



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2) 250

Material No.

05278392001

Lot No.

Y23051

Date of Manufacturing

2017-11-01

Expiry Date

2019-10-17

Parameter**Result****Unit**

Functional Staining

Pass

On 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+).

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

Issue date 2017-11-13

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Parameter**Result****Unit**

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

Disposition by

Lupe Villarreal

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

Issue date 2017-11-13

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