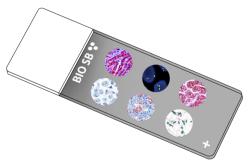
Doc #: P19349 Version #: 2



Pneumocystis jirovecii Control Slides C € IVD



Intended Use

For In Vitro Diagnostic Use.

Summary and Explanation

Anti-Pneumocystis jirovecii antibody reacts with an epitope on the yeast-like fungal microorganism, Pneumocystis jirovecii that is resistant to formalin, picric acid, paraffin, as well as alcohol and xylene. No cross-reactivity has been demonstrated with other fungi or parasitic organisms.

Presentation

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

Catalog No.	Quantity		
BSB-9349-CS	5 slides		
BSB 5881	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

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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 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. Silverberg SG, et al. P.P.S.P, 3rd edition. 1997;182-185
- 2. Linder E, et al. J Immunol Methods. 1987; 98:57-62
- 3. Elvin KM, et al. Br Med J. 1988;297:381-4
- 4. Radio SJ, et al. Modern Pathol. 1990; 3:462-9
- 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 REF	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	[]i	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	\subseteq	Expiration Date Utiliser jusque Verwendbar bis	LOT	Lot Number Code du lot Chargenbezeichnung



