

# Certificate of Analysis

**Product name**

CONFIRM Anti-PR (1E2) Primary Antibody

**Material No.**

05277990001 or 05278392001

**Lot No.**

E09646

**Date of Manufacturing**

04/MAY/2018

**Expiry Date**

2020/04/25

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

Visual Inspection

Pass

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

Reagent must be clear and free of turbidity

Functional Staining

Pass

Breast Carcinoma Tissue

The nuclear staining will be interpreted according to the following approximate percent tumor cell staining criteria:

0-50% cell staining (negative)

51-100% cell staining (positive).

The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result (Scale 0-4+).

The background intensity must be within 0.5 of the negative control slide (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

This lot meets our specification

**Disposition by**

KEN ROCHIN

**Issue date**

05-JUL-2018