



# Certificate of Analysis

**Product name**

CONFIRM ANTI-PR (1E2) 250

**Material No.**

05278392001

**Lot No.**

K15861

**Date of Manufacturing**

2023-08-16

**Expiry Date**

2025-08-03

**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** 2023-09-05

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



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

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

This lot meets our specification

**Disposition by**

Mackenzie Usrey

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

**Issue date** 2023-09-05

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