



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

N20458

Date of Manufacturing

2025-09-18

Expiry Date

2027-09-10

Parameter**Result****Unit**

Functional Staining

Pass

Breast Carcinoma Tissue & 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.

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

Visual Inspection

Pass

Issue date 2025-10-03

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

Visual Inspection

Pass

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

Bioburden

Visible bacterial colonies must be 100 or less CFU/mL

Pass

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 2025-10-03

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