ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	2022 May 30
TO:	Oncology and Pathology, All Sectors
FROM:	Molecular Pathology and Immunohistochemistry Laboratories, APL
RE:	**Provincial NTRK Testing**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- Beginning May 24, 2022, NTRK biomarker testing for unresectable or metastatic solid tumors is available in Alberta through a Bayer-sponsored testing algorithm. Patients who meet criteria for testing may receive screening for NTRK fusions through immunohistochemistry (IHC) and/or next-generation sequencing (NGS) according to the Bayer-approved algorithm. Testing may be requested using the third-party requisition attached to this laboratory bulletin (Appendix 1). Test results will either be available as addenda to the surgical pathology report or in a surgical consult report (immunohistochemistry) or as a separate molecular pathology report in NetCare (South Sector) or the Media tab of EPIC (North Sector).

Background

- NTRK fusions are an oncogenic event that fuses the tyrosine kinase domain of NTRK1, NTRK2, or NTRK3 to a constitutively active partner gene. These fusions are common in some rare neoplasms such as infantile fibrosarcoma and secretory carcinoma and rare in common solid tumors. However, the NTRK inhibitors larotrectinib and entrectinib are Health Canada approved in a tumor-agnostic fashion, meaning that any patient with an NTRK fusion is potentially eligible to receive the therapy. The gold standard for testing for NTRK fusions is NGS of mRNA for fusion transcripts, but this methodology is expensive and not cost-effective for screening in cases where the pre-test probability of a positive result is low. For screening purposes, IHC that detects NTRK expression is the preferred primary method, with reflex to NGS for cases with positive or equivocal staining. Bayer has agreed to fund testing for NTRK fusions for solid tumors according to an algorithm that maximizes cost-effectiveness and identifies as many NTRK positive patients as possible. **This program replaces the send-out program for FastTRK that is currently available to Alberta patients.**

How this will impact you

- Testing for NTRK fusions will be completed in Alberta, improving access and turnaround times for our patients. The new program is designed to report fewer patient-specific details to the sponsoring company, so patient consent for testing is no longer required.

Action Required

- If NTRK testing is required, please use the new requisition (Appendix 1) to order via Alberta Precision Laboratories (APL). These requisitions should be faxed to either the Molecular Pathology Laboratory in North Sector at 780-407-8599 (for patients in Red Deer, Edmonton, Grand Prairie, and other North Sector locations) or South Sector at 403-944-4748 (for patients in Lethbridge, Medicine Hat, Calgary, and other South Sector locations). When possible, specify the surgical case number and block to be tested. If not known, please indicate this on the requisition for the Molecular Pathologist on service to evaluate. Patient consent is no longer required to request NTRK testing for Alberta cancer patients.

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Effective **May 16, 2022**

Questions/Concerns

- Dr. Cheryl Mather, Medical Lead, Molecular Pathology North Sector
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- Dr. Adrian Box, Medical Lead, Molecular Pathology South Sector
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- Dr. Gilbert Bigras, Lead, Immunohistochemistry Laboratory North Sector
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Approved by

- Dr. Imran Mirza, Medical Director, Molecular Pathology Program

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Alberta Precision Laboratories
www.albertaprecisionlabs.ca
THIRD PARTY REQUISITION

407-8599 **SOUTH fax: 403-944-4748**

Scanning Label or Accession # *(lab only)*

Patient

Legal Last Name	Legal First Name	Middle Name	Date of Birth *(dd-Mon-yyyy)*
Alternate Identifier	Preferred Name	☐ Male ☐ Female ☐ Non-binary ☐ Prefer not to disclose	Phone
Address	City/Town	Prov	Postal Code

Provider(s)

Authorizing Provider Name		Copy to Name *(last, first, middle)*	Copy to Name *(last, first, middle)*
Facility: 05100	Phone:	Address	Address
CC Provider / CC Submitter	Legacy ID	Phone	Phone
Financial Class: Company Bill **I602622**		Clinic Name	Clinic Name

Collection

Date *(dd-Mon-yyyy)*	Time *(24 hr)*	Location	Collector ID

Bayer Alberta FastTRK NTRK Gene Fusion Testing of Solid Tumors Program[1]

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 & BRAF *wild*-type
- ❑ **Soft-tissue-sarcomas**: locally advanced unresectable or metastatic
- ❑ **Salivary carcinoma**: locally advanced unresectable or metastatic
- ❑ **Thyroid carcinoma**: radioactive iodine refractory & eligible for treatment w/ TKI
- ❑ **Primary CNS tumors**
- ❑ **Pathognomonic locally advanced unresectable or metastatic tumors**: includes infantile fibrosarcoma (IFS), congenital mesoblastic nephroma (CMN), secretory carcinoma (SC)

Category 2: Qualifies for Pan-TRK Immunohistochemistry (IHC) followed by test for NGS if IHC is positive

- ❑ **Other** (excluding lung cancer and sarcomas): any solid tumor not listed in Cat. 1, metastatic or where surgical resection is likely to result in severe morbidity and/or no satisfactory treatment options

Category 3: Out of province Sarcoma NGS testing request for NTRK 1-3

- ❑ Sarcoma: metastatic or where surgical resection is likely to result in severe morbidity, or no satisfactory treatment options.

Sample Details

Biopsy Site:

Primary Tissue Site:

Block ID:_____

Surgical Case Number:_____

Diagnosis:

Sample Preparation Instructions:

Is viable tumor cellularity >10%?

❑ YES ❑ No

❑ **Solid tumor block (preferred)**

OR

❑ **Pre-cut unstained slides**

Prepare 7 or 10 slides in total as follows:

- **Category 1 or 3**: Serially section the tissue to produce 1 H&E followed by 5 sections at 10 microns on uncharged slides and an additional H&E.
- **Category 2**: Serially section the tissue to produce 1 H&E followed by 3 unstained sections at 4 microns on charged slides, 5 unstained sections at 10 microns on uncharged slides and an additional H&E.

For either Category, place all sections in the lower middle of the slides and air dry at ROOM TEMPERATURE (not in oven)

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

Authorized Provider signature:

*Signature:*_____ *Date of Signature:*_____

1. Bayer Inc., at 2920 Matheson Blvd E., Mississauga, Ontario provides financial support for NTRK fusion testing at Alberta Precision Laboratories.

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