

Instructions For Use A00163-IFU-IVD

Rev. Date: April 15, 2021

Revision: 1

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Cyclin D1; Clone CCND1/3370R

Catalog Number	Format	<u>Volume</u>
A00163-0002	(Ready-To-Use)	2 ml
A00163-0007	(Ready-To-Use)	7 ml
A00163-0025	(Ready-To-Use)	25 ml
A00163-C.1	(Concentrate)	0.1 ml
A00163-C	(Concentrate)	1 ml

Intended Use

For In Vitro Diagnostic use. This antibody is intended for the qualitative visualization of the anatomical elements listed in the Specificity section. It is intended to be used within an Immunohistochemistry (IHC) procedure on formalin-fixed paraffin-embedded (FFPE) human tissue followed by visualization by light microscopy. Any diagnostic interpretation of the results of this antibody is to 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.

Description

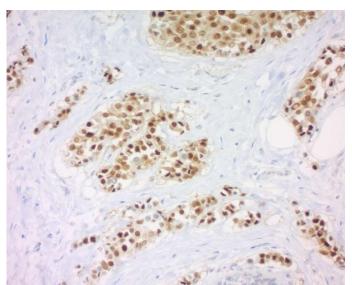
Concentrate: Suggested dilution is 1:50-150
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Species: Rabbit
Immunogen: A synthetic peptide corresponding to residues within aa 270-295
of Cyclin D1.
Clone: CCND1/3370R
Isotype: IgG
Entrez Gene ID: 595
Hu Chromosome Loc.: 11q13.2
Synonyms: B cell CLL/lymphoma 1; B cell leukemia 1; B cell lymphoma 1
protein; BCL-1 oncoprotein; CCND1 protein; CCND1/FSTL3
fusion gene; CCND1/IGHG1 fusion gene; CCND1/IGLC1 fusion
gene; CCND1/PTH fusion gene; G1/S-specific cyclin-D1;
Parathyroid adenomatosis 1; PRAD1 oncogene.
Mol. Wt. of Antigen: 36kDa
Format: Ready-To-Use antibody has been pretitered and quality
controlled to work on formalin-fixed paraffin-embedded as well as
acetone fixed cryostat tissue sections. No further titration is
required.
Concentrate antibody is provided at 200µg/ml of Ab purified from
Bioreactor Concentrate by Protein A/G. Prepared in 10mM PBS
with 0.05% BSA & 0.05% Sodium Azide.
Specificity: This antibody reacts with a 36 kD protein identified as cyclin D1.
Background: Cyclin D1, one of the key cell cycle regulators, is a putative proto-
oncogene overexpressed in a wide variety of human neoplasms.
This antibody neutralizes the activity of cyclin D1 in vivo. About
60% of mantle cell lymphomas (MCL) contain a t(11; 14)(q13;
q32) translocation resulting in over-expression of cyclin D1. This
antibody is useful in identifying mantle cell lymphomas (cyclin D1
positive) from CLL/SLL and follicular lymphomas (cyclin D1
negative). Occasionally, hairy cell leukemia and plasma cell
myeloma weakly express Cyclin D1.
Species Reactivity: Human, Others-not known
Positive Control: Human mantle cell lymphoma, breast or bladder carcinomas
Cellular Localization: Nuclear
Microbiological State: Nonsterile.



8° C

Storage: 2° C

ScyTek Laboratories, Inc. 205 South 600 West Logan, UT 84321 U.S.A.



Human Breast IDC stained using Cyclin D1; Clone CCND1/3370R. Pretreatment with Tris-EDTA HIER Solution pH 9.0 for 5 minutes in a pressure cooker at 21psi. Antibody was visualized using PolyTek Anti-Rabbit Polymerized HRP and DAB Chromogen/Substrate (High Contrast). Counterstained with Hematoxylin, Mayer's (Lillie's Modification). Final magnification 200X.

Materials and Reagents Required but not Provided

1. Control tissue and reagents

2. Xylene, graded alcohols, and deionized/distilled water

3. Antibody Diluent.

4. IHC detection system. Suggested: ScyTek Cat# ABZ125 "CRF Anti-Polyvalent HRP Polymer" and ScyTek Cat# ACV500 "DAB Chromogen/Substrate Kit (High Contrast)".

5. Wash buffer for rinses (ScyTek Cat# TBT500)

6. HIER Retrieval Solution

7. Hematoxylin counterstain and bluing reagent (ScyTek Cat# HMM500 and BRT500)

8. Mounting medium and coverslips

Note: ScyTek Laboratories has a wide range of IHC reagents and ancillaries that can be found at scytek.com.

Procedure

1. Tissue Section Pretreatment (Required): Staining of formalin fixed, paraffin embedded tissue sections is significantly enhanced by pretreatment with pH 8-9 HIER Solution (see ScyTek catalog# ETA or TES for instructions).

2. **Primary Antibody Incubation Time:** We suggest an incubation period of 30 minutes at room temperature. However, depending upon the fixation conditions and the staining system employed, optimal incubation should be determined by the user.

3. **Visualization:** For maximum staining intensity we recommend the "CRF Anti-Polyvalent HRP Polymer" (ScyTek catalog# ABZ125, see IFU for instructions) combined with the "DAB Chromogen/Substrate Bulk Pack (High Contrast)" (ScyTek catalog# ACV500, see IFU for instructions).



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Storage and Stability

Do not Freeze. Store at 2-8°C. Return to 2-8° immediately after use. Do not use after expiration date printed on label. Verify visually that antibody has not been contaminated before use. Do not use if reagent becomes cloudy or precipitates.

Limitations

Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue specimen may cause variations in results. Endogenous peroxidase activity or pseudoperoxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. This data sheet's recommendations and procedures were validated using ScyTek IHC reagents and may not be suitable for other detection systems.

Precautions

1. Contains Sodium Azide as a preservative (0.09% w/v), do not ingest. 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. This product contains no hazardous material at a <u>reportable concentration</u> according to U.S. 29 CFR 1910.1200, OSHA Hazardous Communication Standard and EC Directive 91/155/EC.

2. Do not pipette by mouth.

3. Avoid contact of reagents and specimens with skin and mucous membranes.

4. Avoid microbial contamination of reagents or increased nonspecific staining may occur.

5. The user must validate any procedures and recommendations that differ from this data sheet.

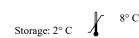
6. The SDS may be found at scytek.com

References

 Peltomaki, P., et al. 1993. Genetic mapping of a locus predisposing to human colorectal cancer. Science 260: 810-812.

Warranty

No products or "Instructions For Use (IFU)" are to be construed as a recommendation for use in violation of any patents. We make no representations, warranties or assurances as to the accuracy or completeness of information provided on our IFU or website. Our warranty is limited to the actual price paid for the product. ScyTek Laboratories, Inc. is not liable for any property damage, personal injury, time or effort or economic loss caused by our products.



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