



# Certificate of Analysis

**Product name**

VENTANA ANTI-P63 (4A4)

**Material No.**

05867061001

**Lot No.**

N19731

**Date of Manufacturing**

2025-10-15

**Expiry Date**

2027-10-09

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

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

Pass

Functional Staining

Pass

Tonsil and Prostate Carcinoma Tissues

For specific stain intensity on a 0 to 4 scale, the test batch and reference batch must score 3.00 points or greater in squamous epithelial cells of the tonsil tissue and 3.00 points or greater in normal cells of the prostate carcinoma tissue.

The neoplastic cells of the prostate carcinoma tissue are used as an intra-tissue control, and specific stain intensity must be less than or equal to 0.50 points.

The specific stain intensity of the test batch must also be within 0.50 points of the reference batch for both tissues.

The background intensity must be 0.50 points or less on both tissues for the test batch and reference batch.

The background intensity of the negative reagent control on both tissues must be 0.50 points or less.

**Issue date** 2025-11-05

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



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

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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