anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody

REF 790-4756

06640613001

IVD Σ 50

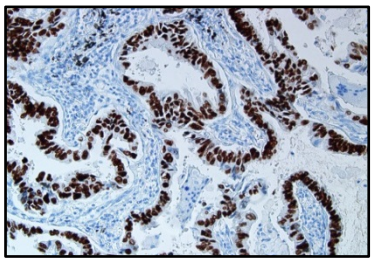

Figure 1. anti-TTF-1 (SP141) antibody staining neoplastic cells in lung adenocarcinoma tissue.

INTENDED USE

Anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of thyroid transcription factor-1 (TTF-1) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This antibody is intended for in vitro diagnostic (IVD) use.

SUMMARY AND EXPLANATION

Detection of TTF-1 protein by immunohistochemistry (IHC) with the Anti-Thyroid Transcription Factor-1 (SP141) Rabbit Monoclonal Primary Antibody (anti-TTF-1 (SP141) antibody) may be used to aid in the classification of neoplasms of the thyroid and lung. It may be used as part of a panel of IHC studies. The staining pattern is nuclear.

TTF-1 is an ~38 kDa homeodomain containing DNA-binding protein.[1] TTF-1 is expressed in the thyroid and lung.[2] In thyroid tissue, TTF-1 is expressed in the follicular and parafollicular cells.[1] In the adult lung, TTF-1 is expressed in type II pneumocytes and Clara cells.[1] In fetal lung, TTF-1 is detected in columnar nonciliated cells as early as 11 weeks of gestation.[1] Expression in epithelial cells of the thyroid gland and lung allows TTF-1 to be a useful marker for the classification of tumors arising in these organs.[3]

PRINCIPLE OF THE PROCEDURE

Anti-TTF-1 (SP141) antibody binds to thyroid transcription factor protein in formalin-fixed, paraffin embedded (FFPE) tissue sections and exhibits a nuclear staining pattern. This antibody can be visualized using OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001), *ultra*View Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001) or *ultra*View Universal Alkaline Phosphatase Red Detection Kit (Cat. No. 760-501 / 05269814001). Refer to the respective method sheet for further information.

MATERIAL PROVIDED

Anti-TTF-1 (SP141) antibody contains sufficient reagent for 50 tests.

One 5 mL dispenser of anti-TTF-1 (SP141) antibody contains approximately 28.5 µg of a rabbit monoclonal antibody.

The antibody is diluted in Tris buffer, pH 7.5, with carrier protein, non-ionic detergent, and sodium azide as preservative.

Specific antibody concentration is approximately 5.7 µg/mL. There is no known non-specific antibody reactivity observed in this product.

Anti-TTF-1 (SP141) antibody is a recombinant rabbit monoclonal antibody produced as purified cell culture supernatant.

Refer to the appropriate VENTANA detection kit method sheet for detailed descriptions of: Principles of the Procedure, Materials and Methods, Specimen Collection and Preparation for Analysis, Quality Control Procedures, Troubleshooting, Interpretation of Results, Limitations.

MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents, such as VENTANA detection kits and ancillary components, including negative and positive tissue control slides, are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

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

1. Recommended control tissue
2. Microscope slides, positively charged
3. Rabbit Monoclonal Negative Control Ig (Cat. No. 790-4795 / 06683380001)
4. OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001)
5. *ultra*View Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001)
6. *ultra*View Universal Alkaline Phosphatase Red Detection Kit (Cat. No. 760-501 / 05269814001)
7. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
8. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
9. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
10. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
11. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
12. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
13. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
14. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
15. Permanent mounting medium
16. Cover glass
17. Automated coverslipper
18. General purpose laboratory equipment
19. BenchMark IHC/ISH instrument

STORAGE AND STABILITY

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the antibody, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

Every antibody dispenser is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

SPECIMEN PREPARATION

Routinely processed FFPE tissues are suitable for use with this primary antibody when used with VENTANA detection kits and BenchMark IHC/ISH instruments. The recommended tissue fixative is 10% neutral buffered formalin.[4] Sections should be cut at approximately 4 µm in thickness and mounted on positively charged slides. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time. Ask your Roche representative for a copy of "Recommended Slide Storage and Handling" for more information.

It is recommended that positive and negative controls be run simultaneously with unknown specimens.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. **CAUTION:** In the United States, Federal law restricts this device to sale by or on the order of a physician. (Rx Only)
4. Do not use beyond the specified number of tests
5. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
6. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.[5,6]
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of reagents as it may cause incorrect results.

9. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components located at dialog.roche.com.
10. Consult local and/or state authorities with regard to recommended method of disposal.
11. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
12. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

STAINING PROCEDURE

VENTANA primary antibodies have been developed for use on BenchMark IHC/ISH instruments in combination with VENTANA detection kits and accessories. Refer to the tables below for recommended staining protocols.

This antibody has been optimized for specific incubation times but the user must validate results obtained with this reagent.

The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument User Guide. Refer to the appropriate VENTANA detection kit method sheet for more details regarding immunohistochemistry staining procedures.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 790-4756.

Table 1. Recommended staining protocol for anti-TTF-1 (SP141) antibody with *ultra*View Universal DAB Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method		
	GX	XT	ULTRA or ULTRA PLUS [a]
Deparaffinization	Selected	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, Standard	CC1, Standard	ULTRA CC1 Standard
Antibody (Primary)	16 minutes 37 °C	16 minutes 37 °C	24 minutes 36 °C
Counterstain	Hematoxylin II, 4 minutes		
Post Counterstain	Bluing, 4 minutes		

[a] Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

Table 2. Recommended staining protocol for anti-TTF-1 (SP141) antibody with OptiView DAB IHC Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method		
	GX	XT	ULTRA or ULTRA PLUS [a]
Deparaffinization	Selected	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, 48 Minutes	CC1, 48 Minutes	ULTRA CC1 64 minutes 100 °C
Pre Primary Peroxidase Inhibitor	Selected	Selected	Selected
Antibody (Primary)	8 minutes 37 °C	8 minutes 37 °C	12 minutes 36 °C
OptiView HQ Linker	8 minutes (default)	8 minutes (default)	8 minutes (default)
OptiView HRP Multimer	8 minutes (default)	8 minutes (default)	8 minutes (default)
Counterstain	Hematoxylin II, 4 minutes		
Post Counterstain	Bluing, 4 minutes		

[a] Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

Table 3. Recommended staining protocol for anti-TTF-1 (SP141) antibody with *ultra*View Universal Alkaline Phosphatase Red Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method		
	GX	XT	ULTRA or ULTRA PLUS [a]
Deparaffinization	Selected	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, Standard	CC1, Standard	ULTRA CC1 64 minutes 95 °C
Antibody (Primary)	12 minutes 37 °C	12 minutes 37 °C	20 minutes 36 °C
Counterstain	Hematoxylin II, 4 minutes		
Post Counterstain	Bluing, 4 minutes		

[a] Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

Due to variation in tissue fixation and processing, as well as general lab instrument and environmental conditions, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens, detection used, and reader preference. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances."[7]

NEGATIVE REAGENT CONTROL

In addition to staining with anti-TTF-1 (SP141) antibody, a second slide should be stained with the appropriate negative control reagent.

POSITIVE TISSUE CONTROL

Optimal laboratory practice is to include a positive control section on the same slide as the test tissue. This helps identify any failures applying reagents to the slide. Tissue with weak positive staining is best suited for quality control. Control tissue may contain both positive and negative staining elements and serve as both the positive and negative control. Control tissue should be fresh autopsy, biopsy, or surgical specimen, prepared or fixed as soon as possible in a manner identical to test sections.

Known positive tissue controls should be utilized only for monitoring performance of reagents and instruments, not as an aid in determining specific diagnosis of test samples. If the positive tissue controls fail to demonstrate positive staining, results of the test specimen should be considered invalid.

Examples of positive control tissues for this antibody are lung adenocarcinoma tissue, normal lung, or normal thyroid tissue.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for anti-TTF-1 (SP141) antibody is nuclear.

SPECIFIC LIMITATIONS

OptiView detection system is generally more sensitive than other detection systems. The user must validate the results obtained with this reagent and detection systems.

All assays might not be registered on every instrument. Please contact your local Roche representative for more information.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Staining tests for sensitivity, specificity, and precision were conducted and the results are listed below.

Sensitivity and Specificity

Table 4. Sensitivity/Specificity of anti-TTF-1 (SP141) antibody was determined by testing FFPE normal tissues.

Tissue	# positive/ total cases	Tissue	# positive/ total cases
Cerebellum	0/3	Myeloid (Bone marrow)	0/3
Cerebrum [a]	0/3	Mesothelium (pleura)	0/5
Adrenal gland	0/3	Lung [b]	20/20
Ovary	0/9	Heart	0/3
Pancreas	0/3	Esophagus	0/3
Parathyroid gland	3/3	Stomach	0/3
Hypophysis (Pituitary)	0/3	Small intestine	0/3
Testis	0/3	Colon	0/3
Thyroid [c]	4/4	Liver	0/4
Breast	0/3	Salivary gland	0/3
Spleen	0/3	Kidney	0/3
Tonsil	0/3	Prostate	0/3
Endometrium	0/3	Cervix	0/3
Skeletal Muscle	0/3	Skin	0/3
Nerve	0/3	Bladder	0/3
Thymus	1/22		

[a] Positive staining noted in scattered glial cells

[b] Positive staining noted in basal and columnar epithelium in both proximal bronchi and terminal bronchioles, and type 2 pneumocytes. All 10 cases of squamous metaplasia exhibited positive staining

[c] Positive staining noted in follicular cells

Table 5. Sensitivity/Specificity of anti-TTF-1 (SP141) antibody was determined by testing a variety of FFPE neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma (Cerebrum)	0/1
Meningioma (Cerebrum)	0/1
Ependymoma (Cerebrum)	0/1
Oligodendroglioma (Cerebrum)	0/1
Serous carcinoma (Ovary)	2/20
Carcinoma (Ovary)	0/1
Neuroendocrine tumor (Pancreas)	0/1
Adenocarcinoma (Pancreas)	0/1
Seminoma (Testis)	0/1
Embryonal carcinoma (Testis)	0/1
Medullary carcinoma (Thyroid)	6/7
Papillary carcinoma (Thyroid)	27/27
Follicular carcinoma (Thyroid)	15/18
Adenoma (Thyroid)	25/26
Oncocytic tumor (Thyroid)	4/4
Ductal carcinoma in situ (Breast)	0/1
Invasive ductal carcinoma (Breast)	0/2
Small cell carcinoma (Lung)	16/18
Squamous cell carcinoma (Lung)	13/57
Adenocarcinoma (Lung)	45/52
Adenosquamous carcinoma (Lung)	3/4
Invasive mucinous adenocarcinoma (Lung)	2/3
Carcinoma (Lung)	1/1
Large cell carcinoma (Lung)	1/6
Papillary carcinoma (Lung)	7/8
Neuroendocrine carcinoma, typical carcinoid tumor (Lung)	17/22
Neuroendocrine carcinoma (Esophagus)	0/1
Adenocarcinoma (Esophagus)	0/1
Mucinous adenocarcinoma (Stomach)	0/1
Gastrointestinal stromal tumor (GIST)	0/3
Adenocarcinoma (Colorectal)	3/23
Melanoma (Anus)	0/1
Hepatocellular carcinoma (Liver)	2/67
Hepatoblastoma (Liver)	0/1
Clear cell carcinoma (Kidney)	0/1
Adenocarcinoma (Prostate)	0/2
Carcinoma (Prostate)	5/14
Carcinosarcoma (Uterus)	3/6
Squamous cell carcinoma (Cervix)	0/2
Carcinoma (Endometrium)	0/11
Clear cell carcinoma (Endometrium)	0/1
Embryonal rhabdomyosarcoma	0/1
Basal cell carcinoma (Skin)	0/1
Squamous cell carcinoma (Skin)	0/1
Urothelial carcinoma (Bladder)	0/1
Mesothelioma	0/5

Pathology	# positive / total cases
Leiomyoma	0/1
Leiomyosarcoma	0/2
Osteosarcoma	0/1
Spindle cell rhabdomyosarcoma	0/1
B-Cell Lymphoma, NOS	0/3
Anaplastic large cell lymphoma	0/1
Hodgkin lymphoma	0/1
Neurofibroma	0/1
Neuroblastoma (Retroperitoneum)	0/1
Thymoma (type A)	2/4
Thymoma (type AB)	0/4
Thymoma (type B1)	1/23
Thymoma (type B2)	0/10
Thymoma (type B3)	0/4
Thymoma (type C)	3/7
Carcinoid (Thymus)	0/3

Precision

Precision studies for anti-TTF-1 (SP141) antibody were completed to demonstrate:

- Between lot precision of the antibody.
- Within run and between day precision on a BenchMark XT instrument.
- Between instrument precision on the BenchMark XT instrument and BenchMark ULTRA instrument.
- Between platform precision between the BenchMark XT instrument and BenchMark ULTRA instrument.

All studies met their acceptance criteria.

Precision on the BenchMark ULTRA PLUS instrument was demonstrated using representative assays. Studies included Within-run Repeatability, Between-day and Between-run Intermediate Precision. All studies met their acceptance criteria.

CLINICAL PERFORMANCE

Clinical performance data relevant to the intended purpose of anti-TTF-1 (SP141) antibody were assessed by systematic review of the literature. The data gathered support the use of the device in accordance with its intended purpose.

REFERENCES

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5. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
6. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
7. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology, 6th edition. In: NR Rose, ed. ASM Press; 2002.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

The summary of safety and performance can be found here:

https://ec.europa.eu/tools/eudamed

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

Global Trade Item Number

Unique Device Identification


Indicates the entity importing the medical device into the European Union

REVISION HISTORY

Rev	Updates
H	Updates to Summary and Explanation section.

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