



# Certificate of Analysis

**Product name**

CONFIRM ANTI-P53 (DO-7)

**Material No.**

05278074001

**Lot No.**

N23683

**Date of Manufacturing**

2025-12-08

**Expiry Date**

2027-11-18

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

Functional Staining

Pass

Colon Carcinoma or Breast Carcinoma

CONFIRM anti-p53 (DO-7) produces nuclear punctate staining of reactive carcinoma cells.

For specific stain intensity on a 0 to 4 scale, the test batch and reference batch must score 3.5 pt or greater in colon carcinoma or breast carcinoma.

The background intensity must be 0.5 pt or less for the test batch and reference batch.

The run is invalid if the reference batch does not exhibit acceptable stain intensity.

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

Visual Inspection

Pass

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

**Issue date** 2026-01-05

Page 1 of 2



# Certificate of Analysis

**Product name**

CONFIRM ANTI-P53 (DO-7)

**Material No.**

05278074001

**Lot No.**

N23683

**Date of Manufacturing**

2025-12-08

**Expiry Date**

2027-11-18

This lot meets our specification

**Disposition by**

Nic Hau

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

**Issue date** 2026-01-05

Page 2 of 2

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