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NEGATIVE CONTROLS

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ENGLISH

Reagents Provided: One of the following

Catalog No	Description
HK119-5M **HK119-7M**	Mouse Super Sensitive ™ Negative Control, 3ml. Mouse Super Sensitive ™ Negative Control, 17ml. Mouse gamma globulin diluted in phosphate buffered saline, pH 7.6, containing 1% BSA and 0.09% sodium azide.
HK406-5G	Goat Super Sensitive ™ Negative Control, 3ml. Normal goat serum diluted in phosphate buffered saline, pH 7.6, containing 1% BSA and 0.09% sodium azide.
HK407-5T	Rat Super Sensitive™ Negative Control, 3ml. Normal rat serum diluted in phosphate buffered saline, pH 7.6, containing 1% BSA and 0.09% sodium azide.
HK408-5R **HK408-7R**	Rabbit Super Sensitive™ Negative Control, 3ml. Rabbit Super Sensitive™ Negative Control, 17ml. Normal rabbit serum diluted in phosphate buffered saline, pH 7.6, containing 1% BSA and 0.09% sodium azide.

Intended Use
BioGenex Negative Control reagents may be used as universal negative controls in immunohistochemistry assays using mouse, rabbit, goat or rat in formalin-fixed, paraffin-embedded tissue sections.

Summary and Explanation
Mouse Negative Control (HK119) is purified mouse IgG from preimmune sera that is used as a non-specific negative control with mouse monoclonal antibodies. Rabbit Negative Control (HK408) is preimmune rabbit serum and is used as a non-specific negative control reagent with rabbit antibodies. Goat Negative Control (HK406) is preimmune goat serum and is used as a nonspecific negative control reagent with goat antibodies. Rat Negative Control (HK407) is preimmune rat serum and is used as a nonspecific negative control reagent with rat antibodies.

Principles of the Procedure
The demonstration of antigens in tissues and cells by immunostaining is a two-step process involving first, the binding of a primary antibody to the antigen of interest, and second, the detection and visualization of bound antibody by one of a variety of enzyme based chromogenic systems. The negative reagent control is recommended for use in all immunohistochemical applications.

Dilution of negative control reagent
BioGenex Ready-to-Use negative control reagent has been optimally diluted for use with all BioGenex Super Sensitive Detection Systems and should not require further dilution. The user must validate any such change.

Materials Required but Not Provided
All the reagents and materials required for immunohistochemistry are not provided. Please refer to the product insert(s) of detection systems for detailed protocols and instructions on use of the reagents.

Storage and Handling
These reagents should be stored at 2-8°C without further dilution. Do not freeze the product.
These reagents are suitable for use till expiry date when stored at 2-8°C. Do not use the product after expiration date printed on vial. If reagents are stored under any conditions other than those specified in the package insert, they must be verified by the user (U.S. Congress, 1992).
The presence of precipitate or an unusual odor indicates that the reagent is deteriorating and should not be used.
Positive controls should be run simultaneously with all patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the reagent is suspected, contact BioGenex Technical Support at 800-421-4149 or customer.service@biogenex.com.

Specimen Collection and Preparation for Analysis
Tissues fixed in 10% (v/v) formalin prior to paraffin embedding are suitable for use. Consult references (Kiernan, 1981; Sheehan & Hrapchak, 1980) for further details on specimen preparation.

Treatment of Tissues Prior to Staining
Pretreatment of tissues if any, should be done as suggested in the staining procedure section.

Precautions
The products contain no hazardous material at a reportable concentration according to U.S. 29 CFR 1910.1200, OSHA Hazard Communication Standard and EC Directive 91/155/EC. However, these products contain sodium azide, at concentrations of less than 0.1%. Sodium azide is not classified as a hazardous chemical at the product concentrations. However, toxicity information regarding sodium azide at product concentrations has not been thoroughly investigated. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing (Center for Disease Control, 1976, National Institute for Occupational Safety and Health, 1976). For more information, a Material Safety Data Sheet for sodium azide in pure form is available upon request**.** Do not pipette reagents by mouth, and avoid contact of reagents and specimens with skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with copious amounts of water. Minimize microbial contamination of reagents or increase in nonspecific staining may occur. Refer to appropriate product inserts for instructions of use and safety information on detection reagents and other materials, which may be used with the antibody.

Staining procedure
Refer to the following table for conditions specifically recommended for these products. Refer to the detection system package insert for guidance on specific staining protocols or other requirements.

Parameter	BioGenex Recommendations
Tissue Type	Paraffin embedded
Pretreatment	As required by protocol
Control Tissue	Same as test tissue
Incubation Time and Temperature	30 min., room temperature

Quality Control
Refer to the appropriate detection system package inserts for guidance on general quality control procedures.

Troubleshooting
Refer to the troubleshooting section in the package inserts of BioGenex Super Sensitive Detection Systems (or other equivalent detection systems) for remedial actions on detection system related issues, or contact BioGenex Technical Service Department at (925) 275-0550 to report unusual staining.

Expected Results
No non-specific color should be seen in cytoplasm or nucleus with this reagent in most tissues. Interpretation of the staining result is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic product or procedure.

Limitations of the Procedure
Immunohistochemistry (IHC) is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can also cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue may cause variations in results (Nadji and Morales, 1983). Endogenous peroxidase activity or pseudoperoxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. Tissues containing hepatitis B surface antigen (HBsAg) may give false positive with horse radish peroxidase systems. (Omata M et al, 1980). Improper counterstaining and mounting may compromise the interpretation of results.

Performance Characteristics
BioGenex has performed studies to evaluate the performance of its negative reagent controls with several BioGenex antibodies and detection systems. The negative reagent controls have been found to show no specific binding to the antigen of interest. BioGenex negative reagent controls have shown reproducible and consistent results when used within a single run, between runs, between lots and wherever applicable between manual and automated runs. The products have been determined to be stable for the periods specified on the labels either by standard real time or accelerated methods. BioGenex ensures product quality through 100% quality control for all products released and through surveillance programs.

Bibliography
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EC REP Representative in the European Community
Mandatario nella Comunità Europea
Bevollmächtigter in der Europäischen Gemeinschaft
Representante autorizado en la Comunidad Europea

IVD In Vitro Diagnostic Medical Device
Dispositivo medico-diagnostico in vitro
In Vitro Diagnostikum
Producto sanitario para diagnóstico in vitro

Cons ult Instructions for use
Consultare le istruzioni per l'uso
Gebrauchsanweisung beachten
Consulte las instrucciones de uso

Temperature Limitation
Limiti di temperatura
Zulässiger Temperaturbereich
Limite de temperatura

Manufacturer
Fabbricante
Hersteller
Fabricante