VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody

REF 790-7214

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IVD Σ 50

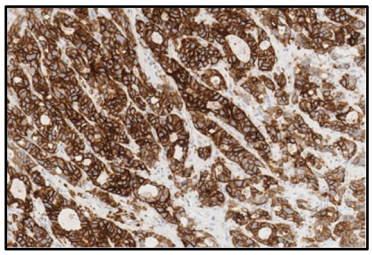

Figure 1. VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody staining in gastric carcinoma tissue.

INTENDED USE

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody is intended for laboratory use in the qualitative immunohistochemical detection of FGFR2b by light microscopy in sections of formalin-fixed, paraffin-embedded tissues 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

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody is an immunohistochemistry (IHC) assay that utilizes a mouse monoclonal antibody (clone FPR2-D) to detect the membranous Fibroblast Growth Factor Receptor type 2b (FGFR2b) proteins. This assay produces membranous staining on formalin-fixed, paraffin-embedded (FFPE) gastric carcinoma including gastroesophageal junction tissue.

The Fibroblast Growth Factor Receptor (FGFR) family is composed of four receptor tyrosine kinase members (FGFR1, FGFR2, FGFR3, FGFR4) that share a high percentage of sequence homology[1,2] and activate multiple cellular signaling cascades related to cell growth, proliferation, differentiation, angiogenesis and survival.[3] The FGFR receptors contain an extracellular ligand-binding domain, a single transmembrane domain and an intracellular tyrosine kinase domain.[2] Binding of FGF ligands to FGFRs can activate downstream signal transduction cascades in several tyrosine kinase pathways including MAPK-ERK, PI3K-AKT, STAT and phospholipase Cγ.[4]

The FGFR2b (FGFR2 isoform IIIb) protein is a specific splice variant resulting from the transcription and subsequent translation of the FGFR2 gene.[5] As a transmembrane protein, FGFR2b is preferentially expressed on the surface of epithelial cells[5] and is known to be highly overexpressed in some cancers, including gastric cancer.[6,7] Some studies among patients with gastric cancer have detected association of FGFR2b with poorly differentiated diffuse-type histology and poor prognosis.[6-10] The FGFR2b-specific mouse monoclonal antibody (FPR2-D) detects FGFR2 expression in gastric cancer tissues with FGFR2b protein overexpression.[11,12,13]

PRINCIPLE OF THE PROCEDURE

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody is a mouse monoclonal primary antibody which binds to FGFR2b protein in FFPE tissue sections. The specific antibody can be visualized by using OptiView DAB IHC Detection Kit. Refer to the detection kit method sheet for more information.

MATERIAL PROVIDED

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody contains sufficient reagent for 50 tests.

One 5 mL dispenser of VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody contains approximately 15 µg of mouse monoclonal antibody.

This antibody contains 0.10% ProClin 300, a preservative.

Specific antibody concentration is approximately 3 µg/mL.

Refer to the appropriate VENTANA detection kit method sheet for detailed descriptions of: Principle of the Procedure, Material and Methods, Specimen Collection and Preparation for Analysis, Quality Control Procedures, Troubleshooting, Interpretation of Results, and 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. Human non-neoplastic skin tissue for use as system level control
2. Negative Control (Monoclonal) (Cat. No. 760-2014 / 05266670001)
3. Microscope slides, positively charged
4. OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001)
5. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
6. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
7. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
8. LCS (Predilute) (Cat. No. 650-010/ 05264839001)
9. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
10. Cell Conditioning Solution (CC1) (Cat No. 950-124/ 05279801001)
11. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
12. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
13. Protease 3 (Cat. No. 760-2020 / 05266718001)
14. General purpose laboratory equipment
15. 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 instrument. The recommended tissue fixative is 10% neutral buffered formalin, processed in accordance with standard practice.[14] Fixatives such as alcohol-formalin-acetic acid (AFA), PREFER fixative and other alcohol-based fixatives may demonstrate a loss of specific staining for FGFR2b and should not be used with this assay. Alternative fixative types have not been assessed.

Both sample and system-level control tissues should be cut approximately 4 µm thick and mounted on positively charged glass microscope slides. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time. Altered staining performance may be observed on sections that have been stored at room temperature longer than 45 days.

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. Do not use beyond the specified number of tests.
4. ProClin 300 solution is used as a preservative in this reagent. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
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.[15,16]

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 navifyportal.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.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
WARNING 	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P261	Avoid breathing mist or vapours.
	P273	Avoid release to the environment.
	P280	Wear protective gloves.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 55965-84-9, a reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

STAINING PROCEDURE

VENTANA antibodies have been developed for use on BenchMark IHC/ISH instruments in combination with VENTANA detection kits and accessories. Refer to Table 2 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 790-7214.

Table 2. Recommended staining protocol for VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody and Negative Control (Monoclonal) with OptiView DAB IHC Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method	
	GX	ULTRA or ULTRA PLUS[a]
Staining Procedure	GX FGFR2b (FPR2-D) 1	U FGFR2b (FPR2-D) 1
Cell Conditioning Enzyme	Locked	Pre Cell Conditioning Enzyme
Cell Conditioning (Antigen Unmasking)	CC1, 24 minutes	Locked
Antibody (Primary)	FGFR2b (FPR2-D) Ab, Selected, 32 minutes, 37C or Negative Control Ab, Selected, 32 minutes, 37C	
Counterstain	Locked	Hematoxylin II, 4 minutes
Post Counterstain	Locked	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."[17]

NEGATIVE REAGENT CONTROL

A negative reagent control is a test specimen that is stained with a mouse monoclonal, Negative Control and serves as a test specimen control to evaluate nonspecific staining allowing accurate interpretation of specific FGFR2b staining on the respective VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody-stained test specimen slide. A matched negative reagent control should be run for every specimen to aid in the interpretation of results. The staining procedure for the negative reagent control should be equivalent to the primary antibody. Not using the negative control reagent can lead to unreliable results. If background staining is excessive, results from the test specimen should be considered invalid.

SYSTEM-LEVEL CONTROL

A system-level control is a control tissue specimen that has been stained in the same manner as the patient specimens and should be run for each set of test conditions to monitor the proper functioning of the reagents and instrument within the staining run, which demonstrates the assay is performing suitably. System-level control may include a positive and negative control tissue fixed and processed in the same manner as the patient specimens. Properly fixed human non-neoplastic skin tissue (with weak and moderate membrane staining) is recommended as the system-level control for VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody. System-level control should be run for each set of test conditions and with every VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody staining run. Such tissue control may monitor all steps of the analysis, from tissue preparation through staining. Control tissue should be biopsy or surgical specimens prepared and fixed as soon as possible in a manner identical to test sections. Tissue specimens that present with tissue autolysis and degeneration or poorly fixed tissues should be rejected. Decalcified tissue should also be rejected. Use of a tissue section fixed or processed differently from the test specimen provides control for all reagents and method steps except fixation and tissue preparation. For appropriate staining of the human non-neoplastic skin tissue refer to Table 3.

Table 3. VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody scoring criteria for evaluation of non-neoplastic skin tissue as system level control (SLC).

Staining Acceptability	Staining Pattern
Acceptable	Presence of weak and moderate membrane staining in the epithelium of skin; and Absence of weak to moderate staining in dermis.
Unacceptable	Absence of weak or moderate membrane staining in the epithelium of skin; or Presence of cytoplasmic-only staining; or Presence of any weak or moderate staining in skin dermis; or Non-specific FGFR2b (FPR2-D) background staining that interferes with interpretation.
Not Evaluable	Interpretation is not possible, e.g., no tissue/tumor present, artifacts, or edge artifacts.

STAINING INTERPRETATION / EXPECTED RESULTS

VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody staining in neoplastic tissue can be observed in tumor cells and exhibits a partial or complete membranous pattern ranging from continuous to finely granular, and/or coarsely granular. The VENTANA automated immunostaining procedure causes a brown colored (DAB) reaction product to precipitate at the antigen sites localized by VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody. A qualified pathologist experienced in immunohistochemical procedures must evaluate system-level controls and qualify the stained product before interpreting results.

SPECIFIC LIMITATIONS

Immunohistochemistry is a multiple step diagnostic process that requires specialized training in the selection of the appropriate reagents, tissue selections, fixation, processing, preparation of the immunohistochemistry slide, and interpretation of the staining results.

Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts, antibody trapping, or false negative results. Inconsistent results may result from variations in fixation and embedding methods, or from inherent irregularities within the tissue.

Fixatives such as alcohol-formalin-acetic acid (AFA), PREFER fixative and other alcohol-based fixatives may demonstrate a loss of specific staining for FGFR2b and should not be used with this assay.

Patient tissue should be stained within 45 days of sectioning from the tissue block and system-level control tissues. Loss of staining performance has been observed with VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody staining of tissue sections that have been stored at room temperature for longer than these times. Slides should be stored with desiccant and stored at room temperature.

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 VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody was determined by testing FFPE non-neoplastic tissues.

Tissue	# Positive[a] / Total Cases	Tissue	# Positive[a] / Total Cases
Adrenal gland	0/4[b]	Ureter	0/2
Bladder, urinary	0/4	Liver	0/4
Bone, bone marrow	0/5[c]	Lung	0/4
Head and neck, salivary gland	0/3	Ovary	0/3
Eye	0/2	Pancreas	1/4[f]
Breast	0/4	Parathyroid	2/3[g]
Brain, cerebellum	0/4	Pituitary gland	0/3[c]
Brain, cerebral cortex	0/3	Placenta	0/3
Brain, NOS	0/1	Prostate	0/4
Fallopian tube	0/3	Skin	1/4[h]
Mesothelium	0/4[c]	Spinal cord	0/2
Esophagus	0/4	Spleen	0/3
Stomach	25/46[d]	Skeletal muscle	0/3
Intestine, small intestine	0/4	Testis	0/4
Intestine, colon	0/4	Thymus	0/3
Intestine, rectum	1/4[e]	Thyroid	0/4
Heart	0/3	Tonsil	0/3
Kidney, cortex	0/4	Uterus, cervix	2/4[i]
Kidney, medulla	0/2	Uterus, endometrium	0/4
Peripheral nerve	0/3[c]		

[a] Staining includes all intensities and cellular localization as detailed in the associated footnotes.

[b] One case had a pathology diagnosis of normal hyperplasia.

[c] Resection cases for four mesothelium, one pituitary, three peripheral nerve, and three bone marrow.

[d] Non-neoplastic stomach showed FGFR2b (FPR2-D) reactivity in cytoplasm for 25 cores with weak stain intensity.

[e] Non-neoplastic rectum showed FGFR2b (FPR2-D) reactivity in cytoplasm with moderate stain intensity.

[f] Non-neoplastic pancreas showed FGFR2b (FPR2-D) reactivity in cytoplasm with weak stain intensity.

[g] Non-neoplastic parathyroid resections showed FGFR2b (FPR2-D) reactivity in membrane and cytoplasm with weak stain intensity.

[h] Non-neoplastic skin showed FGFR2b (FPR2-D) reactivity in membrane with weak stain intensity.

[i] Non-neoplastic cervix showed FGFR2b (FPR2-D) reactivity in cytoplasm with weak stain intensity.

Table 5. Sensitivity/Specificity of VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody was determined by testing FFPE neoplastic tissues.

Pathology	# Positive[a] / Total Cases
Adenoma, cortical (Adrenal gland)	0/1
Adrenocortical carcinoma (Adrenal gland)	1/1[b]
Transitional cell carcinoma (Bladder, urinary)	0/2
Fibroadenoma (Breast)	0/2

Pathology	# Positive[a] / Total Cases
Invasive ductal carcinoma (Breast)	0/3
Osteosarcoma (Bone, tibia)	0/1
Chondrosarcoma (Bone, scapula)	0/1
Meningioma, fibroblastic (Brain, cerebellum)	0/1
Malignant meningioma (Brain, cerebellum)	0/1
Meningioma, fibroblastic (Brain)	0/1
Astrocytoma (Brain)	0/1
Squamous cell carcinoma (Esophagus)	0/3
Adenocarcinoma (Gastric)	2/45[c]
Adenoma (Intestine, small intestine)	0/1
Adenocarcinoma (Intestine, small intestine)	0/1
Adenoma (Intestine, colon)	0/1
Adenocarcinoma (Intestine, colon)	1/3[d]
Adenocarcinoma (Intestine, rectum)	0/3
Clear cell carcinoma (Kidney)	0/2
Hepatocellular carcinoma (Liver)	0/4
Squamous cell carcinoma (Lung)	0/2
Adenocarcinoma (Lung)	0/1
Small cell carcinoma (Lung)	0/1
Reactive (Lymph node)	1/1[e]
Lymphoma, Hodgkin lymphoma (Lymph node, neck)	0/1
Lymphoma, non-Hodgkin B-cell lymphoma (Lymph node, axillary)	0/1
Lymphoma, anaplastic large cell lymphoma (Lymph node, neck)	0/1
Adenocarcinoma (Head and neck, oral cavity, hard palate)	0/1
Squamous cell carcinoma (Head and neck, oral cavity, tongue)	0/1
Nasopharyngeal carcinoma, NPC (Head and neck, nasopharynx)	0/1
Granulosa cell tumor (Ovary)	0/1
Adenocarcinoma (Ovary)	0/1
Endometrioid adenocarcinoma (Ovary)	0/1
Adenocarcinoma (Pancreas)	0/1
Adenoma (Parathyroid)	0/2
Schwannoma (Peripheral nerve)	0/2
Adenocarcinoma (Prostate)	0/2
Pleomorphic adenoma (Head and neck, salivary gland, parotid)	0/1
Adenoid cystic carcinoma (Head and neck, salivary gland)	0/1
Squamous cell carcinoma (Skin, trunk)	0/1
Melanoma (Head and neck, nasal cavity)	0/1
Seminoma (Testis)	0/2
Adenoma (Thyroid)	0/3

Pathology	# Positive[a] / Total Cases
Follicular carcinoma (Thyroid)	0/1
Follicular papillary adenocarcinoma (Thyroid)	0/1
Squamous cell carcinoma (Uterus, cervix)	0/2
Adenocarcinoma (Uterus, endometrium)	1/2[f]
Metastatic colon adenocarcinoma (Liver)	0/1
Metastatic cancers, from gastrointestinal site (Lung)	0/1
Metastatic breast invasive ductal carcinoma (Lymph node)	0/1
Metastatic colon signet ring cell carcinoma (Ovary)	0/1
Metastatic esophagus squamous cell carcinoma (Lymph node)	0/1

[a] Staining includes all intensities and cellular localization as detailed in the associated footnotes.

[b] Neoplastic adrenal gland showed FGFR2b (FPR2-D) staining in the nucleus with weak stain intensity.

[c] Two neoplastic gastric cores showed FGFR2b (FPR2-D) staining in the cytoplasm with weak stain intensity two additional cores demonstrated staining of the parietal, chief, and/or plasma cells where normal tissue was present.

[d] Neoplastic colon showed FGFR2b (FPR2-D) staining in the nucleus with weak stain intensity.

[e] Neoplastic lymph node showed FGFR2b (FPR2-D) staining in the nucleus of one lymphocyte with weak stain intensity.

[f] Neoplastic endometrium showed FGFR2b (FPR2-D) reactivity in the cytoplasm with a weak stain intensity.

In addition to the data provided in Table 4 and Table 5, a random selection of 100 gastric carcinoma resections were stained with FGFR2b(FPR2-D), 5 resections exhibited moderate to strong tumor membrane staining.

Precision

Precision studies for VENTANA FGFR2b (FPR2-D) Mouse Monoclonal Antibody were completed using gastric carcinoma resections to demonstrate:

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

Precision on the BenchMark ULTRA PLUS instrument was demonstrated using representative assays. Studies included Within-run Repeatability, Between-day and Between-Instrument Intermediate Precision.

All studies met their acceptance criteria.

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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.

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see elabdoc.roche.com/symbols for more information).

GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

REVISION HISTORY

Rev	Updates
B	Updates to the Summary and Explanation, Analytical Performance, and References sections. Updated to the current template.

INTELLECTUAL PROPERTY

For USA: Rx only

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