GATA-3

Mouse Monoclonal Antibody

SAM-QHD- MM30-10 tests

QHD-MM30-100 tests

Document Number: IFU-324_MM30-GATA-3

Release Date: 05/07/2019, Rev A

Source	Clone	Species	Isotype	Primary Antibody Diluent
Supernatent	L50-823	Mouse	IgG1/K	NA
Epitope: Not Determined			*Species Reactivity: Human*	

Catalog Number	Description
SAM-QHD-MM30-10 tests	2mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform.
QHD-MM30-100 tests	15mLReady To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform

Intended Use

For In Vitro Diagnostic Use. GATA-3 antibody is intended for qualitative identification by light microscopy for GATA-3 antigen in sections of formalin-fixed, paraffin-embedded tissue sections using immunohistochemical (IHC) test methods. Staining results should be interpreted by a qualified pathologist in conjunction with the patient's clinical history, and other diagnostic tests after the primary diagnosis of cancer has been established.

Summary and Explanation

Trans-acting T-cell-specific transcription factor, GATA-3 is, a protein that in humans is encoded by the GATA3 gene. GATA-3 b regulates luminal epithelial cell differentiation in the mammary gland, is an important regulator of T cell development and plays an important role in endothelial cell biology. GATA-3 is one of the three genes mutated in >10% of breast cancers. Nuclear expression of GATA-3 in breast cancer is considered a marker of luminal cancer in ER+ cancer and luminal androgen responsive cancer in ER-/AR+ tumors. It is highly co-expressed with FOXA1 and serves as negative predictor of basal subtype and HER2 and is also considered a strong predictor of taxane and platin salts insensitivity. GATA3 expression is found in urothelial carcinoma, especially in invasive and high grade tumors. Therefore, anti-GATA3 can be used in a panel of antibodies for diagnosis of unknown primary carcinoma, when carcinomas of the breast or bladder are a possibility. Studies have also shown the utility of GATA-3 in differentiating urothelial carcinoma from prostate adenocarcinoma and squamous cell carcinomas of the uterine, cervix, anus and lung.

Materials and Methods Provided

The stated primary antibody product contains reagent in a vial made for use with the StatLab Quantum HDx IHC slide stainer. The vial is equipped with an RFID tag that is read by the slide stainer to provide product and lot specific information.
This antibody is diluted in Tris Buffer, pH 7.3-7.7, with 1% BSA and <0.1% Sodium Azide.

Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

Materials and Reagents Needed but Not Provided

The following reagents and materials may be required for staining but are not provided with the primary antibody. Please refer to our website at www.StatLab.com.

1. Quantum HD HRP Detection Kit (Cat. No.: QHD-U3-15-HRP-KIT) OR
1. Quantum HD AP Detection Kit (Cat. No.: QHD-U2-15-HRP-KIT)
2. Quantum HD Retrieval Solution, pH 9.0 (Cat. No.:QHD-003)
3. Quantum HD Retrieval Solution, pH 6.0 (Cat. No.: QHD-002)
4. Quantum HD DS2 (Cat. No.: QHD-007)
5. Quantum HD Block (Cat. No.: QHD-006)
6. Wash Buffer (Cat. No.: QHD-015)
7. Positive and Negative Tissue controls

Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

Principles of the Procedures

Antigen detection by immunohistochemistry (IHC) is a two-step process involving first, the binding of a primary antibody to the antigen of interest, and second, the detection of bound antibody by a chromogen. The primary antibody may be used in IHC using manual techniques or using automated IHC Staining Systems.

Warnings and Precautions

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable as hazardous materials.[7]
2. Sodium azide (NaN3) used as a preservative is toxic if ingested. 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.[8]
3. Specimens, before and after fixation and all materials exposed to them, should be handled as if capable of transmitting infections and disposed of with proper precautions.[9]
4. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water.
5. Microbial contamination of reagents may result in an increase in nonspecific staining.
6. Incubation times or temperatures other than those specified may give erroneous results. The use must validate any such change.
7. The SDS is available upon request.
8. Do not use reagents beyond the expiration date printed on the vial.
9. The user must validate any storage conditions other than these specified in the package insert

Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding.[10,11]

The user is advised to validate the use of the products with their tissue specimens prepared and handled in accordance with their laboratory practices

StatLab Quantum HDx Recommended Staining Procedure:

Instrument Parameters	QHD-U3-HRP-Kit	QHD-U2-AP-Kit
Retrieval Reagent	QHD-High pH	QHD-High pH
Antibody Incubation Time	10-45 minutes	10-45 minutes

Step by Step Procedure:

1. Follow the StatLab Quantum HDx instrument instructions for setting up the reagents on the instrument
2. Load slides, antibodies, and detection kit(s) onto StatLab Quantum HDx instrument according to StatLab Quantum HDx instructions for use
3. Start the run.
4. When the staining is complete, remove the slides from instrument, rinse well with distilled water
5. Dehydrate, Clear and Coverslip

Troubleshooting

Positive and negative 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 antibody is suspected, contact StatLab IHC Technical Support via Email ihctech@statlab.com or call us at (800) 442-3573

Cellular Localization and Positive Tissue Control

Positive Tissue Control	
Tissue	Visualization
Breast Carcinoma	Nuclear

Limitations of the Procedure

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.[12] (Endogenous peroxidase activity or pseudo peroxidase 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 horseradish peroxidase systems.[13] Improper counterstaining and mounting may compromise the interpretation of results.

Performance Characteristics

The optimum protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, and tissue section thickness and detection kit used. Due to the sensitivity of these reagents, the recommended incubation times listed may not be applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based exclusively on StatLab products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

NOTE

There are no expressed or implied warranties which extend beyond this datasheet. StatLab is not liable for personal injury, property damage or economic loss caused by this product

References

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