



Certificate of Analysis

Product name

CONFIRM anti-Topoisomerase II (JS5B4)

Material No.

05479339001

Lot No.

K04000

Date of Manufacturing

2023-03-20

Expiry Date

2025-03-14

Parameter**Result****Unit**

Visual Inspection

Pass

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

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

Nic Hau

Issue date 2023-03-25

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Tucson, Arizona 85755
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<http://www.ventana.com>



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