

Anti-Human Myogenin [EP162]

| Catalog No. | Description | | |
|---|---|--|--|
| AN789-5M | 6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system | | |
| AN789-10M | 10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive TM Detection Systems and i6000 TM Automated Staining Systems | | |
| NU789-UC | 1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system | | |
| NU789-5UC | 0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system | | |
| AY789-YCD Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 160 tests | | | |
| AY789-50D | Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests | | |

| Clone | Species | Ig Class |
|-------|---------|----------|
| EP162 | Rabbit | IgG |

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of Myogenin in formalin-fixed, paraffinembedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

Myogenic factors are transcription factors consisting of an amino acid-rich region and a helix-loop-helix (HLH) structure, which can promote muscle development and maintain muscle-specific gene expression by transactivation. Myogenin, one of the myogenic regulatory factors, plays a key role in determining the commitment and differentiation of primitive mesenchymal cells into skeletal muscle. The expression of Myogenin is restricted to cells of skeletal muscle origin, but it is not detected in adult skeletal muscles. It is therefore considered to be an extremely reliable and specific marker for diagnosing rhabdomyosarcomas.

Storage and Handling

Store at 2-8°C. Fresh dilutions, if required, should be prepared prior to use and are stable and steady for up to one day at room temperature (20-26°C). Diluted antibody preparations can be refrigerated or frozen for extended shelf life.

Principles of the Procedure

Antigen detection by immunohistochemistry (IHC) is a two-step process wherein the primary antibody binds to the antigen of interest and that binding is detected by a chromogen. The <u>primary antibody</u> may be used in IHC using manual techniques or BioGenex Automated Staining System. Positive and negative controls should always be run simultaneously with all patient specimens.

Reagents Provided

Rabbit Monoclonal Antibody to Myogenin is affinity purified and diluted in PBS, pH 7.2, containing 1% BSA and 0.09% sodium azide.

Dilution of Primary Antibody

BioGenex Ready-to-Use antibodies have been optimized for use with the recommended BioGenex Detection System and should not require further dilution.

BioGenex concentrated antibodies must be diluted in accordance with the recommended protocol when used with the recommended BioGenex Detection System.

Recommended Protocol

Refer to the following table for conditions specifically recommended for this antibody. Refer to the BioGenex website for guidance on specific staining protocols or other requirements.

| Parameter | BioGenex Recommendations | |
|--|---|--|
| Control Tissue | RHABDOMYOSARCOMAas available with BiogenexFB- 789N*& FG-789N* | |
| Recommended Dilution for Concentrated Antibody | 1:20-50 in HK941 | |
| Recommended Pretreatment (Manual/i6000)** | EZ-AR2 (HK522-XAK) | |
| Recommended | EZ-AR2 Elegance | |
| Pretreatment (Xmatrx) | (HX032-YCD) | |
| Antibody Incubation (Manual/i6000) | 30-60 Min at RT | |
| Antibody Incubation (Xmatrx) | 30-60 Min at 25°C | |
| | Use BioGenex Two-Step OR | |
| Detection System for | One-Step Super Sensitive TM | |
| Manual, Xmatrx & i6000 | Polymer-HRP IHC Detection | |
| systems*** | System/DAB; see p. 2 for more information | |

^{*}FB: positive control micro chamber slides, FG: positive control microscopic slides. Xmatrx requires micro chamber slides.

^{**}Pretreatment times will vary based on individual microwave power.

| Category | Antibodies | Revision No. | Н |
|--------------|-------------|--------------|-------------|
| Document No. | 932-789N-EN | Release Date | 10-Nov-2021 |

***For automation systems (Xmatrx-Elite, Xmatrx-Ultra & i6000 Diagnostics), refer to the factory protocols provided with the instrument.

| Detection | Two-Step | One-Step | Link and |
|---|--|---------------------------|---------------------------|
| System | HRP Kit | HRP Kit | Label Kit |
| Manual | QD440-XAKE (1000 Test) QD430-XAKE (1000 Test) | QD630-XAKE (1000 Test) | QP300-XAKE (1000 Test) |
| | QD420-YIKE (500 Test) QD400-60KE (60 Test) | QD620-XAKE (500 Test) | QP900-9LE (500 Test) |
| Xmatrx - | QD550-YCDE | QD610-YADE | N/A |
| Automation | (200 Test) | (200 Test) | |
| i6000 - | QD410-YAXE | QD610-YAXE | N/A |
| Automation | (200 Test) | (200 Test) | |
| For more information, visit <u>www.biogenex.com</u> . | | | |

Precautions

This product contains sodium azide at concentrations of less than 0.1%. Sodium azide is not classified as a hazardous chemical at the product concentrations, but proper handling protocols should be observed. For more information, a Safety Data Sheet (SDS) for sodium azide is available upon request. Dispose of unused reagents according to Local, State and Federal Regulations. Wear suitable Personal Protective Equipment, 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.

Quality Control

Refer to BioGenex detection system documents for guidance on general quality control procedures.

Troubleshooting

Refer to the troubleshooting section in the documentation for BioGenex Detection Systems (or equivalent detection systems) for remedial actions on detection system related issues, or contact BioGenex Technical Support Department at 1-800-421-4149 or support@biogenex.com or your local distributor to report unusual staining.

Expected Results

This antibody stains nucleus in positive cells in formalin-fixed, paraffin embedded tissue sections. An example image of a tissue section stained with this antibody can be found on the product page on the BioGenex website. Interpretation of the staining result is solely the responsibility of the user. Experimental results should be confirmed by a medically-established diagnostic product or procedure.

Limitations of the Procedure

Improper tissue handling and processing prior to immunostaining can lead to inconsistent results. Variations in embedding and fixation or the nature of the tissue may lead to variations in results. Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and tissue biotin may result in non-specific staining based on the detection system employed. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive with horseradish peroxidase systems. Improper counterstaining and mounting may compromise the interpretation of results.

Bibliography

- 1. Maglott D, et al.: "Entrez Gene: gene-centered information at NCBI". Nucleic Acids Res 2005 33:D54-58
- 2. Chen L, et al.: "The study of myogenin expression in denervated human skeletal muscles". JInt Med Res 2011, 39:378-387
- 3. Kumar S, et al.: "Myogenin is a specific marker for rhabdomyosarcoma: an immunohistochemical study in paraffin-embeded tissue". Mod Pathol2000, 13:988-993
- 4. Heerema-McKenney A, et al.: "Diffuse myogenin expression by immunohistochemistry is an independent marker of poor survival in pediatric rhabdomyosarcoma: a tissue microarray study of 71 primary tumors including correlation with molecular phenotype". Am J SurgPathol2008, 32:1513-1522

| 2°C 8°C | Temperature Limitation | IVD | In Vitro Diagnostic Medical Device |
|----------------|---|-----|---|
| \boxtimes | Use By Date | LOT | Batch Code |
| NON STERILE | Non-Sterile | i | Consult Instructions for Use |
| EC REP | Representative in the European Community | | Manufacturer |

© 2020, BioGenex Laboratories. All rights reserved.

| Category | Antibodies | Revision No. | H |
|--------------|-------------|--------------|-------------|
| Document No. | 932-789N-EN | Release Date | 10-Nov-2021 |