Tissue-Tek Genie®

anti-GATA3 Rabbit Monoclonal Antibody [QR018]

REF 8357-C010

Instructions for use

For *in vitro* diagnostic use.

Intended purpose

Intended use: The Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] is designed to qualitatively detect GATA3 protein in formalin-fixed, paraffin-embedded (FFPE) human tissue specimen sections by immunohistochemistry (IHC) staining on the automated Tissue-Tek Genie® Advanced Staining System.

This device functions as an aid for diagnosis and shall be used by a qualified pathologist with a panel of other antibodies to identify breast and urothelial carcinomas from cancers of unknown origin.

Limitations

The Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] has been optimized for use with the Tissue-Tek Genie® Advanced Staining System, Tissue-Tek Genie® reagents, and FFPE specimen sections. Staining quality may be diminished when used with other systems and/or reagents.

The clinical interpretation must be made in conjunction with histological examination, relevant clinical information, a panel of other antibodies, other diagnostic tests, and proper controls by a qualified pathologist.

Staining quality may be diminished by improper or incomplete removal of the paraffin.

The sensitivity of this antibody to identify the GATA3 protein may be affected by improper specimen handling. This may alter antigenicity, weaken detection, and may generate false negative results.

Special processing of tissues such as decalcification of bone marrow tissues may lead to inconsistent staining.

Positively charged slides are recommended to obtain optimal staining with the Tissue-Tek Genie Advanced Staining System.

Occasional weak cytoplasmic staining can be observed in smooth muscle cells.

Summary and principle

Immunohistochemistry (IHC) staining is an established *in vitro* diagnostic method to visualize the presence of specific proteins expressed within a tissue section to study the microscopic features.

IHC staining is accomplished in two steps:

1) a primary antibody recognizes a particular target protein expressed on a specific cell compartment of a specific cell type on various tissues, and

2) a secondary and tertiary antibody conjugated to a chromogenic enzyme bind with the primary antibody for the detection of the antibody-antigen interaction. In chromogenic detection under a light microscope, an enzyme conjugated to the antibody cleaves a substrate to produce a colored precipitate at the location of the protein.

GATA binding protein 3 (GATA3) is a transcription factor that plays a crucial role in the development and differentiation of various tissues.[1] It is commonly expressed in luminal epithelial cells of breast[2,3], interfollicular T-cells in tonsil[4], urothelial cells in bladder[5], and basal/parabasal epithelial cells of the cervix[6,7]. In kidney, GATA3 expression is found in podocytes and mesangial cells within glomeruli, as well as epithelial cells in the distal tubules and collecting ducts.[8-12] Studies have also shown GATA3 expression in epithelial cells of skin, inner root sheath of hair follicle, adnexal structures (e.g., sebaceous and salivary glands), cells from parathyroid gland, basal cells of prostate, seminal vesicle, and cytotrophoblast of placenta.[12-16] No staining is observed in tonsillar epithelium and B-cells within germinal centers of tonsil as well as cells of the gastrointestinal tract.[9,17]

Although low GATA3 expression can be observed in various tumors including pancreatic adenocarcinoma, gastric carcinoma and non-small cell lung carcinoma,[18] it is commonly used as a marker of breast and urothelial differentiation when attempting to classify the origin of a cancer of unknown primary.[2,9,19-24] GATA3 is expressed in 62-100% of breast carcinomas and 67-100% of urothelial carcinomas.[2,9,19-24] GATA3 is absent in 97-100% of prostate adeno-carcinomas and 100% of non-Hodgkin B-cell lymphomas.[4,16,21,25,26]

In recent studies, GATA3 expression has been observed in Reed-Sternberg cells in Hodgkin lymphomas.[17]

Anti-GATA3 antibody labels GATA3 in both normal and neoplastic cells and has a nuclear staining pattern.

The Tissue-Tek Genie anti-GATA3 Rabbit Monoclonal Antibody [QR018] is a primary antibody against the human GATA3 protein and is provided in buffered saline containing 1% bovine serum albumin and 0.09% sodium azide. FFPE specimen sections are placed on positively charged slides and the paraffin is removed using the Tissue-Tek Genie® Dewax Solution (REF 8865-G001), after which heat-induced epitope retrieval is performed using the Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744-G001).

IHC demonstration of GATA3 protein in FFPE specimen sections is achieved through the use of the Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] and the Tissue-Tek Genie® PRO Detection Kit, DAB (REF 8826-K250). This procedure entails the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® Protein Block
- Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018]
- Tissue-Tek Genie® Peroxidase Block
- Tissue-Tek Genie® Link (binds to the primary antibody)
- Tissue-Tek Genie® Poly HRP-Conjugate (binds to the Link)
- Tissue-Tek Genie® DAB (visualizes the detected protein)
- Tissue-Tek Genie® DAB Intensifier

Tissue-Tek Genie® Hematoxylin (REF 8830-M250) is then used to visualize the nuclei of cells. The IHC stained slide is coverslipped and reviewed using a light microscope.

Expected results

Cellular staining pattern: nuclear

Positive control tissue: cervix, tonsil, kidney, selective breast and urothelial carcinoma

The specificity and intended use of this antibody were validated by performing IHC staining on the Tissue-Tek Genie Advanced Staining System using normal and neoplastic FFPE tissue sections as follows.

Analytical sensitivity/specificity: A total of 34 types and 246 specimens of normal FFPE tissues were tested. Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] exhibited at least moderate nuclear staining in interfollicular T-cells in the tonsil (33/33). No staining was observed in tonsillar epithelium or B-cells within the germinal centers (0/33). Moderate to strong, distinct nuclear staining reaction of podocytes and mesangial cells within glomeruli, as well as epithelial cells in the distal tubules and collecting ducts of the kidney, was observed (35/35). In the cervix, strong nuclear staining was noted in basal cells, while at least weak positivity was seen in suprabasal epithelial cells of the cervix (20/20). No staining was present in superficial epithelial cells of the cervix (0/20). Moderate to strong nuclear positivity was observed in urothelial cells of the bladder (8/8) and urethra (2/2). Nuclear positivity for scattered lymphocytes was also noticed in the thymus (1/1), spleen (9/11), and bone marrow (2/2). Positive staining was also observed in acinar cells of the salivary gland (2/2), luminal epithelial cells of breast glands (7/7), and cytotrophoblasts of the placenta (14/14). No staining was observed in the gastrointestinal tract (0/27), cerebrum (0/6), cerebellum (0/2), pituitary gland (0/1), parathyroid gland (0/1), pancreas (0/8), liver (0/10), testis (0/7), fallopian tube (0/2), skeletal muscle (0/3), cardiac muscle (0/1), uterus (0/2), ovary (0/2), omentum (0/1), and peripheral nerve (0/1).

Precision studies for Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] lots will be completed. FFPE tissue sections of the kidney will be used. Studies will be conducted to demonstrate reproducibility in lot-to-lot (minimum of 2 lots), run-to-run (minimum of 2 Genie runs), instrument-to-instrument (2 Genies), station-to-station (minimum of 2 stations), and operator-to-operator (2 operators). The results will be compared to meet their acceptance criteria: moderate nuclear staining of all epithelial cells in collecting ducts and podocytes in glomeruli in the kidney.

These results will demonstrate the precision of the Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018], which is to be consistent across lots, runs, instruments, stations, and operators.

Diagnostic sensitivity/specificity: A total of 31 types and 200 specimens of neoplastic FFPE tissues were tested. Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] demonstrated positive nuclear staining of neoplastic cells of breast carcinoma (43/43, 100%) and urothelial carcinoma (31/32, 97%). Occasional positivity was observed in Reed-Sternberg cells of Hodgkin Lymphoma (11/16, 69%). Rare to focal positivity was observed in neoplastic cells of non-small cell lung carcinoma (2/13,15%), gastric adenocarcinoma (1/3, 33%), and pancreatic ductal carcinoma (1/5, 20%). GATA3 was not detected in prostate adenocarcinoma (15/15, 100%) and Non-Hodgkin B-cell lymphoma (9/9, 100%). No staining was observed in other neoplasia tested, including thyroid carcinoma (0/5), small cell lung carcinoma (0/3), hepatocellular carcinoma (0/3), colorectal carcinoma (0/6), renal cell carcinoma (0/8), ovarian carcinoma (0/5), melanoma (0/5), and sarcomas (0/4).

Clinical performance:

The Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018] demonstrated conformity with the expected clinical performance through analytical studies and assessments of diagnostic performance in conjunction with established scientific validity (summarized in the “Summary and principle” section above with data from the references at the end of this IFU) based on information on other IVD medical devices with the same antibody, textbooks, and available peer-reviewed literature.

Tissue specimen	Established validity	Tissue specimen tested
Tonsil	GATA3 is commonly expressed in interfollicular T-cells in tonsil.[4] No	At least moderate nuclear staining in interfollicular T-cells in the tonsil (33/33)

	staining is observed in tonsillar epithelium and B-cells of germinal centers.[4]	was observed. No staining was observed in tonsillar epithelium or B-cells within the germinal centers (0/33).
Kidney	In kidney, GATA3 expression is found in podocytes and mesangial cells within glomeruli, as well as epithelial cells in the distal tubules and collecting ducts.[8-12]	Moderate to strong, distinct nuclear staining of podocytes and mesangial cells within glomeruli, as well as epithelial cells in the distal tubules and collecting ducts of kidney was observed (35/35).
Cervix	GATA3 is commonly expressed in basal/parabasal epithelial cells of the cervix.[6,7]	In cervix, a strong nuclear staining was observed in basal cells while at least weak positivity was seen in suprabasal epithelial cells (20/20). No staining was observed in superficial epithelial cells of the cervix (0/20).
Bladder	GATA3 is commonly expressed in urothelial cells in bladder.[5]	Moderate to strong nuclear positivity was observed in urothelial cells of the bladder (8/8).
Gastrointestinal tract	No staining is observed in cells of the gastrointestinal tract.[9,17]	No staining was observed in the gastrointestinal tract (0/27).
Breast Carcinoma	GATA3 is commonly expressed in 62-100% of breast carcinomas.[2,9,19-24]	Positive nuclear staining of neoplastic cells of breast carcinoma (43/43, 100%) was observed.
Urothelial Carcinoma	GATA3 is commonly expressed 67-100% of urothelial carcinomas.[2,9,19-24]	Positive nuclear staining of neoplastic cells of urothelial carcinoma (31/32, 97%) was observed.
Prostate Adenocarcinoma	GATA3 is absent in 97-100% of prostate adenocarcinomas.[4,16,21,25,26]	GATA3 was not detected in prostate adenocarcinoma (15/15, 100%).
Non-Hodgkin B-cell lymphoma	GATA3 is absent in 100% of Non-Hodgkin B-cell lymphomas.[4,16,21,25,26]	GATA3 was not detected in Non-Hodgkin B-cell lymphoma (9/9, 100%).

Together, this information is sufficient to demonstrate conformity with relevant essential principles without the need for additional clinical performance data.

Cautions and warnings

For professional use only.

Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Wear protective gloves, protective clothing, and eye protection.

The product should not be exposed to temperatures outside of the storage conditions.

Capsules filled with ready-to-use, pre-diluted, antibody are for single use only. The in-use stability of each capsule is approximately 72 hours when used outside the storage conditions. Do not attempt to refill or add additional reagent. Discard capsule after use.

It is recommended to include appropriate controls on each specimen slide to help in identifying any deviation that might occur during the staining process.

All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Refer to the SDS for further information.

Specimen collection and preparation for analysis

Routinely processed, formalin-fixed, paraffin-embedded tissues are suitable for use with this reagent when used with Tissue-Tek Genie reagents and a Tissue-Tek Genie Advanced Staining System (see section “Material required but not supplied”). The recommended fixation is performed using 10% (v/v) neutral buffered formalin for 24-72 hours.[27] Variable results may occur because of prolonged fixation or special processes such as decalcification of bone marrow preparations. Each cut section should be 3-5 µm in thickness and placed on a positively charged glass slide. Slides containing the tissue section may be baked for at least 30 minutes to overnight (typically up to 16 hours) in a 58-60°C oven.[27]

Storage conditions

Store this product at 2-8°C. Do not freeze. Return unused capsules to 2-8°C.

For the date of expiration, refer to the label on the product.

The reagent will be stable until its expiration date when stored and handled properly. Do not use the reagent beyond its assigned expiration date. Storage conditions other than those specified above must be verified by the user.

Do not use when precipitate is visible in the reagent container.

Instructions for use

Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018], RTU, 10 capsules/pack (REF 8357-C010):

1. Place the Tissue-Tek Genie® Reagent Dispensing Area Tag (RDA-Tag) attached to the capsule into the RDA.
2. Push the capsule into the RDA with foil side down and click the attached RDA-Tag down into place on the RDA.
3. Place the RDA on the desired station of the Tissue-Tek Genie Advanced Staining System.
4. Place the slide with the specimen section on the same station, specimen section side down.
5. Assign protocol 8357 to the same station.
6. Initiate execution of protocol 8357.
7. The RDA-Tag 8357 will be scanned and registered automatically when the staining process is initiated.
8. During the primary antibody application step, the antibody will be released from the capsule into the RDA and onto the specimen section on the slide.
9. The staining protocol continues to the end.

Material required but not supplied

- Tissue-Tek Genie® Advanced Staining System (REF 8200)
- Positive and negative tissue controls
- Drying oven capable of maintaining a temperature of 58-60°C
- Tissue-Tek Genie® Dewax Solution (REF 8865-G001)
- Tissue-Tek Genie® Wash Buffer Solution (REF 8874-G004)
- Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744-G001)
- Tissue-Tek Genie® Non-Immune Rabbit Ig Antibody, Negative Control (REF 8605-C010)
- Tissue-Tek Genie® PRO Detection Kit, DAB (REF 8826-K250)
- Tissue-Tek Genie® Hematoxylin (REF 8830-M250)
- Tissue-Tek Genie® Reagent Dispense Area [RDA] (REF 8616-G090)

Further information can be found on the Sakura Finetek USA website at **www.sakuraus.com/Genie**

Troubleshooting

Testing run should include proper reagent and tissue controls.

- If the positive control exhibits negative, or weaker, or stronger staining, or more background staining than expected, other positive controls on the same instrument run should be examined to determine if this is due to the antibody, other reagents, software, instrumentation, or the processing and fixation of tissue specimen(s).
- If the paraffin has not been removed completely, the deparaffinization procedure should be verified.
- If tissue sections have washed off, slides should be examined to ensure they are positively charged, and the specimen should be examined for possible inadequate processing or fixation.
- Refer to the Tissue-Tek Genie Advanced Staining System operating manual or contact your Sakura Finetek Technical support representative for information or assistance.

Order information / product provided

Product code, product name and quantity

REF 8357-C010 Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [QR018]; RTU, 10 capsules/pack.

NOTE: The Safety Data Sheet (SDS) is available online on the Sakura Finetek USA website at **www.sakuraus.com/SDS.html**

The Summary of Safety and Performance (SSP) is available online via EUDAMED.

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Contact

If located within the United States, contact Sakura Finetek USA, Inc. by calling toll free **1-800-725-8723** or contact your Sakura Finetek representative or authorized distributor.

In countries other than the United States, contact the nearest authorized Sakura Finetek instrument distributor or representative. Contact details may be found at **www.sakura.com**

Any incident should be reported to the manufacturer. In the European Union, any serious incident that has occurred in relation to the device shall be reported to the manufacturer, authorized representative, and the competent authority of the appropriate Member State in which the user and/or the patient is established.

Symbols

REF	Catalog number
LOT	Batch code
IVD	*in vitro* diagnostic medical device
	Temperature limitation
	Use by
	Manufacturer
	Consult instructions for use
CE	European Conformity
EC REP	Authorized representative in the European Community
	Do not re-use (applies to capsule format only)

LOT Please see product label for lot and expiration date information and if available the date of manufacture

Storage: 2°C 8°C

IVD

CE
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