ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	20 January 2025
TO:	All Oncologists
FROM:	Molecular Pathology, Alberta Precision Laboratories
RE:	**Cell-free DNA testing for metastatic non-small cell lung cancer patients**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- As of January 20, 2025, cell-free DNA (cfDNA) from blood specimens will be available at APL for patients with non-small cell lung carcinoma but **only when tumor tissue testing has failed, or archival tumor tissue is not available**. The currently offered lung tumor tissue testing remains the standard molecular tests when archival tumor tissue is available.
- Testing will be referred to the OncoHelix/Hematology Translational Lab (HTL) in Calgary for their cfDNA panel as an interim solution until the in-house APL test can be launched. Results will be sent to the ordering providers by OncoHelix and will be uploaded to the medical record by APL on receipt.
- Samples collected without the appropriate OncoHelix/HTL requisition will not be processed.
- The test is **only available to lung oncologists and thoracic surgery**. Patients can only be referred to the designated outpatient collection laboratories by authorized medical providers.
- Blood specimen collection will be accessible in the regional cancer centers of Grande Prairie, Edmonton, Red Deer, Calgary, Lethbridge, and Medicine Hat **only**. Detailed collection information on each site can be found below.
- Collections will **NOT** occur on statutory holidays.
- At this time, there is no option for patient pay for cfDNA via APL. Samples collected that do not meet approval criteria will NOT be processed.

Background

- Patients with non-small cell lung cancer may benefit from targeted therapies towards EGFR, ALK, RET, ROS1, and other genes when the appropriate tumor alterations are present. National and international guidelines recommend testing of all patients with advanced non-squamous, non-small cell lung carcinoma for these markers.
- Current testing algorithm in Alberta is to order the lung carcinoma molecular analysis on formalin-fixed paraffin-embedded tumor tissue.
- A small minority of lung tumor tissue specimens may have insufficient tissue for testing or fail the sequencing due to extensive degradation or deamination of the extracted tumor DNA material. Additionally, a number of patients may be ineligible for tissue biopsy and would benefit from cell-free DNA testing to determine biomarker status.
- Testing of circulating tumor DNA in cell-free DNA material isolated from the blood specimen (also known as liquid biopsy), is an alternative method to detect the presence of tumor mutations when tumor tissue testing is not feasible; however, cell-free DNA testing is more expensive and may not be as sensitive due to variable circulating tumor DNA in the blood (ct-DNA is detectable in 60%-70% of the cases only).

- The cell-free DNA assay of the external reference laboratory does not distinguish somatic versus germline origin of the mutation or non-lung cancer mutations attributed to clonal hematopoiesis of indeterminate potential (CHIP).

How this will impact you

- Cell-free DNA assay is available to medical providers as an alternative test for biomarker testing when suitable tumor tissue is not available for stage IIIB or IV non-squamous, non-small cell lung cancer patients.
- The criteria for approval is as follows:
  - Prior tissue-based diagnosis of Stage IIIB or IV non-squamous, non-small cell lung cancer
  - Prior testing of tumor tissue has failed due to insufficient tissue/poor tissue quality AND
  - Patient cannot medically tolerate additional tissue biopsy/ tumor sampling
- The test is **only available to lung oncologists and thoracic surgery**. Patient can only be referred to the designated outpatient collection laboratories by authorized medical providers.
- Designated outpatient collection laboratories include Grande Prairie Regional Hospital, Cancer Centre, Cross Cancer Institute, Red Deer Regional Hospital, Foothills Medical Centre, Chinook Regional Hospital, and Medicine Hat Regional Hospital.
- The target result turnaround time of this cell-free DNA assay is 15 working days.

Action Required

- Ordering clinicians are to complete the OncoHelix/HTL requisition and select the **OncoHelix-4 cfDNA panel** test and provide it to their patient.
- Ensure the patient consent section is completed.
- The requisition can be found at www.oncohelix.org/ and selecting “Sponsored Tests – Pharma”. Alternatively, the testing requirements can be found in the APL Test Directory.
- Patients can present to one of the following APL collections sites for collection.

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Location	Address	Hours of Operation
Medicine Hat Regional Hospital - Outpatient Laboratory	2nd Floor Laboratory 666 5th Street SW Medicine Hat, AB T1A 4H6	M-F 0800-1600
Chinook Regional Hospital – Outpatient Laboratory	960 19 Street S Lethbridge, AB T1J 1W5	M-F 0800-1600 (Last walk-in accepted is 1530)
Arthur J.E. Child Comprehensive Cancer Centre Out Patient Collections Laboratory	5th Floor –APL OP Collections Laboratory, Room YC053166 3395 Hospital Drive NW Calgary, AB T2N 5G2	M-F 0730-1600 By appointment only during hours of 0900-1530 For appointment call: 587-231-3788
Red Deer Regional Hospital Centre – Outpatient Laboratory	3942 50A Avenue Red Deer, AB T4N 4E7	M-F 0800-1600
Cross Cancer Institute (CCI)	11560 University Avenue - Room 1451 Edmonton, AB T6G 1Z2	M-F 0800-1600
Grande Prairie Regional Hospital – Outpatient Laboratory	11205 – 110 Street Grande Prairie, AB T8V 4B1	M-F 0800-1600

- The cfDNA reports will be sent to the requesting provider by OncoHelix and scanned into EPIC by APL. Reports will be available for review under “Molecular Pathology” in the Labs section.
- If individual case questions occur, please contact Molecular Pathology program (North lab: 780-407-6648; South lab: 403-220-4240).

Effective **January 20, 2025**

Questions/Concerns

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Approved by

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