



# Certificate of Analysis

**Product name**

CONFIRM ANTI-PR (1E2) 250

**Material No.**

05278392001

**Lot No.**

M04574

**Date of Manufacturing**

2024-03-22

**Expiry Date**

2026-03-03

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

Visual Inspection

Pass

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

Functional Staining

Pass

Breast Carcinoma Tissue &amp; 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.

**Issue date** 2024-04-08

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

**Disposition by**

Joshua Burgette

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

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