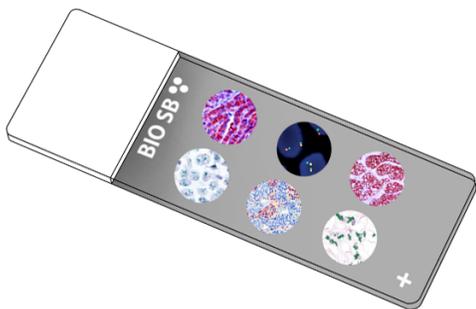


CD163 Control Slides



Intended Use

For In Vitro Diagnostic Use.

Summary and Explanation

CD163 is a protein that in humans is encoded by the CD163 gene. CD163 is the high affinity scavenger receptor for the hemoglobin-haptoglobin complex and in the absence of haptoglobin - with lower affinity - for hemoglobin alone. CD163 is expressed exclusively on the cell surface of human monocytes and macrophages that evolve predominantly in the late phase of inflammation, and is, therefore, very useful for macrophage-phenotyping. A soluble form of the receptor exists in plasma, commonly named sCD163, which is upregulated in a large range of inflammatory diseases including liver cirrhosis, type 2 diabetes, atherosclerosis, macrophage activation syndrome, Gaucher's disease, sepsis, HIV infection, rheumatoid arthritis and Hodgkin Lymphoma.

CD163 positive by IHC can be seen in histiocytes, gut, Kupffer cells, a few alveolar macrophages, the main population of macrophages in the placenta, and in varying degrees in macrophages in inflamed tissue including tumor tissue, depending on the inflammatory stage. Red-pulp, not white-pulp, macrophages in the spleen and cortical macrophages of the thymus are also positive for this marker. CD163 has been found to be helpful in distinguishing synovial macrophages from synovial intimal fibroblasts in the setting of rheumatoid arthritis, with superior specificity for macrophages than CD68, which does not discriminate between these cell types. It also has been confirmed in previous reports of having a prognostic role of tumor-infiltrating macrophages in classical Hodgkin's Lymphoma. Increased levels of CD163 have been detected in patients with microbial infections and myelomonocytic leukemias and studies have confirmed the fact that CD163 expression is limited to leukemias with monocytic differentiation. Another recent study showed that all 5 cases of synovial-type giant cell tumors of the spinal column were positive for CD163.

Presentation

Five slides of CD163 positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

| <i>Catalog No.</i> | <i>Quantity</i> |
|--------------------|-----------------|
| BSB-9074-CS | 5 slides |
| BSB 3278 | 5 slides |
| BSB 6309 | 5 slides |

Storage Store at 20-25°C

Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. 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. 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.

IHC Protocol

1. 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).
2. 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.
3. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
4. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
5. Wash slides with ImmunoDNA washer or DI water.
6. Continue IHC staining 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 IF Protocol

| Step | Incubation Time |
|--|-------------------|
| Rinse slides in IF wash buffer | 5 minutes |
| Drain and wipe excess IF wash buffer off slide | |
| Conduct remaining steps in the dark | |
| Apply Antibody | 30-60 minutes |
| Rinse with 3 changes of IF wash buffer | 3x15 minutes each |
| Coverslip with IF mounting medium | |

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMunter (BSB 0169-0174) or organic solvent based resin such as PermaMunter (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

- Schaer DJ., et al. CD163 is the macrophage scavenger receptor for native and chemically modified hemoglobins in the absence of haptoglobin. *Blood*. 2006 Jan 1;107(1):373-80.
- Lau SK, et al. CD163: a specific marker of macrophages in paraffin-embedded tissues. *Am. J. Clin. Path.* 2004; 122 (5): 794-801.
- Jones K, et al. Serum CD163 and TARC as disease response biomarkers in classical Hodgkin lymphoma. *Clin. Cancer Res.* 2013; 19 (3): 731-42.
- Klein JL, et al. CD163 immunohistochemistry is superior to CD68 in predicting outcome in classical Hodgkin lymphoma. *Am J Clin Pathol.* 2014 Mar; 141 (3): 381-7.
- 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. <https://www.cdc.gov/mmwr/pdf/other/su6101.pdf>

Symbol Key / Légende des symboles/Erläuterung der Symbole

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|---------------|--|---|--|------------|---|
| 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 |