



Certificate of Analysis

Product name

VENTANA ANTI-P63 (4A4)

Material No.

05867061001

Lot No.

N13168M

Date of Manufacturing

2025-07-10

Expiry Date

2027-07-09

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 2025-08-04

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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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Parameter**Result****Unit**

Bioburden
Visible bacterial colonies must be 100 or less CFU/mL

Pass

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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