I understand that KHSC will not provide information to Bayer that would allow Bayer to directly identify me. I agree that Bayer and/or KHSC may use this information to study the prevalence of TRK fusion cancer in Canada, to learn more about NTRK gene fusions, and/or to answer other research questions. I agree that Bayer may share the information with its affiliates and may combine the information with information received from other sources. I understand that Bayer and/or KHSC may publish the results of this research and that I will not be identified or identifiable in such a publication. Bayer's full privacy statement can be found at https://www.bayer.ca/en/privacy-statement/.</p> <p> <input type="checkbox"/> Yes, I consent to the terms noted above. <input type="checkbox"/> No, I do not consent to the terms noted above and understand that not consenting to these terms will not impact my ability to be tested under this program. </p>			
Patient or Substitute Decision Maker:	Signature:	Date:	
	Printed Name	Relationship to Person Being Tested (if applicable):	
Physician Consent			
<p>Confirmation of consent: I confirm that the patient identified in this Requisition and Consent Form has been informed about the details associated with the tests ordered in this Form, including its risks, benefits and limitations.</p>			
<p>X: Physician signature</p>			

Shipping is included. Please contact your Bayer Representative or KHSC to receive the Purolator Account Number.

Send samples to: Attn: Pathology Laboratory Douglas 2, Kingston Health Sciences Center, Kingston General Hospital, 76 Stuart St, Kingston, ON, K7L2V7

****PHOTOCOPY BOTH SIDES OF REQUISITION AND INCLUDE 1 COPY WITH SAMPLES****