



# Certificate of Analysis

**Product name**

CONFIRM ANTI-PR (1E2)

**Material No.**

05277990001

**Lot No.**

M16415

**Date of Manufacturing**

2024-08-26

**Expiry Date**

2026-08-07

**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 &amp; 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** 2024-09-10

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)

**Material No.**

05277990001

**Lot No.**

M16415

**Date of Manufacturing**

2024-08-26

**Expiry Date**

2026-08-07

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

The background intensity of the negative reagent control slide must be 0.5 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

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** 2024-09-10

Page 2 of 2

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