MAYO CLINIC LABORATORIES

1-800-533-1710

PTENC

PTEN (SP218), Semi-Quantitative Immunohistochemistry, Manual

Patient ID	Patient Name		Birth Date	Sex	Age
321	IMPLEMENTATION, TEST LABELS		1973-05-01	F	53
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
X100543037	X100543037	Test,Atlas			
Account Information		**Collected**			
C7028846 DLMP Rochester		08 Oct 2026 06:33			

PTEN (SP218), SemiQuant IHC, Manual

Case Number CR-26-578

Interpretation

MCR

Testing, specimen for PTEN immunohistochemistry studies (PTEN [SP218] RxDx Assay, Ventana/Roche, Tucson, AZ); using a proprietary detection system) (ST26−1010-A1):

PTEN: Approximately 90% loss of tumor cells with no specific cytoplasmic staining.

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.

This result should be interpreted in the appropriate clinical context.

Fixation: This test has been validated for non-decalcified paraffin embedded tissue specimens fixed in 10% neutral buffered formalin. Recommended fixation time is between 6−72 hours. This assay has not been validated on tissues subjected to the decalcification process and /or use of alternative fixatives.

Material Received

MCR

A. ST26−1010: Testing
2 unstained slides

Report electronically signed by

MCR

Alison Smarzyk Carlson

Disclaimer

MCR

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 U.S. Food and Drug Administration.

Received: 08 Oct 2026 14:27

Reported: 08 Oct 2026 14:36

Test Environment PATHDX Template

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	Nikola Baumann Ph.D.	24D0404292