Tissue-Tek Genie®

anti-CD21 Rabbit Monoclonal Antibody [EP64]

Instructions for use

Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64] is designed to qualitatively detect CD21 protein in formalin-fixed, paraffin embedded (FFPE) specimen sections by immunohistochemistry (IHC) staining on the Tissue-Tek Genie® Advanced Staining System. The clinical interpretation must be made in conjunction with histological examination, relevant clinical information, other diagnostic tests and proper controls by a qualified pathologist.

Limitations

This product has been optimized for use with the default protocol for this antibody on the Tissue-Tek Genie Advanced Staining System, using Tissue-Tek Genie® reagents and FFPE specimen sections. Staining quality may diminish when used with other systems and/or reagents.

Summary and principle

CD21 is a membrane protein that serves as the receptor for complement component C3 (C3d) and the Epstein-Barr Virus (EBV). CD21 is expressed on dendritic cells and mature B-cells. Tissue-Tek Genie anti-CD21 Rabbit Monoclonal Antibody [EP64] is useful for identification of follicular dendritic cells, mature B-cells, and follicular dendritic cell tumors when used with a panel of antibodies.

The Tissue-Tek Genie anti-CD21 Rabbit Monoclonal Antibody [EP64] is a primary antibody against the human CD21 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), after which heat-induced epitope retrieval is performed using the Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744). IHC demonstration of CD21 protein in FFPE specimen sections is achieved through use of the Tissue-Tek Genie anti-CD21 Rabbit Monoclonal Antibody [EP64] and the Tissue-Tek Genie® *Pro* Detection Kit, DAB (REF 8826). This procedure entails the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® Protein Block
- Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64]
- Tissue-Tek Genie® Peroxidase Block
- Tissue-Tek Genie® Link (binds to the primary antibody)
- Tissue-Tek Genie® Polymer HRP-Conjugate (binds to the link)
- Tissue-Tek Genie® DAB Substrate (visualizes the detected protein)

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

Expected results

Specificity and intended use of this antibody were validated by performing IHC staining on the Tissue-Tek Genie Advanced Staining System using FFPE normal and tumor specimen sections. Membranous staining is observed in follicular dendritic cells in germinal centers, and active B-cells in the mantle zone, of tonsil and lymphoid tissues. Anti-CD21 antibody gives membranous staining of neoplastic cells of follicular dendritic cell tumors and B-cell lymphomas.

Sensitivity and identification of CD21 protein by this antibody may be affected by improper specimen handling. This may alter antigenicity, weaken detection and may generate false negative results.

Cellular staining pattern: membrane

Positive specimen control: Tonsil, lymph node, appendix, and follicular lymphoma

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, clothing, and eye/face protection.

Capsules filled with ready-to-use, pre-diluted, antibody are for single use only. Do not attempt to refill or add additional reagent. Discard capsule after use.

Cartridges filled with ready-to-use, pre-diluted, antibody are intended for multiple uses. Do not attempt to refill or add additional reagent. Discard cartridge when empty.

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.

Storage conditions

Store this product at 2-8°C.

Instructions for use

Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64], capsules (REF 8260-C010):

1. Place the Tissue-Tek Genie® Reagent Dispense 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 8260 to the same station.
6. Initiate execution of protocol 8260.
7. The RDA-Tag 8260 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.

Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64], cartridge (REF 8260-M250):

1. Prior to placing the cartridge on the carousel of the Tissue-Tek Genie Advanced Staining System, prime the cartridge by facing the nozzle downwards and gently pinching the nozzle tubing until the tubing is filled with the reagent.
2. Place the cartridge on the carousel.
3. Click the RDA-Tag 8260 into place on the RDA.
4. Place the RDA on the desired station of the Tissue-Tek Genie Advanced Staining System.
5. Place the slide with the specimen section on the same station, specimen section side down.
6. Assign protocol 8260 to the same station.
7. Initiate execution of protocol 8260.
8. The RDA-Tag 8260 and the cartridge will be scanned and registered automatically when the staining process is initiated.

9. During the primary antibody application step, the antibody will be dispensed from the cartridge into the RDA and onto the specimen section on the slide.
10. The staining protocol continues to the end.

Material required but not supplied

The following reagents may be required for staining but are not provided:

- Tissue-Tek Genie® Dewax Solution (REF 8865)
- Tissue-Tek Genie® Wash Solution (REF 8874)
- Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744)
- Tissue-Tek Genie® Non-Immune Rabbit Ig Antibody, Negative Control (REF 8605)
- Tissue-Tek Genie® *Pro* Detection Kit, DAB (REF 8826)
- Tissue-Tek Genie® Hematoxylin (REF 8830)

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

Order information

Product code/product name

REF 8260-C010 Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64],
10 capsules, Ready-To-Use.

REF 8260-M250 Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64],
1 cartridge, 250 tests, Ready-To-Use.

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

References

1. Heim-Hall J, and Yohe SL. Arch. Pathol. Lab. Med. 2008; 132:476-489.
2. Perez-Ordonez B, et al. Am. J. Surg. Pathol. 1996; 20:944-955.
3. De Leval L, et al. Am. J. Surg. Pathol. 2001; 25:732-741.

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**

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

Storage: 2°C 8°C

Shipping: 2°C 8°C

IVD

CE

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