

# Cyclin D1

Concentrated and Prediluted Rabbit Monoclonal Antibody  
901-307-092617

**BIOCARE**  
M E D I C A L

<b>Catalog Number:</b>	<b>CRM 307 AK, BK, CK</b>	<b>PRM 307 AA</b>	<b>IPI 307 G10</b>
<b>Description:</b>	0.1, 0.5, 1.0 ml, concentrated	6.0 ml, prediluted	10 ml, prediluted
<b>Dilution:</b>	1:50	Ready-to-use	Ready-to-use
<b>Diluent:</b>	Renoir Red	N/A	N/A

## Intended Use:

For In Vitro Diagnostic Use

Cyclin D1 [SP4] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of Cyclin D1 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. 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 qualified pathologist.

## Summary and Explanation:

This rabbit monoclonal antibody recognizes a protein of 36 kDa, identified as Cyclin D1 (also known as Bcl-1 or PRAD-1). Cyclin D1 is a regulatory subunit of certain protein kinases thought to advance the G1 phase of the cell cycle. Cyclin D1 used in tandem with CD5, CD10 and CD23 is the most reliable immunohistochemical marker for mantle cell lymphoma. Cyclin D1 is also expressed in invasive breast cancer.

## Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. This detection of the bound antibody is evidenced by a colorimetric reaction.

**Source:** Rabbit monoclonal

**Species Reactivity:** Human, mouse and rat

**Clone:** SP4

**Isotype:** IgG

**Total Protein Concentration:** ~10 mg/ml. Lot specific Ig concentration is not available

**Epitope/Antigen:** Cyclin D1

**Cellular Localization:** Nuclear

**Positive Tissue Control:** Mantle cell lymphoma and breast cancer

**Known Applications:**

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

**Supplied As:** Buffer with protein carrier and preservative  
Renoir Red (PD904)

## Storage and Stability:

Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

## Protocol Recommendations (intelliPATH and manual use):

**Peroxide Block:** Block for 5 minutes with Biocare's Peroxidized 1.

**Pretreatment:** Perform heat retrieval using Biocare's Borg or Reveal Decloaker. Refer to the Borg or Reveal Decloaker product data sheet for specific instructions.

**Protein Block (Optional):** Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

**Primary Antibody:** Incubate for 30-60 minutes at RT.

**Probe:** N/A

**Polymer:** Incubate for 30 minutes at RT with a secondary-conjugated polymer.

**Chromogen:** Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Biocare's Warp Red.

## Protocol Recommendations (intelliPATH and manual use) Cont'd:

**Counterstain:** Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

## intelliPATH™ Automated Slide Stainer:

IPI307 is intended for use on the intelliPATH™ Automated Slide Stainer. Refer to the intelliPATH Automated Slide Stainer manual for specific instructions on its use. When using the intelliPATH, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.

## Technical Note:

This antibody has been optimized for use with Biocare's MACH 4 Universal HRP-Polymer Detection and intelliPATH Universal HRP Detection Kit. Use TBS for washing steps.

## Limitations:

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

## Quality Control:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

## Precautions:

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. 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. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (9)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (10)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.

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## Precautions Cont'd:

6. The SDS is available upon request and is located at <http://biocare.net>.

## Troubleshooting:

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

## References:

1. de Leon ED, *et al.* Usefulness of an immunohistochemical panel in paraffin-embedded tissues for the differentiation of B-cell non-Hodgkin's lymphomas of small lymphocytes. *Mod Pathol.* 1998 Nov;11(11):1046-51.
2. Singh N, Wright DH. The value of immunohistochemistry on paraffin wax embedded tissue sections in the differentiation of small lymphocytic and mantle cell lymphomas. *J Clin Pathol.* 1997 Jan;50(1):16-21.
3. Quintanilla-Martinez L, *et al.* Mantle cell lymphomas lack expression of p27Kip1, a cyclin-dependent kinase inhibitor. *Am J Pathol.* 1998 Jul;153(1):175-82.
4. Samaha H, *et al.* Mantle cell lymphoma: a retrospective study of 121 cases. *Leukemia.* 1998 Aug;12(8):1281-7.
5. Nakamura S, Yatabe Y, Seto M. Cyclin D1 overexpression in malignant lymphomas. *Pathol Int.* 1997 Jul;47(7):421-9.
6. van Diest PJ, *et al.* Cyclin D1 expression in invasive breast cancer. Correlations and prognostic value. *Am J Pathol.* 1997 Feb;150(2):705-11.
7. de Boer CJ, *et al.* Cyclin D1 protein analysis in the diagnosis of mantle cell lymphoma. *Blood.* 1995 Oct 1;86(7):2715-23.
8. Bartkova J, *et al.* Cell cycle-related variation and tissue-restricted expression of human cyclin D1 protein. *J Pathol.* 1994 Mar;172(3):237-45.
9. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
10. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.