Tissue-Tek Genie®

anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26]

Instructions for use

Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53-B/A2.26] is an antibody cocktail designed to qualitatively detect cytokeratin 7 and 19 proteins 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 cocktail 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

Cytokeratin 7 (CK7) is expressed in most ductal, glandular, and transitional epithelia. It is expressed in breast, lung, mesothelium, thyroid, pancreatic ducts, bile ducts, salivary gland, cervix, endometrium, renal collecting ducts, and trophoblast of placenta. CK7 is generally expressed in adenocarcinoma of lung, breast, thyroid, salivary gland, endometrium, cervix, ovary, upper gastrointestinal tract, pancreas, and bile duct, as well as urothelial carcinoma and papillary renal cell carcinoma. CK7 is generally negative in colorectal carcinoma, hepatocellular carcinoma, prostatic adenocarcinoma, clear cell renal cell carcinoma, and squamous cell carcinoma.

Cytokeratin 19 (CK19) is often co-expressed with CK7 and is present in both simple and complex epithelia. It is expressed in epithelia from a wide variety of organs including breast, stomach, pancreas (ducts), biliary tract, colon, salivary gland, sweat glands, and bladder. It is also expressed in myoepithelium and basal layers of squamous epithelium. CK19 is negative in hepatocytes and pancreatic islets. CK19 is expressed in breast carcinoma, lung adenocarcinoma, papillary thyroid carcinoma, pancreatic ductal carcinoma, squamous cell carcinoma, and endometrial carcinoma.

Cytokeratin (CK) immunohistochemistry can play an important role in breast carcinoma evaluation. In general, breast cancer is regarded to arise from luminal epithelial cells of the terminal duct lobular unit which express several cytokeratins such as CK7, CK8, CK18, and CK19. CK7 is broadly expressed in about 98% of breast carcinomas. CK19 is a luminal epithelial cell marker broadly expressed in >90% breast carcinomas and is not normally expressed in lymph node tissue. CK7/19 antibody cocktail is a useful aid to identify breast cancer deposits in lymph nodes, when used in a panel of other antibodies.

The Tissue-Tek Genie anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53-B/A2.26] is a primary antibody cocktail against the human CK7 and CK19 proteins 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 cytokeratin 7 and 19 in FFPE specimen sections is achieved through use of the Tissue-Tek Genie anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53-B/A2.26] 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-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26]
- 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® Hematoxylin (REF 8830-M250) 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 cocktail were validated by performing IHC staining on the Tissue-Tek Genie Advanced Staining System using FFPE normal and tumor specimen sections.

Positive cytoplasmic staining is observed in epithelia of breast, lung, thyroid, stomach, bile duct, pancreatic duct, colon/appendix, kidney, placenta, uterus, cervix, and tonsil. No staining is observed in lymphocytes and hepatocytes. Cytoplasmic staining is observed in neoplastic cells of breast carcinomas, including lymph nodes metastases, papillary thyroid carcinoma, lung adenocarcinomas, gastrointestinal carcinoma, pancreatic ductal carcinoma, endometrial carcinoma, cervical carcinoma, urothelial carcinoma, ovarian carcinoma, papillary renal cell carcinoma, and a subset of squamous cell carcinomas.

Sensitivity and identification of CK7 and CK19 proteins by this antibody cocktail may be affected by improper specimen handling. This may alter antigenicity, weaken detection and may generate false negative results.

Cellular staining pattern: cytoplasmic

Positive specimen control: breast, pancreas, appendix, liver, tonsil, breast carcinoma

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-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53-B/A2.26], capsules (REF 8297-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 8297 to the same station.
6. Initiate execution of protocol 8297.
7. The RDA-Tag 8297 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-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53-B/A2.26], cartridge (REF 8297-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 8297 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 8297 to the same station.
7. Initiate execution of protocol 8297.
8. The RDA-Tag 8297 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-G001)
- Tissue-Tek Genie® Wash Solution (REF 8874-G004)
- Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744-G001)
- Tissue-Tek Genie® Non-immune Mouse Ig Antibody, Negative Control REF 8604-C010, 8604-M250)
- Tissue-Tek Genie® *Pro* Detection Kit, DAB (REF 8826-K250)
- Tissue-Tek Genie® Hematoxylin (REF 8830-M250)

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

Order information

Product code, product name and quantity

REF 8297-C010 Tissue-Tek Genie® anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26], Ready-To-Use, 10 capsules; 1 pack.

REF 8297-M250 Tissue-Tek Genie® anti-Cytokeratin 7/19 Mouse Monoclonal Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26], Ready-To-Use, 250 tests, 1 cartridge; 1 unit.

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

References

1. Mamiko Fujisue, et al. Cancers 2013, 5, 1-11
2. Dalia M Abd El-Rehim et al. J Pathol. 2004; 203:661-671
3. Mu-Min Shao, et al. Virchows Archiv 2012; 461, 313–322
4. T Tot. Ann Diagn Pathol. 1999; 3:350-6

5. Ramaekers J, et al. Am J Pathol. 1990; 136: 641–655
6. van de Molengraft FJ, et al. Histopathology. 1993; 22:35-8
7. Kasper M, et al. Eur J Cancer Clin Oncol. 1987; 23:137-47
8. Bártek J, et al. Histochem J. 1986; 18:565-75
9. Karsten U, et al. Eur J Cancer Clin Oncol. 1985; 21:733-40

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

IVD

CE

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