Kingston Health Sciences Centre
Centre des sciences de la santé de Kingston

Requisition and Consent Form
NTRK Testing of Solid Tumours Program

FastTRK

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 or e-mail: pathology.secretaries@kingstonhsc.ca

Shipping is included • Purolator Express Account Number: 7107970 • To be solely used for purposes of the *Fast*TRK program
Send completed forms and samples to: Attn: Pathology Laboratory Douglas 2, Kingston Health Sciences Center, Kingston General Hospital, 76 Stuart St, Kingston, ON, K7L 2V7
Effective: *February 2022*

Contract Number: AA775	**Report to Physician Number:** *(Physician OHIP# (ON)/Physician MSC # (B.C.)/ Other Provinces):*	**For Laboratory Use Only**
Ordering Physician Information ***(All fields are mandatory)***		
Name:	**E-mail:** *To ensure timely communication about your test results*	
Address:	**Secured Fax to Send Report:** **Copy to Fax Number** *(optional)*:	
Institution/Hospital:	**Telephone:**	

☐ **I consent to receiving emails and other electronic messages from Bayer and its affiliates relating to the *Fast*TRK program. I understand I can unsubscribe at any time by contacting Bayer at optoutallbayerinc@bayer.com. or 2920 Matheson Blvd E, Mississauga, ON, L4W 5R6, Tel: 1-800-622-2937. For more details, please refer to Bayer's privacy statement at https://www.bayer.ca/en/privacy-statement/.** *(OPTIONAL)*

Patient Information ***(All fields are mandatory)***

Last name:	**First name:**	**Health card number:**	
Address:	**Telephone:**	**Sex:** ☐ Male ☐ Female ☐ Not specified	**Date of birth:** *MM/DD/YYYY*

General Information

This testing program is supported by Bayer Inc. and sample testing algorithms are done as briefly outlined in Adult and Pediatric Patient Eligibility. For Category 2, testing will be initiated with an immunohistochemistry (IHC) screen using pan-TRK antibody {EPR17341} manufactured by Abcam, followed by detection of TRK protein on Leica Instrumentation. Samples with a positive or inconclusive finding following IHC, as well as samples that go directly to molecular testing (Category 1) will undergo molecular interrogation, via next-generation sequencing (NGS), using the Oncomine Comprehensive Assay Version 3 (DNA) and Oncomine Plus (RNA) assays. This comprehensive massively parallel sequencing panel targets single nucleotide and small insertion and/or deletion variants in >130 tumour-related genes, as well as > 50 relevant oncogenic fusion drivers. **All potentially clinically relevant data will be released as additional findings unless indicated that these findings are not desired, as indicated on page 1 of this requisition.**

Prior Testing

Has the patient's sample tested positive for an *NTRK* gene fusion identified through prior testing under a non-validated test or identified to stain positive for TRK protein through IHC? If so, this patient's sample will be sent straight for NGS testing.

☐ Yes (please include copy of prior test results).
☐ No

Is this a repeat sample for the same patient under the *Fast*TRK program?

☐ Yes. If known, please provide the reference number: RE:_____
☐ No.

Adult and Pediatric Patient Eligibility:

Category 1: Qualifies for comprehensive NGS upfront (includes *NTRK1/NTRK2/NTRK3* gene fusions):

Select ONE of the following:

☐ **Colorectal carcinoma:** Stage IV, MMR-deficient, and BRAF *wild*-type
☐ **Soft-tissue-sarcomas:** locally advanced unresectable or metastatic
☐ **Salivary carcinoma:** locally advanced unresectable or metastatic
☐ **Thyroid carcinoma**: radioactive iodine refractory and eligible for treatment with a tyrosine kinase inhibitor (TKI)
☐ **Primary CNS tumours and Pathognomonic locally advanced unresectable or metastatic tumours**: includes infantile fibrosarcoma (IFS), congenital mesoblastic nephroma (CMN), secretory breast cancer (SBC), and mammary analogue secretory carcinoma (MASC)

Category 2: Qualifies for Pan-TRK Immunohistochemistry (IHC) followed by test by NGS if IHC is positive or inconclusive (includes *NTRK1/NTRK2/NTRK3* gene fusions):

If solid tumour is NOT represented above, please select from below:

☐ **Other:** solid tumour, metastatic or where surgical resection is likely to result in severe morbidity, and no satisfactory treatment options

Sample Details:

Biopsy Site: Primary Tissue Site:

Diagnosis:

Sample Preparation Instructions:

Is viable tumour cellularity >10%?: ☐ Yes ☐ No

☐ **Solid tumourblock** (preferred)

OR

☐ **Pre-cut unstained slides** (charged, non-coated)
Prepare 9 or 12 slides in total as follows:

- Category 1: Mount 9 sections at 4 microns (labelled #1–9) on uncharged slides.
- Category 2: Serially section the tissue to produce 3 slides at 4 microns (labelled #1-3) uncharged (non-coated) slides. Mount remaining 9 sections at 4 microns (labelled #4–12) on uncharged slides.

For either Category, place all sections in the lower middle of the slides, air dry at ROOM TEMPERATURE (not in oven) and include one stained H&E slide.

Expected turn-around time: up to 3 business days for IHC report, with an additional 10-12 business days for NGS report if performed.

☐ **I do NOT want to receive any information on additional gene alterations should they be identified by the additional molecular testing (NGS panel).**

TESTING AND CONTACT WITH PHYSICIAN

☐ Yes, I consent to the terms noted on page 2 of this form.
☐ No, I do not consent to the terms noted on page 2 of this form and choose not to be tested under this program.

SCIENTIFIC RESEARCH

☐ Yes, I consent to the terms noted on page 2 of this form.
☐ No, I do not consent to the terms noted on page 2 of this form and understand that not consenting to these terms will not impact my ability to be tested under this program.

Patient Consent

Confirmation of consent: I confirm as the patient identified in this Requisition and Consent Form that I have been informed about the details associated with the tests ordered in this Form, including its risks, benefits, and limitations. I confirm I have reviewed the Declaration of Patient Consent section on page 2 of this form with my physician and I consent to testing, as described.

X: Patient Signature	*Date of Signature*

If Physician is signing on behalf of patient:

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. I confirm I have reviewed the Declaration of Patient Consent section on page 2 of this form with my patient in accordance with the provided instructions and the patient has provided the consent as indicated below:

X: Physician Signature	*Date of Signature*

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Submission Checklist–Send submission directly to KHSC

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

Declaration of Patient Consent (*Physician to review with patient)*

TESTING AND CONTACT WITH PHYSICIAN

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 andmolecular analyses.

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. I understand that by consenting to the collection, use and disclosure of my personal data as described in this form, there is a small risk that my identity could become known if KHSC's processes or systems are compromised.

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 biologicalsamples.

I agree that my biological samples and personal data will be sent to KHSC at their laboratory, and in some cases may be sent to another clinical laboratory for confirmatory testing, which could increase the turn-around time.

I agree that a copy of the results from the testing of my biological samples will be sent to my ordering physician.

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.

I understand that KHSC will:

(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. If my physician agrees to receive further communication from Bayer, Bayer may contact my physician to provide additional medical information about *NTRK* gene fusions.

I understand that I can refuse consent or later withdraw my consent. I also understand that refusal to provide consent or the withdrawal of consent could affect the ability of KHSC to provide services to me.

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

SCIENTIFIC RESEARCH

I consent to KHSC providing Bayer with information aboutthe 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 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 may publish the results of this research and that I will not be identified or identifiable in such a publication. I understand that consent can be withdrawn at any time. Bayer's full privacy statement can be found at https://www.bayer.ca/en/privacy- statement/.

INSTRUCTIONS FOR OBTAINING VERBAL CONSENT

- Verify identity of patient (e.g.: ask for confirmation of date of birth, health card number, and current address);
- Explain what is being tested and what the tests are looking for;
- Explain that the *Fast*TRK program is sponsored by Bayer, a pharmaceutical company;
- Read the Declaration of Privacy Consent;
- Leave time for questions and answer them as they arise;
- Tell the patient that they are free to decline consent, but that the result of declining consent to "Testing and Contact with Physician" is that the patient cannot participate in the *Fast*TRK program;
- If verbal consent is given, sign the requisition form on the patient's behalf, as indicated on the previous page.

PHOTOCOPY BOTH SIDES OF REQUISITION AND INCLUDE 1 COPY WITH SAMPLES