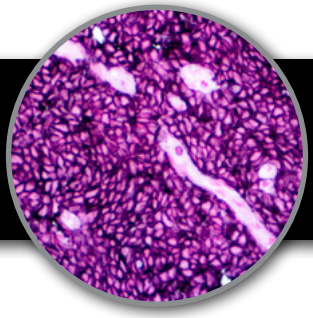
CD45

Clone: 2B11 & PD7/26

Mouse Monoclonal

CE IVD



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Inset: IHC of CD45 on a FFPE Tonsil Tissue

Intended Use

For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical applications on formalin-fixed paraffin-embedded tissues (FFPE), frozen tissue sections and cell preparations. Interpretation of results should be performed by a qualified medical professional.

Immunogen

PD7/26/16: human peripheral blood lymphocytes maintained in T cell growth factor and 2B11: isolated neoplastic cells from T cell lymphoma.

Summary and Explanation

The CD45 antigen is a protein which was originally called Leukocyte Common Antigen. It is a Type I transmembrane protein which is in various forms present on all differentiated hematopoietic cells except erythrocytes and assists in the activation of those cells (a form of co-stimulation). It is expressed in Lymphomas, B-cell Chronic Lymphocytic Leukemia, Hairy Cell Leukemia, and Acute Non-lymphocytic Leukemia.

CD45 is a monoclonal antibody that is routinely used to aid in the differential diagnosis of undifferentiated neoplasms, whenever malignant Lymphoma is suspected by the morphological or clinical data. It is a highly specific antibody; thus, a positive result is highly indicative of lymphoid or myeloid origin. Certain types of lymphoid neoplasms may lack CD45 (Hodgkin's Disease, some T-cell Lymphomas and some Leukemias) so its absence does not rule out a hematolymphoid tumor. This antibody is exclusively expressed by cells of hematopoietic lineage and is present in most benign and malignant lymphocytes, erythrocytes and plasma cell precursors.

Antibody Type	Mouse Monoclonal	**Clone**	2B11 & PD7/26
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Control**	Tonsil, Lymph Node, Spleen, Thymus
Species Reactivity		Human	

Presentation

CD45 is a mouse monoclonal antibody derived from cell culture supernatant that is concentrated, dialyzed, filter sterilized and diluted in buffer pH 7.5, containing BSA and sodium azide as a preservative.

Presentations

Catalog Num.	Antibody Type	Dilution	Volume/Qty
BSB 5246	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 5247	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 5248	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 5249	Concentrated	1:250 - 1:1000	0.1 mL
BSB 5250	Concentrated	1:250 - 1:1000	0.5 mL
BSB 5251	Concentrated	1:250 - 1:1000	1.0 mL
BSB 5252	Control Slides	Not Applicable	5 slides

Precautions

1. For professional users only. Ensure results are interpreted by a medical professional.
2. This product contains sodium azide (NaN3), a toxic chemical which may react with plumbing to form highly explosive build-ups of metal azides. Upon disposal, flush with large volumes of water to prevent sodium azide build-up.
3. Ensure proper handling procedures are used with reagent. Always wear proper laboratory equipment such as laboratory coat and gloves when handling reagents.
4. Unused solution should be disposed of according to local and federal regulations.
5. Do not ingest reagent. If reagent ingested, contact a poison control center immediately.
6. For complete recommendations for handling biological specimens please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" (4).

Storage

Store at 2-8 °C. Do not use after expiration date listed on package label. Temperature fluctuations should be avoided. Store appropriately when not in use, and avoid prolonged exposure to room temperature conditions.

Specimen Preparation

Paraffin sections: The antibody can be used on formalin-fixed paraffin-embedded (FFPE) tissue sections. Ensure tissue undergoes appropriate fixation to ensure best results. Pre-treatment of tissues with heat-induced epitope retrieval (HIER) is recommended using Bio SB ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023), ImmunoDNA Retriever with EDTA (BSB 0030-BSB 0033) or ImmunoDNA Digestor (BSB 0108-0112). See reverse side for complete protocol. Tissue should remain hydrated via use of Bio SB Immuno/DNA Washer solutions (BSB 0029 & BSB 0042).
Frozen sections and cell preparations: The antibody can be used for labeling acetone-fixed frozen sections and acetone-fixed cell preparations.

Staining Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positive charged slides such as Bio SB Hydrophilic Plus Slides (BSB 7028).
2. Air dry for 2 hours at 58° C.
3. Deparaffinize, dehydrate and rehydrate tissues.
4. Subject tissues to heat epitope retrieval using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
5. Any of three heating methods may be used:

a. TintoRetriever Pressure Cooker or Equivalent

Place tissues/slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA, and place in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.

b. TintoRetriever PT Module or Water Bath Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.

c. Conventional Steamer Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a Steamer, cover and steam for 30-60 minutes.

6. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
7. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with IHC wash buffer or DI water.
9. Continue IHC staining protocol.

Recommended IHC Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
Peroxidase/AP Blocker	5 min.	5 min.	5 min
Primary Antibody	30-60 min.	30-60 min.	30-60 min.
1st Step Detection	10 min.	30-45 min.	15 min.
2nd Step Detection	10 min.	Not Applicable	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain	Varies	Varies	Varies

References

1. Mason DY, Am Pathol. 1987;128:1-4
2. Hall PA, Histopathology. 1988;13:149-160
3. Kurtin PJ, Hum Path. 1985;16:353-365
4. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. Supplement / Vol. 61, January 6, 2012.

Performance Characteristics

Normal Tissues

Positive (+)	
Tonsil: germinal centres follicular mantle zones interfollicular regions	Spleen: white pulp lymphoid cells of red pulp thymic lymphocytes bone marrow lymphoid cells mast cells cells of probable monocytic derivation plasma cells (occassional)
Variable (+/-)	
immunoblasts	epithelioid histiocyte
sinus histiocytes	plasma cells
Negative (-)	
Myeloid cells	Erythroid cells
Megakaryocytes	Langerhans cells in skin
Epithelium	Connective tissue

Abnormal Tissues

Positive (+)
Neoplastic cells (Hodgkin's lymphoma) 40/40 and 74/80
low grade B-cell lymphomas 52/52
high grade B-cell lymphomas 99/108
T-cell lymphomas 41/44
Negative (-)
non-lymphoid neoplasms 162/162
small cell anaplastic carcinomas
amelanotic melanomas
alveolar rhabdomyosarcomas
Ewing's sarcoma
germ cell tumours

Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a medical professional.

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands	8°C / 2°C Storage Temperature Limites de température Zulässiger Temperaturbereich	Manufacturer Fabricant Hersteller	REF Catalog Number Référence du catalogue Bestellnummer
IVD In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	Expiration Date Utiliser jusque Verwendbar bis	LOT Lot Number Code du lot Chargenbezeichnung

Bio SB
BIOSCIENCE FOR THE WORLD

69 Santa Felicia Dr., Santa Barbara, CA 93117, USA
Tel: (805) 692-2768 | Tel: (800) 561-1145 | Fax: (805) 692-2769
E-mail: info@biosb.com | Website: www.biosb.com