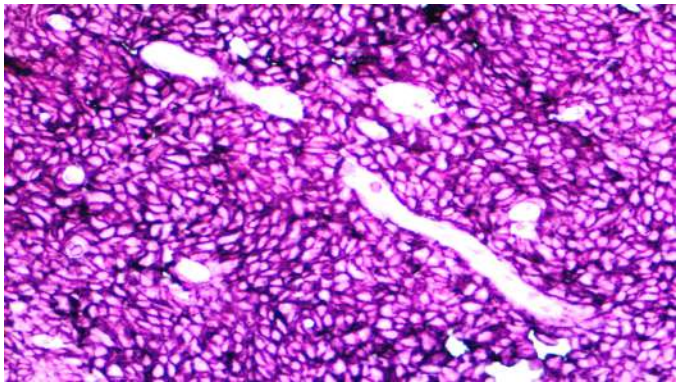
CD45

Clone: 2B11 & PD7/26
Mouse Monoclonal

CE IVD



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	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Spleen, Thymus		
Application	Hodgkin's And Non-Hodgkin Lymphoma, Leukemia & Histiocytic, Undifferentiated Tumor		

Presentation
Anti-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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5246	Predilute	Ready-to-Use	3.0 mL
BSB 5247	Predilute	Ready-to-Use	7.0 mL
BSB 5248	Predilute	Ready-to-Use	15.0 mL
BSB 5249	Concentrate	1:250-1:1000	0.1 mL
BSB 5250	Concentrate	1:250-1:1000	0.5 mL
BSB 5251	Concentrate	1:250-1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9095-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB, Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden	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

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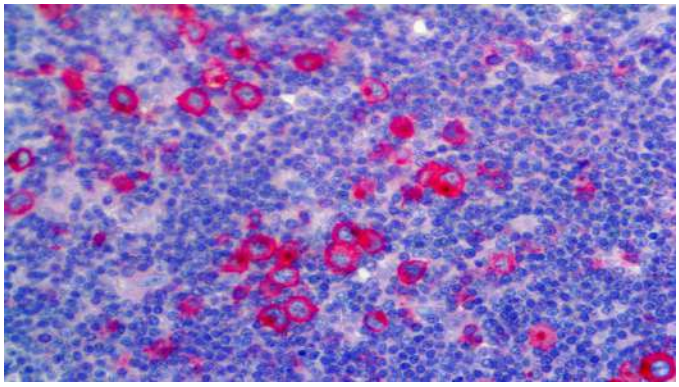
CD30

Clone: Ber-H2
Mouse Monoclonal

CE IVD



Inset: IHC of CD30 on a FFPE Hodgkin's Lymphoma 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
L428 cell line cells.

Summary and Explanation
CD30 is a transmembrane cytokine receptor belonging to the tumor necrosis factor (TNF) receptor superfamily. Mature CD30 has a molecular mass of 120 kDa and is derived from a 90 kDa precursor protein.

CD30 antibody detects an epitope which is expressed by Reed-Sternberg cells in Hodgkin's Disease, the majority of Anaplastic Large-cell Lymphomas, and in Embryonal Carcinomas and Seminomas. This antibody also stains plasma cells intensely in paraffin-embedded tissue.

Antibody Type	Mouse Monoclonal	**Clone**	Ber-H2
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Hodgkin's Lymphoma		
Application	Hodgkin's And Non-Hodgkin Lymphoma, Lymphoma, Testicular Cancer, Ovarian Cancer		

Presentation
Anti-CD30 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5211	Predilute	Ready-to-Use	3.0 mL
BSB 5212	Predilute	Ready-to-Use	7.0 mL
BSB 5213	Predilute	Ready-to-Use	15.0 mL
BSB 5214	Concentrate	1:100-1:500	0.1 mL
BSB 5215	Concentrate	1:100-1:500	0.5 mL
BSB 5216	Concentrate	1:100-1:500	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9084-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to the Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Schwarting R, et al. Blood. 1989;74:1678-1689
2. Fonatsch C, et al. Genomics. 1992;14:825-826
3. Piris J, et al. Histopathology. 1990;17:211-218
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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

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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

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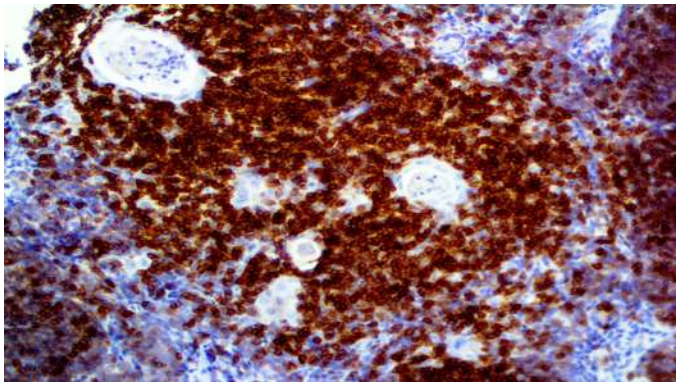
CD5

Clone: RBT-CD5
Rabbit Monoclonal

CE IVD



Inset: IHC of CD5 on a FFPE Thymus 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
Synthetic peptide corresponding to residues from the intercellular region of the human CD5 protein.

Summary and Explanation
CD5 is a glycoprotein monomer with an MW of 67 kDa belonging to the scavenger receptor cysteine-rich (SRCR) family of extracellular domain-like structures. It possesses a large cytoplasmic domain suitable for signal transduction.

CD5 is a T-cell marker that also reacts with a range of neoplastic B-cells, e.g., B-cell Chronic Lymphocytic Leukemia (B-CLL), B-cell Small Lymphocytic Lymphoma (B-SLL), and Mantle Cell Lymphoma. CD5 is expressed in T-lymphocyte subsets and is modulated during cellular activation; however, it does not react with granulocytes or monocytes.

Antibody Type	Rabbit Monoclonal	**Clone**	RBT-CD5
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node		
Application	Leukemia & Histiocytic, Lymphoma		

Presentation
Anti-CD5 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5155	Predilute	Ready-to-Use	3.0 mL
BSB 5156	Predilute	Ready-to-Use	7.0 mL
BSB 5157	Predilute	Ready-to-Use	15.0 mL
BSB 5158	Concentrate	1:25-1:100	0.1 mL
BSB 5159	Concentrate	1:25-1:100	0.5 mL
BSB 5160	Concentrate	1:25-1:100	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9099-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to the Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Chan JKC, et al. Histopathology. 1994;25:517-536
2. Kasaian MT, et al. Proc of the Soc for Exp Bio and Med. 1991;197:226-241
3. Jones NH, et al. Nature. 1986;323:346-349
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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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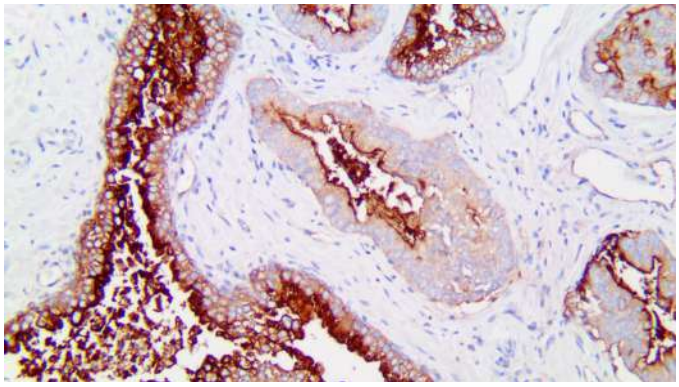
CD10

Clone: RBT-CD10
Rabbit Monoclonal

IVD



Inset: IHC of CD10 on a FFPE Prostate 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
Recombinant external domain of the human CD10 glycoprotein.

Summary and Explanation
CD10, also known as neutral endopeptidase (NEP), neprilysin, and common acute lymphoblastic leukemia antigen (CALLA), is a zinc-dependent metalloprotease enzyme that degrades a number of small secreted peptides, most notably the amyloid beta peptide whose abnormal misfolding and aggregation in neural tissue has been implicated as a cause of Alzheimer's disease.

CD10 is a useful marker for the characterization of childhood leukemia and B-cell lymphomas. This antibody reacts with the antigens of lymphoblastic, Burkitt's, and follicular lymphomas, and chronic myelocytic leukemia. Also, CD10 detects the antigen of glomerular epithelial cells and the brush border of the proximal tubules. Other non-lymphoid cells that are reactive with CD10 are breast myoepithelial cells, bile canaliculi, neutrophils, a small population of bone marrow cells, fetal small intestine epithelium, and normal fibroblasts.

Antibody Type	Rabbit Monoclonal	**Clone**	RBT-CD10
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	**Species Reactivity**	Human
Control	Kidney, Tonsil, Lymph Node, Prostate		
Application	Lymphoma, Kidney & Urothelial Cancer, Liver Cancer, Gall Bladder & Pancreatic Cancer, Endometrial & Genital Cancer, Breast Cancer		

Presentation
Anti-CD10 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 3816-3	Predilute	Ready-to-Use	3.0 mL
BSB 3816-7	Predilute	Ready-to-Use	7.0 mL
BSB 3816-15	Predilute	Ready-to-Use	15.0 mL
BSB 3816-01	Concentrate	1:50-1:200	0.1 mL
BSB 3816-05	Concentrate	1:50-1:200	0.5 mL
BSB 3816-1	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9058-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to the Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
Do not use the after expiration date listed on the 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 for 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-BSB 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1.Ahlem B, Wided A, Amani L, Nadia Z, Amira A, Faten F. Study of Ki67 and CD10 expression as predictive factors of recurrence of ameloblastoma. Eur Ann Otorhinolaryngol Head Neck Dis. 2015 Nov;132(5):275-9.

2. Aziz SJ, Jalal JA, Hamadameen KS. Stromal CD10 expression in gastric adenocarcinoma. J Med Life. 2022 May;15(5):679-684.

3. Gürel D, Kargı A, Karaman I, Onen A, Unlü M. CD10 expression in epithelial and stromal cells of non-small cell lung carcinoma (NSCLC): a clinic and pathologic correlation. Pathol Oncol Res. 2012 Apr;18(2):153-60.

4. Mizutani N, Abe M, Kajino K, Matsuoka S. A New CD10 Antibody Inhibits the Growth of Malignant Mesothelioma. Monoclon Antib Immunodiagn Immunother. 2021;40(1):21-27.

5. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

	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

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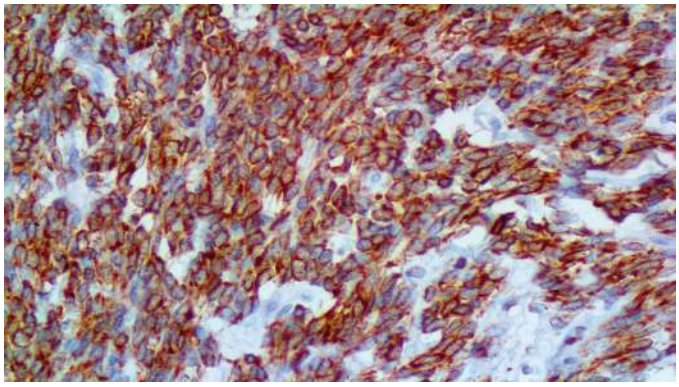
bcl-2

Clone: BSB-5
Mouse Monoclonal

CE IVD



Inset: IHC of bcl-2 on a FFPE Follicular Lymphoma 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
A synthetic peptide corresponding to residues in the N-terminus of human bcl2.

Summary and Explanation
bcl-2 is an integral outer mitochondrial membrane protein that blocks the apoptotic death of some cells such as lymphocytes. Constitutive expression of bcl-2, such as in the case of translocation of bcl-2 to Ig heavy chain loci, is thought to be the cause of Follicular Lymphoma.

Anti-bcl-2 has shown consistent negative reaction on reactive germinal centers and positive staining of neoplastic follicles in Follicular Lymphoma. Consequently, this antibody is valuable when distinguishing between reactive and neoplastic follicular proliferation in lymph node biopsies. This antibody may also be used in distinguishing between those Follicular Lymphomas that express bcl-2 protein and the small number in which the neoplastic cells are bcl-2-negative. Anti-bcl-2 has been used as a predictive biomarker for recurrence of Cancer of the Breast and Non-Small-Cell Carcinoma of the Lung.

Antibody Type	Mouse Monoclonal	**Clone**	BSB-5
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node		
Application	Lymphoma, Endometrial & Genital Cancer, Prostate Cancer, Breast Cancer, Lung Cancer		

Presentation
Anti-bcl-2 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5071	Predilute	Ready-to-Use	3.0 mL
BSB 5072	Predilute	Ready-to-Use	7.0 mL
BSB 5073	Predilute	Ready-to-Use	15.0 mL
BSB 5074	Concentrate	1:50-1:200	0.1 mL
BSB 5075	Concentrate	1:50-1:200	0.5 mL
BSB 5076	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9029-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
Do not use after expiration date listed on the 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. 1. Sujimoto Y, et al. Prac Natl Acad Dcie (USA). 1986;83:5214-5218
2. Clearly ML, et al. Cell. 1986;47:19-28
3. Pezzella F, et al. Am J Pathol. 1990;137:225-232
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5. Moul JW, et al. Eur Urol. 1999;35(5-6):399-407
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7. Martin B, et al. Br J Cancer. 2003 Jul7;89(1):55-64
8. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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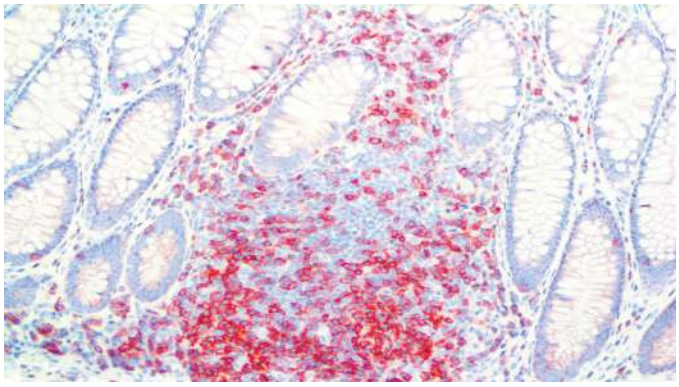
E-mail: sales@biosb.com | Website: www.biosb.com

CD3

Clone: RBT-CD3
Rabbit Monoclonal

CE IVD



Inset: IHC of CD3 on a FFPE Colon 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
Synthetic peptide corresponding to residues in the cytoplasmic domain of the human CD3 protein.

Summary and Explanation
The CD3 antigen is a protein complex composed of three distinct chains (CD3γ, CD3δ and CD3ε) that associate with T-cell receptors and the ζ-chain to generate an activation signal in T-lymphocytes. The TCR, ζ-chain and CD3 molecules together comprise the TCR complex. The CD3γ, CD3δ, and CD3ε chains are highly-related

cell surface proteins of the immunoglobulin superfamily containing a single extracellular immunoglobulin domain. The intracellular tails of the CD3 molecules contain a single conserved motif known as an immunoreceptor tyrosine-based activation motif (or ITAM for short), which is essential for the signaling capacity of the TCR. Phosphorylation of the ITAM on CD3 renders the CD3 chain capable of binding the enzyme ZAP70 (zeta-associated protein), a kinase important in the signaling cascade of the T-cell.
CD3 has been considered the best all-around T-cell marker. This antibody reacts with an antigen present in early thymocytes. The positive staining of this marker may represent a sign of early commitment to the T-cell lineage.

Antibody Type	Rabbit Monoclonal	**Clone**	RBT-CD3
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Liver, Testis, Kidney, Colon, Spleen, Thymus, Lymphoblastic Lymphoma		
Application	Hodgkin's And Non-Hodgkin Lymphoma, Lymphoma		

Presentation
Anti-CD3 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 6422	Predilute	Ready-to-Use	3.0 mL
BSB 6423	Predilute	Ready-to-Use	7.0 mL
BSB 6424	Predilute	Ready-to-Use	15.0 mL
BSB 6425	Concentrate	1:50-1:200	0.1 mL
BSB 6426	Concentrate	1:50-1:200	0.5 mL
BSB 6427	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9082-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
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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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Denning SM, et al. Oxford Univ Press. 1987;144-147
2. Beverley PCL, et al. European J of Immunolgy. 11:329-334
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6. Abbas AK, Lichtman, Cellular and Molecular Immunology (5th Ed.) 2003
7. 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.
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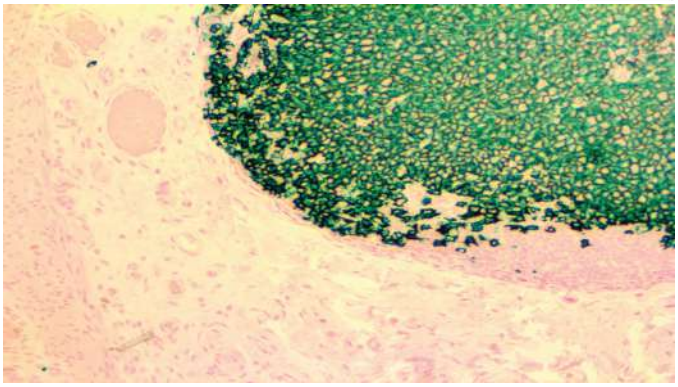
CD20 (L26)

Mouse Monoclonal Antibody

CE IVD



IHC of CD20 on FFPE Colon tissue

PRODUCT IDENTIFICATION REF

Catalog No.	Presentation	Volume
BSB 5190	Predilute Ready-to-Use	3.0 mL
BSB 5191	Predilute Ready-to-Use	7.0 mL
BSB 5192	Predilute Ready-to-Use	15.0 mL
BSB 5193	Concentrate	0.1 mL
BSB 5194	Concentrate	0.5 mL
BSB 5195	Concentrate	1.0 mL

INTENDED PURPOSE

CD20 (L26), Mouse Monoclonal Antibody is a primary antibody intended for laboratory use by trained laboratory personnel in an immunohistochemical (IHC) assay to qualitatively identify CD20 protein by light microscopy in normal and/or pathological formalin-fixed, paraffin-embedded (FFPE) human tissue.

The clinical interpretation of any staining or its absence should be performed by a qualified pathologist and complemented by morphological studies using proper controls and evaluated within the context of the patient's clinical history and other diagnostic tests.

SUMMARY AND EXPLANATION

CD20 is a transmembrane, non-glycosylated protein expressed on B-cell precursors and mature B-cells, but lost following differentiation into plasma cells. CD20 is not expressed in non-hematopoietic neoplasms, but is expressed in Reed-Sternberg cells predominant in Hodgkin's disease.

PRINCIPLE OF PROCEDURE

In general, immunohistochemical (IHC) staining techniques allow for antigen visualization via the sequential application of a specific antibody to the antigen (primary antibody), a secondary antibody to the primary antibody (link antibody), an enzyme complex, and a chromogenic substrate with interposed washing steps. The enzymatic activation of the chromogen results in a visible reaction product at the antigen site. The specimen may then be counterstained and coverslipped. Results are interpreted using a light microscope.

MATERIALS AND PRESENTATION

This monoclonal antibody is derived from cell culture supernatant and provided in a diluent at pH 7.3-7.7 containing Tris buffer, 1% BSA as a stabilizer, and <0.1% sodium azide as a preservative.

Antibody Type	Mouse Monoclonal	**Clone**	L26
Isotype	IgG2a/K	**Reactivity**	Human
Localization	Membranous	**Source**	Supernatant
Recommended Dilution Range	1:250-1:1000		
Immunogen	Human tonsil B cells.		

MATERIALS REQUIRED BUT NOT PROVIDED

Positive and negative control tissues
Positively charged microscope slides, such as Bio SB Hydrophilic Plus Slides *(BSB 7028)*
Drying oven capable of maintaining a temperature of 53-65 °C
Xylene or xylene substitute, such as Tinto Dewaxer *(BSB 7458)*
Ethanol or reagent alcohol
Distilled water
Slide handling equipment, such as staining dishes (*BSB 7009*) and slide holder *(BSB 7010)*
Heating equipment for tissue pretreatment, such as the Bio SB TintoRetriever Pressure Cooker *(BSB 7015)*
Suitable epitope retrieval solution, such as ImmunoDNA Retriever with Citrate (*BSB 0020 through BSB 0023*) or EDTA *(BSB 0030 through BSB 0033)*
IHC Wash Buffer, such as ImmunoDNA Washer *(BSB 0029, BSB 0042, BSB 0149, BSB 0150)*
Antibody diluent, such as ImmunoDetector Protein Blocker/ Antibody Diluent *(BSB 0113 through BSB 0115, BSB 0040, BSB 0041)*
Negative Control Reagent, such as *(BSB 0040A through C, BSB 0041A through C)*
Anti-Mouse detection system, such as the Bio SB PolyDetector Plus HRP Detection System (BSB 0257 through 0266)
Counterstain, such as Bio SB Hematoxylin Counterstainer *(BSB 0024 through BSB 0028)*
Mounting medium, such as PermaMounter *(BSB 0097)* or AquaMounter *(BSB 0090 through BSB 0093)*
Cover glass, such as Tinto Coverslips *(BSB-7100-100, BSB-7100-1000, BSB-7100-20000)*
Timer
Light microscope (40-400x)

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. For professional users only. Results should be interpreted by a qualified medical professional and complemented by morphological studies using proper controls and evaluated within the context of the patient's clinical history and other diagnostic tests.
3. This product contains <0.1% sodium azide (NaN_3) as a preservative. The following hazard and precautionary statements apply: H303 - May be harmful if swallowed. P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. For additional safety information refer to the Safety Data Sheet.
4. Avoid contact with eyes. If contact occurs, flush with large quantities of water.

Template #: T00083
Template Version #: 4

5. 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.
6. Materials of human and animal origin should be handled as biohazardous materials and disposed of with proper precautions. 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."
7. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. Accumulated 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.
10. Dispose of contents and container in accordance with all local, regional, national, and international regulations.
11. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).

REAGENT STORAGE AND STABILITY

1. Store at 2-8 °C in original packaging.
2. This product is stable up to the expiration date on the product label when stored according to instructions. Do not use after expiration date listed on the label.
3. Temperature fluctuations should be avoided. Directly following every run, tightly close product and place in refrigerator in an upright position. Avoid prolonged exposure to room temperature conditions.
4. There are no definitive signs to indicate instability of this product. Contact Bio SB Customer Support if there is a suspected indication of reagent instability.

PROCEDURE

Recommended Specimen Preparation

The antibody can be used on FFPE tissue sections. Ensure tissue undergoes appropriate fixation for best results.
1. Cut and mount 3-5 µm FFPE tissues on positively charged slides.
2. Air dry slides for 1 hour at 60 °C.
3. Deparaffinize and rehydrate FFPE tissues:
   - Heat slides in a 60 °C incubator for 10 min. to partially melt the paraffin.
   - Pass slides through three xylene or xylene alternative baths, 2 min. per bath
   - Pass slides through two 100% ethanol baths, 2 min. per bath
   - Pass slides through one 70% ethanol bath for 2 min.
   - Pass slides through one 30% ethanol bath for 2 min.
   - Pass slides through one distilled water bath for 2 min.
4. Subject tissues to heat-induced epitope retrieval (HIER) using a suitable HIER solution, such as Bio SB ImmunoDNA Retriever with Citrate or ImmunoDNA Retriever with EDTA. Use a heating method such as TintoRetriever Pressure Cooker or equivalent; follow the Instructions for Use for the heating method used.
5. Following retrieval, immediately remove the staining dish with slides from TintoRetriever Pressure Cooker and transfer to room temperature; let cool until the retrieval solution is no longer opaque. Wash slides with Bio SB ImmunoDNA Washer or equivalent and begin IHC protocol. Note: Tissues should remain hydrated via use of a wash buffer.

Recommended Manual Immunohistochemical Protocol

Wash slides between each step in the table below with ImmunoDNA Washer or equivalent at least 3 times, until ImmunoDNA Washer runs evenly on the slide surface.

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
HRP/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.	N/A	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain/Coverslip	Varies	Varies	Varies

Recommended Automated Immunohistochemical Protocol

Perform according to the manufacturer's instructions of the applicable automated instrument.

Preparation of the Working Solution

Prediluted antibody is a ready-to-use product. The concentrated antibody should be diluted and optimized by the user.

Mounting Protocols

For instructions about using a mounting media such as PermaMounter, refer to the Instructions for Use of the product.

QUALITY CONTROL RECOMMENDATIONS

Controls should be fresh autopsy, biopsy, or surgical specimens fixed, processed, and embedded as soon as possible in the same manner as the sample(s). Such a control monitors all steps of the analysis, from tissue preparation through staining. The use of a tissue section fixed or processed differently from the test specimen will act as a control for all reagents and method steps except fixation and tissue processing.

Bio SB Control Slides Available

Catalog No.	Quantity
BSB-9078-CS	5 slides

Positive Tissue Control: A positive tissue control must be run with every test procedure. A tissue with weak positive staining (e.g., low expressor) is optimal for detection of subtle changes in the primary antibody sensitivity from instability or problems with the IHC methodology. Positive tissue control for the antibody may include the following: tonsil, lymph node.

Known positive tissue controls should only be utilized for monitoring the correct performance of processed tissues and test reagents, rather than as an aid in formulating a specific diagnosis. If the positive tissue controls fail to demonstrate positive staining, results with the test specimens should be considered invalid.

Negative Tissue Control: One tissue may contain both positive and negative staining cells or tissue components and serve as both the positive and negative control tissue. Internal negative control sites should be verified by the user. The components that do not stain should demonstrate the absence of specific staining and provide an indication of non-specific background staining.

Negative Control Reagent: A negative control reagent must be run for every specimen to aid in the interpretation of results. A negative control reagent is used in place of the primary antibody to evaluate nonspecific staining. The slide should be treated with negative control reagent, matching the host species of the primary antibody, and ideally having the same IgG concentration.
The incubation period for the negative control reagent should equal the primary antibody incubation period.

INTERPRETATION OF RESULTS

Positive Tissue Control Interpretation: The stained positive tissue control should be examined first to ascertain that all reagents are functioning properly. The presence of an appropriately colored reaction product within the target cells/cellular components is indicative of positive reactivity. Refer to the IFU of the detection system used for expected color reactions. If the positive tissue controls fail to demonstrate positive staining, any results with the test specimens should be considered invalid. Depending on the incubation length and potency of the hematoxylin used, counterstaining will result in a pale to dark blue coloration of the cell nuclei. Excessive or incomplete counterstaining may compromise proper interpretation of results.

Negative Tissue Control Interpretation: The negative tissue control should be examined after the positive tissue control to verify the specificity of the labeling of the target antigen by the primary antibody. The absence of specific staining in the negative tissue control confirms the lack of antibody cross-reactivity to cells/cellular components. If specific staining occurs in the negative tissue control, results with the patient specimen should be considered invalid. Nonspecific staining, if present, usually has a diffuse appearance. Sporadic staining of connective tissue may also be observed in sections from excessively formalin-fixed tissues. Use intact cells for interpretation of staining results. Necrotic or degenerated cells often stain nonspecifically.

Patient Tissue Interpretation: Examine stained patient specimens last. Positive staining intensity should be assessed within the context of any nonspecific background staining of the negative reagent control. As with any IHC test, a negative result means that the antigen was not detected, not that the antigen was absent.

LIMITATIONS

1. Immunohistochemistry is a multi-step process that requires specialized training in the selection of the appropriate reagents; tissue selection, fixation, and processing; preparation of the IHC slide; and interpretation of the staining results.
2. Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts, antibody trapping, or false negative results. Inconsistent results may be due to variations in fixation and embedding methods, or to inherent irregularities within the tissue.
3. Excessive or incomplete counterstaining may compromise proper interpretation of results.
4. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria. 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. It is the responsibility of a qualified pathologist who is familiar with the proper use of IHC antibodies, reagents, and methods to interpret all of the steps used to prepare and interpret the final IHC preparation.
5. Predilute Ready-to-Use antibodies are provided at optimal dilution for use following the recommended instructions for IHC on prepared tissue sections preparation. Any deviation from recommended test procedures may invalidate declared expected results; appropriate controls must be employed and documented. Users who deviate from recommended test procedures must accept responsibility for interpretation of patient results under these circumstances.
6. This product is not intended for use in flow cytometry. Performance characteristics have not been determined for flow cytometry.
7. Tissues from persons infected with hepatitis B virus and containing hepatitis B surface antigen (HBsAg) may exhibit nonspecific staining with horseradish peroxidase.
8. Reagents may demonstrate unexpected reactions in previously untested tissues. The possibility of unexpected reactions even in tested tissue groups cannot be completely eliminated due to biological variability of antigen expression in neoplasms, or other pathological tissues. Contact Bio SB Customer Support with documented unexpected reaction(s).
9. Normal/non-immune sera from the same animal source as secondary antisera used in blocking steps may cause false-negative or false-positive results due to autoantibodies or natural antibodies.
10. False-positive results may be seen due to non-immunological binding of proteins or substrate reaction products. They may also be caused by pseudoperoxidase activity (erythrocytes), endogenous peroxidase activity (cytochrome C), endogenous phosphatase (e.g., lymphoid, intestinal, placenta), or endogenous biotin (e.g., liver, breast, brain, kidney) depending on the type of immunostain used.
11. 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.

REFERENCES

1. Ishii Y, Takami T, Yuasa H, Takei T, Kikuchi K. Two distinct antigen systems in human B lymphocytes: identification of cell surface and intracellular antigens using monoclonal antibodies. *Clin Exp Immunol.* 1984;58(1):183-192.
2. Davey FR, Gatter KC, Ralfkiaer E, Pulford KA, Krissansen GW, Mason DY. Immunophenotyping of non-Hodgkin's lymphomas using a panel of antibodies on paraffin-embedded tissues. *Am J Pathol.* 1987;129(1):54-63.
3. Mason DY. A new look at lymphoma immunohistology. *Am J Pathol.* 1987;128(1):1-4.
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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

SYMBOLS GLOSSARY

The following symbols may be found in this IFU or on the product labeling. Some glossary symbols may not be applicable to this product.

Source	Symbol	Meaning
ISO 15223-1 5.1.1		Manufacturer
ISO 15223-1 5.1.2		Authorized representative in the European Union
ISO 15223-1 5.1.4		Use-by-Date
ISO 15223-1 5.1.5		Batch Code (Lot Number)
ISO 15223-1 5.1.6		Catalog Number
ISO 15223-1 5.1.8		Importer
ISO 15223-1 5.3.7		Temperature Limit
ISO 15223-1 5.4.3		Consult electronic Instructions for Use
ISO 15223-1 5.4.4		Caution
ISO 15223-1 5.5.1		In Vitro Diagnostic Medical Device
ISO 15223-1 5.7.10		Unique Device Identifier
(EU) 2017/746 *In Vitro* Diagnostic Regulation (IVDR)		European Union Conformity
Bio SB Manufacturer symbol		Ready-To-Use; reagent is provided at a prediluted concentration that is ready for use
Bio SB Manufacturer symbol		Reagent is provided as a concentrate that needs to be diluted for use

CONTACT INFORMATION

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Fax: (805) 692-2769

Printed IFU
Available upon request.

Note For Customers Within The European Union (EU):
Any serious incident that has occurred in relation to the device must be reported to Bio SB or local sales representative and the competent authority of the Member State in which the user and/or the patient is established.

Bio SB, Inc.
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QAdvis EAR AB
Ideon Science Park
Scheelevägen 17
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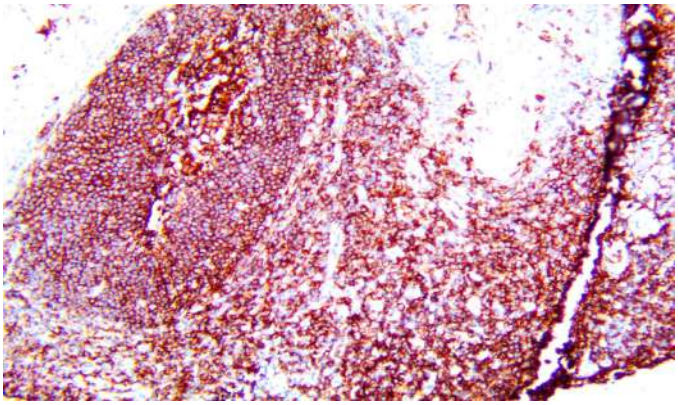
CD19 (RM332)

Rabbit Monoclonal

IVD



IHC of CD19 on FFPE Normal Tonsil tissue

PRODUCT IDENTIFICATION

REF

Catalog No.	Presentation	Volume
BSB-3840-3	Predilute Ready-to-Use	3.0 mL
BSB-3840-7	Predilute Ready-to-Use	7.0 mL
BSB-3840-15	Predilute Ready-to-Use	15.0 mL
BSB-3840-01	Concentrate	0.1 mL
BSB-3840-05	Concentrate	0.5 mL
BSB-3840-1	Concentrate	1.0 mL

INTENDED USE

CD19 (RM332), rabbit monoclonal antibody, is a primary antibody intended for laboratory use by trained laboratory personnel in an immunohistochemical (IHC) assay to qualitatively identify the CD19 protein by light microscopy in normal and/or pathological formalin-fixed, paraffin-embedded (FFPE) human tissue.

The clinical interpretation of any staining or its absence should be performed by a qualified pathologist and complemented by morphological studies using proper controls and evaluated within the context of the patient's clinical history and other diagnostic tests.

SUMMARY AND EXPLANATION

CD19 is a human protein encoded by the *CD19* gene. CD19 is expressed on follicular dendritic cells and immature B-cells; it is present on B-cells from earliest recognizable B-lineage cells during development to B-cell blasts, but is lost on maturation to plasma cells. In normal lymphoid tissue, CD19 is observed in germinal centers (on both B-cells and follicular dendritic cells), in mantle-zone cells, and in scattered cells in the interfollicular areas, with an overall immunoreactivity pattern similar to that of CD20 and CD22. CD19 positivity is seen in the vast majority of B-cell neoplasms (B-Lymphoblastic Lymphoma, Small Lymphocytic Lymphoma/CLL, Mantle Cell Lymphoma, Follicular Lymphoma, Burkitt's Lymphoma, Marginal Zone Lymphoma, Diffuse Large B-cell Lymphoma, T-cell-rich B-cell Lymphoma, Lymphoblastic Lymphoma, Hairy Cell Leukemia), and commonly at a lower intensity than normal B-cell elements.

PRINCIPLE OF PROCEDURE

In general, immunohistochemical (IHC) staining techniques allow for antigen visualization via the sequential application of a specific antibody to the antigen (primary antibody), a secondary antibody to the primary antibody (link antibody), an enzyme complex, and a chromogenic substrate with interposed washing steps. The enzymatic activation of the chromogen results in a visible reaction product at the antigen site. The specimen may then be counterstained and coverslipped. Results are interpreted using a light microscope.

MATERIALS AND PRESENTATION

This antibody is derived from cell culture supernatant that is concentrated, dialyzed, filter sterilized and diluted in buffer pH 7.5, containing BSA and sodium azide.

Antibody Type	Rabbit Monoclonal	**Clone**	RM332
Isotype	IgG	**Reactivity**	Human
Localization	Cytoplasmic	**Source**	Supernatant
Recommended Dilution Range	1:25-1:100		
Immunogen	Synthetic peptide corresponding to the C-terminus of the human CD19 protein		
Diluted In	Tris Buffer, pH 7.3-7.7, 1% BSA and <0.1% Sodium Azide		

MATERIALS REQUIRED BUT NOT PROVIDED

Positive and negative control tissues
Positively charged microscope slides, such as Bio SB Hydrophilic Plus Slides *(BSB 7028)*
Drying oven capable of maintaining a temperature of 53-65°C
Xylene or xylene substitute, such as Tinto Dewaxer *(BSB 7458)*
Ethanol or reagent alcohol
Distilled water
Slide handling equipment, such as staining dishes (*BSB 7009*) and slide holder *(BSB 7010)*
Heating equipment for tissue pretreatment, such as the Bio SB TintoRetriever Pressure Cooker *(BSB 7087)*
Suitable epitope retrieval solution, such as ImmunoDNA Retriever with Citrate (*BSB 0020 through BSB 0023*) or EDTA *(BSB 0030 through BSB 0033)*
IHC Wash Buffer, such as ImmunoDNA Washer *(BSB 0029, BSB 0042, BSB 0149, BSB 0150)*
Antibody diluent, such as ImmunoDetector Protein Blocker/ Antibody Diluent *(BSB 0113 through BSB 0115, BSB 0040, BSB 0041)*
Negative Control Reagent, such as *(BSB 0040A through C, BSB 0041A through C)*
Anti-Rabbit detection system, such as the Bio SB PolyDetector Plus HRP Detection System *(BSB 0257 through 0266)*
Counterstain, such as Bio SB Hematoxylin Counterstainer *(BSB 0024 through BSB 0028)*
Mounting medium, such as PermaMounter *(BSB 0097)* or AquaMounter *(BSB 0090 through BSB 0093)*
Cover glass, such as Tinto Coverslips *(BSB-7100-100, BSB-7100-1000, BSB-7100-20000)*
Timer
Light microscope (40-400x)

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. For professional users only. Results should be interpreted by a qualified medical professional and complemented by morphological

studies using proper controls and evaluated within the context of the patient's clinical history and other diagnostic tests.
3. This product contains <0.1% sodium azide (NaN_3) as a preservative. The following hazard and precautionary statements apply: H303 - May be harmful if swallowed. P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. For additional safety information refer to the Safety Data Sheet.
4. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
5. 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.
6. Materials of human and animal origin should be handled as biohazardous materials and disposed of with proper precautions. 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."
7. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. Accumulated 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.
10. Dispose of contents and container in accordance with all local, regional, national, and international regulations.
11. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).

REAGENT STORAGE AND STABILITY

1. Store at 2-8°C in original packaging.
2. This product is stable up to the expiration date on the product label when stored according to instructions. Do not use after expiration date listed on the label.
3. Temperature fluctuations should be avoided. Directly following every run, tightly close product and place in refrigerator in an upright position. Avoid prolonged exposure to room temperature conditions.
4. There are no definitive signs to indicate instability of this product. Contact Bio SB Technical Support if there is a suspected indication of reagent instability.

PROCEDURE

Recommended Specimen Preparation

The antibody can be used on FFPE tissue sections. Ensure tissue undergoes appropriate fixation for best results.
1. Cut and mount 3-5 µm FFPE tissues on positively charged slides.
2. Air dry slides for 1 hour at 60° C.
3. Deparaffinize and rehydrate FFPE tissues:
   - Heat slides in a 60° C incubator for 10 min. to partially melt the paraffin.
   - Pass slides through three xylene or xylene alternative baths, 2 min. per bath
   - Pass slides through two 100% ethanol baths, 2 min. per bath
   - Pass slides through one 70% ethanol bath for 2 min.
   - Pass slides through one 30% ethanol bath for 2 min.
   - Pass slides through one distilled water bath for 2 min.
4. Subject tissues to heat-induced epitope retrieval (HIER) using a suitable HIER solution, such as Bio SB ImmunoDNA Retriever with Citrate or ImmunoDNA Retriever with EDTA. Use a heating method such as TintoRetriever Pressure Cooker or equivalent; follow the Instructions for Use for the heating method used.
5. Following retrieval, immediately remove the staining dish with slides from TintoRetriever Pressure Cooker and transfer to room temperature; let cool until the retrieval solution is no longer opaque. Wash slides with Bio SB ImmunoDNA Washer or equivalent and begin IHC protocol. Note: Tissues should remain hydrated via use of a wash buffer.

Recommended Immunohistochemical Protocol

Wash slides between each step in the table below with ImmunoDNA Washer or equivalent at least 3 times, until ImmunoDNA Washer runs evenly on the slide surface.

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
HRP/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.	N/A	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain/Coverslip	Varies	Varies	Varies

Preparation of the Working Solution

Prediluted antibody is a ready-to-use product. The concentrated antibody should be diluted and optimized by the user.

Mounting Protocols

For instructions about using a mounting media such as PermaMounter, refer to the Instructions for Use of the product.

QUALITY CONTROL RECOMMENDATIONS

Controls should be fresh autopsy, biopsy, or surgical specimens fixed, processed, and embedded as soon as possible in the same manner as the sample(s). Such a control monitors all steps of the analysis, from tissue preparation through staining. The use of a tissue section fixed or processed differently from the test specimen will act as a control for all reagents and method steps except fixation and tissue processing..

Bio SB Control Slides Available

Catalog No.	Quantity
BSB-9075-CS	5 slides

Positive Tissue Control: A positive tissue control must be run with every test procedure. A tissue with weak positive staining (e.g., low expressor) is optimal for detection of subtle changes in the primary antibody sensitivity from instability or problems with the IHC methodology. Positive tissue control for the antibody may include the following: Tonsil, Lymph Node, Spleen, Colon tissue.

Known positive tissue controls should only be utilized for monitoring the correct performance of processed tissues and test reagents, rather than as an aid in formulating a specific diagnosis. If the positive tissue controls fail to demonstrate positive staining, results with the test specimens should be considered invalid.

Negative Tissue Control: One tissue may contain both positive and negative staining cells or tissue components and serve as both the positive and negative control tissue. Internal negative control sites should be verified by the user. The components that do not stain should

demonstrate the absence of specific staining and provide an indication of non-specific background staining.

Negative Control Reagent: A negative control reagent must be run for every specimen to aid in the interpretation of results. A negative control reagent is used in place of the primary antibody to evaluate nonspecific staining. The slide should be treated with negative control reagent, matching the host species of the primary antibody, and ideally having the same IgG concentration.
The incubation period for the negative control reagent should equal the primary antibody incubation period.

INTERPRETATION OF RESULTS

Positive Tissue Control Interpretation: The stained positive tissue control should be examined first to ascertain that all reagents are functioning properly. The presence of an appropriately colored reaction product within the target cells/cellular components is indicative of positive reactivity. Refer to the IFU of the detection system used for expected color reactions. If the positive tissue controls fail to demonstrate positive staining, any results with the test specimens should be considered invalid. Depending on the incubation length and potency of the hematoxylin used, counterstaining will result in a pale to dark blue coloration of the cell nuclei. Excessive or incomplete counterstaining may compromise proper interpretation of results.

Negative Tissue Control Interpretation: The negative tissue control should be examined after the positive tissue control to verify the specificity of the labeling of the target antigen by the primary antibody. The absence of specific staining in the negative tissue control confirms the lack of antibody cross-reactivity to cells/cellular components. If specific staining occurs in the negative tissue control, results with the patient specimen should be considered invalid. Nonspecific staining, if present, usually has a diffuse appearance. Sporadic staining of connective tissue may also be observed in sections from excessively formalin-fixed tissues. Use intact cells for interpretation of staining results. Necrotic or degenerated cells often stain nonspecifically.

Patient Tissue Interpretation: Examine stained patient specimens last. Positive staining intensity should be assessed within the context of any nonspecific background staining of the negative reagent control. As with any IHC test, a negative result means that the antigen was not detected, not that the antigen was absent.

LIMITATIONS

1. Immunohistochemistry is a multi-step process that requires specialized training in the selection of the appropriate reagents; tissue selection, fixation, and processing; preparation of the IHC slide; and interpretation of the staining results.
2. Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts, antibody trapping, or false negative results. Inconsistent results may be due to variations in fixation and embedding methods, or to inherent irregularities within the tissue.
3. Excessive or incomplete counterstaining may compromise proper interpretation of results.
4. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria. 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. It is the responsibility of a qualified pathologist who is familiar with the proper use of IHC antibodies, reagents, and methods to interpret all of the steps used to prepare and interpret the final IHC preparation.
5. Predilute Ready-to-Use antibodies are provided at optimal dilution for use following the recommended instructions for IHC on prepared tissue sections preparation. Any deviation from recommended test procedures may invalidate declared expected results; appropriate controls must be employed and documented. Users who deviate from recommended test procedures must accept responsibility for interpretation of patient results under these circumstances.
6. This product is not intended for use in flow cytometry. Performance characteristics have not been determined for flow cytometry.
7. Tissues from persons infected with hepatitis B virus and containing hepatitis B surface antigen (HBsAg) may exhibit nonspecific staining with horseradish peroxidase.
8. Reagents may demonstrate unexpected reactions in previously untested tissues. The possibility of unexpected reactions even in tested tissue groups cannot be completely eliminated due to biological variability of antigen expression in neoplasms, or other pathological tissues. Contact Bio SB Technical Support with documented unexpected reaction(s).
9. Normal/non-immune sera from the same animal source as secondary antisera used in blocking steps may cause false-negative or false-positive results due to autoantibodies or natural antibodies.
10. False-positive results may be seen due to non-immunological binding of proteins or substrate reaction products. They may also be caused by pseudoperoxidase activity (erythrocytes), endogenous peroxidase activity (cytochrome C), or endogenous biotin (e.g., liver, breast, brain, kidney) depending on the type of immunostain used.

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1. Cappell KM, Sherry RM, Yang JC, et al. Long-Term Follow-Up of Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy. J Clin Oncol. 2020;38(32):3805-3815.
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5. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

SYMBOLS GLOSSARY

The following symbols may be found in this IFU or on the product labeling. Some glossary symbols may not be applicable to this product.

Source	Symbol	Meaning
ISO 15223-1 5.1.1		Manufacturer
ISO 15223-1 5.1.4		Use-by-Date
ISO 15223-1 5.1.5		Batch Code (Lot Number)
ISO 15223-1 5.1.6		Catalog Number
ISO 15223-1 5.1.8		Importer
ISO 15223-1 5.3.7		Temperature Limit
ISO 15223-1 5.4.3		Consult electronic Instructions for Use
ISO 15223-1 5.5.1		In Vitro Diagnostic Medical Device
ISO 15223-1 5.7.10		Unique Device Identifier
(EC) No. 1272/2008 (GHS/CLP) on classification, labelling and packaging of substances and mixtures		Warning

CONTACT INFORMATION

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US & Canada Telephone +1 (805) 692-2768
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Fax: (805) 692-2769

Printed IFU
Available upon request.

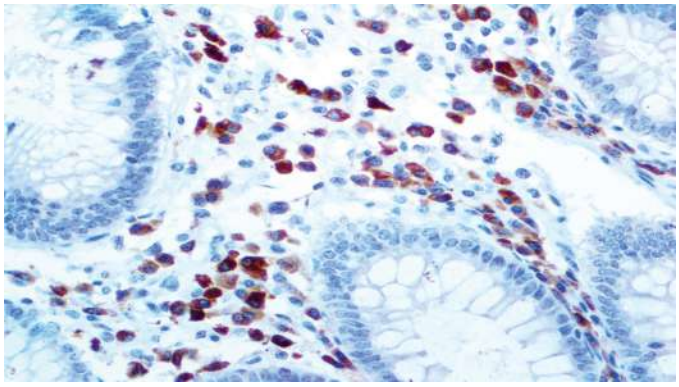
Bio SB, Inc.
5385 Hollister Avenue, Bldg. 8, Ste. 108
Santa Barbara, CA 93111 USA

Template #: T00006
Template Version #: 3

CD79a

Clone: JCB117
Mouse Monoclonal

CE IVD



Inset: IHC of CD79a on a FFPE Colon 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
Recombinant protein containing part of the extracellular portion of the CD79a glycoprotein.

Summary and Explanation
CD79a is non-covalently associated with membrane-bound immunoglobulins on B-cells to constitute the B-cell Ag receptor. CD79a first appears at pre B-cell stage and persists until the plasma-cell stage, where it is found as an intracellular component. CD79a is found in the majority of Acute Leukemias of precursor B-cell type, in B-cell lines, B-cell Lymphomas, and in some Myelomas.

CD79a is a B-cell marker that is generally used to complement CD20. This antibody will stain many of the same Lymphomas as CD20, but also stains more B-precursor Lymphoid Leukemias than CD20. CD79a also stains more cases of Plasma-cell Myeloma and occasionally some types of endothelial cells as well. CD79a will stain many cases of Acute Promyelocytic Leukemia (FAB-M3), but only rarely stains other types of Myeloid Leukemia.

Antibody Type	Mouse Monoclonal	**Clone**	JCB117
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human, Canine, Feline, Mouse
Control	Tonsil, Lymph Node		
Application	Lymphoma, Leukemia & Histiocytic, Hodgkin's And Non-Hodgkin Lymphoma		

Presentation
Anti-CD79a 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5302	Predilute	Ready-to-Use	3.0 mL
BSB 5303	Predilute	Ready-to-Use	7.0 mL
BSB 5304	Predilute	Ready-to-Use	15.0 mL
BSB 5305	Concentrate	1:250-1:1000	0.1 mL
BSB 5306	Concentrate	1:250-1:1000	0.5 mL
BSB 5307	Concentrate	1:250-1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9111-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Van Nosel CJM, et al. J Immunol. 1991;146:3881-3888
2. Van Nosel CJM, et al. J Exp Med. 1992;175:1511-1519
3. Mason DY, et al. Eur J Immun. 1992;22:2753-2756
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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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
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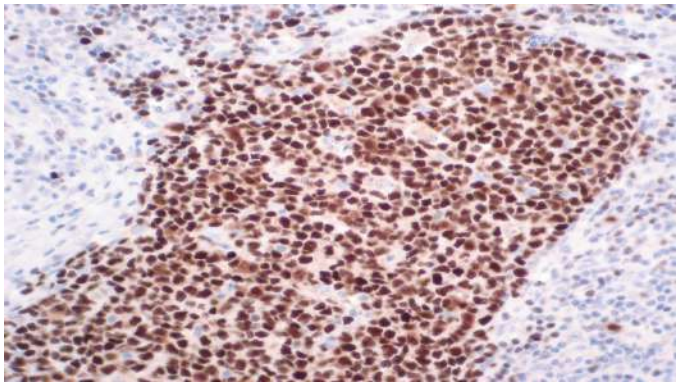
OCT-2

Clone: EP115
Rabbit Monoclonal

CE IVD



Inset: IHC of Oct-2 on a FFPE Lymphoma 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.

* The Oct-2 antibody, clone EP115, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
A synthetic peptide corresponding to residues of human OCT-2 protein.

Summary and Explanation
Octamer transcription factor-2 (OCT-2) possesses a leucine zipper domain and belongs to the POU family of transcription factors. It binds to the octamer motif (5-ATTTCAT-3), activates immunoglobulin gene expression and regulates transcription in a number of tissues. OCT-2 is important for the expression of B cell specific genes, such as CD20 and CRISP-3. OCT-2 is expressed in mature B cells, predominantly germinal center B cells.

The OCT-2 antibody labels various B cell lymphomas with strong expression in germinal center-derived lymphomas.

Antibody Type	Rabbit Monoclonal	**Clone**	EP115
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Nuclear	**Species Reactivity**	Human
Control	Tonsil, Lymph Node		
Application	Hodgkin's And Non-Hodgkin Lymphoma, Lymphoma		

Presentation
Anti-Oct-2 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 2021	Predilute	Ready-to-Use	3.0 mL
BSB 2022	Predilute	Ready-to-Use	7.0 mL
BSB 2023	Predilute	Ready-to-Use	15.0 mL
BSB 2024	Concentrate	1:100-1:500	0.1 mL
BSB 2025	Concentrate	1:100-1:500	0.5 mL
BSB 2026	Concentrate	1:100-1:500	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9314-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Staudt LM, et al. Nature. 1986; 323:640-3
2. Scheidereit C, et al. Cell. 1987; 51:783-93
3. Herr W, et al. Genes Dev. 1995; 9:1679-93
4. Pfi sterer P, et al. Mol Cell Biol. 1996; 16:6160-8
5. Torlakovic E, et al. Am J Pathol. 2001; 159:1807-14
6. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

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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

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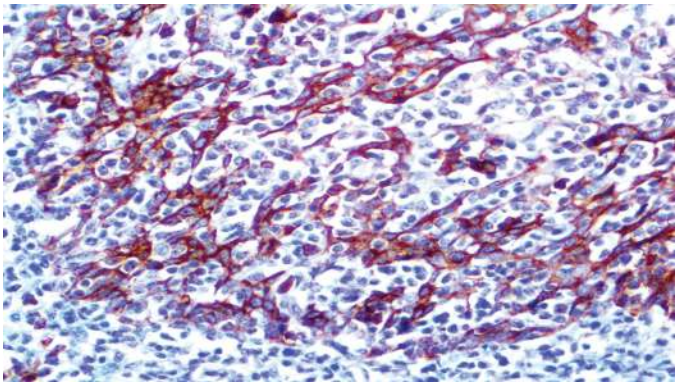
CD138

Clone: EP201
Rabbit Monoclonal

CE IVD



Inset: IHC of CD138 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.

* The CD138 antibody, clone EP201, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
Synthetic peptide corresponding to residues of human CD138 protein

Summary and Explanation
CD138/Syndecan-1 is a transmembrane heparin-sulphate proteoglycan which is made up of one core protein and five glycosaminoglycans. CD138 is expected to play a role in cell adhesion. It is expressed on the surface of pre B-cells and plasma cells but is absent from mature B-cells.

Anti-CD138/syndecan-1 is a useful marker for labeling normal and neoplastic plasma cells and Plasmacytoid Lymphomas. It is a selective marker for B-cell Lymphoblastic Leukemia and Lymphoplasmacytoid Leukemia. It is lost from the apoptotic myeloma cells, and thus, is a useful marker for viable Myeloma cells. Various forms of Hodgkin's Disease have also shown positive staining with this antibody.

Antibody Type	Rabbit Monoclonal	**Clone**	EP201
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human, Predicted: Mouse, Rat
Control	Tonsil, Liver, Kidney, Breast, Lymph Node, Cervix, Plasmacytoma, Adrenal, Skin, Colon, Lung		
Application	Hematopoietic, Lymphoma, Rejection & Autoimmunity		

Presentation
Anti-CD138 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 6527	Predilute	Ready-to-Use	3.0 mL
BSB 6528	Predilute	Ready-to-Use	7.0 mL
BSB 6529	Predilute	Ready-to-Use	15.0 mL
BSB 6530	Concentrate	1:25-1:100	0.1 mL
BSB 6531	Concentrate	1:25-1:100	0.5 mL
BSB 6532	Concentrate	1:25-1:100	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9067-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Chilosi M, Adami F, et al. Mod Pathol. 1999;Dec:12(12):1101-6
2. Sebestzen A, Berezi L, et al. Br J Haematol. 1999;Feb:104(2):412-9
3. Carbone A, Gaidano G, et al. Blood. 1998;Feb:1;91(3):747-55
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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

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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

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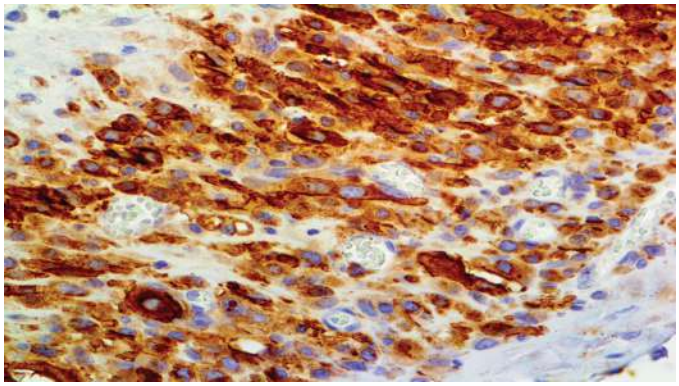
CD56

Clone: 123C3.D5
Mouse Monoclonal

CE IVD



Inset: IHC of CD56 on a FFPE Neuroblastoma 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
Membrane preparation of a small cell lung carcinoma.

Summary and Explanation
CD56 or Neural-Cell Adhesion Molecule (NCAM) is a homophilic binding glycoprotein expressed on the surface of neurons, glia and skeletal muscle. CD56 has been implicated in cell-cell adhesion, neurite outgrowth, synaptic plasticity, and learning and memory.

Normal cells that stain positively for CD56 include NK cells, activated T-cells, brain and cerebellum, and neuroendocrine tissues. Tumors that are CD56-positive are Myeloma, Myeloid Leukemia, Neuroendocrine tumors, Wilm's Tumor, Adult Neuroblastoma, NK/T cell Lymphomas, Pancreatic Acinar-cell Carcinoma, Pheochromocytoma, and Small-cell Lung Carcinoma. It is also expressed on some mesodermally-derived tumors (Rhabdomyosarcoma). Ewing's Sarcoma/PNET is CD56-negative.

Antibody Type	Mouse Monoclonal	**Clone**	123C3.D5
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Membranous, Cytoplasmic	**Species Reactivity**	Human
Control	Neuroblastoma, Brain		
Application	Leukemia & Histiocytic, Lymphoma, Lung Cancer, Neural & Neuroendocrine Cancer, Undifferentiated Tumor		

Presentation
Anti-CD56 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5267	Predilute	Ready-to-Use	3.0 mL
BSB 5268	Predilute	Ready-to-Use	7.0 mL
BSB 5269	Predilute	Ready-to-Use	15.0 mL
BSB 5270	Concentrate	1:250-1:1000	0.1 mL
BSB 5271	Concentrate	1:250-1:1000	0.5 mL
BSB 5272	Concentrate	1:250-1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9100-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

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2. Michalides R, et al. International J of Cancer Sup. 1994;8:34-37
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6. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB, Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden	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

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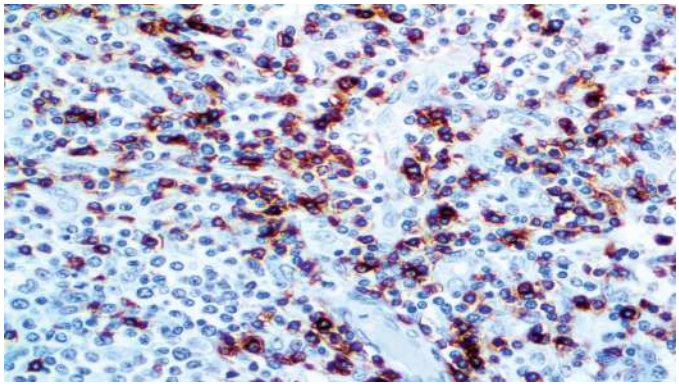
CD7

Clone: EP132
Rabbit Monoclonal

CE IVD



Inset: IHC of CD7 on a FFPE T-Cell Lymphoma 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
Synthetic peptide corresponding to residues of the human CD7 protein.

Summary and Explanation
CD7 is a 40 kDa transmembrane, single-chain glycoprotein, which is a member of the immunoglobulin gene superfamily. It is expressed in the majority of immature and mature T-lymphocytes, and T-cell Leukemia. CD7 is also found in natural killer cells, a small subpopulation of normal B-cells and in malignant B-cells and it plays an essential role in T-cell interactions and also in T-cell/B-cell interaction during early lymphoid development.

CD7 is a consistently-expressed T-cell antigen in Lymphoblastic Lymphomas and Leukemias; therefore, it is a useful marker in the identification of such neoplastic proliferations. CD7 is expressed in the majority of mature peripheral T-cells, the majority of post-thymic T-cells, NK cells, some myeloid cells, T-cell Acute Lymphoblastic Leukemia/Lymphoma, Acute Myelogenous Leukemia and Chronic Myelogenous Leukemia. Interestingly, CD7 is conspicuously absent in adult T-cell Leukemia/Lymphoma and is not expressed in Sezary cells.

Antibody Type	Rabbit Monoclonal	**Clone**	EP132
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Colon, Liver, Spleen, Bone Marrow, Lymphoblastic Lymphoma		
Application	Leukemia & Histiocytic, Lymphoma		

Presentation
Anti-CD7 is a Rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 2321	Predilute	Ready-to-Use	3.0 mL
BSB 2322	Predilute	Ready-to-Use	7.0 mL
BSB 2323	Predilute	Ready-to-Use	15.0 mL
BSB 2324	Concentrate	1:50-1:200	0.1 mL
BSB 2325	Concentrate	1:50-1:200	0.5 mL
BSB 2326	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9106-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Knapp W, et al. Leukocyte typing IV:341. Oxford Univesrity Press, Oxford. 1989
2. Miwa H, et al. Leuk Lymphoma. 1996;21(3-4):239-244
3. Saxena A, et al. Am J Hematol. 1998;58(4):278-284
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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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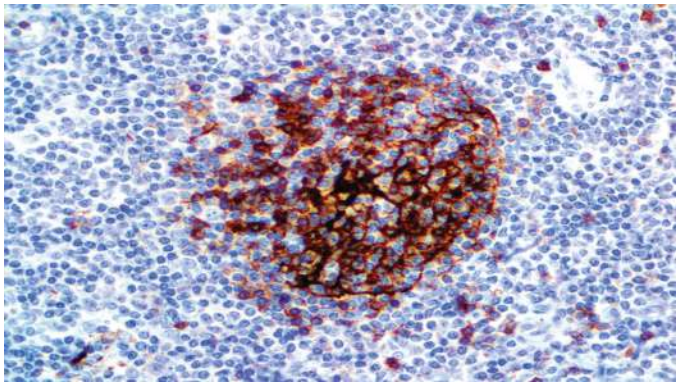
CD23

Clone: EP75
Rabbit Monoclonal

CE IVD



Inset: IHC of CD23 on a FFPE Lymphoma 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.

* The CD23 antibody, clone EP75, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
Synthetic peptide corresponding to residues in human CD23 protein.

Summary and Explanation
CD23, also known as Fc epsilon RII, is the "low affinity" receptor for IgE, an antibody isotype involved in allergy and (arguably) resistance to parasites, and is important in regulation of IgE levels. Unlike many of the antibody receptors, CD23 is a C-type lectin. It is found on mature B-cells, activated macrophages, eosinophils, follicular dendritic cells and platelets.

This is a B-cell antibody that is useful for differentiating between B-CLL and B-SLL's that are CD23-positive from Mantle-cell Lymphomas and Small-Cleaved Lymphomas that are CD23- negative. This antibody reacts with the antigen that is found on a subpopulation of peripheral blood cells, B-lymphocytes and on EBV-transformed B-lymphoblastoid cell lines.

Antibody Type	Rabbit Monoclonal	**Clone**	EP75
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node		
Application	Hodgkin's And Non-Hodgkin Lymphoma, Leukemia & Histiocytic		

Presentation
Anti-CD23 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 6471	Predilute	Ready-to-Use	3.0 mL
BSB 6472	Predilute	Ready-to-Use	7.0 mL
BSB 6473	Predilute	Ready-to-Use	15.0 mL
BSB 6474	Concentrate	1:50-1:200	0.1 mL
BSB 6475	Concentrate	1:50-1:200	0.5 mL
BSB 6476	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9080-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
Do not use after the 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Kaiserlian D, et al. Immunology. 1993;80:90-95
2. Aubry JP, et al. Oxford Univ Press- Oxford, NY, Tokyo. 1987;417-419
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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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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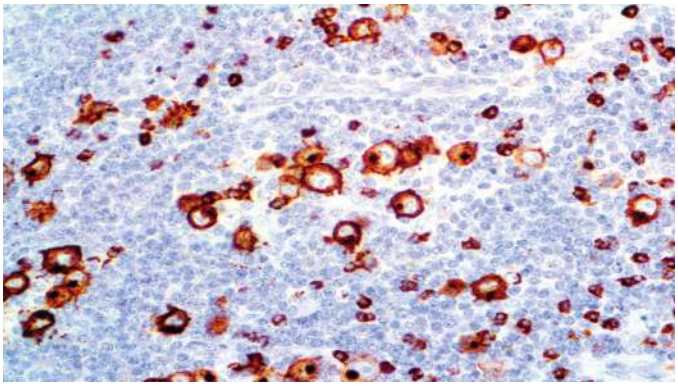
CD15

Clone: BSB-119
Mouse Monoclonal

CE IVD



Inset: IHC of CD15 on a FFPE Hodgkin's Lymphoma 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
The U937 histiocytic cell line was used as the immunogen for the CD15 Leu-M1 antibody.

Summary and Explanation
CD15 is a phosphatidylinositol-anchored transmembrane protein found on neutrophils and which may be involved in phagocytosis. It is expressed in patients with Hodgkin's Disease, some B-cell Chronic Lymphocytic Leukemias, Acute Lymphoblastic Leukemias, and most Acute Non-Lymphocytic Leukemias. It is also called Lewis x.

A positive reaction for CD15 combined with a negative reaction for CD45 and other B and T-lineage markers provides support for Reed-Sternberg cells found in Hodgkin's disease. Also, this antibody does not detect Mesotheliomas, making it a more frequently used antibody to distinguish Epithelial Mesothelioma from Adenocarcinoma.

Antibody Type	Mouse Monoclonal	**Clone**	BSB-119
Isotype	IgM	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Hodgkin's Lymphoma		
Application	Hodgkin's and Non-Hodgkin Lymphoma, Lung Cancer		

Presentation
Anti-CD15 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5183	Predilute	Ready-to-Use	3.0 mL
BSB 5184	Predilute	Ready-to-Use	7.0 mL
BSB 5185	Predilute	Ready-to-Use	15.0 mL
BSB 5186	Concentrate	1:50-1:200	0.1 mL
BSB 5187	Concentrate	1:50-1:200	0.5 mL
BSB 5188	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9072-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

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6. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

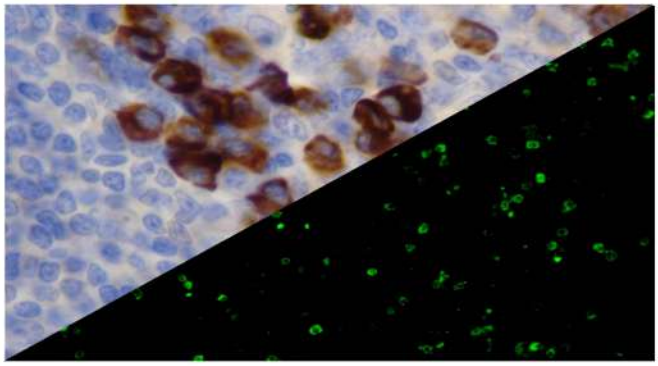
EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	Storage Temperature Limites de température Zulässiger Temperaturbereich	Manufacturer Fabricant Hersteller	REF Catalog Number Référence du catalogue Bestellnummer
IVD In Vitro Diagnostic Medical Device Dispositif médical de 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
5385 Hollister Avenue, Bldg. 8, Ste. 108 Santa Barbara, CA 93111, USA
Tel. (805) 692-2768 | Tel. (800) 561-1145 | Fax. (805) 692-2769
E-mail: sales@biosb.com | Website: www.biosb.com

Kappa Light Chains

Clone: BSB-58
Mouse Monoclonal

CE IVD



Inset: IHC and IF of Kappa Light Chains on a FFPE Tonsil Tissue

Intended Use
For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical and Immunofluorescence 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
Purified Kappa Light chains from human myeloma serum.

Summary and Explanation
Kappa detects surface immunoglobulin on normal and neoplastic B-cells. In paraffin-embedded tissue, Kappa exhibits strong staining of kappa-positive plasma cells and cells that have absorbed exogenous immunoglobulin.

When studying B-cell neoplasms, the determination of light-chain ratios remains the centerpiece. This is sound reasoning because most B-cell Lymphomas express either kappa or lambda light chains, whereas reactive proliferations display a mixture of kappa and lambda-positive cells. If only a single light-chain type is detected, a lympho-proliferative disorder is very likely. Monoclonality is determined by a kappa-lambda ratio greater than or equal to 3:1, a lambda-kappa ratio greater than or equal to 2:1, or a monoclonal population of 75% or more of the total population.

Antibody Type	Mouse Monoclonal	**Clone**	BSB-58
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic	**Species Reactivity**	Human, Dog, Cat
Control	Tonsil, Lymph Node		
Application	Lymphoma, Rejection & Autoimmunity		

Presentation
Anti-Kappa 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.

Catalog No.	*Antibody Type*	*Dilution*	*Volume/Qty*
BSB 5701	Tinto Predilute	Ready-to-Use	3.0 mL
BSB 5702	Tinto Predilute	Ready-to-Use	7.0 mL
BSB 5703	Tinto Predilute	Ready-to-Use	15.0 mL
BSB 5704	Concentrate	1:250-1:1000	0.1 mL
BSB 5705	Concentrate	1:250-1:1000	0.5 mL
BSB 5706	Concentrate	1:250-1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9250-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol
Preparation for Frozen Tissues Procedure
1. Embed the specimen in OCT inside the cryostat.
2. Cut sections at 5 microns.
3. Place the section on a positively charged glass slide.
4. Air dry for 30-60 minutes.
5. Fix in acetone 100% for 2-10 minutes.
6. Air dry for another 10 minutes.

Preparation for FFPE Tissues Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IF\IHC, perform antibody incubation at ambient temperature. For automated IF\IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IF\IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Abbreviated AmpliDetector Plus FITC IF Protocol

Step	Incubation Time
Rinse slides in IF wash buffer	
Drain and wipe excess IF wash buffer off slide	
Peroxidase Blocker	5 min.
Apply Antibody	5 min.
Apply Mouse/Rabbit Link	5 min.
Apply HRP Label	5 min.
Keep FITC reagents and slides in the dark	
Apply AmpliDetector FITC solution	5 min.
Coverslip with IF mounting medium	

Mounting Protocol IHC:

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent-based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

Mounting Protocol IF:

1. Bring FluoroMounter or FluoroMounter with DAPI to room temperature.
2. Rinse slides with distilled or deionized water.
3. Remove excess water from slides before laying them flat in the dark.
4. Turn the media bottle upside down before opening the dropper bottle.
5. Apply 1-3 drops of FluoroMounter to each slide making sure the specimen is covered.
6. Incubate 3-5 minutes at room temperature in the dark.
7. Coverslip.
8. Observe under a fluorescent microscope using the appropriate filters.
9. The slides are recommended to be stored at 2-8 ºC in the dark.

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 qualified medical professional.

References

1. Michie SA et al. A J Clin Path. 1987
2. Hertel BF, et al. Lab Invest. 1977;36:12
3. Taylor CL, Arch Pathol Lab Med. 1978;12:113-121
4. Dogan A, Blood. 1998;91:4708-14
5. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

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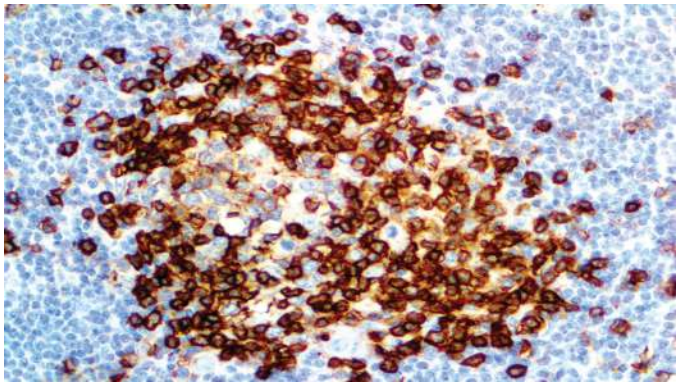
CD43

Clone: MT1
Mouse Monoclonal

CE IVD



Inset: IHC of CD43 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
Human lymph node cells.

Summary and Explanation
CD43 (leukosialin, sialophorin, or leukocyte sialoglycoprotein) is one of the major glycoproteins expressed in all thymocytes and T-cells. It plays a role in the physicochemical properties of the T-cell surface and in lectin binding. During T-cell activation, CD43 is actively removed from the T-cell antigen-presenting cell contact site, suggesting a negative regulatory role in adaptive immune response.

This antibody has been found useful in identification and classification of T-cell malignancies and low grade B-cell Lymphomas. CD43 expression is seen in some cases of B-cell Lymphocytic Lymphoma and Centrocytic Lymphoma. When used in combination with CD45 and CD20, effective immunophenotyping of the majority of Lymphomas can be obtained. Co-staining of a lymphoid infiltrate with CD20 and CD3 argues against a reactive process and favors Lymphoma.

Antibody Type	Mouse Monoclonal	**Clone**	MT1
Isotype	IgG1	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node		
Application	Lymphoma		

Presentation
Anti-CD43 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5239	Predilute	Ready-to-Use	3.0 mL
BSB 5240	Predilute	Ready-to-Use	7.0 mL
BSB 5241	Predilute	Ready-to-Use	15.0 mL
BSB 5242	Concentrate	1:100-1:500	0.1 mL
BSB 5243	Concentrate	1:100-1:500	0.5 mL
BSB 5244	Concentrate	1:100-1:500	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9093-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Cabecades JM., et al. Histopathology. 1991;19:419-424.
2. Strickler JG, et al. Hum Pathol. 1987;18:808-814
3. Sheibani K, et al. Hum Pathol. 1987;18:1051-1062
4. Chan JKC, et al. Histopathology. 1988;12:461-480
5. Arber DA, et al. App Immunohistochem. 1993;1:88-96
6. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

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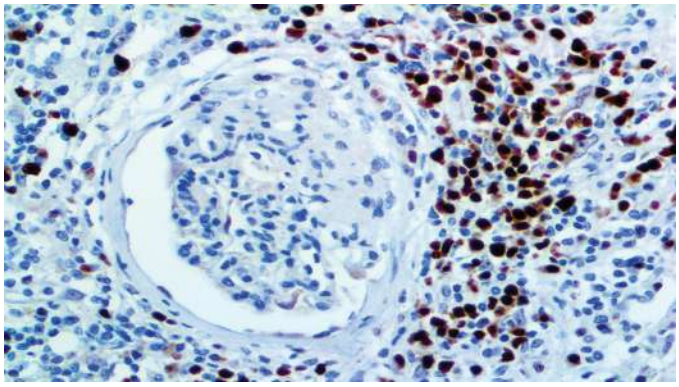
MUM1

Clone: EP190
Rabbit Monoclonal

CE IVD



Inset: IHC of MUM1 on a FFPE Kidney 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
A synthetic peptide corresponding to residues of human IRF4 (MUM1) protein.

Summary and Explanation
MUM1 (multiple myeloma oncogene-1) also known as interferon regulatory factor 4 (IRF4) is a 50 kDa protein and is a member of the interferon regulatory factor family of transcription factors. It is induced by antigen receptor mediated stimuli and plays an important role in cell proliferation, differentiation and survival. MUM1

is expressed in the nuclei and cytoplasm of plasma cells and a small percentage of germinal center (GC) B-cells committed to plasmacytic or memory cell differentiation in the "light zone".

Antibody Type	Rabbit Monoclonal	**Clone**	EP190
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Nuclear	**Species Reactivity**	Human, Canine, Feline
Control	Tonsil, Lymph Node, Plasmacytoma, Hodgkin's Lymphoma		
Application	Hodgkin's and Non-Hodgkin Lymphoma, Lymphoma		

Presentation
Anti-MUM1 is a Rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 6953	Predilute	Ready-to-Use	3.0 mL
BSB 6954	Predilute	Ready-to-Use	7.0 mL
BSB 6955	Predilute	Ready-to-Use	15.0 mL
BSB 6956	Concentrate	1:25-1:100	0.1 mL
BSB 6957	Concentrate	1:25-1:100	0.5 mL
BSB 6958	Concentrate	1:25-1:100	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9292-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Alizadeh AA, et al. Nature. 2000; 403:403503-11
2. Falini B, et al. Blood. 2000 March; 95(6):2084-92
3. Grossman A, et al. Genomics. 1996; 37:229-33
4. Iida S, et al. Nat Genet. 1997; 17:226-30
5. Carbone A, et al. Br J Haematol. 2002 May; 117(2):366-72
6. 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.
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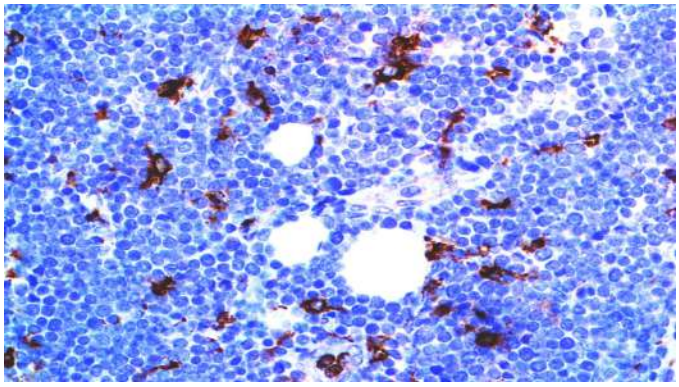
CD68

Clone: KP-1
Mouse Monoclonal

CE IVD



Inset: IHC of CD68 on a FFPE Lymphoblastic Lymphoma 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
Subcellular fraction of human alveolar macrophages.

Summary and Explanation
The CD68 antigen is a heavily glycosylated trans-membrane protein of 87-115 kDa which is specifically expressed by tissue macrophages, Langerhans cells and, at low levels, by dendritic cells. CD68 could play a role in phagocytic activities of tissue macrophages, both in intracellular lysosomal metabolism and extracellular cell-cell and cell-pathogen interactions.

CD68 marks cells of monocyte/macrophage lineage. This antibody is capable of staining monocytes, Kupffer cells, osteoclasts, granulocytes and their precursors; Lymphomas are negative or show a few granules. This antibody may be useful for the identification of Myelomonocytic and Histiocytic Tumors. CD68 may help to distinguish Malignant Fibrous Histiocytoma from other Pleomorphic Sarcomas.
However, since CD68 detects a formalin-resistant epitope that may be associated with lysosomal granules, other lysosome-rich cells may also produce positive results.

Antibody Type	Mouse Monoclonal	**Clone**	KP-1
Isotype	IgG1/K	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	**Species Reactivity**	Human, Hamster, Mouse, Non-Human Primate, Porcine, Rabbit, Rat
Control	Tonsil, Lymph Node		
Application	Leukemia & Histiocytic, Kidney & Urothelial Cancer, Breast Cancer		

Presentation
Anti-CD68 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 2712	Predilute	Ready-to-Use	3.0 mL
BSB 2713	Predilute	Ready-to-Use	7.0 mL
BSB 2714	Predilute	Ready-to-Use	15.0 mL
BSB 2715	Concentrate	1:250-1:1000	0.1 mL
BSB 2716	Concentrate	1:250-1:1000	0.5 mL
BSB 2717	Concentrate	1:250-1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9105-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Facchetti F, et al. Histopathology. 1991;19:141-5
2. Ruco LP, et al. Am J Clin Pathol. 1989;92:273-9
3. Cordell JL, et al. Oxford-New York-Tokyo: Oxford Univ. Press. 1995;925-927
4. Pulford KAF, et al. J Clin Pathol. 1989;42:414-21
5. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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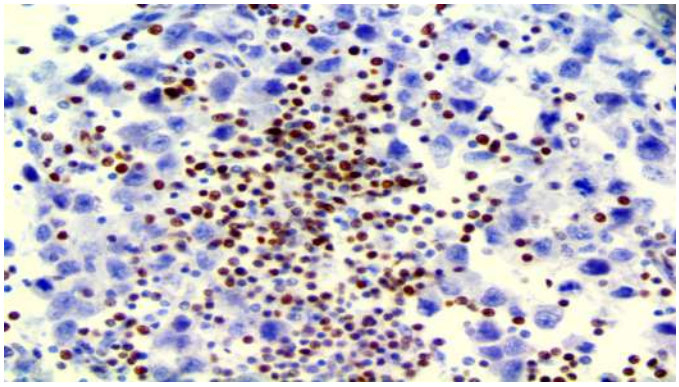
LEF1

Clone: RBT-LEF1
Rabbit Monoclonal

IVD



Inset: IHC of LEF1 on a FFPE Testicular Carcinoma Tissue

Antibody Type	Rabbit Monoclonal	**Clone**	RBT-LEF1
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Nuclear	**Species Reactivity**	Human
Control	Breast, Tonsil, Breast Carcinoma, Small Lymphocytic Lymphoma		
Application	Leukemia, Lymphoma, Colon & Gastrointestinal Cancer, Brain Cancer		

Presentation
Anti-LEF1 is a Rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB-3826-3	Predilute	Ready-to-Use	3.0 mL
BSB-3826-7	Predilute	Ready-to-Use	7.0 mL
BSB-3826-15	Predilute	Ready-to-Use	15.0 mL
BSB-3826-01	Concentrate	1:50 - 1:200	0.1 mL
BSB-3826-05	Concentrate	1:50 - 1:200	0.5 mL
BSB-3826-1	Concentrate	1:50 - 1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9259-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

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
Recombinant fragment (around aa100-200) of human LEF1 protein.

Summary and Explanation
Lymphoid enhancer-binding factor 1 (LEF1) is a protein that in humans is encoded by the *LEF1* gene with a 48-kD nuclear protein that is expressed in pre-B and T cells. LEF1 coupling with β-catenin, functions as a key nuclear mediator of WNT/β-catenin signaling, which regulates cell proliferation and survival. LEF1 has an important role in lymphopoiesis and is normally expressed in T and pro-B cells but not mature B cells. LEF1-mediated canonical Wnt signaling is required for morphogenesis of these skin appendages during embryogenesis. In normal lymphoid tissues, LEF1 is nuclear localized and observed predominantly in T cells of the paracortical regions; staining was undetected in B cells.
LEF1 is highly overexpressed and associated with disease progression and poor prognosis in B-cell chronic lymphocytic leukemia. Strong nuclear expression of LEF1 has been observed in majority of chronic lymphocytic leukemia/small lymphocytic lymphoma cases and LEF1 is not detected in other small B cell lymphomas. Gene expression profiling revealed overexpression of LEF1 in chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). LEF1 immunostaining has been detected in all neoplastic cells of CLL/SLL cases. LEF1 was identified in 50% of high grade follicular lymphoma and 38% of diffuse large B-cell lymphoma, but not in mantle cell lymphoma or marginal zone lymphoma. Recently, high LEF1 was demonstrated as a favorable prognostic marker in cytogenetically normal acute myeloid leukemia. Due to its high sensitivity, LEF1 has been proposed to be a suitable immunohistochemical marker for diagnosis and differential diagnosis for CLL/SLL.
Alternately spliced isoforms may play additional roles in regulating cell growth in colon carcinoma, and nuclear LEF1 immunostaining was detected in 36% of adenocarcinoma brain metastases.

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

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8. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

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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

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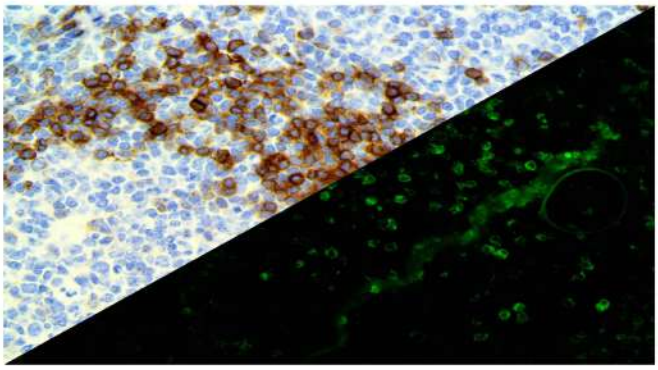
IgD

Clone: EP173
Rabbit Monoclonal

CE IVD



Inset: IHC and IF of IgD on a FFPE Tonsil Tissue

Intended Use
For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical and Immunofluorescence 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.

* The IgD antibody, clone EP173., has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
Synthetic peptide corresponding to residues of human IgD protein.

Summary and Explanation
IgD makes up about 1% of proteins in the plasma membranes of immature B-lymphocytes (coexpressed with IgM) and is also found in serum in very small amounts. It is monomeric and incorporates the alpha-heavy chain in its structure. IgD's function is currently unknown, as mice lacking IgD seem to retain normal immune responses (implying redundancy if not lack of function), and IgD ceases to be expressed in activated B-lymphocytes. It may function as a regulatory antigen receptor. IgD antibody reacts with surface immunoglobulin IgD delta chains. This antibody is useful when identifying Leukemias, Plasmacytomas, and B-cell lineage derived from Lymphomas, specifically Marginal Zone Lymphoma.

Antibody Type	Rabbit Monoclonal	**Clone**	EP173
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Spleen		
Application	Lymphomas, Hodgkin's & Non-Hodgkin's Lymphoma, Rejection & Autoimmunity		

Presentation
Anti-IgD is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 2957	Tinto Predilute	Ready-to-Use	3.0 mL
BSB 2958	Tinto Predilute	Ready-to-Use	7.0 mL
BSB 2959	Tinto Predilute	Ready-to-Use	15.0 mL
BSB 2960	Concentrate	1:50 - 1:200	0.1 mL
BSB 2961	Concentrate	1:50 - 1:200	0.5 mL
BSB 2962	Concentrate	1:50 - 1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9234-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC & IF Protocol
Preparation for Frozen Tissues Procedure
1. Embed the specimen in OCT inside the cryostat.
2. Cut sections at 5 microns.
3. Place the section on a positively charged glass slide.
4. Air dry for 30-60 minutes.
5. Fix in acetone 100% for 2-10 minutes.
6. Air dry for another 10 minutes.

Preparation for FFPE Tissues Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IF\IHC, perform antibody incubation at ambient temperature. For automated IF\IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IF\IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Abbreviated AmpliDetector Plus FITC IF Protocol

Step	Incubation Time
Rinse slides in IF wash buffer	
Drain and wipe excess IF wash buffer off slide	
Peroxidase Blocker	5 min.
Apply Antibody	5 min.
Apply Mouse/Rabbit Link	5 min.
Apply HRP Label	5 min.
Keep FITC reagents and slides in the dark	
Apply AmpliDetector FITC solution	5 min.
Coverslip with IF mounting medium	

Mounting Protocol IHC:

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent-based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

Mounting Protocol IF:

1. Bring FluoroMounter or FluoroMounter with DAPI to room temperature.
2. Rinse slides with distilled or deionized water.
3. Remove excess water from slides before laying them flat in the dark.
4. Turn the media bottle upside down before opening the dropper bottle.
5. Apply 1-3 drops of FluoroMounter to each slide making sure the specimen is covered.
6. Incubate 3-5 minutes at room temperature in the dark.
7. Coverslip.
8. Observe under a fluorescent microscope using the appropriate filters.
9. The slides are recommended to be stored at 2-8 ºC in the dark.

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 qualified medical professional.

References

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2. Mori S, Hagiwara S, Kodo H, Mohri N, Acta Pathol Jpn. 1986;Oct;36(1):1429-40
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6. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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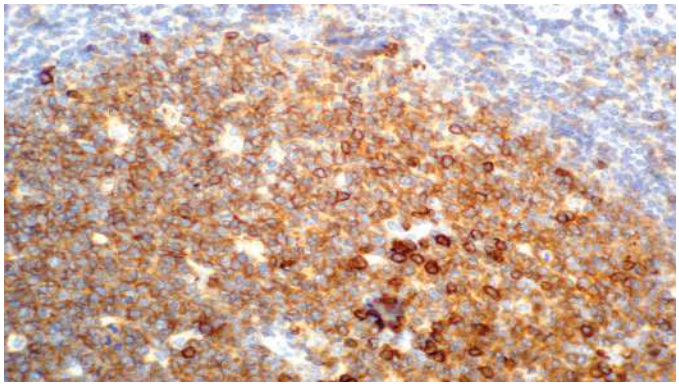
CD38

Clone: EP135
Rabbit Monoclonal

CE IVD



Inset: IHC of CD38 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.

* The CD38 antibody, clone EP135, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
Synthetic peptide corresponding to residues of human CD38 protein.

Summary and Explanation
CD38 is a glycoprotein found on the surface of many immune cells (white blood cells), including CD4+, CD8+, B and natural killer cells. It is a marker of cell activation. The CD38 protein has been linked to HIV infection, Leukemias, Myelomas, solid tumors, Type II Diabetes Mellitus and bone metabolism, as well as some genetically-determined conditions. It has also been used as a prognostic marker in Leukemia. CD38 is highly expressed on thymocytes. It is also expressed by early cells of B and T lineages, NK cells, plasma cells, monocytes and macrophages, and may be detected on cells from Multiple Myeloma, ALL (B and T) and some AML.

Monoclonal antibodies to CD38 have been shown to be useful in subtyping of Lymphomas and Leukemias, inhibition of B-lymphopoiesis, detection of plasma cells, protection of B-cells from apoptosis, and as a marker for activated B and T-cell proliferation.

Antibody Type	Rabbit Monoclonal	**Clone**	EP135
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Membranous	**Species Reactivity**	Human
Control	Breast, Tonsil, Lymph Node		
Application	Leukemia & Histiocytic, Lymphoma, Rejection & Autoimmunity		

Presentation
Anti-CD38 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 6499	Predilute	Ready-to-Use	3.0 mL
BSB 6500	Predilute	Ready-to-Use	7.0 mL
BSB 6501	Predilute	Ready-to-Use	15.0 mL
BSB 6502	Concentrate	1:25-1:100	0.1 mL
BSB 6503	Concentrate	1:25-1:100	0.5 mL
BSB 6504	Concentrate	1:25-1:100	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9089-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Funaro A, Malavasi F, J. Biol. Regul. Homeost. Agents. 1999;13(1):54-61
2. Mallone R, Perin PC, Diabetes Metab. Res. Rev. 2006;22(4):284-94
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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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP — QAdvis EAR AB, Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden	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

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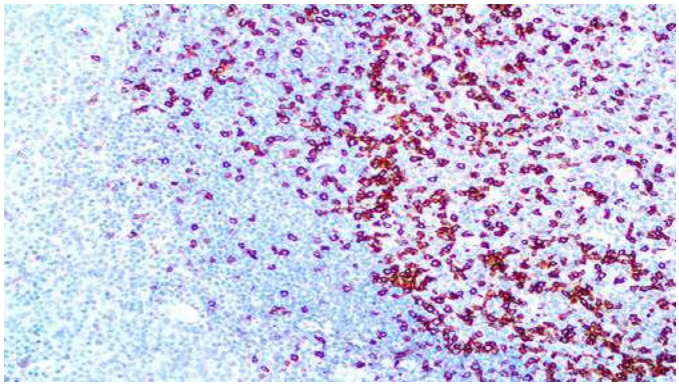
PD-1/CD279

Clone: EP239
Rabbit Monoclonal

CE IVD



Inset: IHC of PD-1\CD279 on a FFPE Tonsil Tissue

Antibody Type	Rabbit Monoclonal	**Clone**	EP239
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	**Species Reactivity**	Human
Control	Tonsil, Lymph Node, Thymus, Spleen		
Application	Lymphoma, Hodgkin's And Non-Hodgkin Lymphoma, Immunotherapy		

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.

* The PD-1\CD279 antibody, clone EP239, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen
A synthetic peptide corresponding to resides of human PD-1 protein.

Summary and Explanation
Programmed Death 1 (PD-1 or CD279) is a Type I membrane protein comprised of 268 amino acids. PD-1 is a member of the extended CD28/CTLA-4 family of T-cell regulators. PD-1 is expressed on the surface of activated T-cells, B-cells, and macrophages. In comparison to CTLA-4, PD-1 more broadly negatively regulates immune responses.

New data suggests that expression of PD-L1 on tumor cells inhibits anti-tumor activity through engagement of PD-1 on effector T-cells. Expression of PD-L1 on tumors is correlated with reduced survival in esophageal, pancreatic and other types of cancers, highlighting the relevance of exploring the PD-1 pathway as a target for immunotherapy. Studies have found that PD-1 is expressed on most T-cells and a small subset of B-cells in the light zone of germinal centers, but not elsewhere in the tonsil. On that basis, it was postulated that PD-1 may play a role in the process of clonal selection of centrocytes, which occurs in this subanatomic site in germinal centers. PD-1 is a new marker of Angioimmunoblastic Lymphoma and suggests a unique cell of origin for this neoplasm. Unlike CD10 and bcl-6, PD-1 is expressed by few B-cells, so it may be a more specific and useful diagnostic marker in Angioimmunoblastic Lymphoma. It also seems to stain a greater percentage of CD3-positive neoplastic cells in Angioimmunoblastic Lymphoma than either CD10 or bcl-6.

Presentation
Anti-PD-1\CD279 is a rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 3148	Predilute	Ready-to-Use	3.0 mL
BSB 3149	Predilute	Ready-to-Use	7.0 mL
BSB 3150	Predilute	Ready-to-Use	15.0 mL
BSB 3151	Concentrate	1:50-1:200	0.1 mL
BSB 3152	Concentrate	1:50-1:200	0.5 mL
BSB 3153	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9338-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Ishida, et al. Embo. 1992;11:3887
2. Agate, et al. Int Immunol. 1996;8:765
3. Dorfman DM, et al. Am J Surg Pathol. 2006;30(7):802-10
4. Iwai Y, et al. Immunol Lett. 2002;1:83(3):215-20
5. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

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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

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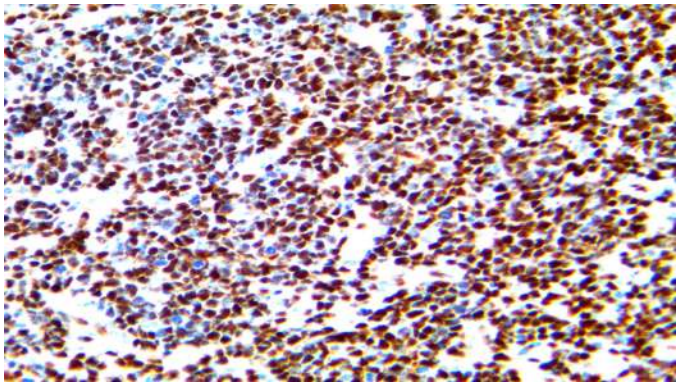
LMO2

Clone: RBT-LMO2
Rabbit Monoclonal

CE IVD



Inset: IHC of LMO2 on a FFPE Lymphoblastic Lymphoma 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
Synthetic peptide corresponding to the N-Terminal of the human LMO2 protein.

Summary and Explanation
LIM domain only 2 (rhombotin-like 1), also known as LIM Domain Only Protein 2 and T-Cell Translocation Protein 2, is a protein which in humans is encoded by the LMO2 gene. LMO2 encodes a cysteine-rich, two LIM domain protein that is required for yolk sac erythropoiesis. The LMO2 protein has a central and crucial role in hematopoietic development and is highly conserved.

HGAL and LMO2 have been found helpful in classifying difficult cases of Follicular Lymphoma (FL) as an adjunct in the identification of FL of the nongastric GI tract. LMO2 expression has been reported to be special feature of GC DLBCL (Diffuse Large B Cell Lymphoma of germinal center subtype) which can be used as a diagnostic marker. LMO2 has shown usefulness as part of an IHC panel of germinal center-associated markers in eliminating cases of Diffuse Follicle Center Lymphoma. This is accomplished by taking into consideration the histologic and immunoarchitectural spectrum of Nodal Marginal Zone Lymphoma (NMZL) and the immunohistochemical analysis for CD43, CD23, CD21, BCL6, HGAL, and LMO2 in the diagnosis of NMZL.

Antibody Type	Rabbit Monoclonal	**Clone**	RBT-LMO2
Isotype	IgG	**Reactivity**	Paraffin, Frozen
Localization	Nuclear	**Species Reactivity**	Human, Mouse
Control	Tonsil, Spleen, Placenta, Follicular and Lymphoblastic Lymphoma		
Application	Lymphoma		

Presentation
Anti-LMO2 is a Rabbit 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 3574	Predilute	Ready-to-Use	3.0 mL
BSB 3575	Predilute	Ready-to-Use	7.0 mL
BSB 3576	Predilute	Ready-to-Use	15.0 mL
BSB 3577	Concentrate	1:50-1:200	0.1 mL
BSB 3578	Concentrate	1:50-1:200	0.5 mL
BSB 3579	Concentrate	1:50-1:200	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9262-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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

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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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Boehm T, et al. "The rhombotin family of cysteine-rich LIM-domain oncogenes: distinct members are involved in T-cell translocations to human chromosomes 11p15 and 11p13". Proceedings of the National Academy of Sciences of the United States of America. 1995; 88 (10): 4367–71.
2. Warren AJ, et al. "The oncogenic cysteine-rich LIM domain protein rbtn2 is essential for erythroid development". Cell. 1994; 78 (1): 45–57.
3. Chapman-Fredricks J, et al. Usefulness of HGAL and LMO2 immunohistochemistry in the identification of follicular lymphomas of the non-gastric gastrointestinal tract. Appl Immunohistochem Mol Morphol. 2013 May; 21(3):200-4.
4. Shams TM. High expression of LMO2 in Hodgkin, Burkitt and germinal center diffuse large B cell lymphomas. J Egypt Natl Canc Inst. 2011 Dec;23(4):147-53.
5. Salama ME, et al. Immunoarchitectural patterns in nodal marginal zone B-cell lymphoma: a study of 51 cases. Am J Clin Pathol. 2009 Jul;132(1):39-49.
6. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

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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

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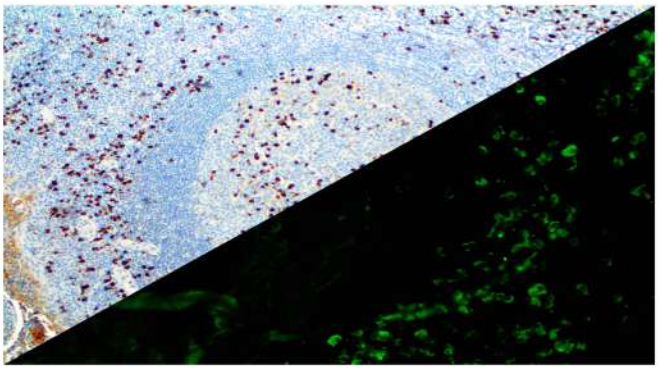
Lambda

Clone: BSB-16
Mouse Monoclonal

CE IVD



Inset: IHC and IF of Lambda on a FFPE Tonsil Tissue

Intended Use
For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical and Immunofluorescence 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
Purified human lambda light chain.

Summary and Explanation
Lambda detects surface immunoglobulin on normal and neoplastic B-cells. Lambda staining is seen in B-cell follicles of human lymphoid tissue.

When studying B-cell neoplasms, the determination of light chain ratios remains the centerpiece. This is sound reasoning because most B-cell Lymphomas express either kappa or lambda light chains, whereas reactive proliferations display a mixture of kappa and lambda-positive cells. If only a single light-chain type is detected, a lymphoproliferative disorder is very likely. Monoclonality is determined by a kappa-lambda ratio greater than or equal to 3:1, a lambda-kappa ratio greater than or equal to 2:1, or a monoclonal population of 75% or more of the total population.

Antibody Type	Mouse Monoclonal	**Clone**	BSB-16
Isotype	IgG2a	**Reactivity**	Paraffin, Frozen
Localization	Cytoplasmic	**Species Reactivity**	Human, Dog, Cat
Control	Tonsil, Lymph Node		
Application	Lymphoma, Rejection & Autoimmunity		

Presentation
Anti-Lambda 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 5715	Tinto Predilute	Ready-to-Use	3.0 mL
BSB 5716	Tinto Predilute	Ready-to-Use	7.0 mL
BSB 5717	Tinto Predilute	Ready-to-Use	15.0 mL
BSB 5718	Concentrate	1:250 - 1:1000	0.1 mL
BSB 5719	Concentrate	1:250 - 1:1000	0.5 mL
BSB 5720	Concentrate	1:250 - 1:1000	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9254-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

Stability
This product is stable up to the expiration date on the product label. 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 for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol
Preparation for Frozen Tissues Procedure
1. Embed the specimen in OCT inside the cryostat.
2. Cut sections at 5 microns.
3. Place the section on a positively charged glass slide.
4. Air dry for 30-60 minutes.
5. Fix in acetone 100% for 2-10 minutes.
6. Air dry for another 10 minutes.

Preparation for FFPE Tissues Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) 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 on trivet 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 IF\IHC, perform antibody incubation at ambient temperature. For automated IF\IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IF\IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

Abbreviated AmpliDetector Plus FITC IF Protocol

Step	Incubation Time
Rinse slides in IF wash buffer	
Drain and wipe excess IF wash buffer off slide	
Peroxidase Blocker	5 min.
Apply Antibody	5 min.
Apply Mouse/Rabbit Link	5 min.
Apply HRP Label	5 min.
Keep FITC reagents and slides in the dark	
Apply AmpliDetector FITC solution	5 min.
Coverslip with IF mounting medium	

Mounting Protocol IHC:

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent-based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

Mounting Protocol IF:

1. Bring FluoroMounter or FluoroMounter with DAPI to room temperature.
2. Rinse slides with distilled or deionized water.
3. Remove excess water from slides before laying them flat in the dark.
4. Turn the media bottle upside down before opening the dropper bottle.
5. Apply 1-3 drops of FluoroMounter to each slide making sure the specimen is covered.
6. Incubate 3-5 minutes at room temperature in the dark.
7. Coverslip.
8. Observe under a fluorescent microscope using the appropriate filters.
9. The slides are recommended to be stored at 2-8 ºC in the dark.

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 qualified medical professional.

References

1. Michie SA et al. A J Clin Path. 1987
2. Hertel BF, et al. Lab Invest. 1977;36:12
3. Taylor CL, Arch Pathol Lab Med. 1978;12:113-121
4. Mann RB, Jaff e ES, Bernard CW, Amer J Pathol. 1979;94(1):105
5. 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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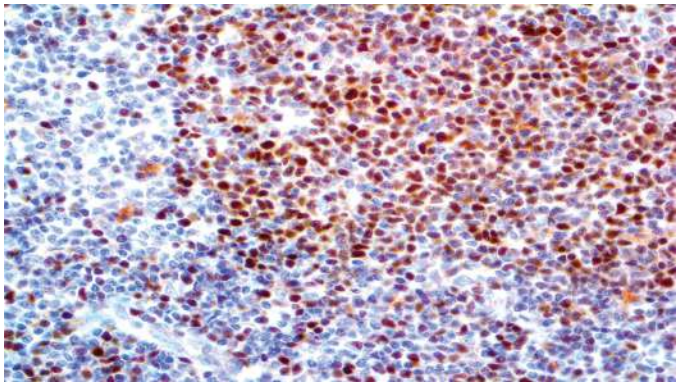
SOX-11

Clone: CL0142
Mouse Monoclonal

CE IVD



Inset: IHC of SOX-11 on a FFPE Mantle Cell Lymphoma 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
Recombinant fragment corresponding to amino acids 56-166 of human SOX-11.

Summary and Explanation
Transcription factor SOX-11 is a member of the group C SOX (SRY-related HMG-box) transcription factor family involved in the regulation of embryonic development and in the determination of the cell fate. The encoded protein may act as a transcriptional regulator after forming a protein complex with other proteins. The protein may function in the developing nervous system and play a role in tumorigenesis and adult neurogenesis. SOX-11 is normally expressed in the developing human central nervous system, Medulloblastoma, and Glioma.

Anti-SOX-11 nuclear protein expression is highly associated with both Cyclin D1-positive and negative Mantle Cell Lymphomas, with a stronger and more homogeneous Immunohistochemistry staining than cyclin D1.

Antibody Type	Mouse Monoclonal	**Clone**	CL0142
Isotype	IgG2a	**Reactivity**	Paraffin, Frozen
Localization	Nuclear	**Species Reactivity**	Human
Control	Mantle Cell Lymphoma		
Application	Lymphomas, Lung Cancer		

Presentation
Anti-SOX-11 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.

Catalog No.	*Presentation*	*Dilution*	*Volume*
BSB 2216	Predilute	Ready-to-Use	3.0 mL
BSB 2217	Predilute	Ready-to-Use	7.0 mL
BSB 2218	Predilute	Ready-to-Use	15.0 mL
BSB 2219	Concentrate	1:25-1:100	0.1 mL
BSB 2220	Concentrate	1:25-1:100	0.5 mL
BSB 2221	Concentrate	1:25-1:100	1.0 mL

Control Slides Available

Catalog No.	*Quantity*
BSB-9383-CS	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. 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" (see References in this document).

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Specimen Preparation
Paraffin sections: The antibody can be used on formalin-fixed paraffin-embedded (FFPE) tissue sections. Ensure tissue undergoes appropriate fixation for 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 on acetone-fixed frozen sections and acetone-fixed cell preparations.

IHC Protocol

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively 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 induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
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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 IHC, perform antibody incubation at ambient temperature. For automated IHC methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical Protocol

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Peroxidase/AP Blocker	5 min.	5 min.	5 min
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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/Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

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 qualified medical professional.

References

1. Jay P, et al. Genomics. 1996 Aug; 29(2):541-5
2. Haslinger A, et al. Eur J Neurosci. 2009 May; 29(11):2103-14
3. Mozos A, et al. Haematologica. 2009; 94:1555-62
4. Hargrave M, et al. Dev Dyn. 1997; 210:79-86
5. Lee CJ, et al. J Neurooncol. 2002; 57:201-14
6. 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.
https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key/Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	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

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IHC Detection Systems

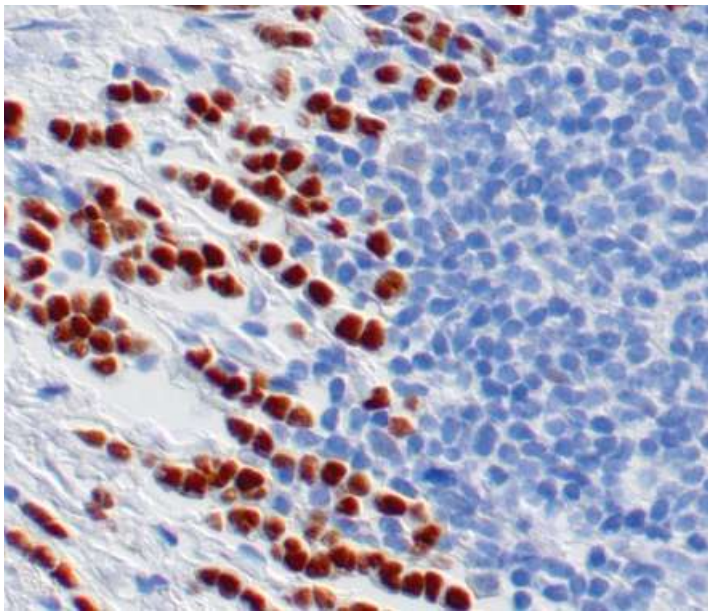
Which detection system is best for your laboratory?

To complement our robust antibody portfolio we offer an array of detection technologies designed to meet the needs of the clinical and research market. The following guide is designed to help you determine the best kit for your application. See the following detection system packages for detailed information on each detection kit. When in doubt you may contact your local representative or our technical service team at lab.reagents@thermofisher.com.

UltraVision Quanto Detection Kit (IVD)

The UltraVision Quanto Detection System utilizes innovative micropolymer technology that enhances sensitivity while reducing costs and turnaround time[2]. This system is optimized for mouse and rabbit antibodies on human specimens and is ideal for routine clinical testing.

Description	REF Num	Use
UltraVision Quanto Detection System AP 60 mL	TL-060-QAL	IVD
UltraVision Quanto Detection System HRP DAB 60 mL	TL-060-QHD	IVD
UltraVision Quanto AP 1 L	TL-999-QAL	IVD
UltraVision Quanto Complete Kit 125 mL	TL-125-QCK	IVD
UltraVision Quanto Complete Kit 60 mL	TL-060-QCK	IVD
UltraVision Quanto Detection System AP 125 mL	TL-125-QAL	IVD
UltraVision Quanto Detection System HRP 125 mL	TL-125-QHL	IVD
UltraVision Quanto Detection System HRP 60 mL	TL-060-QHL	IVD
UltraVision Quanto Detection System HRP DAB 125 mL	TL-125-QHD	IVD
UltraVision Quanto Detection System HRP DAB Sample 15 mL	TL-015-QHD	IVD
UltraVision Quanto HRP 1LTL-999-QPB/QPH and TA-999-PBQ	TL-999-QHL	IVD
UltraVision Quanto HRP DAB 1 L	TL-999-QHD	IVD



[2]NoriQC Review of Technical Test Approach Montreal 2010 http://www.nordiqc.org/seminars/Nielsen-Montreal-08-July-10.pdf

IHC Detection Systems

UltraVision Labeled Polymer (LP) (IVD)

UltraVision LP is the predecessor of UltraVision Quanto. UltraVision LP works well in clinical applications and produces strong, consistent results.

Note: UltraVision LP enhances mouse antibodies but does not enhance rabbit antibodies.

Description	REF Num	Use
Kit PV HRP polymer 1LTL-999-PB/PH and TA-999-PBQ	TL-999-HL	IVD
UltraVision LP HRP Polymer & DAB Chromogen 15 mL	TL-015-HD	IVD
UltraVision LP HRP Polymer & DAB Chromogen 60 mL	TL-060-HD	IVD
UltraVision LP HRP Polymer & DAB Chromogen 125 mL	TL-125-HD	IVD
UltraVision LP Large Vol AP Polymer (RTU) 60 mL	TL-060-AL	IVD
UltraVision LP Large Vol AP Polymer (RTU) 125 mL	TL-125-AL	IVD
UltraVision LP Large Vol HRP Polymer (RTU) 60 mL	TL-060-HL	IVD
UltraVision LP Large Vol HRP Polymer (RTU) 125 mL	TL-125-HL	IVD

IHC Detection Systems

UltraVision ONE (IVD)

UltraVision ONE offers the protocol with the least number of steps and is ideal for clinical applications with frozen section or where few steps are ideal.

Description	REF Num	
UltraVision ONE Large Vol, HRP Polymer (RTU) 125 mL	TL-125-HLJ	IVD
UltraVision ONE Large Vol. AP Polymer (RTU) 125 mL	TL-125-ALJ	IVD
UltraVision ONE, AP Polymer & Fast Red Chromogen 15 mL	TL-015-AFJ	IVD

Multivision (IVD)

The Multivision system is designed for visualizing two antigens on a single slide.

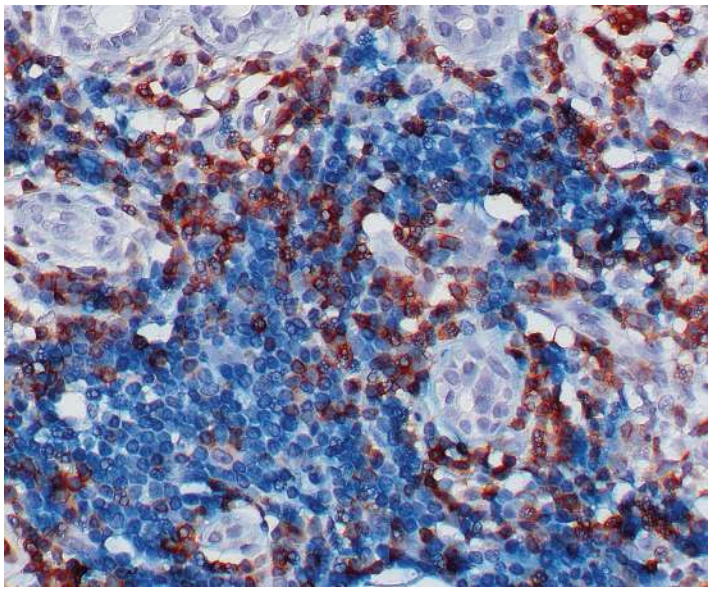
Epredia UltraVision and UltraVision Plus (IVD)

Robust Biotin and Streptavadin System

Epredia UltraVision LP Value (IVD)

Similar technology to UltraVision LP at a more affordable price

Description	REF Num	
MV Polymer/ anti-mouse/ AP+anti Rabbit/HRP 12 mL	TL-012-MARH	IVD
MV Polymer/ anti-mouse/ HRP+anti Rabbit/AP 12 mL	TL-012-MHRA	IVD



IHC Ancillary Products

Description	REF Num	
Antibody Diluent OP Quanto	TA-125-ADQ	IVD
Tween 20 (Polyoxyethelenesorbitan Monolaurate) 125 mL	TA-125-TW	RUO
UltraVision DAB Away 250 mL	TA-250-DA	IVD
UltraVision Protein Blk 125 ml	TA-125-PBQ	IVD
UltraVision Protein Block 60 ml	TA-060-PBQ	IVD
UV Hydrogen Peroxide Block 1 L	TA-999-H2O2Q	IVD
UV Hydrogen Peroxide Block 125 ml	TA-125-H2O2Q	IVD
UV Hydrogen Peroxide Block 60 ml	TA-060-H2O2Q	IVD
FITC Protein Blocking Agent (PBA) 6 mL	TA-006-PBA	IVD
Phosphate Buffered Saline (10X) 10 mL	AP-9009-10	IVD
Phosphate Buffered Saline and Tween 20 Large Vol (20X)	TA-999-PT	IVD
Tris Buffer Saline and Tween 20 Large Vol (20X) 999 mL	TA-999-TT	IVD

Description	REF Num	
Large Vol Phosphate Buffered Saline (25X) 125 mL	TA-125-PB	IVD
Large Vol Phosphate Buffered Saline and Tween 20 (20X) 125 mL	TA-125-PT	IVD
Large Vol Tris Buffer Saline and Tween 20 (20X) 125 mL	TA-125-TT	IVD
Large Vol Tris Buffered Saline (25X) 125 mL	TA-125-TB	IVD
Mayer's Hematoxylin 125 mL	TA-125-MH	IVD
Mayer's Hematoxylin 60 mL	TA-060-MH	IVD
PermaFluor Aqueous Mounting Medium 30 mL	TA-030-FM	IVD
PermaFluor Aqueous Mounting Medium 6 mL	TA-006-FM	IVD
SI Prep, Aqua-Mount 125 mL	TA-125-AM	IVD

Slide clarity – **pure** and **simple**

When conducting immunohistochemistry (IHC) assays, it can be frustrating when pretreated slides come out murky. Incomplete dewaxing can make it feel like you're looking through a dirty window, and can interfere with diagnostics, decrease laboratory efficiency, and drive up operating costs.

Dewax and HIER buffers by Epredia achieve all-in-one epitope retrieval and deparaffinization in the PT Module ahead of IHC. Dewax and HIER buffers demonstrate superior dewaxing performance over other PTM buffers. Unlike other processes, slides are not recoated with molten paraffin, resulting in enhanced clarity in imaging.

Dewax and HIER buffers are color-coded into three pH groups, allowing you to easily differentiate between tanks. All dewax and HIER buffers come pre-measured for ease of use in the PT Module.

For more information on achieving better clarity in your immunohistochemical assays, please contact your local Epredia representative today.

Dewax and HIER buffers come in three pH ranges:

L Dewax and HIER buffer L is a low pH (~6.0) buffer and is citrate-based (orange coloration).

M Dewax and HIER buffer M is a mid pH (~8.0) buffer and is EDTA-based (purple coloration).

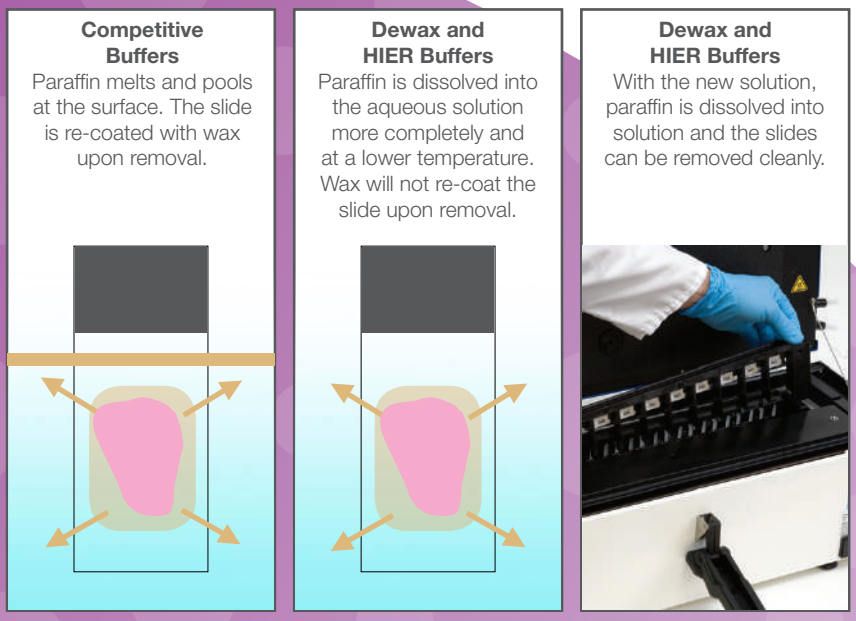
H Dewax and HIER buffer H is a high pH (~9.0) buffer and is Tris-EDTA-based (blue coloration).

Clarity doesn't have to come at a big cost.

Epredia Dewax and HIER Buffers deliver high quality at a competitive cost per slide. Get a clearer picture of how you may be able to save 40% or more per test. Contact your Epredia representative today.

See the difference for yourself.
Contact your Epredia representative today and ask about Dewax and HIER buffers.

Item	Use	REF Num
Dewax and HIER buffer (H, M, L) variety pack	IVD	TA-999-DHBVP
Dewax and HIER buffer H (15x concentrate) 10 x 100 mL	IVD	TA-999-DHBH
Dewax and HIER buffer L (15x concentrate) 10 x 100 mL	IVD	TA-999-DHBL
Dewax and HIER buffer M (15x concentrate) 10 x 100 mL	IVD	TA-999-DHBM



Find out more at **www.epredia.com**

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epredia
Enhancing precision cancer diagnostics

ImmunoDetector Protein Blocker / Antibody Diluent

IVD

Bio SB
BIOSCIENCE FOR THE WORLD

www.biosb.com

Intended Use
For In Vitro Diagnostic Use.

Summary and Explanation
ImmunoDetector Protein Blocker/Antibody Diluent is used to dilute ascites, supernatants, purified antibodies, and polyclonal antibodies. The reagent is designed to minimize the non-specific reaction that may be caused by non-specific antibody interactions and encourages specific antigen-antibody binding.

Presentation
ImmunoDetector Protein Blocker/Antibody Diluent contains TBST, pH 7.6, with bovine serum albumin, and preserved with sodium azide as an anti-microbial. It is provided in liquid form ready-to-use.

Catalog No.	*Concentration*	*Volume*
BSB 0113	Ready-to-use	15 mL
BSB 0040	Ready-to-use	50 mL
BSB 0041	Ready-to-use	100 mL
BSB 0114	Ready-to-use	200 mL
BSB 0115	Ready-to-use	1000 mL

Storage Store at 2-8^{0}C

Stability
This product is stable up to the expiration date on the product label. 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.

Precautions
1 For professional users only. Results should be interpreted by a medical professional.
2. This product contains <0.1% sodium azide (NaN_3) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as laboratory coat, goggles and gloves when handling reagents.
4. Dispose of unused solution according to local and federal regulations.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. 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” (1).

Preparation of Working Solution
The ImmunoDetector Protein Blocker/Antibody Diluent is a ready-to-use working solution and requires no further preparation.

Recommended Protocol

When diluting antibodies, add antibody to the diluent, not diluent to the antibody. Addition of the antibody to the mixing vessel before the diluent can cause contamination of the diluent if multiple dispenses are necessary.

Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies

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 qualified medical professional.

References

1. 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.

Symbol Key / Légende des symboles/Erläuterung der Symbole

	 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

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