

CONFIRM anti-Prostate Specific Antigen (PSA) Rabbit Polyclonal Primary Antibody

REF 760-2506

05266939001

IVD  50

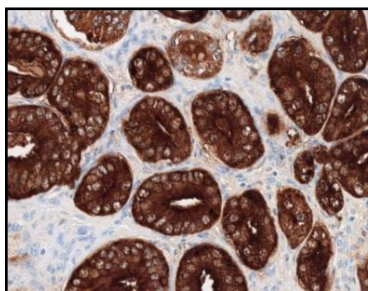


Figure 1. CONFIRM anti-Prostate Specific Antigen (PSA) antibody staining on prostate carcinoma.

INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-Prostate Specific Antigen (PSA) Primary Antibody is a rabbit polyclonal antibody (Ig) directed against both free and bound human prostate specific antigen (PSA). This antibody is intended for use to qualitatively identify PSA by light microscopy in sections of formalin fixed paraffin embedded tissue following staining on a VENTANA automated slide stainer.

The clinical interpretation of any staining, or the absence of staining,

must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

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

SUMMARY AND EXPLANATION

CONFIRM anti-Prostate Specific Antigen (PSA) Primary Antibody (CONFIRM anti-PSA (poly) antibody) is a rabbit polyclonal antibody produced against human PSA protein which is a 33-34 kD chymotrypsin like serine protease (kallikrein family) specifically expressed by prostate epithelium. PSA is present in the cytoplasm of benign and malignant prostate epithelium.^{1,2} It is useful for identification of adenocarcinoma of the prostate in metastatic sites and for differentiating prostate adenocarcinoma from urothelial carcinoma.

PRINCIPLE OF THE PROCEDURE

CONFIRM anti-PSA (poly) antibody binds to free and bound human PSA in formalin-fixed paraffin-embedded tissues and optimally diluted for use with VENTANA detection kits and automated slide stainers.

REAGENT PROVIDED

CONFIRM anti-PSA (poly) antibody contains sufficient reagent for staining 50 slides.

One 5 mL dispenser of CONFIRM anti-PSA (poly) antibody contains approximately 3.5 µg of a rabbit polyclonal antibody.

The antibody is diluted in 0.05 M Tris-HCl with 2% carrier protein, and 0.10% ProClin 300, a preservative containing the active ingredients 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one.

Total protein concentration of the reagent is approximately 11 µg/mL. Specific antibody concentration is approximately 0.7 µg/mL. There is no known irrelevant antibody reactivity observed in this product.

There is a trace (~0.5%) of bovine serum albumin of U.S. origin from the stock solution.

Refer to the appropriate VENTANA detection kit package insert for detailed descriptions of: (1) Principles of the Procedure, (2) Materials and Reagents Needed but Not Provided, (3) Specimen Collection and Preparation for Analysis, (4) Quality Control Procedures, (5) Troubleshooting, (6) Interpretation of Results, and (7) General 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 package insert may be available in all geographies. Consult your local support representative.

STORAGE

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, formalin fixed, paraffin embedded 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.³ Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

Ventana recommends the use of positively charged microscope slides.

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. 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.
4. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
5. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
6. Avoid microbial contamination of reagents as it may cause incorrect results.
7. Consult local and/or state authorities with regard to recommended method of disposal.
8. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining of any IHC assay (for example, lack of primary antibody or counterstain on the tissue). Ask your Roche representative for a copy of "Impacts of Environmental Stresses on IHC Positively Charged Slides" to better understand how to use these types of slides.
9. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Hazard Guide located at www.ventana.com.

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 Table 1 and 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 instruments Operator's Manual. Refer to the appropriate VENTANA detection kit package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended staining protocols for CONFIRM anti-PSA (poly) antibody with *ultraView* Universal IHC DAB detection kit.

Procedure Type	Method		
	BenchMark GX	BenchMark XT	BenchMark ULTRA
Deparaffinization	Selected		
Cell Conditioning (Antigen Unmasking)	30 minutes, CC1, mild	30 minutes, CC1, mild	36 minutes, CC1, mild
Enzyme (Protease)	None required		
Antibody (Primary)	8 minutes, 37°C	12 minutes, 37°C	16 minutes, 36°C
Counterstain	Hematoxylin II, 4 minutes		
Post Counterstain	Bluing, 4 minutes		

Table 2. Recommended Staining protocols for CONFIRM anti-PSA (poly) antibody with *OptiView* DAB IHC detection kit.

Procedure Type	Method		
	BenchMark GX	BenchMark XT	BenchMark ULTRA
Deparaffinization	Selected		
Cell Conditioning (Antigen Unmasking)	16 minutes, CC1	16 minutes, CC1	16 minutes, CC1, 100°C
Enzyme (Protease)	None required		
Antibody (Primary)	8 minutes, 37°C	8 minutes, 37°C	8 minutes, 36°C
Counterstain	Hematoxylin II, 4 minutes		
Post Counterstain	Bluing, 4 minutes		

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".⁴

POSITIVE TISSUE CONTROL

Optimal laboratory practice is to include a positive control section on the same slide as the patient tissue. This practice helps to identify a failure to apply primary antibody or other critical reagent to the patient test slide. A tissue with weak positive staining is more suitable for optimal quality control. The positive staining tissue components are used to confirm that the antibody was applied and the instrument functioned properly. This tissue may contain both positive and negative staining elements and serve as both the positive and negative control tissue. Control tissues should be fresh autopsy, biopsy, or surgical specimens prepared or fixed as soon as possible in a manner identical to the test sections.

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

An example of positive control tissue for CONFIRM anti-PSA (poly) antibody is normal prostate. Positive cytoplasmic staining in the secretory epithelial cells of the prostatic acini should be observed in normal prostate.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for CONFIRM anti-PSA (poly) antibody is cytoplasmic. See above image for an example of cytoplasmic staining in prostate carcinoma.

SPECIFIC LIMITATIONS

This antibody has been optimized for use on BenchMark IHC/ISH instruments in combination with *ultraView* Universal DAB Detection Kit (Cat. No. 760-500; Order No. 05269806001) and *OptiView* DAB IHC Detection Kit (Cat. No. 760-700; Order No. 06396500001). *OptiView* detection system is generally more sensitive than *ultraView* Universal DAB Detection Kit. The user must validate the results obtained with this reagent and detection systems.

PERFORMANCE CHARACTERISTICS

Staining tests for specificity, sensitivity, and repeatability were conducted and the results are listed in Table 3 and Table 4 and in the Repeatability section.

Specificity and Sensitivity

Table 3. Specificity/Sensitivity of CONFIRM anti-PSA (poly) antibody was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Tissue	# positive / total cases	Tissue	# positive / total cases
Cerebrum	0/3	Thymus	0/3
Cerebellum	0/3	Bone marrow	0/3
Adrenal gland	0/3	Lung	0/3
Ovary	0/3	Heart	0/3
Pancreas	0/3	Esophagus	0/3
Parathyroid gland	0/3	Stomach	0/3
Hypophysis	0/3	Small intestine	0/3
Testis	0/3	Colon	0/3
Thyroid	0/3	Liver	0/3
Breast	0/3	Salivary gland ^a	3/3
Spleen	0/3	Kidney	0/3
Tonsil	0/3	Prostate ^b	10/10
Endometrium	0/3	Cervix	0/3
Skeletal muscle	0/3	Skin	0/3
Nerve	0/3	Mesothelium	0/4
Lymph node	0/3	Bladder ^c	1/11

^a Striated duct epithelial cells (luminal staining); ^b Glandular epithelial cells; ^c Umbrella cells

Table 4. Specificity/Sensitivity of CONFIRM anti-PSA (poly) antibody was determined by testing a variety of formalin-fixed, paraffin-embedded neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma (Cerebrum)	0/1
Meningioma (Cerebrum)	0/1
Ependymoma (Cerebrum)	0/1
Oligodendroglioma (Cerebrum)	0/1
Serous adenocarcinoma (Ovary)	0/2
Pancreatic neuroendocrine neoplasm (Pancreas)	0/1
Adenocarcinoma (Pancreas)	0/1

Pathology	# positive / total cases
Seminoma (Testis)	0/1
Embryonal carcinoma (Testis)	0/1
Medullary carcinoma (Thyroid)	0/1
Papillary carcinoma (Thyroid)	0/1
Microinvasive ductal carcinoma (Breast)	0/1
Invasive ductal carcinoma (Breast)	0/2
Small cell carcinoma (Lung)	0/1
Squamous cell carcinoma (Lung)	0/1
Adenocarcinoma (Lung)	0/1
Squamous cell carcinoma (Esophagus)	0/1
Adenocarcinoma (Esophagus)	0/1
Mucinous adenocarcinoma (Stomach)	0/1
Gastrointestinal stromal tumor (GIST) (Small Intestine)	0/1
Gastrointestinal stromal tumor (GIST) (Colon)	0/1
Gastrointestinal stromal tumor (GIST) (Rectum)	0/1
Adenocarcinoma (Colon)	0/1
Adenocarcinoma (Rectum)	0/1
Adenocarcinoma (Small Intestine)	0/1
Hepatocellular carcinoma (Liver)	0/1
Hepatoblastoma (Liver)	0/1
Clear cell carcinoma (Kidney)	0/1
Adenocarcinoma (Prostate)	72/72
Prostatic adenocarcinoma (Metastatic)	10/10
Leiomyoma (Uterus)	0/1
Adenocarcinoma (Uterus)	0/1
Clear cell carcinoma (Uterus)	0/1
Squamous cell carcinoma (Cervix)	0/2
Embryonal rhabdomyosarcoma (Striated muscle)	0/1
Melanoma (Rectum)	0/1
Basal cell carcinoma (Skin)	0/1
Squamous cell carcinoma (Skin)	0/1
Neurofibroma (Lumbar)	0/1
Neuroblastoma (Retroperitoneum)	0/1
Mesothelioma (Peritoneum)	0/1
B-Cell Lymphoma; NOS (Lymph node)	0/3
Hodgkin lymphoma (Lymph node)	0/1
Urothelial carcinoma (Bladder) ^a	1/39

Pathology	# positive / total cases
Squamous cell carcinoma (Bladder)	0/1
Adenocarcinoma (Bladder)	0/1
Leiomyosarcoma (Bladder)	0/1
Leiomyosarcoma (Prostate)	0/4
Leiomyosarcoma (Smooth muscle)	0/1
Spindle cell rhabdomyosarcoma (Peritoneum)	0/1

^a focal staining

Repeatability

Repeatability studies for CONFIRM anti-PSA (poly) antibody were completed to demonstrate:

- Inter-lot reproducibility of the antibody.
- Intra-run and Inter-run reproducibility on a BenchMark ULTRA instrument.
- Intra-platform reproducibility on the BenchMark GX, BenchMark XT and BenchMark ULTRA instrument.
- Inter-platform reproducibility between the BenchMark GX, BenchMark XT and BenchMark ULTRA instrument.

All studies met their acceptance criteria.

REFERENCES

1. Nadji M, Tabei SZ, Castro A, et al. Prostatic-specific antigen: an immunohistologic marker for prostatic neoplasms. Cancer. 1981;48(5):1229-1232.
2. Oesterling JE. Prostate specific antigen: a critical assessment of the most useful tumor marker for adenocarcinoma of the prostate. J Urol. 1991;145(5):907-923.
3. Sheehan DC, Hrapchak BB. Theory and Practice of Histotechnology, 2nd Edition. The C.V. Mosby Company, St. Louis, 1980.
4. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology, 6th edition. (NR Rose Ed.) ASM Press, 2002.

INTELLECTUAL PROPERTY

VENTANA, BENCHMARK, CONFIRM, OPTIVIEW, *ultraView*, and the VENTANA logo are trademarks of Roche.

All other trademarks are the property of their respective owners.

© 2017 Ventana Medical Systems, Inc.

CONTACT INFORMATION



Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
USA
+1 520 887 2155
+1 800 227 2155 (USA)



www.ventana.com



Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany