



Certificate of Analysis

Product name

CONFIRM Anti-PR (1E2) Primary Antibody

Material No.

05277990001 or 05278392001

Lot No.

E21998

Date of Manufacturing

19-SEP-2018

Expiry Date

2020-09-04

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

Final Acceptance Testing

Pass

Breast Carcinoma Tissue

Nuclear staining is interpreted on tissue 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 slides must score ≥ 3.5 for specific staining with a background (non-specific) intensity of ≤ 0.5 . The specific staining intensity of the test must be within a 0.5 intensity score of the reference slide for a passing result (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

Guadalupe Villarreal

Issue date

29 OCT 2018