



## Certificate of Analysis

**Product name**

VENTANA PTEN (SP218)

**Material No.**

07970200001

**Lot No.**

J11939

**Date of Manufacturing**

2022-05-04

**Expiry Date**

2024-05-03

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

Final Acceptance Testing

Pass

PTEN Positive and PTEN Negative tissue

The test batch must score greater than or equal to 1.0 in normal internal control staining elements of qualified prostate adenocarcinoma

The test batch must score 0.0 for the specific cytoplasmic staining on greater than or equal to 50% of the viable malignant cells of qualified PTEN Loss prostate adenocarcinoma

The test batch must score greater than or equal to 1.0 for the specific cytoplasmic staining on greater than 50% of the viable malignant cells of qualified PTEN Intact prostate adenocarcinoma

The specific stain intensity must be within 0.5 pt. of the reference batch for all tissues

The background intensity must be less than or equal to 0.5

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

**Issue date** 2022-06-16

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Ventana Medical Systems, Inc.  
1910 Innovation Park Drive  
Tucson, Arizona 85755  
Phone: + 1 800 227 2155  
<http://www.ventana.com>



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Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

Reagent must be free of foreign material and substantially free of intrinsic particulate matter.

This lot meets our specification

**Disposition by**

Antonio Reyes

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

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