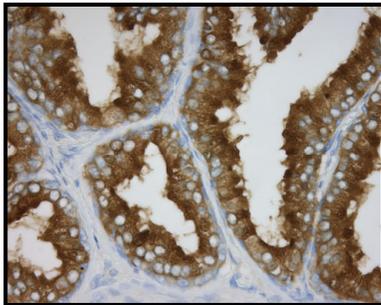


CONFIRM® anti-Prostate Specific Antigen (PSA) Rabbit Polyclonal Primary Antibody

Catalog number 760-2506



INTENDED USE

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

SUMMARY AND EXPLANATION

PSA 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.

REAGENT PROVIDED

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

1 – 5 mL dispenser of CONFIRM anti-PSA (poly) 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 Preparation, (4) Quality Control, (5) Troubleshooting, (6) Interpretation of Staining, and (7) General Limitations.

MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents such as Ventana detection kits (for example, *ultraView™* Universal DAB), rabbit negative control reagent and ancillary components, including negative and positive tissue control slides, are not provided.

STORAGE

Store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and stability of the antibody, after every use the cap must be replaced and the dispenser must be immediately placed 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 a Ventana automated

slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.³ Heat induced epitope retrieval is not recommended. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

There are no definitive signs to indicate instability of this product; therefore, positive and negative controls should be run simultaneously with unknown specimens.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
3. Avoid microbial contamination of reagents.
4. Consult local or state authorities with regard to recommended method of disposal.
5. The preservative in the reagent is ProClin 300. Symptoms of overexposure to ProClin 300 include skin and eye irritation, and irritation of mucous membranes and upper respiratory tract. The concentration of ProClin 300 in this product is less than or equal to 0.10% and does not meet the OSHA criteria for a hazardous substance. Systemic allergic reactions are possible in sensitive individuals.

STAINING PROCEDURE

Ventana primary antibodies have been developed for use on a Ventana automated slide stainer in combination with Ventana detection kits and accessories. A recommended staining protocol for the BenchMark® series with *ultraView* Universal DAB detection kit (Cat. No.760-500) is listed below in Table 1. The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument's Operator's Manual. Refer to the appropriate Ventana detection kit package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocol for CONFIRM anti-PSA Rabbit Polyclonal Primary Antibody with *ultraView* Universal DAB Detection Kit on BenchMark Series.

Procedure Type	Method
	BenchMark Series
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	None Required
Enzyme (Protease)	None Required
Antibody (Primary)	Approximately 16 Minutes, 37 °C
Ultra Wash	Optional
Counterstain	Hematoxylin II, 4 Minutes
Post Counterstain	Bleuing Reagent, 4 Minutes

Due to variation in tissue fixation and processing, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens and detection used. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances".⁴

POSITIVE TISSUE CONTROL

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

STAINING INTERPRETATION

The cellular staining pattern for PSA is cytoplasmic. See above image for example of cytoplasmic staining in normal prostate epithelium.

SPECIFIC LIMITATIONS

This antibody has been optimized for a 16 minute incubation time on BenchMark series automated slide stainers in combination with *ultraView* Universal DAB detection kit (Cat. No.760-500), however the user must validate results obtained with this reagent.

PERFORMANCE CHARACTERISTICS

1. Specificity of CONFIRM anti-PSA (poly) was determined by testing formalin fixed, paraffin embedded normal and neoplastic tissues. For normal tissues, results are as follows: Adrenal gland (0/3), bone marrow (0/3), brain cerebrum (0/3), brain cerebellum (0/3), breast (0/3), cervix (0/1), colon (0/3), esophagus (0/3), heart (0/3), intestine (0/3), kidney (0/3), liver (0/3), lung (0/3), lymph node (0/3), mesothelium (0/3), nerve (0/3), ovary (0/3), pancreas (0/3), parathyroid (0/3), pituitary (0/3), prostate (17/17), salivary gland (0/3), skin (0/3), spleen (0/3), stomach (0/3), striated muscle (0/3), testis (0/3), thymus (0/3), thyroid (0/3), tonsil (0/3), and uterus (0/2). For neoplastic tissues, results are as follows: Atypical meningioma (0/1), glioblastoma (0/1), ependymoma (0/1), oligodendroglioma (0/1), ovarian serous papillary adenocarcinoma (0/1), ovarian mucous papillary adenocarcinoma (0/1), islet cell carcinoma (0/1), pancreatic adenocarcinoma (0/1), testicular seminoma and embryonal carcinoma (0/2), medullary thyroid carcinoma (0/1), papillary thyroid carcinoma (0/1), intraductal, lobular, and infiltrating breast carcinoma (0/3), diffuse B-cell lymphoma in spleen (0/1), small cell lung carcinoma (0/1), squamous cell lung carcinoma (0/1), lung adenocarcinoma (0/1), esophageal squamous cell and adenocarcinoma (0/2), adenocarcinoma in stomach (0/1), intestinal adenocarcinoma and mesenchymoma (0/2), colorectal adenocarcinoma and mesenchymoma (0/4), hepatocellular carcinoma (0/1), hepatoblastoma (0/1), adenocarcinoma in prostate (1/1), transitional cell carcinoma in prostate (0/1), uterine leiomyoma (0/1), endometrial carcinoma (0/1), uterine clear cell and squamous carcinomas (0/3), embryonal rhabdomyosarcoma (0/1), rectal melanoma (0/1), basal cell carcinoma and squamous cell carcinoma in skin (0/2), neurofibroma and neuroblastoma (0/2), transitional cell carcinoma and leiomyosarcoma in bladder and stomach (0/3), osteosarcoma (0/1), Hodgkin's lymphoma (0/1), and diffuse type lymphoma (0/2).
2. Sensitivity of CONFIRM anti-PSA (poly) was determined by testing a variety of formalin fixed, paraffin embedded prostate carcinoma samples. 72/72 samples stained positively.
3. Inter lot reproducibility of CONFIRM anti-PSA (poly) was determined by testing three lots of predilute antibody across five normal prostate tissues on a BenchMark XT. Five out of five tissues tested scored equivalently across all three lots.
4. CONFIRM anti-PSA (poly) is compatible with the following instruments: NexES, BenchMark, and BenchMark XT. CONFIRM anti-PSA (poly) is compatible with the following detection chemistries: *ultraView* Universal DAB, *ultraView* Universal Red, AEC, MIEW™ DAB, and Enhanced Alkaline Phosphatase Red detection kits.

REFERENCES

1. Nadji M, Tabei SZ, Castro A, Chu TM, Murphy GP, Wang MC, Morales AR. Prostatic-Specific Antigen: An immunohistologic marker for prostatic neoplasms. *Cancer* 48(5):1229-1232, 1981.
2. Oesterling JE. Prostate Specific Antigen: A critical assessment of the most useful tumor marker for adenocarcinoma of the prostate. *J Urology* 145(5):907-923, 1991.
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.

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