



# Certificate of Analysis

**Product name**

CONFIRM ANTI-P53 (DO-7)

**Material No.**

05278074001

**Lot No.**

K02111

**Date of Manufacturing**

2023-02-16

**Expiry Date**

2025-02-01

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

Final Acceptance Testing

Pass

CONFIRM anti-p53 (DO-7) positive colon or breast carcinoma tissue

The test batch must score 3.5+ or greater on CONFIRM anti-p53 (DO-7) -positive colon or breast carcinoma tissue

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

The background intensity must be within 0.5 of the negative control slide

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

**Issue date** 2023-03-06

Page 1 of 2



# Certificate of Analysis

**Product name**

CONFIRM ANTI-P53 (DO-7)

**Material No.**

05278074001

**Lot No.**

K02111

**Date of Manufacturing**

2023-02-16

**Expiry Date**

2025-02-01

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

Reagent must be free of foreign material and substantially free of intrinsic particulate matter.

This lot meets our specification

**Disposition by**

Ken Eblen

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

**Issue date** 2023-03-06

Page 2 of 2

Ventana Medical Systems, Inc.  
1910 Innovation Park Drive  
Tucson, Arizona 85755  
Phone: + 1 800 227 2155  
<http://www.ventana.com>