



Certificate of Analysis

Product name

CONFIRM ANTI-P53 (DO-7)

Material No.

05278074001

Lot No.

E18793

Date of Manufacturing

2018-08-23

Expiry Date

2020-07-30

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 2018-09-13

Page 1 of 2



Certificate of Analysis

Product name

CONFIRM ANTI-P53 (DO-7)

Material No.

05278074001

Lot No.

E18793

Date of Manufacturing

2018-08-23

Expiry Date

2020-07-30

Parameter**Result****Unit**

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

This lot meets our specification

Disposition by

Lucia Romero

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

Issue date 2018-09-13

Page 2 of 2

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