

## PD-L1 (CAL10)

Rabbit Monoclonal Antibody

SAM-QHD- RM200-10 tests

QHD-RM200-100 tests

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Source	Clone	Species	Isotype	Primary Antibody Diluent
Synthetic peptide derived from a region of the PD-L1 protein	CAL10	Rabbit	IgG <sub>1</sub>	NA
<i>Epitope: Not Determined</i>		<i>Species Reactivity: Human</i>		

Catalog Number	Description
SAM-QHD-RM200-10 tests	2 mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform.
QHD-RM200-100 tests	15 mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform

### Intended Use

For In Vitro Diagnostic Use. PD-L1 (CAL10) Rabbit Monoclonal Primary antibody is intended for laboratory use in the detection of the PD-L1 protein in formalin-fixed, paraffin-embedded tissue stained in qualitative immunohistochemistry (IHC) testing.

The results using this product should be interpreted by a qualified pathologist in conjunction with the patient's relevant clinical history, other diagnostic tests and proper controls.

### Summary and Explanation

Programmed death ligand 1 (PD-L1, also known as CD274) inhibits tumor-reactive T cells via binding to the programmed death-1 (PD-1) receptor, rendering tumor cells resistant to CD8+ T cell-mediated lysis.<sup>1</sup> Studies have shown that the inhibitory receptor PD-1 is expressed on tumor-infiltrating lymphocytes (TIL) while PD-L1 is expressed on tumor cells. Assessment of PD-L1 expression in combination with CD8+TIL density may be a useful predictive metric in multiple cancers, including stage III NSCLC, hormone receptor negative breast cancer and sentinel lymph node melanoma.<sup>2-4</sup> Clinical trials utilizing humanized chimeric antibodies that block inhibitory checkpoints, such as anti-PD-1 and anti-PD-L1, have demonstrated delayed tumor growth and increased survival.<sup>5</sup> While identification of PD-L1 overexpression by IHC is not yet standardized, it

has become increasingly important to identify these tumors, as a directed therapy may improve clinical outcomes in these patients.<sup>6</sup> In cutaneous melanoma, the targeting of PD-1/PD-L1 has provided meaningful clinical benefit for patients in just the past 5-10 years.<sup>7</sup> The use of IHC for protein identification, along with novel therapies, such as checkpoint inhibitors and vaccines, are generating new options for the treatment of cancer patients. The PD-L1 [CAL10] clone does not cross react with PD-L2.

### Materials and Methods Provided

The stated primary antibody product contains reagent in a vial made for use with the StatLab Quantum HDx IHC slide stainer. The vial is equipped with an RFID tag that is ready by the slide stainer to provide product and lot specific information.

This antibody is diluted in Tris Buffer, pH 7.3-7.7, with 1% BSA and <0.1% Sodium Azide.

### Materials and Reagents Needed but Not Provided

The following reagents and materials may be required for staining but are not provided with the primary antibody. Please refer to our website at: [www.StatLab.com](http://www.StatLab.com).

1. Quantum HD HRP Detection Kit (Cat. No.: QHD-U3-15-HRP-KIT) OR
1. Quantum HD AP Detection Kit (Cat. No.: QHD-U2-15-HRP-KIT)
2. Quantum HD Retrieval Solution, pH 9.0 (Cat. No.: QHD-003)
3. Quantum HD Retrieval Solution, pH 6.0 (Cat. No.: QHD-002)
4. Quantum HD DS2 (Cat. No.: QHD-007)
5. Quantum HD Block (Cat. No.: QHD-006)
6. Wash Buffer (Cat. No.: QHD-015)
7. Positive and Negative Tissue controls

### Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

### Principles of the Procedures

Antigen detection by immunohistochemistry (IHC) is a two-step process involving first, the binding of a primary antibody to the antigen of interest, and second, the detection of bound antibody by a chromogen. The primary antibody may be used in IHC using manual techniques or using automated IHC Staining Systems.

### Warnings and Precautions

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable as hazardous materials.<sup>7</sup>
2. Sodium azide (NaN<sub>3</sub>) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing.<sup>8</sup>
3. Specimens, before and after fixation and all materials exposed to them, should be handled as if capable of



transmitting infections and disposed of with proper precautions.<sup>9</sup>

4. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water.
5. Microbial contamination of reagents may result in an increase in nonspecific staining.
6. Incubation times or temperatures other than those specified may give erroneous results. The use must validate any such change.
7. The SDS is available upon request
8. Do not use reagents beyond the expiration date printed on the vial.
9. The user must validate any storage conditions other than those specified in the package insert

The SDS is available upon request

#### Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding.<sup>10,11</sup>

The user is advised to validate the use of the products with their tissue specimens prepared and handled in accordance with their laboratory practices

#### StatLab Quantum HDx Recommended Staining Procedure:

Instrument Parameters	QHD-U3-HRP-Kit	QHD-U2-AP-Kit
Retrieval Reagent	QHD-High pH	QHD-High pH
Antibody Incubation Time	10-45 minutes	10-45 minutes

#### Step by Step Procedure:

1. Follow the StatLab Quantum HDx instrument instructions for setting up the reagents on the instrument
2. Load slides, antibodies, and detection kit(s) onto StatLab Quantum HDx instrument according to StatLab Quantum HDx instructions for use
3. Start the run.
4. When the staining is complete, remove the slides from instrument, rinse well with distilled water
5. Dehydrate, Clear and Coverslip

#### Troubleshooting

Positive and negative controls should be run simultaneously with all patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact StatLab IHC Technical Support via Email at: [ihctech@statlab.com](mailto:ihctech@statlab.com) or call us at (800) 442-3573.

#### Cellular Localization and Positive Tissue Control

Positive Tissue Control	
Tissue	Visualization
Human Lymph Node	Membranous
Lung Carcinoma	Membranous

#### Limitations of the Procedure

IHC is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can also cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue may cause variations in results.<sup>12</sup> Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive with horseradish peroxidase systems.<sup>13</sup> Improper counterstaining and mounting may compromise the interpretation of results.

#### Performance Characteristics

The optimum antibody protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, and tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times may vary. The data sheet recommendations and protocols are based on exclusive use of products manufactured for StatLab. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

#### NOTE

There are no expressed or implied warranties which extend beyond this datasheet. StatLab is not liable for personal injury, property damage or economic loss caused by this product.

#### References

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