



Certificate of Analysis

Product name

CONFIRM ANTI-P53 (DO-7)

Material No.

05278074001

Lot No.

N21677

Date of Manufacturing

2025-10-14

Expiry Date

2027-09-28

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 2025-10-28

Page 1 of 2



Certificate of Analysis

Product name

CONFIRM ANTI-P53 (DO-7)

Material No.

05278074001

Lot No.

N21677

Date of Manufacturing

2025-10-14

Expiry Date

2027-09-28

This lot meets our specification

Disposition by

Lupe Villarreal

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

Issue date 2025-10-28

Page 2 of 2

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