Overview

Useful For
Identification of neoplasms expressing programmed cell death 1-ligand 1 (clone SP142)

Special Instructions
- PD-L1 by Immunohistochemistry: Options for Companion and Complementary Diagnostic Assays

Method Name
Immunohistochemistry (IHC)

NY State Available
Yes

Specimen

Specimen Type
Special

Ordering Guidance
For information on selection of programmed cell death 1-ligand 1 (PD-L1) testing, see PD-L1 by Immunohistochemistry: Options for Companion and Complementary Diagnostic Assays in Special Instructions.

Shipping Instructions
Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information
A pathology/diagnostic report and a brief history, including primary site of neoplasm, are required.

Specimen Required
Supplies: Pathology Packaging Kit (T554)

Specimen Type: Formalin-fixed, paraffin-embedded tissue block; or 3 unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information: One slide will be stained with hematoxylin and eosin and returned.

Forms
If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To
<table>
<thead>
<tr>
<th>Tissue/Slides</th>
<th>Wet/frozen tissue</th>
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<tbody>
<tr>
<td></td>
<td>Cytology smears</td>
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<tr>
<td></td>
<td>Nonformalin fixed tissue</td>
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<tr>
<td></td>
<td>Nonparaffin embedded tissue</td>
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<tr>
<td></td>
<td>Non charged slides</td>
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<td>ProbeOn slides</td>
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Clinical and Interpretive

Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tr>
<td>Special</td>
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Clinical Information

Programmed cell death 1-ligand 1 (PD-L1), also known as B7 homolog 1 (B7-H1) or CD274, is a transmembrane protein involved in the regulation of cell-mediated immune responses through interaction with the receptor programmed death protein-1 (PD-1). PD-L1 has been identified as both a prognostic and theranostic marker in a variety of neoplasms. Overexpression of PD-L1 has been observed in carcinomas of the urinary bladder, lung, thymus, colon, pancreas, ovary, breast, kidney, and in melanoma and glioblastoma.

Interpretation

The results of the test will be reported in form of scores. The scoring system is based on type and origin of tumor. If additional interpretation or analysis is needed, order PATHC / Pathology Consultation along with this test.

Cautions

Preclinical studies suggest that positive programmed cell death 1-ligand 1 (PD-L1) immunohistochemistry in tumor cells may predict tumor response to therapy with immune checkpoint inhibitors. This result should not be used as the sole factor in determining treatment, as other factors (eg, tumor mutation burden and microsatellite instability) have also been studied as predictive markers.

This test has been validated for nondecalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. This assay has not been validated on tissues subjected to the decalcification process or use of alternative fixatives for bone and bone marrow specimens or cell blocks.

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen-dependent. Best practice is for paraffin sections to be cut within 6 weeks.

Clinical Reference

5. Mansfield AS, Roden AC, Peikert T, et al: B7-H1 expression in malignant pleural mesothelioma is associated with
sarcomatoid histology and poor prognosis. J Thorac Oncol 2014;9(7):1036-1040

Performance

Method Description
Immunohistochemistry on sections of paraffin-embedded tissue using Ventana PD-L1 clone SP142. (Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
5 to 7 days

Specimen Retention Time
Until reported

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
88360

LOINC® Information

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