



## Certificate of Analysis

**Product name**

CONFIRM ANTI-PR (1E2)

**Material No.**

05277990001

**Lot No.**

Y19671

**Date of Manufacturing**

2017-09-14

**Expiry Date**

2019-08-30

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

Functional Staining

Pass

On Breast Carcinoma Tissue

The nuclear staining will be interpreted according to the following approximate percent tumor cell staining criteria: 0-50% cell staining (negative) 51-100% cell staining (positive).

The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result (Scale 0-4+).

The background intensity must be within 0.5 of the negative control slide (Scale 0-4+).

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

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

**Issue date** 2017-09-26

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

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** 2017-09-26

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