



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

E27213

Date of Manufacturing

2018-11-19

Expiry Date

2020-11-04

Parameter**Result****Unit**Final Acceptance Testing
Breast Carcinoma Tissue

Pass

Nuclear staining is interpreted on tissue that is positive for percent tumor cell staining according to the following approximate percent tumor cell staining criteria:

0-50% cell staining (negative)
51-100% cell staining (positive).

Nuclear staining of test and reference slides must score #3.5 for specific staining with a background (non-specific) intensity of #0.5. The specific staining intensity of the test must be within a 0.5 intensity score of the reference slide for a passing result (Scale 0-4).

The intensity of the negative reagent control slide must be 0.5 or less (Scale 0-4).

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 2018-12-24

Page 1 of 2

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



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

E27213

Date of Manufacturing

2018-11-19

Expiry Date

2020-11-04

Parameter**Result****Unit**

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

This lot meets our specification

Disposition by

Whitney Croft

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

Issue date 2018-12-24

Page 2 of 2

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