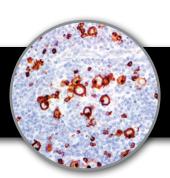
C€ IVD





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	MMA
Isotype	lgM	Reactivity	Paraffin, Frozen
Localization	Cytoplasmic, Membranous	Control	Tonsil, Lymph Node, Hodgkin's Lymphoma
Species Reactivity		Human	

Presentation

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.

Presentations

Catalog Num.	Antibody Type	Dilution	Volume/Qty
BSB 5183	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 5184	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 5185	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 5186	Concentrated	1:25 - 1:100	0.1 mL
BSB 5187	Concentrated	1:25 - 1:100	0.5 mL
BSB 5188	Concentrated	1:25 - 1:100	1.0 mL
BSB 5189	Control Slides	Not Applicable	5 slides

Precautions

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

Storage

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

Specimen Preparation

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

Frozen sections and cell preparations: The antibody can be used for labeling acetone-fixed frozen sections and acetone-fixed cell preparations.

Staining Procedure

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

a. TintoRetriever Pressure Cooker or Equivalent

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

b. TintoRetriever PT Module or Water Bath Method

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

c. Conventional Steamer Method

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

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

Recommended IHC Protocol

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

Product Limitations

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

References

- 1. Skubitz K, et al. Oxford Univ Press. 1989:800-805
- 2. Hsu SM, et al. Am J Clin Path. 1984;82
- 3. Pinkus GS, et al. Am J Path. 1985;119:244-252
- 4. Wieczorek R, et al. Am J Path. 1985;121:374-380
- 5. Swerdlow SH, et al. Am J Path. 1986;85:283-282
- 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.

Symbol Key / Légende des symboles/Erläuterung der Symbole





