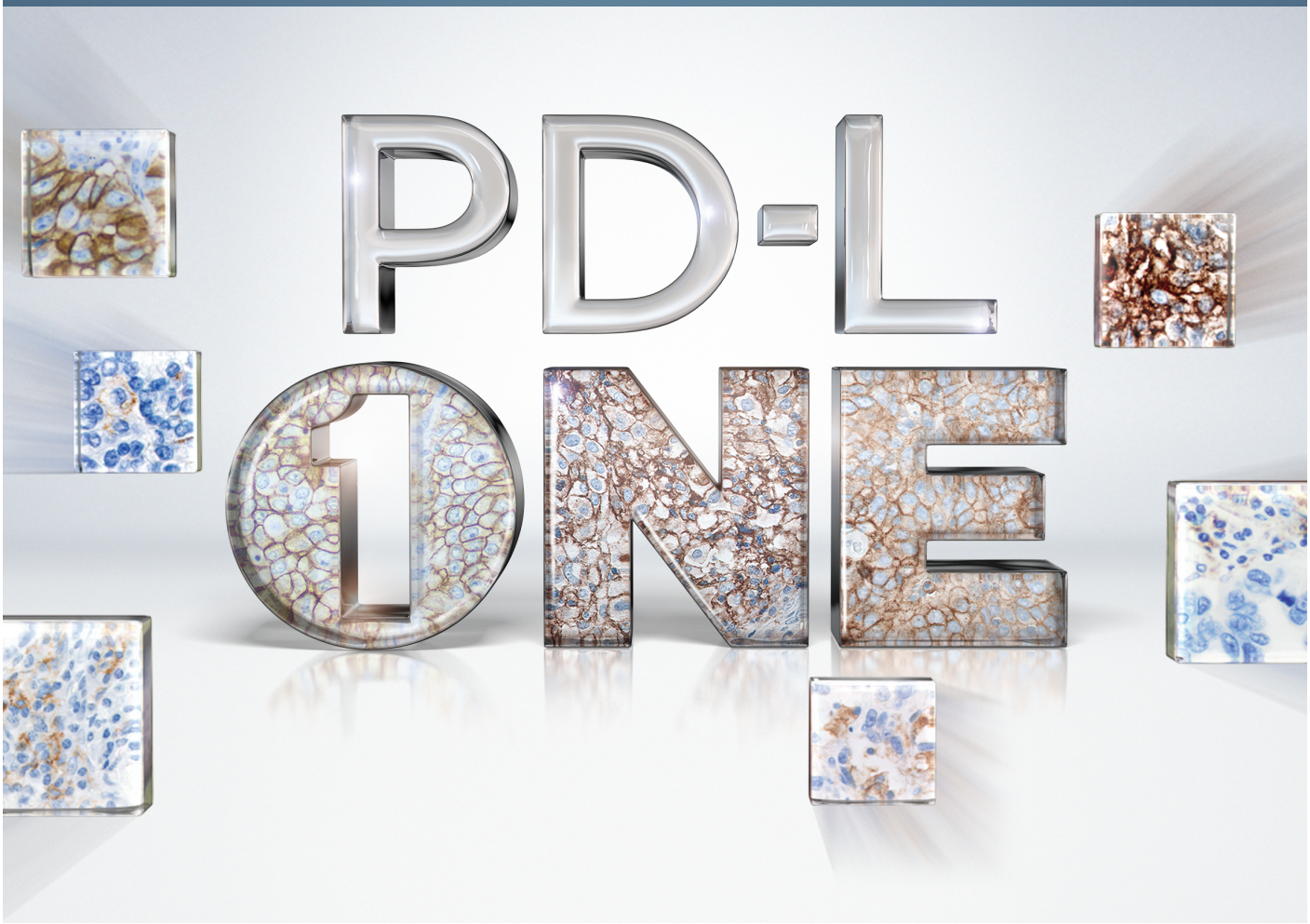
Altium

Agilent
Trusted Answers

Agilent
Dako

Monoclonal Mouse Anti-Human PD-L1, Clone 22C3

Choose Clone 22C3: **ONE** high-quality PD-L1 antibody in **ONE** core concentrate as an aid in the assessment of PD-L1 expression in tumors



ONE Essential PD-L1 Clone

Monoclonal Mouse Anti-Human PD-L1, Clone 22C3, is a concentrate of the 22C3 antibody specifically for PD-L1 analysis[1]

Clone 22C3 offers the quality and staining relevance of a PD-L1 antibody in **ONE** core concentrate[1]

The same high-quality PD-L1 antibody

As used in the CE-IVD–marked PD-L1 IHC 22C3 pharmDx[2]

High sensitivity and specificity[1]

Provide proven PD-L1 detection

ISO-certified manufacturing facilities

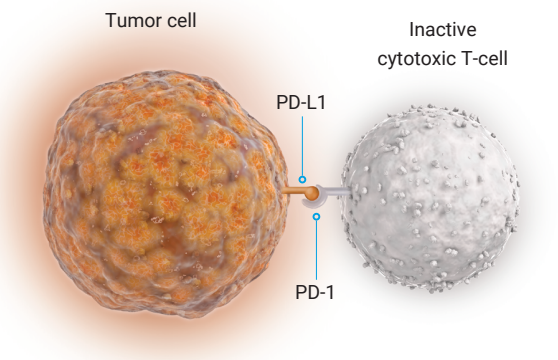
Meets all applicable quality assurance standards

The flexibility of seamless integration into any pathology platform, system, and workflow upon validation

- Ability to validate Clone 22C3 with your staining instrument, in your workflow, and on your visualization system gives your lab maximum flexibility
- Diagnostic compatibility in multiple tissue types increases your lab's versatility

PD-L1 Testing Should Be an Integral Part of Patient Care From Day **ONE**

Tumors upregulate PD-L1 expression to evade our natural immune response[1]



- Programmed death-ligand 1 (PD-L1) is a transmembrane protein that binds to the programmed death-1 (PD-1) receptor during immune system modulation
- Normal cells express PD-L1 to downregulate the immune response of cytotoxic T cells
- Some tumor cells mimic the behavior of healthy cells by emitting the PD-L1 signal, thereby inhibiting action of T cells and avoiding detection and elimination

Immunohistochemical testing with Clone 22C3 can aid in the assessment of PD-L1 expression in tumor cells[1]

Two Solutions. **ONE** That's Right for Your Lab.

Validate companion diagnostic assay or core concentrated antibody? It's your choice.

- Pathology labs require different options to meet their PD-L1 testing needs: complete companion diagnostic solutions, laboratory developed tests, and lab outsourcing
- We provide the 22C3 clone in two options to address your testing preferences: the complete PD-L1 IHC 22C3 pharmDx kit and the core PD-L1 22C3 concentrate[1,2]

PD-L1 IHC 22C3 pharmDx

PD-L1 22C3 concentrate

CE-IVD

Both PD-L1 IHC 22C3 pharmDx and the core 22C3 concentrate comply with the European In Vitro Diagnostic Devices Directive[1,2]

Find the 22C3 solution that's best for your lab

<table>
<tr><th></th><th>PD-L1 IHC 22C3 pharmDx[2]</th><th>PD-L1 22C3 Concentrate[1]</th></tr>
<tr><td>Intended Use</td><td>For in vitro diagnostic use.

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using monoclonal mouse anti-PD-L1, Clone 22C3, intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), urothelial carcinoma, head and neck squamous cell carcinoma (HNSCC), and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. PD-L1 protein expression in urothelial carcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.

PD-L1 protein expression in HNSCC is determined by using CPS and/or TPS.

<table><tr><th>Tumor Indication</th><th>PD-L1 Expression Level</th><th>Intended Use</th></tr><tr><td rowspan="2">NSCLC</td><td>TPS ≥ 1%</td><td rowspan="2">PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab).*</td></tr><tr><td>TPS ≥ 50%</td></tr><tr><td>Urothelial Carcinoma</td><td>CPS ≥ 10</td><td>PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab).*</td></tr><tr><td rowspan="2">HNSCC</td><td>CPS ≥ 1</td><td rowspan="2">PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying HNSCC patients for treatment with KEYTRUDA® (pembrolizumab).*</td></tr><tr><td>TPS ≥ 50%</td></tr></table>*See the KEYTRUDA® product label for PD-L1 expression cutoff values and specific clinical circumstances guiding therapy.</td><td>For in vitro diagnostic use.

Monoclonal Mouse Anti-Human PD-L1, Clone 22C3, is intended for use in immunohistochemistry. This antibody labels PD-L1 in normal and neoplastic tissue.

The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a certified pathologist. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using nonimmunologic histochemical stains.</td></tr>
<tr><td>Code</td><td>SK006</td><td>M3653</td></tr>
<tr><td>Type of Product</td><td>Validated companion diagnostic assay</td><td>Reagent</td></tr>
<tr><td>Materials Provided</td><td>All materials for a full staining run</td><td>Antibody only</td></tr>
<tr><td>Clinical Performance Data</td><td>Included</td><td>Not included</td></tr>
<tr><td>Reproducibility Data</td><td>Included</td><td>Not included</td></tr>
<tr><td>Automated Staining</td><td>Yes</td><td>No, requires continuous cross-batch verification</td></tr>
<tr><td>Platform</td><td>Autostainer Link 48</td><td>Multiple</td></tr>
<tr><td>Additional Resources</td><td>Interpretation Manual, scoring guidelines, training resources</td><td>None</td></tr>
</table>

For countries outside of the European Union, see the local KEYTRUDA product label for approved indications and expression cutoff values to guide therapy.

References

1. Monoclonal Mouse Anti-Human PD-L1, Clone 22C3 [package insert]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2020.
2. PD-L1 IHC 22C3 pharmDx [package insert]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2020.

Published, March 09, 2020
29178 D58914 2020MAR04

Altium International Sp. z o.o.
ul. Puławska 303, 02-785 Warszawa
telefon +48 22 549 14 00
patologia.pl@altium.net
www.perlan.com.pl
www.altium.net

Agilent
Trusted Answers