



Certificate of Analysis

Product name

VENTANA PTEN (SP218)

Material No.

07970200001

Lot No.

N26324

Date of Manufacturing

2025-12-08

Expiry Date

2027-12-07

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 2026-01-14

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



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Parameter**Result****Unit**

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

Pass

Visible bacterial colonies must be 100 or less CFU/mL

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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