MAYO CLINIC LABORATORIES

Test Definition: PTENC

PTEN (SP218), Semi-Quantitative Immunohistochemistry, Manual

Overview

Useful For
Aiding in detecting PTEN-deficient invasive prostate adenocarcinoma

Method Name
Immunohistochemistry (IHC)

NY State Available
Yes

Specimen

Specimen Type
Special

Shipping Instructions
Attach the green "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

Necessary Information
A pathology/diagnostic report and a brief history are required.

Specimen Required
Specimen Type: Tissue
Supplies: Pathology Packaging Kit (T554)
Submit:
Formalin-fixed, paraffin-embedded tissue block
OR
3 Unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue
Additional Information: One slide will be stained with hematoxylin and eosin and returned.

Forms
If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

Decalcified paraffin embedded	Reject

tissue	
Wet/frozen tissue	Reject
Cytology smears	Reject
Noncharged slides	Reject
ProbeOn slides	Reject
Snowcoat slides	Reject
Nonformalin fixed tissue, including CytoLyt, SurePath, alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER and zinc formalin fixatives	Reject
Nonparaffin embedded tissue	Reject
Broken or cracked unstained slides	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

The PTEN (SP218) RxDx Assay is indicated as a companion diagnostic to detect and select PTEN-deficient invasive prostate carcinoma patients who may potentially benefit from a combination treatment with capivasertib (TRUQAP).

Clinical cutoff for PTEN loss is greater than or equal to 90% of viable malignant cells with no specific cytoplasmic expression.

Reference Values

An interpretive report will be provided.

Interpretation

The PTEN protein is localized in the cytoplasm and nucleus, and is an essential enzyme expressed in several non-neoplastic tissues. The PTEN (SP218) RxDx Assay is indicated as a companion diagnostic to aid in identifying patients who may be eligible for treatment with TRUQAP (capivasertib). Clinical cutoff for PTEN loss is greater than or equal to 90% of viable malignant cells with no specific cytoplasmic expression. Nuclear expression in viable malignant cells should be disregarded.(1)

Cautions

This test has been validated for non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral buffered formalin at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 6 hours and 72 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen dependent. Best practice is for paraffin sections to be cut within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.

Best practices for storage of positively charged slides:
-Minimize time slides are stored after being unpackaged
-Limit exposure to high humidity and heat
-Minimize exposure to plastics

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Clinical Reference

1. Ventana PTEN (SP218) RxDx Assay Data Sheet. Roche Diagnostics; 1019742US, 02/01/2026
2. Jamaspishvili T, Berman DM, Ross AE, et al. Clinical implications of PTEN loss in prostate cancer. Nat Rev Urol. 2018;15(4):222-234
3. Shah RB, Shore KT, Yoon J, Mendrinos S, McKenney JK, Tian W. PTEN loss in prostatic adenocarcinoma correlates with specific adverse histologic features (intraductal carcinoma, cribriform gleason pattern 4 and stromogenic carcinoma). Prostate. 2019;79(11):1267-1273
4. Fizazi K, Clarke NW, De Santis M, et al. Capivasertib plus abiraterone in PTEN-deficient metastatic hormone-sensitive prostate cancer: CAPItello-281 phase III study. Ann Oncol. 2026;37(1):53-68. doi:10.1016/j.annonc.2025.10.004

Performance

Method Description
Immunohistochemical staining and detection of PTEN (SP218) is performed in formalin-fixed, paraffin-embedded tissue sections using the VENTANA PTEN (SP218) RxDx Assay. The 4-micron tissue sections are deparaffinized, subjected to heat-induced antigen retrieval and peroxidase inhibitor, incubated with a rabbit monoclonal antibody (SP218), and visualized using a proprietary kit detection system. Sections are counterstained with hematoxylin and post counterstained with bluing. Stained slides are examined microscopically by the consulting anatomic pathologist.(Package insert: VENTANA PTEN [SP218] RxDx Assay. Ventana Medical Systems, Inc; 1019742US, 02/01/2026)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
5 to 7 days

Specimen Retention Time
Until reported

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
88360

LOINC® Information

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Test ID	Test Order Name	Order LOINC® Value
PTENC	PTEN (SP218), SemiQuant IHC, Manual	81706-4

Result ID	Test Result Name	Result LOINC® Value
624278	Interpretation	59465-5
624287	Participated in the Interpretation	No LOINC Needed
624288	Report electronically signed by	19139-5
624289	Material Received	81178-6
624290	Disclaimer	62364-5
624291	Case Number	80398-1