



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

K27790

Date of Manufacturing

2023-12-22

Expiry Date

2025-12-07

Parameter**Result****Unit**

Visual Inspection

Pass

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

Functional Staining

Pass

Breast Carcinoma Tissue & Normal Breast Tissue

Nuclear staining will be interpreted on Breast Carcinoma 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 breast carcinoma slides must have a specific stain intensity of 3.5 or greater and a background of 0.5 or less on a 0 to 4 scale.

The test batch on normal breast slide must exhibit a heterogeneous staining pattern of the luminal cells, with a mixture of a variable number of cells exhibiting weak, moderate, and intense immunoreactivity.

Issue date 2024-01-29

Page 1 of 2

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



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

K27790

Date of Manufacturing

2023-12-22

Expiry Date

2025-12-07

Parameter**Result****Unit**

The background 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

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 2024-01-29

Page 2 of 2

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