



# Certificate of Analysis

**Product name**

CONFIRM anti-Topoisomerase II (JS5B4)

**Material No.**

05479339001

**Lot No.**

N16697

**Date of Manufacturing**

2025-08-11

**Expiry Date**

2027-07-30

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

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

Pass

Functional Staining

Pass

Breast CA

For specific stain intensity on a 0 to 4 scale, the test batch and reference batch must score 3.5 pt or greater in breast cancer tissue.

The background intensity must be 0.5 pt or less for the test batch and reference batch.

The background intensity of the negative reagent control must be 0.5 pt or less.

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

**Disposition by**

Antonio Reyes

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

**Issue date** 2025-08-28

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