



## Certificate of Analysis

**Product name**

CONFIRM anti-Keratin (34E12) Mouse Mono

**Material No.**

05479266001

**Lot No.**

J08974

**Date of Manufacturing**

2022-04-04

**Expiry Date**

2024-03-29

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

Final Acceptance Testing

Pass

Positive prostate carcinoma and breast carcinoma.

The test batch must score 3.5+ or greater for benign areas adjacent to the tumor of prostate and breast CA.

The tumor will show a decrease/loss in staining of the basal cells and myoepithelial cells.

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

The background intensity must be 0.5 or less.

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

Bioburden

Pass

**Issue date** 2022-04-19

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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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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**

Mia Cazares

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

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