



Certificate of Analysis

Product name

VENTANA ANTI-P63 (4A4)

Material No.

05867061001

Lot No.

F18327

Date of Manufacturing

2019-08-15

Expiry Date

2021-08-14

Parameter**Result****Unit**

Final Acceptance Testing

Pass

Anti-p63 (4A4) Mouse Monoclonal Primary Antibody stains the nuclei of human prostatic basal cells in normal regions of prostate carcinoma and squamous epithelial cells in the tonsil.

The specific staining of the Anti-p63 (4A4) Mouse Monoclonal Primary Antibody test lot must score 3.0 or greater in normal cells of the prostate carcinoma tissue.

The neoplastic cells will be used as an intra-tissue control, and specific stain intensity must score less than or equal to 0.5.

Specific staining in the tonsil must score 3.0 or greater on squamous epithelial cells.

The test lot specific stain intensity must also be within 0.5 pt. of the reference lot for a passing result.

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

Issue date 2019-08-28

Page 1 of 2

Ventana Medical Systems, Inc.
1910 Innovation Park Drive
Tucson, Arizona 85755
Phone: + 1 520 887 2155
<http://www.ventana.com>



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Parameter**Result****Unit**

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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Page 2 of 2

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