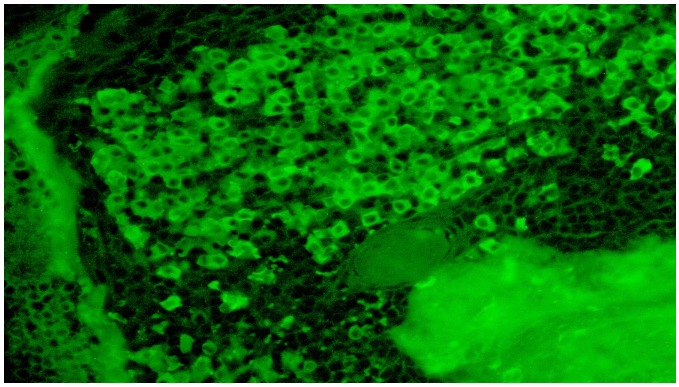
Kappa Light Chains/FITC (Polyclonal)

Goat Polyclonal

CE IVD



Inset: IF of Kappa on FFPE Tonsil Tissue

PRODUCT IDENTIFICATION REF

Catalog No.	Presentation	Volume
BSB-3009-3	Predilute	3.0 mL
BSB-3009-7	Predilute	7.0 mL
BSB-3009-15	Predilute	15.0 mL
BSB-3009-05	Concentrate	0.5 mL
BSB-3009-1	Concentrate	1.0 mL

INTENDED PURPOSE

Kappa Light Chains/ FITC (GPab), Goat Polyclonal Antibody is a primary antibody intended for laboratory use by trained laboratory personnel in an immunofluorescence (IF) assay to qualitatively identify Kappa Light Chain protein by fluorescent 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

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. 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. In IgG-dominant immune complex-mediated glomerulonephritis, there are multiple pathological findings that strongly suggest the diagnosis of lupus nephritis including immunofluorescence staining for IgG, IgM, IgA, Kappa or Lambda, C3 and C1.

PRINCIPLE OF PROCEDURE

In general, direct immunofluorescence (IF) staining techniques allow for antigen visualization via the application of a primary antibody specific to the antigen. The antibody is conjugated with fluorescent molecules, thus the presence of the fluorophores results in a visible signal at the antigen site. The specimen may then be coverslipped with antifade mounting media. Results are interpreted using a fluorescent microscope

MATERIALS AND PRESENTATION

This antibody is a purified immunoglobulin fraction of goat antiserum that is 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	Goat Polyclonal	**Clone**	Polyclonal
Isotype	IgG	**Reactivity**	Human
Localization	Cytoplasmic	**Source**	Goat antiserum
Recommended Dilution Range	1:25-1:100		
Immunogen	Purified Kappa light chains from human		

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)*
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)*
Antifade mounting medium, such as FluoroMounter *(BSB 0157 through BSB 0162)* or FluoroMounter with DAPI *(BSB 0163 through BSB 0168)*
Cover glass, such as Tinto Coverslips *(BSB-7100-100, BSB-7100-1000, BSB-7100-20000)*
Timer
Light microscope (40-400x) with fluorescent lamp and filters rated for FITC and DAPI (optional) spectra

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 Customer Support if there is a suspected indication of reagent instability.

PROCEDURE

Recommended FFPE 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 IF protocol. Note: Tissues should remain hydrated via use of a wash buffer.

Recommended Manual Immunofluorescence 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	Incubation Time
Rinse slides in IF wash buffer	
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	3x5 seconds each
Coverslip with IF mounting medium	

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 IF Protocol

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 °C in the dark.

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.

BioSB Control Slides Available

Catalog No.	*Quantity*
BSB-9250-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 IF 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 a fluorescent reaction product within the target cells/cellular components is indicative of positive reactivity. Refer to the IFU of the detection system used for expected fluorescent reactions. If the positive tissue controls fail to demonstrate positive staining, any results with the test specimens should be considered invalid.

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 IF test, a negative result means that the antigen was not detected, not that the antigen was absent.

LIMITATIONS

1. Immunofluorescence is a multi-step process that requires specialized training in the selection of the appropriate reagents; tissue selection, fixation, and processing; preparation of the 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. 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 antibodies, reagents, and methods to interpret all of the steps used to prepare and interpret the final IF preparation.
4. Predilute Ready-to-Use antibodies are provided at optimal dilution for use following the recommended instructions for IF 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.
5. This product is not intended for use in flow cytometry. Performance characteristics have not been determined for flow cytometry.
6. 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).
7. 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.
8. 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. Dogan A, Du MQ, Aiello A, et al. Follicular lymphomas contain a clonally linked but phenotypically distinct neoplastic B-cell population in the interfollicular zone. *Blood*. 1998;91(12):4708-4714.
2. Huerta A, Bomback AS, Liakopoulos V, et al. Renal-limited 'lupus-like' nephritis. *Nephrol Dial Transplant*. 2012;27(6):2337-2342.
3. Arnold A, Cossman J, Bakhshi A, Jaffe ES, Waldmann TA, Korsmeyer SJ. Immunoglobulin-gene rearrangements as unique clonal markers in human lymphoid neoplasms. N Engl J Med. 1983;309(26):1593-1599.
4. Brancaccio D, Ghiggeri GM, Braidotti P, et al. Deposition of kappa and lambda light chains in amyloid filaments of dialysis-related amyloidosis. J Am Soc Nephrol. 1995;6(4):1262-1270.
5. Hristov AC, Comfere NI, Vidal CI, Sundram U. Kappa and lambda immunohistochemistry and in situ hybridization in the evaluation of atypical cutaneous lymphoid infiltrates. J Cutan Pathol. 2020;47(11):1103-1110.
6. Warnnissorn AN, Treetipsatit J, Limvorapitak W. The cut-offs for kappa/lambda ratio in bone marrow immunohistochemistry for the diagnosis of multiple myeloma. Hematology. 2020;25(1):292-298.
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.

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

Contact Bio SB Customer Support:
US & Canada Telephone +1 (805) 692-2768
International Telephone +1 (800) 561-1145
Email: support@biosb.com | Website: www.biosb.com
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.
5385 Hollister Avenue, Bldg. 8, Ste. 108
Santa Barbara, CA 93111 USA

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