



# Certificate of Analysis

**Product name**

VENTANA PTEN (SP218)

**Material No.**

07970200001

**Lot No.**

N29297

**Date of Manufacturing**

2026-02-06

**Expiry Date**

2028-02-02

**Parameter****Result****Unit**

Visual Inspection

Pass

Reagent must be clear of foreign material and particulate matter, and free of turbidity

Visual Inspection

Pass

Reagent must be clear of foreign material and particulate matter, and free of turbidity

Functional Staining

Pass

Prostate adenocarcinoma with PTEN staining

Prostate adenocarcinoma without PTEN staining

Staining Intensity of normal internal control staining elements greater than or equal to 1.00

Prostate adenocarcinoma without PTEN staining must exhibit greater than or equal to 50% of the viable malignant cells with no (= 0.0 pt) specific cytoplasmic staining

Prostate adenocarcinoma with PTEN staining must exhibit greater than 50% of viable malignant cells with greater than 1.0 specific cytoplasmic staining

**Issue date** 2026-02-25

Page 1 of 2

Ventana Medical Systems, Inc.  
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Tucson, Arizona 85755  
Phone: + 1 800 227 2155  
<http://www.ventana.com>



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The background intensity must be 0.5 or less

The specific staining intensity of normal internal control staining elements must also be within 0.5 pt. of the reference batch for a passing result

The intensity of the negative reagent control slide must be 0.5 or less

Bioburden

Visible bacterial colonies must be 100 or less CFU/mL

Pass

This lot meets our specification

**Disposition by**

Lupe Villarreal

This certificate is a computer printout and has therefore not been signed by hand.

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Page 2 of 2

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