

Date: January 4, 2019
To: All Laboratory Personnel (All Zones), Thoracic Surgeons, Oncologists, and Radiologists
From: AHS Laboratory Services
Re: PD-L1 Testing- Update to samples accepted

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message:

- PD-L1 biomarker immunohistochemistry (IHC) testing for advanced non-small cell lung carcinoma (NSCLC) has been available for ordering within Alberta since December 12, 2016.
- Update to **samples accepted:** Formalin fixed Cytology cell blocks are now accepted for testing.

Samples Accepted	Samples Not Accepted
<p style="text-align: center;">*Must be formalin fixed*</p> <ul style="list-style-type: none"> • Surgical specimens • Core biopsies • Material for cytology cell blocks (will be formalin fixed by laboratory staff). Please refrigerate if any delay in transportation is anticipated. • Bone biopsy (testing will be performed if there is no other sample available; however the assay is not fully validated for decalcified samples and false negative results cannot be excluded given the decalcification process) 	<ul style="list-style-type: none"> • Specimens fixed in any fixatives other than formalin (including alcohol based)

- Pathologists have been informed of the testing updates and will be responsible for reflex ordering on all advanced NSCLC patients whose samples fit the testing criteria.

Information required for test requests (if known):

- Cold ischemic time (time from when sample is removed from patient to time the sample is placed in formalin)
 - Expected to be short (**<30 minutes is desirable otherwise false negative rate might increase**)
- Total fixation time (total time that the sample is in formalin)
 - **Why this is important:** The PD-L1 testing method is validated for a 12-72 hour formalin fixation timeframe (**testing will still be performed if fixation time falls outside this range but false negative results cannot be excluded**)
- Requesting testing on the acceptable sample types and providing the required information will help to provide optimal test results and will help expedite the testing process.

Action Required:

- Clinicians should be aware of their sites' ordering process for lung biomarker testing.

Advanced NSCLC- Squamous	PD-L1 biomarker testing performed
Advanced NSCLC- Non-squamous (Adenocarcinoma)	EGFR/ALK-5A4/PD-L1 biomarker testing algorithm is performed

Inquiries and feedback may be directed to:

- Dr. Gilbert Bigras (Medical Lead, EZIHC lab) at gilbert.bigras@ahs.ca

This bulletin has been reviewed and approved by: Dr. Carolyn O'Hara, Provincial Medical Director