



# Certificate of Analysis

**Product name**

VENTANA ANTI-P63 (4A4)

**Material No.**

05867061001

**Lot No.**

J20645

**Date of Manufacturing**

2022-08-16

**Expiry Date**

2024-08-15

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

Visual Inspection

Pass

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

Functional Staining

Pass

Tonsil and Prostate Carcinoma Tissues

For specific stain intensity, the test batch and reference batch must score 3.0 or greater in squamous epithelial cells of the tonsil tissue and 3.0 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 0.5.

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

The background intensity must be 0.5 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 0.5 or less.

**Issue date** 2022-08-30

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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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Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

**Disposition by**

Nic Hau

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

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